Interstate Shellfish Sanitation Conference

Task Force II Report

2015 Biennial Meeting
October 24 - 29, 2015

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Proposal Subject	Post-Harvest Processing
Specific NSSP Guide Reference	NSSP Guide Section I Definitions and Section II Model Ordinance New Chapter XVII.
Text of Proposal/ Requested Action	Action #1 Add a new definition to B. Definition of Terms for Post-Harvest Handling and renumber Definitions Section accordingly. **Post-Harvest Handling** means a control(s) employed by a dealer to further reduce, beyond controls currently in place under the NSSP, the post-harvest growth of naturally occurring pathogens for the purposes of handling product outside of as an alternative to the Authority's existing NSSP management plans. Action #2 Add a new chapter to the NSSP Guide Section II. Model Ordinance as follows: Chapter XVII. Post-Harvest Handling A. If a dealer elects to use a post-harvest handling control(s) to reduce the levels of post-harvest growth of a naturally occurring pathogen(s) of public health concern in shellfish, the dealer shall: (1) Have a HACCP plan (approved by the Authority) for the control(s) that reduces post-harvest growth of the target pathogen(s). (a) The dealer must validate that the post-harvest handling control(s) reduces the post-harvest growth of naturally occurring pathogen(s). The validation study must be approved by the State Shellfish Control Authority with FDA concurrence. (b) The ability of the post-harvest handling control(s) to reliably achieve the appropriate reduction in post-harvest growth of the target pathogen(s) shall be routinely verified at a frequency determined by the State Shellfish Control Authority. (2) Package and label all shellfish in accordance with the requirements of this Ordinance. (3) Keep records in accordance with Chapter X. 07.
Public Health Significance	The changes recommended by this proposal provide added opportunities for shellfish dealers to meet the required State Control Plans for naturally occurring pathogens.
Cost Information	
Action by 2009 Task Force II	Recommended referral of Proposal 09-231 to an appropriate committee as determined by the Conference Chairman.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force II on Proposal 09-231.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 09-231.
Action by 2011 Post-Harvest Processing	Recommended no action on Proposal 09-231.

Committee	Rationale: The proposed new definition and new chapter are not necessary because the State *Vibrio* Management Plans already allow handling practices to reduce levels of naturally occurring pathogens. The recommended changes are adequately addressed in the Model Ordinance.
Action by 2011 Task Force II	Recommended referral of Proposal 09-231 to an appropriate Committee as determined by the Conference Chairman with instructions that the Committee establish validation protocols for activities that reduce levels of naturally occurring pathogens so that a dealer can work outside the Authority's *Vibrio* Management Plan. Additionally, the Committee is charged with ensuring the Post-Harvest Handling (PHH) definition and section in Chapter XVII is consistent so that they are directing a process that reduces levels not just growth. The intent of Task Force II is that Post-Harvest Handling activities are not intended to be used to support labeling claims.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force II on Proposal 09-231.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 09-231.
Action by 2013 Post-Harvest Processing Committee	The Post-Harvest Processing Committee recommended: 1. No action on proposal 09-231 as written. 2. Change the title of Model Ordinance Chapter XVI, Post-Harvest Processing to "Processes and Procedures for Pathogen Reduction" in order to include pathogen reduction processes that are not associated with labeling claims, which was the intent of Proposal 09-231. 3. Add a new section to the newly titled Chapter XVI (Recommendation 2) to be titled "Pathogen Reduction Processes that are not associated with Labeling Claims." 4. The committee recommended that a work group be established to develop language for the new section of Chapter XVI and report the findings to the appropriate committee as determined by the Conference Chairman. It is further recommended that the work group meet quarterly until the new section is complete so that it can be submitted as a proposal at the next ISSC meeting. 5. Requested the Conference Chairman to appoint an appropriate work group or committee to work with FDA to establish target levels for pathogen reduction processes that do not require labeling that will achieve the required risk reduction goals. (The intent of the committee is to use the information developed by this workgroup to determine if additional validation protocols are needed.) Recommendation 5 should be done as soon as possible to allow validation protocols to be developed as necessary
Action by 2013 Task Force II	Recommended referral of Proposal 09-231 back to Committee with instructions to continue the work on the proposal which includes recommendations 2. – 5. as a charge to the Committee; with further instructions that recommendation 5. should be completed as soon as possible to allow validation protocols to be developed as necessary.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 09-231.

Action by FDA May 5, 2014	Concurred with Conference action on Proposal 09-231.
Action by 2015 PHP Committee	Recommended approval of the following recommendations: 1. The title of Chapter XVI should be changed to Processes and Procedures for Pathogen Reduction. A new section @.01 Processes and Procedures Involving Labeling Claims should be added to the existing chapter between the Title and A (see proposal 15-223). A new section @.02 Processes and Procedures Not Involving Labeling Claims should be added to Chapter XVI 2. The contents of the new section @.02 should be as indicated in proposal 15-223. 3. The subcommittee concluded that the development of blanket target levels and validation protocols for all possible processes for pathogen reduction would be complex without knowing what the processes are. The committee recommends an alternate approach as follows: (a) A new committee be established to serve as a resource to the ISSC to assist with evaluation of specific processes designed to reduce pathogens to determine target levels and recommend specific validation and verification protocols. (b) The Committee should be a standing committee and would develop target levels and validation and verification protocols as needed to support the NSSP. These recommendations are addressed in Proposal 15-302.
Action by 2015 Task Force II	Recommends no action on Proposal 09-231. Rationale: This proposal is addressed by new proposals.

Proposal Subject	*Vibrio vulnificus* Risk Management of Oysters
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Article IV. Section II Model Ordinance, Chapter II Risk Assessment and Risk Management @.01 Outbreaks of Shellfish Related Illnesses @.04 *Vibrio vulnificus* Risk Management for Oysters Section IV. Guidance Documents, Chapter IV. Naturally Occurring Pathogens
Text of Proposal/ Requested Action	Article IV. Executive Board, Officers, Committees Section 10. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairman. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference: Education, Foreign Relations, Proposal Review, Patrol, Research Guidance, Resolutions, ~~and~~ Shellfish Restoration, and *Vibrio* Management Committee. The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Biennial Meeting. Section 14. The Executive Board Chairperson shall appoint a sixteen (16) member *Vibrio* Management Committee. The Committee will be comprised of a Chairperson with at least two (2) industry members from the East, Gulf and West coasts and at least one (1) state regulatory from each of the ISSC regions. The Committee will also include one voting member from NOAA, one voting member from FDA, one voting member from EPA and one voting member from CDC. The Federal entities will appoint these members. Non-voting advisors will be appointed as appropriate. The Committee will assess if additional changes are needed in the NSSP Guide for the Control of Molluscan Shellfish Model Ordinance to reduce the risk of *Vibrio* illnesses. The Committee will annually review trends in *Vibrio* illnesses. Chapter II Risk Assessment and Risk Management @.01 Outbreaks of Shellfish Related Illnesses ~~J. The Authority shall assess annually Vibrio parahaemolyticus illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all V. 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.~~ @.02 Annual Assessment of *Vibrio vulnificus* and *Vibrio parahaemolyticus* Illnesses. 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. @. 0~~2~~3 Presence of Human Pathogens in Shellfish Meats. @.0~~3~~4 Presence of Toxic Substances in Shellfish Meats.

~~.04 Vibrio vulnificus Risk Management for Oysters.~~

~~A. For states having 2 or more etiologically confirmed shellfish-borne Vibrio vulnificus illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement a Vibrio vulnificus Management Plan.~~

~~B. The Source State's Vibrio vulnificus Management Plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. The goal of the Vibrio vulnificus Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne Vibrio vulnificus septicemia illnesses reported collectively by California, Florida, Louisiana, and Texas, from the consumption of commercially harvested raw or undercooked oysters by 40 percent for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average illness rate for the years 1995 -1999 of 0.303/million. The list of states (California, Florida, Louisiana, Texas) used to calculate rate reduction may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The illness rate shall be calculated as the number of illnesses per unit of population. The goal may be reevaluated prior to the year 2006 and adjusted in the event that new science, data, or information becomes available. State's compliance with the Plan will require States to maintain a minimum of 60% reduction in years subsequent to 2008. Determination and compliance after 2008 will be based on two-year averages beginning in 2009.~~

~~C. The Source State's Vibrio vulnificus Management Plan shall include, at a minimum:~~

~~(1) The ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for Vibrio vulnificus illnesses;~~

~~(2) A process to collected standardized information for each Vibrio vulnificus illness: including underlying medical conditions; knowledge of disease status; prior counseling on avoidance of high risk foods, including raw oysters; existence of consumer advisories at point of purchase or consumption; and, if possible, whether consumer was aware and understood the advisories;~~

~~(3) A standardized process for tracking products implicated in Vibrio vulnificus illnesses;~~

~~(4) Identification and preparation for achieving a goal of post harvest processing capacity of 25 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a Source State by the end of the third year (December 31, 2004). The percentage of post harvest processing will include the capacity of all operational plants and the capacity of plants under construction;~~

~~(5) Identification and preparation for implementation of required post harvest processing capacity of 50% of all oysters intended for the raw, half-shell market during the months of May through September, harvested from a Source State, which shall be implemented should the 40 percent illness reduction goal not be achieved by December 31, 2006. The percentage of post harvest processing will include the capacity of all operational plants and the capacity of plants under construction. In the alternative, the state may utilize the control measures, or equivalent control measures, listed in .04, (C), (6) (a), (b), (c), and (d) below for such periods of time which, in combination with post harvest processing,~~

~~will provide equivalent outcomes. This portion of the plan shall be completed no later than December 31, 2005; and~~

~~(6) Identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent rate of illness reduction goal not be achieved collectively by 2008. The control measures identified in the plan shall be appropriate to the state and reflect that state's contribution to the number of Vv illnesses and the controls that have been implemented by each state. This portion of the Plan shall be completed no later than December 2007. The temperature and month of the year parameters identified in the following controls may be adjusted by the ISSC Executive Board as recommended by the Vibrio Management Committee (VMC) on a state by state basis, as needed to achieve the established illness reduction goal. The adjustment to the State's plan can take into account the illness rate reduction that has occurred since the last review of the plan.~~

~~(a) Labeling all oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 75°F;~~

~~(b) Subjecting all oysters intended for the raw, half-shell market to an Authority- approved post harvest processing that reduces the Vibrio vulnificus levels to <30 MPN/gram when the Average Monthly Maximum Water Temperature exceeds 75°F;~~

~~(c) Closing shellfish growing areas for the purpose of harvest of oysters intended for the raw, half-shell market when the Average Monthly Maximum Water Temperature exceeds 75°F;~~

~~(d) Labeling all oysters, "For shucking by a certified dealer", during the months of May through September, inclusive;~~

~~(e) Subjecting all oysters intended for the raw, half-shell market to a post harvest processing that is both approved by the Authority and reduces the Vibrio vulnificus levels to <30 MPN/gram during the months of May through September, inclusive; and~~

~~(f) Closing shellfish growing areas for the purpose of harvesting oysters intended for the raw, half-shell market during the months of May through September, inclusive.~~

~~Effective January 1, 2012:~~

~~@.04 *Vibrio vulnificus* Risk Management for Oysters~~

~~A. For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement a *Vibrio vulnificus* Risk Management Plan.~~

~~B. The Source State's *Vibrio vulnificus* Risk Management Plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness risk reduction program. The goal of the *Vibrio vulnificus* Risk Management Plan will be to reduce the risk per serving to a 60% illness rate reduction for etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, and Texas, from the consumption of commercially harvested raw or undercooked oysters to a level equivalent to a 60% illness rate reduction from 1995 – 1999 baseline average illness rate of 0.278 per million.~~

~~C. The Source State's *Vibrio vulnificus* Risk Management Plan shall include, at a~~

~~minimum:~~

~~(1) The ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses;~~

~~(2) A process to collect standardized information for each *Vibrio vulnificus* illness: including underlying medical conditions; knowledge of disease status; prior counseling on avoidance of high risk foods, including raw oysters; existence of consumer advisories at point of purchase or consumption; and, if possible, whether consumer was aware and understood the advisories;~~

~~(3) A standardized process for tracking products implicated in *Vibrio vulnificus* illnesses; and~~

~~(4)~~(1) Identification and implementation of the controls, or equivalent controls, which produced an illness per serving equivalent to a 60% illness rate reduction in the core states.

@05 Vibrio vulnificus Control Plan

A. Risk Evaluation

Each shellfish producing State that is not currently implementing a *Vibrio vulnificus* control plan shall conduct a *Vibrio vulnificus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining the risk of *Vibrio vulnific*us infection from the consumption of shellfish harvested from the State's growing waters.

(1) In conducting the risk evaluation the State Authority will at a minimum consider the following:

(a) The number of *Vibrio vulnificus* cases etiologically confirmed and epidemiologically linked to the consumption of commercially harvested shellfish from the State; and

(b) Levels of *Vibrio vulnificus* in the growing waters and in shellfish, to the extent that such data exists; and

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

B. States which have previously met the illness threshold requiring a *Vibrio vulnificus* Control Plan will continue to maintain and implement a *Vibrio vulnificus* Control Plan.

C. 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

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. 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~~5~~°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~~5~~°F.
(iii) ~~Labeling oysters, "For shucking by a certified dealer", during the months of April through November, inclusive.~~
~~(iv) Subjecting oysters intended for the raw, half-shell market to Authority approved post harvest processing during the months of April through November, inclusive.~~
(iiiv) 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 *Vv* plans will include controls when water temperature promotes *Vv* levels and risk of illness increases. The controls will minimize risk to less than three (3) illnesses per 100,000 servings when water temperature exceeds 80°F. Authority approved Best Management Practices (BMPs) will be applied to minimize *Vv* growth to the extent possible when water temperature exceeds 70°F but is less than 80°F. BMPs will ensure that when the water temperature exceeds 70°F but is less than 75°F risk is minimized to less than 1.75 illnesses per 100,000 servings and when water temperatures exceed 75°F but are less than 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.
(ivvi) The State Authority may implement other comparable to that will reduce the risk per servings 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.
(i) Changes in the annual number of *Vibrio vulnificus* cases associated with the State's growing waters.
(ii) Environmental changes which could affect total *Vibrio vulnificus* 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.

F. 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 *Vv* Control Plan.
(2) Contingency Plan Evaluation
In consultation with FDA the Authority will evaluate the adequacy of their Contingency Plan.

@.06~~5~~ *Vibrio parahaemolyticus* Control Plan

Guidance Documents, Chapter IV. Naturally Occurring Pathogens

~~.01 *Vibrio* Risk Management for Oysters Background~~
~~Current information concerning *Vibrio vulnificus*, which is responsible for several shellfish associated illnesses and deaths each year can be found in Watkins and McCarthy (1994).~~
~~A small number of shellfish-borne illnesses have also been associated with bacteria of the genus *Vibrio* (Bonner, 1983; Blake *et al.*,1979; Morris, 1985; Joseph *et al.*,1982; Roderick, 1982). The *Vibrios* are free-living aquatic microorganisms, generally inhabiting marine and estuarine waters (Joseph *et al*, 1982: Spira, 1984; Colwell 1984; Bachman, 1983). Among the marine *Vibrios* classified as pathogenic are strains of non-01 *Vibrio cholerae*, *V. parahaemolyticus*, and *V. vulnificus* (Bachman, 1983; Desmarchelier, 1984; Blake, 1980). All three species have been recovered from coastal waters in the United States and other parts of the world (Joseph, 1982; Colwell, 1984; Blake, 1980; DePoala, 1981; Madden, 1982; Davey, 1982; Oliver, 1983; Tamplin, 1982; NIH, 1984). These and other *Vibrios* have been detected in some environmental samples recovered from areas free of overt sewage contamination and coliform (Bonner, 1983; Joseph, 1982; Spira, 1984).~~

~~In general, shellfish-borne vibrio infections have tended to occur in coastal areas in the summer and fall when the water was warmer and vibrio counts were higher (Bonner, 1983; Morris, 1985; Joseph, 1982). *V. parahaemolyticus* and non-01 *V. cholerae* are commonly reported as causing diarrhea illness associated with the consumption of seafood including shellfish (Bonner, 1983; Blake, 1979; Morris, 1985; Joseph, 1982; Baross and Liston, 1970; Morris, 1981). In contrast, *V. vulnificus* has been related to two distinct syndromes: wound infections, often with tissue necrosis and bacteria, and primary septicemia characterized by fulminant illness in individuals with severe chronic illnesses such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy (Bonner *et al.*, 1983; Tacket, 1984). Increasing evidence shows that individuals with such chronic diseases are susceptible to septicemia and death from raw seafood, especially raw oysters (Bonner *et al.*, 1983; Blake, 1979; Morris, 1985; Rodrick, 1982; Bachman, 1983; Blake, 1980; Oliver, 1983; NIH, 1984; Tacket, 1984; Oliver 1982; FDA, 1985). Shellfish borne vibrio infections can be prevented by cooking seafood thoroughly, keeping them from cross contamination after cooking, and eating them promptly or storing them at hot (60°C or higher) or cold (4°C or lower) temperatures. If oysters and other seafood are to be eaten raw, consumers are probably at lower risk to vibrio infection during months when seawater is cold than when it is warm (Blake, 1983 and 1984).~~

~~.02 *Vibrio vulnificus* Management Plan~~

~~The voting delegates at the 1999 Annual Meeting in New Orleans created the Vibrio Management Committee (VMC). Subsequently, *Vibrio vulnificus* and *Vibrio parahaemolyticus* subcommittees have been charged to develop appropriate illness control measures for these two pathogens. The VMC provides guidance and oversight~~

~~to the subcommittees. Subcommittee recommendations are reviewed by the VMC before submittal to Task Forces. At the 2001 annual meeting, Task Forces reviewed the VMC's recommendation of reducing the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia with the intention to submit the recommendation to the voting delegates. The goal is to reduce the rate of illness reported in California, Florida, Louisiana and Texas due to the consumption of commercially harvested raw or undercooked oysters by 40 percent, for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average illness rate for the years 1995 – 1999 of 0.306/million. The list of states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The rate of illness shall be calculated as the number of illnesses adjusted for population. This adjustment will be performed in consultation with statisticians and epidemiologists from California, Florida, Louisiana and Texas and Federal agencies. The baseline data and all future data for measuring illness reduction shall be the reported illnesses in the California, Florida, Louisiana and Texas for the period 1995 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 2002 data. For the purpose of maintaining an accurate count of the number of illnesses report by each state (California, Florida, Louisiana and Texas), the following will apply:~~

~~(a) Illness cases counted are those reported by California, Florida, Louisiana and Texas;~~
~~(b) Each illness case is recorded under the state that reports it;~~
~~(c) Each case is not counted more than once; and~~
~~(d) In the event more than one report per case is filed, the case is recorded under the state of diagnosis.~~

~~The formula for calculating the rate of illness is as follows:~~

$$\frac{\text{number of cases}}{\text{population}}$$

~~The *Vv* subcommittee members will include, at a minimum, balanced representation from industry and state shellfish control authorities from *Vibrio vulnificus* Illness Source States California, Florida, Louisiana and Texas, FDA, NOAA, EPA, CDC, state epidemiologists; as well as industry and shellfish control representatives from other regions. *Vibrio vulnificus* Illness Source States are those states reporting two (2) or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state. Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met.~~

~~Recognizing the increasing importance and roles for the Committee, leadership will be expanded and structured in a similar manner as stated in the ISSC By-Laws for Task Forces (reference: ISSC By-Law, Article I Task Forces). The VMC Chair shall alternately be selected from a state shellfish control authority and from industry. The Board Chairman, with approval of the Board, shall appoint a VMC Chair and Vice-Chair. If the VMC Chair represents a state shellfish control authority, the Vice-Chair shall be an industry representative. At the end of the VMC Chair's term of office, the Vice-Chair will become Chairman and a new Vice-Chair will be appointed who represents the same segment of the Conference as the outgoing VMC Chair. A VMC Chair and Vice-Chair should be appointed before October 1, 2001 in order to be consistent with plans for annual VMC meetings and with the effective date of *Vibrio*~~

	~~*vulnificus* Risk Management Plans. Likewise, the term of office shall be for (2) years. The VMC will meet at least annually to develop and approve annual VMC work plans for *Vibrio vulnificus* illness reduction and review progress. A series of work plans, each covering a one-year period shall be adopted. The first work plan and progress review period will cover a seventeen-month period from August 1, 2001 to December 31, 2003 followed subsequently by annual work plans. Work plans will include goals, tasks, performance measures and assessment methods to track and achieve progress towards the illness reduction goals. The work plans will be developed by the VMC and approved by the VMC membership. The chair of the VMC will deliver a written annual progress report, including a summary of the previous year's progress made in the education program, to the ISSC March executive board meeting. The report shall be made available to the general membership. The annual work plan structure, outlined below, provides adaptive management and assures consistent progress towards the illness reduction goals. If annual assessment of progress towards achieving the illness rate reduction goals show inadequate progress the VMC shall incorporate actions into current and subsequent work plans to assure success in achieving those goals. In addition, if annual review shows inadequate progress the VMC will develop issues for deliberation at the 2005 biennial meeting to consider actions such as:~~ ~~• increased educational efforts,~~ ~~• limited harvest restriction,~~ ~~• reduction in time from harvest to refrigeration,~~ ~~• phased-in post-harvest treatment requirements, or~~ • ~~other equivalent controls.~~ ~~Work plans developed by the VMC shall include the following elements and shall define the administrative procedures and resources necessary for accomplishment (i.e. establishment and maintenance):~~ ~~(a) An ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* infection. The Education Program's objectives will be 1) to increase the target audience's awareness that eating raw, untreated oysters can be life-threatening to them, and; 2) to change the at-risk group's oyster-eating behavior, i.e., to reduce or stop eating raw, untreated oysters. The ISSC Vibrio Management Committee and the *Vibrio vulnificus* Education Subcommittee will evaluate Year 2001 survey results and compare them with the Year 2003 or 2004 survey results to determine the effectiveness in meeting the two objectives of the *Vv* education effort: (1) Show 40% increase in awareness of risk from *Vv*; and (2) Show 15% increase in at-risk consumers no longer eating raw oysters while minimizing impacts to non-at-risk consumer raw oyster consumption.~~ ~~(i) The Consumer Education Program will focus educational efforts in California, Florida, Louisiana and Texas. The Education Program will make educational materials available to additional states upon request.~~ ~~(ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures deemed effective such as the USDA Physician Notification Program.~~ ~~(iii) Survey assessments at the state level shall be used as a means of assessing the baseline knowledge and effectiveness of educational interventions.~~ ~~(b) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state.~~ ~~(c) Creation of a working group to work cooperatively with local, state, and federal agencies and programs to assist in the collection of environmental and epidemiological~~

~~data to further expand on the current information available. A coordinator may be utilized to facilitate the activities of this working group to develop standardized collection of environmental and epidemiological information from harvest to consumer.~~

~~(d) The Voting Delegates at the 2007 Biennial Meeting in Albuquerque, New Mexico approved appointment of a committee that will consist of three (3) epidemiologists and advisors as appropriate. The Committee will use this form to screen cases for the purposes of determining if a case is attributable to a single source state as well as whether the case is includable in the Vv Illness Reduction Goals. In addition, to ensure uniformity, the form shall be used for screening 2007-2008 cases and that cases from the baseline will be screened using the same form.~~

~~Criteria FOR INCLUDING *Vv* CASES IN ILLNESS REDUCTION CALCULATIONS and determining source states~~

1. ~~Each case that is considered must be reported on a Center for Disease Control and Prevention Cholera and Other *Vibrio* Illness Surveillance Report (COVIS) Form CDC 52.79.~~
2. ~~Each case must also be listed be on the FDA database (NSSP Guide for the Control of Molluscan Shellfish Guidance Documents Chapter IV .02).~~
3. ~~The ISSC committee to review reported *Vv* illnesses to determine the appropriateness of inclusion into the database used for illness reduction calculations must have access to the COVIS form for each case (patient names and other necessary information appropriately redacted). The ISSC addendum form is also provided, where available. This access to the COVIS form is critical for adequate interpretation of the data collected during the state epidemiological investigation.~~
4. ~~The ISSC *Vv* Illness Review Committee will complete the following criteria table for each case. These tables serve as documentation.~~
5. ~~For cases to be included in illness reduction calculations the following criteria must be met:~~
   - ~~Item 1-4 and 5a must be answered yes.~~
   - ~~Should the COVIS form include information that suggests other exposures that may be responsible for the Vv illness further investigation may occur. Consultation with State Shellfish Control Authorities and Epidemiologist from the state is encouraged to determine which exposure should be recorded as the cause of illness. Should oyster consumption not be determined to be the cause of illness the case will not be counted. Should there be disagreements with the inclusion of a case; the disagreeing party may request a review. The request must include a rationale for the review and should be addressed to the Executive Board Chairman.~~
   - ~~If 5b is no, other exposures should be considered. If no other exposures exist, the case will not be counted.~~
   - ~~Should the only exposure be consumption of cooked oysters or unknown 5b will be checked yes.~~

~~*Vibrio vulnificus* Criteria Table~~

~~**Case Identifier / Number _____**~~	~~**Criteria Status Determination**~~		
~~**Criteria**~~	~~**Yes**~~	~~**No**~~	~~**Unknown**~~

~~**1. Etiologically Confirmed**~~	☐	☐	☐	
~~**2. Septicemia Illness**~~	☐	☐	☐	
~~**3. Reporting State (CA, FL, LA, TX)**~~	☐	☐	☐	
~~**4. Commercial Harvest from US Production**~~	☐	☐	☐	
~~**5. Exposures**~~				
~~a. Onset Consistent with Consumption of Oysters~~	☐	☐	☐	
~~b. Raw or undercooked oysters~~	☐	☐	☐	
~~**6. Traceback Information**~~				
~~a. Were shipping tags available or was othe traceback information reported~~	☐	☐	☐	
~~b. State of harvest and harvest area (s)~~			☐	
~~c. Harvest date (s)~~			☐	
~~**7. Case Determination**~~				
~~a. Is case included in Vv illness reductio Calculations~~	☐	☐		
~~b. Is case attributed to a single source state~~	☐	☐		

~~Instructions for completing Criteria Table:~~

- ~~Check YES if Criterion is confirmed from the COVIS form o addendum.~~
- ~~Check NO if Criterion is not confirmed from the COVIS form o addendum.~~
- ~~Check UNKNOWN if Criterion is not clear or absent from th COVIS form or addendum.~~
- ~~No Criterion can have more than one check entered.~~
- ~~Each Criterion must have one check entered (YES, NO, o UNKNOWN).~~

~~These criteria tables will be used to review reported *Vv* illnesses to determine th appropriateness of inclusion into the database used for illness reductio calculations and will also be used for identifying other source states.~~

~~(e) Industry-implemented post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock which may include: time-temperature, post-harvest treatment (i.e. hydrostatic pressure, cool pasteurization, IQF, and irradiation - pending approval), rapid chilling and other emerging technologies.~~

~~(f) Pursuit of ISSC options such as industry education and communication; FDA label incentives; PHT-specific growing area classifications; targeted time/temperature assessment by FDA during annual shellfish program evaluations; assistance, as necessary, for the further study and possible implementation of dockside icing to investigate its effects on shelf life and variations in the effectiveness of the method as a result of seasonal and regional differences and incentives to add refrigeration capacity to harvest vessels. The goal will be to provide incentives necessary to post-harvest treat 25 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a Source State by the end of the third year (December 31, 2004). The assessment will include the capacity of all operational plants and the capacity of plants under construction. Should the 25 percent goal not be accomplished, the VMC will investigate and report their findings as to why the goal was not reached.~~

~~(g) Development by the VMC of a list of issues relating to public health, various technologies including Post-harvest treatments; marketability; shelf -life and similar matters that lend themselves to investigation. The VMC will work with FDA, NOAA, CDC, EPA, the shellfish industry and other entities as appropriate to obtain or facilitate the investigation of the issues listed and take the results into account as it~~

	~~develops plans or recommended Issues for the ISSC.~~ ~~(h) Provision for VMC compilation and review of the data on rates of illness, which will be made available to the ISSC at the ISSC Biennial meeting following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC membership. In the event there is no Biennial meeting scheduled for a certain year, the VMC shall meet and review the data when it becomes available and issue a compilation report which will be made available to the entire membership.~~ ~~(i) Provision for a VMC evaluation of the effectiveness of reduction efforts, which will be conducted at the end of the fifth year (December 31, 2006). The evaluation will determine whether the 40 percent, 5-year goal to reduce the rate of illness or education/consumer intervention or post harvest controls performance measures set forth in prior work plans have been achieved. Should the VMC evaluation indicate the 40 percent, 5 year goal has not been accomplished, the committee will identify additional harvest controls in the 2007 – 2008 work plan to assure achievement of the 60 percent reduction in the rate of illness goal by the close of the seventh year. In addition, the VMC will evaluate the requirements in Section 04.C. with the possibility of changing the controls to achieve remaining illness reduction goals.~~ ~~(j) Should a disagreement arise between FDA and the Authority on the equivalency of a control as described in .04(C), the V.v. Subcommittee will be requested to provide guidance.~~ ~~(k) In 2006 the Executive Board directed the elimination of the Vv & Vp subcommittees. The VMC assumed all responsibilities of the subcommittees as outlined in the Vibrio vulnificus Management Guidance Document. Representation on the VMC Committee will be consistent with all guidance (VMC and Vv subcommittee) outlined in the Vibrio vulnificus Management Guidance Document.~~ ~~(l) Shellstock Harvested in Source States Harvesters must include on the tag of all product harvested for restricted use the statement "for shucking by a certified dealer" and/or "For PHP Only." Harvesting controls must be provided by the Authority to ensure that restricted use shellstock is not diverted to retail or food service. Dealers must establish a restricted use shellstock Critical Limit as part of their HACCP Plan for receiving. A shipping Critical Control Point must include a restricted use shellstock disposition step. Restricted use shellstock is not intended for retail or food service.~~ ~~Should a disagreement arise between FDA and the Authority on the equivalency of a control as described in .04(C), the V.v. Subcommittee will be requested to provide guidance.~~ ~~In 2006 the Executive Board directed the elimination of the Vv & Vp subcommittees. The VMC assumed all responsibilities of the subcommittees as outlined in the Vibrio vulnificus Management Guidance Document. Representation on the VMC Committee will be consistent with all guidance (VMC and Vv subcommittee) outlined in the Vibrio vulnificus Management Guidance Document.~~ ~~(l) Shellstock Harvested in Source States Harvesters must include on the tag of all product harvested for restricted use the statement "for shucking by a certified dealer" and/or "For PHP Only." Harvesting controls must be provided by the Authority to ensure that restricted use shellstock is not diverted to retail or food service. Dealers must establish a restricted use shellstock Critical Limit as part of their HACCP Plan for receiving. A shipping Critical Control Point must include a restricted use shellstock disposition step. Restricted use shellstock is not intended for retail or food service.~~ ~~Should a disagreement arise between FDA and the Authority on the equivalency of a control as described in .04(C), the V.v. Subcommittee will be requested to provide guidance.~~

	~~In 2006 the Executive Board directed the elimination of the Vv & Vp subcommittees. The VMC assumed all responsibilities of the subcommittees as outlined in the Vibrio vulnificus Management Guidance Document. Representation on the VMC Committee will be consistent with all guidance (VMC and Vv subcommittee) outlined in the Vibrio vulnificus Management Guidance Document.~~ .01~~3~~ *Vibrio parahaemolyticus* Control Plan .02~~4~~ Post Harvest Processing Validation Verification Interim Guidance for *Vibrio vulnificus* and *Vibrio parahaemolyticus* .03~~5~~ Guidance for Demonstrating the Effectiveness of Time to Temperature Reduction Criteria for *Vibrio vulnificus* and *Vibrio parahaemolyticus*
Public Health Significance	The level of *V.v.* in oysters at the time of harvest can cause illness in immuno compromised individuals with increased susceptibility. This risk ranges from approximately .06 to 3.33 illnesses per 100,000 servings depending upon water temperature. The controls presently required by State *Vibrio vulnificus* Control Plans, if properly implemented, can reduce growth and reduce *Vibrio vulnificus* levels after harvest. Changes will provide additional options for managing the risks associated with *Vv.* These options will not require Post-Harvest Processing (PHP) controls which are presently not economically feasible. The RTI Economic Study suggested that it would take 2 to 3 years to implement PHP and, even with that time for implementation, would create a significant economic burden. References: (1) VMC Committee Reports (Al Rainosek's updated illness rate Calculations); (2) RTI International Report Project Number 0211460.008 (3) "Analysis of How Post-harvest processing Technologies for Controlling Vibrio vulnificus Can Be Implemented"; Dr. Steve Otwell, Laura Garrido,Victor Garrido and Dr.Charlie Sims report "Sensory Assessment Study for Post -Harvest Processed (PHP) Oysters
Cost Information	
Action by 2011 Task Force II	Recommended adoption of Vibrio Management Committee Substitute Proposal 11-201-A as amended. Additionally, Task Force II recommended: That a committee be established to consider options for water temperature determinations which can be used in the implementation of Proposal 11-201-A. That a Committee be established to develop criteria for verifying reduction in harvest for raw consumption and the percentage of post-harvest processed product on a monthly basis for those States required to have a *Vibrio vulnificus* Control Plan. An implementation date of January 1, 2012 for Proposal 11-201-A. Recommended referral of Proposal 11-201-B to an appropriate committee with representation from all regions to develop Model Ordinance language changes to support the time temperature requirements of the State's *Vibrio* Management Plans. This committee will be appointed and approved by the Executive Board at its closing Board meeting. The committee will be expected to meet within two (2) weeks of the close of the Conference. After its initial meeting, the committee shall meet by

	teleconference biweekly prior to an Executive Board meeting until the proposal is completed and at least once subsequent to the dissemination of the proposal and prior to an Executive Board meeting. The draft proposal that is to be considered by the Executive Board shall be disseminated to the ISSC membership a minimum of three (3) weeks prior to the next Executive Board meeting and posted on the ISSC web site. The Committee is directed to make recommendations to the Executive Board for interim approval with an effective date prior to the 2012 *Vibrio* season. The State's Authorities are requested to begin advising and educating their industries of these changes. Additionally, the committee will develop guidance for implementation of these controls.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force II on Proposal 11-201 Part A. Adopted recommendation of 2011 Task Force II on Proposal 11-201 Part B.
Action by USFDA February 26, 2012	FDA concurred with Conference action on Proposal 11-201 Part B but did not concur with Conference action on Proposal 11-201 Part A. FDA comments and recommendations in response to Proposal 11-201 Part A: In October of 2009, the Food and Drug Administration (FDA) informed the Interstate Shellfish Sanitation Conference (ISSC) of its intention to reformulate the Agency's policy regarding implementation of the Seafood HACCP Regulation with the intent that post-harvest processing (PHP) or equivalent measures be implemented for the control of *Vibrio vulnificus (V.v.).* The new policy would require that oysters harvested from the Gulf of Mexico and intended for the raw half shell market be post-harvest processed during those months when illness from *V.v.* is reasonably likely to occur. Given that PHP can largely eliminate *V.v.* while preserving the sensory qualities of raw untreated product FDA remains committed to this approach as the most prudent means of reducing the risk of illness from *Vv.* The efficacy of PHP is evidenced by the fact that since 2003, when the State of California banned the sale of untreated Gulf oysters harvested between April and October, there has been only one *V.v.* illness in the State. Prior to 2003 California reported on average six *V.v.* related illnesses per year. In November 2009, having heard from elected State and Federal representatives, the oyster industry and State regulatory officials regarding the feasibility of implementing PHP or other equivalent controls, FDA acknowledged the need to further examine the process and timing of industry adoption of PHP technology and placed in abeyance the Agency's intent to change its policy for controlling *V.v.* while taking steps to complete an independent study to assess how PHP controls can be implemented. In the interim, FDA has expressed its intention to continue working cooperatively with the ISSC to implement alternate controls which would reduce illnesses and meet the goals adopted by the ISSC in Proposal 00-201. Since adoption of Proposal 00-201 FDA has repeatedly expressed concerns relative to its implementation by the ISSC, including failure to consider national illness numbers and the lack of success in achieving the 60% illness rate reduction goal. FDA reiterated its concerns during ISSC deliberation of Proposal 11-201 at the October 2011 biennial meeting and those concerns were not adequately addressed by Conference action on Proposal 11-201. It is the position of FDA that Proposa111-201 deviates from current FDA policy in that it weakens the control measures adopted by the ISSC in Proposal 00-201. Therefore, FDA cannot concur with Proposal11-201 without further Conference action. FDA requests that the ISSC address the following issues and concerns.

	ISSC adoption of Proposal 00-201 in 2001 established a 60% illness rate reduction goal. Although FDA no longer considers this the most appropriate goal given the efficacy of PHP, FDA has continued to recognize and support ISSC efforts to achieve this level of illness reduction. However, the level of reduction reported by the ISSC *Vibrio* Management Committee (VMC) indicates only marginal success in moving toward that goal. Proposal 00-201 included specific control measures to be taken by the *V.v.* Source States if the 60% goal was not met. Those measures, intended for all oysters harvested during periods of risk included; closing shellfish growing areas to harvest, labeling oysters for shucking by a certified dealer, and subjecting oysters to PHP. Although the 60% illness rate reduction goal has not been achieved, none of these control measures have been implemented. Disagreement by States and the ISSC to pursue these more effective control measures has been a significant concern to FDA. That concern is further exacerbated by the fact that Source States, with ISSC support, have now adopted a policy that focuses control efforts toward more stringent time to temperature controls, for which compliance by industry is proving difficult. Section @.05 E. (1) (b) (iii) ofProposal11-201 establishes risk per serving standards for States using time/temperature controls and Section @.05 E. (1) (b) (iv) allows for alternative controls that achieve those same risk per servings standards. The risk per serving standards in Proposal11-201 are based on controls that were derived from the FDA developed *V.v.* calculator. These controls have not yet been demonstrated to achieve a 60% illness rate reduction. The FDA maintains that until these risk per serving standards are demonstrated to achieve the intended 60% illness rate reduction, evaluation of their effectiveness is imperative. Guidance needs to be developed for how to evaluate State programs to determine if risk per serving standards are being achieved. Section @.05 E. (2) (a) ofProposal11-201 States that the State Authority in conjunction with FDA will evaluate the implementation and effectiveness of these controls. As written, FDA would consider a State to be in non-compliance when there is ineffective implementation due to industry noncompliance or when the controls are determined ineffective in achieving the risk per serving standards. FDA would expect a State to discontinue the use of the time/temperature control measures and implement other control options outlined in @.05 E. (1) (b) should the State evaluation indicate that the State is not meeting the risk per serving standards. Proposal 11-201, based on temperature modeling using the *V.v.* calculator, establishes risk per serving standards that are intended to achieve a 60% illness rate reduction. Determining the ability of the ISSC control strategy, based on implementing risk per serving standards, will focus on the number of nationally reported illnesses associated with oysters from the Source States. FDA expects that if the risk per serving standards established in Proposal 11-201 prove to be effective, the number of nationally reported *V.v.* illnesses associated with Gulf oysters will be reduced by 60%. The Source States have generically incorporated as part of their risk reduction measurement a 10% reduction in harvest attributed to stricter time/ temperature controls and a 15% reduction attributed to product diversion to PHP. Actual percentages are certain to vary from State to State and year to year, making it necessary that each State provide data supporting the use of these assumptions. FDA is concerned that efforts to assess the effectiveness of time/temperature controls in achieving risk per serving standards will be difficult. Given the small number of illnesses associated with oysters from an individual State, annual fluctuation of those numbers, and fluctuations in oyster production from year to year, calculating achievement of risk per serving numbers using national illness data and oyster

	production data from each *V.v.* Source State will be challenging. Beginning with the April2012 *V.v.* season, FDA will be evaluating State *V.v.* Control Plans, industry compliance, and State enforcement. While FDA is developing guidance regarding what Shellfish Specialists should consider when conducting *V.v.* evaluations, presently neither FDA nor the ISSC has developed specific criteria for determining compliance with State *V.v.* plan goals. FDA requests that an ISSC committee be appointed to work with FDA to develop State evaluation criteria. FDA requests development of: Evaluation criteria for determining proper and effective use of the *V.v.* calculator; Evaluation criteria for determining State *V.v.* control plan compliance with NSSP requirements; Evaluation criteria for determining the effectiveness of State regulatory efforts to ensure industry compliance with State *V.v.* Control Plan requirements; A formula for calculating State compliance with risk per serving standards; and Actions and sanctions should a State be found out of compliance. In this regard FDA envisions that the established ISSC noncompliance process would be followed, which could result in advising receiving States of issues of noncompliance and recommending that shipments of oysters intended for raw consumption from non-compliant States not be accepted. FDA remains committed to addressing *V.v.* illnesses associated with consumption of raw Gulf oysters. As stated, FDA considers these illnesses to be preventable utilizing PHP technology. FDA will continue to support ISSC efforts to better control the risk of *V.v.* until the obstacles associated with full implementation of PHP are addressed. In the interim, however, FDA cannot support Conference action to change existing *V.v.* control requirements in such a way that they are less likely to achieve the existing 60% illness rate reduction goal. As adopted, FDA considers Proposal 11-201 a less effective approach to preventing *V.v.* illnesses.
Action by FDA October 10, 2012	Food and Drug Administration concurred with adoption of the Conference's Proposal 11-201Part A to initiate a new plan to reduce illnesses and deaths resulting from *Vibrio vulnificus* in raw oysters and looks forward to cooperating with ISSC members to put the plan in effect.
Action by 2013 Vibrio Management Committee	Recommended adoption of the following Vibrio Management Committee (VMC) recommendations: 1. Develop a database to input the *V.v.* Illness Review Committee information. 2. Develop criteria for verifying reduction in harvest for raw consumption and the percentage of post-harvest processed product. Executive Office has had very little success in identifying approaches for obtaining this kind of information and the VMC had no suggestions on how to achieve this either.
Action by 2013 Task Force II	Recommended adoption of VMC recommendation No. 1 to develop a database to input the *V.v.* Illness Review Committee information. Recommended no action on recommendation No. 2 to develop criteria for verifying reduction in harvest for raw consumption and the percentage and refer to ISSC Executive Office. Rationale: The Executive Office has had very little success in

	identifying approaches for obtaining this kind of information and the VMC had no suggestions on how to achieve this.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 11-201 Part A.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-201 Part A.
Action by 2015 Vibrio Management Committee	Recommended no action on Proposal 11-201-A. Rationale: At the 2013 Biennial Meeting the Voting Delegates directed the development of a *V.v*. database. The database has been developed and is in use. No additional action by Task Force II is required.
Action by 2015 Task Force II	Recommends adoption of VMC recommendation of no action on Proposal 11-201-A. Rationale: At the 2013 Biennial Meeting the Voting Delegates directed the development of a *V.v*. database. The database has been developed and is in use. No additional action by Task Force II is required.

Proposal Subject	Review of CDC *V.p.* Illness Information
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management Section @.07 *Vibrio parahaemolyticus* Control Plan
Text of Proposal/ Requested Action	N/A
Public Health Significance	The number of cases of *V.p.* associated with consumption of shellfish reported to the CDC by states in 2009 shows a significant increase from previous years. There were not any large outbreaks that occurred during the year, but the total number of reported cases was the second highest since 1998, which included cases from outbreaks associated with product from all three coasts. The large number of 2009 cases, in the absence of a large outbreak, suggests that the ISSC needs to review current CDC *V.p.* illness information and determine the adequacy of current control strategies in the NSSP. The VMC and the ISSC Executive Board briefly discussed the 2009 reported illnesses and agreed that a *V.p.* subcommittee should discuss the CDC reported information and make appropriate recommendations for VMC review. The purpose of this proposal is to notify the interested parties that change to the controls of Chapter II @.05 may be discussed at the ISSC 2011 Biennial Meeting.
Cost Information	
Action by 2011 Task Force II	Recommended adoption of Vibrio Management Committee recommendation on Proposal 11-206 to refer to an appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted the recommendation of Task Force II on Proposal 11-206.
Action by USFDA 02/26/2012	Concurred with Conference action on Proposal 11-206.
Action by 2013 Vibrio Management Committee	The Vibrio Management Committee recommended that FDA request CDC to be present at Task Force II to answer questions on their data including, (1) does the data include exposures to other foods especially to crustaceans, (2) does data include actual cases or under-reporting factors, and (3) explanation of the *V.p.* death data.
Action by 2013 Task Force II	Recommended referral of Proposal 11-206 back to committee. Task Force II further recommended that CDC be asked to participate as a member of the committee.
Action by 2013 General Assembly	Adopted recommendation of Task Force II on Proposal 11-206.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-206.
Action by 2015 Vibrio Management Committee	Recommended CDC be present at Task Force II to answer questions regarding their data. Other charges of the VMC related to proposal 11-206 have been addressed.

Action by 2015 Task Force II	Recommends no action on Proposal 01-206. Rationale: Charges of the VMC related to this proposal have already been addressed.

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. Requested Action Items: 1. Rewrite Chapter II. Risk Assessment *V.p.* (section 05). 2. Incorporate salinity (and other environment factors?) into *V.v.* and *V.p.* risk calculators. 3. Develop protocol for validating the effectiveness of non-labeling PHPs 4. Develop protocol for ensuring that growing/harvest/handling (production) practices do not increase risk of Vibrio illness. 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 6. Develop new labeling/tagging system for oysters produced under conditions achieve equivalent levels as validated PHP (for labeling), including validation protocol 7. ISSC request FDA to reexamine risk assessments and risk calculators (*V.p.* and *V.v.*) 8. ISSC request FDA to reexamine illness and landings data to determine observed risk per serving 9. Develop the process for using local data to refine calculators to more accurately reflect risk in the region or state 10. Determine how best to estimate national consumption patterns for molluscan bivalves 11. Mega study 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) 13. States request FDA assistance with developing approved method(s) to temper clams 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 (Optional)	
a. Proposed specific research need/ problem to be addressed	1. Is total *V.v.* a valid indicator of risk? 2. Are there differential effects of validated PHP on virulent subpopulations? 3. How do environmental factors affect levels of virulent subpopulations? 4. Compile collection of *V.v.* for future virulence research. 5. Do other species react to controls the same as *V.v.* and *V.p.*? 6. Determine relative virulence of *V.p.* subpopulations. 7. What are Vibrio (total and virulent) levels at harvest (in oysters and clams)? 8. How much Vibrio (total and virulent) growth results from the current time/temperature controls (in oysters and clams)? Priorities: 1. What information is needed to supply more tools to the "toolbox"? 2. What regional information is needed to refine risk assessments and risk calculator tools for implementation of effective control plans? 3. What is the significance of salinity to Vibrio levels in shellfish? 4. Is there a salinity/temperature matrix that determines Vibrio levels? 5. What are the key virulence factors (or combination thereof) for *V.v.* and *V.p.*? 6. Need to know dose response of different Vibrio strains and populations 7. What are the regional differences in pathogenic strains of *V.v.* and *V.p.*? 8. What is the percentage of pathogenic strains of Vibrio in growing waters? 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: 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. 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. 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. 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. 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. 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: 1. 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. 2. Continue to monitor the activities addressed in items 2 & 3 and report annually to the VMC regarding progress. 3. 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	Recommends 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.

Proposal Subject	Vibrio Control Plans
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. @ .05 *Vibrio vulnificus* Control Plan Chapter II. @ .06 *Vibrio parahaemolyticus* Control Plan
Text of Proposal/ Requested Action	@.05 *Vibrio* ~~*vulnificus*~~ Control Plan ~~(Effective January 1, 2012)~~ A. Risk Evaluation 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. (1) In conducting the risk evaluation the State Authority may ~~will at a minimum~~ consider any number of factors, for example~~the following~~: (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 (b) Levels of *Vibrio vulnificus* and *Vibrio parahaemolyticus* in the growing waters and in shellfish, to the extent that such data exists; and (c) Levels of tdh+ and trh+ *Vibrio parahaemolyticus* in the growing area to the extent that such data exists; and (d) The water temperatures in the growing area; and (e) The air temperatures in the growing area; and (f) Salinity in the growing area; and (g) Harvesting techniques in the growing area; and (h) The quantity of harvest from the area and its uses i.e. shucking, half shell, PHP. B. The State shall develop a *Vibrio* Contingency Plan should the risk evaluation indicate: (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 (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; 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~~.~~ 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;~~

EF. *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.~~

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

~~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. 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. 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: 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; 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.

	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	Recommends 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.

Proposal Subject	Re-submerging of Shellstock
Specific NSSP Guide Reference	Section I. Purpose and Definitions Section II. Model Ordinance Chapter V. Shellstock Relaying
Text of Proposal/ Requested Action	Chapter I. Purpose and Definitions Add new definition (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. Renumber existing definitions 92 through 121. Chapter V. Shellstock Relaying and Re-submerging @.01 General The Authority shall assure that: A. The shellstock: (1) U~~u~~sed in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted; (2) Used in re-submerging activities is harvested from growing areas classified as approved or conditionally approved; B. The level of contamination in the shellstock can be reduced to levels safe for human consumption; 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 D. If shellstock are relayed in containers: (1) The containers are: (a) Designed and constructed so that they allow free flow of water to the shellstock; and (b) Located so as to assure the contaminant reduction required in Section C.; and (2) The shellstock are washed and culled prior to placement in the containers. @.02 Contaminant Reduction. 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. B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The study report shall demonstrate that, after the completion of the relay activity:

	(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 (2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA tolerance levels. (3)
Public Health Significance	
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.
Action by 2015 Shellstock Resubmerging Committee	Recommended adoption of the following substitute language. 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. 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 Add a new section Resubmerging. Renumber existing sections as appropriate. @.02 Resubmerging A. General. The Authority shall assure that: (1) The shellstock used in re-submerging activities is harvested from growing areas classified as approved, conditionally approved, restricted or conditionally restricted; (2) The level of contamination in the shellstock can be reduced to levels safe for human consumption; (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 B. Natural Pathogen Reduction (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. (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. (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	Recommends referral of Proposal 13-209 to an appropriate committee as determined by the Conference Chairperson.

Proposal Subject	Aquaculture Facilities Inspections
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VI. Shellfish Aquaculture Requirements for the Authority
Text of Proposal/ Requested Action	@.01 General C. The Authority shall inspect commercial land-based aquaculture systems facilities at least every six months, and open-water grow-out operations, floating aquaculture operations, remote setting operations and nursery systems at least annually. The Authority shall at a minimum (1) Inspect operator records to verify that appropriate permits are up to date and operational plans are being adhered to, and (2) Determine if seed from restricted or prohibited waters are being cultured and if appropriate safeguards are in place to ensure such seed are purged for an appropriate period of time before harvest.
Public Health Significance	The term "aquaculture systems" is undefined. The Model Ordinance only requires the inspection of "floating aquaculture and land-based aquaculture facilities." Bottom culture aquaculture operations do not appear to require inspections at all. The Model Ordinance does not describe what an inspector should examine when inspecting aquaculture systems. For open water and floating aquaculture grow-out operations in open and conditionally approved waters, an annual inspection should be adequate to ensure that appropriate permits are in place and operational plans are being adhered to. Additional inspections do not ensure a higher level of public health protection. Land-based molluscan aquaculture includes hatcheries (exempt), larval-setting operations (that should also be exempt), and nursery systems for very small seed. Grow-out systems do not currently exist because pumping costs are prohibitive, however should economics change to make such systems affordable, these systems will be functionally similar to wet storage systems and will justify more extensive (twice annual) monitoring
Cost Information	Since the current Model Ordinance does not describe what an inspection of an aquaculture system entails, it is difficult to determine the cost impact of this change.
Action by 2013 Task Force II	Recommended referral of Proposal 13-210 to an appropriate Committee as determined by the Conference Chairman with instructions that the Committee address the definition of aquaculture, the frequency of inspection, the items that should be inspected, and the nature of an operational plan.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 13-210.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-210.
Action by 2015 Aquaculture Facility Inspection Committee	Recommended adoption of Proposal 13-210 as amended. @.01 General C. The Authority shall inspect commercial land-based and floating aquaculture systems facilities at least every six months annually.

	The Authority shall at a minimum inspect operator records to verify that appropriate permits are up to date and operational plans are being implemented as written. Delete the following due to duplication: @.03 A. ~~The Authority shall inspect commercial land-based and floating aquaculture systems facilities at least every six months.~~
Action by 2015 Task Force II	Recommends adoption of Aquaculture Facility Inspection Committee recommendation on Proposal 13-210 as amended. @.01 General C. The Authority shall inspect commercial land-based and floating aquaculture systems facilities at least annually. The Authority shall at a minimum inspect operator records to verify that appropriate permits are up to date and operational plans required in @ .03 B. are being implemented ~~as written~~.

Proposal Subject	Tagging Requirements for Wet Stored Shellstock
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers
Text of Proposal/ Requested Action	Section II. Model Ordinance Chapter X. General Requirements B. Tags. (2) The dealer's tag 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) The harvest date; or if depurated, the date of depuration processing, or if wet stored, the original harvest date, the dealers lot designation, the letter "W" and the final harvest date which is the date removed from wet storage. Section IV. Guidance Documents Chapter III. Harvesting, Handling, Processing, and Distribution .04 Shellstock Tagging. Except for shellstock that originated from a depuration-processor, shellstock transported across State lines and placed in wet storage must include the following information on its shipping tag after removal from wet storage: • All information required on a dealer's tag as specified above; and • The statement that "THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO AND WAS REMOVED FROM WET STORAGE ON (DATE)"
Public Health Significance	Having multiple dates on the dealer's tag has proven to be confusing to the customers. The CFIA has chosen to avoid this confusion by listing date of removal from wet storage and listing that as the harvest date. This is the most efficacious method of clarifying the issue of when the shellfish comes out of the water which determines the shelf life of the product. Trace back is still dependent upon the Dealer's inventory control and the ability of the wet storage operator to distinguish which lots of shellfish came from which harvest area on certain dates and which lots went to which customers on which ship dates. This information trail is still vital to the trace back and will still be required. This will make Canadian CFIA wet storage tagging requirements consistent with those of the ISSC and maintain true equivalence between the two programs. This is important since products from both countries compete directly in the marketplace.
Cost Information	Trace back will still be dependent on the wet storage operator's ability to maintain accurate inventory records demarcating which lots from which harvest areas and dates were shipped to which customers on which dates. Requiring this information on the tags as well only adds a layer of complexity and confuses the customers.

Action by 2013 Task Force II	Recommended referral of Proposal 13-212 to an appropriate Committee as determined by the Conference Chairman with instructions to the Committee to try and find ways to increase foreign compliance on this issue.
Action by 2013 General Assembly	Adopted recommendation of Task Force II on Proposal 13-212.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-212.
Action by 2015 Wet Storage Tagging Committee	Recommended no action on Proposal 13-212. Rationale: There is no need for any revisions to the Model Ordinance. This is adequately addressed in the Model Ordinance.
Action by 2015 Task Force II	Recommends adoption of the Wet Storage Tagging Committee recommendation on Proposal 13-212.

Proposal Subject	PHP Validation and Verification Costs
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XVI. Post-Harvest Processing
Text of Proposal/ Requested Action	In 2003 the Interstate Shellfish Sanitation Conference (ISSC) acknowledged the public health benefits of Post-Harvest Processing (PHP) to reduce *Vibrio vulnificus (V.v.)* levels in shellfish. The Conference has continued to support the voluntary adoption of PHP by the shellfish industry. In subsequent years the Conference adopted validation and verification procedures for dealers utilizing PHP. The cost of validation and verification continues to be an obstacle for many smaller dealers. The procedure should be reviewed to identify ways to reduce costs while continuing to provide a reasonable level of public health protection.
Public Health Significance	See Requested Action.
Cost Information	
Action by 2013 Task Force II	Recommended referral of Proposal 13-220 to an appropriate committee as determined by the Conference Chairman.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 13-220.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-220.
Action by 2015 PHP Committee	Recommended no action on Proposal 13-220. Rationale: It has been determined that the current costs of PHP validation and verification is not an obstacle to the voluntary expansion of PHP.
Action by 2015 Task Force II	Recommends adoption of the PHP Committee recommendation on Prooposal 13-220.

Proposal Subject	*Vibrio parahaemolyticus (V.p.)* Control Plan Risk Per Serving
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management
Text of Proposal/ Requested Action	@.06 *Vibrio parahaemolyticus* Control Plan A. Risk Evaluation. Every State from which oysters 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 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 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 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;

(i) Closing the area to oyster harvest.;

(ii) 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.;

(iii) 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.;

(iv) 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.;

(v) 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.

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

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.

	D. States implementing a *Vibrio parahaemolyticus* Control Plan shall determine the level of protection afforded by calculating the observed risk per serving based on the number of annual illnesses attributed to shellfish harvested from the state and the state's annual oyster and/or hard clam production. Modify the Control Plan when the observed risk per serving is greater than one (1) illness per 100,000 servings.
Public Health Significance	In the absence of a requirement for states to determine the observed risk per serving, it is not possible to verify that the level of protection offered by state Control Plans is consistent with the level of protection (≤1 illness per 100,000 servings) intended by time and temperature controls as defined by the *Vibrio parahaemolyticus* risk calculator. Requiring states to determine the observed risk per serving using annual illness data and annual production data will allow the ISSC to gauge the success of state control plans and engage states in developing additional controls where necessary. During periods of unacceptable risk, further restrictions on time and temperature controls, or other equivalent measures, should be considered to reduce risk to an acceptable level.
Cost Information	
Action by 2013 Task Force II	Recommended referral of Proposal 13-223 to an appropriate committee as determined by the Conference Chairman.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 13-223.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-223.
Action by 2015 Vibrio Management Committee	Recommended adoption of Proposal 13-223 as amended. States implementing a *Vibrio parahaemolyticus* control plan shall determine the level of protection afforded by calculating the observed risk per serving based on the number of ~~annual~~ illnesses attributed to shellfish harvested from the state and the state's ~~annual~~ oyster and/or hard clam production for the state's identified risk period. Modify the control plan when the observed risk per serving over a five year period is greater than 1 illness per 100,000 servings.
Action by 2015 Task Force II	Recommends no action on Proposal 13-223 Rationale: Adequately covered in the Model Ordinance.

Proposal Subject	Shellfish Related Illnesses Associated with *V.p.*
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment & Risk Management @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)*
Text of Proposal/ Requested Action	Amend Model Ordinance Chapter II. Risk Assessment & Risk Management @.02 A. (4) (a) to provide clarification regarding closures associated with sporadic cases that 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) day period from an implicated area in which no two (2) cases occurred from a single harvest day. Two (2) options are offered below that could provide needed clarification. Option 1: @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)* A. 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 as follows. (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) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall: (a) ~~d~~Determine the extent of the implicated area; and (b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and (c) ~~The Authority will m~~Make reasonable attempts to ensure compliance with the existing Vibrio Management Plan. (2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed four (4) but not more than ten (10) 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 day from the implicated area, the Authority shall: (a) Determine the extent of the implicated area; and (b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and (c) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish. (3) When the number of cases exceeds ten (10) illnesses within a thirty (30) day period from the implicated area or four (4) or more cases occurred from a single harvest date from the implicated area, The Authority shall: (a) Determine the extent of the implicated area; and (b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and (c) 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) 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 seven (7) days when sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves four (4) or less cases occurring within a thirty (30) day period from the implicated area in which no two (2) cases occurred from a single harvest date from the implicated area. (b) 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. (c) 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) 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. (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.

Option 2:

@.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)*

A. 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 as follows.

(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) 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 compliance with the existing Vibrio Management Plan.

(2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed four (4) but not more than ten (10) 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 day from the implicated area, the Authority shall:

(a) Determine the extent of the implicated area; and

(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and

(c) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish.

(3) When the number of cases exceeds ten (10) illnesses within a thirty (30) day period from the implicated area or four (4) or more cases occurred from a single harvest date from the implicated area, The Authority shall:

(a) Determine the extent of the implicated area; and

(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and

(c) 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) 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 seven (7) days when sporadic cases do not exceed a risk of one (1) illness~~

	~~per 100,000 servings or involves four (4) or less cases occurring within a thirty (30) day period from the implicated area in which no two (2) cases occurred from a single harvest date from the implicated area.~~ ~~(b)~~(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. ~~(c)~~(b) 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) 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. (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.
Public Health Significance	Following the adoption of Proposal 13-202 at the 2013 Biennial Meeting, the Executive Board was asked to clarify the language of the proposal associated with sporadic cases that 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) day period from an implicated area in which no two (2) cases occurred from a single harvest day. To address this concern, the Executive Board, with FDA concurrence, took interim action to delay the implementation of the closure requirement associated with @.02 A. (4) (a). The intent of this Board action was to allow the ISSC to discuss the intent of @.02 A. (4) (a).

Cost Information	
Action by 2015 Task Force II	Recommends adoption of Proposal 15-201 Option 2 as submitted.

Proposal Subject	Shellfish Related Illness Associated with *Vibrio parahaemolyticus(V.p.)*
Specific NSSP Guide Reference	Section II Model Ordinance Chapter II. Section @.02. A. (4)
Text of Proposal/ Requested Action	@.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)* A. 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 as follows. (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) 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 compliance with the existing Vibrio Management Plan. (2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed four (4) but not more than ten (10) 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 day from the implicated area, the Authority shall: (a) Determine the extent of the implicated area; and (b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and (c) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish. (3) When the number of cases exceeds ten (10) illnesses within a thirty (30) day period from the implicated area or four (4) or more cases occurred from a single harvest date from the implicated area, The Authority shall: (a) Determine the extent of the implicated area; and (b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and (c) 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) 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 seven (7) days when sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves four (4) or less cases occurring within a thirty (30) day period from the implicated~~

	~~area in which no two (2) cases occurred from a single harvest date from the implicated area.~~ ~~(b)~~(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. ~~(c)~~(b) 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) 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. (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.
Public Health Significance	Model Ordinance Chapter II. @.02 was adopted by the ISSC Voting Delegates at the 2013 meeting. Subsequent discussion revealed an inconsistency in that reopening criteria were adopted for a tier that does not specify a required closure. This amendment is intended to eliminate this point of confusion.
Cost Information	None.
Action by 2015 Task Force II	Recommends no action on Proposal 15-202. Rationale: This proposal was adequately addressed in Proposal 15-201.

Proposal Subject	Annual Assessment of Shellfish Production and Utilization
Specific NSSP Guide Reference	Section II Model Ordinance Chapter II. Risk Assessment and Risk Management @.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. 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	Recommends adoption of Proposal 15-203 as amended with instructions that a workgroup be formed to investigate production reporting standardization and methodology. 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.).

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas
Text of Proposal/ Requested Action	.04 Wet Storage in Artificial Bodies of Water (Land-Based) A. General (1) If the dealer chooses to practice wet storage in artificial bodies of water, the dealer shall meet the requirements of Chapter VII. .01 and .02. (2) For the purpose of permitting, each wet storage site or activity shall be evaluated in accordance with @.01. B. The evaluation shall include a review of the plan and operating procedures for conducting land-based wet storage activity as submitted by the dealer. ~~(3) Prior to commencing construction, all plans for construction or remodeling of wet storage facilities shall be reviewed and authorized by the Authority.~~ (~~4~~3) The wet storage facility evaluation shall include a review of: (a) The purpose of the wet storage activity, such as holding, conditioning or increasing the salt content of shellstock; (b) Any species specific physiological factors that may affect design criteria; and (c) The plan giving the design of the land-based wet storage facility, source and quantity of process water to be used for wet storage, and details of any process water treatment (disinfection) system. B. Operation Specifications. (1) General. Each land-based wet storage activity shall meet the following design, construction, and operating requirements. (a) Effective barriers shall be provided to prevent entry of birds, animals, and vermin into the area. (b) Storage tanks and related plumbing shall be fabricated of safe material and shall be easily cleanable. This requirement shall include: (i) Tanks constructed so as to be easily accessible for cleaning and inspection, self-draining and fabricated from nontoxic, corrosion resistant materials; and (ii) Plumbing designed and installed so that it can be cleaned and sanitized on a regular schedule, as specified in the operating procedures. (c) Storage tank design, dimensions, and construction are such that adequate clearance between shellstock and the tank bottom shall be maintained. (d) Shellstock containers, if used, shall be designed and constructed so that the containers allow the free flow of water to all shellstock within a container. ~~(2) Buildings. When a building is used for the wet storage activity:~~ ~~(a) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of Chapter XI; and~~ ~~(b) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of Chapter XI.~~ (~~3~~2) Outdoor Tank Operation. When the wet storage activity is outdoors or in a structure other than a building, tank covers shall be used. Tank covers shall: (a) Prevent entry of birds, animals or vermin; and

	(b) Remain closed while the system is in operation except for periods of tank loading and unloading, or cleaning.
Public Health Significance	These requirements are not necessary.
Cost Information	
Action by 2015 Task Force II	Recommends adoption of Proposal 15-204 as submitted.

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting
Text of Proposal/ Requested Action	@.01 Control of Shellstock Growing Areas B. Patrol of Growing Areas. (3) Exceptions. (a) Patrol is not required under the following conditions: (i) There is no shellfish productivity, as demonstrated by one of the following methods: a. pH, salinity, temperature, or turbidity are not favorable to the growth of shellfish; or b. The water bottom does not support shellfish growth; or c. The area has been depleted of shellfish by dredging, disease, or other means; ~~(ii) Harvest from the area is not economically feasible (i.e., the cost of harvesting exceeds the market value of the product);~~ (~~i~~ii) The area meets all of the following conditions: a. The area is unclassified; b. Historically there has not been interest in commercial harvesting; and ~~c. Known points of pollution do not exist; and~~ ~~d~~c. The Authority has current evidence that commercial harvesting does not occur. This can be accomplished by information gathered from periodic patrols or reliable non-patrol sources. (b) Where natural sets resulting in commercially harvestable quantities of shellfish do not exist and advanced aquaculture methods (e.g., racks, bags, lantern nets, long lines and/or floats) are used in the area: The area shall be patrolled at the frequencies specified in Section B. (2) unless the authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities that supplement the minimum required patrol frequency of one (1) time per thirty (30) harvestable days. The Risk Management Plan at least should include the following: (i) Description of the area; (ii) Classification of the area; (iii) Description of adjacent growing areas; (iv) Procedure used to prevent shellfish from prohibited or closed waters to be commingled with shellfish from an aquaculture area; and (v) If, the patrol agency receives assistance from other state, federal, or tribal agencies, a memorandum of agreement (MOA) must be developed describing responsibilities of each agency. A copy of such MOA must be kept in a central file. (c) If the area is geographically remote, sparsely populated and has limited access (e.g., no or very poor roads) such that the potential

for marketing the shellfish is severely restricted:

(i) The area shall be patrolled at the frequencies specified in Section B. (2) unless the Authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities (e.g., airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities, and the area should be patrolled at least one (1) time per thirty (30) harvestable days. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:

a. Description of the area;
b. Classification of the area;
c. Description of adjacent growing areas; and
d. If the patrol agency receives assistance from other state, federal, or tribal agencies, a memorandum of agreement must be developed describing responsibilities of each agency. A copy of such MOA must be kept in a central file.

(ii) If the Authority has current evidence that commercial illegal harvesting is occurring, the Management Risk Plan should be reevaluated.

(d) Where the entire state is closed to harvesting during traditional non-harvesting seasons:

(i) The area shall be patrolled at the frequencies specified in Section B. (2) unless the Authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities (e.g., airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:

a. Description of the area;
b. Classification of the area;
c. Description of adjacent growing areas; and
d. If the patrol agency receives assistance from other state, federal, or tribal agencies, a memorandum of agreement must be developed describing responsibilities from each agency. A copy of such MOA must be kept in a central file.

(ii) The area shall be patrolled in low risk areas at least once (1) per thirty (30) harvestable days, for medium risk areas at least twice (2) per thirty (30) harvestable days, and for high-risk areas at least four (4) times per thirty (30) harvestable days.

	(iii) If the Authority has current evidence that commercial illegal harvesting is occurring, the state agency shall resume patrol at the frequency specified in B. (2). .02 Shellstock Harvesting and Handling. D. Disposal of Human Sewage from Vessels. (1) 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. ~~(2) The Authority shall educate all licensed harvesters and shellstock dealers concerning the public health significance of discharging human sewage overboard.~~ (~~3~~2) 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. (~~4~~3) Portable toilets shall: (a) Be used only for the purpose intended; (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage; (c) Be emptied only into a sewage disposal system; (d) Be cleaned before being returned to the boat; and (e) Not be cleaned in equipment used for washing or processing food. (~~5~~4) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are: (a) Constructed of impervious, cleanable materials and have tight fitting lids; and (b) Meet the requirements in Section D. (3).
Public Health Significance	Chapter VIII. @.01 B. (3) (ii): More appropriate for industry to determine whether something is "economically feasible" or not. Chapter VIII. @.01 B. (3) (iii) (c): To maintain the pollution source requirement means that areas that are completely void of shellfish would still have to be patrolled if a pollution source exists. Chapter VIII. .02 D. (2): This is a Requirement for the Authority and should not appear in a section containing Requirements for Harvesters
Cost Information	
Action by 2015 Task Force II	Recommends adoption of Proposal 15-205 as amended. @.01 Control of Shellstock Growing Areas B. Patrol of Growing Areas. (3) Exceptions. (a) Patrol is not required under the following conditions: (i) There is no shellfish productivity, as demonstrated by one of the following methods: a. pH, salinity, temperature, or turbidity are

not favorable to the growth of shellfish; or

b. The water bottom does not support shellfish growth; or

c. The area has been depleted of shellfish by dredging, disease, or other means;

(ii) The area meets all of the following conditions:

a. The area is unclassified;

b. Historically there has not been interest in commercial harvesting; and

c. The Authority has current evidence that commercial harvesting does not occur. This can be accomplished by information gathered from periodic patrols or reliable non-patrol sources.

(b) Where natural sets resulting in commercially harvestable quantities of shellfish do not exist and advanced aquaculture methods (e.g., racks, bags, lantern nets, long lines and/or floats) are used in the area: The area shall be patrolled at the frequencies specified in Section B. (2) unless the authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities that supplement the minimum required patrol frequency of one (1) time per thirty (30) harvestable days. The Risk Management Plan at least should include the following:

(i) Description of the area;

(ii) Classification of the area;

(iii) Description of adjacent growing areas;

(iv) Procedure used to prevent shellfish from prohibited or closed waters to be commingled with shellfish from an aquaculture area; and

(v) If, the patrol agency receives assistance from other state, federal, or tribal agencies, a memorandum of agreement (MOA) must be developed describing responsibilities of each agency. A copy of such MOA must be kept in a central file.

(c) If the area is geographically remote, sparsely populated and has limited access (e.g., no or very poor roads) such that the potential for marketing the shellfish is severely restricted or not economically feasible:

(i) The area shall be patrolled at the frequencies specified in Section B. (2) unless the Authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities (e.g., airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities, and the area should be patrolled at least one (1) time per thirty (30) harvestable days. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:

a. Description of the area;

b. Classification of the area;
c. Description of adjacent growing areas; and
d. If the patrol agency receives assistance from other state, federal, or tribal agencies, a memorandum of agreement must be developed describing responsibilities of each agency. A copy of such MOA must be kept in a central file.

(ii) If the Authority has current evidence that commercial illegal harvesting is occurring, the Management Risk Plan should be reevaluated.

(d) Where the entire state is closed to harvesting during traditional non-harvesting seasons:

(i) The area shall be patrolled at the frequencies specified in Section B. (2) unless the Authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities (e.g., airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:
a. Description of the area;
b. Classification of the area;
c. Description of adjacent growing areas; and
d. If the patrol agency receives assistance from other state, federal, or tribal agencies, a memorandum of agreement must be developed describing responsibilities from each agency. A copy of such MOA must be kept in a central file.

(ii) The area shall be patrolled in low risk areas at least once (1) per thirty (30) harvestable days, for medium risk areas at least twice (2) per thirty (30) harvestable days, and for high-risk areas at least four (4) times per thirty (30) harvestable days.

(iii) If the Authority has current evidence that commercial illegal harvesting is occurring, the state agency shall resume patrol at the frequency specified in B. (2).

.02 Shellstock Harvesting and Handling.

D. Disposal of Human Sewage from Vessels.

(1) 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.

(2) 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.

	(3) Portable toilets shall: (a) Be used only for the purpose intended; (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage; (c) Be emptied only into a sewage disposal system; (d) Be cleaned before being returned to the boat; and (e) Not be cleaned in equipment used for washing or processing food. (4) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are: (a) Constructed of impervious, cleanable materials and have tight fitting lids; and (b) Meet the requirements in Section D. (3).

Proposal Subject	Harvester Training Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting and Chapter X. General Requirements for Dealers
Text of Proposal/ Requested Action	Chapter VIII. Requirements for Harvesters. .01 General. A. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities. ~~NOTE: The provisions in Section B. below will take effect January 1, 2014.~~ B. Prior to licensing each harvester shall obtain Authority approved training ~~every two (2) years~~ at an interval to be determined by the Authority. 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. (1) A harvester shall obtain proof of completion of the required training. Proof of training obtained by the harvester ~~within the past two (2) years~~ shall be presented to the Authority prior to certification, recertification, or licensing. (2) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training. (3) The harvester shall maintain record of the completed training. C. Persons who are working in a boat crew under the supervision of a licensed harvester need not have a valid harvester's license. 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. Chapter X. General Requirements for Dealers .04 Certification Requirements. A. General. (1) No person shall act as a dealer prior to obtaining certification. (2) Any person who wants to be a dealer shall: (a) Make application to the Authority for certification; (b) Have and implement a HACCP Plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the *Federal Register* of December 18, 1995, except for the requirement for harvester identification on a dealer's tag. ~~NOTE: Requirement (c) below effective January 1, 2014.~~ (c) Obtain Authority approved training at an interval to be determined by the Authority. ~~every two (2) 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. (i) A dealer shall receive proof of completion of the

	required training. Proof of training obtained by the dealer ~~within the past two (2) years~~ 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. (iii) 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.
Public Health Significance	Approved training every two (2) years may not be necessary in some situations. The Authority should be allowed to determine the most appropriate interval for training.
Cost Information	
Action by 2015 Task Force II	Recommends adoption of Proposal 15-206 as amended. Chapter VIII. Requirements for Harvesters. .01 General. A. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities. B. ~~Prior to licensing~~E~~e~~ach 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. (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. (2) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training. (3) The harvester shall maintain record of the completed training. C. Persons who are working in a boat crew under the supervision of a licensed harvester need not have a valid harvester's license. 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. Chapter X. General Requirements for Dealers .04 Certification Requirements. A. General. (1) No person shall act as a dealer prior to obtaining certification. (2) Any person who wants to be a dealer shall: (a) Make application to the Authority for certification; (b) Have and implement a HACCP Plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the *Federal Register* of December 18, 1995, except for the requirement for harvester

	identification on a dealer's tag. (c) 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. (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. (ii) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training. (iii) 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 Subject	Onboard Waste Receptacles
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting Section .02 Shellstock Harvesting and Handling D. (5) (a) and (b)
Text of Proposal/ Requested Action	D. Disposal of Human Sewage from Vessels. (1) 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. (2) The Authority shall educate all licensed harvesters and shellstock dealers concerning the public health significance of discharging human sewage overboard. (3) 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. (4) Portable toilets shall: (a) Be used only for the purpose intended; (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage; (c) Be emptied only into a sewage disposal system; (d) Be cleaned before being returned to the boat; and (e) Not be cleaned in equipment used for washing or processing food. (5) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are: (a) Constructed of impervious, cleanable materials and have tight fitting lids; ~~and~~ (b) Indelibly labeled "Human Waste" in contrasting letters at least three (3) inches in height; and (c) ~~(b)~~ Meet the requirements in Section D. (4). ~~(3).~~
Public Health Significance	Labeling a bucket intended for human waste indicates that the bucket is dedicated to that sole use and assures that a generic unlabeled bucket will not be used for another purpose. It also makes the boat inspection clear in that the Officer inspecting the boat that will know that the bucket is truly a waste bucket and that it is appropriately secured to prevent spillage. The change in (5) (c) is an editorial clean up since there are no requirements to meet in D. (3)
Cost Information	The cost is negligible
Action by 2015 Task Force II	Recommends adoption of Proposal 15-207 as submitted.

Proposal Subject	Reduced Oxygen Packaging (ROP) of Shucked Shellfish Meats
Specific NSSP Guide Reference	Section I. Purposes and Definitions Section II. Model Ordinance Chapter IX. Transportation Section .04 Shipping Temperatures; Section II. Model Ordinance Chapter X. General Requirements for Dealers Section .04 Certification Requirements; Section II. Model Ordinance Chapter X. General Requirements for Dealers Section .06 Shellfish Labeling; Section II. Model Ordinance Chapter XI. Shucking and Packing Section .01 Critical Control Points D. Processing Critical Control Point – Critical Limits and E. Shucked Meat Storage Critical Control Point – Critical Limit; Section II. Model Ordinance Chapter XIV. Reshipping Section .01 Critical Control Points A. Receiving Critical Control Point - Critical Limits and D. Shucked Meat Storage Critical Control Point – Critical Limit
Text of Proposal/ Requested Action	Definitions Add a new definition for Reduced Oxygen Packaging and number appropriately: Reduced Oxygen Packaging means the reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level) and involves a food for which the hazard of *Clostridium botulinum* requires control in the final packaged form. Chapter IX. .04 Shipping Temperatures. A. Shellfish dealers shall ship shellstock adequately iced; or in a conveyance pre-chilled at or below 45°F (7.2°C) ambient air temperature. B. Shellfish dealers shall ship shucked meats that are packed in Reduced Oxygen Packaging (ROP) containers adequately iced; or in a conveyance pre-chilled below 38ºF (3.3ºC) ambient air temperature. Chapter X. .04 Certification Requirements B. Types of Certification. (1) Shucker-packer. Any person who shucks shellfish shall be certified as a shucker-packer. (2) Repacker. (a) Any person who repacks shucked shellfish shall be certified as a shucker-packer or repacker;

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

(3) Shellstock Shipper. Any person who ships and receives shellstock in interstate commerce shall be certified as a shellstock shipper, repacker, or shucker-packer.

(4) Reshipper. Any person who purchases shellstock or shucked shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers or retailers shall be certified as a reshipper.

.06 Shucked Shellfish Labeling

A. Shellfish Labeling

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

(2) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section of the regulation. When returnable containers are used, the shipment shall be accompanied by a transaction record containing:
(a) The original shucker-packer's name and certification number;
(b) The shucking date; and
(c) The quantity of shellfish per container and the total number of containers.

(3) If the dealer uses master shipping cartons, the master cartons are exempt from these labeling requirements when the individual containers within the carton are properly labeled.

(4) At a minimum the dealer shall label each individual package containing fresh or frozen shucked shellfish meat in a legible and indelible form in accordance with CFR 21, Part 101; Part 161, Subpart B (161.30, and 161.136) and the Federal Fair Packaging and Labeling Act.

(5) The dealer shall assure that the shucker-packer's or repacker's certification number is on the label of each package of fresh or frozen shellfish.

(6) The dealer shall label each individual package containing less than 64 fluid ounces of fresh or fresh frozen shellfish with the following:
(a) The words "SELL BY" or "BEST IF USED BY" followed by a reasonable date when the product would be expected to reach the end of its shelf life;
(b) The date shall consist of the abbreviation for the month and number of the day of the month; and
(c) For fresh frozen shellfish, the year shall be added to the date.

(7) The dealer shall label each individual package containing 64 fluid ounces or more of fresh or fresh frozen shellfish with the following:
(a) The words "DATE SHUCKED" followed by the date shucked located on both the lid and sidewall or bottom of the container;
(b) The date shall consist of either the abbreviation for the month and number of the day of the month or in Julian format (YDDD), the last digit of the four digit year and the three digit number corresponding the day of the year; and

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

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

(9) If the dealer freezes fresh shucked shellfish, the dealer shall label all frozen shellfish as frozen in type of equal prominence immediately adjacent to the type of the shellfish and the year shall be added to the date (for non-Julian format).

(10) If the dealer uses lot codes to track shellfish containers, the lot codes shall be distinct and set apart from any date listed on the container.

(11) The dealer shall assure that each package of fresh or frozen shucked shellfish shall include a consumer advisory. The following statement, from Section 3-603.11 of the Current Food Code, or an equivalent statement, shall be included on all packages: "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

(12) The dealer shall assure that each package of fresh shucked shellfish packed in ROP containers is labeled "Keep below 38°F (3.3°C) ambient air temperature."

(13) The dealer shall assure that each package of frozen shucked shellfish packed in ROP containers is labeled "Important, Keep frozen. Thaw under refrigeration below 38ºF (3.3°C) immediately before use."

Chapter XI. Shucking and Packing
.01 Critical Control Points

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

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

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

(2) Have an alert indicator at a combination of time and temperature exposures that will prevent the formation of non-proteolytic C. botulinum toxin formation; and

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

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

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

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

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

(a) ~~s~~Shucked meats are chilled to an internal temperature of 45°F (7.2°C) or less within three (3) hours of shucking. **[C]**

(b) Shucked meats packed into ROP containers are chilled to an internal temperature below 38ºF (3.3ºC) within three (3) hours of shucking. **[C]**

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

(a) ~~s~~Shucked meats are chilled to an internal temperature of 45°F (7.2°C) or less within four (4) hours of removal from

refrigeration. **[C]**

(b) Shucked meats packed into ROP containers are chilled to an internal temperature below 38ºF (3.3ºC) within four (4) hours of shucking. **[C]**

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

(a) ~~t~~The shucked shellfish meats shall be cooled to 45°F (7.2°C) or less within two (2) hours after the heat shock process. **[C]**

(b) Shucked meats packed into ROP containers are chilled to an internal temperature below 38ºF (3.3ºC) within two (2) hours of shucking. **[C]**

(4) When heat shocked shellstock are cooled and held under refrigeration for later shucking, the heat shocked shellstock shall be cooled to an internal temperature of 45°F (7.2°C) within two (2) hours from time of heat shock. **[C]**

(5) For in-shell product the internal temperature of meats does not exceed 45°F (7.2°C) for more than two (2) hours during processing. **[C]**

(6) For shucked shellfish that are ROP packaged, each individual container must have a TTI properly attached and activated per manufacturer specifications. **[C]**

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

(1) ~~s~~Store shucked and packed shellfish in covered containers at an ambient temperature of 45°F (7.2°C) or less or covered with ice. **[C]**

(2) Store shucked meats packed into ROP containers at an ambient air temperature below 38ºF (3.3ºC) or covered in ice. **[C]**

~~F~~G. Shellstock Shipping Critical Control Point – Critical Limits.

H. TTI Storage Critical Control Point – Critical Limits.
The dealer shall store TTIs under conditions that prevents loss of functionality.

Chapter XIV. Reshipping

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits.

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

(a) Identified the shellstock with a tag as outlined in Chapter X. .05, identified the in- shell product with a tag as outlined in Chapter X. .07, and/or identified the shucked shellfish with a label as outlined in Chapter X. .06; and **[C]**

(b) Provided documentation as required in Chapter IX. .04 and .05; and **[C]**

(c) Adequately iced the shellstock; or **[C]**

(d) Shipped the shellstock in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; or **[C]**

(e) Cooled the shellstock to an internal temperature of 50°F (10°C) or less. **[C]**

(f) Shipped shucked meats packed in ROP containers below an

	ambient air temperature of 38ºF (3.3ºC) or covered in ice. **[C]** (g) Shipped shucked meats packed in ROP containers with an appropriately attached and activated TTI that indicates the temperature was maintained below 38ºF (3.3ºC) throughout transit. **[C]** D. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall: (1) ~~s~~Store shucked shellfish at an ambient temperature of 45°F (7.2°C) or less. **[C]** (2) Store shucked shellfish packed into ROP containers below an ambient air temperature of 38ºF (3.3ºC) or covered in ice. **[C]**
Public Health Significance	Available upon request.
Cost Information	
Action by 2015 Task Force II	Recommends no action on Proposal 15-208. Rationale: Not recognized as a public health issue that warrants attention for shucked shellfish at this time.

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers
Text of Proposal/ Requested Action	.01 General HACCP Requirements F. Corrective Actions. (1) Whenever a deviation from a critical limit occurs, a dealer shall take corrective action either by: (a) Following a corrective action plan that is appropriate for the particular deviation, or (b) Following the procedures in Section .01 F. (3). (2) Dealers may develop written corrective action plans, which become part of their HACCP plans in accordance with Section .01 C. (5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that: (a) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and (b) The cause of the deviation is corrected. (3) When a deviation from a critical limit occurs and the dealer does not have a corrective action plan that is appropriate for that deviation, the dealer shall: (a) Segregate and hold the affected product~~, at least~~ until: ~~the requirements of Section .01 F. (3) (b) and (c) are met;~~ ~~(b) Perform or obtain~~ (i) There is a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with Section .01 I.; and ~~(c) Take corrective action,~~ (ii) Corrective action is taken when necessary~~, with respect to the affected product~~ to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.~~;~~ ~~(d) Take corrective action, when necessary, to correct the cause of the deviation;~~ (~~e~~b) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Section .01 I., to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary. (4) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Section .01 G. and the record keeping requirements of Section .01 H.

	.04 Certification Requirements A. General. (1) No person shall act as a dealer prior to obtaining certification. (2) Any person who wants to be a dealer shall: (a) Make application to the Authority for certification; (b) Have and implement a HACCP Plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the *Federal Register* of December 18, 1995, except for the requirement for harvester identification on a dealer's tag. ~~NOTE: Requirement (c) below effective January 1, 2014~~ (c) Obtain Authority approved training every two (2) 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.
Public Health Significance	Chapter X. .01 F. (3) (d): Remove rewording to eliminate repetitiveness. Chapter X. .04 A. (2) (b): The stated effective date has passed and the note no longer serves any purpose.
Cost Information	
Action by 2015 Task Force II	Recommends adoption of Proposal 15-209 as submitted.

Proposal Subject	Dealer Tagging
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers
Text of Proposal/ Requested Action	05. Shellstock Identification A. General (1) The dealer shall keep the harvester's tag affixed to each container of shellstock until the container is: (a) Shipped with his/her dealer tag affixed to each container of shellstock; or (b) Emptied to wash, grade, or pack the shellstock. (2) When the dealer is also the harvester and he elects not use a harvester tag, the dealer shall affix his dealer tag to each container of shellstock prior to shipment.
Public Health Significance	As written, there is no requirement for a dealer to affix his/her dealer tag to each container of shellstock prior to shipment. The language for affixing tags to each container is currently for harvesters who are also dealers. The NSSP requires that the product be identified with certain information showing that the shellfish were harvested by licensed diggers and shipped and processed by certified dealers. This information assists in tracing the product back through the distribution system to the growing area in the event the shellfish are associated with a disease outbreak. Additionally, the Federal Food, Drug and Cosmetic Act requires that food labels provide an accurate statement which includes the name and address of either the manufacturer, packer, or distributor; the net amount of food in the package; the common or usual name of the food; and the ingredients, unless the product conforms to standard of identity requirements. Foods shipped in interstate commerce having labels that do not meet these requirements are deemed misbranded and in violation of Section 405 of the Food, Drug and Cosmetic Act.
Cost Information	Dealers are already adding tags; no additional cost.
Action by 2015 Task Force II	Recommends adoption of Proposal 15-210 as submitted.

Proposal Subject	Shucked Shellfish Labeling
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers
Text of Proposal/ Requested Action	.06 Shucked Shellfish Labeling. A. Shellfish Labeling. (1) The dealer shall maintain… (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" 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; (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)
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.

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing
Text of Proposal/ Requested Action	.02 Sanitation B. Condition and Cleanliness of Food Contact Surfaces (2) Cleaning and sanitizing of food contact surfaces. (a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall: (i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant; **[K]** (ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; **[K]** (iii) Wash and rinse equipment and utensils at the end of each day. **[K]** (b) Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling. **[K]** (c) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. **[K]** (d) Shucked shellfish shall be packed in clean covered containers and stored in a manner which assures their protection from contamination: (i) Fabricated from food grade materials; and **[K]** (ii) Stored in a manner which assures their protection from contamination. **[K]** (e) If used, the finger cots or gloves shall be: (i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; **[O]** (ii) Sanitized at least twice daily; **[K]** ~~(iii) Cleaned more often, if necessary **[K]**;~~ (iii~~v~~) Properly stored until used; and **[K]** (iv) Maintained in a clean, intact, and sanitary condition. **[K]**
Public Health Significance	This is addressed in Chapter XI. .02 B. (2) (e) (v).
Cost Information	
Action by 2015 Task Force II	Recommends adoption of Proposal 15-212 as submitted.

Proposal Subject	Temperature Control Following Receipt from Harvesters
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing .03 Other Model Ordinance Requirements F. Shellfish Storage and Handling (11) and Chapter XIII. Shellstock Shipping .03 Other Model Ordinance Requirements F. Shellfish Storage and Handling (6)
Text of Proposal/ Requested Action	Chapter XI. Shucking and Packing .03 Other Model Ordinance Requirements F. Shellfish Storage and Handling (11) All shellstock obtained from a licensed harvester shall be (a) Adequately iced within two (2) hours of receipt; (b) Placed in a storage area maintained at 45°F (7.2°C) within two (2) hours of receipt; or (c) Shucked within two (2) hours of receipt. **[SC/K]** Chapter XIII. Shellstock Shipping .03 Other Model Ordinance Requirements F. Shellfish Storage and Handling (6) All shellstock obtained from a licensed harvester shall be (a) Adequately iced within two (2) hours of receipt; or (b) Placed in a storage area maintained at 45° F (7.2° C) within two (2) hours of receipt.~~; or~~ ~~(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. 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. 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. 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."

	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." 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	Recommends referral of Proposal 15-213 to an appropriate committee as determined by the Conference Chairperson.

Proposal Subject	Program Element Evaluation Criteria
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing, Chapter XII. Repacking of Shucked Shellfish, Chapter XIII. Shellstock Shipping, and Chapter XIV. Reshipping
Text of Proposal/ Requested Action	.03 Other Model Ordinance Requirements. A. Plants and Grounds. ~~(1) General. The physical facilities shall be maintained in good repair. **[O]**~~ (~~2~~1) Flooding. (a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. **[C]** (b) If facilities are flooded: (i) Shellfish processing, shucking or repacking activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. **[C]** (ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use. **[C]** ~~(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. **[S~~ ~~C/K~~ ~~]**~~ ~~(4) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in the facility.~~ ~~(a) Tight fitting, self closing doors: **[K]**~~ ~~(b) Screening of not less than fifteen (15) mesh per inch; **[K]** and~~ ~~(c) Controlled air current. **[K].**~~ (~~5~~2) Plant Interior. ~~(a) Sanitary conditions shall be maintained throughout the facility. **[O]**~~ (~~b~~a) All dry area floors shall be hard, smooth, easily cleanable; and **[O]** (~~c~~b) All wet area floors used in areas to store shellfish, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which: (i) Are graded to provide adequate drainage; **[O]** (ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; **[O]** (iii) Have sealed junctions between floors and walls to render them impervious to water,~~; and~~ **[O]** (~~d~~c) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials **[O]**. ~~(6) Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:~~

	~~(a) Rodent attraction and harborage; and~~ **[O]** ~~(b) Inadequate drainage.~~ **[O]**
Public Health Significance	Requirements recommended for deletion are either not critical to the safety of shellfish product or already addressed by one or more of the eight sub-sections at .02 Sanitation.
Cost Information	
Action by 2015 Task Force II	Recommends no action on Proposal 15-214. Rationale: Proposal is adequately addressed in Model Ordinance.

Proposal Subject	Program Element Evaluation Criteria
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing, Chapter XII. Repacking of Shucked Shellfish, Chapter XIII. Shellstock Shipping, and Chapter XIV. Reshipping
Text of Proposal/ Requested Action	.03 Other Model Ordinance Requirements. C. Utilities. ~~(1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. [S C/K]~~ ~~(2)~~ The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[S C/K]**
Public Health Significance	Requirements recommended for deletion are either not critical to the safety of shellfish product or already addressed by one or more of the eight sub-sections in @.02 Sanitation.
Cost Information	
Action by 2015 Task Force II	Recommends no action on Proposal 15-215. Rationale: Proposal is adequately addressed in Model Ordinance.

Proposal Subject	Program Element Evaluation Criteria
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing, Chapter XII. Repacking of Shucked Shellfish, Chapter XIII. Shellstock Shipping, and Chapter XIV. Reshipping
Text of Proposal/ Requested Action	Chapter XI. .03 Other Model Ordinance Requirements ~~D. Disposal of Other Wastes.~~ ~~(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]~~ ~~(2) Shell and other non-edible materials shall be promptly and effectively removed from the shucking bench or table. [O]~~ ~~(3) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; and [O]~~ Chapter XII., Chapter XIII., and Chapter XIV. .03 Other Model Ordinance Requirements ~~D. Disposal of Other Wastes.~~ ~~(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]~~ ~~(2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; [O]~~
Public Health Significance	Requirements recommended for deletion are either not critical to the safety of shellfish product or already addressed by one or more of the eight sub-sections at .02 Sanitation.
Cost Information	
Action by 2015 Task Force II	Recommends no action on Proposal 15-216. Rationale: Proposal is adequately addressed in Model Ordinance.

Proposal Subject	Shucked Meat Storage Critical Control Point – Critical Limit
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XII. Repacking of Shucked Shellfish and Chapter XIV. Reshipping
Text of Proposal/ Requested Action	Chapter XII. Repacking of Shucked Shellfish .01 Critical Control Points C. Shucked Meat Storage Critical Control Point – Critical Limit. (1) 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]** and (2) The dealer shall store repacked shellfish in covered containers at an ambient temperature of 45°F (7.2°C) or less or covered with~~in~~ ice. **[C]** Chapter XIV. Reshipping 01. Critical Control Points D. Shucked Meat Storage Critical Control Point – Critical Limit. The dealer shall store shucked shellfish at an ambient temperature of 45°F (7.2°C) or less or covered with ice. **[C]**
Public Health Significance	The critical limits for the storage of shucked meats are inconsistent throughout the Model Ordinance chapters and should be consistent. Additionally, repackers have requirements for storing repacked shucked shellfish, but no critical limit requirement for storing shucked meats that they purchase before repacking. Shucked shellfish are an excellent medium for the growth of bacteria. Therefore, it is very important that the packaged shellfish meats be cooled and refrigerated promptly so that bacteria growth is minimized. Studies have shown that bacterial growth is significantly reduced at storage temperatures of less than 7.2°C (45°F) and that storage in wet ice is the most effective method for refrigeration of shucked meats.
Cost Information	Dealers are already holding shucked meats at 45°F or below, or in ice.
Action by 2015 Task Force II	Recommends adoption of Proposal 15-217 as amended. Chapter XII. Repacking of Shucked Shellfish .01 Critical Control Points C. Shucked Meat Storage Critical Control Point – Critical Limit. ~~(1) 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]** and~~ ~~(2)~~ 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]** Chapter XIV. Reshipping 01. Critical Control Points D. Shucked Meat Storage Critical Control Point – Critical Limit. The dealer shall store shucked shellfish at an ambient temperature of 45°F (7.2°C) or less or covered with ice. **[C]**

Proposal Subject	Program Element Evaluation Criteria
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing, Chapter XII. Repacking of Shucked Shellfish, Chapter XIII. Shellstock Shipping, and Chapter XIV. Reshipping
Text of Proposal/ Requested Action	.03 Other Model Ordinance Requirements. H. Supervision. (1) A reliable, competent individual shall be designated to supervise general plant management and activities; **[K]** (2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. **[K]** (3) All supervisors shall be: (a) Trained in proper food handling techniques and food protection principles; and **[K]** (b) Knowledgeable of personal hygiene and sanitary practices **[K]** (4) The dealer shall require: (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. **[K]** (b) Supervisors to assure that proper sanitary practices are implemented, including: (i) Plant and equipment clean-up; **[K]** (ii) Rapid product handling; and **[K]** (iii) Shellfish protection from contamination. **[K]** (c) Supervisors shall not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. **[K]** (d) Employees shall~~:(i) B~~be trained in proper food handling and personal hygiene practices~~, and~~ **[K]** ~~(ii) Report any symptoms of illness to their supervisor. [K]~~
Public Health Significance	Requirements recommended for deletion are either not critical to the safety of shellfish product or already addressed by one or more of the eight sub-sections at .02 Sanitation.
Cost Information	
Action by 2015 Task Force II	Recommends adoption of Proposal 15-218 as submitted.

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing
Text of Proposal/ Requested Action	.02 Sanitation B. Condition and Cleanliness of Food Contact Surfaces (1) Equipment and utensil construction for food contact surfaces. ~~(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guides.* **[K]**~~ (~~b~~a) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are: (i) Constructed in a manner and with materials that can be cleaned, and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; **[K]** (ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and **[K]** (iii) Fabricated from food grade materials. **[K]** (~~c~~b) The dealer shall assure that all joints on food contact surfaces (i) Have smooth easily cleanable surfaces; and **[K]** (ii) Are welded. **[K]** (~~d~~c) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI. .02 B. (1) (a), (b), and (c). **[K]** (~~e~~d) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it: (i) Is easily accessible for cleaning and inspection; **[K]** (ii) Is self-draining; and **[K]** (iii) Meets the requirements for food contact surfaces. **[K]** C. Prevention of Cross Contamination (1) Protection of shellfish. (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. **[S$^{C/K}$]** ~~(b) Shellfish shall be protected from contamination. **[S$^{C/K}$]**~~ (b~~e~~) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. **[K]** (c~~d~~) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[S$^{K/O}$]**
Public Health Significance	Chapter XIII. .02 B. (1) (a): Equipment should become current with updated laws. Chapter XIII. .02 C. (1) (b): Duplicate requirements listed.
Cost Information	
Action by 2015 Task Force II	Recommeneds adoption of Proposal 15-219 as amended.

	.02 Sanitation B. Condition and Cleanliness of Food Contact Surfaces (1) Equipment and utensil construction for food contact surfaces. (a) The dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guides*. **[K]** (b) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are: (i) Constructed in a manner and with materials that can be cleaned, and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; **[K]** (ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and **[K]** (iii) Fabricated from food grade materials. **[K]** (c) The dealer shall assure that all joints on food contact surfaces (i) Have smooth easily cleanable surfaces; and **[K]** (ii) Are welded. **[K]** (d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI. .02 B. (1) (a), (b), and (c). **[K]** (e) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it: (i) Is easily accessible for cleaning and inspection; **[K]** (ii) Is self-draining; and **[K]** (iii) Meets the requirements for food contact surfaces. **[K]** C. Prevention of Cross Contamination (1) Protection of shellfish. (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. **[S$^{C/K}$]** (b) Shellfish shall be protected from contamination. [SC/K] (c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. **[K]** (d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[S$^{K/O}$]**

Proposal Subject	Shellfish Storage and Handling
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIII. Shellstock Shipping
Text of Proposal/ Requested Action	.03 Other Model Ordinance Requirements F. Shellfish Storage and Handling. (1) The dealer shall: (a) Assure that shellstock is: (i) Alive; **[K]** (ii) Reasonably free of sediment **[O]**; and (iii) Culled.~~;~~ **[K]** (2) The dealer shall inspect incoming shipments and shall reject dead or inadequately protected shellstock.~~;~~ **[K]** (3) A dealer ~~whose activity consists of trucks or docking facilities only~~ shall: (a) Have a permanent business address at which records are maintained and inspections can be performed in a timely fashion; and **[K]** (b) Not repack shellstock or be the original shipper of shellstock received from a harvester if their facility consists of trucks or docking facilities only. **[K]**
Public Health Significance	Control of naturally occurring Vibrios.
Cost Information	
Action by 2015 Task Force II	Recommends referral of Proposal 15-220 to an appropriate committee as determined by the Conference Chairperson with instruction to committee to review requirements for reshipping and shipping for consistency. Committee is directed to develop criteria for evaluating the adequacy of trucks and conveyances as storage facilities.

Proposal Subject	Reshipping Shucked and In-shell Product Receiving Critical Limit
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIV. Reshipping .01 Critical Control Points
Text of Proposal/ Requested Action	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]** or (f) Shipped the shucked shellfish and/or in-shell product iced or in a conveyance at or below 45°F (7.2°C) ambient air temperature; **[C]**
Public Health Significance	The subject requirement appeared in the 2009 Model Ordinance but was inadvertently removed when the ISSC Executive Board adopted new time to temperature controls on an interim basis prior to the 2011 Conference.
Cost Information	Cost will be the same as it was before the requirement was removed.
Action by 2015 Task Force II	Recommends adoption of Proposal 15-221 as submitted.

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XV. Depuration
Text of Proposal/ Requested Action	.01 Critical Control Points A. Receiving Critical Control Point - Critical Limits. ~~(1) The dealer shall receive and depurate only shellstock which is obtained from a licensed harvester who has:~~ ~~(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag;~~ **~~[C]~~** ~~and~~ ~~(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment;~~ **~~[C]~~** ~~and~~ ~~(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].~~** ~~(2) The dealer shall receive and depurate only shellstock obtained and transported from a dealer who has:~~ ~~(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);~~ **~~[C]~~** ~~and~~ ~~(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]~~** ~~(3) Should a dealer receive shellstock from a dealer who is shipping shellstock harvested in accordance with Chapter VIII. @.02 A. (3) or restricted use shellstock that has not been cooled to an internal temperature of 50° F (10° C), the shellstock must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. This product can be received without meeting the receiving requirements of Chapter XIII. .01 A. (2) (c), (d) or (e). Shipments of four (4) hours or less will not be required to have a time/temperature device.~~ **~~[C]~~** ~~(4)~~ The dealer shall receive and depurate only shellstock obtained from a special licensed harvester who has: (1~~a~~) Harvested or supervised the harvest of shellstock from a Restricted or Conditionally Restricted area in the open status; **[C]** and (2~~b~~) Identified the shellstock by transaction records which include the harvest area, the special-licensed harvester's name, harvester license number(s), the harvest date, and the amount of shellstock shipped in each lot. **[C]**
Public Health Significance	This practice should not be permitted under the NSSP since product from approved or conditionally approved waters (in the open status) can be harvested and sold without depuration. Permitting this practice suggests that the growing area classification section of

	the NSSP is not adequate.
Cost Information	
Action by 2015 Task Force II	Recommends no action on Proposal 15-222. Rationale: This proposal was previously addressed in Proposal 01-206.

Proposal Subject	Post-Harvest Processing
Specific NSSP Guide Reference	Section II Model Ordinance Chapter XVI. Post-Harvest Processing
Text of Proposal/ Requested Action	Chapter XVI. ~~Post-Harvest Processing~~ Processes and Procedures for Pathogen Reduction .01 Processes and Procedures Involving Labeling Claims. A. If a dealer elects to use a process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concern in shellfish, and wishes to make labeling claims regarding the reduction of pathogens, the dealer shall: (1) Have a HACCP plan approved by the Authority for the process that ensures that the target pathogen(s) are at safe levels for the at risk population in product that has been subjected to the process. The HACCP Plan shall include: (a) Process controls to ensure that the end point criteria are met for every lot; and (b) A sampling program to periodically verify that the end point criteria are met. (c) Analytical results used for validation and verification of a PHP shall come from an analytical laboratory that is evaluated by the State and/or FDA and found to be in compliance with applicable NSSP laboratory requirements. (2) Validate the process by demonstrating that the process will reliably achieve the appropriate reduction in the target pathogen(s). The process shall be validated by a study as outlined in Guidance Documents Chapter IV., Naturally Occurring Pathogens, Section .02 and be approved by the Authority, with concurrence of FDA. (a) The dealer must demonstrate that the process reduces the level of Vibrio vulnificus and/or Vibrio parahaemolyticus in the process to non-detectable (<30MPN/gram) and the process achieves a minimum 3.52 log reduction. Determination of V. vulnificus and/or V. parahaemolyticus levels must be done using the MPN protocols described in Guidance Documents, Chapter IV., Naturally Occurring Pathogens, Section .02 followed by confirmation using methods approved for use in the NSSP. (b) For processes that target other pathogens the dealer must demonstrate that the level of those pathogens in processed product has been reduced to levels below the appropriate FDA action level, or, in the absence of such a level, below the appropriate level as determined by the ISSC. (3) Conduct verification sampling to verify that the validated process is working properly. Verification sampling shall be at least equivalent to the verification protocol found in Guidance Documents, Chapter IV., Naturally Occurring Pathogens, Section .02 as determined by the Authority and shall be reviewed annually by the Authority. (4) Package and label all shellfish in accordance with all requirements of this Ordinance. This includes labeling all shellfish which have been subject to the process but which are not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter X. .05 and X. .06. (5) Keep records in accordance with Chapter X. .07.

	B. A dealer who meets the requirements of this section may label product that has been subjected to the reduction process as: (1) "Processed for added safety", if the process reduces the levels of all pathogens of public health concern to safe levels for the at risk population; (2) "Processed to reduce [name of target pathogen(s)] to non-detectable levels," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or (3) "Processed to reduce [name of target pathogen(s)] to non-detectable levels for added safety," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or (4) A term that describes the type of process applied (e.g., "pasteurized," "individually quick frozen," "pressure treated") may be substituted for the word "processed" in the options contained in B. (1) - (3). C. For the purpose of product temperature the receiving and storage critical control points of Chapter XI., shall apply to shellstock prior to PHP processing. Following PHP processing, if the product is dead, the product shall be treated as in-shell or shucked product. If the product is live, the product shall be treated as shellstock. .02 Processes and Procedures Not Involving Labeling Claims. A. If a dealer elects to use a post-harvest process(es) to reduce the levels of a naturally occurring pathogen(s) of public health concern in shellfish, the dealer shall: (1) Have a HACCP plan (approved by the Authority) for the control(s) that reduces the target pathogen(s). (a) The dealer must validate that the post-harvest process(es) reduces naturally occurring pathogen(s). The validation study must be approved by the State Shellfish Control Authority with FDA concurrence. (b) The ability of the post-harvest process(es) to reliably achieve the appropriate reduction in the target pathogen(s) shall be verified at a frequency determined by the State Shellfish Control Authority. (2) Package and label all shellfish in accordance with the requirements of this Ordinance. (3) Keep records in accordance with Chapter X. 07.
Public Health Significance	The changes recommended by the proposal provide added opportunities for shellfish dealers to meet the required State Control Plans for naturally occurring pathogens.
Cost Information	
Action by 2015 Task Force II	Recommends adoption of Proposal 15-223 as submitted.

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XVI. Post-Harvest Processing
Text of Proposal/ Requested Action	B. A dealer who meets the requirements of this section may label product that has been subjected to the reduction process as: (1) "Processed for added safety", if the process reduces the levels of all pathogens of public health concern to safe levels for the at risk population; (2) "Processed to reduce [name of target pathogen(s)] to non-detectable levels," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or ~~(3) "Processed to reduce [name of target pathogen(s)] to non-detectable levels for added safety," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or~~ (~~4~~3) A term that describes the type of process applied (e.g., "pasteurized," "individually quick frozen," "pressure treated") may be substituted for the word "processed" in the options contained in B. (1) - (~~3~~2).
Public Health Significance	Chapter XVI. B. (2) and Chapter XVI. B. (3) are duplicate requirements and one should be removed.
Cost Information	
Action by 2015 Task Force II	Recommends no action on Proposal 15-224. Rationale: Proposal is adequately addressed in Model Ordinance.

Proposal Subject	Conveyances Used to Transport Shellstock Directly to Retail
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter III. Harvesting, Handling, Processing, and Distribution .07 Time and Temperature Controls
Text of Proposal/ Requested Action	Chapter IX. Conveyances Used to Transport Shellstock to the Original Dealer. Conveyances used to transport shellstock from the harvest area to the original dealer shall be constructed to prevent contamination, deterioration, or decomposition of the shellstock during transport. For shellstock being delivered within the time to temperature controls of Chapter VIII. @.02 A. (1) (2) and (3), refrigeration of the conveyance is not required. However, shellstock transport must comply with Chapter IX. .01 C. and may not be shipped in a manner which would cause the temperature of the shellstock to increase. Persons responsible for transporting shellstock must take reasonable steps to assure that the shellstock temperature is not increased unnecessarily as a result of the method of transport. An example would be a closed-in truck with a high internal temperature caused by very warm ambient temperature or exposed to direct sunlight for a long period of time while closed. The Authority shall monitor this activity to assure compliance. When temperature control is necessary during transport to the original dealer to comply with the Authority established time to temperature controls, the shellstock must be cooled with ice or mechanical refrigeration. This cooling must be capable of achieving the required internal temperature of 55°F (12.7°C) for shellstock harvested under State V.v. Plans or 50°F (10°C) for all other shellstock. Should compliance with internal temperatures involve refrigeration on board the vehicle or in the transportation conveyance prior to reaching the original dealer, shellstock must be cooled as necessary to comply with the internal temperature of 55°F (12.7°C) for shellstock harvested under State V.v. Plans or 50°F (10°C) for all other shellstock. Refrigeration units must be pre-chilled to 45°F (7.2°C) and the refrigeration unit must be maintained at a temperature to ensure that the shellstock temperature is not allowed to increase. Ice can also be used to cool shellstock. Any ice on-site at a certified dealer shall be from potable water in a commercial ice machine or come from a source certified by the Authority or the appropriate regulatory Authority. Once cooling of the shellstock begins, that cooling must be continued using an acceptable cooling method. Conveyances Used to Transport Shellstock from Dealer to Dealer. 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. 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. 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. 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. Conveyances Used to Transport Shellstock Directly to Retail 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. 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 additional language is needed for clarification involving shipments of shellstock directly to retail.
Cost Information	
Action by 2015 Task Force II	Recommends adoption of Proposal 15-225 as submitted.

Proposal Subject	*V.p.* Illness Response Guidance Document
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter V. Illness Outbreaks and Recall Guidance
Text of Proposal/ Requested Action	Add new section: .03 *V.p.* Illness Response Guidance Document I. Introduction 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: 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. 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.* 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. 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. II. Illness Investigation 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 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. VIII. Laboratory 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. IX. Approved Laboratory Methods Methods for the analyses of shellfish and shellfish growing or harvest waters shall be: 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	Recommends referral of Proposal 15-226 to an appropriate committee as determined by the Conference Chairperson. This section should be removed from the NSSP Guide as interim guidance pending further ISSC action.

Proposal Subject	Determining the Size of Closed Area as a Result of Illnesses
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Risk Assessment and Risk Management
Text of Proposal/ Requested Action	.03. Determining the Size of Closed Area as a Result of Illnesses A. Barriers that would inhibit pathogen and toxin distribution within the growing area (based on documented data/information in the sanitary survey considering the following, as applicable: (1) Salinity (2) Temperature (3) Stratification (4) Circulation (5) Hydrographic patterns and bathymetry B. Water movement (based on documented information in sanitary survey) considering the following, as applicable: (1) Tidal influence and range (2) Flows (3) Precipitation (4) Wind C. Laboratory results and/or field measurements and/or other relevant information or data. D. Closure boundaries (1) Must be enforceable. (2) May be part of one area, a whole area, or all or parts of multiple areas depending on size of areas and pattern of harvest-related illnesses. (3) Configuration of area may change over time as more information is available, or water quality/tissue samples show no exceedance. (4) In the absence of information to the contrary, the entire harvest area should be closed. E. If sufficient data listed in .03 (A. - D.) is not available then the entire growing area(s) should immediately be closed. If data is obtained at a later date that can further define the spatial extent of source of the implicated shellfish a more defined closure area within the shellfish growing area(s) may be designated by the authority with subsequent changes to associated embargoes or recalls. F. Species subject to closure. Closure may be limited to where specific species are harvested in an area or limited to certain species (NSSP Chapter II @.01.G (4)). .04. Determining the Harvesting Periods Associated with Implicated Product for Identifying Shellfish to be Included in the Recall A. Identify the harvest date of all reported illness(es). B. Determining the likelihood of product remaining in the marketplace with consideration of shellstock vs. in-shell vs. fresh shucked vs. frozen shucked. C. Identify the date of [last] most recently reported illness(es) and the date of growing area closure

	.05 Determining the Scope of Implicated Product for Conducting a Recall A. Are illnesses related to: (1) single harvester (2) single dealer or (3) single route of transportation (4) single retailer (5) single consumption event (e.g. party) (6) single product type or species (7) single growing area or harvest area B. Have any post-harvest handling issues been identified that may have contributed to the occurrence of illness(es) including but not limited to harvesters, dealers, restaurants, retail, common carriers, or consumers. C. Production Consideration (1) Harvest event(s) and amount of production from growing area or areas (if commingling has occurred). (2) Number of harvesters associated with implicated shellfish (3) Number of dealers associated with implicated shellfish (4) Determine likelihood of product remaining in the marketplace (shellstock vs. in-shell vs. fresh shucked vs. frozen shucked). (5) Harvest or culture practices including wet storage, relay, resubmergence, transplant, etc. D. Strength of evidence, i.e. the evaluation should consider strength of evidence collected in relation to items .05 A., B., and C. above.
Public Health Significance	The purpose of this document is to provide guidance to State Shellfish Control Authorities (SSCAs) in determining scope of closures and recalls in response to illness outbreaks.
Cost Information	
Action by 2015 Task Force II	Recommends adoption of Proposal 15-227 as amended. .03. Determining the Size of Closed Area as a Result of Illnesses A. Barriers that would inhibit pathogen and toxin distribution within the growing area (based on documented data/information in the sanitary survey considering the following, as applicable: (1) Salinity (2) Temperature (3) Stratification (4) Circulation (5) Hydrographic patterns and bathymetry B. Water movement (based on documented information in sanitary survey) considering the following, as applicable: (1) Tidal influence and range (2) Flows (3) Precipitation (4) Wind C. Laboratory results and/or field measurements and/or other relevant information or data. D. Closure boundaries (1) Must be enforceable.

(2) May be part of one area, a whole area, or all or parts of multiple areas depending on size of areas and pattern of harvest-related illnesses.

(3) Configuration of area may change over time as more information is available, or water quality/tissue samples show no exceedance.

~~(4) In the absence of information to the contrary, the entire harvest area should be closed.~~

E. If sufficient data listed in .03 (A. - D.) is not available then the entire growing area(s) should immediately be closed. If data is obtained at a later date that can further define the spatial extent of source of the implicated shellfish a more defined closure area within the shellfish growing area(s) may be designated by the authority with subsequent changes to associated embargoes or recalls.

F. Species subject to closure.
Closure may be limited to where specific species are harvested in an area or limited to certain species (NSSP Chapter II @.01.G (4)).

.04. Determining the Harvesting Periods Associated with Implicated Product for Identifying Shellfish to be Included in the Recall

A. Identify the harvest date of all reported illness(es).

B. Determining the likelihood of product remaining in the marketplace with consideration of shellstock vs. in-shell vs. fresh shucked vs. frozen shucked.

C. Identify the date of [last] most recently reported illness(es) and the date of growing area closure

.05 Determining the Scope of Implicated Product for Conducting a Recall

A. Are illnesses related to:

(1) single harvester
(2) single dealer or
(3) single route of transportation
(4) single retailer
(5) single consumption event (e.g. party)
(6) single product type or species
(7) single growing area or harvest area

B. Have any post-harvest handling issues been identified that may have contributed to the occurrence of illness(es) including but not limited to harvesters, dealers, restaurants, retail, common carriers, or consumers.

C. Production Consideration

(1) Harvest event(s) and amount of production from growing area or areas (if commingling has occurred).
(2) Number of harvesters associated with implicated shellfish
(3) Number of dealers associated with implicated shellfish
(4) Determine likelihood of product remaining in the marketplace (shellstock vs. in-shell vs. fresh shucked vs. frozen shucked).
(5) Harvest or culture practices including wet storage, relay, resubmergence, transplant, etc.

D. Strength of evidence, i.e. the evaluation should consider strength of evidence collected in relation to items .05 A., B., and C. above.