Interstate Shellfish Sanitation Conference

Summary of Actions

2013 Biennial Meeting
January 25 – January 31, 2014

The St. Anthony Riverwalk Hotel
"a national historic landmark"

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Proposal No. 05-111

Proposal Subject: Rapid Extraction Method for PSP and ASP

Specific NSSP Guide Reference: Section II. Model Ordinance Chapter III Laboratory @.02 Methods
ISSC Constitution, Bylaws, and Procedures
Procedure XVI.

Text of Proposal/ Requested Action

Procedure for Acceptance and Approval of Analytical Methods for the NSSP

Marine Biotoxins affect farmed and wild fish and shellfish, as well as having a deleterious effect on humans. Jellett Rapid Testing has designed and developed rugged tests for the presence of Paralytic Shellfish Poison, Amnesic Shellfish Poison and Diarrhetic Shellfish Poison (under development at the time of this submittal). To facilitate the use of these tests in the field (for aquaculturists, campers, regulatory officials, etc.), Jellett Rapid Testing has developed a "low-tech" rugged alternative to the standard AOAC method designed to extract the toxins in the field as well as the laboratory. The AOAC method requires the sample to be boiled in acid at low pH and the pH adjusted with strong acids. This requires a fully equipped laboratory and significant safety precautions. The JRT Rapid Extraction Method was designed for use in remote areas, with little sophisticated backup support, by average individuals with little training and education. It is faster, less labor-intensive and less expensive than the other available method.

The rapid extraction method requires vinegar and rubbing alcohol to extract the toxins. A simple, rapid, safe method such as this would make rapid tests for marine Biotoxins available in remote areas, to fishermen, aquaculturists, and regulatory officials on an instant basis.

The method developed by Jellett Rapid Testing Ltd has been presented to regulatory bodies over the past several years. In cooperation with individuals, governments and those organizations, the analytical method has been refined and improved. The Rapid Extraction Method is being tested in several states and foreign countries. Publications will be forthcoming.

The CONSTITUTION BY-LAWS and PROCEDURES of the INTERSTATE SHELLFISH SANITATION CONFERENCE allows the ISSC, through the Laboratory Methods Review Committee, to accept analytical methods that are sufficiently validated but are not AOAC or APHA methods. This is defined in the Constitution, PROCEDURE XVI. PROCEDURE FOR ACCEPTANCE AND APPROVAL OF ANALYTICAL METHODS FOR THE NSSP. Two possible reasons for considering a method are found in Subdivisions i and ii.

Subdivision i. Meets immediate or continuing need;

Subdivision ii. Improves analytical capability under the NSSP as an alternative to other approved or accepted method(s)

Currently, only the AOAC extraction for PSP and ASP are accepted. The need for a simple safe extraction method has been expressed by regulatory agencies, governmental organizations and industry for many years. The Jellett Rapid Extraction Method is being validated over a wide geographic area to demonstrate its simplicity, reliability, precision and accuracy. As a result of demonstrations of efficacy and the need that has been expressed by industry and state agencies, the Jellett Rapid Extraction Method is presented as an alternative extraction method for PSP and ASP for the NSSP as a Type III or Type IV method.

Please see attached additional information.

Suggested wording:

Section II, Chapter III Laboratory @.02 Methods

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:

(1) The current AOAC and APHA methods used in bioassay for paralytic shellfish poisoning toxins; and

(2) The current APHA method used in bioassay for *Karemia breve* toxins.

(3) The Jellett Rapid Extraction Method may be used for extracting PSP and ASP toxins from Shellfish by regulatory and industry laboratories.

Public Health Significance:

Currently, only the AOAC extraction for PSP and ASP analyses are accepted. Because of many significant constraints, in practical terms, this means that analyses can be conducted only in laboratories, and then under dangerous conditions. Acceptance of the Jellett Rapid Extraction Method for PSP and ASP would allow harvesters, processors, and regulatory agencies to screen for PSP and ASP with an accepted standardized method that provides valid useable data.

The Jellett Rapid Extraction Method for PSP and ASP was developed over several years in answer to the oft-stated need for a rapid, reliable, rugged, simple and safe sample preparation method. The Jellett Rapid Extraction Method for PSP and ASP is not meant to be a definitive "Standard Method", but rather to provide a supplementary extraction method that can be used in the field as well as in the lab.

Possible applications for The Jellett Rapid Extraction Method for PSP and ASP include:

- as a supplement to analytical methods of screening out negative samples in shellfish regulatory labs;
- as a harvest management tool at aquaculture facilities or in wild shellfish harvest areas (especially near shore areas) to supplement available methods to determine if shellfish are free of PSP or ASP and safe to harvest;
- as a supplement to quality control methods for shellfish processing plants, distributors and wholesalers to ensure incoming shellfish are free of PSP and ASP toxins before processing or further distribution (this test could become part of the plant's HACCP program);
- as a supplement to analytical methods for water classification for Biotoxins; and
- as a supplement to analytical methods for broad scale ecological monitoring.

The rationale for using the Jellett Rapid Extraction Method for PSP and ASP is that the method provides a rapid, reliable, rugged, simple, safe and cost-effective extraction method (especially in low-volume laboratories) for PSP and ASP that can supplement accepted tests and substantially reduce the cost of analyses. Used in conjunction with other rapid methods, the Jellett Rapid Extraction Method for PSP and ASP will supplement regulatory agency efforts and help prevent the harvest of contaminated product. Having the ability to conduct tests using an accepted rapid extraction method will allow those processors who choose to use this test to demonstrate that they are truly controlling for PSP and ASP hazards in the harvested shellfish.

The Jellett Rapid Extraction Method for PSP and ASP could contribute to building long-term databases on broader scales than a regulatory lab can afford and, by using an accepted standardized method, will provide consistent results. These databases could be supplemented with industry testing in areas where there is no testing currently. This would extend, augment and strengthen the current food safety system broadening and refining the food safety net by increasing the number of testing sites and generating long term data in more areas.

A simple, rapid, rugged, effective, reliable, safe and cost-effective extraction method, available to all harvesters, regulators, and processors, would increase the monitoring and reduce the chance that shellfish containing ASP toxins above the regulatory limit would be harvested or marketed.

Cost Information (if available): It is difficult to determine exact costs because many government cost models do not consider capital costs. Both extraction methods are the same through puree step, the chemicals used in both cases are minimal, as is the cost of incidental equipment (blender, pipettes, etc.). However, a comparison of time required using the Rapid Extraction Method (Add rapid liquid; Filter) with the time required using the AOAC Extraction (Add HCL; Boil; Wait; Filter; Pour in tube; Check PH) shows a significant difference. Our experience shows that it takes about 22 minutes for this portion of the AOAC extraction while it takes less than 2 minutes to complete the Jellett Rapid Extraction Method. At a salary of $33 / hour, that is a savings of $11.00 per sample extract.

Action by 2005 LMRC Recommended referral of Proposal 05-111 to the appropriate committee as determined by the Conference Chairman.

Action by 2005 Task Force I Recommended adoption of the Laboratory Methods Review Committee recommendation of Proposal 05-111.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force I.

Action by USFDA Concurred with Conference action.

Action by 2007 LMRC Recommended no action on Proposal 05-111. Rationale – Alternative extraction method for JRT PSP should be adopted to expand utility of the test; however there are insufficient data for acceptance at this time. The submitter will send data to the Executive Office for Conference approval.

Action by 2007 Task Force I Recommended referral of Proposal 05-111 to an appropriate committee as determined by the Conference Chairman.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force I.

Action by USFDA December 20, 2007
Concurred with Conference action with the following comments and recommendations for ISSC consideration.

The Conference has made considerable progress in its efforts to recognize new and developing analytical methods for the detection of indicators, pathogens, and marine toxins. Much credit goes to the Laboratory Methods Review Committee and its leadership for ensuring a scientifically defensible process for adopting analytical methods under the NSSP.

At the 2007 meeting numerous analytical methods were proposed for ISSC adoption. However, many of these methods were lacking the validation and associated data needed by the Laboratory Methods Review Committee to make a final determination regarding their efficacy for use in the NSSP. As a result the General Assembly voted "No Action" on analytical method Proposals 05-107, 05-108, 05-109, 05-111, 05-113, and 05-114. It is FDA's understanding that the intent of the "No Action" vote was not to remove these Proposals from ISSC deliberation as "No Action" normally suggests, but rather to maintain them before the Conference pending submission of additional

data for further consideration. The Voting Delegates, by requesting the Proposal submitters provide additional data to the Executive Office for methods approval consistent with Procedure XVI, clearly recognized the importance and utility of these methods and intended to maintain them before the Conference for possible adoption following additional data submission. FDA requests that the ISSC Executive Board confirm FDA's understanding of this outcome. FDA fully supports such a Conference action and encourages the Executive Office to pursue submission of additional data as necessary to move forward with acceptance of these methods.

Action by 2009 LMRC Recommended no action on Proposal 05-111. Rationale: Requested additional information has not been submitted.

Action by 2009 Task Force I Recommended adoption of Laboratory Methods Review Committee recommendation of Proposal 05-111.

Action by 2009 General Assembly Referred Proposal 05-111 to the Laboratory Methods Review Committee.

Action by USFDA 02/16/2010 Concurred with Conference action on Proposal 05-111.

Action by 2011 LMRC Recommended acceptance of the rapid extraction method in Proposal 05-111, specifically 70% isopropanol: 5% acetic acid 2.5:1, only for use with the Abraxis shipboard ELISA for PSP as an Emerging Method solely for use in the onboard screening dockside testing protocol in the Northeast region, including George's Bank.

The Laboratory Methods Review Committee further recommends:

1. The data collected during the dockside testing study be submitted to the LMRC in the SLV Method Application Protocol within 6 months of the concurrence by FDA in the Summary of Actions.

2. The validation study conducted by the State of Maine of the Abraxis laboratory ELISA with the extraction method in Proposal 05-111 be submitted to the LMRC in the SLV Method Application Protocol within 6 months of the concurrence by FDA in the Summary of Actions.

3. No action on the requested language change in Proposal 05-111 for the Model Ordinance Section II, Chapter III Laboratory @.02 Methods.

   Section II, Chapter III Laboratory @.02 Methods
   C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:
   (1) The current AOAC and APHA methods used in bioassay for paralytic shellfish poisoning toxins; and
   (2) The current APHA method used in bioassay for *Karenia breve* toxins.
   (3) The ~~Jellett Rapid Extraction Method may be used for extracting PSP~~ ~~and~~ ~~ASP toxins from Shellfish by regulatory and industry~~ ~~laboratories.~~

Action by 2011 Task Force I Recommended adoption of Laboratory Methods Review Committee recommendations on Proposal 05-111.

Action by 2011 General Assembly Adopted recommendation of 2011 Task Force I on Proposal 05-111.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 05-111.

Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended no action on Proposal 05-111 Rationale - Proposal 05-111 is resolved by action on Proposal 13-109.
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 05-111.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 05-111.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 05-111.

Proposal Subject:	Thermazyme™ ACP Test
Specific NSSP Guide Reference:	NSSP Section IV Guidance Documents Chapter II. Growing Areas .11 Approved Laboratory Tests
Text of Proposal/ Requested Action	Advanced Instruments, Inc. request ISSC adoption of this method for use in the National Shellfish Sanitation Program
Public Health Significance:	Thermazyme™ ACP Test will provide the basis for determining if shellfish have been thermally processed. This test will allow decisions to be based on a rapid, quantitative method rather than sensory related methods.
Cost Information (if available):	Not available
Action by 2005 LMRC	Recommended the Conference direct the ISSC Executive Office to continue to investigate the issue of standards and pursue the development of standards and report back to the Laboratory Methods Committee with progress on the issue in six (6) months.
Action by 2005 Task Force I	Recommended adoption of the Laboratory Methods Review Committee recommendation for Proposal 05-115.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force I.
Action by USFDA	Concurred with Conference action.
Action by 2007 LMRC	Recommended referral of Proposal 05-115 to the Executive Board for consideration for interim approval. Insufficient data at this time to approve this method under Procedure XVI. Need AP curves at 145 for 15 seconds for each type of shellfish.
Action by 2007 Task Force I	Recommended adoption of the Laboratory Methods Review Committee recommendation on Proposal 05-115.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action.
Action by 2009 LMRC	Recommended referral of Proposal 05-115 to an appropriate Committee as determined by the Conference Chairman, to review new data as it becomes available.
Action by 2009 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 05-115.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force I on Proposal 05-115.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 05-115.
Action by 2011 LMRC	Recommends referral of Proposal 05-115 to the appropriate committee as determined by the Conference Chairman to continue the validation of the Thermazyme ACP Test for possible use in the NSSP. LMRC further recommends the information requested by the testing lab and Advanced Instruments for validation be submitted within 6 months to be considered as an emerging method.

Action by 2011 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 05-115.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 05-115.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 05-115.
Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended no action on Proposal 05-115. Rationale: There is insufficient data to determine if the method is fit for purpose within the NSSP
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 05-115.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 05-115.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 05-115.

Proposal Subject: Domoic Acid Test Kit

Specific NSSP Guide Reference: Section IV. Guidance Documents, Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods.

Text of Proposal/ Requested Action

Mercury Science Inc., in collaboration with the NOAA Center for Coastal Fisheries and Habitat Research has developed a new quantitative immunoassay for the detection of Domoic acid. The assay has been commercialized and is currently sold for research use as the Domoic Acid Test Kit (product # DAK-36) (Information online at http://mercuryscience.com/DA).

This product underwent thorough testing by Mercury Science to define the performance characteristics of the assay prior to commercialization. In addition, the product has been independently validated in several labs in a variety of matrices. The results of these internal and external validation studies strongly suggest that the Domoic Acid Test Kit is a rapid, low-cost, and accurate method for analysis of food, water and phytoplankton samples.

At this time, Mercury Science would like to submit a partially complete Method Application to the ISSC Laboratory Methods Review Committee. Please note that the Method Application at this time does not include the completed Single Lab Validation report. The DA analyses to complete Section C. Validation Criteria are currently in progress and will continue throughout the summer. My laboratory has just received funding from the North Pacific Research Board and will be running ISSC Single Laboratory Validation Testing on butter clams (*Saxidomus giganteus*), blue mussels (*Mytilus edulis*), geoducks (*Panopea abrupta*), manila clams (*Venerupis japonica*), oysters (*Crassostrea virginica*) and razor clams (*Siliqua patula*) from Alaska later this summer. The NOAA CCFHR laboratory has similarly received their MERHAB funds last week and will be conducting a parallel Single Laboratory Validation study on butter clams, blue mussels, geoducks, manila clams, oysters, and razor clams from California, Oregon and Washington, oysters from North Carolina and quahogs (*Mercenaria mercenaria*) from Georges Bank, Massachusetts. The goal is to test a broad array of commercial species to ensure that matrix affects do not affect the assay. The results will be made available to the ISSC as they become available.

The work to date includes 1) publishing the complete ELISA methodology and initial validation studies in the December 2008 issue of the Journal of Shellfish Research and 2) completing the first validation series using oysters from North Carolina. The technique was also independently validated by the Quinault tribe in Washington State. They ran the ELISA on razor clam samples gathered by the tribe for a year and sent duplicate samples to the Washington Department of Health HPLC for analyses and have made their results available for inclusion in this preliminary application.

The purpose of this submission is to bring the new method to the attention of the committee in a manner that enables the method to be evaluated in a timely way. I am also seeking the committee's advice and guidance on the validation studies that will be conducted this coming summer by my laboratory and that of Wayne Litaker at NOAA. In the initial study using the oyster tissues I have closely followed the ISSC guidelines, but wanted to ensure that my interpretation was correct. I would therefore request the committee to review the methodology used in the initial oyster validation study to ensure the procedures used meet current requirements and that no additional data need to be gathered. If necessary, the protocol can be altered to meet the committee requirements.

Please find in association with this cover letter a series of materials relevant to the evaluation of the Domoic Acid Test Kit by the ISSC Laboratory Methods Review Committee.

These items included:

- ISSC Method Application with Section A, Section B**,** and Section D completed (see below).
- A pdf file containing the User Guide for the Domoic Acid Test Kit (DAK-36) that is included in the commercial product.
- A pdf file containing a reprint of the research paper entitled " RAPID ENZYME-LINKED IMMUNOSORBENT ASSAY FOR DETECTION OF THE ALGAL TOXIN DOMOIC ACID," published in the December, 2008 issue of Journal for Shellfish Research. This paper describes correlation data comparing the Domoic Acid Test Kit versus HPLC analysis using several sample matrices. (Also available online at: http://mercuryscience.com/LitakerStewartDec2008.pdf)
- An Excel file showing the results of a study done by the Quinault Indian Nation and the Washington Department of Health comparing razor clam analysis performed by the Domoic Acid Test Kit versus HPLC analysis. This independent study used samples collected over a nineteen month period and was planned and performed without any input from Mercury Science or NOAA. (also available online at: http://mercuryscience.com/QINWDOHdata.xls)
- Preliminary tests using oyster spiked materials (see below)

The ELISA method has been used independently in six laboratories and provided results equivalent to those obtained using HPLC, FMOC-HPLC and LC-MS. This is detailed in the Litaker et al. 2008 publication listed above. Based on the correlation studies conducted so far, I request that this method be considered for interim approval by the LMR committee until the remaining validation data can be provided over the next six months. Upon completion of the SLV, consideration for approval of the assay as a Level 4 method will be requested.

Public Health Significance: The regulatory method for DA detection sanctioned by the Interstate Shellfish Sanitation Conference is a high performance liquid chromatography (HPLC) assay. Though accurate, these analyses are generally run by centralized state facilities with results typically not available for 3 to 14 days after the samples are collected. In more remote communities, many of which depend heavily on subsistence clam harvests, these long delays and the costs of sample analysis are causes for public health concern. The average cost of approximately $100 per sample limits the number of samples that can be analyzed (Harold Rourk, Washington State Department of Health, personal communication). Resource managers in coastal communities have expressed their desire for a cost-effective method for rapid and accurate determination of DA concentrations in shellfish and phytoplankton samples.

Cost Information (if available): Anticipated cost is $7.00 per duplicate reaction

Proposed Specific Research Need/Problem to be Addressed:

This research focuses on the development is an accurate, rapid, cost-effective ELISA for use by environmental managers and public health officials to monitor Domoic Acid concentrations in environment samples. The regulatory method for DA detection sanctioned by the Interstate Shellfish Sanitation Conference is a high performance liquid chromatography (HPLC) assay. Though accurate, these analyses are generally run by centralized state facilities with results typically not available for 3 to 14 days after the samples are collected.

In more remote communities, many of which depend heavily on subsistence clam harvests, these long delays and the costs of sample analysis are causes for public health concern. The average cost of approximately $100 per sample limits the number of samples that can be analyzed (Harold Rourk, Washington State Department of Health, personal communication). Resource managers in coastal communities have expressed their desire for a cost-effective method for rapid and accurate determination of DA concentrations in shellfish and phytoplankton samples. The high throughput capacity of the assay also allows for much faster response times when Domoic acid events occur. The relatively low cost of the assay means that significantly more sampling is also possible on the same or smaller budget.

How will addressing this research support/improve the mission/role of the ISSC/NSSP/Industry? Support need with literature citations as appropriate.

This Assay will allow better protect public health and provide a rapid response capability when DA outbreaks occurs. It can also be adapted to monitoring phytoplankton samples so that toxic blooms can be identify and tracked. Toxic phytoplankton cells generally appear several weeks before the shellfish become toxic and can be used as an early warning system for when shellfish are likely to become toxic/

More detailed information on the assay and its potential uses is provided in a recently published article:
RAPID ENZYME-LINKED IMMUNOSORBENT ASSAY FOR DETECTION OF THE ALGAL TOXIN DOMOIC ACID, Journal of Shellfish Research, Vol. 27, No. 5, 1301–1310, 2008.
Available online at: http://mercuryscience.com/LitakerStewartDec2008.pdf

Relative Priority Rank in Terms of Resolving Research Need:

Immediate	☐	**Important**	☐
Required	☐	**Other**	☐
Valuable	☐		

Estimated Cost: $7.00 per duplicate sample (~$200.00 for ELISA kit capable of analyzing 36 duplicate samples in 1.5 h)

Proposed Sources of Funding/Support: Grants have been awarded by NPRB and NOAA MERHAB program for the completion of the validation studies.

Time Frame Anticipated: Validation should be completed by January or February 2010.

Action by 2009 LMRC	Recommended referral of Proposal 09-105 to the appropriate committee as determined by the Conference Chairman.
Action by 2009 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 09-105.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force I on Proposal 09-105.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 09-105.
Action by 2011 LMRC	Recommends referral of Proposal 09-105 to the appropriate committee as determined by the Conference Chairman to await further data to be provided by Mercury Science the developer of the method to determine if the method is fit for purpose within the NSSP as a screening tool.
Action by 2011 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendations on Proposal 09-105.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 09-105.

Action by FDA February 26, 2012	Concurred with Conference action on Proposal 09-105.
Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended no action on Proposal 09-105. Rationale - There is insufficient data to determine if the method is fit for purpose within the NSSP
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 09-105.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 09-105.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 09-105.
NOTE:	Click here for Proposal 09-105 Supporting Documentation

Proposal Subject:	Saxitoxin (PSP) ELISA Kit
Specific NSSP Guide Reference:	Section IV. Guidance Documents, Chapter II Growing Areas, .11 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods Section II. Model Ordinance Chapter III. Laboratory @.02 Methods C. Biotoxin
Text of Proposal/ Requested Action	See attached ISSC Method Application Faster, easier, and/or more reliable methods are needed to satisfy the needs of the regulatory community and shellfish industry. The proposed ELISA method is a fast and easy to perform method with ready to use reagents i.e. analyst only needs to extract shellfish sample or dilute water sample before analysis. The proposed ELISA also provides a quantitative and/or semi-quantitative screening for shellfish extracts and/or water samples. This assay is part of Abraxis platform for marine toxin testing and complements the company's other offering for NSP, DSP, and ASP testing. The proposed ELISA can be used on-site (boat, dock) or established analytical laboratories.
Public Health Significance:	
Cost Information (if available):	As low as $15 per sample.
Action by 2009 LMRC	Recommended no action on Proposal 09-107. Rationale: Insufficient data.
Action by 2009 Task Force I	Recommends adoption of Laboratory Methods Review Committee recommendation on Proposal 09-107.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 09-107 with the following comments and recommendations for ISSC consideration. The Laboratory Methods Review Committee determined that Proposal 09-107 was accompanied by insufficient data necessary for the Committee to make a determination regarding the efficacy of the proposed Saxitoxin test method for use under the NSSP. As a result the General Assembly voted "No Action" on the proposed analytical method. It has been FDA's observation and experience that the proposed ELISA method for Saxitoxins presents itself as a reliable screening method to supplement existing NSSP tools for managing Paralytic Shellfish Poisoning (PSP). Therefore, FDA recommends the Conference pursue submission of additional data from Abraxis, LLC via the Proposal submission process to advance a thorough examination of this method for Saxitoxin screening.
Action by ISSC Executive Board March 2010	The Executive Office will send a letter to the submitter of Proposal 09-107 to resubmit Proposal 09-107 Saxitoxin (PSP) Elisa Kit with additional information.
Action by 2011 Task Force I	Recommended adoption of Proposal 09-107 as an emerging method.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 09-107.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 09-107.

Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended no action on Proposal 09-107. Rationale - Action by the committee was not necessary. Requested additional action on this proposal was addressed by Proposal 13-109
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 09-107
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 09-107.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 09-107.

Proposal Subject: Post Harvest Processing

Specific NSSP Guide Reference: NSSP Section II Model Ordinance Chapter IV Shellstock Growing Areas @.03 Growing Area Classification D (1) (a) (ii)

Text of Proposal/ Requested Action

D. Restricted Classification.
(1) General
(a) A growing area may be classified as restricted when:
(i) A sanitary survey indicates a limited degree of pollution; and
(ii) Levels of fecal pollution, human pathogens, or poisonous or deleterious substances are at such levels that shellstock can be made safe for human consumption by either relaying, depuration or low acid-canned food processing or by other verifiable processes.

Public Health Significance:

Cost Information (if available):

Action by 2011 Task Force I Recommended referral of Proposal 11-100 to the appropriate committee as determined by Conference Chairman.

Action by 2011 General Assembly Adopted recommendation of 2011 Task Force I on Proposal 11-100.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-100.

Action by 2013 Growing Area Classification Committee Recommended no action on Proposal 11-100.

Rationale: No details have been provided to determine what other verifiable processes could be used and added to the restricted classification.

Action by 2013 Task Force I Recommended adoption of Growing Area Classification Committee recommendation on Proposal 11-100.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force I on Proposal 11-100.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 11-100.

Proposal Subject: Re-opening Conditional Areas using Male-specific Coliphage after WTP Malfunction

Specific NSSP Guide Reference: NSSP Section II Model Ordinance Chapter IV Shellstock Growing Areas @ .03 Growing Area Classification A. (5) (c) (ii)

Text of Proposal/ Requested Action (ii) For emergency closures ~~(not applicable for conditional closures)~~ of harvest areas caused by the occurrence of raw untreated sewage or partially treated sewage discharged from a large community sewage collection system or wastewater treatment plant, the analytical sample results shall not exceed background levels or a level of 50 male-specific coliphage per 100 grams from shellfish samples collected no sooner than 7 days after contamination has ceased and from representative locations in each growing area potentially impacted; or

Public Health Significance: Male-specific Coliphage (MSC) is an RNA virus of E. coli present in high numbers in raw sewage (on the order of 10^5 PFU/100gm). MSC is similarly resistant to chlorine disinfection as are norovirus and hepatitis A viruses, which are the viral pathogens of primary concern in sewage. MSC is a good surrogate or marker for these enteric viruses. Raw or partially treated sewage accidentally discharged into a growing area by sewage by-pass from pump station failures, broken sewage lines, or malfunctions at the wastewater treatment facilities represent a serious public health risk and require emergency closure of adjacent conditional growing areas. These closures are typically 21 days after the wastewater treatment system returns to normal operation. Recent work has shown that persistence of viruses in the growing waters is much lower in the summer months than in the winter months. Likewise, bio-accumulation rates and retention of enteric viruses in molluscan shellfish is much lower in the summer months than the winter months. MSC can be a useful tool for state shellfish programs to mitigate the negative effect of prolonged conditional closures due to wastewater treatment system failures. This approach is most appropriate in the late-spring and summer months to shorten these closures from 21 to 7 days.

Cost Information (if available): The Male-specific Coliphage (MSC) Method is an inexpensive double-agar pour plate method that can be run in any state-certified microbiological laboratory. A refrigerated centrifuge capable of 9,000G is required which costs $10K to $12K (USD). Re-opening after 7 days using MSC method is optional for state shellfish control agencies.

Action by 2011 Task Force I Recommended referral of Proposal 11-101 to the appropriate committee as determined by the Conference Chairman. To include FDA prepare and provide to the committee data collected using MSC in wastewater treatment plant and to work with the submitter in this proposal in analyzing that data.

Action by 2011 General Assembly Adopted recommendation of 2011 Task Force I on Proposal 11-101.

Action by FDA February 26, 2012 FDA concurred with Conference action on Proposal 11-101 with the following recommendations.

FDA concurs with Conference action to refer Proposal 11-101 to an appropriate committee as determined by the Conference Chairperson. The intent of these Proposals is to expand the application of Male Specific Coliphage (MSC) for use in the management of conditional areas affected by raw or partially untreated sewage discharges from wastewater treatment plants (WWTP) or community sewage collection systems and for assessing the impact of WWTP discharges and/or sewerage collection system leaks in determining the size of adjacent areas for classification as conditionally restricted or conditionally approved. Presently, however, there is insufficient data from which to make sound science based

decisions regarding the use of MSC as a more comprehensive tool for growing area management.

Support for using MSC for conditional area management is based on uptake and elimination data for a single shellfish species, soft-shelled clams (Mya arenaria), impacted by effluent from a highly efficient WWTP at one geographic location over just one harvest season. Those data are not adequate to ensure the efficacy of MSC to safely manage other conditional areas for other species of shellfish, in other geographic regions, and over other seasons.

Careful consideration needs to be given to the fact that a WWTP malfunction is often a consequence of adverse weather conditions, most notably excessive rainfall over short periods. Such rainfall events usually cause excessive land based runoff, carrying non-point fecal pollution to conditional areas. While MSC are generally ubiquitous in municipal wastewater, that is not the case with smaller pollution sources. For this reason MSC are inappropriate for indexing smaller sources and do not lend themselves well to managing areas subject to pollution from both WWTPs and other sources. Shellfish associated norovirus (NoV) outbreaks investigated by FDA's Gulf Coast Seafood Laboratory (GCSL) in the past several years have, in nearly all instances, shown MSC levels in shellfish below the assay's sensitivity(< 10 pfu/lOOml), while testing positive for NoV. These results indicate that the source of NoV was not from a WWTP. Though MSC appear to have utility and promise in assessing potential viral contamination in shellfish, much remains to be learned about their prevalence and ability to reliably index fecal contamination from various sources of human sewage.

Several approaches for generating additional information and data needed to better define how MSC could potentially be used for growing area management and classification include:

- Continued studies to examine the uptake and elimination of NoV, enterovirus, and MSC by shellfish species other than soft-shelled clams. These investigations should be conducted in multiple geographic locations representative of the country and over all seasons.
- A SL V has been conducted and adopted by the ISSC for the method to enumerate SC in soft-shelled clams and oysters. A SL V is needed to demonstrate the efficacy of this or another method to enumerate MSC in other species of shellfish.
- Understanding the efficiency of various wastewater treatment systems to inactivate/remove enteric viruses prior to discharge.

- Continued studies to examine and compare MSC and enteric virus levels in wastewater influent and effluent, shellfish receiving waters, and shellfish.

As requested by Task Force I, information is currently being compiled by FDA regarding MSC data from WWTP sampling. Those data should be available to the ISSC in March, 2012.

Action by 2013 Growing Area Classification Committee

Recommended referral of Proposal 11-101 to the appropriate committee as determined by the Conference Chairman. It was additionally recommended that a workgroup be formed to look at current MSC data and the science behind its potential use and applicability for use in the NSSP. The workgroup will organize a summit of outside experts, academia, and scientists to present current information and science on MSC. The group will meet at least quarterly and respond back to the Growing Area Classification Committee on its findings and recommendations.

Recommended that the ISSC pursue funding to facilitate scheduling a summit to bring together experts to present the current science in the use of MSC.

Action by 2013 Task Force I	Recommended adoption of Growing Area Classification Committee recommendation on Proposal 11-101.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 11-101.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-101.

Proposal Subject:	Using Male-specific Coliphage as a Tool to Refine Determinations of the Size of the Areas to be Classified as Prohibited Adjacent to Each Outfall
Specific NSSP Guide Reference:	NSSP Section II Model Ordinance Chapter IV Shellstock Growing Areas @.03 Growing Area Classification E. (5)
Text of Proposal/ Requested Action	(c) An assessment of the combined impact of waste water treatment plant outfall and/or ex-filtration (leakage) from sewerage collection systems may be performed using male-specific coliphage assays on shellstock from adjacent growing areas. A male-specific coliphage standard of ≤ 50 PFU/100gm in shellfish meats may be used as the basis for the determination of the size of the adjacent area to be classified as conditionally restricted or approved.
Public Health Significance:	Male-specific Coliphage (MSC) is a RNA virus of E. coli present in high numbers in raw sewage (on the order of 10^5 PFU/100gm). MSC is similarly resistant to chlorine disinfection as are norovirus and hepatitis A viruses, which are the viral pathogens of concern in sewage. MSC is a good surrogate or marker for these enteric viruses and is a powerful tool to assess the impact on a growing area of raw, partially treated and treated sewage on adjacent growing areas. US and EU studies show that during the summer months MSC and associated pathogenic enteric viruses are at seasonal lows. Conversely, the risk of viral disease transmission is significantly higher in the winter months as evidenced by epidemiological studies as well as studies conducted using MSC and molecular detection of target pathogens. A better assessment of the risk of viral contamination at a particular location in an adjacent growing area at a particular time of year can be ascertained directly using MSC assays of the shellstock. Performing and evaluating dye studies on waste water treatment plant outfall evaluation is expensive and complicated. Difficulties assessing ex-filtration and leakage from the sewage collection system are well known. Few tools and less guidance are available to adequately assess the performance of a particular waste water treatment plant design and its operation with respect to virus removal. The advantages of using this specialty viral indicator to assess the overall impact of a municipal wastewater treatment system on a particular growing area are many. In growing areas impacted by waste water treatment systems, positive norovirus detected by molecular methods at significant levels in the shellfish are accompanied by corresponding high levels of MSC. MSC assays are a direct and straightforward method to determine the viral risk or validate traditional assessment techniques.
Cost Information (if available):	The Male-specific Coliphage (MSC) method is an inexpensive double-agar pour plate method, which can be run in any state-certified microbiological laboratory. A refrigerated centrifuge capable of 9,000G is required which costs $10K to $12K (USD). Cost savings and a higher level of public health protection may be realized using MSC assays of shellfish verses the level of effort needed to ascertain the viral risk indirectly through dye studies, 1000:1 dilution line determinations and performance evaluations.
Action by 2011 Task Force I	Recommended referral of Proposal 11-102 to the appropriate committee as determined by the Conference Chairman. To include FDA prepare and provide to the committee data collected using MSC in wastewater treatment plant and to work with the submitter in this proposal in analyzing that data.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 11-102.
Action by FDA February 26, 2012	FDA concurred with Conference action on Proposal 11-102 with the following recommendations.

FDA concurs with Conference action to refer Proposal 11-102 to an appropriate committee as determined by the Conference Chairperson. The intent of these Proposals is to expand the application of Male Specific Coliphage (MSC) for use in the management of conditional areas affected by raw or partially untreated sewage discharges from wastewater treatment plants (WWTP) or community sewage collection systems and for assessing the impact of WWTP discharges and/or sewerage collection system leaks in determining the size of adjacent areas for classification as conditionally restricted or conditionally approved. Presently, however, there is insufficient data from which to make sound science based decisions regarding the use of MSC as a more comprehensive tool for growing area management.

Support for using MSC for conditional area management is based on uptake and elimination data for a single shellfish species, soft-shelled clams *(Mya arenaria),* impacted by effluent from a highly efficient WWTP at one geographic location over just one harvest season. Those data are not adequate to ensure the efficacy of MSC to safely manage other conditional areas for other species of shellfish, in other geographic regions, and over other seasons.

Careful consideration needs to be given to the fact that a WWTP malfunction is often a consequence of adverse weather conditions, most notably excessive rainfall over short periods. Such rainfall events usually cause excessive land based runoff, carrying non-point fecal pollution to conditional areas. While MSC are generally ubiquitous in municipal wastewater, that is not the case with smaller pollution sources. For this reason MSC are inappropriate for indexing smaller sources and do not lend themselves well to managing areas subject to pollution from both WWTPs and other sources. Shellfish associated norovirus (NoV) outbreaks investigated by FDA's Gulf Coast Seafood Laboratory (GCSL) in the past several years have, in nearly all instances, shown MSC levels in shellfish below the assay's sensitivity(< 10 pfu/lOOml), while testing positive for NoV. These results indicate that the source of NoV was not from a WWTP. Though MSC appear to have utility and promise in assessing potential viral contamination in shellfish, much remains to be learned about their prevalence and ability to reliably index fecal contamination from various sources of human sewage.

Several approaches for generating additional information and data needed to better define how MSC could potentially be used for growing area management and classification include:

- Continued studies to examine the uptake and elimination of NoV, enterovirus, and MSC by shellfish species other than soft-shelled clams. These investigations should be conducted in multiple geographic locations representative of the country and over all seasons.
- A SL V has been conducted and adopted by the ISSC for the method to enumerate SC in soft-shelled clams and oysters. A SL V is needed to demonstrate the efficacy of this or another method to enumerate MSC in other species of shellfish.
- Understanding the efficiency of various wastewater treatment systems to inactivate/remove enteric viruses prior to discharge.
- Continued studies to examine and compare MSC and enteric virus levels in wastewater influent and effluent, shellfish receiving waters, and shellfish.

As requested by Task Force I, information is currently being compiled by FDA regarding MSC data from WWTP sampling. Those data should be available to

the ISSC in March, 2012.

Action by 2013 Growing Area Classification Committee

Recommended referral of Proposal 11-102 to the appropriate committee as determined by the Conference Chairman. It was additionally recommended that a workgroup be formed to look at current MSC data and the science behind its potential use and applicability for use in the NSSP. The workgroup will organize a summit of outside experts, academia, and scientists to present current information and science on MSC. The group will meet at least quarterly and respond back to the Growing Area Classification Committee on its findings and recommendations.

Recommended that the ISSC pursue funding to facilitate scheduling a summit to bring together experts to present the current science in the use of MSC.

Action by 2013 Task Force I

Recommended adoption of Growing Area Classification Committee action on Proposal 11-102.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force I on Proposal 11-102.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 11-102.

Proposal Subject: Alternative Male-specific Coliphage Meat Standard for Restricted Classification of Growing Areas Impacted by wastewater treatment plant outfall.

Specific NSSP Guide Reference: NSSP Section II Model Ordinance Chapter IV Shellstock Growing Area @ .02 Bacteriological Standards G. – add new section (4)

Text of Proposal/ Requested Action (4) Exception. If the Male-specific Coliphage indicator is used for supplemental process verification using an end-point meat standard of < 50PFU/100gm and existing fecal coliform testing requirements in Chapter XV .03 J. are used, then FC water quality monitoring is not required for the restricted classification of growing areas affected by point sources such as wastewater treatment plant outfall.

Public Health Significance: Under shellfish relay, water quality requirements are not needed for the restricted classification when a contaminant reduction study is conducted and a minimum time period of two weeks is used. For depuration, the restricted classification requires water quality monitoring and standards. The reason for these upper FC limits is that FC meat indicator does not adequately reflect the viral risk and/or viral depuration kinetics. Male-specific coliphage is a viral indicator organism to be used in growing areas impacted by point source sewage contamination. MSC demonstrates significant advantages over FC alone for both the assessment of viral contamination and assessment of viral depuration kinetics. Upper FC limits were put into the NSSP to prevent shellfish with higher levels of viruses from being depurated. Several studies clearly show that conventional depuration using FC for process validation is not adequate to protect public health with respect to virus contamination in growing areas with significant wastewater treatment plant and sewage impact. Studies have also shown that viral levels in shellfish impacted by sewage and partially treated sewage detected using MSC and molecular techniques are much lower in the summer months than the winter months. Additionally, the viral depuration rate is higher in the summer with process waters >18°C. Recent studies have also shown that MSC is an appropriate viral indicator to assess viral depuration. Therefore, seasonal viral depuration using male-specific coliphage as well as FC for process verification is a superior approach to taking water samples using FC in a growing area adjacent to wastewater treatment plant outfall. Combining the bacterial indicator of FC and the viral indicator MSC for mitigation strategies that use meat scores is far more direct and effective than water quality sampling in this context.

Cost Information (if available): The Male-specific Coliphage (MSC) method is an inexpensive double-agar pour plate method that can be run in any state-certified microbiological laboratory. A refrigerated centrifuge capable of 9,000G is required which costs $10K to $12K (USD). Significant cost savings and a higher level of public health protection may be realized using strategies such as seasonal coliphage depuration process validated using MSC and seasonal coliphage relay using MSC in contaminant reduction studies than requiring water quality limits using FC.

Action by 2011 Task Force I Recommended referral of Proposal 11-103 to the appropriate committee as determined by the Conference Chairman.

Action by 2011 General Assembly Adopted recommendation of 2011 Task Force I on Proposal 11-103.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-103.

Action by 2013 Growing Area Classification Recommended referral of Proposal 11-103 to an appropriate committee as determined by the Conference Chairman.

Committee	It was additionally recommended that a workgroup be formed to look at current MSC data and the science behind its potential use and applicability for use in the NSSP. The workgroup will organize a summit of outside experts, academia, and scientists to present current information and science on MSC. The group will meet at least quarterly and respond back to the Growing Area Classification Committee on its findings and recommendations. Recommended that the ISSC pursue funding to facilitate scheduling a summit to bring together experts to present the current science in the use of MSC.
Action by 2013 Task Force I	Recommended adoption of Growing Area Classification Committee action on Proposal 11-103.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 11-103.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-103.

Proposal Subject:	Real ASP (Domoic Acid) Test Kit
Specific NSSP Guide Reference:	Section IV Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests, Table 4 - Marine Biotoxin Test Methods
Text of Proposal/ Requested Action	We request review of the validation study submission for the Reveal ASP (domoic acid) test kit and consideration of the method for approval as a Type IV marine biotoxin screening method for qualitative determination of domoic acid in shellfish. Add Reveal ASP (domoic acid) test to list of approved Type III and Type IV marine biotoxin methods.
Public Health Significance:	Amnesic shellfish poisoning is caused by the toxin Domoic acid, produced by phytoplankton of the genus Pseudonitzschia. It is associated with eating contaminated oysters, clams, mussels, and other shellfish. There have been numerous outbreaks of ASP, and there is evidence that the occurrence of the phytoplankton responsible for ASP is widespread. Current methods for detection of domoic acid consist primarily of instrumental chemistry methods, which are laborious and time-consuming. Methods for rapid screening for domoic acid, in field and laboratory settings, are needed and will assist the industry and public health authorities in responding to this health concern. The Reveal ASP test is a lateral flow immunoassay designed for qualitative determination of domoic acid in shellfish at levels of 10 ppm (mg/kg) and above. The test uses minimal equipment and simple reagents, does not require specialized training, and can provide results in 20 minutes from sample receipt, including sample preparation.
Cost Information (if available):	Approximately $17.00 per test.
Action by 2011 LMRC	Recommended Proposal 11-107 be referred to the appropriate committee as determined by the Conference Chairman and further recommends the following guidance on the data needed from the submitter: • Analysis of samples with naturally incurred residues over a range of toxin concentrations. • Evaluate extraction recovery by comparison with HPLC. • Additional replicates of spiked samples of shellfish species. Eliminate theoretical data regarding dose response curve.
Action by 2011 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendations on Proposal 11-107.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 11-107.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-107.
Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended no action on Proposal 11-107. Rationale: This proposal is resolved by action on Proposal 13-112.
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 11-107
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 11-107.

Action by FDA Concurred with Conference action on Proposal 11-107.
May 5, 2014

Proposal Subject:	Update Microbiology Laboratory Evaluation Checklist
Specific NSSP Guide Reference:	NSSP Section IV. Guidance Documents Chapter II. Growing Areas .12 Evaluation of Laboratories By State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists Laboratory Evaluation Checklist – Microbiology
Text of Proposal/ Requested Action	Update Microbiology Laboratory Evaluation Checklist. Please find the updated Microbiology Laboratory Checklist attached - word document titled "Revised Microbiology Checklist 11-08-2010.doc". A summary of the changes is: • Renumbered checklist items to accommodate proposed additions and deletions and to better identify each checklist item. • Added, deleted or changed language for checklist items to be consistent with the PSP laboratory evaluation checklist. • Deleted the requirement for metals testing on reagent water and the inhibitory residue test for washed lab ware and increased the requirements for the bromothymol blue test. • Clarified and defined requirements for laboratory equipment, reagents including the bacterial quality control requirements for media productivity and method process control testing. • Update thermometer requirements to accommodate state bans on the use of mercury thermometers. • Updated the sterility check requirements for both in lab sterilized items and purchased pre-sterilized items.
Public Health Significance:	The current microbiology laboratory checklist was last revised in 2009 when the male specific coliphage method was approved and added to the checklist. Deficiencies have been identified while using the microbiology checklist in evaluation of laboratories and the microbiology checklist is inconsistent with some requirements in the PSP checklist. It is important that the checklist items and quality assurance requirements are clear and understandable. It is important that quality assurance requirements among the different laboratory evaluation checklists remain as consistent as possible since many monitoring laboratories perform multiple types of tests and are evaluated using multiple NSSP checklists; inconsistencies among the checklist cause confusion, extra expense and work for the laboratories.
Cost Information (if available):	None
Action by 2011 LMRC	Recommended Proposal 11-108 be referred to the appropriate committee as determined by the Conference Chairman.
Action by 2011 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 11-108.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 11-108.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-108.
Action by 2013 Laboratory Methods Review and Quality Assurance	Recommended Proposal 11-108 be adopted with substitute updated document attached. Available upon request (20 page document)

Committee

Action by 2013 Task Force I	Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 11-108.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 11-108.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-108.

Proposal Subject:	Update PSP Laboratory Evaluation Checklist
Specific NSSP Guide Reference:	NSSP Section IV. Guidance Documents Chapter II. Growing Areas .12 Evaluation of Laboratories By State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists-Laboratory Evaluation Checklist - PSP
Text of Proposal/ Requested Action	Update PSP Laboratory Evaluation Checklist. Please find the updated PSP Laboratory Checklist attached - word document titled "Revised PSP Checklist 11-08-2010.doc". A summary of the changes is: • Added the checklist items for Jellett Rapid Test for PSP • Renumbered checklist items to accommodate proposed additions and deletions and to better identify each checklist item. • Added, deleted or changed language for checklist items to be consistent with the microbiology laboratory evaluation checklist including added laboratory education and experience requirements • Deleted the requirement for metals testing on reagent water • Clarified and defined requirements for laboratory equipment, reagents and the mouse bioassay method.
Public Health Significance:	The current PSP laboratory checklist was last revised in 2005. Since that time the Jellett Rapid Test has received approval and is not in the checklist. Deficiencies have been identified while using the PSP checklist in evaluation of laboratories and the PSP checklist is inconsistent with some requirements in the microbiology checklist which has more recently been revised . It is important that the checklist items and quality assurance requirements are clear and understandable. It is important that quality assurance requirements among the different laboratory evaluation checklists remain as consistent as possible since many monitoring laboratories perform multiple types of tests and are evaluated using multiple checklists; inconsistencies among the checklist cause confusion, extra expense and work for the laboratories.
Cost Information (if available):	None
Action by 2011 LMRC	Recommended Proposal 11-109 be referred to the appropriate committee as determined by the Conference Chairman.
Action by 2011 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 11-109.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 11-109.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-109.
Action by 2013 Laboratory Method Review & Quality Assurance Committee	Recommended Proposal 11-09 be referred to the appropriate committee as determined by the Conference Chairman.
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 11-109.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 11-109.

Action by FDA Concurred with Conference action on Proposal 11-109.
May 5, 2014

Proposal Subject:	Addition to the Requirements for the Authority During a Suspected Shellfish Related Outbreak
Specific NSSP Guide Reference:	NSSP Section II Model Ordinance Chapter II Risk Assessment and Risk Management @.01 Outbreaks of Shellfish-Related Illness
Key Words:	Reconditioning
Text of Proposal/ Requested Action:	J. Whenever the Molluscan shellfish products are deemed to be contaminated with a pathogen that would subject it to a recall, reconditioning of the product will be permitted as an alternative to control the hazard. Any such reconditioning process that is used must be validated to reduce the level of the pathogen in question to a level which is not reasonably likely to cause illness or alter the product to a form that is intended to be cooked.
Public Health Significance:	
Cost Information (if available):	
Action by 2011 Task Force I	Recommended referral of Proposal 11-115 to the appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 11-115.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-115.
Action by 2013 Growing Area Classification Committee	Recommended Proposal 11-115 be referred to the appropriate committee as determined by the Conference Chairman and that a workgroup be formed to further explore available options for PHP methods that could be used for reconditioning recalled product. The workgroup should determine a definition for "validated reconditioned process". The Committee further recommended that the workgroup report back to the Growing Area Classification Committee with its findings.
Action by 2013 Task Force I	Recommended adoption of Growing Area Classification Committee recommendation on Proposal 11-115.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 11-115.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-115.

Proposal Subject: ASP ELISA for Determination of Domoic Acid in Molluscan Shellfish

Specific NSSP Guide Reference: Section IV Guidance Documents, Chapter II. Growing Areas, .11 Approved National Shellfish Sanitation Program Laboratory Tests

Text of Proposal/ Requested Action

I am submitting for your consideration an ELISA method for the determination of domoic acid in molluscan shellfish. The method is a direct competitive ELISA based on HRP –conjugated polyclonal sheep antibodies, and has been developed and commercialized in collaboration with AgResearch (Hamilton, NZ) under the name of *ASP cDirect ELISA* and *ASP ELISA* by my company Biosense Laboratories AS, Bergen, Norway. The commercially available ASP ELISA kit is being produced under a strict QC/QA program, and manufactured in compliance with the written quality policy.

The ASP ELISA has been subject to a single laboratory validation study in accordance with the AOAC guidelines, and the SLV performance parameters were published in J AOAC (Kleivdal *et al*, 2007a). The SLV study demonstrated that the ASP ELISA is a fully quantitative analytical method with good recovery and precision.

Furthermore, a comprehensive inter-laboratory study was organized with the aim to obtain collaborative study data on precision and accuracy on the ASP ELISA according to AOAC Collaborative Study Guidelines (Kleivdal *et al*, 2007b). This study involved 16 laboratories in 10 countries (including US laboratories), which also performed a method comparison between the ASP ELISA and LCMS and the HPLC reference method. The collaborative study data showed that the ASP ELISA is both accurate and precise between analytical laboratories, and that the sample data compared well with the analytical methods based on liquid chromatography. The collaborative study data was submitted to the AOAC for Official Method accreditation in 2005, and was approved First Action in 2006 (AOAC OMA 2006.02).

The AOAC accredited ASP ELISA method was then proposed to the European Union (EU) as an alternative to the HPLC-based reference method used by the EU member states for the regulation of domoic acid levels in shellfish products intended for human consumption. The ASP ELISA was approved by the EU Central Reference Laboratory on Marine Biotoxins and the National Reference Laboratory network as an alternative method suitable for official use and implemented in EU regulations (EC 1224/2007).

The ASP ELISA of Biosense has not previously been presented/submitted to the ISSC, but the method was mentioned in the 2005 ISSC Summary of Actions as a separate document "AOAC Review of Biotoxin Laboratory Methods" 10-08-
2004. In this document the ASP ELISA was mentioned as a method that would "supply alternatives to existing official methods" once it attained the AOAC official status.

Through comprehensive validation studies we have demonstrated that the ASP ELISA from Biosense is accurate and precise, and a suitable alternative to analytical methods based on liquid chromatography. This has been acknowledged by the AOAC through Official Method Accreditation, leading to the approval by the European Union and implementation in the EU regulations.

Based on the attached documentation, I request that the ASP ELISA is considered by the ISSC LMR Committee as an analytical method for the determination of domoic acid in molluscan shellfish as an alternative to the current HPLC-based method.

Public Health

While the analytical methods based on liquid chromatography is acknowledged

Significance:

by NSSP for the determination of domoic acid in shellfish, such methods require special facilities, expensive instrumentation, in addition to high-infrastructure laboratories and highly skilled operators. The strict method requirements allow only some specialized laboratories to operate the LC-methods, and these test laboratories are in many cases located far away from the production or processing site. The shellfish grower, fisher, processor or dispatch center must therefore ship their samples away from their operation (*off-site testing*) and wait for several days before the results are returned. This time lag between sampling and return of sample results can cause problems – in particular when there is a rapid onset of toxicity in the harvesting area. The delayed communication of sample results, caused by the logistics of shipping samples and a low sample turnaround time at the off-site test laboratories cause loss of processed product, delays in product recalls and withdrawals. The continued practice with off-site testing and the lack of an effective HACCP system with *on-site monitoring* of shellfish toxins, may lead to future cases of late product recalls putting the public health at risk. Without an on-site ability to test for shellfish toxins, the risk based food safety management approach is limited to traditional monitoring programs and intensive end-product testing regimes being examples of *retroactive* and *reactive* countermeasures. While these countermeasures are useful, they still do not contribute to *solve* any of the *identified* problems occurring locally in shellfish harvesting areas.

The development of an accessible, cost-efficient, and relatively simple ASP ELISA test kit for domoic acid, will make it possible to implement on-site testing at test facilities close to the point-of-problem. Such a *preventive* countermeasure will be a valuable risk management tool for pre-harvesting and post-harvest testing, allowing an immediate on-site response to elevated domoic acid levels in shellfish. The ASP ELISA will contribute to the empowerment of the shellfish industry, as they will be able to make sound harvesting decisions based *rapid and reliable* test results. Such preventive countermeasures will generally lead to reduced harvesting and catching of contaminated shellfish, with a lower fraction of non-compliant shellfish products released on the market for human consumption.

Cost Information (if available):

The full cost per ASP ELISA 96-well kit is USD 500. Based on this the cost of obtaining a fully quantitative test result pr sample on a full plate is USD 13.9.

Action by 2013 Laboratory Method Review and Quality Assurance Committee

Recommended no action on Proposal 13-100. Rationale - There is insufficient data to determine if the method is fit for purpose within the NSSP

Action by 2013 Task Force I

Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-100.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force I on Proposal 13-100.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 13-100.

NOTE:

Click here for Proposal 13-100 Supporting Documentation

Proposal Subject: Outbreaks of Shellfish Related Illness

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority and Section IV. Guidance Documents Chapter V Illness Outbreaks and Recall Guidance

Text of Proposal/ Requested Action Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority @.01 Outbreaks of Shellfish-Related Illness.

A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one or more persons in the case of paralytic shellfish poisoning [PSP]), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:

(1) Each consumer's food history;
(2) Shellfish handling practices by the consumer and/or retailer;
(3) Whether the disease has the potential or is known to be transmitted by shellfish; and
(4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.

NOTE: Illness outbreaks involving sporadic cases of *Vibrio parahaemolyticus* illnesses will be defined as two (2) or more persons not from the same household becoming ill from shellfish from the same harvest area within a seven (7) day period

B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall:

(1) Conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.
(2) Determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated products.

C. When the investigation outlined in Section .02 B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:

(1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status (unless more than thirty (30) days have passed since the last reported illness and no additional illnesses have occurred;
(2) Notify receiving states, the ISSC and the FDA Regional Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;
(3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and
(4) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products (unless more than thirty (30) days have passed since the last reported illness [associated date of harvest]

and no implicated product is likely to remain in the market place).

Guidance Documents Chapter V Illness Outbreaks and Recall Guidance
.01 Guidance for Investigating an Illness Outbreak and Conducting Recall

A. Requirements for the Authority

When an illness outbreak has occurred, immediate closure of the implicated growing area(s) will significantly reduce the chance of additional illnesses during the investigatory process. Immediate closure for the purposes of this Guidance Document means within twenty-four (24) hours of notification of the illness (NSSP Model Ordinance Chapter IV. @.03 A. (1)). If a preliminary investigation reveals that the growing area is not implicated, an immediate closure is not necessary. Additional information concerning investigation of an outbreak of shellfish related illness believed to be associated with a naturally occurring pathogen can be found in the NSSP Guidance Documents: *Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak* (ISSC/FDA, 2011). Additional information concerning the disease causing potential of shellfish can be found in the NSSP Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Guidance for Developing Marine Biotoxin Contingency Plans*, and *Shellstock Relay* (ISSC/FDA, 2011).

In determining the appropriateness of harvest area closures in response to sporadic cases of *V.p.* illness, the Authority will:

(1) Define Illness outbreaks involving sporadic cases of *Vibrio parahaemolyticus* illnesses as two (2) or more persons not from the same household becoming ill from shellfish from the same harvest area within a seven (7) day period.
(2) Not institute a harvest closure if more than thirty (30) days has passed since the last reported illness.

The Authority should assign an Illness Investigation/Recall Coordination Lead (the Lead) for the agency to be listed on the ISSC website as the agency contact person. The Lead will be the agency contact for the duration of the event.

During and after the immediate closure, the Authority must be in the process of investigating, evaluating and conducting increased surveillance. Immediate closures will not always result in an immediate recall of product. It is imperative that the Authority communicate with State Epidemiologists, local health officials, pertinent State agencies, industry and others as necessary to complete a thorough investigation.

Additionally, immediate closures may not be necessary if the investigation reveals that the illness outbreak was caused by a specific activity by a single entity which can be controlled through a product recall and an immediate corrective action in the processing or transport of product.

An illness outbreak investigation must include an evaluation of the health hazard presented and consideration of the following factors, including but not limited to:

1. Immediately send staff members out to perform growing area reconnaissance,
2. Review documentation of the information supporting growing area classification, review environmental sample trends, secure additional shellstock and/or water samples if necessary
3. Review toxin sample trends, sampling protocol and supporting information for Biotoxin closures, secure additional shellstock and/or water samples if necessary

4. Interview local sources regarding any anecdotal or factual information on the origin of contaminants (large passenger vessels, point and non-point sources),
5. Immediately send staff members out to interview certified dealer(s), restaurant staff members or retail establishment staff members to secure additional details regarding tagging, record keeping, refrigeration temperatures, handling practices, shipping and receiving information and where and from whom the shellfish products were purchased, name and telephone number of contact person,
6. When possible, interview harvesters in the area of concern to determine handling practices and specific harvest area(s)
7. Determine the identity of the product involved, the extent of distribution of implicated product, total amount of the suspected product, total amount in distribution chain, distribution information and proposed recall strategy.

A product recall may not be appropriate when an illness outbreak investigation reveals the following, including but not limited to:

1. When the etiological and epidemiological evidence confirms that shellfish from a specific growing area or lease area are the cause of the illnesses

2. When it has been determined that a specific process conducted by a dealer is the cause of the illnesses

A product recall may not be appropriate when an illness outbreak investigation reveals, but is not limited to, the implicated product is no longer available in the market. It is reasonable for the Authority to conclude that a recall is not necessary when more than thirty (30) days has passed since the last reported case of illness.

When the source of the illness is found to be the distribution and processing system, shellfish product should be also detained and an effective recall of product initiated, and the problem immediately corrected. Under these circumstances no closure of the growing waters is warranted in accordance with NSSP Model Ordinance, Chapter II. @.01 D.

Public Health Significance:

Cost Information (if available):

Action by 2013 Task Force II

At the request of the submitter Proposal 13-101 was discussed in conjunction with Proposal 13-202. See Task Force II action on Proposal 13-202.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force II on Proposal 13-101.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 13-101.

Proposal Subject: Laboratory Evaluations

Specific NSSP Guide Reference: Model Ordinance Chapter III. Laboratory
@.01 Quality Assurance

Text of Proposal/ Requested Action Model Ordinance Chapter III. Laboratory
@.01 Quality Assurance

A. NSSP Conformance Required for all laboratories supporting the NSSP. All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish Laboratory Evaluation Officer or FDA certified State Shellfish Laboratory Evaluation Officer ~~(LEO)~~ in accordance with the requirements established under the NSSP.

B. State Program ~~Requirements~~ Responsibilities. The Authority shall ~~assure~~ ensure that all samples are collected, maintained, transported, and analyzed in a manner that assures the validity of the analytical results. Accordingly the
Authority shall:

(1) Require laboratories to develop a written quality assurance plan that:

(a)

(b)

(c) Describes all procedures and methods used to ~~collect, maintain, transport and~~ analyze samples;

(d)

(e)

(f) ~~Provides a quality assessment program to demonstrate laboratory and analyst competence. At a minimum this program must~~ includes an annual internal assessment and ~~triennial onsite laboratory evaluations conducted by either FDA laboratory evaluation officers, and annual internal laboratory audits. For microbiological laboratories,~~ requires participation in a recognized ~~the~~ annual ~~FDA sponsored~~ proficiency test program~~s is also required~~ (FDA, NELEOM, etc.)~~.; and~~

(g) Requires corrective action for any deficiencies found in the laboratory quality assurance program

(2) Require~~s~~ laboratories to implement their quality assurance plan;

(3)

(4) ~~Require triennial or more frequent evaluations of all laboratories which conduct both microbial and marine biotoxin analyses used to officially support the state shellfish program;~~Require laboratories to participate in the laboratory evaluation process:~~and~~

~~(5) Require a laboratory to be re-evaluated when any major changes in personnel ,workload, or facilities occur and when a laboratory is found in~~
nonconformance. Inform FDA Shellfish Laboratory Evaluation Officers and/or the State Shellfish Laboratory Evaluation Officer as appropriate of major changes in laboratory personnel, laboratory workload or laboratory facilities; and

(6) Require corrective action for any deficiencies/nonconformities found in the quality assurance program, laboratory operations and laboratory performance.

~~C.~~ FDA Responsibilities. The FDA will ensure that all laboratories

generating data in support of the NSSP will be evaluated at a minimum frequency of once every three (3) years. ~~An FDA certified State Shellfish Laboratory Officer may evaluate laboratories in a different State under a memorandum of understanding agreement between the States and the FDA. The agreement shall be consistent with NSSP requirements.~~

(1) Evaluations will be conducted by either an FDA Shellfish Laboratory Evaluation Officer or an FDA certified State Shellfish Laboratory Evaluation Officer as appropriate. Normally the initial evaluation of a laboratory will be conducted by FDA

(2) Evaluations are generally onsite but can under certain circumstances be by desk audit (evaluation follow-up, action plan monitoring, nonconformity corrections, major changes in personnel, workload or facilities, etc.

D. Laboratory Evaluations.

(1) Laboratory status is determined by the number and types of nonconformities found in the evaluation using NSSP standardized criteria contained in the FDA Shellfish Laboratory Evaluation Checklists~~,~~ found in the Guidance documents Chapter II Growing Areas .12 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.

(a) Conforms. In order to achieve or maintain ~~its~~ conforms status under the NSSP, a laboratory ~~shall~~ must meet the following ~~requirements under the NSSP standardized~~ laboratory evaluation criteria:

(i) No critical nonconformities in the microbiological or marine Biotoxin (PSP or NSP) component under evaluation have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist, and;

(ii) Not more than twelve (12) key nonconformities ~~for~~ in the microbiological component or five (5) ~~for~~ in the ~~paralytic shellfish poisoning~~ marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist, and;

(iii) Not more than seventeen (17) critical, key, and other nonconformities in total in the microbiological component or nine (9) critical, key and other nonconformities in total in ~~for~~for the ~~paralytic shellfish poisoning~~ marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist. This number must ~~(~~not ~~to~~ exceed the numerical limits established for either the critical ~~and~~ or key criteria~~)~~; and

(iv) No repeat key nonconformities have been identified in the microbiological or marine Biotoxin component under evaluation in consecutive evaluations using the appropriate FDA Shellfish Laboratory Evaluation Checklist.

(b) Provisionally Conforms. In order to ~~achieve~~ be deemed provisionally conforming ~~status~~ under the NSSP, a laboratory ~~shall~~ must meet the following ~~requirements under the NSSP standardized microbiological~~ laboratory evaluation criteria:

(i) Not more than three (3) critical nonconformities ~~for~~ in the microbiological component or two (2) ~~for~~ in the marine Biotoxin (PSP or NSP) ~~paralytic shellfish poisoning~~ components have been identified using the

appropriate FDA Shellfish Laboratory Evaluation Checklist, and;

(ii) Not more than twelve (12) key nonconformities ~~for~~ in the microbiological component or five (5) ~~for~~ in the marine Biotoxin (PSP or NSP) ~~paralytic shellfish poisoning~~ components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist, and;

(iii) Not more than seventeen (17) critical, key and other nonconformities in total in the microbiological component or nine (9) critical, key and other nonconformities in total in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and,

(iv) Not more than one (1) repeat ~~K~~key nonconformity has been identified in the microbiological or marine Biotoxin component under evaluation in consecutive evaluations using the appropriate FDA Shellfish Laboratory Evaluation Checklist.

(c) Nonconformance. When a laboratory exceeds the following criteria, ~~the laboratory shall~~ it will be determined to be in nonconformance:

(i) More than three (3) critical nonconformities ~~for~~ in the microbiological component or two (2) ~~for paralytic shellfish poisoning~~ in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist, or;

(ii) More than twelve (12) key nonconformities ~~for~~ in the microbiological component or five (5) ~~for paralytic shellfish poisoning~~ in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist, or;

(iii) More than seventeen (17) critical, key and other nonconformities in total ~~for~~ in the microbiological component or more than nine (9) critical, key and other nonconformities in total ~~for paralytic shellfish poisoning~~ in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist, or;

(iv) One (1) or more repeat critical or two (2) or more repeat key nonconformities have been identified in consecutive evaluations in either the microbiological or marine Biotoxin components using the appropriate FDA Shellfish Laboratory Evaluation Checklist.

E. Time Limit on Laboratory Status.

(1) Conforming Status. A laboratory found to be in conforming status for either the microbiological or marine Biotoxin component or for both components has up to ninety (90) days to successfully correct all nonconformities noted in ~~the evaluation~~ each component evaluated or has an approved action plan in place to deal with the nonconformities noted. After this period, the laboratory's status

will ~~shall~~ be downgraded to nonconforming if any key nonconformities remain to be successfully corrected. As a result, data being generated by the laboratory will ~~is~~ no longer be acceptable for use in support of the NSSP for the laboratory component in question

(2) Provisionally Conforms Status. A laboratory found to be in provisionally conforming status for either the microbiological or marine Biotoxin component or for both components has up to sixty (60) days to successfully correct all nonconformities found in each provisionally conforming component evaluated or has an approved action plan in place to deal with the nonconformities noted. After this period, the laboratory will ~~shall~~ be assigned ~~a~~ the following status ~~of~~ for the laboratory component(s) in question:

(a) Conforms if all critical and key nonconformities have been successfully corrected in each provisionally conforming component evaluated;

(b) Nonconforming if any critical or key nonconformities remain to be successfully corrected in each provisionally conforming component evaluated. As a result, data being generated by the laboratory ~~is~~ will no longer be acceptable for use in support of the NSSP for the laboratory component in question.

(3) Nonconformance

(a) Upon a determination of nonconforming status in either the microbiological or marine Biotoxin component or in both components the laboratory has up to thirty (30) days to demonstrate successful correction of all noconformities found. After this period, if all critical and key nonconformities have been successfully corrected, the status of the laboratory will be upgraded to conforming for the laboratory component(s) in question. However, if any critical or key nonconformities remain to be successfully corrected, the status of the laboratory for the laboratory component(s) in question will ~~shall~~ continue to be nonconforming; and as a result, data being generated by the laboratory for this/these laboratory component(s) will ~~is no longer~~ continue to be unacceptable ~~acceptable~~ for use in support of the NSSP.

(b) When a laboratory is found to be nonconforming in either the microbiological or marine Biotoxin component or in both components ~~either~~ for failure to successfully implement the required corrective action, or for having repeated critical or key nonconformities in consecutive evaluations, the Authority ~~shall~~ will ensure that an action plan is developed to correct the situation in an acceptable and expeditious manner or discontinue use of the laboratory to support the NSSP.

(c) ~~When all critical and key nonconformities have been successful corrected by a nonconforming laboratory;~~ for each laboratory component evaluated, the laboratory will be ~~evaluated~~ reevaluated either on-site or through a ~~careful review of appropriate documentation~~ thorough desk audit as determined by the FDA Shellfish Laboratory Evaluation Officer and the FDA certified State Shellfish Laboratory Evaluation Officer ~~LEO~~ if one is utilized by the State. Only a finding of fully conforming in laboratories whose data has ceased to be acceptable to the NSSP will restore its acceptability for use in the NSSP for the laboratory

components in question.

F. ~~Laboratory Services for Depuration~~, Wet Storage and Post-Harvest Processors. For any laboratory providing analytical testing services for depuration, wet storage or Post Harvest Processing (PHP) ~~the quality assurance program (e.g. water quality) including end product testing of any depuration processor,~~ initial and subsequent triennial evaluations will be required and conducted in accordance with @.01 and @.02 of this Chapter by an FDA Shellfish Laboratory Evaluation Officer or an FDA certified State Shellfish Laboratory Evaluation Officer as appropriate. It is understood that academic laboratories involved in PHP Validation or Verification have special circumstances such as extended periods of inactivity resulting from university schedules or funding constraints; however, written documentation of Quality Control practices will be required for time periods in which they are preparing for or actively participating in a PHP validation or verification. Times in which the lab is inactive can be explained with a not applicable notation.

~~a. The Authority shall:~~

~~A. Require the annual inspection of the laboratory in accordance with .01 and .02 of this Chapter; and~~

~~B. Require the laboratory to retain its records for a minimum of the previous two (2) years.~~

Public Health Significance:

This proposal updates and clarifies the roles and responsibilities of the state and the FDA in the laboratory evaluation process. It also clarifies how laboratory status is determined and its effect on the acceptability of the data for use in the NSSP.

In the National Shellfish Sanitation Program (NSSP) Model Ordinance Chapter XVI. Post-Harvest Processing (PHP) it states that if a dealer elects to utilize a PHP for the purpose of making safety added labeling claims they must conduct a validation study to demonstrate the ability of the PHP to reduce the target pathogen(s) to acceptable levels. Specifics on target levels and approved methods of detection for pathogens are found in the Model Ordinance. All laboratory analysis must be performed by a laboratory that has been evaluated by FDA or an FDA certified LEO and found to "conform" or "provisionally conform" with the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance Chapter III and supporting Guidance Documents. Results of the validation study should be submitted in the following format for review and consideration by state and federal shellfish control authorities. For validation of Vibrio vulnificus or *Vibrio parahaemolyticus* methods, checklist may be used as a guide.

Cost Information (if available):

NA

Action by 2013 Task Force I

Recommended adoption of Proposal 13-102 as submitted.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force I on Proposal 13-102.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 13-102.

Proposal Subject: Emergency Conditions Contingency Plan

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance Chapter IV @ .03 A. (1)

Text of Proposal/ Requested Action

Section II. Model Ordinance Chapter IV Shellstock Growing Areas @ .03 A. (1)

(1) Emergency Conditions. A growing area shall be placed in the closed status under Section .03 A. (5) when pollution conditions exist which were not included in the database used to classify the area. Each state shall develop and maintain a current Emergency Conditions Contingency Plan that defines what the state considers to be pollution conditions which were not included in the database used to classify the area. If it is determined that an emergency condition or situation exists as defined in the Contingency Plan or other pollution condition that the state believes would compromise the sanitary condition of shellfish, then the growing area will be immediately (within 24 hours) placed in the closed status under ~~§~~Section .03 A. (5).

Public Health Significance: When emergency conditions (spills, extreme meteorological events,) occur that can result in water quality conditions that were not considered as part of the growing area's classification, decisions and actions must be taken quickly to close or not close the area. The need for quick action can make it difficult for the Authority to fully assess all factors involved and to determine if the conditions are different than those on which the classification was originally based. By developing an Emergency Conditions Contingency Plan, the Agency will have had sufficient time to develop the criteria while not under the pressure of responding to an emergency. As with other NSSP Contingency Plans (e.g. Biotoxin), this plan may also include a description of actions that would be taken in response to the Emergency Conditions. These actions could include responses to effectively to minimize illness, a follow-up monitoring strategy and reopening criteria.

Cost Information (if available):

Action by 2013 Task Force I Recommended no action on Proposal 13-103.

Rationale: Current language in Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @ .03 A. (1) is sufficient.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force I on Proposal 13-103.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-103.

Proposal Subject: Re-Opening Conditional Areas using Male-Specific Coliphage after WTP Malfunction

Specific NSSP Guide Reference: NSSP Guide Section II. Model Ordinance
Chapter IV. Shellstock Growing Areas @ .03 A. (5) (c) (ii)

Text of Proposal/ Requested Action

@ .03 Growing Area Classification

A. General

(5) Status of Growing Areas

(c) Reopened Status. A growing area temporarily placed in the closed status as provided in (b) above, shall be returned to the open status only when:

(ii) For emergency closures (not applicable for conditional closures) of harvest areas caused by the occurrence of raw untreated sewage discharged from a large community sewage collection system or wastewater treatment plant, the analytical sample results shall not exceed background levels or a level of fifty (50) male-specific coliphage per 100 grams from shellfish samples collected no sooner than seven (7) days and no later than twenty-one (21) days after contamination has ceased and from representative locations in each growing area potentially impacted provided that water temperatures exceed 45° F; or

Public Health Significance: Raw or partially treated sewage accidentally discharged into a growing area by sewage by-pass from pump station failures, broken sewage lines, or malfunctions at the Wastewater Treatment facilities represent a serious public health risk and require emergency closure of adjacent conditional growing areas.

Male-specific Coliphage (MSC) is a RNA virus of E. coli present in high numbers in raw sewage (on the order of 10^5 PFU/100gm). MSC is similarly resistant to chlorine disinfection as are norovirus and hepatitis A viruses, which are the viral pathogens of concern in sewage. MSC may be a good surrogate for enteric viruses.

Recent work has shown that persistence of viruses in the growing waters is much lower in the summer months than in the winter months. Depuration rates of enteric viruses in molluscan shellfish is also faster in summer months. MSC can be a useful tool for state shellfish programs to mitigate the negative effect of prolonged conditional closures due to WTP system failures. This approach has been shown to work well in late-spring and summer months to shorten these closures from 21 to as short as 7 days.

Most of the validation work developing this assay has been done using soft-shelled clams and oysters, during months when temperatures are above 50°F. Relatively little work on the use of this assay has been done using hard clams or when temperatures fall below 50°F. Until the assay has been appropriately validated for other shellfish species such as hard-shelled clams, and a sound correlation between MSC and enteric viruses of concern such as Norwalk virus over a range of temperatures, use of this assay on hard clams and in cold waters may result in unnecessarily prolonged closures not correlated with a real public health risk.

Consider also the comments on proposal 11-102 by the FDA: *"Support for using MSC for conditional area management is based on uptake and*

elimination data for a single shellfish species, soft-shelled clams (Mya arenaria), impacted by effluent from a highly efficient WWTP at one geographic location over just one harvest season. Those data are not adequate to ensure the efficacy of MSC to safely manage other conditional areas for other species of shellfish, in other geographic regions, and over other seasons." (emphasis added) and also: *"A SL V has been conducted and adopted by the ISSC for the method to enumerate SC in soft-shelled clams and oysters. A SL V is needed to demonstrate the efficacy of this or another method to enumerate MSC in other species of shellfish."*

For several decades emergency closures have lasted for 21 days after the WTP system returns to normal operation. This practice was not associated with reports of illness associated with enteric viruses.

Some states have investigated using the MSC assay to assist in speeding the reopening of waters following emergency closures, however persistent high levels have led some states to resist implementation of the MSC assay. Following Hurricane Sandy some states shipped shellfish despite high MSC counts and no illnesses were reported (Keith Skiles, personal communication).

Cost Information (if available):

The Male-specific Coliphage (MSC) Method is an inexpensive double-agar pour plate method, which can be run in any state-certified microbiological laboratory. A refrigerated centrifuge capable of 9,000G is required which cost $10K to $12K (US dollars). Re-opening after 7 days using MSC method is optional for the State shellfish control agency.

Action by 2013 Task Force I

Recommended no action on Proposal 13-104.

Rationale: Limiting the sample collection to no later than twenty-one days could restrict SSCAs from gathering important data that could be used to evaluate the risk of further illnesses.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force I on Proposal 13-104.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 13-104.

Proposal Subject: Management Plans for Wastewater Treatment Plants

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance
Chapter IV Shellstock Growing Areas
@. 03 Growing Area Classification

Text of Proposal/ Requested Action

C. Conditional Classification

(2) Management Plan Required. For each growing area, a written management plan shall be developed and shall include:

(a) For management plans based on wastewater treatment plant function, performance standards that include:

(i) Peak effluent flow, average flow, and infiltration flow;
(ii) ~~Bacteriological or viral~~ Microbiological quality of the effluent;
(iii) Physical and chemical quality of the effluent;
(iv) Conditions which cause plant failure;
(v) Plant or collection system bypasses;
(vi) Design, construction, and maintenance to minimize mechanical failure, or overloading;
(vii) Provisions for monitoring and inspecting the waste water treatment plant; and
(viii) Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with Section E. Prohibited Classification;

Public Health Significance: This change is to make the language consistent with that proposed for Section II, Chapter IV @.03 E (5) Wastewater Discharges

Cost Information (if available): This change does not incur any additional cost to the Authority or the industry beyond that inferred by the current wording.

Action by 2013 Task Force I Recommended adoption of Proposal 13-105 as submitted.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force I on Proposal 13-105.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-105.

Proposal Subject: Wastewater Discharges for Addressing Viruses

Specific NSSP Guide Reference: Section II Model Ordinance
Chapter IV Shellstock Growing Areas
@. 03 Growing Area Classification

Text of Proposal/ Requested Action

E. Prohibited Classification

(5) Wastewater Discharges.

(a) An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance.

(b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria:

(i) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the ~~bacteriological or viral~~ microbiological quality of the effluent;

(ii) The decay rate of the contaminants of public health significance in the wastewater discharged;

(iii) The wastewater's dispersion and dilution, including sufficient dilution to mitigate the impact of viruses in the effluent, and the time of waste transport to the area where shellstock may be harvested; and

(iv) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

Public Health Significance: Changing "bacteriological or viral" to "microbiological is a fairly innocuous change, since the only biological concerns for shellfish safety in wastewater are bacteria and viruses and all of these are microorganisms. This word change will also allow for any other emerging microbiological hazards, for example, *Cryptosporidium, Giardia, Cyclosporidium*, etc.

Adding the phrase "including sufficient dilution to mitigate the impact of viruses in the effluent" in (iii) simply emphasizes in plain language the heightened current concern for viral pathogens in shellfish, which is thoroughly justified by the following facts related to enteric viral pathogens: (1) they only derive from humans and are most commonly and readily found in human sewage; (2) they are today's most prevalent pathogenic threat to shellfish consumers; (3) they are less effectively removed or inactivated by wastewater treatment and disinfection than bacteria; (4) they survive longer at cooler temperatures in environmental waters than bacteria; (5) they reside far longer in molluscan shellfish than bacteria; (6) they are not well indexed or predicted by the NSSP bacterial indicators; (7) routine monitoring for pathogens is not an effective preventative strategy; and, (8) ensuring sufficient dilution of contaminants by receiving waters is a proven, effective strategy for ensuring against enteric pathogens in molluscan shellfish, which is the entire intent of the statement in (a).

Cost Information (if available): It is not intended that any of these wording changes require any additional testing or incur any additional cost for the Authority or the industry beyond that incurred by the current Model Ordinance wording.

Action by 2013 Task Force I Recommended adoption of Proposal 13-106 as amended.

E. Prohibited Classification

(5) Wastewater Discharges.

(a) An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source

outfall of public health significance.

(b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria:

(i) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the microbiological quality of the effluent;

(ii) The decay rate of the contaminants of public health significance in the wastewater discharged;

(iii) The wastewater's dispersion and dilution, ~~including sufficient dilution to mitigate the impact of viruses in the effluent~~, and the time of waste transport to the area where shellstock may be harvested; and

(iv) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force I on Proposal 13-106.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-106.

Proposal Subject: Sources of Seed for Aquaculture

Specific NSSP Guide Reference: NSSP Section II Model Ordinance
Chapter VI Shellfish Aquaculture

Text of Proposal/ Requested Action

.03 Seed Shellstock

Seed may come from any growing area, or from any growing area in any classification, provided that:

A. The source of the seed is sanctioned by the Authority
B. Seed from growing areas ~~or growing areas~~ in the restricted or prohibited classification have acceptable levels of poisonous or deleterious substances; and
C. Seed from growing areas ~~or growing areas~~ in the prohibited classification are cultured for a minimum of ~~six (6) months~~ one month while average daily water temperatures are above 50 degrees F.

Public Health Significance:

Shellfish seed collected or cultured in certain growing areas that are in the prohibited classification have been shown through repeated sampling to be free of deleterious substances (John Mullen RI DOH, unpub. data, Rheault unpubl. data, Rice unpub. data, Leavitt unpub. data). A period of one month is typically adequate to purge viral and bacterial contaminants provided water temperatures are high enough to maintain active metabolic activity (above 60 degrees F or 15 degrees C) (Richards 1988).

Once the Authority is satisfied that adequate sampling has demonstrated that the seed have "acceptable levels of deleterious substances", then a 30 day period of culture in open waters should be adequate to allow purging of bacterial and viral contaminants to ensure that public health is protected. The Authority retains the right to deny seed collection and culture in any area, or to require additional testing for deleterious substances, or to require longer periods to purge contaminants as necessary.

The original intent of this section was to provide for purging of viral and bacterial contamination prior to harvest for consumption on the assumption that deleterious substances were at acceptable levels prior to moving the seed to grow out areas The six-month requirement was implemented as a short-hand way to ensure that seed were grown for at least one month when water temperatures exceeded 60 degrees F.

It makes little sense to require relay times in excess of one month for seed that are typically more than six months from harvest size when shellstock relay times as short as two weeks are common.

References Cited:

Richards, G. (1988), Microbial Purification of Shellfish: A Review of Depuration and Relaying, J. Food Protection 51(3)218-251.

Supporting Information:

RI DOH metals data
(oyster seed grown in Billington Cove Marina)
Unpublished data from Rd. Dale Leavitt
(clam seed grown in Warwick Cove Marina)

Cost Information (if available):

This change should facilitate record keeping and documentation efforts required to ensure that seed from prohibited waters do not get harvested until bacterial and viral contamination has been purged.

Action by 2013 Task Force I	Recommended referral of Proposal 13-107 to an appropriate committee as determined by the Conference Chairman.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-107.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-107.

Proposal Subject: Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood

Specific NSSP Guide Reference: NSSP Section IV Guidance Documents Section IV. Chapter II. Growing Areas .05 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood

Text of Proposal/ Requested Action

The FDA has established action levels, tolerances and guidance levels for poisonous or deleterious substances to control the levels of contaminants in human food, including seafood (FDA Federal Register, 1977; FDA, ~~1985~~2002). Action levels are established and revised according to criteria specified in the ***Code of Federal Regulations*** (21 CFR 109 and 509), and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective. Action levels and tolerances represent limits at or above which FDA will take legal action to remove adulterated products, including shellfish, from the market. Action levels and tolerances are established based on the unavoidability of the poisonous or deleterious substance and do not represent permissible levels of contamination where it is avoidable. Guidance levels are used to assess the public health impact of the specified contaminant.

Table 1 lists action levels, tolerances and guidance levels established by the FDA for poisonous or deleterious substances in seafood, including shellfish.
Notices are published in the ***Federal Register*** as new action levels are established or as existing action levels are revised or revoked. Should any of these notices affect Table 1, FDA will issue an interpretation advising NSSP participants of this revision or addition.

Table 1

Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood

Class of Substance	Substance	Level	Food Commodity	Reference
Deleterious Substance	Aldrin/Dieldrin c	0.3 ppm	All Fish	CPG sec 575.100b
Deleterious Substance	Chlordane	0.3 ppm	All Fish	CPG sec 575.100b
Deleterious Substance	Chlordecone d	0.3 ppm	All Fish	CPG sec 575.100b
	DDT, DDE, TDE e	5.0 ppm	All Fish	CPG sec 575.100b
	Diquat g	2.0 ppm	All Fish	40 CFR 180.226
	Diquat g	20.0 ppm	Shellfish	40 CFR 180.226
	Glyphosate g	0.25 ppm	Fin Fish	40 CFR 180.364
	Glyphosate g	3.0 ppm	Shellfish	40 CFR 180.364
	Carbaryl	0.25 ppm	Oysters	40 CFR 180.169
	Endothall and its Monomethyl ester	0.1 ppm	All Fish	40 CFR 180.293
	Methyl Mercury	1.0 ppm	All Fish	CPG sec 540.600
	Heptachlor /	0.3 ppm	All Fish	CPG sec

	Heptachlor Epoxide f			575.100
	Mirex	0.1 ppm	All Fish	CPG sec 575.100
	Polychlorinated Biphenyls (PCBs)g	2.0 ppm	All Fish	21 CFR 109.30
	2,4-D g	0.1 ppm	Fish	40 CFR 180.142
	2,4-D g	1.0 ppm	All Fish Shellfish	40 CFR 180.142
Chemotherapeutics	Chloramphenicol	No Residue	All Fish	21 CFR 530.41
Chemotherapeutics	Clenbuterol	No Residue	All Fish	21 CFR 530.41
Chemotherapeutics	Diethylstilbesterol (DES)	No Residue	All Fish	21 CFR 530.41
	Demetridazole	No Residue	All Fish	21 CFR 530.41
	Ipronidazole and other nitroimidazoles	No Residue	All Fish	21 CFR 530.41
	Furazolidine and other nitrofurans	No Residue	All Fish	21 CFR 530.41
	Fluoroquinolones	No Residue	All Fish	21 CFR 530.41
	Glycopeptides	No Residue	All Fish	21 CFR 530.41
Natural Toxins	Paralytic Shellfish Poisoning (PSP) toxins	80 µg/100g	All Fish	CPG sec 540.250
Natural Toxins	Neurotoxic Shellfish Poisoning (NSP) toxins	20 MU/100g	Clams, mussels, oysters, fresh frozen or canned	NSSP MO
Natural Toxins	Azaspiracid Shellfish Poisoning (AZP) toxins	0.16 mg/kg	Clams, mussels, oysters, fresh frozen or canned	NSSP MO
Natural Toxins	Diarrhetic Shellfish Poisoning (DSP) toxins	0.16 mg/kg	Clams, mussels, oysters, fresh frozen or canned	NSSP MO
Natural Toxins	Amnesic Shellfish Poisoning (ASP) toxins	20 mg/kg	All Fish (except in the viscera of Dungeness crab where 30 mg/kg is permitted)	Compliance Program 7303.842

Note: the term "fish" refers to fresh or saltwater fin fish, crustaceans, other forms of aquatic animal life other than birds or mammals and all mollusks as defined in *21*

CFR 123.3(d).

Footnotes for Table 1

a) Unless otherwise specified, the action levels, tolerances and other values listed apply to both the raw and processed food commodity. Procedures for sample collection and analyses are specified in Sections 420 and 450 of the ***FDA Investigations Operation Manual***; ***FDA Pesticide Analytical Manual* (PAM)** Volume I or II; ***AOAC Official Methods of Analysis***; ***APHA Recommended Procedures for the Examination of Sea Water and Shellfish***, Fourth Edition, 1970; or, peer reviewed literature for Domoic Acid (ASP) methodologies.
b) References designated as CPG represent the FDA Compliance Policy Guides and all associated numbers as they appear in appropriate sections of FDA's Compliance Policy Guides Manual.
c) The action level for aldrin and dieldrin are for residues of the pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin do not count aldrin or dieldrin found at the level below 0.1 ppm for fish.
d) Previously listed as Kepone, the trade name for chlordecone.
e) The action level for DDT, TDE, and DDE are for residues of the pesticides individually or in combination. However, in adding amounts of DDT, TDE, and DDE do not count any of the three found below 0.2 ppm for fish.
f) The action level for heptachlor and heptachlor epoxide are for the pesticides individually or in combination. However, do not count heptachlor or heptachlor epoxide found below 0.1 ppm.
g) The levels published in 21 CFR and 40 CFR represent tolerances rather than guidance levels or action levels.

Public Health Significance: "Table 1" within this guidance has been updated to be consistent with current FDA action levels, tolerances and guidance levels for poisonous or deleterious substances in seafood.

Cost Information (if available): N/A – no cost

Action by 2013 Task Force I Recommended adoption of Proposal 13-108 as amended:

Table 1

Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood

Class of Substance	Substance	Level	Food Commodity	Reference
Deleterious Substance	Aldrin/Dieldrin c	0.3 ppm	All Fish	CPG sec 575.100b
Deleterious Substance	Chlordane	0.3 ppm	All Fish	CPG sec 575.100b
Deleterious Substance	Chlordecone d	0.3 ppm	All Fish	CPG sec 575.100b
	DDT, DDE, TDE e	5.0 ppm	All Fish	CPG sec 575.100b
	Diquat g	2.0 ppm	All Fish	40 CFR 180.226
	Diquat g	20.0 ppm	Shellfish	40 CFR 180.226
	Glyphosate g	0.25 ppm	Fin Fish	40 CFR 180.364
	Glyphosate g	3.0 ppm	Shellfish	40 CFR 180.364

	Carbaryl	0.25 ppm	Oysters	40 CFR 180.169
	Endothall and its Monomethyl ester	0.1 ppm	All Fish	40 CFR 180.293
	Methyl Mercury	1.0 ppm	All Fish	CPG sec 540.600
	Heptachlor / Heptachlor Epoxide f	0.3 ppm	All Fish	CPG sec 575.100
	Mirex	0.1 ppm	All Fish	CPG sec 575.100
	Polychlorinated Biphenyls (PCBs)g	2.0 ppm	All Fish	21 CFR 109.30
	2,4-D g	0.1 ppm	Fish	40 CFR 180.142
	2,4-D g	1.0 ppm	Shellfish	40 CFR 180.142
Chemotherapeutics	Chloramphenicol	No Residue	All Fish	21 CFR 530.41
Chemotherapeutics	Clenbuterol	No Residue	All Fish	21 CFR 530.41
Chemotherapeutics	Diethylstilbesterol (DES)	No Residue	All Fish	21 CFR 530.41
	Demetridazole	No Residue	All Fish	21 CFR 530.41
	Ipronidazole and other nitroimidazoles	No Residue	All Fish	21 CFR 530.41
	Furazolidine and other nitrofurans	No Residue	All Fish	21 CFR 530.41
	Fluoroquinolones	No Residue	All Fish	21 CFR 530.41
	Glycopeptides	No Residue	All Fish	21 CFR 530.41
Natural Toxins	Paralytic Shellfish Poisoning (PSP) toxins	80 µg/100g	All Fish	CPG sec 540.250
Natural Toxins	Neurotoxic Shellfish Poisoning (NSP) toxins	20 MU/100g	Clams, mussels, oysters, fresh frozen or canned	NSSP MO
Natural Toxins	Azaspiracid Shellfish Poisoning (AZP) toxins	0.16 mg/kg	Clams, mussels, oysters, fresh frozen or canned	NSSP MO
Natural Toxins	Diarrhetic Shellfish Poisoning (DSP) toxins	0.16 mg/kg	Clams, mussels, oysters, fresh frozen or canned	NSSP MO
Natural Toxins	Amnesic Shellfish Poisoning (ASP) toxins	20 mg/kg	All Fish (except in the viscera of Dungeness crab where 30 mg/kg is permitted)	Compliance Program 7303.842

Note: the term "fish" refers to fresh or saltwater fin fish, crustaceans, other forms of

aquatic animal life other than birds or mammals and all mollusks as defined in *21 CFR 123.3(d).*

Footnotes for Table 1

a) Unless otherwise specified, the action levels, tolerances and other values listed apply to both the raw and processed food commodity. Procedures for sample collection and analyses are specified in Sections 420 and 450 of the ***FDA Investigations Operation Manual***; ***FDA Pesticide Analytical Manual* (PAM)** Volume I or II; ***AOAC Official Methods of Analysis***; ***APHA Recommended Procedures for the Examination of Sea Water and Shellfish***, Fourth Edition, 1970; or, peer reviewed literature for Domoic Acid (ASP) methodologies.
b) References designated as CPG represent the FDA Compliance Policy Guides and all associated numbers as they appear in appropriate sections of FDA's Compliance Policy Guides Manual.
c) The action level for aldrin and dieldrin are for residues of the pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin do not count aldrin or dieldrin found at the level below 0.1 ppm for fish.
d) Previously listed as Kepone, the trade name for chlordecone.
e) The action level for DDT, TDE, and DDE are for residues of the pesticides individually or in combination. However, in adding amounts of DDT, TDE, and DDE do not count any of the three found below 0.2 ppm for fish.
f) The action level for heptachlor and heptachlor epoxide are for the pesticides individually or in combination. However, do not count heptachlor or heptachlor epoxide found below 0.1 ppm.
g) The levels published in 21 CFR and 40 CFR represent tolerances rather than guidance levels or action levels.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force I on Proposal 13-108.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-108.

Proposal Subject:	Expanding the use of the Abraxis Shipboard ELISA for the determination of paralytic shellfish poisoning (PSP) toxins
Specific NSSP Guide Reference:	Section IV. Guidance Documents Chapter II. Growing Areas, .11 Approved NSSP Laboratory Tests, 4. Approved Limited Use Methods for Marine Biotoxin Testing
Text of Proposal/ Requested Action	This submission presents the Abraxis Shipboard ELISA for paralytic shellfish poisoning (PSP) toxins as a screening method for consideration as an NSSP Approved Limited Use Method. Currently the Abraxis Shipboard ELISA is approved for limited use in conjunction with the Jellett Rapid Extraction (mixture of rubbing alcohol and vinegar) and specifically for the onboard testing protocol. This proposal presents more data on the Abraxis test using the rapid extraction and also provides new data and comparisons of the test when AOAC extractions (boiling with hydrochloric acid) are performed. The data presented supports expanding the use of the Abraxis Shipboard ELISA to (1) allow for the rapid extraction OR the AOAC extraction method and (2) allow the kit to be used as a screening method beyond the onboard screening protocol.
Public Health Significance:	Paralytic shellfish poisoning intoxications result from the consumption of seafood (primarily bivalve molluscs) contaminated with neurotoxins known as paralytic shellfish toxins (PSTs). To protect public health, harvesting closures are implemented when toxicity exceeds the guidance level of 80 micrograms Saxitoxin equivalents per 100 grams of shellfish tissue. As such, accurate screening and analytical methods are needed to monitor shellfish toxicity for making decisions regarding opening and closing shellfish growing areas accordingly. While the Abraxis Shipboard ELISA is already an NSSP Approved Limited Use Method for PSP toxicity determination, being able to use AOAC extractions with this kit would allow for the same extraction to be used with this method during screening and with the MBA as necessary for confirmation (without requiring a second extraction). Further expanding the use of the method beyond the onboard screening protocol would be beneficial as it would make the Abraxis Shipboard ELISA available for use by monitoring laboratories.
Cost Information (if available):	Each 96 well plate costs ~$500.
Action by 2013 Laboratory Method and Quality Assurance Review Committee	Recommended Proposal 13-109 be referred to an appropriate committee as determined by the Conference Chairman.
Action by 2013 Task Force I	Recommended adoption of Laboratory Method and Quality Assurance Review Committee recommendation on Proposal 13-109.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-109.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-109.

Proposal Subject:	Immunoassay Method for Detection of Saxitoxin (PSP) from Shellfish
Specific NSSP Guide Reference:	NSSP Guide Section IV. Guidance Document Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests, 2. Approved Methods for Marine Biotoxin Testing and 4. Approved Limited Use Methods for Marine Biotoxin Testing.
Text of Proposal/ Requested Action	Review the validation for Saxitoxin (PSP) Microtiter Plate Test Kit by the Proposal Review Committee. Single Laboratory Validation Protocol for Method Approval attached.
Public Health Significance:	Rapid screening method can handle numerous samples and screen out negative samples so that it recudes the size of sample to be confirmed with regulatory methods such as mouse bioassay (MBA) or liquid chromatography with post-column oxidation (PCOX). This results in saving resources of the laboratories, and make the laboratories enable to provide rapid warning. References attached.
Cost Information (if available):	Approximate cost for the basic set up of the method is $3600
Action by 2013 Laboratory Method and Quality Assurance Review Committee	Recommended Proposal 13-110 be referred to an appropriate committee as determined by the Conference Chairman and direct the Executive Office send a letter to the submitter requesting additional information as requested by the Laboratory Methods Review and Quality Assurance Committee.
Action by 2013 Task Force I	Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-110.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-110.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-110.
NOTE:	Click here for Proposal 13-110 Supporting Documentation

Proposal Subject:	DSP PPIA Kit for Determination of Okadaic Acid Toxins Group (OA, DTX1, DTX2) in Molluscan Shellfish
Specific NSSP Guide Reference:	NSSP Guide Section IV Guidance Documents Chapter II Growing Areas .11 Approved NSSP Laboratory Tests: Marine Biotoxin Testing
Text of Proposal/ Requested Action	The DSP PPIA kit be approved as a Marine Biotoxin Laboratory Test Method
Public Health Significance:	Okadaic acid (OA) and its analogues, DTX1, DTX2, together with their ester forms are known as the group of OA-toxins. These toxins, lipophilic and heat stable are produced by dinoflagellates and can be found in various species of shellfish, mainly in filter feeding bivalve molluscs. The OA-toxins group causes Diarrhoeic Shellfish Poisoning (DSP), which is characterized by symptoms such as diarrhea, nausea, vomiting and abdominal pain. These symptoms may occur in humans shortly after consumption of contaminated bivalve molluscs such as mussels, clams, scallops or oysters. Inhibition of serine/threonine phosphoprotein phosphatases is assumed to be responsible for these toxic effects. Recently in the Pacific Northwest harvest areas, outbreaks of DSP have occurred.
Cost Information (if available):	Refer to Para D.1. of the Checklist
Action by 2013 Laboratory Method and Quality Assurance Review Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chairman and direct the Executive Office send a letter to the submitter requesting additional information as provided by the Laboratory Methods Review and Quality Assurance Committee.
Action by 2013 Task Force I	Recommended adoption of the Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-111.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-111.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-111.
NOTE:	Click here for Proposal 13-111 Supporting Documentation

Proposal Subject:	Reveal 2.0 ASP
Specific NSSP Guide Reference:	NSSP Guide Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	We request review of the validation study submission for the Reveal 2.0 ASP (domoic acid) test kit and consideration of the method for approval as a screening method for qualitative determination of domoic acid in shellfish. Add Reveal ASP to Section IV. Guidance Documents, Chapter II. Growing Areas, .11 Approved NSSP Laboratory Tests.
Public Health Significance:	Amnesic shellfish poisoning is caused by the toxin domoic acid, produced by phytoplankton of the genus Pseudonitzschia. It is associated with eating contaminated oysters, clams, mussels, and other shellfish [1,2]. There have been numerous outbreaks of ASP, and there is evidence that the occurrence of the phytoplankton responsible for ASP is widespread. Current methods for detection of domoic acid consist primarily of instrumental chemistry methods, which are laborious and time-consuming. Methods for rapid screening for domoic acid, in field and laboratory settings, are needed and will assist the industry and public health authorities in responding to this health concern. The Reveal ASP test is a lateral flow immunoassay designed for qualitative determination of domoic acid in shellfish at levels of 10 ppm (mg/kg) and above. The test uses minimal equipment and simple reagents, does not require specialized training, and can provide results in 20 minutes from sample receipt, including sample preparation. 1] J. Sobel and J. Painter (2005), Illness caused by Marine Biotoxins. Clin. Infect. Dis. 4, 1290. [2] Van Dolah, Frances M. (2000), Marine algal toxins: origins, health effects, and their increased occurrence. *Environmental health perspectives* 108. Suppl 1, 133.
Cost Information (if available):	Approximately $17.00 per test. Reader based assay – approximate cost of Reader $1995.
Action by 2013 Laboratory Method and Quality Assurance Review Committee	Recommended adoption of this method as a Limited Use Method for the purpose of screening and precautionary closure for ASP and direct the Executive Office send a letter to the submitter requesting additional information as provided by the Laboratory Method Review and Quality Assurance Committee.
Action by 2013 Task Force I	Recommended adoption of the Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-112 and recommended that the Conference be made aware the submitter of Proposal 13-112 is looking for samples to be used in testing.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-112.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-112.
NOTE:	Click here for Proposal 13-112 Supporting Documentation

Proposal Subject:	Reveal 2.0 DSP
Specific NSSP Guide Reference:	NSSP Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	We request review of the validation study submission for the Reveal 2.0 DSP (okadaic acid group) test kit and consideration of the method for approval as a screening method for qualitative determination of okadaic acid group in shellfish. Add Reveal DSP to Section IV. Guidance Documents, Chapter II. Growing Areas, .11 Approved NSSP Laboratory Tests.
Public Health Significance:	Toxins that cause diarrhetic shellfish poisoning (DSP) include the okadaic acid (OA) group of toxins [1, 2] OA is produced by marine dinoflagellates such as *Dinophysis*, and has structural analogues referred to as the dinophysistoxins (DTXs). The U.S. Food and Drug Administration action limits are 160 ppb OA equivalents (OA, DTX1, DTX2, DTX3) in shellfish. LC-MS/MS methods [3] have been accepted as quantitative reference methods in many parts of the world. Assays facilitating more rapid determination of OA toxins with simplified procedures are needed by the shellfish industry and regulatory authorities. [1] J. Sobel and J. Painter (2005), Illness caused by Marine Biotoxins. Clin. Infect. Dis. 4, 1290. [2] Van Dolah, Frances M. (2000), Marine algal toxins: origins, health effects, and their increased occurrence. *Environmental health perspectives* 108. Suppl 1, 133**.** [3]Community Reference Laboratory for Marine Biotoxins (CRLMB)., Agencia Española de Seguridad Alimentaria y Nutrición (AESAN). (2009). EU Harmonised Standard Operating Procedure for determination of OA-Group Toxins by LC-MS/MS. Version 1.
Cost Information (if available):	Approximately $17.00 per test. Reader based assay – approximate cost of Reader $1995.
Action by 2013 Laboratory Method and Quality Assurance Review Committee	Recommended Proposal 13-113 be referred to an appropriate committee as determined by the Conference Chairman and await data to determine if the method is fit for purpose within the NSSP.
Action by 2013 Task Force I	Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-113.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-113.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-113.
NOTE:	Click here for Proposal 13-113 Supporting Documentation

Proposal Subject: Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination

Specific NSSP Guide Reference: NSSP Guide Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests, 4. Approved Limited Use Methods for Marine Biotoxin Testing

Text of Proposal/ Requested Action This submission presents the 'Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination' for consideration as an NSSP Approved Limited Use Method. The RBA is a competition-based assay that employs radiolabeled Saxitoxin (^{3}H-STX) to compete with PSP toxins present in standards/samples for binding sites on natural receptors in the assay. Following incubation with the receptors, unbound ^{3}H-STX is removed and the remaining labeled toxin is measured with a scintillation counter. The amount of remaining ^{3}H-STX is inversely proportional to standard/sample toxicity.

The RBA offers a high-throughput, sensitive, and quantitative alternative to the mouse bioassay (MBA), which has been the long-standing reference method for PSP toxicity. Further, the RBA eliminates the use of live animals for detection of these toxins. While the RBA still uses receptors prepared from animals, the number of animals required for analysis is significantly reduced. Using native receptors as the analytical recognition elements for the assay allows for a composite measure of overall toxicity, as opposed to toxin concentrations measured by liquid chromatographic methods that require conversion factors of equivalent toxicity to calculate the overall toxicity.

The RBA has undergone AOAC single- and multi-laboratory validation and is designated through AOAC as an Official Method of Analysis (OMA 2011.27). Results from those studies, and additional data, are included in this proposal submission for the RBA to be considered for approval as an NSSP Approved Limited Use Method for Marine Biotoxin Testing.

Public Health Significance: Paralytic shellfish poisoning intoxications result from the consumption of seafood (primarily bivalve molluscs) contaminated with neurotoxins known as paralytic shellfish toxins (PSTs). This suite of toxins binds to voltage-gated sodium channels and may result in paralysis if enough toxin is consumed. In extreme cases when respiratory support is not available to the patient, the intoxication may prove fatal. Since the toxins cannot be destroyed during cooking and there is no way to remove the toxins from seafood, the best control strategy is to ensure that contaminated product never reaches the market. To protect public health, harvesting closures are implemented when toxicity exceeds the guidance level of 80 micrograms Saxitoxin equivalents per 100 grams of shellfish tissue. As such, accurate analytical methods are needed to monitor shellfish toxicity for making decisions regarding opening and closing shellfish growing areas accordingly. Acceptance of the RBA as an NSSP Approved Limited Use Method for PSP toxicity determination would provide monitoring and management programs with an additional tool that can be used for monitoring toxin levels and making regulatory decisions. Not only does the RBA eliminate the need for live animals for PSP testing, it is also more sensitive than the MBA, thereby providing an early warning system for monitoring programs as toxin levels begin to rise.

Cost Information (if available): The estimated cost for a full 96-well plate assay is ~$95.00. Including standards and samples with triplicate measurements (as well as three dilutions per sample to ensure the unknown samples fall within linear range of assay), the cost per sample for quantitative results would be ~$13.60. If running multiple plates or in screening mode, sample costs would be reduced. Further, the filter plates used in the RBA differ from ELISA plates in that all reagents are added to each well as needed rather than already being a component of the plate, making it more

practical and cost-effective to analyze samples when there is less than a full plate.

Action by 2013 Laboratory Method and Quality Assurance Review Committee

1. Recommended approval of this method as an alternative to the mouse bioassay for PSP in mussels.
2. Recommended approval of this method for Limited Use for clams and scallops for the purpose of screening and precautionary closure for PSP.
3. Recommended referral of this proposal to an appropriate committee as determined by the Conference Chairman to address this method in oysters.
4. Recommended Executive Office send a letter to submitter to request a checklist for evaluation of labs using this method with said checklist to be submitted within three (3) months

Action by 2013 Task Force I

Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendations on Proposal 13-114.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force I on Proposal 13-114.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 13-114.

NOTE:

Click here for Proposal 13-114 Supporting Documentation

Proposal Subject:	PSP HPLC-PCOX Method Evaluation Checklist
Specific NSSP Guide Reference:	2011 NSSP Section IV. Guidance Documents Chapter II. Growing Areas .12 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers including Laboratory Evaluation Checklist-Laboratory Checklist-PSP
Text of Proposal/ Requested Action	Establish a PSP Laboratory Evaluation Checklist for the HPLC-PCOX method. Please find the HPLC-PCOX checklist attached-word document titled "PSP HPLC PCOX checklist.docx" There is no summary of changes as no previous checklist exists for this procedure
Public Health Significance:	The HPLC-PCOX method has been an approved limited use method since 2009, yet no checklist exists to allow evaluation of laboratories who utilize this method. Use of this method provides states much more detailed toxin profiles as well as helping eliminate animal testing. It is important that the checklist items and quality assurance requirements are clear and understandable.
Cost Information (if available):	For laboratories that do not already possess a HPLC post column reaction system, the upfront cost can be significant. Once in place, the costs per test are not significantly different than that imposed by the capital cost of the mouse bioassay.
Action by 2013 Laboratory Method and Quality Assurance Review Committee	Recommended Proposal 13-115 be referred to an appropriate committee as determined by the Conference Chairman.
Action by 2013 Task Force I	Recommended adoption of the Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-115.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-115.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-115.

Proposal Subject: Shellfish Quarantine Guidance Document

Specific NSSP Guide Reference: NSSP Guide Section II. Model Ordinance Chapter IV. @.04 A. (4)
Section IV. Guidance Documents Chapter II. Growing Areas
.02 Guidance for Developing Marine Biotoxin Contingency Plans

Text of Proposal/ Requested Action

Chapter IV, @.04 A (4) describes agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting during marine Biotoxin closures under specific, controlled conditions. The state of Florida has successfully implemented such an agreement to address Neurotoxic Shellfish Poisoning (NSP) for over a decade. This pilot project, developed in consultation with FDA, has resulted in zero cases of NSP in commercially harvested shellfish from Florida waters. NSP may affect any Gulf or South Atlantic state and therefore Florida wishes to provide ISSC member states with a proven quarantine protocol template for incorporation into the Model Ordinance Section IV. Guidance Documents.

Chapter II. Growing Areas .02 Guidance for Developing Marine Biotoxin Contingency Plans. Text of the proposed guidance is as follows:

Example Protocol For Quarantine Harvest of Shellfish From Aquaculture Leases During *Karenia brevis* Closures:

A. Closure of an entire shellfish growing area due to *Karenia brevis* shall be in accordance with Model Ordinance Chapter IV @.04 C (1).

B. When a shellfish growing area is closed due to *Karenia brevis*, the Authority may allow harvest of shellfish from selected aquaculture leases within a specific zone by authorized harvesters and subsequent controlled quarantine at a certified shucker packer or shellstock shipper. This option would not be available if any Authority-collected water samples in the specific zone exceeded 200,000 cells per liter of *Karenia brevis*. Zone is defined as an Authority-delineated geographic area within a Conditionally Approved or Approved classified shellfish growing area.

Controlled quarantine conditions:

The Authority will determine and plot the specific zones. Certified processors possessing a valid shellfish processing plant certification license must have written permission from the Authority to engage in this activity. To be eligible for participation in the quarantine program, the certified processor must:

(1) Provide the Authority with written and signed agreements the processor has with shellfish aquaculture leaseholders who would be supplying the shellfish and;
(2) Notate on their application letter which FDA-approved marine Biotoxin laboratory will be used to conduct the approved mouse bioassay and;
(3) Provide the Authority with the cooler capacity, physical address and current certification number of the facility to be used for controlled quarantine of shellfish. All quarantine coolers must be non-mobile, secure from unauthorized access and equipped with warning signs in a language readily understood by all employees.

Participation in each week's quarantine program is only possible for certified processors who:

(1) have written permission on file with the Authority and are on an

Authority-controlled document listing current approved quarantine program processors and;

(2) possess emailed permission granted by the Authority the day before harvest for that one specific quarantine and;

(3) propose harvesting a quantity of shellfish that meets the Authority-established minimum number but does not exceed the maximum allowed number of shellfish of one specific species for that day.

Under no circumstances may any approved processor participate in any quarantine until they possess written (emailed) documentation sent by the Authority before each specific quarantine event.

- The authorization email sent by the Authority shall explicitly state the permissible species that may be harvested by that approved processor.
- The Authority will notify the appropriate law enforcement entity in charge of patrol of shellfish growing areas with a list of participants in that specific day's harvest.
- Persons harvesting a species not authorized for that day's harvest will be subject to seizure of that harvest by the Authority. In addition, the Authority will immediately seize and destroy product which is improperly tagged, violates any National Shellfish Sanitation Program (NSSP) Model Ordinance regulations, state laws or is from non-authorized participants.
- Co-mingling of species is not allowed to make up an individual lot.

Violation of the terms of this protocol may result in the termination of the participant's future eligibility in the quarantine program, as determined by the Authority.

Prior to being considered for participation in any specific quarantine event, approved processors shall be contacted by the Authority and asked to provide the name of the species they plan to harvest and the quantity they plan on harvesting. Quantities shall be described as approximate total number by species in addition to total number of baskets, containers, bags, etc. with specific weights (if applicable) for those baskets, containers, bags, etc.

Eligible processors should be aware that daily implementation of this program is contingent on marine Biotoxin laboratory availability as well as Authority staffing considerations given staff time necessary to fulfill the requirements of the program.

Regulatory considerations on behalf of the Authority and staffing considerations on behalf of the marine Biotoxin lab necessitate an Authority-developed maximum number of samples that could be potentially tested on any given week.

The Authority may implement a lottery, random rotation or similar procedure to ensure a fair distribution of testing opportunities among the eligible processors. It is suggested that the Authority develop this procedure with industry involvement.

Once specific permission is received from the Authority, the processor:

(1) may receive properly tagged shellfish from eligible aquaculturists only as indicated in the Authority's authorization email;
(2) must upon receipt of shellfish, separate and maintain the shellfish into specific lots [A Lot is defined as shellfish of one species from no more than one day's harvest from a specific zone within a shellfish growing area];
(3) must place shellfish under proper controls and quarantine; Proper controls and quarantine are defined by bold, clear, warning signage signaling the properly tagged and segregated shellfish within the processor's cooler are under quarantine and must not be moved until Authority permission is obtained pending outcome of laboratory testing. The signage should be such that it is clear to anyone entering the cooler (including facility employees and/or regulatory inspectors) that the affected shellfish are under quarantine. Wrapping of the entire lot with a single bright red or yellow ribbon or equivalent attached to the bold warning sign will further reinforce the warning message.
(4) must allow the Authority to take 2 random samples [minimum of 20 shellfish per each sample] from each lot and deliver to the approved laboratory for approved mouse bioassay;
(5) must hold all shellfish in quarantine at the approved processor's certified facility until receiving official written test result notice from the Authority via email or fax that the shellfish are cleared for sale;
(6) must either return shellfish to aquaculture lease(s) in the zone(s) from where harvested if any sample in a lot is 20 Mouse Units / 100 grams or greater or destroy the shellfish, both activities of which must be witnessed and documented by the Authority;
(7) may release the shellfish in a lot to the market if both samples from that lot are <20 Mouse Units / 100 grams;
(8) must cease this activity if any Authority collected red tide cell counts in the specific zone exceeds 200,000 cells per liter of *Karenia brevis*;, and
(9) must document all of the requirements listed above in the approved facility HACCP plan.

C. If cell counts in all water samples fall to 5,000 cells/L or less *Karenia brevis* in the entire area, the Authority will collect shellfish meat samples for toxicity testing and the entire Shellfish Harvesting Area will be reopened if results of all samples are <20 MU/100g.

I _____ (print name) have received a copy of this quarantine protocol and I agree to abide by all terms and conditions. I understand I am bound by the terms of this agreement during the period of time that I am processing shellfish from a shellfish growing area that is currently in the closed status due to *Karenia brevis*.

_____ _____
Signed Date

Public Health Significance:

Closures of shellfish growing areas due to Neurotoxic Shellfish Poisoning (NSP) may occur at any time in the Gulf of Mexico and to a lesser degree, the Atlantic coast. Well established procedures for detecting and responding to *Karenia brevis* blooms have safeguarded public health. Clear early warning signs, a cell count action level with a high factor of safety and established sampling networks provide excellent public health protection. A very real impact of *Karenia brevis* blooms is the resulting long-term closures of shellfish growing areas and severe economic impact to commercial shellfish operations. Florida addressed this issue after studying years of water quality samples and mouse bioassay results from shellfish

growing areas. Hydrodynamic studies linked to water samples obtained from fixed stations over an extended period of time established clear patterns in distribution of *Karenia brevis*. Working in conjunction with harmful algal bloom researchers, shellfish growing area managers, FDA and industry, Florida developed a NSP quarantine protocol that has resulted in the retention of a shellfish industry in one of the most severely impacted HAB regions of the Gulf while protecting public health as required by the Model Ordinance. An enormous amount of data has been generated and reviewed during the years this protocol has been used. Repeated mouse bioassay testing on shellfish exposed to different levels of *Karenia brevis* has provided Florida with sufficient data to refine the protocol into a powerful management tool. Florida's experience pre-quarantine protocol was unfortunate, as several fledgling businesses failed due to repeated NSP closures. It was this economic damage that spurred the aforementioned collaborative effort between leading edge HAB researchers, shellfish growing area managers, FDA and industry. If adopted, shellfish producing states impacted by *Karenia brevis* could reference this protocol in the Guidance Document and use it to effectively manage NSP closures.

Cost Information (if available):

Action by 2013 Task Force I Recommended referral of Proposal 13-116 to an appropriate committee as determined by the Conference Chairman.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force I on Proposal 13-116.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-116.

Proposal Subject: Certification of State Shellfish Laboratory Evaluation Officers

Specific NSSP Guide Reference: NSSP Guide Section IV Guidance Documents
Chapter II. Growing Areas .12 Evaluation of Laboratories By State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists

Text of Proposal/ Requested Action

Laboratory results from the ~~bacteriological~~ microbiological and marine Biotoxin testing of shellfish and shellfish growing waters ~~and meats~~ are widely used in the National Shellfish Sanitation Program (NSSP) to aid in determining the safety of shellfish for human consumption. Experience with the ~~bacteriological~~ microbiological and marine Biotoxin analyses of shellfish and shellfish growing waters have indicated that minor differences in laboratory procedures or techniques might cause wide variations in the results. ~~Improper handling of the sample may also cause variations in results during collection or transportation to the laboratory~~. To ensure uniformity ~~nationwide~~ NSSP wide in the application of standards for shellfish and shellfish growing waters, a comprehensive, effective laboratory quality assurance (QA) program is necessary to ~~substantiate~~ demonstrate the validity of analytical results. ~~A~~ The laboratory ~~quality assurance~~ QA program is the systematic application of the practices essential to remove or minimize errors that may occur in any laboratory operation caused by personnel, ~~apparatus,~~ equipment, media, reagents~~, sampling procedures,~~ and analytical methodology. ~~(APHA, 1985).~~ Integral to laboratory quality assurance is a strong program for the external assessment or evaluation of laboratory performance.

The laboratory evaluation process has evolved over the years to accommodate changes in microbiology and marine Biotoxin procedures brought about by NSSP Workshops and more recently by the Interstate Shellfish Sanitation Conference (ISSC). In 1985, FDA issued an interpretation entitled "Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers" (SS#35). This Interpretation allowed NSSP laboratories which had been previously evaluated by FDA Shellfish Laboratory Evaluation Officers to be subsequently evaluated by qualified state personnel as certified State Shellfish Laboratory Evaluation Officers. This guidance describes the procedure for the certification of these individuals as State Shellfish Laboratory Evaluation Officers.

~~Requirements for evaluating laboratories that analyze samples under the NSSP have increased significantly since the 1970's. The number of laboratories participating in the shellfish program has also increased. Several states now have multiple laboratories that provide these analyses. Some states have officially designated city, county or private laboratories to conduct analyses supporting their shellfish sanitation programs. Some states are also authorizing the use of private laboratories to monitor depuration operations. More states are maintaining a marine biotoxin analytical capability in their laboratories; and more foreign laboratories are involved in the NSSP. Historically, FDA has evaluated all these laboratories. Reduction in FDA staffing has made it difficult to evaluate the many state, county, municipal, and foreign shellfish laboratories operating in support of the NSSP. If states with multiple laboratory support would exercise their option to accept responsibility for evaluating their laboratories by employing a State Shellfish Laboratory Evaluation Officer (State Shellfish LEO), FDA would be able to better meet its NSSP responsibilities.~~

General Provisions

1. If the State Shellfish Control Authority (Authority) uses the analytical services of private/commercial/fee for services laboratories to support the NSSP, then he/she should select a qualified individual to become certified as a State Shellfish Laboratory Evaluation Officer (State Shellfish LEO).

2. If the Authority uses the analytical services of multiple public laboratories (state, county, parish town, etc.) to support the NSSP, then he/she may select a qualified individual to become a State Shellfish LEO.
3. If the Authority chooses not to participate in the certification process, FDA can evaluate the state's public laboratories. FDA, however, does not normally evaluate private/commercial/fee for services laboratories. FDA may, under certain circumstances as resources permit, evaluate these laboratories on a case-by-case basis at the request of the Authority. This request must be in writing and made through the FDA Regional Shellfish Specialist.
4. State Shellfish LEOs will perform official NSSP evaluations of laboratories which have been previously evaluated by FDA and been found to fully conform to NSSP laboratory requirements.
5. State Shellfish LEOs may evaluate laboratories in a different state under a memorandum of understanding between the states involved and FDA consistent with NSSP requirements.
6. State Shellfish LEOs may not evaluate laboratories in which they are employed or which they supervise or laboratories within the same supervisory chain of command to ensure complete objectivity in the evaluation process and avoid the appearance of a conflict of interest.
7. To qualify for certification, the prospective State Shellfish LEO should be:
    a. A state employee;
    b. Have shellfish laboratory experience or a laboratory background;
    c. Preferably have laboratory evaluation experience; and,
    d. Be free from any commercial, financial or other pressures or conflicts of interest that might cause or appear to cause the prospective State Shellfish LEO to act in other than an impartial or non-discriminatory manner.
8. If the prospective or current State Shellfish LEO is employed by the laboratory supporting the NSSP, that laboratory must be fully conforming to NSSP requirements or the individual will not be certified and if currently certified, certification will be revoked.

Responsibilities of the State Shellfish Control Authority

1. The Authority must ensure that appropriate written documentation is provided to FDA to demonstrate that a prospective State Shellfish LEO is adequately qualified to assume the responsibilities of a State Shellfish LEO as described above.
2. The Authority must provide or ensure that adequate time, resources and support are made available to the State Shellfish LEO to fully participate in the certification process and to fulfill his/her obligation as a State Shellfish LEO.

FDA's Responsibilities

1. FDA is responsible for the certification/recertification of State Shellfish LEOs.
2. As a result FDA must:
    a. Select qualified individuals to receive training based upon the documentation supplied by the Authority;
    b. Develop and provide training that will enable prospective and current State Shellfish LEOs to consistently and uniformly apply evaluation criteria in determining the competence of laboratories to support or continue to support the NSSP;
    c. Certify prospective State Shellfish LEOs that successfully complete the certification process;
    d. Maintain communication with State Shellfish LEOs as needed to

provide guidance and updates relevant to the NSSP laboratory evaluation program;

e. Recertify current State Shellfish LEOs pursuant to the criteria established for satisfactory performance below;

f. Monitor the performance of State Shellfish LEOs to ensure that the evaluation process is being performed consistent with NSSP requirements as described in the current NSSP *Guide for the Control of Molluscan Shellfish* and this guidance;

g. Maintain communication as needed with the Authority and other pertinent state officials, prospective and current State Shellfish LEOs and FDA Regional Shellfish Specialists relevant to the certification/recertification process;

h. Revoke certification of State Shellfish LEOs for cause; and,

i. Void certification when the need for a State Shellfish LEO no longer exists within the state shellfish sanitation program or when the State Shellfish LEO is no longer employed by the state.

Selection of State Shellfish LEOs should be based on the following criteria:

~~1.The individual must be administratively attached to a state central shellfish sanitation laboratory that has been found by the FDA to be in full conformance with NSSP requirements. To avoid the appearance of impropriety and maintain objectivity in the evaluation process, individuals certified as State Shellfish LEOs will not be allowed to evaluate their own laboratories. FDA will maintain the responsibility for evaluating these laboratories.~~

~~2.The individual must be an experienced analyst and should have laboratory supervision experience. To maintain the integrity of the evaluation process, this individual should not, however, have overall supervisory responsibilities for the laboratory or laboratories to be evaluated. If deemed necessary by an FDA Laboratory Evaluation Officer, the individual must conduct several laboratory evaluations jointly with the FDA Laboratory Evaluation Officer.~~

~~3.During the joint on-site laboratory evaluation with an FDA Laboratory Evaluation Officer, the individual must demonstrate competence in evaluating the laboratory's capability to support the NSSP. The evaluation will be performed and documented using the most current version of the applicable FDA Shellfish Laboratory Evaluation Checklist.~~

~~4. The individual must submit a written narrative report of the joint on-site evaluation to the FDA co-evaluator for review and comment. The report should consist of the completed FDA Shellfish Laboratory Evaluation Checklist and a narrative discussion that accurately and concisely describes the overall operation of the laboratory. All nonconformities noted should be described in this evaluation write-up; and, where relevant an explanation provided relating the potential impact of the deficiency on the analytical results. Recommendations for corrective action or, if applicable, suggestions to enhance laboratory operations must be included in this write-up.~~

~~The FDA will issue a letter certifying each individual who successfully completes the certification process and will clear the evaluation report(s) for distribution to the laboratories evaluated with copies to the appropriate Shellfish Specialist.~~

Certification is normally effective for a period of three (3) years. Once certified, the individual is then expected to assume the following responsibilities:

State Shellfish Laboratory Evaluation Officer's Responsibilities

1. Conduct onsite laboratory evaluations at least every three (3) years. However, more frequent evaluations are strongly encouraged and may be ~~required~~ necessary with marginally performing laboratories, or when major changes in workloads or priorities have occurred or when there

has been a substantial turnover of personnel, or, at the specific request of the Authority. ~~State Shellfish Control Authorities:~~

2. Provide appropriate post-evaluation follow-up for each laboratory evaluated;
3. Prepare timely narrative evaluation reports for all laboratories evaluated. The report should consist of the completed FDA Shellfish Laboratory Evaluation Checklist for the component(s) evaluated and a narrative discussion that accurately and concisely describes the overall operation of the laboratory. All nonconformities noted should be described in this narrative; and, where relevant, an explanation provided relating the potential impact of the deficiency on the analytical results. Recommendations for corrective action or, if applicable, suggestions to enhance laboratory operations should also be included in the narrative report. ~~Incorporating the requirements specified in 4 above;~~
4. Distribute completed evaluation reports with checklists to FDA and to the appropriate FDA Regional Shellfish Specialist.~~:~~
5. Inform ~~the appropriate~~ FDA Shellfish Laboratory Evaluation Officers when a laboratory has been found to be in nonconforming status.~~;~~
6. Coordinate proficiency testing at least yearly for all laboratories in the state supporting the microbiology component of the NSSP.
7. Prepare ~~at least~~ annually (in December) a summary list of ~~qualified analysts for each~~ all laboratories and qualified analysts within each laboratory by NSSP laboratory component supported ~~laboratory supporting the NSSP in the state~~ and transmit it to the ~~appropriate~~ FDA Shellfish Laboratory Evaluation Officers.

Certification Process

Certification is designed to be accomplished through individualized training and field standardization. Individuals are certified for evaluating either the microbiological and/or post-harvest processing (PHP) and/or marine Biotoxin components of the NSSP depending on their qualifications and the needs of the state shellfish sanitation program and at the discretion of FDA.

Field Standardization

1. Field standardization is designed to evaluate the prospective State Shellfish LEO's ability to determine the competence of the laboratory to meet NSSP laboratory requirements; recognize laboratory practices inconsistent with NSSP requirements when they occur; make appropriate recommendations for corrective action; and, provide the necessary follow-up activity to bring the laboratory into conformity with the NSSP.
2. Field standardization consists of one or several joint but independent onsite evaluations with an FDA Shellfish Laboratory Evaluation Officer and preparation of the corresponding narrative evaluation reports. The report(s) should consist of the completed FDA Shellfish Laboratory Evaluation Checklist(s) and a narrative discussion that accurately and concisely describes the overall operation of the laboratory. All nonconformities noted should be described in the narrative; and where relevant an explanation provided relating the potential impact of the deficiency on the analytical results. Recommendations for corrective action or, if applicable, suggestions to enhance laboratory operations should be included in this narrative report(s).
3. Field standardization should be performed in NSSP laboratories within the prospective State Shellfish LEO's home state to provide realistic evaluation scenarios. The narrative evaluation report detailing the evaluation findings must be prepared. The draft narrative report(s) with accompanying checklist(s) must be submitted to the certifying FDA

Shellfish Laboratory Evaluation Officer within 60 days of the evaluation(s). All documents submitted will be reviewed for appropriate content, accuracy and uniformity of approach by the certifying FDA Shellfish Laboratory Evaluation Officer.

4. Field standardization is based on a pass fail system.

Certification

1. Certification is dependent upon the perspective State Shellfish LEO satisfying all the following performance criteria.
   a. Demonstration of good familiarity with evaluation requirements.
   b. Demonstration of a thorough knowledge of the evaluation methods and documents.
   c. Demonstration of the technical knowledge/familiarity with the analytical procedures being used.
   d. Ability to communicate effectively both orally and in writing.
   e. Successful completion of both training and field standardization.
2. Upon successful completion of the certification process, a letter of certification will be issued by the FDA Shellfish Laboratory Evaluation Officer and a copy will be sent to both the requesting Authority and the FDA Regional Shellfish Specialist.
3. Certification is normally valid for up to five (5) years unless revoked or voided.

Failure to be Certified

1. If a prospective State Shellfish LEO fails to satisfy any of the performance criteria listed above, he/she will not be certified.
2. As resources permit and at the discretion of FDA, the prospective State Shellfish LEO may receive additional training to better prepare him/her to be certified.
3. The requesting Authority may withdraw the prospective State Shellfish LEO from consideration.

Recertification

1. Recertification normally occurs every five (5) years and is contingent upon the continuing need in the state shellfish sanitation program for **the** services of a State Shellfish LEO.
2. Recertification is based on the State Shellfish LEO satisfactorily meeting the following employment and performance criteria.
   a. The individual must continue to be employed by the state and be free of any commercial, financial or other pressures or conflicts of interest real or perceived that may cause the State Shellfish LEO to act in other than an impartial and non-discriminatory manner.
   b. The individual must demonstrate continued competence in the evaluation of NSSP laboratories by performing one to several joint evaluations with an FDA Shellfish Laboratory Evaluation Officer and providing an appropriate narrative evaluation report to the FDA co-evaluator for review and comment for each of the laboratories jointly evaluated.
   c. The individual must have performed laboratory evaluations at the minimum frequency prescribed in the current edition of the *Guide for the Control of Molluscan Shellfish* and have all Narrative evaluation reports up to date.
3. State Shellfish LEOs who successfully complete recertification will

be issued a letter of recertification by FDA and be cleared to distribute the completed report(s) to the appropriate Regional Shellfish Specialist. A copy of this letter will be sent to the State Shellfish Control Authority and appropriate Regional Shellfish Specialist.

4. If FDA is unable to conduct a recertification visit by the expiration of the individual's certification, his/her certification may be extended until such time as recertification can be completed. If requested, a letter extending the certification can be provided as appropriate.

Revocation of Certification

1. State Shellfish LEO's who fail to meet any of the certification/recertification, employment or performance criteria listed above will have their certification revoked.
2. Certification may be voided when state shellfish sanitation programs no longer have a need for the services of a State Shellfish LEO.
3. Voided certifications may be reactivated at the discretion of FDA if the need for the analytical services of additional laboratories by the state shellfish sanitation program recurs.
4. Revoked certifications will not normally be restored.

~~Recertification of State Shellfish LEOs will normally occur triennially and will be based on satisfactorily meeting the following criteria:~~

~~1. The individual must continue to be administratively attached to a central state shellfish laboratory which is in full conformance with NSSP requirements;~~

~~2. The individual is not the supervisor of any of the laboratories to be evaluated;~~

~~3. The individual must demonstrate continued competence in evaluating the capability of laboratories to support the NSSP. If considered necessary, the individual will be required to performance to several joint evaluations with FDA Laboratory Evaluation Officer.~~

~~4. The individual must submit a written narrative report of the joint evaluation(s) to the FDA co-evaluator for review and comment. The report should consist of the completed FDA Shellfish Laboratory Evaluation Checklist and the narrative portion should be prepared as above;~~

~~5. The individual must have all state laboratory evaluations, split sample(proficiency) test examinations, and reports current;~~

~~6. The individual should receive training as necessary, in laboratory evaluations and analytical procedures to remain proficient.~~

~~State Shellfish LEOs who successfully complete this process will be issued a Letter of recertification by FDA and be cleared to distribute the evaluation reports to the laboratories evaluated with a copy to the appropriate Regional Shellfish Specialist. Normally recertification is effective for a period of three (3) years. Individuals who fail to meet the requirements for recertification will lose their certification until it is demonstrated that all requirements including adequate training are met.~~

Public Health Significance: This guidance document is virtually unchanged since the inception of the program for utilizing State Shellfish Laboratory Evaluation Officers (State Shellfish LEOS) in the NSSP. This revised guidance updates and clarifies the process for selection, certification and recertification of State Shellfish LEOs.

Cost Information NA

(if available):

Action by 2013 Task Force I	Recommended referral of Proposal 13-117 to an appropriate committee as determined by the Conference Chairman.
Action by 2013 General Assembly	Adopted recommendation of Task Force I on Proposal 13-117.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-117.

Proposal Subject: Dilution Guidance for Prohibited Zones Associated with Wastewater Discharges

Specific NSSP Guide Reference: NSSP Guide Section IV. Guidance Documents
Chapter II. Growing Areas

Text of Proposal/ Requested Action US Food and Drug Administration requested that Task Force I consider the substitute language.

16 Determining Appropriately Sized Prohibited Areas Associated with Wastewater Treatment Plants

Introduction

Molluscan shellfish are filter feeders and therefore have the ability to concentrate microorganisms from the water column, including human pathogens and toxigenic micro-algae if these organisms are present. Concentrations of microorganisms in the shellfish may be as much as 100 times greater than those found in the water, and if the microorganisms are harmful to humans, illness can result. The correlation between sewage pollution of shellfish waters and illness has been demonstrated many times. Certain shellfish-borne infectious diseases are transmitted via the fecal-oral route, with the cycle beginning with the fecal contamination of the shellfish growing waters.

In the winter of 1924-25, an oyster-borne typhoid outbreak occurred in the United States which caused a large number of illnesses and deaths (Lumsden, et al 1925). In response to this outbreak the National Shellfish Sanitation Program (NSSP) was initiated by the States, the U.S. Public Health Service, and the shellfish industry. Research at the time indicated that typhoid fever would not ordinarily be attributed to shellfish harvested from water in which not more than 50% percent of the one cc (ml) portions of water examined were positive for fecal coliform bacteria (an MPN of approximately 70 per 100 ml), provided that the areas were not subject to direct contamination with small amounts of fresh sewage which would not likely be revealed by routine bacteriological examination. As a result water quality criteria were established, namely;

(1) The area be sufficiently removed from major sources of pollution so that the shellfish are not subjected to fecal contamination in quantities which might be dangerous to public health;

(2) The area be free from pollution by even small quantities of fresh sewage;

(3) Bacteriological examination does not ordinarily show the presence of the coli- aerogenes group of bacteria in one cc dilution of the growing area water.

Once these standards were adopted in the United States in 1925, reliance on these criteria for evaluating the safety of shellfish harvesting areas has generally proven effective in preventing major outbreaks of disease transmitted by the fecal-oral route. Today, fecal and total coliforms are used as an index of the sanitary quality of a growing area and to foretell the possible presence of fecal transmitted bacterial pathogens. The goal of the NSSP remains the same – to ensure the safety of shellfish for human consumption by preventing harvest from contaminated growing areas.

However, there is now ample scientific evidence to show that the current bacterial indicators are inadequate to predict the risk of viral illness for the following reasons:

(1) Enteric viruses are resistant to treatment and disinfection processes in a wastewater treatment plant (WWTP) and are frequently detected in the WWTP's final effluent under normal operating conditions (Baggi et al. 2001; Burkhardt et al. 2005).

(2) Shellfish can bioaccumulate enteric viruses up to 100-fold from surrounding water (Seraichekas et al. 1968; Maalouf et al. 2011).

(3) Certain enteric viruses are retained by molluscan shellfish to a greater extent and for longer than the indicator bacteria currently used to classify shellfish growing areas (Sobsey et al. 1987; Dore & Lees 1995; Love et al. 2010). It has been well documented that enteric virus detection is not indexed by levels of conventional indicator bacteria.

For several decades now viral illnesses (in particular norovirus (NoV) and Hepatitis A (HAV)) have been the most common food safety problem associated with bivalve molluscan shellfish (Woods & Burkhardt. 2010; Iwamoto et al 2010; Scallan et al. 2011; Batz et al. 2012). NoV genogroups I, II and IV and HAV are human specific and transferred by the fecal-oral route. Because WWTPs do not completely remove infectious enteric viruses emphasis should be placed on the importance of ensuring there is adequate dilution between a sewage source and a shellfish growing area.
The purpose of this guidance is to provide the scientific basis and recommendations for determining appropriately sized Prohibited Areas (closure zones) based on the minimum criteria established under Section II, Chapter IV. @.03 E(5) of the Model Ordinance (Section E Prohibited Classification).

Classification Requirements for Growing Areas Associated with Waste Water Treatment Plants

The NSSP Model Ordinance (MO) requires that a comprehensive sanitary survey be undertaken prior to the classification of the growing area as Approved, Conditionally Approved, Restricted, or Conditionally Restricted.

The sanitary survey must take careful recognition of any WWTPs as they represent one of the major sources of human sewage pollution. It is preferable that the shellfish growing areas be sited so far away from sewage discharges that the WWTP effluent has no hazardous effect, because there is a direct relationship between the level of WWTP effluent dilution and the level of enteric viruses detected in the shellfish (Goblick et al. 2011).

Delineation of the Prohibited Zone around a Wastewater Treatment Plant

The NSSP MO Section II, Chapter IV. @.03 (2) (b) states that all growing areas which have a sewage treatment plant outfall or other point source outfall of public health significance within or adjacent to the shellfish growing area shall have a prohibited classification established adjacent to the outfall taking account of the following factors:

(1) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the bacteriological or viral quality of the effluent;

(2) The decay rate of the contaminants of public health significance in the wastewater discharged;

(3) The wastewater's dispersion and dilution and the time of waste transport to the area where shellstock may be harvested; and

(4) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

There are several important considerations for the shellfish authority to consider when establishing the size of the prohibited zone:

(1) The distance to ensure that there is adequate dilution when the WWTP is operating as normal. "Normal" means that the WWTP is operating fully within the plant's design specifications, including design flows, treatment stages, disinfection, as well as compliance with all permit conditions.

If the plant is operating outside of the normal parameters it shall be considered to be malfunctioning.

(2) That the collection system has no malfunctions, bypasses or other factors that would lead to significant sewage leakages to the marine environment.

(3) That there is adequate time when any malfunction occurs to ensure that all harvesting ceases and closures are enforced, so that contaminated product does not reach the market.

The following guidelines shall be used when assessing these factors in the dilution analysis for the closure zone:

Volume flow rate: For a minimally sized prohibited zone for Conditionally Approved areas managed in part based on the performance of the WWTP, the maximum monthly average flow at the WWTP recorded in the Monthly Operating Reports (MORs) maintained by the WWTP permitting authority should be used considering at a minimum the most recent two years of flow records. If the maximum monthly average flow at the WWTP from two consecutive years of flow records is within 85 – 100% of the design flow, then the design flow should be used. Thus, these flow values are appropriate when establishing a minimally sized prohibited zone when the WWTP is considered to be operating under normal operating conditions.

Additional information and historical data may be accessed on the U.S. Environmental Protection Agency (EPA) website at:

http://cfpub.epa.gov/dmr/index.cfm. Consistent with the EPA regulations in 40 CFR 122.2, the maximum monthly average flow, which is typically reported in the MOR, is defined as the average ''daily discharges'' over a calendar month, calculated as the sum of all '' daily discharges '' measured during a calendar month divided by the number of ''daily discharges'' measured during that month typically expressed in units of million gallons per day (MGD). Thus, the maximum monthly average flow is defined as the highest average monthly flow (MGD) within at a minimum the most recent consecutive two years of flow records. The design flow is defined as the flow (MGD) that the WWTP is designed to discharge and can be expressed as a daily, monthly, or annual discharge. In the design of WWTPs, various flow regimes are considered such as the average flow, maximum flow and peak (instantaneous) flow. However, it is important to note that certain tolerances are allowed under EPA NPDES program and WWTPs are not necessarily expected to meet permit conditions over all flow regimes. Thus, if permit limits are expressed as a monthly average it is considered acceptable for the permitted pollutants to exceed the permit on a short term basis as long as the permit condition (monthly average) is met. It is also important to note that EPA does

not have any permit limitations established for the discharge of viruses.

In the context of public health, some of these flow regimes such as when average hourly flows exceed the design flow can be associated with periods of effluent degradation leading to an increase in the viral load in the effluent. Utilizing average hourly flows and comparing against the design flow ensures that the periods when effluent degradation are most likely to occur are adequately identified and assessed. Average hourly flow rates within the most recent two years of records should be evaluated to assess the likelihood that the average hourly flows can exceed the design flow. In the absence of supporting data, the conditional area should be closed when the average hourly flow rates exceed the WWTP design flow due to the potential degradation of the virological quality of treatment. FDA studies have determined that when WWTP average hourly flow rates exceed design flow the virological quality of effluent typically degrades beyond what is considered as normal treatment. Moreover, FDA bioaccumulation studies indicate that shellfish can accumulate significant levels of viral pathogens when exposed in durations of less than one hour. However, a flow level threshold above the design flow could be determined on a case by case basis provided the virological quality of the effluent is assessed. The average hourly flow is defined as the average flow measured over an hour. More detailed flow records are typically maintained and can be accessed through the permitted WWTP.

When conditional management based on WWTP performance is not employed the prohibited zone shall be sufficient in size to dilute the microbial loadings resulting from a WWTP malfunction (such as a sewage bypass or a loss of disinfection) to ensure the Approved area adjacent to the prohibited zone will meet the bacteriological standards for Approved area classification under all conditions including a WWTP malfunction. If the WWTP has no prior history of sewage bypasses then at a minimum a loss of disinfection malfunction shall be considered when sizing the prohibited zone. As many WWTP malfunctions occur from hydraulic overloading as a result of rainfall, snowmelt, storm events or periods of high flow, a maximum average hourly rate shall be considered when determining the size of the prohibited zone. The maximum average hourly flow is defined as the highest average hourly flow recorded within at a minimum) the most recent two consecutive years of flow records.

Location of discharge: The location of the discharge must be determined in order to define the distance from the point of effluent discharge to shellfish growing areas that could be impacted. The distance from shore and the depth of the WWTP outfall also can be used in the dilution analysis of the discharge. The location of discharge includes the location, number, size and orientation of the discharge port(s) on the outfall or its diffuser.

When determining if a WWTP within the watershed or catchment area draining to a shellfish estuary potentially impacts a shellfish growing area, in the absence of a database collected, the NSSP recommends that a worst case raw sewage discharge be assumed. In this circumstance a level of 1.4×10^6 FC/100ml assumed for a raw sewage release-requires a 100,000:1 dilution to dilute the sewage sufficient to meet the approved area standard of 14 FC/100ml. If dilution analysis determines that the location of the discharge is such that the dilution of effluent would be greater than 100,000:1 then the WWTP could be considered located outside the zone of influence to the shellfish growing area. A lower dilution level could be justified provided that specific data to that particular WWTP demonstrates that a lower bacteriological level associated with a potential raw sewage discharge is supported. Additional or other site specific information also can be used to justify alternative approaches that may take into account other

factors (such as no prior history of raw sewage discharges or containment structures sufficiently sized to accommodate a raw sewage event preventing a discharge).

It should also be noted that if shellfish harvesting occurs within the zone of influence from a WWTP then these areas are subject to a WWTP Management Plan as defined in Section II Chapter IV @. 03 C.(2)(a) of the MO. Additionally, if a departure of the normal WWTP function could potentially impact a shellfish growing area then the areas affected should be managed under a conditional management plan as defined in Section II Chapter IV @. 03 C.(2)(a) of the MO.

The minimum size of a prohibited zone for a conditional area under a WWTP management plan should be determined considering both the minimum dilution (1000:1) needed to mitigate the presence of viruses in treated effluent (or a scientifically based alternative approach) as well as the prerequisite notification time to close the conditional area during a WWTP malfunction or period of degraded effluent quality, prior to the conditional area receiving the impact from the WWTP effluent.

Performance of the WWTP: When considering the present and past performance of the WWTP, this review should include information regarding the wastewater collection system, inspection of essential plant components (including any monitoring and alarm systems), events whereby the plant exceeds its design capacity and an evaluation of the disinfection system. The plants past performance should also include a file review of the plant 's Discharge Monitoring Reports, considering at a minimum, the most recent two years of permit records.
When there is evidence that the WWTP exceeds design capacity, consideration should then be given to the frequency of such events and the effect this will have on the plant's ability to reduce the viral load of the effluent .

Consideration should also be given to the frequency of which the WWTP bypasses any stage of treatment or any condition that may degrade the quality of the effluent to determine the potential frequency a conditional growing area may need to close over the course of a year. This assessment will determine the feasibility of operating a conditionally managed area based on WWTP performance.

Bacteriological or viral quality of the effluent: Discharge Monitoring Reports for WWTPs should be examined and periodically monitored to assess the reliability of the disinfection systems. Any samples collected to assess the reliability of the disinfection system should be collected during the period(s) of the year that the State Shellfish Control Authority (SSCA) deems most likely to experience adverse conditions in the treatment or disinfection processes that could affect effluent quality impacting receiving waters.

Results from any bacteriological or viral sampling and analyses must be correlated with WWTP operation and evaluated in terms of the minimum treatment expected when there is a malfunction, overloading or other poor operational condition. However, it is essential to recognize that water samples collected near discharge outfalls are not useful for determining the size of prohibited zones because normal operating conditions in WWTPs can effectively reduce or even eliminate the fecal and total coliforms - the current indicator microorganisms used to assess treatment efficiency. In contrast, many human enteric viruses are not inactivated by functional WWTP systems, hence the need for an adequate dilution zone between the outfall and the shellfish resource.

Decay rate of contaminants: It should be assumed that there is no fecal coliform or viral inactivation in the effluent during possible upset conditions in the WWTP. There are a number of conditions that affect bacterial and viral inactivation, including temperature, exposure to sunlight and sedimentation levels in the water (Burkhardt et al, 2000; Lees, 2002; LaBelle, 1980; Griffen, 2003). Scientists are unsure how long viruses remain viable in the marine environment, but it is likely to be weeks or months (Younger, 2002), and enteroviruses have been found in marine sediments suggesting that these sediments can be a source upon resuspension (Lewis, 1986). Moreover, molluscan shellfish have been found to retain viruses to a greater extent and for much longer periods than they do bacteria (Sobsey et al, 1987; Richards, 1988; Dore and Lees, 1995; Dore et al, 2000; Shieh et al, 2000).

Waste water dispersion and dilution: Dispersion of the effluent refers to the spread, location, and shape of the discharge plume with time as it leaves the WWTP outfall. Dilution of the effluent refers to the amount of receiving water that is entrained within a particular time or distance from the outfall, e.g. the dilution of the effluent within the time or distance it takes to reach the border of the prohibited zone. A dye study can be used to measure the dilution and dispersion of the effluent during specific discharge conditions. Computer modeling programs can also be used to estimate the dispersion and dilution of the effluent plume from WWTPs.

In poorly flushed estuaries and coastal embayments there is the potential for WWTP effluent build-up that further reduces the availability of "clean" waters to both dilute contaminant loadings and purge shellfish of contaminants (Goblick et al., 2011).

Time of waste transport to the shellfish harvest site: When there is a WWTP malfunction it is important that adequate systems are in place to officially close the harvest area before the effluent impacts the shellfish. This is a mandatory requirement for conditional management of shellfish harvest areas and all parties must agree in writing on the process steps necessary to close the harvest area after such events. Both time of travel and dilution should be considered when sizing a prohibited zone around a WWTP outfall adjacent to a conditional growing area. The overall sizing of the prohibitive zone should satisfy both a minimum dilution of 1000:1 and also factor in adequate time to respond to a malfunction event. When establishing the time of travel between the WWTP and the classified area, consideration should be given to the worst scenarios which would cause the fastest travel. For example, the peak current flows at or near the outfall during ebb tide and flood tide to determine effluent transport speeds. Current velocity information may need to be generated if such information is not available or adequate for the area of the outfall. Current velocity information can be obtained from hydrographic dye studies, drogue studies, or current meter data conducted in the vicinity of the outfall.

Location of shellfish resources: The best information that is available should be used for locating shellfish resources near the outfall. Subtidal shellfish resources may also be identified in sanitary surveys near WWTP outfalls. Therefore the SSCA must establish closure zones at WWTP outfalls in accordance with the classification requirements of the Model Ordinance.

Classification of Adjacent Waters: If the SSCA's dilution analysis determines that the shellfish water quality standards for approved waters are met at the boundary of the prohibited area during potential upset conditions, the shellfish area adjacent to the prohibited area need not be classified as Conditionally Approved and may be classified as Approved.

Scientific Rationale for 1000:1 Dilution Guidance

Since 1987 FDA has recommended at training courses and other venues the use of a 1000:1 dilution as the minimum level of dilution needed around a WWTP outfall to mitigate the impact of viruses for shellfish harvest areas managed conditionally based on the performance of the WWTP. It has been advised that conditional management based on WWTP performance may not be appropriate for all WWTP' s that are e located within proximity to shellfish harvest areas and recommended only for large, highly efficient WWTPs that are well monitored.. In 1995 this estimated level of necessary dilution was further calculated and explained by FDA using assumptions based on the most relevant scientific literature available at that time (Kohn, et al. 1995; Havelaar et al. 1993; Kapikian et al. 1990; Liu et al. 1966). Since then major advances in the detection and enumeration of NoV in wastewater and shellfish have been made, and advances in fluorometer technologies have enabled more sophisticated hydrographic dye study methods. Using these advances, FDA has conducted dye studies supplemented with the testing of shellfish sentinels for enteric viruses and their surrogates. This has afforded FDA for the first time with a means to directly determine the viral risk posed by WWTP effluent on shellfish resources. During recent years FDA has presented the findings from these studies at regional shellfish meetings, at the biennial ISSC meeting, at international scientific conferences and to international partners engaged in collaborative projects. Results from these studies are referred to herein as part of the scientific basis for the current recommended guidance.

In 2008 FDA performed an investigation in the upper portion of Mobile Bay, Alabama, the results of which were published in the Journal of Shellfish Research (Goblick, et al., 2011). The article describes how FDA used the aforementioned technical advances to prospectively assess the 1995 1000:1 dilution estimate recommendation and determine if this level of dilution is appropriate to mitigate the risk of viruses discharged in treated wastewater effluent. From 2008 through 2012 FDA conducted four additional studies (Hampton Roads, Virginia; Yarmouth, Maine; Coos Bay, Oregon; Blaine, Washington). In each of these studies, FDA evaluated male-specific coliphage (MSC) and NoV levels in shellfish together with the dilutions of WWTP effluent. The studies were designed to build a more comprehensive and in- depth understanding of viral impacts posed by WWTPs on shellfish resources.

To date, findings from these studies demonstrate that achieving a steady-state 1000:1 dilution level in the requisite Prohibited area appears to be adequate for mitigating the impacts of viruses on shellfish when WWTPs have typical treatment and disinfection practices, such as secondary treatment and the use of chlorine, and when they are operating under normal conditions. Results further indicate that in certain instances, such as when WWTPs begin to exceed their design capacity, bypass treatment, or otherwise malfunction, the 1000:1 dilution level may be inadequate and emergency closure procedures should be considered within the conditional area management plan. Under such circumstances, conditional area management plans should ensure there is sufficient time for notification to the State Shellfish Control Authority (SSCA) and for subsequent notifications closing the conditional area to harvesting.

MSC results in shellfish from the 2008-2012 studies were evaluated using 50 PFU/100 g as the threshold level of concern for MSC, since this is the level under the Model Ordinance (Section II, Chapter IV, @.03 A(5)(c)(ii)) used for re-opening harvest areas after an emergency closure due to raw untreated sewage discharged from a large community sewage collection system or a WWTP. For conventional WWTPs operating under normal conditions, there were at least four occasions when dilution levels were between 700:1 and 1000:1 and MSC levels in

shellfish exceeded 50 PFU/100g, but there were no occasions in which MSC levels exceeded 50 PFU/100g and dilution was greater than 1000:1. For conventional WWTPs operating under malfunction conditions, such as when flow rates exceeded the design capacity or during a treatment stage bypass, MSC levels in shellfish exceeded 50 PFU/100g in at least 13 instances in which dilution was greater than 1000:1.

When evaluating the NoV results of the 2008 – 2012 studies FDA used a value of 300 RT-PCR units of NoV/100 gram of digestive gland (digestive diverticula) as the threshold. This value was considered significant since at this level shellfish related illnesses have been reported and demonstrated by the analysis of meal remnants.

In examining the results from all the studies, there were no cases in which conventional WWTPs operating under normal conditions produced results greater than 300 NoV particles/100 g of DD in oyster sentinels when dilution levels at the associated sentinel stations were greater than 1000:1. When dilution levels were less than 1000:1, levels of NoV GII greater than 300 NoV particles/100 g of DD were detected, and on one occasion around 8000 NoV particles/100g DD were found.

On three occasions during which WWTPs were operating under malfunction conditions (as previously described), thirteen (13) oyster samples were found with NoV GII levels greater than 300 NoV particles/100 g DD when dilution was close to or greater than 1000:1. These results emphasize the critical need for sufficient notification time, meaning travel time from the WWTP discharge in Prohibited Area is long enough to close the shellfish growing area in the event of a malfunction. This preventative measure may necessitate the Prohibited Area be larger than the zone necessary to achieve 1000:1 dilution.

In one instance, an unconventional WWTP that used membrane filtration technology rather than conventional treatment with chlorine or UV disinfection was assessed. The levels of NoV GII in shellfish sentinels near this WWTP were greater than 300 NoV particles/100 g of DD, even when dilution levels were greater than 1000:1, and on two occasions when dilution levels exceeded 10,000:1. In seven (7) instances, NoV levels at the plant were greater than 300 NoV particles/100g of DD. MSC levels were similarly high, with all six (6) samples tested having MSC levels greater than 800 PFU/100g, and in one sample greater than 10,000 PFU/100g, even though dilution levels were higher than 1000:1. This analysis demonstrates the need to assess WWTPs with unique treatment systems on a case by case basis, since some may perform better than conventional WWTPs at removing viruses and some may perform significantly worse.

The overall results of FDA's studies demonstrate a strong relationship between increased levels of enteric viruses and MSC and decreased levels of dilution. This trend was observed in all of the studies conducted by FDA at conventional WWTPs. The FDA studies also suggested that certain factors, such as the quality of sewage treatment or the time of year, may exert influences on the levels of viruses discharged and hence the minimum level of dilution needed to ensure shellfish safety. However, at this time FDA does not have reliable data to justify a recommended minimum dilution less than 1000:1 or to establish any variable dilution thresholds corresponding to and dependent on such factors. It is recognized that these criteria could be determined by a State Shellfish Control Authority (SSCA) on a case by case basis, where factors of WWTP performance, disinfection method, tidal flushing, and seasonal impacts may vary. These and other factors that might influence virus levels in the shellfish can be considered by SSCAs when assessing how best to manage conditional growing areas based

on WWTP performance. Using dilution levels lower than 1000:1 or other alternative approaches for managing the viral risk posed by WWTP effluents are cited in Alternate Options section (see below). However, when there is insufficient information available for a growing area to support the use of a lower level of dilution, the 1000:1 dilution should be employed.

Alternate Options

It is expected that the principles of this guidance shall be followed to ensure compliance with the dilution requirements of the Model Ordinance. An alternative minimum waste water dilution threshold value may be appropriate for situations in which highly effective WWTP facilities reduce the viral load of the effluent, or seasonal or geographical factors reduce the risk of viral contamination at the shellfish growing area. Alternative options for calculating the size of the prohibited zone to mitigate the virological effects of WWTP discharges at the shellfish growing area may be used provided that they are based on sound scientific principles that can be verified. For example, it is reasonable to expect a potentially higher reduction in viral load from a properly maintained wastewater treatment system employing ultraviolet (UV) disinfection with tertiary treatment operating under optimum design flow conditions. Regardless of the technology employed any proposed alternative minimum threshold would need validation. MSC could potentially be used on a case- by-case basis as the validation process (for example to validate treatment efficiency) if demonstrated it is a successful/feasible strategy for the given location/situation

It should be noted that any alternate approach would need to consider the time of waste transport to the shellfish harvest site. As described in this guidance in geographic regions with large tidal amplitudes and/or swift tidal currents, the time of waste transport to the shellfish harvest site may be the determining factor in sizing the prohibited zone. However, there may be various strategies that could be employed to address the time of waste transport to the shellfish harvest site. For example, it may be reasonable to expect that if a facility utilized a sufficiently sized containment structure (such as the equivalent to 24-hour holding for the design capacity of the plant) in the event of a malfunction, this would allow the SSCA additional time to react to the event and take any necessary precautions. Regardless of technology or best management practices employed any proposed alternative strategy would need to be validated (i.e. verifying that a containment structure is properly sized and working effectively).

There are likely other alternatives in addressing the potential impact of wastewater on shellfish growing areas and approaches in validating these options. However, the flexibility remains with the SSCA's to determine the appropriate alternate option and validation process that can be verified.

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Public Health Significance:

The public health purpose of this guidance is to provide the scientific basis and recommendations for determining appropriately sized Prohibited Areas (closure zones) around waste water treatment plants (WWTP). Section II, Chapter IV @ .03 (5) currently mandates that a prohibited zone be established, but there is no specific guidance information on how to calculate the size of the prohibited zone to ensure that microbiological pathogens (particularly viruses) from WWTP do not adversely impact the growing area at the time of harvest. It is expected that this guidance will provide all ISSC stakeholders with better information on which to make informed, scientifically based decisions

Cost Information (if available):

Action by 2013 Task Force I

Recommended referral of Proposal 13-118 to an appropriate committee as determined by the Conference Chairman with additional instructions to the ISSC

Executive Office to create a workgroup to meet quarterly and report back to the Conference at the next ISSC meeting.

Action by 2013 General Assembly Adopted recommendation of Task Force I on Proposal 13-118.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-118.

Proposal Subject: Revisions to Chapter III. Requirements for the Authority

Specific NSSP Guide Reference: 2011 NSSP Guide Section II. Model Ordinance
Chapter III. Laboratory

Text of Proposal/ Requested Action

@.02 Methods

A. Microbiological. Methods for the analyses of shellfish and shellfish growing or harvest waters shall be:

(1) 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 Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests.

(2) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used:

(a) A validated AOAC, BAM, or EPA method;

(b) An Emergency Use Method pursuant to .02 D. (1) and (2) below.

B. Chemical and Physical. Methods for the analyses of shellfish and shellfish harvest waters shall be:

(1) 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 cited in the Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. ~~Methods for the analysis of shellfish and shellfish growing or harvest waters shall:~~

~~(a) Be the current AOAC or APHA method for all physical and chemical measurements; and~~

~~(b) Express results of all chemical and physical measurements in standard units, and not instrument readings.~~

(2) Results shall be expressed for chemical and physical measurements in standard units and not instrument readings.

(3) When there is an immediate or ongoing critical need for a Method and no Approved NSSP Method exists, the following may be used:

(a) A validated AOAC, BAM, or EPA method;

(b) An Emergency Use Method pursuant to .02 D. (1) and (2) below.

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:

(1) 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 cited in the Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. ~~The current AOAC and APHA methods used in the bioassay for paralytic shellfish poisoning toxins; and~~

~~(2) The current APHA method used in the bioassay for *Karenia brevis* toxins; or~~

~~(3) Approved NSSP Methods validated for use under Procedure XVI. of the Constitution, Bylaws and Procedures of the ISSC and/or cited in the Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests.~~

~~(~~2~~4)~~ When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used:

(a) A validated AOAC, BAM, or EPA method;

(b) An Emergency Use Method pursuant to .02 D. (1) and (2) below.

D. Emergency Use Methods.
(1) When there is an immediate or critical need and no Approved NSSP Method exists, an unapproved or non-validated method may be used for a specific purpose provided that:
(a) The appropriate FDA Regional Office is notified within a reasonable period of time regarding the method employed; and
(b) The ISSC Executive Board is notified within a reasonable period of time regarding the method employed.
(2) When it is necessary to continue the use of the emergency method employed under D. (1) beyond the initial critical need, then the following minimum criteria shall be provided to the ISSC Executive Board for interim approval:
(a) Name of Method.
(b) Date of Submission.
(c) Specific purpose or intent of the method for use in the NSSP.
(d) Step by step procedure including equipment, reagents and safety requirements necessary to run the method.
(e) Data generated in the development and/or trials of the method and/or comparing to approved methods if applicable.
(f) Any peer reviewed articles detailing the method.
(g) Name of developer(s) or Shellfish Control Authority submitter.
(h) Developer/submitter contact information.
(3) Within two (2) years of Executive Board interim approval of the Emergency Use Method, the entire Single Lab Validation Protocol should be submitted. The Laboratory Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation Protocol data submission.

Public Health Significance: This revision to Chapter III. Laboratory is necessary to clarify and guide users to the location within the Guidance Documents that lists the approved NSSP laboratory tests in .11 Approved NSSP Laboratory Tests. All approved laboratory tests are now listed in Table .11 Approved NSSP Laboratory Tests with the Guidance Document.

Cost Information (if available):

Action by 2013 Task Force Recommended adoption of Proposal 13-119 as amended.

@.02 Methods.

A. Microbiological. Methods for the analyses of shellfish and shellfish growing or harvest waters shall be:
(1) 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 Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests.
(2) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used:
(a) A validated AOAC, BAM, or EPA method;
(b) An Emergency Use Method pursuant to .02 D. (1) and (2)

below.

B. Chemical and Physical. Methods for the analyses of shellfish and shellfish harvest waters shall be:
   (1) 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 Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests.
   (2) Results shall be expressed for chemical and physical measurements in standard units and not instrument readings.
   (3) When there is an immediate or ongoing critical need for a Method and no Approved NSSP Method exists, the following may be used:
      (a) A validated AOAC, BAM, or EPA method;
      (b) An Emergency Use Method pursuant to .02 D. (1) and (2) below.

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:
   (1) 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 Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests.
   (2) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used:
      (a) A validated AOAC, BAM, or EPA method;
      (b) An Emergency Use Method pursuant to .02 D. (1) and (2) below.

D. Emergency Use Methods.
   (1) When there is an immediate or critical need and no Approved NSSP Method exists, an unapproved or non-validated method may be used for a specific purpose provided that:
      (a) The appropriate FDA Regional Office is notified within a reasonable period of time regarding the method employed; and
      (b) The ISSC Executive Board is notified within a reasonable period of time regarding the method employed.
   (2) When it is necessary to continue the use of the emergency method employed under D. (1) beyond the initial critical need, then the following minimum criteria shall be provided to the ISSC Executive Board for interim approval:
      (a) Name of Method.
      (b) Date of Submission.
      (c) Specific purpose or intent of the method for use in the NSSP.
      (d) Step by step procedure including equipment, reagents and safety requirements necessary to run the method.
      (e) Data generated in the development and/or trials of the method and/or comparing to approved methods if applicable.
      (f) Any peer reviewed articles detailing the method.
      (g) Name of developer(s) or Shellfish Control Authority submitter.
      (h) Developer/submitter contact information.
   (3) Within two (2) years of Executive Board interim approval of the Emergency Use Method, the entire Single Lab Validation Protocol should be submitted. The Laboratory Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation Protocol data submission.

Action by 2013 General Assembly	Adopted recommendation of Task Force I on Proposal 13-119.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-119.

Proposal Subject:	Male-specific Coliphage Method for Quahogs (M. mercenaria)
Specific NSSP Guide Reference:	NSSP Guide Section IV Guidance Documents Chapter II Growing Areas .11 Approved Limited Use Methods for Microbiological Testing
Text of Proposal/ Requested Action	This submission presents the 'Male-specific Coliphage method for Quahogs (M. mercenaria)' for consideration as an approved limited use method for microbiological testing. At the 2009 ISSC, the 'Modified Double Agar Overlay Method for Determining Male-specific Coliphage in Soft-shelled Clams and American Oysters' was accepted as an approved limited use method for microbiological testing for re-opening growing areas after emergency closures due to sewage spills. SLV work with quahogs has demonstrated comparable performance characteristics as with soft-shelled clams and American oysters. The requested action is to include quahogs in the footnote for MSC along with soft-shelled clams and American oysters in NSSP Guide Section IV Guidance Documents Chapter II Growing Areas .11 Approved Limited Use Methods for Microbiological Testing.
Public Health Significance:	The MSC method for quahogs was used recently by the State of New Jersey to re-open growing areas after the devastating effects of Superstorm Sandy. Increasingly, enumeration of male-specific coliphage (MSC) in soft-shelled clams, American oysters, and quahogs is needed in the NSSP to assess *viral* contamination in molluscan shellfish harvested from growing areas where fecal coliform levels in both water quality and shellfish meats may be misleading. MSC is a specialized indicator of *viral* sewage contamination, which is substantially more meaningful than fecal coliform or E. coli in evaluating the safety of shellstock harvested from growing areas potentially impacted by treated and partially treated wastewater.
Cost Information (if available):	This method for the enumeration of male-specific coliphage in soft-shelled clams, American oysters, and quahogs is inexpensive, easy to perform, and rapid, providing results within 24 hours. The cost of laboratory glassware, plastic-ware, agars, and reagents is approximately $25 per shellfish sample. In a well-equipped laboratory, the method requires 6 hours of time from initiating host to pouring plates. Hands on technician time to perform this test is significantly less on the order of 1-4 hours per test depending upon how many tests are done per day. The most expensive piece of equipment is a refrigerated centrifuge plus rotor, which costs approximately $12,000. There are no special skill sets required beyond those required to operate a state-approved shellfish laboratory under the NSSP.
Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended adoption of this method for use in detecting MSC in hard clams and direct the Executive Office to amend the table at Section IV. Chapter 2 @ .11 to add Quahogs to footnote #1
Action by 2013 Task Force I	Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-120.
Action by 2013 General Assembly	Adopted recommendation of Task Force I on Proposal 11-320.

Action by FDA Concurred with Conference action on Proposal 13-120.
May 5, 2014

Proposal Subject: Identification of Wet Stored Shellstock

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance
Chapter X. General Requirements for Dealers
@ .05 Shellstock Identification B. Tags (2)

Text of Proposal/ Requested Action

.05 B. (2) The dealers tag…

(a) The dealer's name…
(b) The dealer's certification…
(c) The original shellstock …
(d) The date of harvest…
(e) If depurated …
(f) The most precise…
(g) **When the shellstock has been transported from the original area and wet stored in another approved growing area within the same state for at least two weeks, the dealer will:**
  (i) use the date shellstock was harvested from the last growing area as the harvest date;
  (ii) identify the last growing area as the harvest location.
~~(g)~~ **(h)** When the shellstock has been transported across state lines…
~~(h)~~ **(i)** The type and quantity …
~~(i)~~ **(j)** The following statement…
~~(j)~~ **(k)** All shellstock intended…

Public Health Significance: There is no guidance in the Model Ordinance on tagging shellstock that is moved from one growing area to another within the same state. After 2 weeks in a growing area, the shellstock would have the characteristics of the new growing area and the product should be tagged appropriately. This will facilitate product recall and trace backs in the event of human illnesses.

Cost Information (if available): None

Action by 2003 Task Force II Recommended referral of Proposal 03-204 to the appropriate committee as determined by the Conference Chairman.

Action by 2003 General Assembly Adopted recommendation of 2003 Task Force II.

Action by USFDA Concurred with Conference Action.

Action by 2005 Post-Harvest Processing Committee Recommended adoption of Proposal 03-204 with the following change to (g):

(i) use the date shellstock was harvested from the last most recent growing area as the harvest date;
(ii) identify the last most recent growing area as the harvest location.

Action by 2005 Task Force II Recommended referral of Proposal 03-204 to appropriate committee as determined by the Conference Chairman.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA	Concurred with Conference action.
Action by 2007 Traceability/PHP Committees	Recommended no action on Proposal 03-204. Rationale – No scientific information has been provided to support the suggestion that shellstock harvested and wet stored for a specified period of time in a site other than the original harvest site takes on the characteristics of the wet storage area.
Action by 2007 Task Force II	Recommended referral of Proposal 03-204 back to the Post Harvest Processing Committee with direction to address confusion over whether activity is wet storage, relay, or transplanting under aquaculture and to secure whatever science is available relative to length of time in growing area to take on new characteristics of that growing area.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.
2011 NOTE:	The only pending action associated with this proposal will be a report from FDA. The report will be shared with the membership when available.
Action by 2011 Task Force II	Recommended no action on Proposal 03-204. Rationale: No additional information has been provided on this proposal.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force II on Proposal 03-204.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 03-204.
Action by 2013 Task Force II	Recommended no action on Proposal 03-204. Rationale: No additional information is available.
Action by 2013 General Assembly	Adopted recommendation of Task Force II on Proposal 03-204.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 03-204.

Proposal Subject: Post-Harvest Handling

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance Definitions and 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 (if available):

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 Committee

Recommended no action on Proposal 09-231.

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.

Proposal Subject: *Vibro 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

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.

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

~~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.

@. 03~~2~~ Presence of Human Pathogens in Shellfish Meats.

@.04~~3~~ Presence of Toxic Substances in Shellfish Meats.

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

~~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.~~

~~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.~~

~~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~~

~~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.~~

~~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.~~

~~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.

@.0<u>5 Vibrio vulnificus Control Plan</u>

<u>A. Risk Evaluation</u>

<u>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.</u>

<u>In conducting the risk evaluation the State Authority will at a minimum consider the following:</u>

<u>The number of *Vibrio vulnificus* cases etiologically confirmed and epidemiologically linked to the consumption of commercially harvested shellfish from the State; and</u>
<u>Levels of *Vibrio vulnificus* in the growing waters and in shellfish, to the extent that such data exists; and</u>
<u>The quantity of harvest from the area and its uses i.e. shucking, half shell, PHP.</u>

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.

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

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

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
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

The *Vibrio vulnificus* Control Plan shall include the following:
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:
The water temperatures in the area; and
The air temperatures in the area; and
Salinity in the area; and
Harvesting techniques in the area; and
Other factors which affect risk which can be used as a basis for reducing risk.
Implementation of one or more of the following control measures to reduce the risk of *Vibrio vulnificus* illness:
Labeling oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 70~~5~~°F.
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.
~~Labeling oysters, "For shucking by a certified dealer", during the months of April through November, inclusive.~~
~~Subjecting oysters intended for the raw, half-shell market to Authority approved post harvest processing during the months of April through November, inclusive.~~
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.

) 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

In consultation with FDA the Authority will evaluate the implementation and effectiveness of their Control Plan.
Changes in the annual number of *Vibrio vulnificus* cases associated with the State's growing waters.
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.
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

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.
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:~~

~~i) 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~~

~~ii) 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):~~

~~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.~~

~~) 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.~~

~~:) 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.~~

~~ii) Survey assessments at the state level shall be used as a means of assessing the baseline knowledge and effectiveness of educational interventions.~~

~~) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state.~~

~~) 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.~~

~~) 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**~~

~~- 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.~~

~~- Each case must also be listed be on the FDA database (NSSP Guide for the Control of Molluscan Shellfish Guidance Documents Chapter IV .02).~~

~~- 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.~~

~~- The ISSC *Vv* Illness Review Committee will complete the following criteria table for each case. These tables serve as documentation.~~

~~- For cases to be included in illness reduction calculations the following criteria must be met:~~

~~- Item 1-4 and 5a must be answered yes.~~

~~ould 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 other 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 reduction 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 or addendum.~~

~~Check NO if Criterion is not confirmed from the COVIS form or addendum.~~

~~Check UNKNOWN if Criterion is not clear or absent from the COVIS form or addendum.~~

~~No Criterion can have more than one check entered.~~

~~Each Criterion must have one check entered (YES, NO, or UNKNOWN).~~

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

~~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.~~

~~- 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.~~

~~) 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.~~

~~) 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.~~

~~- 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.~~

~~- 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.~~

~~- 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~~2~~3 *Vibrio parahaemolyticus* Control Plan
Post Harvest Processing Validation Verification Interim Guidance for *Vibrio vulnificus* and *Vibrio parahaemolyticus*
Guidance for Demonstrating the Effectiveness of Time to Temperature Reduction Criteria for *Vibrio vulnificus* and *Vibrio parahaemolyticus*

Public Health Significance:

The level of *Vv* 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: (if available)

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 FDA 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 (Vv).* 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 *Vv* is reasonably likely to occur. Given that PHP can largely eliminate *Vv* 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 *Vv* illness in the State. Prior to 2003 California reported on average six *Vv* 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 *Vv* 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 *Vv* 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 *Vv* 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 *Vv* 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

Vv 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 *Vv* Source State will be challenging.

Beginning with the April2012 *Vv* season, FDA will be evaluating State *Vv* Control Plans, industry compliance, and State enforcement. While FDA is developing guidance regarding what Shellfish Specialists should consider when conducting *Vv* evaluations, presently neither FDA nor the ISSC has developed specific criteria for determining compliance with State *Vv* 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 *Vv* calculator;
Evaluation criteria for determining State *Vv* control plan compliance with NSSP requirements;

Evaluation criteria for determining the effectiveness of State regulatory efforts to ensure industry compliance with State *Vv* 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 *Vv* 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 *Vv* until the obstacles associated with full implementation of PHP are addressed. In the interim, however, FDA cannot support Conference action to change existing *Vv* 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 *Vv* illnesses.

Action by FDA October 15, 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.

Proposal Subject: Transportation and Critical Control Points

Specific NSSP Guide Reference: Section II Model Ordinance, Chapter IX. Transportation
Section II Model Ordinance, Chapter XI. Shucking and Packing
Section II Model Ordinance, Chapter XII. Repacking of Shucked Shellfish
Section II Model Ordinance, Chapter XIII. Shellstock Shipping
Section II Model Ordinance, Chapter XIV. Reshipping

Text of Proposal/ Requested Action:

Recommended Changes to Chapter IX. Transportation

Requirements for the Harvester/Dealer.

.01 Trucks or Other Vehicles Used to Transport Shellstock to the Original Dealer.

A. The harvester, or dealer who transports shellstock from the harvester to the original dealer, shall assure that all trucks used to transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition.
B. Storage bins on trucks or other vehicles used in the transport of shellstock for direct marketing shall be:
   (1) Kept clean with potable water or water from an approved area or conditionally approved area in the open status; and
   (2) Provided with effective drainage.
C. Shellstock shall be transported in adequately refrigerated trucks or iced when the shellstock have been previously refrigerated or when ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur.
D. Prechilling trucks or other vehicles to 45º or below shall be required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.
E. When mechanical refrigeration units are used, the units shall be:
   (1) Equipped with automatic controls; and
   (2) Maintained at an ~~Capable of maintaining the~~ ambient air temperature in the storage area at temperatures of 45º Fahrenheit (7.2º Centigrade) or less in the storage area
F. Any ice used to cool shellstock during transport shall meet the requirements of Chapter XI.02A~~(~~. (2).
G. Cats, dogs, and other animals shall not be allowed in any part of the truck or other vehicle where shellstock is stored.

.02 Receiving Shellfish

A. The dealer shall reject or discard any shellfish shipments which:
   (1) Do not originate from a licensed harvester or dealer; and/or
   (2) Are unwholesome, inadequately protected, or whose source cannot be identified.
B. Transportation agents or common carriers used by a dealer are not required to be certified.
C. The dealer shall:
   (1) Inspect incoming shellfish shipments to assure that the shipments are received under the conditions required in this Chapter;
   (2) Place shellstock under temperature control within 2 hours after receipt from the harvester, or when the dealer is also the harvester, when shellstock reaches the dealer's facility;
   (3) Ensure that shellstock are not permitted to remain without ice,

mechanical refrigeration, or other approved means of lowering the internal body temperature of the shellstock to, or maintaining it at, 50° Fahrenheit (10° Centigrade) or less for more than 2 hours at points of transfer such as loading docks;

(4) Ensure that shucked shellfish and in-shell product are not permitted to remain without ice, mechanical refrigeration, or other approved means of maintaining shellfish temperature at 45° Fahrenheit (7.2° Centigrade) or less; and

(5) Ensure that frozen shellfish remain frozen.

D. For the purpose of this section, temperature control is defined as the management of the environmental temperature of the shellstock by means of ice, mechanical refrigeration or other means approved by the Authority.

.05 Shipping Times.

A. Shipping Time is No More Than Four Hours.

(1) When the shipping time is four hours or less, the dealer shall ship all shellfish:

(a) Well iced; or

(b) Using other acceptable means of refrigeration.

(2) When mechanical refrigeration units are used, the units shall be equipped with automatic controls and shall be ~~capable of~~ maintained~~ing the ambient air in the storage area~~ at temperatures of 45° Fahrenheit (7.2°Centigrade) or less in the storage area.

(3) The dealer shall not be required to provide thermal recorders during shipment.

(4) Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.

B. Shipping Time is Greater Than Four Hours.

(1) When the shipping time is greater than four hours, the dealer shall ship all shellfish in:

(a) Mechanically refrigerated conveyances ~~which are equipped with automatic controls and capable of maintaining the ambient air in the storage area~~ at temperatures of 45° Fahrenheit (7.2° Centigrade) or less in the storage area; or

(b) Containers with an internal ambient air temperature maintained at or below temperatures of 45° Fahrenheit (7.2° Centigrade) or less.

(2) Unless the dealer has an approved HACCP plan with an alternate means of monitoring time-temperature, the initial dealer shall assure that a suitable time-temperature recording device accompanies each shipment of shellfish.

(3) The initial dealer shall note the date and time on the temperature-indicating device, if appropriate.

(4) Each receiving dealer shall write the date and time on the temperature-indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened.

(5) The final receiving dealer shall keep the time-temperature recording chart or other record of time and temperature in his files and shall make it available to the Authority upon request.

(6) An inoperative temperature-indicating device shall be considered as no recording device.

Recommended Changes to Chapters XI. Shucking and Packing

Requirements for Dealers.
.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall shuck and pack only:
   (1) Shellstock 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; and [C]
      (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or [C]
   (2) Shellstock obtained from a dealer other than the original harvester who has:
      (a) ~~Shipped the shellstock adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature;~~ and~~or~~ 50°F (10°C) internal temperature or less; ~~or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less;~~ [C]; and
      (b) Identified the shellstock with a tag on each container or transaction record with each bulk shipment. [C]
   (3) In-shell product obtained from a dealer who has:
      (a) Shipped the in-shell product adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 45°F (7.2°C) internal temperature or less; and [C]
      (b) Identified the in-shell product with a tag on each container [C]

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:
   (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**
   (2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be;
      (a) Iced; or **[C]**
      (b) Placed and stored in a storage area or conveyance maintained at 45° F (7.2° C) or less; and **[C]**
      (c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in **§**B (1) or **§**B (2) for more than 2 hours at points of transfer such as loading docks. **[C]**

C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be:
   (1) Iced; or **[C]**
   (2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. **[C]**

D. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:
   (1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within three hours of shucking. **[C]**
   (2) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within four hours of removal from refrigeration. **[C]**

(3) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45° F (7.2° C) or less within two hours after the heat shock process. **[C]**

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

E. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked and packed shellfish in covered containers at an ambient temperature of 45° F (7.2° C) or less or covered with ice. **[C]**

~~F. Shellstock Shipping Critical Control Point.~~

(1) The dealer shall ensure that Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

Recommended Changes to Chapter XII. Repacking of Shucked Shellfish
.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:

(1) Originated from a dealer who has:

(a) Shipped the shellfish iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature; **[C]** and

(b) Identified the shellfish with a label as outlined in Chapter X.06. **[C]**

B. Processing Critical Control Point - Critical Limits. The dealer shall ensure that repacked shucked shellfish do not exceed an internal temperature of 45° F (7.2° C) for more than 2 hours. **[C]**

C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store repacked shellfish in covered containers at an ambient temperature of 45° F (7.2° C) or less or covered in ice. **[C]**

D. Shellstock Shipping Critical Control Point Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

Recommended Changes to Chapter XIII. Shellstock Shipping
.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall ship or repack only:

(1) Shellstock obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and **[C]**

(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or **[C]**

(2) Shellstock obtained from a dealer other than the original harvester who has:

(a) ~~Shipped the shellstock adequately iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature~~ and~~or~~ 50°F (10°) internal temperature ~~or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°) or less **[C];**~~ and

(b) Identified the shellstock with a tag on each container. **[C]**

(3) In-shell product obtained from a dealer who has;

(a) Shipped the in-shell product adequately iced; or in a conveyance or at or below 45°F (7.2°C) ambient air temperature; or 45°F (7.2°C) internal temperate or less; and **[C]**

(b) Identified the in-shell product with a tag on each container. **[C]**

B. Receiving Critical Control Point - Critical Limits. The dealer shall ship or repack only:

(1) Shellstock obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and **[C]**

(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or **[C]**

(2) Shellstock obtained from a dealer other than the original harvester who has:

(a)Shipped the shellstock adequately iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature or 50°F (10°) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°) or less **[C]**; and

(b)Identified the shellstock with a tag on each container. **[C]**

(3) In-shell product obtained from a dealer who has:

(a) Shipped the in-shell product adequately iced; or in a conveyance or at or below 45°F (7.2°C) ambient air temperature; or 45°F (7.2°C) internal temperate or less; and **[C]**

(b) Identified the in-shell product with a tag on each container **[C]**

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

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**

(2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:

(a) Iced; or **[C]**

(b) Placed in a storage area or conveyance maintained at 45° F (7.2° C) or less; and **[C]**

(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §~~B(~~B (1) or §B (2) for more than 2 hours at points of transfer such as loading docks. **[C]**

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

(1) Iced; or **[C]**

(2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. **[C]**

E. Shellstock Shipping Critical Control Point

(1) Shellstock that is received bearing a restricted use tag shall only be

shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

(2) Should a State be implementing a *Vibrio parahaemolyticus* or *Vibrio vulnificus* Control Plan the dealer shall only ship shellstock that has been cooled to the temperature outlined in the State Plan.

Recommended Changes to Chapter XIV. Reshipping
.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall reship only shellfish which:

(1) Originated from a dealer other than the original harvester who has:

(a) ~~Shipped the shellstock adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature; and~~or 50°F (10°C) internal temperature or less; ~~or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less; [C];~~ and/or

(b) 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]** and

(c) 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. **[C]**

Shellstock Shipping Critical Control Point Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

Public Health Significance:

The present *Vv* and *Vp* Control Plans of the Model Ordinance include time to temperature controls which require that shellstock be cooled and maintained at specific temperatures to limit post-harvest growth of *Vv* and *Vp*. For these controls to be effective it is imperative that the shellstock be maintained at the temperatures outlined in the Control Plans. The proposed changes to Chapter IX., XI., XIII., and XIV. are intended to modify present requirements to ensure that these temperatures are maintained. Recent FDA audits of *Vv* and *Vp* Control Plan compliance and reports from States and the industry suggest that these modifications are necessary.

Action by 2011 Task Force II

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 B

Action by USFDA 02/26/2012

FDA concurred with Conference action on Proposal 11-201Part B but did not concur with Conference action on Proposal 11-201 Part A.

Action by 2012 Shipping and Receiving Committee

Recommended adoption of Proposal 11-201B as amended.

Recommended Changes to Definitions

(1) Adequate Icing means that the amount and application of the ice is sufficient to ensure that immediate cooling begins and continues for all shellfish. If ice slurry is used and the shellfish are submerged the presence of ice in the slurry indicates adequate icing.

(23) Conveyance means any type of container used to transport shellfish. The controls of the National Shellfish Sanitation Program (NSSP) are intended to address the container in which the shellfish are being held during transport from landing to final consumer. For the purposes of meeting the NSSP time temperature requirements for conveyances, the containers in which the shellfish are being held must meet the required temperatures. Should shellfish be shipped in a small container within a cargo space the temperature requirement would apply only to the temperature within the container.

(62) Landing means the point at which shellstock is put on land or a dock.

(65) Lot of Shellstock means a single type of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area gathered by one or more harvesters. A lot may also be used to segregate the harvest times and intended uses of shellstock for the purposes of complying with time to temperature requirements.

(87) Processing means any activity associated with the handling, shucking, freezing, packing, labeling or storing of shellfish in preparation for distribution. This would include the activities of a shellstock shipper, shucker packer, repacker, reshipper, or depuration processor.

(92) Receipt of Shellfish means the Critical Control Point where a shellfish dealer takes possession of shellfish at a location where it will be processed and/or will be shipped to another dealer or retail establishment. At this (location) point the dealer will monitor at receiving Critical Control Points to ensure compliance with Critical Limits. This is also the (location) point at which the dealer will monitor storage and shipping Critical Control Points.

(120) Trip Records means a form of written documentation that includes the date and time of each lot of shellfish harvested.

Recommended Changes to Chapter VIII. Control of Shellfish Harvesting

@.02 Shellstock Time to Temperature Controls

A. Each shellfish producing State shall establish time to temperature requirements for the harvesting of all shellstock to ensure that harvesters

shall comply with one of the following:

(1) The State *Vibrio vulnificus* Control Plan as outlined in Chapter II. @.04; or

(2) The State *Vibrio parahaemolyticus* Plan as outlined in Chapter II. @.05; or

A. All other shellstock shall comply with the matrix below:

Action Level	**Average Monthly Maximum Air Temperature**	**Maximum Hours from Exposure to Receipt at a Dealer's Facility**
Level 1	<50°F (10°C)	36 hours
Level 2	50°F - 60 °F (10°C - 15 °C)	24 hours
Level 3	>60 °F - 80 °F (15 °C - 27 °C)	18 hours
Level 4	>80 °F (>27 °C)	12 hours

B. For the purposes of this section, temperature control is defined as the management of the temperature of shellstock by means of ice, mechanical refrigeration or other approved means necessary to lower and maintain the temperature of the shellstock to comply with Chapter XI, XIII., or XIV.

C. The Authority shall establish the water or air temperature to be applied to the requirements above for each growing area by averaging the previous five (5) years maximum monthly water or air temperatures.

D. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.

E. The Authority shall ensure that harvesters document and provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements

F. Shellstock intended for Wet Storage, Depuration, Post Harvest Processing (PHP) or "For Shucking Only by a Certified Dealer" must either be shucked, introduced into PHP, Wet Storage, or Depurated within the times outlined in the matrix in Chapter VIII. @ .02 A (3) or meet the applicable time to temperature controls of Chapter VIII. @ .02 A. (3). Shellstock harvested under a State *Vibrio* Plan intended for Wet Storage or Depuration, must be placed in Wet Storage, Depuration or refrigeration to comply with time to temperature controls outlined in the State Authority *Vv* or *Vp* Control Plan.

G. Ocean Quahogs (*Arctica islandia*) and surf clams (*Spisula solidissima*) are exempt from this temperature control plan when these products are intended for thermal processing.

H. ~~H.~~ Authorities shall consider the need for shading in developing *Vv* and *Vp* Control Plans. Shading shall be required when deemed appropriate by the Authority when implementing @.02 A. (1) (2) and (3).

.02 Shellstock Harvesting and Handling.

G. Shellstock Temperature Control

(1) All harvesters shall comply with the applicable time to temperature requirements of

(a) State *Vv* and *Vp* Control Plans outlined in Chapter II. @.04 and @.05; or

(b) Chapter VIII. @.02 Shellstock Time to Temperature Controls A. (3).

(2) All harvesters shall provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements.

NOTE: State *Vv* and *Vp* Control Plans can be accessed on the ISSC web site using the following link: www.issc.org.

~~**.03 Shellstock Temperature Control.**~~

~~Note: The Authority shall select one of the following options for implementation in its State. The time-temperature matrix for each of the options applies only to the original harvester or harvester/dealer of shellstock for the purposes of handling and transporting shellstock to the first point of processing or packing.~~

~~OPTION 1~~

~~**(Mandatory for confirmed *Vibrio vulnificus* problem) *If the waters of a State have been confirmed as an original source of product associated with two (2) or more Vibrio vulnificus illnesses, the Authority shall adopt the following exposure time to temperature controls in the time-temperature matrix below only for shellfish intended to be consumed raw.***~~

~~**For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering the temperature of the shellstock and will maintain it at 50 degrees Fahrenheit (10 degrees Centigrade) or less.**~~

~~**Time-Temperature Matrix for *Vibrio vulnificus*:**~~

~~**Action Level**~~	~~**Water Temperature**~~	~~**Maximum Hours from Exposure to Temperature Control**~~
~~**Level 1**~~	~~**<65 °F**~~	~~**36 hours**~~
~~**Level 2**~~	~~**65 °F - 74 °F (18 °C - 23 °C)**~~	~~**14 hours**~~
~~**Level 3**~~	~~**>74 °F - 84 °F (>23 °C - 28 °C)**~~	~~**12 hours**~~
~~**Level 4**~~	~~**> 84 °F (>28 °C)**~~	~~**10 hours**~~

~~**The Authority shall establish the water temperature to be applied in the matrix above for each growing area by averaging the previous 5 years maximum monthly water temperatures.**~~

~~**The time to refrigeration in the above matrix shall be based upon the first**~~

~~**shellstock harvested.**~~

~~**During Action Levels 2, 3, and 4, the product shall be shaded.**~~

~~**The Authority may approve other measures proposed by the industry to provide controls equivalent to the time-temperature requirements in the above matrix.**~~

~~**The Authority may set up a plan that allows for exemption of this option for shellstock that is to be post-harvest processed with an approved post-harvest process in accordance with NSSP Model Ordinance Chapter XVI. The Authority must develop a plan to ensure the security of shellstock harvesting.**~~

~~**The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.**~~

~~OPTION 2~~

~~***If a growing area in the State has been confirmed as an original source of product associated with two (2) or more* Vibrio parahaemolyticus illnesses within the past three years, the Authority shall adopt the following exposure time to temperature controls in the time-temperature matrix below or use Option 1. This *Vibrio parahaemolyticus* control measure applies only to shellfish from the affected growing area(s) which are intended to be consumed raw.**~~

~~***For the purposes of this control measure, identify and define growing areas in the State affected by* Vibrio parahaemolyticus based on hydrographic and geographic parameters and other considerations relevant to control of a naturally occurring pathogen.**~~

~~**For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering temperature of the shellstock to, and will maintain it at 50 °Fahrenheit (10 °Centigrade) or less.**~~

~~**Temperature determinations for application in the time-temperature matrix below shall be based on average monthly maximum air temperatures for defined regions within the state. The average monthly maximum air temperature for each region shall be established by determining the mean daily high temperature for the month in each of the previous five years as reported by the National Weather Service and then averaging the five resulting temperatures. Ocean Quahogs (*Arctica islandia*) are exempted from this temperature control plan.**~~

~~**The Authority may set up a plan that allows for exemption of this option for shellstock that is to be post-harvest treated with an approved post-harvest process in accordance with NSSP Model Ordinance Chapter XVI. The Authority must develop a plan to ensure the security of shellstock harvesting.**~~

~~**The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.**~~

~~**Time-Temperature Matrix for *Vibrio parahaemolyticus*:**~~		
~~**Action Level**~~	~~**Average Monthly Maximum Air**~~	~~**Maximum Hours from**~~

	~~Temperature~~	~~Exposure to Temperature Control~~
~~Level 1~~	~~<66 °F (18 °C)~~	~~36 hours~~
~~Level 2~~	~~66 °F - 80 °F (19 °C - 27 °C)~~	~~12 hours~~
~~Level 3~~	~~≥81 °F (≥27 °C)~~	~~10 hours~~

~~OPTION 3~~

~~For those states that do not have to follow Option 1 or Option 2, the following time/temperature matrix will apply.~~

~~For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering temperature of the shellstock to, and will maintain it at, 50 °Fahrenheit (10 °Centigrade) or less.~~

~~Ocean Quahogs (*Arctica islandia*) and surf clams (*Spisula solidissima*) are exempted from this temperature control plan when these products are intended for thermal processing.~~

~~Temperature determinations for application in the time-temperature matrix below shall be based on average monthly maximum air temperatures for defined regions within the state. The average monthly maximum air temperature for each region shall be established by determining the mean daily high temperature for the month in each of the previous five years as reported by the National Weather Service, and then averaging the five resulting temperatures. Ocean Quahogs (*Arctica islandia*) are exempted from this temperature control plan.~~

~~The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.~~

~~Action Level~~	~~Average Monthly Maximum Air Temperature~~	~~Maximum Hours from Exposure to Temperature Control~~
~~Level 1~~	~~<66 °F (18 °C)~~	~~36 hours~~
~~Level 2~~	~~66 °F - 80 °F (19 °C - 27 °C)~~	~~24 hours~~
~~Level 3~~	~~≥81 °F (≥27 °C)~~	~~20 hours~~

Recommended Changes to Chapter IX. Transportation

Requirements for the Harvester/Dealer.

~~**Requirements for the Authority**~~

~~**@.01 General.**~~

~~A. The Authority shall apply these requirements to all shellfish shipped in interstate commerce.~~

~~B. The Authority shall assure that:~~

(1) Shellfish are transported and maintained in accordance with the requirements of this Chapter; and
(2) Shellfish shipments originate from a dealer.

C. The Authority shall use the temperatures included in the sections below entitled @.02 Shipment Acceptability, @.03 Shipment Rejection, and @.04 Bacteriological Examination of Shellfish Shipments as the initial basis for taking regulatory action against any shellfish shipment in interstate commerce.

D. If an interstate shipment of shellfish is monitored, the monitoring shall take place within 24 hours of the shellfish entering the State.

@.02 Shipment Acceptability.

Shellfish shipments shall be considered acceptable when:

E. Shipments are properly identified with tags and/or labels and shipping documents;

F. Shellstock is alive and cooled to an internal shellstock body temperature of 50° Fahrenheit (10 ° Centigrade) or less;

G. Shucked shellfish and in-shell product are cooled to a temperature of 45° Fahrenheit (7.2 ° Centigrade) or less; and

H. The time-temperature indicating device shows that the ambient air temperature has exceeded 45° Fahrenheit (7.2 ° Centigrade) but the shellstock internal body temperature is 50 ° Fahrenheit (10 ° Centigrade) or less; and

I. All other conditions of shipment in this Chapter are met.

Additional Guidance – Section IV Guidance Documents
Chapter II.12 Bacteriological Examination of Shellfish Shipments Decision Tree

@.03 Shipment Rejection.

J. Shellfish shall be rejected when:

(1) Shellfish are not properly identified with tags or shipping documents;
(2) The internal shellstock body temperature exceeds 60° Fahrenheit (15.6 Centigrade) unless the harvest initiation time can be documented and indicates that the time from harvest has not exceeded the requirements in Chapter VIII §@.03;
(3) Shucked shellfish temperature or the internal body temperature of in-shell product exceeds 50° Fahrenheit (10° Centigrade); or
(4) The Authority determines that the product is unwholesome or unsafe for human consumption.The Authority shall notify the shipping dealer, the receiving dealer, and the Authority in the State where the shipment originated of the shipment's rejection.

@.04 Bacteriological Examination of Shellfish Shipments.

If the State chooses to sample, the following protocol shall be used.

K. Bacteriological samples of any shellfish taken for the purpose of rejection of shipments from out-of-state dealers shall be collected within twenty-four hours of the shellfish entering a State.

L. Bacteriological examination shall be made of the shellfish shipment if:

(1) The internal body temperature of the shellstock exceeds 50° Fahrenheit (10° Centigrade) and is less than or equal to 60° Fahrenheit

~~(15.6° Centigrade) unless the harvest initiation time can be documented and indicates that the time from harvest has not exceeded the requirements in Chapter VIII @.03;~~
~~(2) The shucked shellfish temperature or the internal body temperature of in-shell product exceeds 45° Fahrenheit (7.2° Centigrade) and is less than or equal to 50° Fahrenheit (10° Centigrade);~~
~~(3) The shipping time exceeds four hours and there is no temperature recording device or the recording device is inoperative; or~~
~~(4) The Authority determines it is necessary.~~

.01 Trucks or Other ~~Vehicles~~ **Conveyances** Used to Transport Shellstock to the Original Dealer.

~~b.~~A. The harvester, or dealer wh~~o transports shellstock from the harvester to the original dealer, shall assure that all trucks~~Any conveyance used to transport shellstock ~~are~~ to the original dealer shall be properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition.

~~c.~~B. Storage bins on conveyances ~~trucks or other vehicles~~ used in the transport of shellstock ~~for direct marketing~~ shall be:

~~a.~~(1) Kept clean with potable water or water from an approved area or conditionally approved area in the open status; and

~~b.~~(2) Provided with effective drainage.

~~d.~~C. Shellstock shall be transported in adequately refrigerated trucks~~ or iced when the shellstock have been previously refrigerated or when ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur.~~ When transporting shellstock to the original dealer within the applicable time to temperature controls in Chapter VIII @ .02 A (1), (2) and (3) the temperature inside the conveyance or truck shall not exceed the ambient air temperature when the ambient air temperature is above 50° F (10°C).

~~e. Prechilling trucks or other vehicles to 45º or below shall be required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.~~

~~f.~~D. When mechanical refrigeration units are used, the units shall be:

~~a.~~(1) Equipped with automatic controls; and

~~b.~~(2) Maintained at an ambient air temperature necessary to comply with .01C above. ~~in the storage area at temperatures of 45º Fahrenheit (7.2º Centigrade) or less in the storage area~~

~~g.~~E. Any ice used to cool shellstock during transport shall meet the requirements of Chapter XI. .02 A. (2).

~~h.~~F. Cats, dogs, and other animals shall not be allowed in any part of the ~~truck or other vehicle~~ conveyance where shellstock is stored.

~~**.02 Receiving Shellfish**~~

~~A. The dealer shall reject or discard any shellfish shipments which:~~
~~(1) Do not originate from a licensed harvester or dealer; and/or~~
~~(2) Are unwholesome, inadequately protected, or whose source cannot be identified.~~

~~B. Transportation agents or common carriers used by a dealer are not required to be certified.~~

~~C. The dealer shall:~~
~~(1) Inspect incoming shellfish shipments to assure that the shipments are~~

~~received under the conditions required in this Chapter;~~
~~(2) Place shellstock under temperature control within 2 hours after receipt from the harvester, or when the dealer is also the harvester, when shellstock reaches the dealer's facility;~~
~~(3) Ensure that shellstock are not permitted to remain without ice, mechanical refrigeration, or other approved means of lowering the internal body temperature of the shellstock to, or maintaining it at, 50° Fahrenheit (10° Centigrade) or less for more than 2 hours at points of transfer such as loading docks;~~
~~(4) Ensure that shucked shellfish and in-shell product are not permitted to remain without ice, mechanical refrigeration, or other approved means of maintaining shellfish temperature at 45° Fahrenheit (7.2° Centigrade) or less; and~~
~~(5) Ensure that frozen shellfish remain frozen.~~

~~D. For the purpose of this section, temperature control is defined as the management of the environmental temperature of the shellstock by means of ice, mechanical refrigeration or other means approved by the Authority.~~

.0~~3~~2 ~~Transportation Containers~~.Conveyances Used to Transport Shellstock from Dealer to Dealer

A. All containers used to transport shellstock shall be:
(1) Constructed to allow for easy cleaning; and
(2) Operated and maintained to prevent product contamination.

B. All containers shall be cleaned with:
(1) Potable water; and
(2) Detergents, sanitizers, and other supplies acceptable for food contact surfaces.

.0~~4~~3 Cargo Protection From Cross Contamination.

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

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

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

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

.0~~5~~4 Shipping **Temperatures**~~Times~~.

Shellfish dealers shall ship shellstock adequately iced; or in a conveyance pre-chilled at or below 45°F (7.2°C) ambient air temperature.

~~E. Shipping Time is No More Than Four Hours.~~
~~(1) When the shipping time is four hours or less, the dealer shall ship all~~

~~shellfish:~~

~~(a) Well iced; or~~

~~(b) Using other acceptable means of refrigeration.~~

~~(2) When mechanical refrigeration units are used, the units shall be equipped with automatic controls and shall be maintained at temperatures of 45° Fahrenheit (7.2°Centigrade) or less in the storage area.~~

~~(3) The dealer shall not be required to provide thermal recorders during shipment.~~

~~(4) Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.~~

~~F. Shipping Time is Greater Than Four Hours.~~

~~(1) When the shipping time is greater than four hours, the dealer shall ship all shellfish in:~~

~~(a) Mechanically refrigerated conveyances at temperatures of 45° Fahrenheit (7.2° Centigrade) or less in the storage area; or~~

~~(b) Containers with an internal ambient air temperature maintained at or below temperatures of 45° Fahrenheit (7.2° Centigrade) or less.~~

~~(2) Unless the dealer has an approved HACCP plan with an alternate means of monitoring time-temperature, the initial dealer shall assure that a suitable time-temperature recording device accompanies each shipment of shellfish.~~

~~(3) The initial dealer shall note the date and time on the temperature-indicating device, if appropriate.~~

~~(4) Each receiving dealer shall write the date and time on the temperature-indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened.~~

~~(5) The final receiving dealer shall keep the time-temperature recording chart or other record of time and temperature in his files and shall make it available to the Authority upon request.~~

~~(6)~~(1) An inoperative temperature-indicating device shall be considered as no recording device.

.05 Transportation Records

All shipments of shellstock shall be accompanied with documentation indicating the time of shipment and that all shipping conveyances comply with the requirements of Chapter IX. .04. This documentation must include a notice of all shellstock harvested under the requirements of Chapter VIII. @.02 A. (3) that has not been cooled to an internal temperature of 50°F (10°C) and indicate the presence of a time/temperature recording device.

Recommended Changes to Chapters XI. Shucking and Packing

Requirements for Dealers.
.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. ~~The dealer shall shuck and pack only:~~

~~a.~~(1) The dealer shall shuck and pack only ~~S~~shellstock obtained from a licensed harvester who has:

~~i.~~(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and [C]

(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; ~~or~~and

~~ii.~~(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 shuck and pack only ~~S~~shellstock obtained and transported from a dealer ~~other than the original harvester~~ who has:
~~(a) and 50°F (10°C) internal temperature or less; [C]; and~~
(a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05 or transaction record with each bulk shipment as outlined in Chapter VIII. .02 F. (8); and~~.~~
(b) Provided documentation as required in Chapter IX. .04 and .05; and
~~(a)~~(c) ~~Shipped the shellstock a~~Adequately iced the shellstock; ~~or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 50°F (10°C) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C)~~ or ~~less~~
~~(b)~~(d) Placed 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 ~~50°F (10°C)~~ internal temperature of 50°F (10°C) or less.~~; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less;~~ [C]

(3) A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c) (d) or (e). The product must be accompanied with documentation as outlined in Chapter XIII. A. (2) (b) and must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**

(4) The dealer shall shuck and pack only ~~I~~in-shell product obtained from a dealer who has:
(a) Shipped the in-shell product:
(i) Aadequately iced; or
(ii) in a conveyance at or below 45°F (7.2°C) ambient air temperature; or
(iii)At an internal temperature of 45°F (7.2°C) or less; and [C]
(b) Identified the in-shell product with a tag on each container [C]

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:
~~(7)~~(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**
~~(1)~~(2) Once placed under temperature control and until shucked the ~~sale to the processor or final consumer,~~ shellstock shall ~~be;~~:
(a) Be ~~I~~iced; or **[C]**
(b) Be ~~P~~placed and stored in a storage area or conveyance maintained at 45° F (7.2° C) or less; and **[C]**
(c) Not be permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in ~~§~~ **.01** B (1) or ~~§~~ **.01** B (2) (a) or (b) for more than two (2) hours at points of processing or transfer such as loading docks. **[C]**

C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be:
(1) Iced; or **[C]**
(2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. **[C]**

D. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:
(1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within three (3) hours of shucking. **[C]**
(2) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within four (4) hours of removal from refrigeration. **[C]**
(3) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45° F (7.2° C) or less within two (2) hours after the heat shock process. **[C]**
(4) When heat shock shellstock are cooled and held under refrigeration for later shucking, the heat shocked shellstock shall be cooled to an internal temperature of 45° F (7.2° C) within two (2) hours from time of heat shock. **[C]**
(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]**

E. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked and packed shellfish in covered containers at an ambient temperature of 45° F (7.2° C) or less or covered with ice. **[C]**

F. Shellstock Shipping Critical Control Point.
(1) The dealer shall ensure that Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

.03 Other Model Ordinance Requirements

G. Shellfish Storage and Handling
(11) All shellstock obtained from a licensed harvester shall be:
(a) Adequately iced;
(b) Placed in a storage area maintained at 45°F (7.2°C); or
(c) Shucked within two (2) hours of receipt. **[S C/K]**

Recommended Changes to Chapter XII. Repacking of Shucked Shellfish
.01 Critical Control Points.

H. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:
(1) Originated from a dealer who has:
(a) Shipped the shellfish iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature; **[C]** and
(b) Identified the shellfish with a label as outlined in Chapter X.06. **[C]**

I. Processing Critical Control Point - Critical Limits. The dealer shall ensure that repacked shucked shellfish do not exceed an internal temperature of 45° F (7.2° C) for more than 2 hours. **[C]**

J. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store repacked shellfish in covered containers at an ambient temperature of 45° F (7.2° C) or less or covered in ice. **[C]**

~~K. Shellstock Shipping Critical Control Point Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.~~

Recommended Changes to Chapter XIII. Shellstock Shipping
.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. ~~The dealer shall ship or repack only:~~

(1) The dealer shall ship or repack only ~~S~~shellstock obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and **[C]**

(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; ~~or~~ and **[C]**

~~(b)~~(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 ship or repack only ~~S~~shellstock obtained and transported from a dealer who has ~~other than the original harvester who has:~~

(a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05; 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 convenyance 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) A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c) (d) or (e). The product must be accompanied with documentation as outlined in Chapter XIII. A. (2) (b) and must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**

~~11.~~(4) The dealer shall ship or repack only ~~i~~in-shell product obtained from a dealer who has;

~~•~~(a) Shipped the in-shell product:

(i) ~~a~~Adequately iced; or

(ii) ~~i~~In a conveyance or at or below 45°F (7.2°C) ambient air temperature; or

(iii) At an internal temperature of 45°F (7.2°C) ~~internal temperate~~ or less; and **[C]**

~~(a)~~(b) Identified the in-shell product with a tag on each container. **[C]**

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

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**

(2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall ~~be~~:

(a) Be ~~I~~iced; or **[C]**

(b) Be ~~P~~placed in a storage area or conveyance maintained at 45° F (7.2° C) or less; and **[C]**

(c) Not be permitted to remain without ice, mechanical refrigeration or other approved methods of ~~refrigeration~~storage, as required in ~~$B(~~.01 B. (1) or ~~$~~.01 B. (2) (a) or (b) for more than two (2) hours at points of processing or transfer such as loading docks. **[C]**

(3) All oysters harvested under State Vibrio Control Plans other than those labeled for a restricted use shall meet the following temperature requirements:

(a) Cooled to an internal temperature of 55°F (12.7°C) within the time periods outlined in the State Vv Control Plans. [C]

(b) Cooled to an internal temperature of 50°F (10°C) within the time periods outlined in the State Vp Control Plans. Shellstock cooled to an internal temperature of 55°F (12.7°C) to comply with a Vv Control Plan is considered in compliance with this requirement. [C]

(4) All other shellstock obtained from a licensed harvester shall be placed in a conveyance pre-chilled or a storage area maintained to 45°F (7.2°C) or less and cooled to an internal temperature of 50°F (10°C) prior to shipment. [C]

(5) Product intended for relay, wet storage, depuration, or Mercenaria sp which is being cooled utilizing an Authority approved tempering plan are exempt from the requirement listed above in .01 B. (4) above.[C]

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

(1) Iced; or **[C]**

(2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. **[C]**

D. Shellstock Shipping Critical Control Point. The dealer shall ensure that

(1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

(2) Should a State be implementing a ~~*Vibrio parahaemolyticus* or *Vibrio vulnificus* Control Plan the dealer shall only ship shellstock that has been cooled to the temperature outlined in the State Plan.~~ All shellstock is cooled to meet the requirements outlined in .01 B. 3. and 4. above prior to shipment. The original dealer may elect to ship restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. 3. prior to achieving the internal temperature of 50°F (10°C). Should the original dealer choose this option 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. **[C]**

.03 Other Model Ordinance Requirements

F. Shellfish Storage and Handling.

(6) All Shellstock obtained from a licensed harvester shall be:

(a) Adequately iced;

(b) Placed in a storage area maintained at 45°F (7.2°C); or

(c) Processed within two (2) hours of receipt. **[S$^{c/k}$]**

Recommended Changes to Chapter XIV. Reshipping

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. ~~The dealer shall reship only shellfish which:~~

(1) The dealer shall reship only shellfish obtained and transported ~~Originated~~ from a dealer ~~other than the original harvester~~ who has:

~~(a) and 50°F (10°C) internal temperature or less; and/or~~

~~(b) 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]** and~~

(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. **[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]**

(2) A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c) (d) or (e). The product must be accompanied with documentation as outlined in Chapter XIII. A. (2) (b) and must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that once placed under temperature control and until sale to the processor or final consumer, shellstock shall ~~be~~:

~~a.~~(1) Be ~~i~~iced; or **[C]**

~~b.~~(2) Be ~~P~~placed in a storage area or conveyance maintained at 45 °F (7.2 ° C) or less; and **[C]**

~~c.~~(3) Not be permitted to remain without ice, mechanical refrigeration, or other approved means of storage for more than two (2) hours at points of processing or transfer such as loading docks. **[C]**

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

(1) Iced; or **[C]**

(2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. **[C]**

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.**[C]**

E. Shellstock Shipping Critical Control Point. The dealer shall ensure that:

~~(1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.~~ **[C]**

(2) All shellstock received from a dealer which elected to ship restricted use shellstock or shellstock which has been harvested in accordance with Chapter VIII. @.02 A. 3. prior to achieving the internal temperature of 50°F (10°C) must be cooled to an internal temperature of 50°F (10°C) prior to shipment. The dealer may elect to ship restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. 3. prior to achieving the internal temperature of 50°F (10°C). Should the dealer choose this option 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. **[C]**

Recommended Changes to Chapter XV. Depuration.
Requirements for the Dealer
.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) iIdentified 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:

(a) Harvested or supervised the harvest of shellstock from a Restricted or Conditionally Restricted area in the open status; **[C]** and

(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]**

B. Processing Critical Control Points - Critical Limits. The dealer shall assure that:

(1) All depuration lots are treated for a minimum of 44 hours; **[C]** and

(2) The water treatment system is operating to design specifications; **[C]** and

(3) All critical limits established during verification of the specific depuration process are being met. **[C]**

C. Finished Shellstock Storage Critical Control Point - Critical Limits. The dealer shall assure that:

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; **[C]** and

(2) Once placed under temperature control while in the possession of the dealer, shellstock shall be:

(a) Iced; **[C]** or

(b) Placed in a storage area or conveyance maintained at 45 °Fahrenheit (7.2 °Centigrade) or less; **[C]** and

(c) Not permitted to remain outside temperature control for more than 2 hours at points of processing or transfer such as loading docks. **[C]**

.03 Other Model Ordinance Requirements

F. Shellstock Storage and Handling.

(11) Depurated packaged shellstock shall be protected from contamination at all times and be held at an ambient temperature not to exceed 45 °Fahrenheit (7.2 °Centigrade). **[K]**

(12) All shellstock received from a licensed harvester intended for depuration must be introduced into depuration, adequately iced, or placed in a storage area maintained at 45 °F (7.2 °C) within two (2) hours of receipt.

Recommended Changes to Chapter XVI. Post Harvest Processing.

C. For the purpose~~s~~ of ~~refrigeration~~ 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.

Recommended Changes to Section IV Guidance Documents, Chapter III. .07 Time and Temperature Controls.

Introduction.

National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish Guidance Documents provide the public health principles supporting major components of the NSSP, its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate commerce although most States apply the requirements intrastate. All requirements of the Program can be found in the current edition of the NSSP Model Ordinance.

A goal of the NSSP is to control the safety of molluscan shellfish for human consumption by preventing unnecessary growth of bacterial pathogens resulting from improper or ineffective cooling or from time to temperature abuse.

Chapter II. Risk Assessment and Risk Management.

Authorities must conduct Risk Assessments to determine the appropriateness of developing *Vibrio vulnificus (V.v.)* or *Vibrio parahaemolyticus (V.p.)* Control Plans.

The Authority in conjunction with the FDA will determine whether the State will implement a *V.v.* plan, a *V.p.* plan, or the control option for all other harvested shellstock (see Table 1). In developing *V.v.* and *V.p.* Control Plans the Authority must conduct *V.v.* and *V.p.* risk evaluations. The specific requirements of these evaluations are detailed in Chapter II. @ .04 and Chapter II. @ .05.

Chapter VIII. Harvesters Time to Temperature Control.

There are several pathogens that can cause illness from consumption of molluscan shellfish. Not all known pathogens associated with shellfish reproduce in the shellfish. However there are several pathogens that multiply in shellfish and present a health concern. Most Vibrios grow in shellfish and the rate of growth is dependent upon temperature. To minimize illness, the NSSP includes controls to limit exposure to warm temperatures. The controls begin at harvest and are applied at every level of processing and handling. This guidance document provides an explanation of those controls.

A. Authority Responsibilities.

Authorities must establish time to temperature controls for harvesters. The Authority in conjunction with the FDA will determine whether the State will implement a *V.v.* Plan (Chapter II. @.04), a *V.p.* Plan (Chapter II. @.05), or the control option of Chapter VIII. @.02 A. (3). In developing *V.v.* and *V.p.* Control Plans the Authority must conduct *V.v.* and *V.p.* risk evaluations. The specific requirements of these evaluations are detailed in Chapter II. @.04 and Chapter II. @.05. The Authority will advise the industry of the applicable harvest controls. The water and air temperatures used to establish these controls shall be representative of the temperatures of growing areas of the state from which harvesting is occurring.

B. Harvesters.

Harvesters must be aware of the applicable time to temperature requirements. Harvesters can obtain this information by contacting the

Shellfish Control Authority responsible for regulating shellfish harvesting. Harvesters must adhere to the time to temperature requirements of the individual State Vibrio Plans or follow the matrix below.

Action Level	**Average Monthly Maximum Air Temperature**	**Maximum Hours from Exposure to Receipt at the Dealers Facility**
Level 1	≤50°F (10°C)	36 hours
Level 2	50°F - 60 °F (10°C - 15 °C)	24 hours
Level 3	>60 °F - 80 °F (15 °C - 27 °C)	18 hours
Level 4	>80 °F (>27 °C)	12 hours

The harvest controls and *V.v.* and *V.p.* State Control Plans and the matrix above apply only to the harvester or harvester/dealer of shellstock for the purposes of handling and delivery of shellstock to the original dealer.

The harvester must provide harvest records to the original shellfish dealer demonstrating compliance with the applicable time and temperature requirements. This record may be in the form of a harvester tag, trip record, or other record deemed appropriate by the Authority. The record must include the date and time harvest begins for each lot of shellfish harvested. For States that establish and limit harvest times the recording of the time harvest begins may not be necessary. The time harvest begins is the time when the first shellstock in a lot is taken from the water or, in the case of intertidal harvest, the time of first exposure. Should the harvesting technique used involve re-submerging, the Authority must approve the harvesting technique to assure that the harvest method does not promote post harvest growth of pathogens associated with shellfish. The Authority shall not allow re-submerging techniques that promote Vibrio growth. It is expected that some harvest vessels will be equipped with refrigeration capabilities to accommodate large volume harvesting. Where cooling occurs on a harvest vessel, or prior to delivery to the original dealer, the harvester must provide documentation to the original dealer that the time and temperature requirements established by the Authority have been met.

To comply with the time to temperature requirements for harvested shellstock (Chapter VIII. @.02 A (1), (2), and (3)), the type of cooling must be capable of achieving the required internal temperature within the time frames required in the State Vibrio Control Plans or 50°F (10°C) prior to shipment (see shellstock storage critical control point Chapter XIII. .01 B. (3) and (4)). The use of temporary or inadequate cooling is not acceptable. Cooling that occurs prior to receipt by the original dealer does not alleviate the dealer requirement to document the time to internal temperature requirements.

To comply with the time to temperature requirements for shellstock intended for Wet Storage, Depuration, Post Harvest Processing (PHP), or "For Shucking Only by a Certified Dealer", the dealer must comply with one of the options below:

Option 1

The dealer must shuck or introduce into Wet Storage or Depuration, within the applicable time to temperature controls of Chapter VIII. @.02 A (3) and Chapter XIII .03; or

Option 2
The dealer must place the shellstock in temperature control within the applicable time to temperature controls of Chapter VIII. @.02 A (3) and Chapter XIII .03.

Ocean Quahogs (*Arctica islandia*) and Surf Clams (*Spisula solidissima*) are excluded from the time to temperature controls of State Vibrio Control Plans or the matrix outlined in Chapter VIII. @.02 A. (1) (2) and (3). This exclusion applies only when these products are intended for thermal processing. Authorities may exclude other species when intended for thermal processing.

In harvesting situations which expose shellstock to direct sunlight that increases product temperature, the Authority must consider the appropriateness of shading in the development of *V.v.* and *V.p.* Control Plans and may require shading when implementing controls for all other shellstock harvesting.

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.

Chapter XI. Shucking and Packing Dealer Requirements.

Shellstock Received from Harvesters

Dealers receiving shellstock from a harvester must only accept shellstock that is accompanied by documentation from the harvester indicating the time of harvest. The original dealer must document and maintain a record that cooling of the shellstock began at a time that was compliant with the time to temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3). Shellstock intended for shucking must include the same harvester documentation as shellstock intended for raw consumption. The documentation may be in the form of a harvester tag which includes date and time of harvest or a trip record, or other form that meets the requirements of the Authority.

Although a record is not required of the shipment temperature from the harvester, dealers should make sure that the means of transport to the dealer does not allow unreasonable temperature increases.

The dealer must document and maintain a HACCP record that the shellstock received from harvesters are either shucked or placed in a refrigeration unit at or below 45°F (7.2°C) within the time to temperature requirements of Chapter VIII. @.02 A. (1), (2), and (3) and Chapter XIII .03.

Storage Requirements

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. This two (2) hour requirement does not allow the dealer to exceed the time to temperature requirements of Chapter VIII. @.02 A. (1) or (2) as outlined in State Vibrio Control Plans.

In cases when shellstock that is harvested in compliance with State *V.v.* or *V.p.* Plans does not reach the dealer within the time periods outlined in the State Vibrio Plans, the dealer may elect as a corrective action to convert the shellstock to a restricted use such as PHP or "For Shucking Only by a Certified Dealer". Should the dealer choose this option the dealer must adhere to the time to temperature requirements of Chapter VIII. @ .02 A. (3).

Shellstock Received from Another Certified Dealer

Dealers receiving shellstock from another certified dealer for shucking and packing must document and maintain a record that the shellstock was received iced; in a conveyance at or below 45°F (7.2°C); or at an internal temperature of 50°F (10°C) or less. Dealers receiving shellstock from another certified dealer must also document and maintain a record that the shipment was accompanied by documentation indicating (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.

When a dealer receives shellstock that was harvested in compliance with Chapter VIII @ .02 A (3) not cooled to an internal temperature of 50°F (10°C) prior to shipment the receiving dealer must review the data of the time/temperature recording device and document in a record that continuing cooling has occurred since the time of shipment, as required in Chapter XI. .05 (Indicate in a record the presence of a time/temperature recording device). For shipments that have multiple deliveries, it is acceptable for each delivery to have an individual time/temperature recording device or be shipped with a single time/temperature recording device that each receiving dealer can use for documentation. Note that allowances for routine refrigeration defrost cycles and other short duration temperature fluctuations may be necessary. If the shipment is less than four (4) hours, a time temperature recording device is not required.

Storage Requirements

Shellstock that has been refrigerated must not be allowed to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required

in Model Ordinance Chapter XI. .01 B. (1) or B. (2) for more than two (2) hours at points of processing or transfer such as loading docks.

Once shellstock has been shucked by the dealer, the dealer shall comply with the processing and storage Critical Control Points of Chapter XI. .01 D. and E.

All shucked shellfish shall be maintained and shipped at or below 45°F (7.2°C).

Chapter XIII. Shellstock Shipping Dealer Requirements.

Shellstock Received from Harvesters

Dealers receiving shellstock from a harvester must only accept shellstock that is accompanied by documentation from the harvester indicating the time of harvest. The original dealer must document and maintain a record that cooling of the shellstock began at a time compliant with the time to temperature requirements of Chapter VIII. @.02 A. (1), (2), and (3). Shellstock intended for further processing must include the same harvester documentation as shellstock intended for raw consumption. The documentation may be in the form of a harvester tag which includes date and time of harvest or a trip record or other form that meets the requirements of the Authority.

Although a record is not required of the shipment temperature from the harvester, dealers should make sure that the means of transport to the dealer does not allow unreasonable temperature increases.

The dealer must document and maintain a HACCP record that the shellstock was shucked, iced, or placed in a refrigeration unit at or below 45°F (7.2°C) within the time to temperature requirements of Chapter VIII. @.02 A. (1), (2), and (3).

Storage Requirements

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. This two (2) hour requirement does not allow the dealer to exceed the time to temperature requirements of Chapter VIII. @.02 A. (1)or (2) as outlined in State Vibrio Control Plans.

Shellstock received from harvesters that harvested shellstock in compliance with the State *Vibrio vulnificus* Control Plan as outlined in Chapter VIII. @.02 A. (1) must be placed in refrigeration within the times outlined in the State *V.v.* Control Plan and cooled by the original shipper to 55°F (12.7°C) within the time period outlined in the State *V.v.* Control Plan (see Chapter XIII. .01 B. (3)), unless the shellstock is labeled for a restricted use. The original dealer must document that the internal temperatures listed above were achieved within the time frame outlined in the State *V.v.* Control Plan.

Shellstock received from harvesters that harvested shellstock in compliance with the State *V.p.* Control Plan as outlined in Chapter VIII. @.02 A. (2) must be cooled by the original shipper to 50°F (10°C) (see Chapter XIII. .01 B. (3)), unless the shellstock is labeled for a restricted use. The original dealer must document that the internal temperatures listed above were achieved within the time frame outlined in the State *V.v.* Control Plan. Shellstock cooled to an internal temperature of 55°F (12.7°C) to comply with a *V.v.* Control Plan is

considered in compliance with this requirement. It is assumed that refrigeration capable of achieving an internal temperature of 55°F (12.7°C) within six (6) hours would also achieve an internal temperature of 50°F (10°C) within ten (10) hours.

Shellstock received from harvesters that harvested shellstock in compliance with the time to temperature control matrix outlined in Chapter VIII. @.02 A. (3) and restricted use shellstock must be cooled to an internal temperature of 50°F (10°C) prior to shipment (see Chapter XIII. .01 B. (4)). (Product intended for relay, wet storage, depuration, or *Mercenaria sp* which is being cooled utilizing an Authority approved tempering plan are exempt from the requirement listed in Chapter XIII. .01 B. (4).) The original dealer must document that the internal temperatures listed above have been achieved prior to shipment.

In cases when shellstock that is harvested in compliance with State *V.v.* or *V.p.* Plans does not reach the dealer within the time periods outlined in the State Vibrio Plans, the dealer may elect as a corrective action to convert the shellstock to a restricted use such as PHP or "For Shucking Only by a Certified Dealer". Should the dealer choose this option the dealer must adhere to internal temperature requirements of Chapter XIII .01 B. (4).

Where cooling occurs on a harvest vessel, or prior to delivery to the original dealer, the harvester must provide documentation to the original dealer that the time and temperature requirements the Authority and outlined in the State Vibrio Control Plan have been met. The information must be included in the dealer's HACCP records.

Shipping Requirements

All shipments of shellstock must be accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of any shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature recording device indicating that continuing cooling has occurred.

Prior to shipping shellstock received from harvesters the dealer must comply with the internal temperature requirements of Chapter XIII. .01 B. (3) and (4).

Should the original dealer choose to ship shellstock which was harvested in compliance with the time to temperature control matrix outlined in Chapter VIII. @.02 A. (3) but has not been cooled to an internal temperature of 50°F (10°C), the dealer shall include a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**

Note that allowances for routine refrigeration defrost cycles and other short duration temperature fluctuations may be necessary.

Shellstock Received from Another Certified Dealer

Dealers receiving shellstock from another certified dealer for shipping and repacking must document and maintain a record that the shellstock was

received iced; in a conveyance at or below 45°F (7.2°C); or at an internal temperature of 50°F (10°C) or less. Dealers receiving shellstock from another certified dealer must also document and maintain a record that the shipment was accompanied by documentation indicating (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of any shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.

When a dealer receives shellstock that was not cooled to an internal temperature of 50°F (10°C) prior to shipment the receiving dealer must review the data of the time/temperature recording device and document in a record that continuing cooling has occurred since the time of shipment, as required in Chapter XI. .05. Additionally the dealer must indicate in a record the presence of a time/temperature recording device. For shipments that have multiple deliveries, it is acceptable for each delivery to have an individual time/temperature recording device or be shipped with a single time/temperature recording device that each receiving dealer can use for documentation. Note that allowances for routine refrigeration defrost cycles and other short duration temperature fluctuations may be necessary. If the shipment is less than four (4) hours, a time temperature recording device is not required.

Shellstock acceptability (receiving Critical Control Points) can be determined as follows:

1. The presence of enough ice on the shellfish to provide cooling to achieve required internal temperatures; or
2. An ambient temperature of 45°F (7.2°C) or less in the conveyance as measured by a thermometer; or
3. An internal temperature of 50°F (10°C) which can be measured by opening the shellstock and measuring the meat or using a temperature indicating gun which measures product temperature; or
4. The shipment of shellfish is accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of any shellstock that was shipped prior to meeting internal temperature required and notice of the presence of a time/temperature device indicating that continuous cooling has occurred.
5. For shellstock which was shipped prior to achieving an internal temperature of 50°F (10°C) the dealer must review the data of the time/temperature recording device and document in a record that continuing cooling has occurred since the time of shipment, as required in Chapter XI. .05. The dealer must indicate in a record the presence of a time/temperature recording device. For shipments that have multiple deliveries, it is acceptable for each delivery to have an individual time/temperature recording device or be shipped with a single time/temperature recording device that each receiving dealer can use for documentation.

Storage Requirements for Dealers Receiving Shellstock from another Certified Dealer

All shellstock that has been refrigerated must not be allowed to remain without ice, mechanical refrigeration, or other approved methods of refrigeration, as required in Model Ordinance Chapter XI. .01 B. (1) or B. (2) for more than two (2) hours at points of processing or transfer such as loading docks. All shucked shellfish shall be maintained and shipped at or below 45°F (7.2°C).

Shipping Requirements for Dealers Receiving Shellstock from another Certified Dealer

All shipments of shellstock must be accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.

Should the original dealer choose to ship shellstock which was received with documentation indicating that the product was not cooled to an internal temperature of 50°F (10°C) prior to shipment, the dealer must adhere to one of the following:

1. Include documentation indicating that the shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuing cooling has occurred. The shipment must 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 device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**
2. Should a dealer receive shellstock from a dealer who has elected to ship the shellstock prior to achieving required internal temperatures the dealer may choose to cool the product to an internal temperature of 50°F (10°C) or less prior to shipment. In this case a time temperature device will not be required. The dealer must document in a HACCP record that the internal temperature of 50°F (10°C) was met prior to shipment.

Chapter XIV. Reshipping

Shellstock Received from Another Certified Dealer

Dealers receiving shellstock from another certified dealer for reshipping must document and maintain a record that the shellstock was received iced; in a conveyance at or below 45°F (7.2°C); or at an internal temperature of 50°F (10°C) or less. Dealers receiving shellstock from another certified dealer must also document and maintain a record that the shipment was accompanied by documentation indicating (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.

Should the shipping dealer have chosen to ship product harvested under the time temperature requirements of Chapter VIII @.02 A. (3) or restricted use shellstock prior to achieving required internal temperatures, the shellstock must be accompanied by a time/temperature recording device which indicates that continuing cooling has occurred. The shipment must also be accompanied by a shipping document indicating the time of shipment and that all shipping containers were prechilled.

Shellstock acceptability (receiving Critical Control Points) can be determined as follows:

1. The presence of enough ice to contact the shellfish and provide cooling to achieve required internal temperatures; or
2. An ambient temperature of 45°F (7.2°C) or less in the conveyance as measured by a thermometer; or
3. An internal temperature of 50°F (10°C) which can be measured by opening the shellstock and measuring the meat or using a temperature indicating gun which measures product temperature; or
4. The shipment of shellfish is accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of shellstock that was shipped prior to meeting internal temperature required and notice of the presence of a time/temperature device indicating that continuous cooling has occurred.
5. For shellstock which was shipped prior to achieving an internal temperature of 50°F (10°C) the dealer must review the data of the time/temperature recording device and document in a record that continuing cooling has occurred since the time of shipment, as required in Chapter XI. .05. The dealer must indicate in a record the presence of a time/temperature recording device. For shipments that have multiple deliveries, it is acceptable for each delivery to have an individual time/temperature recording device or be shipped with a single time/temperature recording device that each receiving dealer can use for documentation.

Storage Requirements for Dealers Receiving Shellstock from another Certified Dealer

All shellstock that has been refrigerated must not be allowed to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in Model Ordinance Chapter XI. .01 B (1) or B (2) for more than two (2) hours at points of processing or transfer such as loading docks. All shucked shellfish shall be maintained and shipped at or below 45°F (7.2°C).

Shipping Requirements for Dealers Receiving Shellstock from another Certified Dealer

All shipments of shellstock must be accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.
Should the original dealer choose to ship shellstock which was received with documentation indicating that the product was not cooled to an internal temperature of 50°F (10°C) prior to shipment, the dealer must adhere to one of the following:

1. Include documentation indicating that the shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuing cooling has occurred. The shipment must 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 device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**
2. Should a dealer receive shellstock from a dealer who has elected to ship the shellstock prior to achieving required internal temperatures the dealer may

choose to cool the product to an internal temperature of 50°F (10°C) or less prior to shipment. In this case a time temperature device will not be required. The dealer must document in a HACCP record that the internal temperature of 50°F (10°C) was met prior to shipment.

Internal Temperature Measurements.

When monitoring the internal temperature of shellstock, it is acceptable to open the shellstock and measure the temperature of the shellfish directly using a thermometer or use a temperature detector device which provides the external temperature of the product. Where possible, but especially in cases in which product appears to be packaged for final sale, methods for determining the internal temperature of the shellstock should not compromise the integrity of the container. Should circumstances dictate that the measurement of the internal temperature of individual shellfish is necessary then particular care should be taken so as to avoid transferring heat from the equipment used by, and from the hands of the inspector to the shellfish. Individual oysters are typically no more than 0.2 kg in mass and can be warmed relatively quickly through handling by bare hands and when exposed to equipment or environments which are at a higher temperature than the original internal temperature of the animal.

Prying open the shells of shellfish is a time consuming and inherently destructive process (those animals measured must be discarded). The internal temperature of shellstock is, under most circumstances, reflected by the external temperature of the space surrounding the shellfish, or the external temperature of the shell of the animal, at the center of a packaged mass of shellstock (box, sack, bag, etc.). This temperature may be measured by inserting a standard analog or digital thermometer probe into the package to an appropriate depth or by exposing the shellfish at the center of the package for rapid measurement of the external shell temperature such as is made possible with laser guided infrared temperature measurement devices.

Time/Temperature Recording Devices – The time/temperature recording device must allow the receiving dealer to document that continuing cooling has occurred during transport.

Cooler Process Study Guidance

An alternative to monitoring product temperatures would be properly designed cooling process studies that demonstrate that cooling critical limits will be met. The cooling process studies must evaluate cooling times under worst case conditions found in the facility.

Factors including ambient air temperatures, product temperatures at arrival, amount of product to be cooled, arrangement of product in the cooler, and opening of the cooler door must be considered in the study. In conducting the studies, confirmatory product temperatures should be taken at the area of the cooler that is likely to have the least cooling ability. For instance, product temperature should be taken in the middle of a pallet in the most difficult cooling portion of the cooler.

Once a study is completed, the study should detail requirements needed to achieve compliance with the critical limits. Requirements could include such items as cooler capacity or arrangement of product in the cooler. Once

identified, the monitoring of the critical limits would include records to document that the requirements identified in the study to meet the critical limit are in place. The written study remains with the HACCP records.

This guidance can be utilized as a guide by the Authority when a certified dealer chooses not to physically monitor the initial temperature storage Critical Control Point (CCP) for each incoming lot of shellstock under the NSSP Model Ordinance as required by State *Vibrio vulnificus (V.v.)* or *Vibrio parahaemolyticus (V.p.)* Control Plans. The dealer can demonstrate the ability of the cooler to achieve required internal shellstock temperatures through a study that demonstrates that their mechanical refrigeration unit is able to cool shellstock to 50°F for *V.p.* or 55°F for *V.v.* within the required maximum time frame. This would enable the firm to monitor the ambient temperature of the refrigeration unit without requiring the firm to take the internal shellstock temperatures at the exact time of ten (10) hours (*V.p.*) or six (6) hours (*V.v.*) for each lot of shellfish on each day of the *V.v.* or *V.p.* Control Plan season. This guidance assumes that the refrigeration unit has a continuous temperature recording device (TRD) or the dealer manually monitors the cooler ambient temperature each day.

1. Determine the parameters of the cooler process study based on expected maximum load during implementation of a *V.v.* or *V.p.* Control Plan. This study can be used to satisfy internal temperature requirements for A. (3) shellstock.

2. Over three (3) days of refrigerated storage, starting with the first day of the *V.v.* or *V.p.* season, record the "internal" shellstock temperature at the time of loading into the cooler.

3. Record the days' maximum air and water temperature in the vicinity of the harvest area.

4. Record the internal shellstock temperatures after six (6) hours of refrigerated storage for *V.v.* and at ten (10) hours of refrigerated storage for *V.p.* and record the results.

5. If the internal shellstock temperatures meet the Model Ordinance requirements for cooling, continue to only monitor the cooler ambient temperatures as you normally would under your HACCP Plan.

6. When the air or water temperatures in the vicinity of the harvest area have increased by 10°F since the initial process study date repeat process study as described in No. 1 through No. 4 above.

7. If results meet the Model Ordinance requirements for cooling continue to only monitor the cooler ambient temperatures as you normally would under your HACCP Plan.

8. When the air or water temperatures in the vicinity of the harvest area have increased by another 10°F since the initial process study date repeat process study as described in No.1 through No. 4 above.

9. If results meet the Model Ordinance requirements for cooling continue to only monitor the cooler ambient temperatures as you normally would under your HACCP Plan.

10. If following the process studies the cooler has been shown to achieve the required internal shellstock temperature, including at least one (1) three (3)-day period of maximum loading under elevated air and water temperatures, then the study is considered successful and the certified dealer needs only to continue to monitor the routine cooler ambient temps as per their HACCP Plan.

Note: Changes to maximum shellfish loading or cooler capacity or changes to cooler compressor would require additional Re-Validation Process Studies.

Time/Temperature Decision Trees

Click here for Proposal 11-201-B Decision Trees

Action by ISSC Executive Board 01/22/2013

The ISSC Executive Board adopted 2012 Shipping and Receiving Committee recommendations on Proposal 11-201Part B.

NOTE: These changes were adopted as interim requirements and are included in the 2011 Revision of the NSSP Guide for the Control of Molluscan Shellfish.

Action by USFDA 02/28/2013

FDA concurred with ISSC Executive Board action on Proposal 11-201Part B.

Action by 2013 Task Force II

Recommends adoption of Proposal11-201-B as amended.

Chapter VIII. @.02

I. Shellstock intended for a validated pathogen reduction process where refrigeration would reduce efficacy of the process (and appropriately labeled with name of the receiving dealer) is exempt from the requirements in Chapter VIII. @.02 A. (1) and (2).

Chapter VIII. @.02

E. The Authority shall ensure that harvesters document and provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements. For states that establish and limit harvest times that assure compliance with the times outlined in the matrix of Chapter VIII. @.02 A. (3) recording the time harvest begins is not required.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force II on Proposal 11-201-B.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 11-201-B.

Proposal Subject:	Review of CDC *V.p.* Illness Information
Specific NSSP Guide Reference:	Section II Model Ordinance Chapter II @.05
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 (if available):	
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 FDA February 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.

Proposal Subject: *Vibrio cholera*

Specific NSSP Guide Reference: Section II Model Ordinance Chapter II Risk Assessment and Risk Management

Text of Proposal/ Requested Action

Public Health Significance: In April of 2011, the State of Florida reported a shellfish related illness outbreak associated with a toxigenic strain of *Vibrio cholera* O75. Current knowledge of *Vibrio cholera* O75 suggests that this toxigenic strain can be pollution oriented or naturally occurring. The National Shellfish Sanitation Program (NSSP) requirements for addressing outbreaks are different for pollution related hazards and naturally occurring hazards. The determination of whether an outbreak of *Vibrio cholera* O75 is pollution related or naturally occurring is difficult and creates management problems for public health officials and shellfish control authorities.

Procedure XIV of the ISSC Constitution, Bylaws, and Procedures outlines steps for addressing pathogens and deleterious substances newly recognized in shellfish. The purpose of this proposal is to provide notice to the membership that FDA and the ISSC will be discussing appropriate steps to address the *Vibrio cholera* situation. If recommendations for NSSP controls are developed for consideration at the 2011 Biennial Meeting, the ISSC membership will be notified.

Cost Information (if available):

Action by 2011 Task Force II Recommended adoption of the Pathogen Review Committee recommendation to refer Proposal 11-207 to an appropriate committee as determined by the Conference Chairman.

Action by 2011 General Assembly Adopted the recommendation of Task Force II on Proposal 11-207.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-207.

Action by 2013 Pathogen Review Committee The Pathogen Review Committee recommended that *Vibrio cholera* O75 should be treated as a naturally occurring pathogen unless the Authority determines there is evidence of association with pollution.

Action by 2013 Task Force II Recommended adoption of Pathogen Committee recommendation on Proposal 11-207 and further recommended wording be placed in the NSSP Model Ordinance as determined by the Executive Board.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 11-207.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 11-207.

Proposal Subject:	Aquaculture Facility Inspection Frequency
Specific NSSP Guide Reference:	Section II Model Ordinance Chapter VI. Shellfish Aquaculture @.01 General C.
Text of Proposal/ Requested Action:	The Authority shall inspect commercial aquaculture systems at least annually.
Public Health Significance:	Moving to a lesser number of inspections per year will not impact public health.
Cost Information (if available):	States are facing serious budget restrictions. Some find the current requirement for semiannual inspections to be excessive and not in furtherance of public health. States may maintain a higher frequency of inspection if they choose while allowing other states to decrease the frequency. States should, within limits, be able to determine priorities and allocate resources accordingly.
Action by 2011 Task Force III	Recommended referral of Proposal 11-208 to the appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-208.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-208.
Action by 2013 Aquaculture Facility Inspection Committee	The Committee recommended no action on Proposal 11-208.
Action by 2013 Task Force II	Recommended adoption of the Aquaculture Facility Inspection Committee recommendation of no action on Proposal 11-208. Rationale: Deficiencies will be resolved by action on another proposal.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 11-208.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-208.

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 (if available):

Research Needs ***The purpose of this section is to allow the submitter to identify research needs associated with the proposal. Please use additional pages as necessary.***

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)?

Research 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?

Please explain the relationship between the proposed research need and the program change recommended in the proposal. Support need with literature citations as appropriate.

Estimated Cost: $

Proposed Sources of Funding/Support:

Time Frame Anticipated:

For Research Guidance Committee Use Only

Relative Priority Rank in Terms of Resolving Research Need:

☐Immediate **☐ Required** **☐ Valuable** **☐Important**

☐Other Click here to enter text.

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.

Proposal Subject: Shellfish Plant Inspection Documentation

Specific NSSP Guide Reference: NSSP Section II Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority @ .02. Dealer Certification F. Inspections

Text of Proposal/ Requested Action

Add new:

3. The Authority shall document deficiencies observed during the inspection. Documentation of observed deficiencies corrected during the inspection must remain on the inspection form as a complete and accurate documentation of corrections.
4. The Authority shall verify if observations made during a prior inspection are corrected. If an observation made during a prior inspection has not been corrected, or is a recurring observation, it must be documented on the inspection form.

Public Health Significance:

The unique nature of shellfish as a food consumed whole and raw in the form as it comes from the growing area requires the state shellfish control authority to have sufficient capacity to enforce the public health based restrictions on sanitation controls and to obtain meaningful penalties for violation of those controls. Dealer certification is intended to provide an unbroken chain of sanitation control to many shellfish from the moment of harvest to its sale at the wholesale or retail level. Dealers having major non-conformities with the NSSP Model Ordinance should not be certified. Certified dealers found to have major non-conformities should have their licenses, or permits suspended, or certifications revoked.

Dealer certification is dependent on a dealer maintaining acceptable operational and sanitary conditions and is determined through uniform inspections by standardized inspectors. State officials who certify dealers must fully comply with the administrative requirements for certification for the process to remain viable. For the certification process to be effective, dealers must fully comply with the applicable Model Ordinance sanitation guidelines pertaining to the type of operation involved. Accurate documentation of observed deficiencies by the Authority is critical for maintaining and enforcing compliance with the sanitation controls in the *Guide for the Control of Molluscan Shellfish Model Ordinance.*

Cost Information (if available): N/A

Action by 2013 Task Force II

Recommended no action on Proposal 13-201.

Rationale: This proposal is adequately addressed in in the NSSP Guide Model Ordinance.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force II on Proposal 13-201.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 13-201.

Proposal Subject: Outbreaks of Shellfish Related Illness

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority

Text of Proposal/ Requested Action

@.01 Outbreaks of Shellfish-Related Illness.

D. When shellfish harvested within ten (10) days of each other from the same growing area are implicated in an illness outbreak involving ~~two (2)~~three (3) or more persons not from the same household (or one or more persons in the case of paralytic shellfish poisoning [PSP]), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:

(1) Each consumer's food history;
(2) Shellfish handling practices by the consumer and/or retailer;
(3) Whether the disease has the potential or is known to be transmitted by shellfish; ~~and~~
(4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent~~.~~ ; and
(5) Harvest tags, dealer tags and shipping and receiving records to determine the origin of shellfish implicated in an illness outbreak. Copies of harvest tags, dealer tags and shipping and receiving records are to be provided to the Authority. Failure to provide accurate harvest tags, dealer tags or shipping and receiving records substantiating the origin of the shellfish would preclude the existence of an epidemiological association.

E. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall:

(1) Conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.
(2) Determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated products.

F. When the investigation outlined in Section .02 B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:

(1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status (unless more than thirty (30) days have passed since the last reported illness and no additional illnesses have occurred;
(2) Notify receiving states, the ISSC and the FDA Regional Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;
(3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and
(4) Promptly initiate recall procedures consistent with the Recall

Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products (unless more than thirty (30) days have passed since the last reported illness [associated date of harvest] and no implicated product is likely to remain in the market place).

Public Health Significance:

Cost Information (if available):

Action by 2013 Task Force II

Recommended adoption of Proposal 13-202 as substituted.

Chapter II. Risk Assessment and Risk Management

@.01 Outbreaks of Shellfish Related Illness

F. 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 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 and when 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) 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 with two (2) or more cases but less than four (4) cases occurring 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 a three (3) log reduction for Pacific Coast oysters;

(b) 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;

(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.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force II on Proposal 13-202.

Action by FDA May 5, 2014

FDA concurred with Conference action on Proposal 13-202 with the following comments and recommendations.

Proposal 13-202 is a significant step toward developing a consistent approach among States for responding to *V. parahaemolyticus (Vp)* illnesses. The tiered approach outlined in Proposal 13-202 establishes a mandatory protocol for notification, closure, recall, and reopening based on a combination of pre-established illness numbers and illness time frames. FDA plans to work with the ISSC membership to achieve the optimal public health protection intended by Proposal 13-202. While FDA agrees that Proposal 13-202 moves in the direction of improved public health protection, there remain several concerns that need to be addressed by the Conference for effective implementation. At a minimum, the ISSC needs to cons9ider the following as part of the overall approach set forth in Proposal 13-202 for responding to *Vp* illnesses.

- Attribution of cases to a state and harvest area:
  - How will multi-source illnesses be handled?
  - What are the public health rationale and criteria for case exclusion?
- 1/100,000 risk per serving:
  - What is the process/criteria for determining risk/serving and compliance?
  - How can retrospective annual risk/serving determinations be used to evaluate performance of state *Vp* control plans?
- Illness reporting:
  - Timeliness of reporting to state shellfish authorities
  - Engaging state epidemiologists and local health agencies to improve reporting o State notification of illnesses to ISSC and FDA
- Performance criteria for evaluating state compliance

Proposal 13-202 was adopted without a specific implementation date. Given its significance and intended public health benefits, FDA recommends Conference action to establish immediate implementation.

Proposal Subject: Annual Assessment of Shellfish Production and Utilization

Specific NSSP Guide Reference: NSSP Section II Model Ordinance Chapter II Risk Assessment and Risk Management

Text of Proposal/ Requested Action

@ .02 Annual Assessment of *Vibrio vulnificus* and *Vibrio parahaemolyticus* Illnesses and Shellfish Production

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 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 a volume breakdown by utilization type (raw, shucked, PHP, etc.).

Public Health Significance: *Vibrio parahaemolyticus* and *V. vulnificus* control plans are based on risk per serving as determined by risk calculators developed by FDA. The predicted risk is applicable to consumption of raw oysters as this product use is assumed to present the greatest risk and is associated with the majority of seafood related illnesses. However predicted risk per serving levels in raw or half-shell oysters cannot currently be validated using observed data because only total landings are reported. The risk assessments assume that 50% of oysters are consumed raw but this can vary greatly from state to state and seasonally. A breakdown of total landings by product utilization would allow more accurate assessment of the associated risk of the various product categories.

Cost Information (if available):

Action by 2013 Task Force II Recommended adoption of Proposal 13-203 as amended.

@ .02 Annual Assessment of *Vibrio vulnificus* and *Vibrio parahaemolyticus* Illnesses and Shellfish Production

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 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, a volume breakdown by utilization type (raw, shucked, PHP, etc.).

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-203.

Action by FDA
May 5, 2014

FDA concurred with Conference action on Proposal 13-203 with the following comments and recommendations.

FDA concurs with adoption of Proposal 13-203 to make annual reporting of harvest volume by species a requirement of each shellfish producing state. Having these numbers will assist the ISSC in better defining the risk per serving associated with individual shellfish species for *V. vulnificus (Vv)* and *Vp.* Although not required by Proposal 13-203 as adopted, reporting landings by product category (half shell, post-harvest processing, shucked, etc.) would enable greater refinement to risk per serving calculations associated with shellfish intended for the half shell market. While Proposal 13-203 as submitted was intended to require reporting by product category, FDA recognizes the additional burden that detail of reporting places on States already facing limited resources. For States that do not have landings data by product category, the 50% raw consumption value used in the *Vp* and *Vv* risk assessments will continue to be used as the default for calculating risk per serving.

Proposal Subject: Vibrio Control Plans

Specific NSSP Guide Reference: Chapter II @.05 *Vibrio vulnificus* Control Plan
Chapter II @.06 *Vibrio parahaemolyticus* 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;~~

E*F*. *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~~

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

~~(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 (if available):

Research Needs	***The purpose of this section is to allow the submitter to identify research needs associated with the proposal. Please use additional pages as necessary.***

Proposed Specific Research Need/Problem to be Addressed:

Quantity of ice needed to cool oysters to 50F at various ambient temperatures

Please explain the relationship between the proposed research need and the program change recommended in the proposal. Support need with literature citations as appropriate.

Estimated Cost: $

Proposed Sources of Funding/Support:

Time Frame Anticipated:

For Research Guidance Committee Use Only
Relative Priority Rank in Terms of Resolving Research Need:
☐Immediate ☐ Required ☐ Valuable ☐Important
☐Other

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

FDA concurred with Conference action on Proposal 13-204 with the following comments and recommendations.

Prior to and during the 2013 Conference, FDA reached out to a number of States experiencing increasing Vibriosis in recent years for input regarding Proposal 13-204. The calculated illness reduction and associated public health benefit associated

with immediate icing and temperature reduction to 50°F within one hour of harvest was questioned by State and industry representatives. It became evident that the majority of State voting delegates were not willing to support the adoption of Proposal 13-204. As a result, FDA submitted and the Conference adopted substitute Proposal 13-204. Proposal 13-204 tasks the ISSC with obtaining funds to support studies that will further the science and public health benefits of existing and potential Vibrio control strategies. It also calls for the compilation of existing data and information available from States and industry regarding the science and impact of various control measures currently in place or previously tested.

FDA has secured initial funds for the ISSC to begin implementation of Proposal 13-204. These funds will serve to assist States with studies that support the intent of the substitute proposal. FDA is also looking at ways to provide resources and expertise from its Gulf Coast Seafood Laboratory to assist States with additional studies. Looking forward, FDA urges the ISSC to consider that the evidence most needed for determining the public health benefit of various control strategies would be to compare Vibrio levels at harvest to levels achieved with currently implemented time to temperature control measures and levels achieved using various other control strategies, including immediate cooling. If funding allows, it would be beneficial to conduct a follow-up to the 2007 market survey for purposes of comparing Vibrio levels from the 2007 survey to levels achieved under current *Vp* and *Vv* control plans. To expand further, a more comprehensive approach could examine changes in Vibrio levels as half shell product moves from harvest through processing and distribution. These data could inform allocation of regulatory resources to achieve the greatest public health benefit. Efforts outlined above are intended to help improve existing Vibrio controls, identify additional approaches for reducing risk and improve the effectiveness of the National Shellfish Sanitation Program (NSSP).

Proposal Subject: Control Plan Evaluation

Specific NSSP Guide Reference: NSSP Guide for Control of Molluscan Shellfish, Section II. Chapter II @ .05 E. (1) and (2)

Text of Proposal/ Requested Action Section II. Chapter II @ .05 E. (1) and (2)

E. Control Plan

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

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

(i) The water temperatures in the area; and

(ii) The air temperatures in the area; and

(iii) Salinity in the area; and

(iv) Harvesting techniques in the area; and

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

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

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

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

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

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

(2) Control Plan Evaluation

(a) The State Authority will conduct an evaluation of the plan.

At a minimum the Authority will consider:~~In consultation with FDA the Authority will evaluate the implementation and effectiveness of their Control Plan.~~:

(i) ~~Changes in t~~The annual number of *Vibrio vulnificus* cases associated with the State's growing waters and the amount of shellstock sold for half shell consumption to determine risk per servings for each temperature period.

(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.~~For the purposes of determining Authority compliance the FDA will conduct an annual Vibrio evaluation of Authority to determine the following:

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

(ii) For States requiring the development of *V.v.* Control Plans, compliance with Control Plan requirements of Chapter II @ .05 E. (1) Control Plan. The evaluation should determine:

a. Appropriate identification of trigger to determine when control measures are needed.

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

c. For Authority implementing Chapter II @ .05 E. (1) (b) (i) or (ii), were the controls implemented adequately.

d. For Authority implementing Chapter II @ .05 E. (1) (b) (iii) (time and temperature control), did the Authority establish controls consistent with water temperature and was the FDA developed *V.v.* calculator used correctly.

(iii) For Authorities required to develop *V.v.* Contingency Plans the evaluation should determine:

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

b. For States requiring the development of a Contingency Plan, does the plan include the regulatory steps to be implemented should the number of illnesses reach the threshold for a *V.v.* Plan.

(c) Should the findings of the State evaluation indicate that the Authority was in compliance with the items audited in (2) (b) and the observed risk per servings exceeded established risk per serving for one or more water temperature, the Authority will be deemed in compliance with the NSSP Model Ordinance. The

FDA will include this finding in a report to the ISSC.

(d) The results of the State and USFDA risk per serving 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.

Public Health Significance:

In 2001 the Interstate Shellfish Sanitation Conference (ISSC) adopted a *Vibrio vulnificus* (*V.v.*) illness reduction strategy (Proposal 00-201). This proposal established illness rate reduction goals that were based on actual *V.v.* illnesses reported by four (4) States. The implementation of this strategy has been controversial since its inception and there has never been consensus from the participants of the ISSC regarding an appropriate and effective evaluation strategy.

The initial goal of 40% was met, the 60% goal has never been achieved. The USFDA has been very critical of State efforts to meet the established illness rate reduction goal of 60% and in 2009 publicly withdrew its support for the illness rate reduction strategy, stating that the USFDA would pursue a requirement that oysters harvested from the Gulf of Mexico during periods of high risk could only be shipped in interstate commerce if post-harvest processed to reduce *V.v.* to non-detectable levels. The USFDA was requested to conduct an economic analysis of the impact of the proposed requirement. The study was conducted and the results indicated that the PHP requirement would financially devastate the industry and was not a viable option.

In 2009, the ISSC passed Proposal 09-207 which converted the illness rate reduction approach adopted in Proposal 00-201 to a risk per serving approach. The ISSC followed adoption of Proposal 09-207 with the adoption of Proposal 11-201A which established risk per serving based on the USFDA *V.v.* Risk Calculator. The established risk per servings was equivalent to the 60% illness rate reduction goal. The primary reason for ISSC adoption of Proposal 09-207 and Proposal 11-201A was the recognition of the many problems encountered by the ISSC in an attempt to use actual illness numbers to evaluate effectiveness and determine State compliance. Food safety programs have historically used illness trends to evaluate the effectiveness of food safety controls and this approved should be used rather than critiquing each illness and determine State compliance using actual reported illnesses. The adoption of Proposal 09-207 and Proposal 11-201A by the ISSC Voting Delegates was an acknowledgement of the need to move the focus of ISSC efforts to evaluation of controls rather than determinations of State compliance based on reported illnesses. This shift in focus would allow full ISSC debate of the effectiveness of controls and a collective review of the appropriateness of new controls. The results of State evaluations of *V.v.* Control Plans and USFDA evaluation of State programs would provide the ISSC with the necessary information to make decisions regarding other economically viable approaches that could be applied to the *V.v.* problem.

The language of Proposal 11-201A outlined controls that were to be implemented by Authorities to achieve the established risk per serving levels. The proposal did not include additional control or a means of evaluating the scientific basis or the economic impacts of additional controls should States not meet the established risk per serving levels. It is unrealistic to expect States to adopt controls that are not economically feasible or have not been adopted as a control of the NSSP. This unrealistic expectation has resulted in much controversy between the ISSC and the USFDA.

The ISSC has imposed severe harvesting restrictions on the shellfish industry in

Texas, Louisiana, Mississippi, Alabama, Florida, and Virginia, which has resulted in significant economic hardship to those industries.

Although not required, States were requested to implement the control of Proposal 11-201A in 2012 and the implementation of these controls were evaluated by the USFDA in 2012. The present number of *V.v.* illnesses from 2012 is much lower than in any year since 2001. Should this reduction become a trend, additional controls may not be needed. Should that not be the case, ISSC should fully debate additional controls to assure that they are scientifically based and economically feasible.

In correspondence dated May 29, 2013, the USFDA shared criteria which were developed by the USFDA for evaluating compliance with the established risk per serving outlined in Chapter II. @ .05 E. This criteria was shared with the ISSC Executive Board and Authorities for comments. Every comment received indicated disagreement with the USFDA criteria. Many commenters are concerned with the rigid evaluation approach of the USFDA. Host susceptibility issues, retail and consumer handling, and the very small number of cases continue to be issues of concern.

It appears there is agreement regarding the interpretation of the requirements outlined in Chapter II @ .05 E. (1) (a) and (b). The disagreement involves the interpretation of Chapter II @ .05 E. (2) and how the USFDA should evaluate States when the established risk per serving is not achieved for one or more water temperature periods. The USFDA has indicated it will deem a State in non-compliance if the risk per serving is not achieved for one or more water temperature periods and the State will be requested to develop an action plan. It is the opinion of States that conformance with the controls of Chapter II @ .05 E. (1) would indicate State compliance. Additionally States believe that modification of V.v. Control Plans to include additional controls should not occur without ISSC debate to allow discussion of effectiveness, scientific basis and economic feasibility. This proposal is being submitted by the VMC to allow full Conference debate regarding the intent and scope of the USFDA evaluation on State *V.v.* Plans.

Cost Information (if available):

Action by 2013 Task Force II

Recommended adoption of Proposal 13-205 as submitted.

Action by 2013 General Assembly

Adopted recommendation of Task Force II on Proposal 13-205.

Action by FDA May 5, 2014

FDA concurred with Conference action on Proposal 13-205 with the following comments and recommendations.

While Proposal 13-205 removes risk per serving as a measure of compliance, the NSSP continues to require annual risk per serving determinations by States that have implemented a *Vv* Control Plan. As stipulated in the Model Ordinance, results of annual risk per serving determinations must be shared with the ISSC Vibrio Management Committee for trend evaluation.

Proposal Subject: Analytical Capability and Capacity for Vibrio Testing

Specific NSSP Guide Reference: Model Ordinance Chapter II Section @.05 and Section @.06

Text of Proposal/ Requested Action

Chapter II Section @.05 add new G.

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 *V.v.* Control Plan.

(2) Contingency Plan Evaluation

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

G. States required to implement a *Vibrio vulnificus* Control Plan shall develop analytical capability and capacity to monitor *V.v.* levels with corresponding environmental data (water temperature and salinity) to determine and establish baseline data.

Chapter II Section @.06 add new D.

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 required to implement a *Vibrio parahaemolyticus* Control Plan shall develop analytical capability and capacity to monitor total and pathogenic *V.p.* levels with corresponding environmental data (water temperature and salinity) to determine and establish baseline data.

Public Health Significance: Most shellfish producing states have environmental conditions in their growing areas at certain times that present a vibrio risk. Development of the analytical capability and capacity within each state will greatly facilitate the characterization and control of this risk with regard to season, location, conditions and practices.

Cost Information (if available): Depending on the analytical method of choice, cost per sample for one organism (either *V.v.* or *V. p.*) is ~$10-75.

Action by 2013 Task Force II Recommended no action on Proposal 13-206.

Rationale: The cost of implementation is too expensive.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-206.

Action by FDA May 5, 2014 FDA concurred with Conference action on Proposal 13-206 with the following comments and recommendations.

Most shellfish producing States experience environmental conditions within their shellfish growing areas at certain times that present a greater Vibrio risk. Development of the analytical capability and capacity to test for Vibrio within each state will greatly facilitate the characterization and control of this risk with regard to season, location, environmental conditions and industry practices. While Proposal 13-206 was not

adopted by the Conference, FDA continues to encourage States required to implement a Vp or Vv Control Plan to develop analytical capability and capacity to monitor total and pathogenic Vibrio levels. States are further encouraged to link Vibrio levels to corresponding environmental data, including air temperature, water temperature and salinity. This will help establish baseline data that can be used to assess the effectiveness of Vibrio Control Plans and to make Vibrio management and control decisions. FDA has assisted a number of States with enhancing their Vibrio analytical capability and capacity by providing guidance, training and performance assessment. It is the intent of the Agency to continue to make this assistance available to ISSC stakeholders.

Proposal Subject: *Vibrio vulnificus* Contingency Plan

Specific NSSP Guide Reference: National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish: 2011 Revision Section II – Chapter II Risk Assessment & Risk Management @05 D. (1), (2)

Text of Proposal/ Requested Action

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~~ @.05 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;~~

Public Health Significance: There are no known levels of Vibrio vulnificus in growing waters or in shellfish that are reasonably likely to cause illness. V. v. is present in all coastal waters in the US, there is not public health reason for States that do not have any illnesses associated with their product to have a contingency plan. Requirement of a contingency plan should not be mandatory and if needed would be included in the State's annual evaluation for Vibrio.

Cost Information (if available): This change could possibly be a cost savings.

Action by 2013 Task Force II Recommended adoption of Proposal 13-207 as submitted.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-207.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-207.

Proposal Subject: Shellstock Cooling Guidance

Specific NSSP Guide Reference: Section IV. Guidance Documents, Chapter III. Harvesting, Handling, Processing, and Distribution .08 Icing, Cold Water Dips and Ice Slurries for Cooling Shellstock

Text of Proposal/ Requested Action

Section IV. Guidance Documents

Chapter III. Harvesting, Handling, Processing, and Distribution

.08 Icing, Cold Water Dips and Ice Slurries for Cooling Shellstock

For States implementing a *Vibrio vulnificus* (*V.v.*) or *Vibrio parahaemolyticus* (*V.p.*) control plan, there exist several options for temperature control to limit post-harvest *Vibrio* growth. NSSP recognized methods of temperature control include ice, mechanical refrigeration, or other approved means capable of lowering and maintaining the temperature of shellstock at 50°F (10°C) or less. The State Shellfish Control Authority is responsible for approving measures used by industry to control shellstock temperature for the purpose of complying with the State's *Vibrio* Control Plan. The desired outcome of temperature control is to inhibit bacterial growth after harvest.

In the past, questions have arisen regarding the efficacy and safety of icing as a means of controlling the post-harvest growth of *Vibrio* species. Icing has long been recognized in the NSSP as an acceptable and effective means of temperature control. The use of ice for temperature control is found throughout the NSSP Model Ordinance (MO). MO Chapter VIII defines temperature control as "*the management of temperature of shellstock by means of* ***ice****, mechanical refrigeration or other approved means necessary to lower and maintain the temperature of the shellstock to comply with Chapters XI, XIII, or XIV.*" The use of ice is not a new or novel control measure and has been applied effectively by the industry for many years. Several States have established icing shellstock onboard harvest vessels and at landing as a temperature control measure with documented success. Icing shellstock for the purpose of temperature control under a State's *Vibrio* Control Plan should be considered an acceptable practice.

In the past, questions have also arisen concerning the safety of chilled water and ice slurry dips as a means for controlling post-harvest growth of *Vibrio* bacteria. Specifically questioned has been the potential for microbial contamination when oysters are submerged in cold water or ice slurries whereby repeated use of the same

cold water or ice slurry could produce a microbial rich environment, consisting not just of *Vibrio* species but of fecal coliforms and other bacteria as well. Properly maintained, the water temperature of the dip should be sufficiently cold to retard the growth and proliferation of most microorganisms. Maintaining the dip at or below 50°F (10°C) will inhibit growth and proliferation of bacteria. To help ensure that cold water and ice slurry dips do not become overloaded with mud, sediment, and debris, in accordance with MO requirements, shellstock are to be washed making them reasonably free of mud, bottom sediments, and other material. Once removed from warm harvest waters and washed, shellstock placed in cold water or ice slurries close their bivalve shells, cease filtering activity, and can remain closed for extended periods. They generally remain closed and inactive throughout the time needed to cool while held in cold water dips and ice slurries, thereby minimizing the potential for the introduction of *Vibrio* species or other microorganisms during these cooling processes. Additionally, except for naturally occurring bacteria such as *Vibrio* species, oysters harvested from approved areas should not carry with them, or their

sediments, pathogens of public health concern. Furthermore, the use of warm water dips for heat shock, which is typically followed by a cold water dip to rapidly bring shellstock temperature back down, has been a long recognized and accepted NSSP process. The proper use of dips for rapidly cooling shellstock at harvest can be an effective measure to controlling post-harvest growth of *Vibrio* species and should not introduce other public health risks when practiced safely under the approval of the State Shellfish Control Authority. For these reasons, the use of cold water baths and ice slurries should be considered acceptable for controlling the post-harvest growth of *Vibrio* species.

Studies conducted by Texas A&M and the University of Florida Oyster Industry Laboratory have demonstrated that rapid cooling using ice and ice slurries not only prevents the growth of *Vibrio* bacteria, but can reduce *Vibrio* levels in Gulf oysters with no significant increase in oyster mortality. Methods varied from ice slurry dips to ice packing followed by cold storage, using both shucked and live product. The study data clearly suggests that icing and ice slurry dips are effective in maintaining and even reducing *V.v.* and *V.p.* levels after harvest. Additional preliminary studies performed by FDA at the Gulf Coast Research Laboratory in Dauphin Island, Alabama demonstrated no evidence of significant increases in levels of *Vibrio* species, fecal coliforms and other bacterial indicators resulting from ice slurry use.

To help ensure the safe use of ice and rapid cooling dips, the following should be considered:

(1) Water used to wash shellstock free from mud, sediment and other material should be from a potable water source or from a growing area classified as Approved and open to harvest.
(2) Ice should be made from a potable water source and properly protected from contamination prior to use.
(3) Water used in cold water or ice slurry dips should be from a potable water source or from a growing area classified as Approved and open to harvest.
(4) When icing shellstock, proper drainage should be provided to allow gravimetric removal of melting ice.
(5) When recirculated cold water is used to cool shellstock, water temperature should be monitored to ensure proper cooling and water quality should be monitored to ensure against impairment from sediment and particulate buildup due to extended use, which could result in a microbial or filth hazard.
(6) When cooling shellstock in cold water dips, water should be monitored to ensure proper cooling temperatures are maintained and to ensure against impairment from sediment and particulate buildup due to extended use.
(7) When ice slurries are used to rapidly cool shellstock, water quality should be monitored to ensure against impairment from sediment and particulate buildup due to extended use.

As with all control measures, the State must approve prescribed applications for use. It remains the State's responsibility to ensure the safety and efficacy of approved procedures for temperature control. It follows that before approving any system for temperature control, whether onboard harvest vessels, at landing sites, or in processing plants, prospective systems for cooling should be evaluated by the State. Existing guidelines on the safety and quality of ice and water used for cooling shellstock should suffice to address recent questions. Additionally, consultation with FDA Regional Shellfish Specialists or CFSAN is always available to States needing further guidance.

Public Health Significance:	The proposed guidance document provides specific information regarding the safe and effective use of ice, ice slurries and cold water dips for rapidly cooling shellstock. These cooling techniques provide an excellent strategy for effectively controlling post-harvest growth of *Vibrio spp.* When properly applied, these rapid cooling strategies have even been shown to reduce Vibrios to levels below those at the time of harvest.
Cost Information (if available):	
Action by 2013 Task Force II	Recommended adoption of Proposal 13-208 as submitted.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 13-208.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-208.

Proposal Subject: Re-submerging of shellstock

Specific NSSP Guide Reference: Model Ordinance Chapter V Section @.01 Paragraphs A and C; and Chapter V Section @.02 Paragraph B: Model Ordinance Chapter I. Purpose and Definitions

Text of Proposal/ Requested Action

Chapter I. Purpose and Definitions

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

Section @.01 Paragraph A.

A. The shellstock:

(1) ~~u~~Used 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

Section @.02 Paragraph B

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 Authority shall retain the written study report indefinitely. The study report shall demonstrate that, after the completion of the relay or re-submerging 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; or~~.~~

(3) The level of naturally occurring pathogens (*Vibrio* spp.) in each shellfish species is the same level of naturally occurring pathogens as that of the same species already present in the approved or conditionally approved area.

Public Health Significance: States that have a significant vibrio risk as determined by risk assessment have adopted requirements to limit the time between harvest and initial refrigeration.

Compliance with these time restrictions have created operational difficulties for various industry sectors and re-submerging oysters after initial harvest is being pursued as a means to mitigate vibrio growth during temperature abuse. However, the effectiveness of this approach for reducing Vibrios has not been demonstrated for the various approaches and practices that have been employed or proposed. This practice has the potential to greatly increase vibrio levels, especially if the oysters are unable to purge due to handling issues, transfer to different environmental conditions, gear type or over stacking. If the oysters are unable to pump, Vibrios will continue to grow at a rate determined largely by water temperature. While re-submerging has great potential to reduce vibrio levels, the best practices need to be determined and implemented.

Cost Information (if available):

Action by 2013 Task Force II

Recommended referral of Proposal 13-209 to an appropriate committee as determined by the Conference Chairman.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force II on Proposal 13-209.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 13-209 with the following comments and recommendations.

FDA concurs with Conference action to refer Proposal 13-209 to committee. Proposal 13-209 requires that a study be conducted to ensure that shellstock transplanted or re-submerged, for purposes of mitigating levels of naturally occurring pathogens, are allowed sufficient time to reduce levels to background. While the intended purpose of re-submerging is to reduce naturally occurring pathogens such as Vibrio spp. to pre-harvest levels, re-submerging also has the potential to greatly increase Vibrio levels, especially if shellstock purging is limited as a result of environmental conditions, handling practices, over-stacking, etc. If shellstock cannot effectively pump, Vibrio levels will remain the same or possibly increase, depending on water temperature. While re-submerging can effectively reduce Vibrio levels, as demonstrated by FDA-ISSC studies conducted in 2013, effective application needs to be scientifically demonstrated.

Proposal Subject: Aquaculture Facilities Inspections

Specific NSSP Guide Reference: Section II Chapter VI Shellfish Aquaculture Requirements for the Authority @ .01 General

Text of Proposal/ Requested Action

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 (if available): 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.

Proposal Subject: Bulk Tagging for Transport to Original Dealer (Harvest Control)

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance
Chapter VIII. Control of Shellfish Harvesting F. (7)

Text of Proposal/ Requested Action

F. Shellstock Identification.

(7) Bulk tagging of a lot of shellstock during transport from harvest area to the dealer facilities.

(a) When shellstock are harvested from one harvest area on a single day by a single harvester or aquaculture leaseholder, multiple containers may be utilized on a wrapped pallet, in a tote, in a net brailer, in a single boat, vehicle, conveyance or other container and the unit tagged with a single tag in accordance with the requirements of Section .02 F.

(b) In addition to the information required in Section .02 F. the unit tag shall also include:

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

(ii) Number of individual containers in the unit or an estimate of the total weight, volume or count.

Public Health Significance: When a harvester is transporting shellstock from a single harvest area or lease to a dealer, and all of the shellstock is from the same harvest area and harvested on the same date, a single tag describing the entire lot should suffice.

This practice should only be allowed as long as there is no opportunity for co-mingling, and no question about the origin or harvest date of individual containers within the boat's, vehicle's or conveyance's cargo area.

This practice will eliminate repetitive, time consuming, wasteful and unnecessary paperwork, thereby improving compliance.

Cost Information (if available): Will save approximately 25 cents in labor and tag costs for every duplicate tag eliminated, potentially saving hundreds of dollars per year.

Action by 2013 Task Force II Recommended adoption of Proposal 13-211 as submitted.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-211.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-211.

Proposal Subject: Tagging Requirements for Wet Stored Shellstock

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance
Chapter X. General Requirements .05 B. (2) (d)

NSSP Guide Section IV. Guidance Documents
Chapter III. Harvesting, Handling, Processing, and Distribution

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 (if available): 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.

Proposal Subject:	Review of .03 Requirements for Dealers
Specific NSSP Guide Reference:	NSSP Guide Model Ordinance Chapters XI, XII, XIII, XIV, and XV Section .03
Text of Proposal/ Requested Action	Subsequent to the adoption of Federal Regulation 123 Fish and Fishery Products, the ISSC incorporated HACCP principles into the NSSP Model Ordinance. In this transition many items which were not associated with Critical Control Points or sanitation were incorporated into the .03 Sections of Chapters XI, XII, XIII, XIV, and XV. Many of these controls are not critical to ensuring that shellfish are safe for human consumption. While Section .03 does have a few important requirements, most are not essential to the effectiveness of the NSSP and should be eliminated. The submitter requests that a committee be appointed to determine which of the requirements presently included in the .03 Sections of Chapters XI, XII, XIII, and XIV should be retained and recommend an appropriate placement for incorporating these requirements into Section .01 and .02. The remaining requirements should then be deleted. The effort would make inspection, standardization, and evaluation of State programs more relevant to assuming that shellfish are safe for human consumption.
Public Health Significance:	The proposal would streamline inspection, standardization, and State evaluations. These changes would allow public health officials to focus on requirements that address illness risk.
Cost Information (if available):	
Action by 2013 Task Force II	Recommended adoption of Proposal 13-213 as submitted.
Action by 2013 General Assembly	Adopted recommendation of Task Force II on Proposal 13-213.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-213.

Proposal Subject: Shellstock Storage and Handling

Specific NSSP Guide Reference: Section II. Model Ordinance Chapter XI. .03 F. (1), Chapter XIII. .03 F. (1), and Chapter XV. .03 F. (1)

Text of Proposal/ Requested Action

Chapter XI. .03 F. (1)

F. Shellfish Storage and Handling.
~~The dealer shall:~~
~~(1) Assure that shellstock is:~~
~~(a) Reasonably free of sediment [O]; and~~
(b) Culled; ~~[K]~~
(1) ~~(2)~~ Assure…

Chapter XIII. .03 F. (1)

F. Shellfish Storage and Handling.
(1) The dealer shall~~:~~
(a) Assure that shellstock is~~:~~
(i) ~~A~~a live~~;~~ .[K]
~~(ii) Reasonably free of sediment [O]; and~~
(iii) Culled; [K~~]~~
(2) The dealer shall…

Chapter XV. .03 F.

F. Shellfish Storage and Handling.
(1) ~~The dealer shall assure that shellstock is:~~
~~(a) Reasonably free of sediment [O]; and~~
(b) Culled; [K]
(2) Shellstock shall be stored…

Public Health Significance: There is no documented public health significance to the condition of shellstock in relation to whether it is culled or muddy in the plant. Muddy shellstock may cause cleaning issues during processing and if the plant or equipment is not cleaned adequately should be debited for those conditions and not for the fact that the shellstock are muddy in storage or during processing. Culling is routine plant activity as product is handled and relates to quality control not public health. Muddy shellstock and culling should not be separate debit items during plant inspections.

Cost Information (if available): No cost involved

Action by 2013 Task Force II Recommended no action on Proposal 13-214.

Rationale: This issue is adequately addressed in the NSSP Model Ordinance.

Action by 2013 General Assembly Adopted recommendation of Task Force II on Proposal 13-214.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-214.

Proposal Subject: Ice Production, Source of Ice

Specific NSSP Guide Reference: 2011 NSSP MO Chapter XI .02. (A.)(2.), Chapter XII .02 (A.)(2.), Chapter XIII .02 (A.)(2.), Chapter XIV .02 (A.)(2.), Chapter XV .02 (A.)(2.) AND Chapter XI .03 (E.)(4)(c), Chapter XII .03 (E.)(4)(c), Chapter XIII .03 (E.)(5)(c), Chapter XVI .03 (E.)(4)(c), and Chapter XV .02 (E.)(6)(c)

Text of Proposal/ Requested Action

Chapter XI. .02 A.

(2) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall:
- (a) be made on-site from potable water in a commercial ice machine; [**C**] or
- (b) come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]

Chapter XI. 03. E.

(4) Protection of ice used in shellfish processing.
- (c) ~~Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]~~

Chapter XII. .02 A.

(2) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall:
- (a) be made on-site from potable water in a commercial ice machine; [**C**] or
- (b) come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]

Chapter XII. .03 E.
(4)
- (c) ~~Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]~~

Chapter XIII. .02. A.

(2) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall:
- (a) be made on-site from potable water in a commercial ice machine; [**C**] or
- (b) come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]

Chapter XIII. .03 E.
(5)
- (c) ~~Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]~~

Chapter XIV. .02 (A)

(2) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall:
- (a) be made on-site from potable water in a commercial ice machine; [**C**] or

(b) come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]

Chapter XIV. .03 (E)

(4)

(c) ~~Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]~~

Chapter XV. .02 A.

(2) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall:

(a) be made on-site from potable water in a commercial ice machine; [**C**] or

(b) come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]

Chapter XV. .02 D.

(6)

(c) ~~Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]~~

Public Health Significance:

Temperature control of shellstock and shucked shellfish prevents the growth of pathogenic bacteria and, as written, the only acceptable source for ice for shucker-packers, re-packers, shellstock shippers, re-shippers, and depuration processors is from an on-site commercial ice machine. In order to encourage dealers properly icing product, the allowance for sourcing ice from facilities sanctioned by the Authority or other appropriate regulatory agency is necessary. By moving the text for other than on-site ice manufacture/sourcing from the Protection from Adulterants section which is not appropriate, and moving it to the Safety of Water for Processing and Ice Production as an option for sourcing ice meets the public health mission of the NSSP. The requirement for the protection of ice, whether from an on-site or approved off-site source remains, appropriately, in the Protection from Adulteration section.

Move/remove the sourcing of ice for processing, storage, and transport of shellfish from a facility sanctioned by the Authority or the appropriate regulatory agency in the .03 section for Protection from Adulterants to the section for safety of source of ice and water under the .02 Sanitation section.

Cost Information (if available):

N/A

Action by 2013 Task Force II

Recommended adoption of Proposal 13-215 as submitted.

Action by 2013 General Assembly

Adopted recommendation of Task Force II on Proposal 13-215.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 13-215.

Proposal Subject: *Panopea generosa* as Species Exempted from Shellstock Storage Critical Control 'Point

Specific NSSP Guide Reference: NSSP Guide Section II. Model Ordinance
Chapter XIII. Shellstock Shipping .01 Critical Control Points
C. Shellstock Storage Critical Control Point - Critical Limits.

Text of Proposal/ Requested Action Product intended for relay, wet storage, depuration, *mercenaria spp*. which is being cooled utilizing an Authority approved tempering plan, or geoduck clams (*Panopea generosa*) are exempt from the requirements listed above in .01.B.(4) with implementation beginning January 1 after proposal adoption.

Public Health Significance: The geoduck clam (*Panopea generosa* – until 2010 referred to by the extinct clam name of *Panopea abrupta*) is a fishery dominated by the native tribes in Washington. The optimum handling, keeping and shipping temperature is 47° to 52° Fahrenheit (8.3°-11.1° Celsius). The lower temperatures contained in the shellstock critical control point at Chapter XIII. @.01.B. (4) would cause significant mortality in this product. There is no record of geoduck clams being associated with Vibriosis; laboratory testing of geoduck clams in 2007 by DOH revealed no detected presence of *Vibrio parahaemolyticus*.

Cost Information (if available): There is no projected cost for this proposal. There is expected cost savings associated with this proposal due to the high loss of product expected with compliance.

Action by 2013 Task Force II Recommended adoption of Proposal 13-216 as substituted.

(5) Product intended for relay, wet storage, or depuration, or either geoduck clams (*Panopea generosa*), or *Mercenaria sp* which are being cooled utilizing an Authority approved tempering plan are exempt from the requirement listed above in .01 B. (4) above.**[C]**

Implementation is to begin three (3) months after concurrence by FDA. This achieves the goal of not waiting until publication of the new NSSP Guide and takes into account the requirement that FDA approve all changes adopted at the ISSC Biennial Meeting, while minimizing unnecessary loss of geoduck product.

Substitute Public Health Significance
The geoduck clam (*Panopea generosa*) was until 2010, referred to by the extinct clam name of *Panopea abrupta*. The optimum handling, keeping and shipping temperature is 47° to 52° Fahrenheit (8.3°-11.1° Celsius). The lower temperatures contained in the shellstock critical control point at Chapter XIII. .01. B. (4) would cause significant mortality in this product.

Action by 2013 General Assembly Adopted recommendation of 2013Task Force II on Proposal 13-216.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-216.

Proposal Subject: Shellfish Storage and Handling-Shucking

Specific NSSP Guide Reference: NSSP Guide for the Control of Molluscan Shellfish, Section II. Chapter XIII. .03 F. (6) (c)

Text of Proposal/ Requested Action Section II. Chapter XIII. .03 F.

(6) All shellstock obtained from a licensed harvester shall be
(a) Adequately iced;
(b) Placed in a storage area maintained at 45° F (7.2° C); or
(c) Processed within two (2) hours of receipt. **If the dealer is shucking quantities of shellfish that cannot be shucked within two (2) hours the Authority may allow a dealer to exceed the two (2) hours. To exceed the two (2) hour requirement the dealer must reduce the time from harvest exposure to receipt at the dealer facility. The dealer must not exceed the total amount of time between harvest exposure and shucking [Chapter VIII. @ .02 A. (3)] and the two (2) hour requirement of Chapter XI. .03 F. (11). These time/temperature modifications must be included in the dealers HACCP Plan.** **[$S^{C/K}$]**

Public Health Significance:

Cost Information (if available):

Action by 2013 Task Force II Recommended no action on Proposal 13-217.

Rationale: This issue is adequately addressed in the NSSP Guide Model Ordinance.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-217.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-217.

Proposal Subject: Accounting of Shellfish Quantities in Depuration Facilities

Specific NSSP Guide Reference: NSSP Section II Model Ordinance Chapter XV. Depuration

Text of Proposal/ Requested Action

Chapter XV. Depuration

Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this Chapter in regulation.]

A. Prior to authorizing depuration, the Authority shall develop and maintain an effective program to:
   (1) Control shellstock harvesting by special license in accordance with Chapter VIII. @.01 C.;
   (2) Control shellstock transportation between the harvest area and the depuration facility to prevent shellstock from being illegally diverted to direct marketing;
   (3) Approve the design and construction of the depuration facility or activity including subsequent changes;
B. If shellstock is transported interstate to be depurated, the Authorities in both States shall execute a memorandum of agreement to provide adequate control measures to prevent diversion prior to depuration.
C. The Authority shall review and approve the Depuration Plant Operating Manual prior to granting depuration certification.
D. The Authority shall review the depuration plant performance index and other records as part of the monthly inspections to verify that the process and CCP are effective and the process verification analysis is being performed properly.
E. The Authority shall maintain adequate records for each depuration facility. The following records for each facility shall be kept for the period of five years:
   (1) Inspection reports and reviews of the plant performance in accordance to Section D. (above);
   (2) Current Depuration Plant Operations Manual for each dealer (Section.03).; and
   (3) Precise inventory control and bio-security, before and after the depuration process.
F. The Authority shall assure that each dealer has procedures to assure that no shellstock which has not been depurated is removed from the depuration facility without the direct supervision of the Authority.

Chapter XV. Depuration

Requirements for the Dealer

.03 Other Model Ordinance Requirements

I. Plant Operations Manual. The dealer shall prepare a written Depuration Plant Operations Manual (DPOM) according to Minimum Requirements of a Depuration Plant Operations Manual (below); and update the DPOM as necessary. A copy of the DPOM shall be kept in a location readily accessible to the trained personnel responsible for the depuration activity. The minimum requirements for a Depuration Plant Operations Manual shall address:

(1) Introduction including:
  (a) Status of document (to create, revise, or update DPOM);
  (b) Ownership and principal(s) involved with operation of facility;
  (c) Address and phone number of owners and principles; and
  (d) Summary of proposed use of the depuration facility including statement of objectives of the operation of the plant, species to be processed, proposed periods of facility operation, proposed sources of shellfish, including potential harvest areas, and maximum capacity of plant.
(2) Description of the facility including:
  (a) Site plan drawings;
  (b) Facility layout including detailed schematic of the entire depuration system;
  (c) Schematic drawing of process;
  (d) Product flow diagram showing product movement through facility (may be combined with Section 01 B. (3);
  (e) Statement that construction materials and fabrication will meet the requirements of Section 03 E. (1) and (2); and
  (f) Schematic of seawater delivery and distribution system.
(3) Design specifications of depuration unit including:
  (a) Depuration tank diagram including tank dimensions and construction details, influent and effluent locations, operating water level, and typical container configuration;
  (b) Process water system describing type of system (flow-through or recirculating), pretreatment and filtration systems, disinfection system, and hydraulic schematic;
  (c) Shellfish containers construction and material meets Section .04 and Section .08 of this Chapter; and
  (d) List of equipment including washing, culling, and packing equipment, material handling equipment, and cleaning and sanitation equipment.
(4) Laboratory to be utilized for microbial analyses (in house, government agency, private commercial);
(5) Depuration process monitoring including:
  (a) Sampling protocols including frequency of sampling, number of samples, sampling locations, and methodology for process water analyzing, incoming shellstock, depurated shellstock, and growing waters;
  (b) Monitoring equipment maintenance and calibration procedures and copy of activity log forms that will be used for data entry;
  (c) Process water monitoring protocol for physical and chemical parameters; and
  (d) Data analysis and evaluation.
(6) Standard Operating Procedure for:
  (a) Receiving and holding;
  (b) Washing, culling, and placement of undepurated product in process tanks;
  (c) Depuration unit operation;
  (d) Monitoring of depuration unit operation;
  (e) Removal of depurated product from process tanks;
  (f) Storage parameters and procedures;
  (g) Labeling/tagging procedures;
  (h) Plant cleaning and sanitation; and
  (i) Data analysis.
  (j) Recall procedures.

(7) Record Keeping. List categories of information that will be recorded. Include copies of proposed forms to be used in each category. A single form may be used for several categories if properly designed.
(a) Shipping and receiving records;
(b) Plant Operation Log, including provisions for recording the values for chemical and physical parameters;
(c) Maintenance and Sanitation Log(s);
(d) Laboratory records; and
(e) Counts of shellfish before and after the depuration process, specifically including the total number, or volume of shellfish. Shellfish sold by the piece after depuration shall be counted by the piece upon landing. If sold by volume, then volume would be recorded at landing.

Public Health Significance: To ensure that all product delivered to the depuration plant is properly placed into the depuration process it is critical that counts and amounts of shellfish are properly counted and volumes properly assessed upon receipt. Harvester allegations of missing or diverted shellfish imply that some product may be diverted from the process.

Cost Information (if available): Since plant operators typically count product after the process, counting at the beginning instead should not impact the cost of the operation.

Action by 2013 Task Force II Recommended no action on substitute Proposal 13-218.

Rationale: There is no public health issue.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 03-218.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-218.

Proposal Subject: Depuration Equipment Sanitizing Requirements

Specific NSSP Guide Reference: NSSP Guide for the Control of Molluscan Shellfish, Section II. Chapter XV. .02 B. (2)

Text of Proposal/ Requested Action

(2) Cleaning and sanitizing of food contact surfaces.

(a) Food contact surfaces of the depuration units, equipment and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces. Depuration tanks and trays are not considered to be food contact surfaces.

The dealer shall:

(i) Provide applicable adequate cleaning supplies and equipment, brushes, detergents, and sanitizers, hot water and pressure hoses; [K]

(ii) ~~Wash, rinse and s~~Sanitize equipment 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 at the end of each day. [K]

(b) Containers which may have become contaminated during storage shall be properly washed, rinsed and sanitized prior to use or are discarded. [K]

(c) Shellstock depuration tanks shall be cleaned ~~and sanitized~~ on a regular schedule as part of a plant sanitation standard operating procedure. [K]

Public Health Significance: The present language of Chapter XV requires depuration processors to wash, rinse and sanitize equipment prior to beginning each day's operation. This proposal seeks to eliminate the need to wash and rinse at the start of each day and allow this at the end of each day's operations. In addition, this proposal will eliminate the need to sanitize equipment such as depuration tanks and shellfish trays used in depuration. Equipment used in depuration does not present a risk of food borne illnesses. The Depuration process is intended to eliminate pathogens and is highly monitored and it is not reasonably likely for product contamination to occur as a result of the condition of equipment. During the depuration process, process water is *continuously* sanitized and depuration waters are monitored on a daily basis with lot testing requirements as an additional safeguard.

Other processes such as land based wet storage operations do not have specified cleaning and sanitizing requirements specified by the Model Ordinance. Depuration equipment is no more likely to cause illness than wet storage equipment. The depuration process is more highly controlled and tested than wet storage; therefore depuration equipment is less likely to contaminate product than equipment used in wet storage.

Cost Information (if available):

Action by 2013 Task Force II Recommended adoption of Proposal 13-219 as amended.

(2) Cleaning and sanitizing of food contact surfaces.

(a) Food contact surfaces of the depuration units, equipment and containers shall be cleaned and sanitized to prevent contamination of shellstock and

food contact surfaces. Depuration tanks and trays are not considered to be food contact surfaces.

The dealer shall:

(i) Provide applicable adequate cleaning supplies and equipment, brushes, detergents, and sanitizers, hot water and pressure hoses; [K]

(ii) Sanitize equipment 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 at the end of each day. [K]

(b) Containers which may have become contaminated during storage shall be properly washed, rinsed and sanitized prior to use or are discarded. [K]

(c) Shellstock depuration tanks shall be cleaned and sanitized on a regular schedule as part of a plant sanitation standard operating procedure. [K]

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-219.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-219.

Proposal Subject: PHP Validation and Verification Costs

Specific NSSP Guide Reference: NSSP Guide Section II. 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:

Cost Information (if available):

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.

Proposal Subject: *Vibrio parahaemolyticus* Control Plan for Hard Clams (*Mercenaria Mercenaria)*

Specific NSSP Guide Reference: NSSP Guide Section II Chapter II Risk Assessment and Risk Management Section @.06 *Vibrio parahaemolyticus* Control Plan

Text of Proposal/ Requested Action @.06 *Vibrio parahaemolyticus* Control Plan

A. Risk Evaluation.
Every State from which oysters or hard clams (*Mercenaria Mercenaria*) 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 or hard clams 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 or hard clams 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 or hard clams harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or
(2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:
(a) Waters bordering the 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 or hard clams harvested from those areas.
(i) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section;
(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the state and adjoining states that have been the

source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or

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

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

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

(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include: (i) Post harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and hard clams and a three (3) log reduction for the Pacific Coast oysters;

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

(ii) Restricting oyster and/or hard clams 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 or hard clams) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;

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

(d) Evaluate the effectiveness of the Plan.
(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.
(f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.

~~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: Hard clams, of the species *Mercenaria mercenaria,* from the Atlantic coast have been increasingly implicated in *Vibrio parahaemolyticus* illnesses in recent years and now constitute a significant risk second to oysters with regard to reported illnesses in the US. In order to reduce the incidence of *Vibrio parahaemolyticus* illnesses, States with a history of illnesses associated with hard clams harvested from their growing areas, and states where a risk evaluation has determined that the risk of *Vibrio parahaemolyticus* is reasonably likely, need to develop and implement a *Vibrio parahaemolyticus* control plan aimed at reducing the incidence of illness to no more than 1 illness in 100,000 servings.

Cost Information (if available):

Action by 2013 Task Force II Recommended adoption of Proposal 13-221-L as amended.

@.06 *Vibrio parahaemolyticus* Control Plan

A. Independent Species Specific Risk Evaluation.
Every State from which oysters or hard clams (*Mercenaria mercenaria*) 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 or hard clams 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 or hard clams 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. Independent Species Specific Control Plan
(1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters or hard clams harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or
(2) If a State has a shellfish growing area in which harvesting occurs at a

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

(a) Waters bordering the 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 or hard clams harvested from those areas.

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

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

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

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

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

(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include: (i) Post harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and hard clams and a three (3) log reduction for the Pacific Coast oysters;

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

(ii) Restricting oyster and/or hard clams 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 or hard clams) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;

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

(d) Evaluate the effectiveness of the Plan.

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

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

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.

Implementation will be delayed until June 1, 2015, for States not involved with *V.p.* outbreaks in clams to allow adequate time for States to work with industry to develop enforceable clam tempering plans.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force II on Proposal 13-221.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 13-221.

Proposal Subject: *Vibrio parahaemolyticus* Control Plan Water Temperatures

Specific NSSP Guide Reference: NSSP Guide Section II Chapter II Risk Assessment and Risk Management Section
@.06 *Vibrio parahaemolyticus* Control Plan
B. Control Plan (2)

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) Waters bordering the Atlantic Ocean (NY and north): 60°F.
(~~c~~d) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters 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.~~

Public Health Significance: Presently Chapter II. Section @.06 B. (2) does not include a water temperature for New York and north.

Cost Information (if available):

Action by 2013 Task Force II Recommended adoption of Proposal 13-222 as submitted.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-222.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-222.

Proposal Subject: *Vibrio parahaemolyticus* Control Plan Risk Per Serving

Specific NSSP Guide Reference: NSSP Guide Section II Chapter II Risk Assessment and Risk Management Section
@.06 *Vibrio parahaemolyticus* Control Plan
New D.

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.

B. 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 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 (if available):

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.

Proposal Subject:	Implementation Date for Harvester and Dealer Training Requirements
Specific NSSP Guide Reference:	NSSP Guide Section II Chapter VIII Control of Shellfish Harvesting .01 General A. and Chapter X General Requirements for Dealers .04 Certification Requirements
Text of Proposal/ Requested Action	Change the implementation date for the harvester and dealer training requirements adopted in Proposal 09-212 from January 1, 2014 to January 1, 2015.
Public Health Significance:	In 2013 the ISSC Voting Delegates adopted Proposal 09-212 which requires training for harvesters and dealers. The Voting Delegates established an implementation date of January 1, 2014, for these training requirements. States are not prepared at this time to implement these requirements and a later implementation date is being suggested.
Cost Information (if available):	
Action by 2013 Task Force II	Recommended no action on Proposal 13-224. Rationale: Task Force II did not agree that a change to the implementation date was appropriate.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 13-224.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-224.

Proposal Subject: Guidance for Submission of Post-Harvest Process Validation Studies

Specific NSSP Guide Reference: NSSP Guide Section II Model Ordinance Chapter XVI. and Section IV Guidance Documents Chapter IV.

Text of Proposal/ Requested Action Add a new Section .05 Template for Submission of Post-Harvest Process Validation Studies as follows:

In the *National Shellfish Sanitation Program* (NSSP) *Model Ordinance Chapter XVI: Post Harvest Processing* (PHP) it states that if a dealer elects to utilize a PHP for the purpose of making safety added labeling claims they must conduct a validation study to demonstrate the ability of the PHP to reduce the target pathogen(s) to acceptable levels. Specifics on target levels and approved methods of detection for pathogens are found in the Model Ordinance. All laboratory analysis must be performed by a laboratory that has been evaluated by FDA or an FDA certified LEO and found to "conform" or "provisionally conform" with the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance Chapter III and supporting Guidance Documents. Results of the validation study should be submitted in the following format for review and consideration by state and federal shellfish control authorities. For validation of *Vibrio vulnificus* or *Vibrio parahaemolyticus* methods, checklist may be used as a guide.

1) TITLE OF PHP METHOD VALIDATED
2) SUMMARY
3) OBJECTIVES (Study Purpose)
    a) Detailed description of the PHP method validated.
    b) Target pathogen(s) and prescribed reduction.
4) METHOD OF ANALYSIS
    a) Post-Harvest Process description.
        i) Identify temperatures, weights or other pertinent information for the PHP method. Methods of mollusk preparation, for example acclimation to temperature or salinity, include all details. All variables that could affect the outcome of the PHP must be detailed.
        ii) Identify number of animals used in study and number of trials performed.
    b) Laboratory: (Pre and post processing pathogen measurement and description of analytical procedure)
        i) Initial pathogen levels and pathogen detection model: microbiological or chemical analysis.
            (1) How was initial pathogen load achieved, i.e. naturally occurring population, inoculation or thermal abuse.
            (2) Provide adjusted Geometric Mean (AGM) calculations and unit of measure appropriate for target (i.e.: MPN/g for Vibrio or coliforms, CFU/100g for Elevated Temperature Coliform Plates (ETCP fecals).
            (3) Analytical methodology used for pathogen quantification and confirmation. This method must be recognized in the NSSP Guide for the Control of Molluscan Shellfish (Accepted methods listed in Section IV. Guidance Documents Chapter II.10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods.)
        ii) Post Process Product Analysis: microbiological or chemical analysis

(1) Quantify pathogen level(s) in processed product utilizing the same analytical method used to attain initial load.

c) Validation Outcome:

i) Provide specific information regarding outcome measurements. Metric used to validate method (these will vary depending on targeted pathogen and are located in the Model Ordinance). Documentation that process achieved target reduction.

5) RESULTS

a) Graphs, tables and charts outlining the validation study results.

i) Data from validation demonstration; levels achieved in post process.

ii) Pathogen measurements (for example: AGM interval, grams per tube and the number of positive tubes as per the guidance document for verification/validation).

6) CONCLUSIONS:

a) Demonstrate reduction of the target pathogen to NSSP established standards.

7) APPENDIX

a) Tables or graphical interpretations of data.

8) OPTIONAL INFORMATION

a) If appropriate, include optional items such as interpretation of confounding factors or applicable industry limitations.

b) Acknowledgements, for example funding sources, technical help or bibliography.

Public Health Significance: The purpose of this proposal is to provide guidance for dealers conducting post-harvest processing validation studies for the purposes of labeling shellfish as outlined in Model Ordinance Chapter XVI.

Cost Information (if available):

Action by 2013 Task Force Recommended adoption of Proposal 13-225 as submitted.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-225.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-225.

Draft- Checklist for Submission of Post-Harvest Process Validation Studies for *Vibrio vulnificus* and *Vibrio parahaemolyticus*	
	Explanation of PHP Method Validated
	1. Method name
	2. Specific information about machinery, equipment, or supplies necessary to perform the method of PHP is provided
	3. Standard operating procedures: Detailed description of the PHP method validated is provided
	4. What are the specific issues that must be accounted for during processing? For example, is there a limit to number of shellfish, spacing, hold times that are considered part of the
	5. Internal quality control measures for equipment calibration, maintenance, and repair and for performance checks are explained.
	Objectives to be Accomplished
	1. Does the process reduce the level of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* in the process to non-detectable (<30MPN/gram) and achieve a minimum 3.52 log reduction?
	2. Was the process validated by demonstrating that the process will reliably achieve the appropriate reduction in the target pathogen(s) in a study as outlined in Guidance Documents Chapter IV, Naturally Occurring Pathogens.
	Method of Analysis
	1. Was laboratory analysis performed by a laboratory that has been evaluated by FDA or an FDA certified LEO and found to "conform" or "provisionally conform" with the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance Chapter III and supporting Guidance Documents? 2
	2. Are all variables that could affect the outcome of the PHP identified: temperatures, weights or other pertinent information?
	Pre Processed Samples to attain initial levels
	1. Microbiological testing for initial levels was done by a 3-tube MPN using appropriate dilutions (10-1 to 10-6).
	2. Was the initial level of Vibrios for each lot of shellfish used in the validation 10,000 MPN per gram or greater based on the adjusted geometric mean (AGM) of the MPNs/g of four samples?
	3. How were the zero hour levels achieved: through naturally occurring Vibrio levels in shellfish, time/temperature abuse, inoculation? (Inoculation is not preferred)
	Enumeration of or Processed Samples
	1. Does a sample consist of a composite of 10 to 12 oysters processed at one time from one day?
	2. Is there data on ten processed samples obtained on each of three processing days (total of 30 samples)?
	3. Microbiological testing for processed samples was done with a single dilution five-tube MPN, inoculating with either 0.01 g or 0.1 g of shellfish.
	4. Are only analytical methods to determine Vibrio levels previously endorsed by the ISSC as indicated in Model Ordinance Chapter XVI. Post-Harvest Processing?
	5. Was microbiological testing for processed samples done with a single dilution five-tube MPN, inoculating with either 0.01 g or 0.1 g of shellfish per tube?
	6. **For the process to be validated, no more than three samples out of 30 may fail**. Failure is based on the Guide for the Control of Molluscan Shellfish 2009 Section IV. Guidance Documents Chapter IV. Naturally Occurring Pathogens .04 Post Harvest Processing (PHP) Validation/Verification Guidance for *Vibrio vulnificus* and *Vibrio parahaemolyticus*.

Proposal Subject: Guidelines for Primary Certified Shellfish Processors on Using Controls for Irradiation of Containers of Molluscan Shellfish Pre-labeled with Vibrio Reduction Language

Specific NSSP Guide Reference: Section IV. Guidance Documents
Chapter III. Harvesting, Handling, Processing, and Distribution

Text of Proposal/ Requested Action

Add New Section .09

.09 Irradiation Pre-labeling Guidance

This document provides guidance to primary certified shellfish processors involved in transferring pre-labeled shellfish to be processed at irradiation post-harvest process (PHP) facilities.

Vibrios are highly sensitive to ionizing radiation. The National Shellfish Sanitation Program (NSSP) recognizes Vibrio reduction processes such as irradiation and provides general requirements for dealers using them. For irradiation the following guidelines provide additional detail:

- All shellfish irradiation facilities and shellfish processors using an irradiation facility to PHP shellfish must be recognized by their State Shellfish Control Authority (SSCA) as a certified PHP facility and comply with NSSP Model Ordinance Chapter XVI.

- Irradiation facilities must utilize a process that has been validated in accordance with the NSSP to achieve a reduction of *V.v.* and/or *V.p.* to less than 30 MPN/g. The process shall not irradiate shellfish to an absorbed dose of greater than 5.5 kGy, as provided by 21 CFR § 179.26. While the size of the container of shellfish does not affect the ability of the process to provide the proper dose of irradiation to all shellfish in a process batch, once a process has been validated it is essential that all containers be of uniform size with the same number of containers on each pallet. This is also important for purposes of product tracking and control. Each processor wishing to use an irradiation facility that has already been recognized and validated in accordance with the NSSP does not have to revalidate the irradiation process being used. Further, if a NSSP recognized irradiation facility conducts verification sample testing, processors using that facility to PHP shellfish may use those verification sample results to fulfill their NSSP verification requirements.

- The shellfish processor and the irradiation facility must have implemented a Hazard Analysis Critical Control Point (HACCP) plan approved by the respective SSCAs for the PHP process that ensures the target pathogen(s) in shellfish are consistently reduced to levels recognized as safe in the NSSP Model Ordinance.

- Once the irradiation process is completed containers of irradiated shellfish should be segregated from other shellfish or seafood products.

Under 21 CFR § 179.26(c), molluscan shellfish that are irradiated must bear a specific logo and a statement specifying that the shellfish have been treated by irradiation or treated with radiation. However, PHP irradiation facilities that irradiate shellfish may not have the capability to also label the shellfish as irradiated; such facilities can only irradiate the shellfish, not label them. As such, the primary processor may pre-label the pallets of shellfish as irradiated and may also provide a statement detailing Vibrio reduction.

For dealers who ship shellfish to an irradiation facility in containers that have been pre-labeled as irradiated with vibrio reduction information the following guidelines provide additional detail:

- A signed agreement should be in place between the irradiation facility and the primary certified shellfish dealer specifying the post office addresses of each party and outlining the specifications needed to ensure that the pre-labeled containers of shellfish do, in fact, undergo the validated irradiation process set forth within the agreement.

- Both the primary shellfish dealer and the irradiation facility must each have an implemented HACCP plan to ensure that shellfish pre-labeled as irradiated undergo the validated irradiation process set forth in the agreement.

- The agreement should provide for transport of the shellfish in sealed trucks and the transport should be secured with a tamperproof seal at the primary certified dealer and a record should be made of the seal number.

- The agreement should also establish that the oyster shellstock is washed, sorted, and placed into pre-labeled containers by the primary certified shellfish dealer.

- The agreement should specify how to palletize pre-packaged and pre-labeled oyster containers.

- Pallets of oyster containers shall be clearly labeled with the words "TO BE IRRADIATED."

- The number of pre-labeled containers should be documented in a HACCP record and in an additional record to be provided to the operator at the irradiation facility. This transport should be limited to pallets of shellfish to be irradiated and no other seafood or shellfish products.

- When the transport arrives, the irradiation facility operator may remove the seal, record the number of containers, verify the number of containers in the transport matches the record provided by the primary certified dealer and then record the number of containers in the irradiation facility's HACCP record.

- The irradiation facility operator shall record all other required HACCP receiving critical limit information in HACCP records.

- Irradiated shellfish shall be placed in cooler storage or on transports maintained at the appropriate temperature (cooler maintained at 45 degrees and transport pre-chilled to 45 degrees).

- Irradiated shellfish shall be segregated from other seafood or shellfish products.

- The irradiation facility shall also have implemented a HACCP plan that includes the critical control points for receiving, the irradiation process, and refrigerated storage.

Public Health Significance: Vibrio bacteria are predominately found in estuarine environments and naturally present in most shellfish. Most cases of disease attributed to Vibrio species are

associated with the consumption of raw molluscan shellfish, particularly raw oysters and hard clams. Vibrio-related sicknesses can cause severe illness, including mortality. The most common Vibrio species found in shellfish are *Vibrio vulnificus* (*V.v.*) and *Vibrio parahaemolyticus (V.p.*). *V.v.* is associated with 95 percent of all seafood-related deaths in the United States. Thus, Vibrio species in uncooked molluscan shellfish provide a significant public health risk which may be minimized by enabling industry to streamline this process for irradiation PHP.

Cost Information (if available):

Action by 2013 Task Force II Recommended adoption of Proposal 13-226 as submitted.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 13-226.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-226.

Proposal Subject: Eliminate Requirements for the Authority to Retain Records of a Trade Secret or Proprietary Nature. Such records to be available at the dealer's place of business during normal business hours.

Specific NSSP Guide Reference:
NSSP Guide Section II. Model Ordinance
Chapter V. Shellstock Relaying @.01 General D.;
Chapter V. Shellstock Relaying @.02 Contaminant Reduction B.; and
Chapter XV. Depuration Requirements for the Authority E. (1) and (2)

Text of Proposal/ Requested Action

Chapter V. @.01

D. The ~~Authority~~ dealer shall retain records covering all aspects of the establishment of the heat shock process.

Chapter V. @.02

B. The person responsible for conducting the study ~~Authority~~ shall retain the written study report indefinitely.

Chapter XV. Requirements for the Authority

~~E. The Authority shall maintain adequate records for each depuration facility. The following records for each facility shall be kept for the period of five years: (1) Inspection reports and reviews of the plant performance in accordance to Section D. (above); (2) Current Depuration Plant Operations Manual for each dealer (Section .03).~~

Delete all other elements that require the Authority to keep on file or retain records of a trade secret or proprietary nature. Such records will be required to be maintained at the dealer facility and available to the authority for review during normal business hours.

Public Health Significance: There is no cost to the Authority to eliminate these requirements.

Cost Information (if available): Freedom of Information Act (and similar state act) requests can be time consuming, costly, and detract from public health activities of the Authority. Industry should be required to make records available to the Authority at the dealer's facility during normal business hours. Requiring the Authority to collect and maintain such records that may be subject to Freedom of Information Act release undermines the relationship of industry and regulators and further serves as a disincentive for businesses to conduct research, innovate and develop new products, processes and procedures

Action by 2013 Task Force II Recommends adoption of Proposal 13-227 as amended.

Chapter V. @.01

D. The Authority shall retain records covering all aspects of the establishment of the heat shock process.

Chapter V. @.02

~~B. Authority shall retain the written study report indefinitely.~~

Chapter XV. Requirements for the Authority

E. The Authority shall maintain adequate records for each depuration facility. The following records for each facility shall be kept for the period of five years: (1) Inspection reports and reviews of the plant performance in accordance to Section D. (above); ~~(2) Current Depuration Plant Operations Manual for each dealer (Section .03).~~

~~Delete all other elements that require the Authority to keep on file or retain records of a trade secret or proprietary nature. Such records will be required to be maintained at the dealer facility and available to the authority for review during normal business hours.~~

Proposal Subject: Press Releases

Specific NSSP Guide Reference: Section II Model Ordinance Chapter II. Risk Assessment and Risk Management

Text of Proposal/ Requested Action: The US FDA issued press releases associated with outbreaks in the Pacific Northwest in the summer of 2006 and in Texas in March of 2007. These press releases created concern regarding the appropriateness and effectiveness of press releases as a public health measure to address an illness outbreak.
Use of press is to inform consumers.

The ISSC Executive Board discussed the issuance of these press releases and directed the formation of a working group to further investigate and review the use of press by state and federal agencies. The workgroup is to look for ways to coordinate use of press and provide recommendations for discussion at the 2007 Biennial Meeting.

Public Health Significance:

Cost Information (if available):

Action by 2007 Use of Press Committee Recommended that this Committee continue its deliberations and that a meeting be held in January 2008 in conjunction with appropriate FDA officials and report back to the Executive Board in March 2008. In the interim FDA will consult with the involved state regulatory agency on the content and timing of the release of press.

Action by 2007 Task Force III Recommended adoption of the Press Release Committee recommendation on Proposal 07-305.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force III.

Action by USFDA December 20, 2007
Concurred with Conference action

Action by 2009 Use of Press Committee The Committee held a conference call on March 13, 2008, and planned a meeting in Washington, DC for April 30, 2008. The plans for this meeting were reported to the Executive Board on April 3, 2008.

On April 30, 2008, several members of the Committee and the ISSC Executive Director met with FDA officials at FDA headquarters and discussed agency procedures regarding use of press. The discussions of this meeting were presented to the Executive Board at the September 11, 2008, Executive Board meeting. The Committee reported that it is working to develop a press protocol for use in addressing press releases associated with outbreaks and product recall

The Committee held a meeting at the 2009 Biennial Conference and is continuing to develop a press protocol. The Committee will continue to fine tune a list of issues to be considered when use of press is contemplated. This list should be incorporated into NSSP Guidance Documents that address outbreaks and product recall.

Action by 2009 Task Force III Recommended adoption of the Use of Press Committee recommendations on Proposal 07-305. Additionally, the Task Force recommended the Committee address the use of

press in situations where significant time lapses have occurred between the last reported illness and the proposed use of press. The protocol should address the rationale for using press in situations where product is not likely to still be available for consumption.

Task Force III further recommended the Use of Press Committee complete the protocol and present the protocol to the Executive Board at the 2010 Spring Meeting. In the interim, as noted in the March 13, 2008, Use of Press Committee report, FDA should be requested to continue to consult with the involved State regulatory agencies on the content and timing of press releases.

Action by 2009 General Assembly

Adopted recommendation of 2009 Task Force III on Proposal 07-305.

Action by USFDA 02/16/2010

Concurred with Conference action on Proposal 07-305.

Action by 2011 Use of Press Committee

Recommended to the Executive Board that the ISSC request that the FDA Core Group coordinate with the ISSC Use of Press Committee concerning use of press protocols. Criteria should include whether suspect product has been accounted for and the degree of public health risk. The Code of Federal Regulations protocols for use of press should be a guiding document as was the case for recall protocols developed by ISSC and FDA.

The Committee requested that a work group be appointed to craft a decision tree using the work done to date and the CFR guidance.

Members of the Committee that have volunteered for the work group include: Leslie Palmer, Chair; Maryanne Guichard; Don Ullstrom; Bill Dewey; Mike Antee; Tom Mahan; Lori Howell; and Mike Hickey.

Action by 2011 Task Force III

Recommended referral of Proposal 07-305 to an appropriate committee as determined by the Conference Chairman to continue to address the recommendations outlined in the 2011 Use of Press Committee report.

Action by 2011 General Assembly

Adopted the recommendation of Task Force III on Proposal 07-305.

Action by FDA February 26, 2012

Concurred with Conference action on Proposal 07-305.

Action by 2013 Use of Press Committee

Developed recommendation on use of press which were submitted to the USFDA for incorporation into the CORE SOP. The committee further recommended:

1. The committee review and discuss the new CORE document which was effective on 01/16-2014.
2. The committee continue to monitor use of press under the CORE SOP

Action by 2013 Task Force III

Recommended adoption of Use of Press Committee recommendations on Proposal 07-305. The Task Force further recommended that the committee report its findings to the Executive Board.

Action by 2013 General Assembly

Adopted recommendations of Task Force III on Proposal 07-305.

Action by FDA Concurred with Conference action on Proposal 07-305.
May 5, 2014

Proposal Subject: ISSC State Membership Fees

Specific NSSP Guide Reference: ISSC Constitution, Bylaws, and Procedures
Article III. Registration and Fees

Text of Proposal/ Requested Action:

Section 4. There shall be two (2) categories of membership:

Subdivision a. State
Subdivision i. Shellfish producing states
Subdivision ii. Non-producing states

Subdivision b. Individual Member

The fee for each category of membership and the membership period shall be set by the Executive Board. The membership fees may be paid annually or biennially. The state authority membership dues shall include membership for one Voting Delegate. State membership shall be set to provide for forty (40%) per cent and individual membership shall be set to provide for five (5%) per cent of the previous ISSC fiscal year budget. Persons other than Voting Delegates shall be considered members by payment of the individual membership fee. The membership period shall coincide with the calendar year. Applications for membership shall be mailed at least thirty (30) days prior to the beginning of the membership period to the two (2) previous years' membership rolls.

Public Health Significance:

Cost Information (if available):

Action by 2011 Task Force III Recommended referral of Proposal 11-302 to the appropriate committee as determined by the Conference Chairman.

Action by 2011 General Assembly Adopted the recommendation of Task Force III on Proposal 11-302.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-302.

Action by 2013 Executive Committee

Note: The Executive Committee consulted with the Executive Board in the development of the committee recommendations on Proposal 11-302

Executive Board Policy on Use of Membership Funds

The purpose of this policy is to outline how the ISSC will utilize state membership funds. The recommended state membership fees are established to support 10% of the ISSC projected budget. Presently the majority of ISSC funding is made available from NOAA and USFDA. Should the present federal funding continue to support the ISSC projected budget, state membership fees will be made available to states in the form of travel assistance to the biennial meeting or Executive Board meeting. The level of travel assistance will not exceed the amount of the state membership fees paid.

	Biennial Meeting Year	Non-Biennial Meeting Year
Producing States	1350	1000
Non-Producing States	1000	1000

Article III. Membership and Registration ~~and Fees~~

Procedure XVIII. Executive Board Procedures for Establishing Membership Fees

ARTICLE III. MEMBERSHIP AND REGISTRATION ~~AND FEES~~

Section 1. The membership and registration fees shall be set by the Executive Board as necessary to defray the costs of the Biennial Meeting and the operating costs of the Conference.

Section 2. Membership Fees

Subdivision a. The fee for each category of membership and the membership period shall be set by the Executive Board. State membership fees will be established as necessary to provide, at a minimum, ten percent (10%) of the operating budget of the Conference. The Executive Board will follow the guidelines of Procedure XVIII in establishing membership fees.

Subdivision b. There shall be two (2) categories of membership:

Subdivision i. State

Subdivision (a) Shellfish producing states

Subdivision (b) Non-producing states

Subdivision ii. Individual member

Subdivision c. The membership fees may be paid annually or biennially.

Subdivision d. The State authority membership fees shall include membership for one Voting Delegate. Persons other than Voting Delegates shall be considered members by payment of the membership fee.

Subdivision e. The membership period shall coincide with the calendar year.

Subdivision f. Applications for membership shall be mailed at least thirty (30) days prior to the beginning of the membership period to the two (2) previous years' membership rolls.

Section 3. Registration Fees

Subdivision a. Registration fees shall include those amounts required by Article V. Section 9. of this Constitution.

Subdivision b. Any person who is interested in promoting the availability of safe, wholesome shellfish may register at the Conference meeting.

Subdivision c. Persons attending and participating in a Conference meeting must first register their name, address, and

affiliation with the Executive Director and pay the appropriate registration fee.

~~**Section 1.** Any person who is interested in promoting the availability of safe, wholesome shellfish may register at the Conference meeting.~~

~~**Section 2.** Persons attending and participating in a Conference meeting must first register their name, address, and affiliation with the Executive Director and pay the appropriate registration fee.~~

Section 3. ~~Registration fees shall include those amounts required by Article V., Section 9. of this Constitution.~~

~~**Section 4.** There shall be two (2) categories of membership:~~

~~Subdivision a. State~~
~~Subdivision i. Shellfish producing states~~
~~Subdivision ii. Non-producing states~~
~~Subdivision b Individual Member~~

~~The fee for each category of membership and the membership period shall be set by the Executive Board. The membership fees may be paid annually or biennially. The state authority membership dues shall include membership for one Voting Delegate. Persons other than Voting Delegates shall be considered members by payment of the membership fee. The membership period shall coincide with the calendar year. Applications for membership shall be mailed at least thirty (30) days prior to the beginning of the membership period to the two (2) previous years' membership rolls.~~

Section 5. The Board Chairperson, with the approval of the Board, shall appoint a non-voting Consumer Advisory representative. The Consumer Advisor shall serve a two (2) year term. The initial Consumer Advisory term shall be one (1) year to coincide with the Biennial meeting schedule.

Section 6. Each Board member and alternate must be a member when elected. For producing state and non-producing state elections, each state may cast one (1) vote by the authorized ISSC Voting Delegates (or alternates). For industry elections, industry registrants within each state may cast one (1) collective vote. Industry may caucus among its registrants in order to determine the voting member.

Section 7. Elected Board members shall serve four-year terms. Terms of the elected Board members shall expire at the end of the voting General Assembly of the regular Biennial Conference meeting.

Section 8. The Board shall elect a Chairperson and Vice-Chairperson for a two, (2) year term at the Executive Board meeting following the voting General Assembly of the regular Biennial Conference meeting. New officers shall take office at the beginning of the Spring Executive Board meeting.

~~**Section 9.**~~ The Board shall direct the Executive Director to collect membership and registration fees. ~~as necessary to defray the costs of the meeting~~

~~and operation of the Conference.~~ The Executive Director shall pay all bills approved by the Board. ~~The registration fee amount shall be set by the Board.~~ The Board shall cause an audit to be made of the Executive Director's financial report annually. The Board shall direct the Executive Director to prepare annually a written financial report listing all receipts, expenditures, and financial balance of the ISSC for the previous year. A copy of the financial report shall be distributed to the membership at each Biennial Meeting.

Section 10. The Board shall authorize the form used to tally and record votes in Board meetings and Conference meetings.

Section 11. The Board shall direct the Executive Director to prepare written minutes of all Board meetings and make copies of such minutes for the previous two years available to the ISSC membership on the ISSC website at www.issc.org.

PROCEDURE XVIII. EXECUTIVE BOARD PROCEDURES FOR ESTABLISHING MEMBERSHIP FEES

Section 1. The ISSC Executive Board will follow the guidelines of Procedure XVIII in establishing membership fees for State and individual members.

Subdivision a. Membership fees will be established as necessary to provide at a minimum, ten (10) percent of the operating costs of the ISSC.

Subdivision b. The Executive Board will consider appropriate changes to the minimum of ten percent (10%) should decreases in other funding sources occur.

Subdivision c. The Executive Board will allocate travel assistance to member States when the revenue acquired from membership fees is not critical to supporting the Conference operating budget.

Action by 2013 Task Force III Recommended adoption of the Executive Committee recommendation on Proposal 11-302.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force III on Proposal 11-302.

Proposal Subject: ISSC Constitutional Cost-Benefit Requirement for New Proposals that have a Significant Financial Impact on the States and Shellfish Industry

Specific NSSP Guide Reference:

Text of Proposal/ Requested Action: Article XIII. Procedure for the Submission of Proposals

Section 1. The Executive Director shall provide each registrant of the preceding Conference meeting at least one hundred sixty-five (165) days prior to the next Conference meeting with forms on which proposal for problems are to be submitted to the Executive Director for assignment to the appropriate Task Force.

Section 2. All proposals must be submitted to the Executive Office no later than one hundred twenty (120) days prior to the Conference meeting.

Section 3. Proposals submitted by any Conference participants requiring Conference action are to be referred to the Executive Director for assignment to the appropriate Task Force.

Section 4. Proposals submitted by any Conference participant that may have a significant cost to implement by either the SSCA or the shellfish industry must include an independent cost benefit analysis and an economic impact study.

Section 5~~4~~. The Executive Director shall review and assign all problems or proposals received for Task Force and Conference deliberation. Problem or proposal assignment shall be made according to subject matter and in accordance with Article XIII. Section 4., Section 5., Section 6., and Section 7. of the Constitution of the Conference.

Section 6~~5~~. Task Force I - Growing Areas: all proposals submitted to the Conference dealing with the classification or patrol of shellfish growing waters, relaying, training and research, or similar items concerning growing areas shall be assigned to Task Force I by the Executive Director.

Section 7~~6~~. Task Force II – Harvesting, Handling, and Distribution: all proposals submitted to the Conference dealing with the sanitation of harvesting, depuration, processing, labeling, transporting, storage, fill or content, training and research, or similar items concerning processing and distribution shall be assigned to Task Force II by the Executive Director.

Section 8~~7~~. Task Force III - Administration: all proposals submitted to the Conference dealing with Conference agreements, memorandums of understanding, complaints and challenges of reciprocity and program evaluations, or similar items, or items not specifically relating to Task Force I or II shall be assigned to Task Force III by the Executive Director.

Section 9~~8~~. The Executive Director shall provide the appropriate shellfish control authorities in each state and all members, at least ninety (90) days prior to each Conference meeting, with the proposals to be discussed under the heading of Unfinished Business.

Section 10~~9~~. Proposals submitted after the deadline, established in Article XIII Section 2 of the Constitution, will be reviewed and may be accepted by the Executive

Board for Task Force Consideration. The Executive Board will use the following criteria in accepting late proposals.

Subdivision a. Why is the proposal being submitted after the deadline?
Subdivision b. Was the information available prior to the deadline?
Subdivision c. What is the criticality of the proposal to the safety of molluscan shellfish or the future of the ISSC?
Subdivision d. Does the proposal involve an NSSP Guide for the Control of Molluscan Shellfish change or an ISSC administrative change?

Section 11~~10~~. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid.

Section 12~~11~~. The Proposal Review Committee will review and prioritize proposals for Task Force consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.

Public Health Significance: Cost-Benefit Analyses and Economic Impact Studies are required by Federal and State Agencies prior to imposing new regulations. For too many years the ISSC through amendments made to the NSSP without any regards to the costs imposed on the SSCA and Shellfish Industry to implement the new guidelines.

Cost Information (if available): The cost to conduct cost-benefit analyses and economic impact studies will be much less on the SSCA'S and Shellfish Industry than the cost to implement by the SSCA's or by the shellfish industry.

Action by 2011 Task Force III Recommended referral of Proposal 11-305 to the appropriate committee as determined by the Conference Chairman. The committee is instructed to identify ways to better utilize the cost information portion of the proposal submission form.

Action by 2011 General Assembly Adopted the recommendation of Task Force III on Proposal 11-305.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-305.

Action by 2013 Proposal Review Committee Recommended no action on the proposed change to the procedures for submission of Proposals. The committee further recommended that an appropriate committee, as determined by the Conference Chair, work with the Executive Office to develop Proposal Submission Instructions. In addition to technical instructions about how to use the form, the instructions should address each field of the submission form and shall be completed prior to the next call for proposals. The instructions for the "cost" field should provide further guidance, including examples, of the type of cost information that may be useful to those reviewing the proposal.

Action by 2013 Task Force III Recommended adoption of the Proposal Review Committee recommendations.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force III on Proposal 11-305.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 11-305.

H.R.2751
FDA Food Safety Modernization Act
SEC. 114. REQUIREMENT FOR GUIDANCE RELATING TO POST HARVEST PROCESSING OF RAW OYSTERS.

(a) In General- Not later than 90 days prior to the issuance of any guidance, regulation, or suggested amendment by the Food and Drug Administration to the National Shellfish Sanitation Program's Model Ordinance, or the issuance of any guidance or regulation by the Food and Drug Administration relating to the Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration (parts 123 and 1240 of title 21, Code of Federal Regulations (or any successor regulations), where such guidance, regulation or suggested amendment relates to post harvest processing for raw oysters, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report which shall include--

(1) an assessment of how post-harvest processing or other equivalent controls feasibly may be implemented in the fastest, safest, and most economical manner;
(2) the projected public health benefits of any proposed post-harvest processing;
(3) the projected costs of compliance with such post-harvest processing measures;
(4) the impact post-harvest processing is expected to have on the sales, cost, and availability of raw oysters;
(5) criteria for ensuring post-harvest processing standards will be applied equally to shellfish imported from all nations of origin;
(6) an evaluation of alternative measures to prevent, eliminate, or reduce to an acceptable level the occurrence of foodborne illness; and
(7) the extent to which the Food and Drug Administration has consulted with the States and other regulatory agencies, as appropriate, with regard to post harvest processing measures.

(b) Limitation- Subsection (a) shall not apply to the guidance described in section 103(h).

(c) Review and Evaluation- Not later than 30 days after the Secretary issues a proposed regulation or guidance described in subsection (a), the Comptroller General of the United States shall--

(1) review and evaluate the report described in (a) and report to Congress on the findings of the estimates and analysis in the report;

(2) compare such proposed regulation or guidance to similar regulations or guidance with respect to other regulated foods, including a comparison of risks the Secretary may find associated with seafood and the instances of those risks in such other regulated foods; and

(3) evaluate the impact of post-harvest processing on the competitiveness of the domestic oyster industry in the United States and in international markets.

(d) Waiver- The requirement of preparing a report under subsection (a) shall be waived if the Secretary issues a guidance that is adopted as a consensus agreement between Federal and State regulators and the oyster industry, acting through the Interstate Shellfish Sanitation Conference.

(e) Public Access- Any report prepared under this section shall be made available to the public.

United States Senate
WASHINGTON, DC 20510

January 25, 2011

Mr. Ken Moore
Executive Director
Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223

Dear Mr. Moore:

As you know, Congress recently passed P.L. 111-353 the "FDA Food Safety Modernization Act." We were proud to author section 114 of the law pertaining to the regulation of raw oysters. We wrote this language to provide the Secretary a waiver only if state regulators, the oyster industry, and Interstate Shellfish Sanitation Conference's, (ISSC), voting delegates approved the regulation or guideline proposed by the Food and Drug Administration or ISSC. As the ISSC moves forward, we wanted to clarify the intent of section 114(d) which states:

> Waiver- The requirement of preparing a report under subsection (a) shall be waived if the Secretary issues a guidance that is adopted as a consensus agreement between Federal and State regulators and the oyster industry, acting through the Interstate Shellfish Sanitation Conference.

This clearly states that the oyster industry through ISSC should be an intricate part of the process. Specifically, the language is intended to ensure that new guidelines or regulations cannot move forward without the consensus from the oyster industry.

Thank you for the opportunity to clarify the intent of Congress in these matters. We look forward to working with you and the Interstate Shellfish Sanitation Conference on the implementation of the FDA Food Safety Modernization Act.

Sincerely,

David Vitter
United States Senator

Mary Landrieu
United States Senator

Proposal Subject: Determining Effectiveness of NSSP Changes

Specific NSSP Guide Reference: ISSC Constitution, Bylaws, and Procedures Article I. Task Forces
Procedure X. Procedure for Handling ISSC Summary of Actions

Text of Proposal/ Requested Action:

Article I. Task Forces

Section 6. Each Task Force shall deliberate all proposals during the times specified at the Conference meeting. Each Task Force Chairperson shall report the actions recommended by his/her respective Task Force to the voting delegates at the Conference under the heading of New Business for final Conference consideration. Any "No Action" recommended by a Task Force shall contain the reasons for the "No Action" recommendation. The Task Force will designate each proposal with a determination of cost of implementation. The designation will be all of the following:

Subdivision a. Significant costs to industry.

Subdivision b. Significant costs to State Shellfish Control Authority.

Subdivision c. Insignificant costs.

Procedure X. Procedure for Handling ISSC Summary of Actions

Section 5. All NSSP changes that have significant costs will be reviewed and assessed for effectiveness. This assessment will occur as part of the Conference meeting held in the fourth calendar year following adoption of the change. Those changes that are determined to be ineffective will be deleted.

Public Health Significance: N/A

Cost Information (if available):

Action by 2011 Task Force III Recommended referral of Proposal 11-306 to the appropriate committee as determined by the Conference Chairman.

Action by 2011 General Assembly Adopted the recommendation of Task Force III on Proposal 11-306.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-306.

Action by 2013 Program Review Committee Recommended adoption of Proposal 11-306 with the following substitute language:

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, Shellfish Restoration, *Vibrio* Management Committee, and Model Ordinance Effectiveness Review 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 15. The Executive Board Chairperson shall appoint a thirteen (13) member Model Ordinance Effectiveness Review Committee. The Committee will be comprised of a Chairperson with at least (1) industry members from the East, Gulf and West coasts, at least one (1) state regulatory from each of the ISSC regions and at least one (1) state regulatory person from a non-producing state. The Committee will also include one voting member from NOAA, one voting member from FDA and one voting member from EPA. The Federal entities will appoint these members. This Committee will review the requirements of the NSSP Model Ordinance and identify requirements that are deemed to be ineffective. The Committee will present recommendations in proposal form to the appropriate Task Force for the deletion or modification of ineffective requirements; or requirements that are excessively costly for the intended public health benefit. New requirements will not be reviewed until the fourth year following the implementation date. A four year waiting period will provide adequate time to determine effectiveness of new controls.

Note: Initially the Committee will review all of the requirements in the NSSP that have been in existence for four (4) years or more. Following the initial review, the procedure outlined above would be followed by the Committee prior to the proposal submission deadline.

Action by 2013 Task Force III Recommended adoption of the recommendation of the Program Review Committee as amended.

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, Shellfish Restoration, *Vibrio* Management Committee, and Model Ordinance Effectiveness Review Committee. The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of

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Note: Initially the Committee will review all of the requirements in the NSSP that have been in existence for four (4) years or more. Following the initial review, the procedure outlined above would be followed by the Committee prior to the proposal submission deadline.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force III on Proposal 11-306.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 11-306.

Proposal Subject: Internal Authority Self-Assessment Using a National Program Standards Manual

Specific NSSP Guide Reference: Section II Model Ordinance
Chapter I Shellfish Sanitation Program Requirements for the Authority
@.01 Administration

Text of Proposal/ Requested Action

@.01 Administration

A. Scope…
B. State Law and Regulations…
C. Records…
D. Shared Responsibilities…
E. Administrative Procedures…
F. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness…
G. Commingling…
H. Program Evaluation. The Authority shall conduct a self-assessment using the National Program Standards Manual and report annually to the U.S. Food and Drug Administration the results of the assessment.

Public Health Significance: The purpose of this proposal is to begin discussions on how a self-assessment can be used by Authorities to conduct a comprehensive evaluation of their ability to promote the protection of public health. An assessment conducted by an Authority may encourage continuous improvement and innovation and can assure that individual program activities provide comparability among other domestic and international shellfish programs. The evaluation can be used to assist both the FDA and shellfish Authorities in fulfilling regulatory obligations and ensuring the implementation of the requirements set forth in the NSSP Model Ordinance

Cost Information (if available)

Action by 2011 Task Force III Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairman.

Action by 2011 General Assembly Adopted the recommendation of Task Force III on Proposal 11-310.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-310.

Action by 2013 NSSP Evaluation Criteria Committee Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairperson with the following instructions.

Establish a workgroup to evaluate the Manufactured Food Standards and determine the applicability of and/or use of these Manufactured Standards to the National Shellfish Sanitation Model Ordinance requirements and report their findings and recommendations to the NSSP Evaluation Criteria Committee at the next ISSC Meeting.

The Committee further recommended that self-assessments should be voluntary and that the word “shall” should be replaced with the word “may”.

Action by 2013 Task Force III Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-310.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force III on Proposal 11-310.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 11-310.

Proposal Subject: State Program Evaluation Criteria

Specific NSSP Guide Reference: ISSC Constitution, Bylaws, and Procedures
NSSP Guide Model Ordinance Chapters and Guidance Documents

Text of Proposal/ Requested Action The ISSC has adopted State Program Evaluation Criteria for several program elements including laboratory, patrol, and processing plants. These evaluation criteria are incorporated into the NSSP as follows:

Laboratory:
Model Ordinance Chapter II and
Guidance Documents Chapter II Growing Areas
.12 and Shellfish Laboratory Evaluation Checklists

Patrol:
Model Ordinance Chapter VIII;
Guidance Documents Chapter I General .03; and
Guidance Documents Chapter II Growing Areas .09

Shellfish Plant Inspection Program:
ISSC Constitution, Bylaws, and Procedures
Procedure XV

The purpose of this proposal is to move all NSSP evaluation criteria used by the USFDA to evaluate State program elements into a new Model Ordinance Chapter XVII. This proposed change will not involve modification of any criteria. The purpose is to locate all State evaluation criteria into one central location. Presently the criteria are difficult to locate.

Public Health Significance: The proposed change does not have public health significance.

Cost Information (if available):

Action by 2013 Task Force III Recommended referral of Proposal 13-300 to an appropriate committee as determined by the Conference Chairman.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force III on Proposal 13-300.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-300.

Proposal Subject: Growing Area Classification Criteria

Specific NSSP Guide Reference: To Be Determined

Text of Proposal/ Requested Action The ISSC has adopted evaluation criteria for several program elements within the NSSP. These include laboratories, plant sanitation, and patrol. The development of these criteria has seemed to provide a better understanding of expectations, improve uniformity in State evaluations and enhance compliance. The ISSC should expand its evaluation criteria efforts to include growing area classification. Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification. Although more complex, this element of the program could benefit from the development of evaluation criteria. The purpose of this proposal is to request the Evaluation Criteria Committee be charged with the task of developing evaluation criteria for the growing area element.

Public Health Significance: Growing area classification criteria will enhance State classification efforts and ensure a high level of uniformity and effectiveness in FDA evaluations.

Cost Information (if available):

Action by 2013 Task Force III The submitter of Proposal 13-301 requested that the following sentence be deleted from the proposal.

~~Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification.~~

The Task Force recommended adoption of Proposal 13-301 with the amendment as requested by the submitter.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force III on Proposal 13-301.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-301.

Proposal No. 13-302

Proposal Subject:	Executive Board Voting
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws and Procedures, Article IV. Executive Board Officers, Committees Section 2.
Text of Proposal/ Requested Action	The Board shall be comprised of eighteen (18) voting members selected as follows……. Only those members of the Executive Board representing shellfish producing states and non-producing states will have a vote for recommended changes to the NSSP Model Ordinance. Each shellfish producing state Executive Board member shall be entitled to one (1) full vote and each non-producing state shall be entitled to (1) vote in Executive Board meetings with the exception of issues involving recommendations Task Force I.
Public Health Significance:	Voting with regard to changes to the NSSP Model Ordinance by the Executive Board should be the same as the Biennial Meeting of the ISSC Voting Delegates.
Cost Information (if available):	
Action by 2013 Task Force III	Recommended no action on Proposal 13-302. Rationale: The Constitution, Bylaws and Procedures adequately address Executive Board voting.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-302.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-302.

Proposal Subject:	ISSC Executive Board Retail Advisor
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws, and Procedures Article IV. Executive Board, Officers, Committees
Text of Proposal/ Requested Action	Section 5. The Board Chairperson, with the approval of the Board, shall appoint a non-voting Consumer Advisory representative and a Retail Advisory representative. The Consumer Advisor and the Retail Advisor shall serve a two (2) year term. The ~~initial~~ Consumer Advisory term and Retail Advisor term shall ~~be one (1) year to~~ coincide with the Biennial meeting schedule.
Public Health Significance:	
Cost Information (if available):	
Action by 2013 Task Force III	Recommended adoption of Proposal 13-303 as submitted.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-303.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-303.

Proposal Subject:	ISSC Proposal Review Committee
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws, and Procedures Article IV. Executive Board, Officers, Committees
Text of Proposal/ Requested Action	Section 13. The Executive Board Chairperson shall appoint a 12-member Proposal Review Committee. The Committee will be comprised of a Chairperson and four (4) regulatory members, four (4) industry members, and a representative from the FDA, NOAA, and EPA. The Committee will review and link ~~prioritize~~ proposals for Conference consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.
Public Health Significance:	
Cost Information (if available):	
Action by 2013 Task Force III	Recommended adoption of Proposal 13-304 as submitted.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-304.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-304.

Proposal Subject: Executive Board Interim Changes to NSSP Model Ordinance

Specific NSSP Guide Reference: ISSC Constitution, Bylaws & Procedures

Text of Proposal/ Requested Action

Article V. Duties of the Board

Section 1. The Board shall manage the affairs of the Conference. The Board may not act on behalf of the Voting Delegates between voting Conference meetings unless directed to do so by 2/3 vote from the voting delegates at the general assembly of the last meeting. The Board may act on behalf of the Voting Delegates in the case of a public health emergency or event that requires changes in the NSSP. ~~in keeping with the spirit and intent of the delegates.~~ Any decision or action taken by the Board which would require Voting Delegate approval in accordance with the remainder of this Constitution, By-Laws, or Procedures, shall be submitted as a proposal to the next voting meeting for concurrence or correction.

Public Health Significance: Interim changes to the Model Ordinance implemented by the Executive Board between Biennial Meetings of the ISSC have caused angst to some of the voting members of the conference. Changes to the Model Ordinance should be deliberated by the full Conference prior to implementation and evaluation of a State program by USFDA for compliance. Many changes require regulatory changes that States have difficulty promulgating since there has not been an opportunity to fully understand or embrace these changes or the possibility of these interim requirements to change at the next Biennial Meeting of the ISSC. It makes it extremely difficult for States to consider the sometimes long and tedious process of regulatory change when in fact the Voting Delegates might change the items implemented by the Board. Changes to the NSSP Model Ordinance need to be deliberated and considered by full participation of the Voting Delegates of the ISSC.

Cost Information (if available): This change could possibly be a cost savings since States would not have to change regulations as often and regulation changes would be thoroughly vetted by the Voting Delegates of the ISSC.

Action by 2013 Task Force III Recommended no action on Proposal 13-305.

Rationale: The Constitution, Bylaws and Procedures adequately address Executive Board voting.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force III on Proposal 13-305.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-305.

Proposal No. 13-306

Proposal Subject: ISSC Biennial Meeting

Specific NSSP Guide Reference: ISSC Constitution, Bylaws, and Procedures
Article XI. Rules of Biennial Conference Meetings

Text of Proposal/ Requested Action

ARTICLE XI. Rules of Annual~~Biennial~~ Conference Meetings

Section 1. Except for special meetings, as provided for in Article V., Section 5. of this Constitution, the Conference will convene a meeting annually ~~through 1999 and biennially during the odd numbered years thereafter~~ and will rotate it among the different Regions of the country.

NOTE: If adopted, all other references to Biennial in the ISSC Constitution, Bylaws, and Procedures will be changed to annual.

Public Health Significance:

Cost Information (if available):

Action by 2013 Task Force III Recommended adoption of Proposal 13-306 as submitted.

The Task Force further recommended an implementation date of 2016. The next Biennial Meeting will be held in 2015 and subsequent meetings would then be held annually. The Task Force recommended that the Executive Board explore condensing the meeting schedule to reduce the number of meeting days.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force III on Proposal 13-306.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-306.

Proposal No. 13-307

Proposal Subject: Voting by the State Delegates

Specific NSSP Guide Reference: Constitution, Bylaws & Procedures of the ISSC (Updated March 28, 2013) Constitution of the Interstate Shellfish Sanitation Conference Article XI. Rules of Biennial Conference Meetings

Text of Proposal/ Requested Action

Article XI. Rules of Biennial Conference Meetings

Section 3. Business Rules of Conference Meetings

Subdivision a. Robert's Rules of Order shall prevail, unless specific rules are established by the Conference.

Subdivision b. Each shellfish producing State shall be entitled to one (1) full vote in the Conference meeting general assembly and each nonproducing State shall be entitled to one (1) vote in the Conference meeting General Assembly with the exception of ~~issues~~ proposals involving Task Force I recommendations and Task Force II proposals involving harvesters or their activities. Non-producing States shall be entitled to one-half (1/2) vote on proposals involving Task Force I recommendations or Task Force II proposals involving harvesters or their activities.

Public Health Significance: Non-producing States may not have the necessary insight and experience related to factors that impact harvesters and those responsible for regulating/enforcing them. For proposals that require State Regulatory changes impacting harvesters, more weight of the vote should be given to growing area States.

Cost Information (if available): This change could possibly be a cost savings since State agencies must consider economic impact to businesses when promulgating new regulations.

Action by 2013 Task Force III Recommended no action on Proposal 13-307.

Rationale: The Constitution, Bylaws and Procedures adequately address Delegate voting.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force III on Proposal 13-307.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-307.

Proposal Subject:	Changes to Procedure for Evaluation of Shellfish Sanitation Program Elements.
Specific NSSP Guide Reference:	ISSC Constitution, Bylaws & Procedures Procedure XV. Procedure for Evaluation of Shellfish Sanitation Program Elements
Text of Proposal/ Requested Action	**Refer to the *Proposals for Consideration at the 2013Biennial Meeting.***
Public Health Significance:	Current Infield Plant criteria automatically "fails" a plant even if the critical deficiency is address and corrected. This puts a plant in non-compliance but still operating which is inconsistent with the evaluation of deficiency follow-up in Subdivision v (f). States are deemed in compliance when evaluating deficiency follow-up when critical deficiencies have been addressed. During a plant inspection, the professional discretion of the inspector is used to determine the severity of the critical deficiency. In some cases a critical deficiency that is addressed and corrected at the time of inspection allows the plant to legally continue to process and sell product. Critical deficiencies that are addressed and corrected at the time of the infield Plant Sanitation Element should be consistent with this. Deficiencies with a criticality code of "Other" vary widely in public health significance and in many cases may be the result of normal wear or use during the operating season. This is especially true with items in Item 17; Plants and Grounds, and Item 21; Equipment Condition, Cleaning, Maintenance and Construction of Non-Food Contact Surfaces. Many of these "other" deficiencies are addressed prior to re-certification for the following season.
Cost Information (if available):	No cost to states or industry.
Action by 2013 Task Force III	Recommended referral of Proposal 13-308 to the NSSP Evaluation Criteria Committee.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-308.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-308.

Proposal Subject: NSSP Method Approval Review Process

Specific NSSP Guide Reference: ISSC Constitution, Bylaws, and Procedures
Procedure XVI. Procedure for the Approval of Analytical Methods for the NSSP

Text of Proposal/ Requested Action

Section 1. Prior to NSSP adoption, all laboratory methods shall be evaluated by the ISSC. ~~using the validation criteria developed as detailed in the Single Laboratory Validation Protocol;~~ Persons interested in submitting a method for inclusion in the NSSP must submit a pre-proposal outlining the following:

a. Description of Method;
b. Proposed Use of Method;
c. Time Table for SLV.

~~Section 2. All methods shall be submitted to the ISSC in proposal form requesting approval of the analytical method for use in the NSSP~~

~~Subdivision a.~~ ~~Proposals shall include a completed Single Laboratory Validation Method Application and Checklist.~~

~~Subdivision b.~~ ~~The ISSC Executive Director shall submit the proposal to the Laboratory Methods Review Committee for review and development of recommendations to Task Force I.~~

Section 2. The submitter of the proposal will be notified by the ISSC Executive Office of the action taken on the pre-proposal by the ISSC.

Section 3. Submitters of pre-proposals receiving approval will be requested to submit a full proposal to the ISSC and a liaison from the Laboratory Methods Review Committee will be assigned.

Section 4. The full proposal shall be submitted to the ISSC in proposal form requesting approval of the analytical method for use in the NSSP.

Subdivision a. All proposals shall include a completed Single Laboratory Validation Method Application and Checklist. AOAC approved methods that have undergone the AOAC Official Methods of Analysis (OMA) or FDA Office of Foods Level 3 or 4 validations may be accepted as an NSSP method without Single Lab Validation providing the AOAC or FDA multi-laboratory validation was performed in the raw molluscan shellfish matrix for which the Conference intends it to be used, and is deemed by ISSC as fit for purpose. Submitters of AOAC and FDA validated methods will provide a Single Laboratory Validation Method Application and Checklist along with the AOAC OMA or FDA Office of Foods Level 3 or 4 validation.

Subdivision b. The ISSC Executive Director shall submit the proposal to the Laboratory Methods Review and Quality Assurance Committee for review and development of recommendations to Task Force I.

Section 5. Within six (6) months of receipt the Laboratory Method Review and Quality Assurance Committee will review the proposal package for completeness and recommend to the Executive Board the suitability of the method for a full review for possible inclusion into the NSSP. The recommendation of the Executive Board will be presented to the ISSC Voting Delegates for approval.

Section ~~3~~6. Review by Laboratory Methods Review Committee;

Subdivision a. Within six (6) months of receipt of a complete application proposal, ~~T~~the Laboratory Methods Review Committee shall conduct an evaluation of the data which describes the performance characteristics of the ~~method~~ new proposal, the AOAC approved method or FDA Office of Foods Level 3 or 4 method;

Subdivision i. These performance characteristics include:

Subdivision (a) Accuracy (Trueness);
Subdivision (b) Measurement uncertainty;
Subdivision (c) Precision;
Subdivision (d) Recovery;
Subdivision (e) Specificity;
Subdivision (f) Linear range;
Subdivision (g) Limit of detection;
Subdivision (h) Limit of quantitation (sensitivity);

Subdivision (i) Ruggedness;
Subdivision (j) Comparability if applicable (comparison of the performance of the new/modified method to the accepted method.

Subdivision ii. Method documentation including:

Subdivision (a) Method title,

scope and references;

Subdivision (b) Equipment and reagents required;

Subdivision (c) Sample collection, preservation and storage requirements;

Subdivision (d) Safety requirements;

Subdivision (e) Step by step procedure;

Subdivision (f) Specific quality control measures associated with the method;

Subdivision (g) Cost of the method;

Subdivision (h) Sample turnaround time.

Subdivision iii. Specific application(s);

Subdivision b. Review of need for the method;

Subdivision i. Method meets an immediate or continuing need;

Subdivision ii. Improves analytical capability under the NSSP as an alternative to an accepted method(s);

. Subdivision iii Replaces other approved or accepted method(s).

Section 47. The Laboratory Methods Review Committee shall submit one of the following recommendations to Task Force I within six (6) months of receiving a complete proposal application for a method:

Subdivision a. Non-acceptance pending further information as defined by the Committee;

Subdivision b. Accept as an Approved NSSP Method;

Subdivision c. Accept as an Approved Limited Use NSSP Method;

Subdivision d. Accept as an Emergency Use NSSP Method.

Section ~~5~~8. Requests for ISSC recantation of an approved method shall be submitted using the ISSC proposal form. The request for recantation must include reason for the request, i.e. the need no longer exists, poor performance, equipment or reagents no longer available, etc.

Section ~~6~~9. Types of NSSP Analytical Methods.

Subdivision a. Approved NSSP Methods.

Approved NSSP methods are those accepted for use as permanent methods and cited in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. These methods have been long used in the NSSP or have completed the Single Laboratory Validation Method Protocol to show that the method is fit for purpose in the NSSP. Approved NSSP Methods have been:

Subdivision i Described in a scientific or other peer-reviewed professional publication;

Subdivision ii. Used successfully to detect or quantify;

Subdivision iii. Evaluated and the performance characteristics for specific applications have been determined and found fit for purpose;

Subdivision iv. Collaboratively studied and/ or collaboratively tested.

Subdivision b. Approved Limited Use Methods.

Approved Limited Use Methods are methods accepted for use in NSSP and listed in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. These methods are alternative methods within the NSSP that can meet an immediate need of the NSSP, improve turnaround time, cost effectiveness, and/or increase analytical capacity. Approved Limited Use Methods can include screening, provisional, or methods with limitations as defined by the LMRC evaluation of the method.

Subdivision c. Emergency Use Methods.

Emergency Use Methods are methods used to meet an immediate or ongoing critical need for a method of analysis and no NSSP approved method exists. Emergency Use Methods may be given interim approval by the ISSC Executive Board provided the following criteria are provided:

Subdivision i.	Name of Method;
Subdivision ii.	Date of Submission;
Subdivision iii.	Specific purpose or intent of the method for use in the NSSP;
Subdivision iv.	Step by step procedure including equipment, re-agents and safety requirements necessary to run the method;
Subdivision v.	Data generated in support of the efficacy of the method if available;
Subdivision vi.	Any peer reviewed articles detailing the method and its efficacy;
Subdivision vii.	Name of the developer or SSCA submitter;
Subdivision viii.	Developer or submitter contact information.

Public Health Significance:
Cost Information (if available):

Action by 2013 Task Force III Recommended adoption of Proposal 13-309 as submitted.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force III on Proposal 13-309.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-309.

Proposal Subject: *V.v.* Illness Review Subcommittee Procedures
Procedure XVII.

Specific NSSP Guide Reference: Constitution, Bylaws, and Procedures

Text of Proposal/ Requested Action Procedure XVII. ~~Reciprocity~~ Procedure for *Vibrio vulnificus (V.v.)* Illness Review Committee Procedures

Section 1. Charge.

The *V.v.* Illness Review Committee will annually review all *V.v.* cases involving the consumption of shellfish which are reported to FDA regional specialists and the Center for Disease Control (CDC). The Committee will determine which cases meet the case definition of a National Shellfish Sanitation Program (NSSP) *V.v.* case as outlined in Model Ordinance Section II Chapter II @.05. All cases meeting the NSSP definition will be included in an annual report which will be presented to the Interstate Shellfish Sanitation Conference (ISSC) Executive Board and the Vibrio Management Committee. Following ISSC Executive Board approval the report will be made available to the ISSC membership and posted on the ISSC website. This data is expected to be used by USFDA, State Authorities, and the ISSC for the following purposes:

Subdivision a. Conducting annual *V.v.* Risk Evaluations;
Subdivision b. Risk per serving determinations;
Subdivision c. *V.v.* Control Plan Evaluations;
Subdivision d. *V.v.* Contingency Plan Evaluations; and
Subdivision e. Reviewing illness trends.

Section 2. Procedures.

Subdivision a. The Committee will only consider cases that are reported on a CDC and Prevention Cholera Vibrio Illness Surveillance Report (COVIS) Form CDC 52.79 or other means.

Subdivision b. FDA (currently Shellfish Specialist Mark Glatzer) will coordinate the collection of cases and COVIS forms, and other information and after redacting identifying information will make this information available to the Committee.

Subdivision c. The information from the COVIS forms will be shared with the *V.v.* Illness Review Committee for review.

Subdivision d. The *V.v.* Illness Review Committee will review the cases and incorporate the appropriate information into a chart (see attachment A) which will serve as the Committee report.

Subdivision e. The report will be presented to the ISSC Executive Board for approval and then forwarded to the Vibrio Management Committee.

Subdivision f. The availability of the report will be announced to the ISSC membership.

Section 3. A copy of the report will be posted on the ISSC website.

Criteria and Guidelines. The Committee will use the following

criteria and guidelines in reviewing reported cases:

Subdivision a. Was the illness etiologically confirmed? In this context "etiologically confirmed "shall mean laboratory confirmation by wound, stool or blood culture. Confirmation may be by a laboratory other than a State laboratory."

Subdivision b. Was the illness epidemiologically linked to shellfish? Epidemiologically linked will mean "associated with" the consumption of oysters. Consumption means ingested; eaten within 7 days of onset of symptoms. Date of onset may be before hospitalization. Further information may be warranted; discretion may be exercised.

Subdivision c. Were the shellfish commercially harvested? Commercially harvested shall mean the shellfish were intended for sale or distribution in commerce. Commercial harvest will include those cases involving a foreign state.

Subdivision d. Were the shellfish raw or undercooked? If the victim developed *V.v.* septicemia after consumption the shellfish are considered to have been raw or undercooked.

Subdivision e. From what State was the shellfish harvested?

Subdivision f. Did the case involve septicemia from consumption: The following guidance will be used in determining if the case is a septicemia or a gastroenteritis case. Clinical signs and symptoms *V.v.* septicemia include:

Subdivision i. *V.v.* bacteria isolated from blood.

Subdivision ii. Fever measured as above 100 degree Fahrenheit.

Subdivision iii. Death as outcome (septicemia has a mortality rate of over 50% - 70%).

Subdivision iv. Bullae (blood filled blisters) but this also can occur after a wound infection which becomes septic.

Subdivision v. Shock because of the sepsis (again this can happen also because of a wound infection).

Subdivision g. Indications case may not be *V.v.* septicemia from consumption:

Subdivision i. Bacteria are only isolated from wound fluid or stool and no clinical evidence of septicemia

Subdivision ii. Cellulitis. Since cellulitis is a localized or diffuse inflammation of connective tissue with severe inflammation of dermal and subcutaneous layers of the skin (bacteria entering bodies through the skin, there might be a visible wound or just a small scratch),

therefore more likely a wound infection.

Subdivision iii. History of pre-existing and sustained wound infection (If both wound and oyster/seafood consumption is documented and happened within the incubation period, there is no way to differentiate why the patient is septic.)

Subdivision iv. Septicemia has a much shorter incubation period compared to gastroenteritis, according to CDC data, *V.v.* septicemia has an incubation period between 12-72 hours, although we have seen cases with shorter incubation periods.

Section 4. Challenges to Committee Findings

Persons wishing to challenge the information included in the report must notify the ISSC Executive Director within sixty (60) days of the posting of the report on the ISSC website. The ISSC Executive Board will review all challenges at the next scheduled Executive Board meeting.

Vibrio Vulnificus Illness Review Criteria Table on next page.

Procedure XVIII. Reciprocity

Public Health Significance:

Cost Information (if available):

Action by 2013 Task Force III Recommended adoption of proposal 13-310 as submitted.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force III on Proposal 13-310.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-310.

Vibrio vulnificus Illness Review Criteria Table

Review Date: _____

Case Identifier/Number:	**Criteria Status Determination**		
Criteria	**Yes**	**No**	**Unknown**
1. Etiologically Confirmed Blood Stool			
2. Epidemiologically Linked?			
3. Septicemia Illness?			
4. Reporting State?			
5. Commercial Harvest?			
6. Were shellfish consumed?			
a. Specify shellfish consumed:	**Oysters**	**Clams**	**Specify Other**
b. Date of consumption: _____			
c. Is onset consistent with consumption of shellfish? Date of onset _____			
7. Trace-back Information			
a. Were shipping tags available? If other trace-back information reported, list:			
b. State of harvest, harvest area (s), and harvest date (list all reported).			

Harvest Area	Harvest State	Harvest Date	Species	Comment

ISSC *V.v.* Illness Review Subcommittee Form (06/28/2013)

Resolution Subject: Resolution in Memory of Michael C. Voisin

Text of Resolution: ***Whereas,*** Michael Christopher Voisin was born on April 10, 1953, and passed away

unexpectedly on February 2, 2013. Mike was born into the family of a sixth-generation oyster family and raised in Torrance, California, where upon graduation from Torrance High School, he could not resist the allure of South Louisiana so he moved with his father, Ernest Voisin, to Houma, Louisiana, in 1971 to help his father return to the oyster business, thereby becoming a seventh-generation oysterman; and

Whereas, in Houma, Mike met the love of his life, Sarah Theriot, from Theriot, Louisiana and married her in 1975 spending more than forty years together living a life with six children Kevin, Gregory, Amy, Sally, Sandy, and Terrance Conrad – and fourteen grandchildren; and

Whereas, from his position in the front office, and in imitation of his father's public service, Mike became the face and voice of the Louisiana seafood industry and grew into one of the strongest advocates for the Gulf of Mexico seafood industry throughout the nation; and

Whereas, Mike Voisin served on and chaired many other seafood related entities including the Louisiana Oyster Dealers and Growers Association, the Gulf and South Atlantic Fisheries Foundation, the Interstate Shellfish Sanitation Conference, the Louisiana Restaurant Association, the Southeastern Fisheries Association, the Louisiana Seafood Processors Council, the Gulf Oyster Industry Council, the National Fisheries Institute, and the Molluscan Shellfish Institute of North America; National Fish and Seafood Promotion Council, the National Shellfish Pollution Indicator Program, the Louisiana Oyster Lease Damage Evaluation Board, and Governor's Advisory Commission on Coastal Protection, Restoration, and Conservation, and most recently, he was appointed by Governor Bobby Jindal to serve on the Louisiana Wildlife and Fisheries Commission; and

Whereas, Mike also was called upon to serve his state, his industry, and his region through participation on governmental entities supportive of the seafood industry and in doing so, he was instrumental in the creation of the Louisiana Seafood Promotion and Marketing Board, for which he served as the original chairman; and

Whereas, in addition to service to the seafood industry Mike was active in his service to the city of Houma and Terrebonne Parish where he served on the Terrebonne Parish Economic Development Consortium, the Houma-Terrebonne Chamber of Commerce, the South Louisiana Economic Council, the Louisiana Association of Business and Industry, and the Terrebonne General Medical Center Board of Commissioners, serving as chair at the time of his death; and

Whereas, Mike was also active in the academic community where he served as a board member for the Louisiana Marine Consortium, was on the LSU Marine and Coastal Fisheries Advisory Board, was an advisory member for the Nicholls State University College of Business and for the John Folse Culinary School at Nicholls State, and in December of 2012, Mike was awarded an honorary Doctorate of Commerce from Nicholls State University.

Whereas, Mike was also a strong and active leader in his life in the Church of Jesus Christ of Latter Day Saints, where he served in many capacities including Bishop of the Thibodaux congregation from 1996 through 2001, Branch President for the Larose Branch from 2005 to 2006, Stake High Councilor from 2006 to 2007 and most recently as High Priest Group Leader; and

Whereas, Mike along with Chris Nelson and Al Sunseri instituted an annual trip to Washington, D.C., coordinated by the Gulf Oyster Industry Council, where members of the Gulf oyster industry met with members of Congress and congressional aides and Administrative Departments to discuss the state of the oyster industry and the needs of the industry.

Therefore, Be It Resolved that the Interstate Shellfish Sanitation Conference does hereby express its condolences upon the untimely and unexpected death of Michael Christopher Voisin from Houma, Louisiana, a founding member of the Conference and advocate and spokesperson for the Louisiana oyster community and the coastal fishing community.

Be It Further Resolved, that the Interstate Shellfish Sanitation Conference acknowledge his contributions by a letter to that effect to his family.

Action by 2013 Resolutions Committee Recommended adoption of Resolution 13-001 as submitted.

Action by 2013 General Assembly Adopted Resolution 13-001.

Resolution No. 13-002

Resolution Subject: Resolution in Memory of Phil Busby

Text of Resolution:

Whereas, Phil Busby was born in Edgecumbe, New Zealand on December 29th, 1947 and died 65 years later on the 8th March, 2013. He was one of seven children and was brought up on a dairy farm. He never lost his love of country and family life.

Whereas, Phil initially wanted to be a plumber, but changed his mind to train as an Inspector of Health in the New Zealand Department of Health. He enjoyed many adventures doing field work throughout New Zealand. He gave up the field work to run the Department of Health's training course for health inspectors in 1983. Those who went through the course under Phil will never forget his no-nonsense marking style!

Whereas, from 1989 he was seconded to the Ministry of Agriculture and Forestry from the Department of Health to run the New Zealand shellfish program. He became responsible for all public health aspects of the New Zealand shellfish quality assurance program and in 1992 wrote the first New Zealand standard.

Whereas, from the late 1980s Phil was actively involved with the US National Shellfish Sanitation Program. He participated in many of the Interstate Shellfish Sanitation Conference committees. He always looked forward to the conferences as a time to catch up with US colleagues, have a beer and debate the latest issues. He usually took the opportunity for a post conference tour to gather information that could be used in the New Zealand shellfish program.

Whereas, in 1993 the first New Zealand marine biotoxin event catapulted Phil into the national and international spotlight. He was responsible in 1996 for mandatory accreditation of the national phytoplankton program prior to phytoplankton being accepted as part of the NZ program. In 2001 he was responsible for the validation and approval of LC-MS method for marine biotoxins, in 2003 for the mandatory hydrolysis of DSP samples and in 2004 for the approval of the LC-MS screen test method for brevetoxins. Each of these initiatives represented international trend setting decisions and showed the resolve of Phil to provide novel outcome based solutions to improve public health.

In 2004 he was asked to chair the joint FAO/IOC/WHO Expert workshops on Biotoxins in Molluscan Bivalves and to act as Vice Chair of the UNESCO Intergovernmental Oceanographic Commission Panel on Harmful Algal Blooms and Biotoxin Monitoring and Management, roles that he held for several years. His election and re-election to these positions showed the respect in which he was held by his national and international peers.

Whereas, Phil was married to Verina-Mary for 36 years and proudly raised his son Bede. They in turn lovingly cared for him over the two year period of his progressively debilitating illness. Throughout his illness he showed courage, fortitude and a sense of optimism.

Whereas, Phil was a person who was passionate about his public health work and the shellfish sanitation program. He did rise to the challenge, simply was always there and made a difference through persuasion and presence.

Be It Therefore Resolved, that the Interstate Shellfish Sanitation Conference extends its gratitude for Phil's leadership and the lasting contributions to the organization.

Be It Further Resolved, that the Interstate Shellfish Sanitation Conference acknowledge his contributions by a letter to that effect to his family.

Action by 2013 Resolutions Committee Recommended adoption of Resolution 13-002 as submitted.

Action by 2013 General Assembly Adopted Resolution 13-002.

Resolution No. 13-003

Resolution Subject: Resolution in Memory of Larry Simns

Text of Resolution: ***Whereas,*** Lawrence W. "Larry" Simns Sr., was born September 14, 1937. He was the son of George Clifton Simns, a waterman and part-time barber, and his wife, Rebecca. He was raised in the small Eastern Shore fishing village of Rock Hall, where he lived his entire life. After graduating from Rock Hall High School in 1956, he looked to the Chesapeake Bay for his livelihood. Larry died March 14, 2013, of bone cancer at his Rock Hall, Maryland home.

Whereas, Larry, was a fourth-generation waterman and longtime advocate for the Chesapeake Bay and those who make their living from its waters. More than 40 years ago, pointing out the virtual disappearance of some fish stocks and low oyster and crab yields from what was clearly an ailing estuary, Larry found the mission that occupied him for the remainder of his life.

Whereas, Larry stood sentry for the watermen of the Chesapeake Bay for over 40 years and courageously carried their banner into the 21st century. He fought to preserve their traditions and their opportunity to work on the water like their forefathers. He also had the tough challenge of helping them navigate a tough economy and difficult environmental factors facing his beloved bay. In 1973, he established the Maryland Watermen's Association and served as its president until his death.

Whereas, He represented state watermen on numerous committees and panels, including the Atlantic States Marine Fisheries Commission, the Maryland Tidal Fish Advisory Committee and the Commercial Fishermen of America Association, among others.

Whereas, In that role, Larry was a passionate voice representing watermen at all levels of government. The boy who grew up yearning to make his living on the water found himself meeting presidents — including both Ronald Reagan and Bill Clinton — governors and senators.

Whereas, Last year, Larry wrote an autobiography, "The Best of Times on the Chesapeake Bay: An Account of a Rock Hall Waterman," in collaboration with Robert Rich, Jr., which focuses largely on the 1960s and '70s. Larry said "I want to leave a record of the abundance I have known, so people will have an idea of what we need to get back to. I don't want people to save this Bay, because it's not good enough," he said in the Bay Journal interview last year. "We need to restore it."

Whereas, it has been said that Larry had amazing strength and fought and kept on pushing until the end. He was always looking ahead to set the course for the future for both the industry and watermen. In addition to his mother, Simns is survived by his wife, Carolyn Simns, a sister, three children, five stepchildren, 12 grandchildren, and three great-grandchildren.

Be It Therefore Resolved, that the Interstate Shellfish Sanitation Conference extends its gratitude for Larry's leadership and the lasting contributions to the organization.

Be It Further Resolved, that the Interstate Shellfish Sanitation Conference acknowledge his contributions by a letter to that effect to his family.

Action by 2013 Resolutions Committee Recommended adoption of Resolution 13-003 as submitted.

Action by 2013 General Assembly Adopted Resolution 13-003.

Resolution Subject: Resolution in Honor of Walter J. Canzonier

Text of Resolution: ***Whereas***, Walter J. Canzonier was a son of New Jersey; born of Italian-Irish-Scottish heritage in which he took great pride. He attended St. Peter's College and later did graduate work at Rutgers University, both in New Jersey. Walter recently suffered an illness that makes it impossible for him to continue to participate with the Interstate Shellfish Sanitation Conference.

Whereas, Walter Canzonier devoted his life to the study of marine life. He then spent a decade working at and later attaining the position of director of the Coastal Resources Applied Research Laboratory in Chioggia, Italy. He served as a consultant to UNESCO and traveled to many locations in Europe and the Middle East to design marine laboratories.

Whereas, on Walter's return to the United States he returned also to New Jersey and resumed research at Rutgers where he helped to design the Haskins Shellfish Laboratory. Later, working with local growers, he founded a non-profit organization to assist New Jersey shellfishermen.

Whereas, Walter believed himself to be a science generalist. He believed that applied research was of paramount importance and that modern scientists were too narrowly focused and often missed the big picture.

Whereas, Walter did not seek out awards or positions of acclaim. He preferred to work in support of those leading the charge.

Whereas, Walter had an abundant, yet quirky, sense of humor. He often greeted others with his trademark greeting, "How's the Garugala?"- a question to which there is no answer. He commonly introduced himself when calling on the telephone or when writing his return address on an envelope as the "Short, fat, red-headed guy from the banks of the Maurice River." Occasionally he would use the acronym SFRGBMR.

Whereas, Walter worked on issues to pertaining to phytoplankton, oyster meat quality, diseases of oysters, depuration, remote setting, shellfish culture techniques, water quality, shellfish safety and more. He kept meticulous records of the cost of oyster culture methods. He authored scholarly articles in both English and Italian and also wrote articles intended for a less lofty and more applied audience; his beloved oystermen. He served on countless boards and organizations supporting the shellfish industry and was an engaged member of the ISSC for more than 30 years.

Whereas, Walter was nothing if not passionate. He recognized that he occasionally carried his passion a bit beyond social norms. He was known to give a draft of a letter speaking on an issue to others and ask the recipient to "read and sanitize the letter".

Whereas, Walter was a fair man. His home contained a rental unit where rather than charging a set rental fee; he divided the common expenses even though he could have charged much more. This generous attitude suffused his work with the shellfish industry.

Whereas, Walt always had time to help the industry. If a grower ever experienced a perplexing problem involving tanks or pumps or if the oysterman observed an unusual phenomena with oysters, the industry member could be assured of receiving scholarly articles, photos, bibliographies, and hand drawn pictures explaining the issue. Only in the last few years did Walter ever use a fax machine or email- so these arrived in manila

envelopes, bearing the SFRGBMR return address acronym.

Be it Therefore Resolved, that the Interstate Shellfish Sanitation Conference extends its gratitude for Walter's lasting contributions to the organization, and

Be it Further Resolved, that the Interstate Shellfish Sanitation Conference acknowledges Walter's contributions by the presentation of this Resolution and sending a plaque commemorating his dedication and service to the Interstate Shellfish Sanitation Conference.

Action by 2013 Resolutions Committee Recommended adoption of Resolution 13-004 as submitted.

Action by 2013 General Assembly Adopted Resolution 13-004.

Resolution No. 13-005

Resolution Subject: Resolution of Appreciation

Text of Resolution: ***Whereas,*** the twenty-fifth meeting of the Interstate Shellfish Sanitation Conference convened January 25 – 31, 2014, at The St. Anthony Hotel in San Antonio, Texas, and

Whereas, the following industry sponsors, companies, and individuals were instrumental in contributing to the outstanding success of the Interstate Shellfish Sanitation Conference Chairman's Reception.

Be It Therefore Resolved that the Interstate Shellfish Sanitation Conference goes on record expressing appreciation to:

The Staff of the St. Anthony Hotel, particularly,

Debbie Gonzalez, Director of Sales and Marketing
Jacqueline Bosworth, Sales Manager
Rebekah Alvarez, Director of Meetings and Events

Banquet Captains Roque Padilla, Jesus Tavarez, and Cy Kariminia
Rolando Lopez, Banquet Server
Ernest Remirez, Banquet Setup

Mike Mata, Executive Chef
Gren Sanchez, Sous Chef
Chef's Staff including Joseph, Macy, Oscar,
Tim, Anthony, Chris, Linda,
Vicente, Beto, Michael, Zack, and Baltazar

Swank Audio Visuals

William E. Long. Consulting Executive Chef

The Volunteer ISSC Staff
William J. Eisele, Office Manager

Be It Further Resolved, that the Interstate Shellfish Sanitation Conference directs the Executive Director to write a letter of appreciation to each of the above mentioned individuals and organizations.

Action by 2013 Resolutions Committee Recommended adoption of Resolution 13-005 as submitted.

Action by 2013 General Assembly Adopted Resolution 13-005.

Resolution No. 13-006

Resolution Subject: Resolution of Appreciation

Text of Resolution: ***Whereas,*** the twenty-fifth meeting of the Interstate Shellfish Sanitation Conference convened January 25 – 31, 2014, at The St. Anthony Hotel in San Antonio, Texas, and

Whereas, the following industry sponsors, companies, and individuals were instrumental in contributing to the outstanding success of the Interstate Shellfish Sanitation Conference Chairman's Reception.

Be It Therefore Resolved that the Interstate Shellfish Sanitation Conference goes on record expressing appreciation to:

The Gulf Oyster Industry Council

Buddy Ward and Sons *13 Mile Brand Tommy Ward*
Apalachicola, Florida

Jeri's Seafood
Tracy Woody, General Manager Smith Point, Texas

Be It Further Resolved, that the Interstate Shellfish Sanitation Conference directs the Executive Director to write a letter of appreciation to each of the above mentioned individuals and organizations.

Action by 2013 Resolutions Committee Recommended adoption of Resolution 13-006 as submitted.

Action by 2013 General Assembly Adopted Resolution 13-006.