Interstate Shellfish Sanitation Conference

2015 Biennial Meeting

Summary of Actions

October 24 - 29, 2015

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	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 Laboratory Methods Review Committee	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 Laboratory Methods Review Committee	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 Laboratory Methods Review Committee	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 Laboratory Methods Review Committee	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.
Action by 2015 Laboratory Methods Review Committee	Recommended the following: 1) Change the name of the Jellett Rapid Test to Scotia Rapid Test and the Jellett Rapid Extraction to Scotia Rapid Extraction in the next revision of the NSSP Guide for the Control of Molluscan Shellfish (Section IV. Guidance Documents Chapter II Growing Areas 4. Approved Limited Use Methods for Marine Biotoxin Testing). 2) Refer Proposal 05-111 for PSP to an appropriate committee as determined by the Conference Chair and further recommended to direct the Executive Office to send a letter to the method submitter requesting additional information as detailed by the LMRC. 3) No action on the Scotia Rapid Extraction Method for ASP as there is no data

	nor did the submitter indicate that data would be submitted for ASP.
Action by 2015 Task Force I	Recommended adoption of the Laboratory Methods Review Committee on Proposal 05-111 with the following amendments: 1. Remove "and ASP" and change "toxins" to "toxin" throughout the proposal and adopt the Laboratory Method Review Committee recommendation 1 2. Refer Proposal 05-111 to appropriate committee as determined by Conference Chair. 3. No action on recommendation 3 as this is covered by the proposal as amended by the Task Force.
Action by 2015 General Assembly	Adopted recommendations 2. And 3. of Task Force I on Proposal 05-111. Recommendation 1. Was ruled out of order and the General Assembly did not take any action on this recommendation.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 05-111.

Proposal Subject	Re-opening Conditional Areas using Male-specific Coliphage after WTP Malfunction
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas
Text of Proposal/ Requested Action	@.03 Growing Area Classification A. (5) (c) (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 105 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	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.
Action by 2015 Growing Area Classification Committee	Recommended no action on Proposal 11-101. Rationale: This proposal is resolved by Proposal 15-102 and Proposal 15-106.
Action by 2015 Task Force I	Recommended adoption of the Growing Area Classification Committee recommendation on Proposal 11-101.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 11-101.
Action by FDA January 11, 2016	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	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas
Text of Proposal/ Requested Action	@.03 Growing Area Classification E. (5) (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 105 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	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.
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 recommendation 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.
Action by 2015 Growing Area Classification Committee	Recommended no action on Proposal 11-102. Rational: This proposal is resolved by Proposal 15-102 and Proposal 15-106.
Action by 2015 Task Force I	Recommended adoption of the Growing Area Classification Committee on Proposal 11-102.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 11-102.
Action by FDA January 11, 2016	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	Section II. Model Ordinance Chapter IV. Shellstock Growing Area @ .02 Bacteriological Standards
Text of Proposal/ Requested Action	G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration. (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	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	Recommend 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 Committee	Recommend referral of Proposal 11-103 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 11-103.
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.
Action by 2015 Growing Area Classification Committee	Recommended referral of Proposal 11-103 to appropriate committee as determined by the Conference Chair.
Action by 2015 Task Force I	Recommended adoption of Growing Area Classification Committee recommendation on Proposal 11-103.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 11-103.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 11-103.

Proposal Subject	Update PSP Laboratory Evaluation Checklist
Specific NSSP Guide Reference	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	None

PUBLIC HEALTH SERVICE
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COLLEGE PARK, MD 20740-3835
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SHELLFISH LABORATORY EVALUATION CHECKLIST

LABORATORY:		
ADDRESS:		
TELEPHONE:	**FAX:**	
EMAIL:		
DATE OF EVALUATION:	**DATE OF REPORT:**	**LAST EVALUATION:**

LABORATORY REPRESENTED BY:	**TITLE:**
LABORATORY EVALUATION OFFICER:	**SHELLFISH SPECIALIST:** **REGION:**
OTHER OFFICIALS PRESENT:	**TITLE:**

Items which do not conform are noted by:

C- Critical K - Key O - Other NA - Not Applicable Conformity is noted by a "√"

Check the applicable assays performed:

	Mouse Bioassay (MBA)
	Jellett Rapid Test (JRT)

PART I – QUALITY ASSURANCE

		ITEM
CODE		
		1.1 Quality Assurance (QA) Plan
K	☐	1. 1.1 Written plan adequately covers all the following [check (√) those that apply]
		a. Organization of the laboratory.
		b. Staff training requirements.

		c. Standard operating procedures (SOPs).
		d. Internal quality control measures for equipment, calibration, maintenance repair ~~and~~, performance and rejection criteria established.
		e. Laboratory safety.
		f. ~~Quality assessment.~~ Internal performance assessment.
		g. ~~Proper animal care.~~External performance assessment.
		h. Animal care.
C	☐	**2. 1.1.2 QA plan implemented.**
		1.2 Educational/Experience Requirements
C	☐	**1.2.1 In state/county laboratories, the supervisor meets the state/county educational and experience requirements for managing a public health laboratory.**
K	☐	1.2.2 In state/county laboratories, the analysts meet the state/county educational and experience requirements for processing samples in a public health laboratory.
C	☐	**1.2.3 In commercial laboratories, the supervisor must have at least a bachelor's degree in microbiology, biology or an equivalent discipline with at least two years of laboratory experience.**
K	☐	1.2.4 In commercial laboratories, the analysts must have at least a high school diploma and shall have at least three months of experience in laboratory science.
		1.~~2~~3 Work Area
O	☐	1. 1.3.1 Adequate for workload and storage.
O	☐	2. 1.3.2 Clean and well lighted.
O	☐	3. 1.3.3 Adequate temperature control.
O	☐	4. 1.3.4 All work surfaces are nonporous and easily cleaned.
C	☐	**5. 1.3.5 A separate, quiet area with adequate temperature control for mice acclimation and injection is maintained.**
		1.~~3~~4 Laboratory Equipment
O	☐	1.1.4.1 The pH meter has a standard accuracy of 0.1 pH unit.
K	☐	~~pH paper in the appropriate range (i.e. 1-4) is used with minimum accuracy of 0.5 pH units.~~ 2. 1.4.2 pH paper in the appropriate range (i.e., pH <2 to >4.5) having a minimum accuracy of 0.5 units is used.
K	☐	3.1.4.3 The pH electrodes being used consist of a pH half cell and reference half cell or equivalent combination electrode/triode free from silver/silver chloride (Ag/AgCl) or contains an ion exchange barrier to prevent the passage of silver (Ag) ions into the ~~medium that may result in inaccurate pH readings~~ substance being measured.
K	☐	4.1.4.4 pH meter is calibrated daily or with each use. Results are recorded and records maintained.
K	☐	5.1.4.5 Effect of temperature has been compensated for by an ATC probe, use of a triode or by manual adjustment.
K	☐	6.1.4.6 A minimum of two standard buffer solutions (pH 2 & pH 7) is used to calibrate the pH meter. Standard buffer solutions are used once and discarded.
K	☐	7.1.4.7 Electrode ~~efficiency~~acceptability is determined daily or with each use ~~following either slope or~~ by the millivolt procedure or through determination of the slope. (circle the method used.)
K	☐	~~8. The balance provides a sensitivity of at least 0.1g at a load of 150 grams.~~ 1.4.8 The differing sensitivities in weight measurements required by the various steps in the assay are met by the balance/balances being used. a. To prepare the reference solution, the balance used must have a sensitivity of at least 0.1 gram at a load of 1 gram.

		b. For sample extraction, the balance used must have a sensitivity of at least 0.1 gram at a load of 100 grams. c. For gravimetric extract volume adjustment, the balance used must have a sensitivity of at least 0.1 gram at a load of 200 grams. d. To determine the weight of the mice, the balance must have a sensitivity of at least 0.1 gram at a load of 20 grams.
K	☐	~~9. The balance calibration is checked monthly using NIST Class S or ASTM Class 1or 2 weights or equivalent. Records maintained.~~ 1.4.9 Balance calibrations are checked monthly according to manufacturer's specifications using NIST Class S or ASTM Class 1 or 2 weights or equivalent. The accuracy of the balance is verified at the weight range of use. Results are recorded and records maintained.
K	☐	10.1.4.10 Refrigerator temperatures ~~is~~are maintained between 0 and 4°C.
O	☐	111.4.11 Refrigerator temperatures ~~is~~are monitored at least once daily on workdays. Results are recorded and records maintained.
K	☐	12.1.4.12 Freezer temperatures ~~is~~ are maintained at ~~-20°C~~or below -15°C.
O	☐	13.1.4.13 Freezer temperatures ~~is~~ are monitored at least once daily on workdays. Results are recorded and records maintained.
O	☐	14.1.4.14 All glassware is clean.
O C	☐	~~15. Once during each day of washing, several pieces of glassware from each batch washed are tested for residual detergent with aqueous 0.04% bromthymol blue solution. Records are maintained.~~ **1.4.15 With each load of labware/glassware washed, the contact surface of several dry pieces from each load are tested for residual detergent (acid or alkali) with aqueous 0.04% bromthymol blue (BTB) solution. Results are recorded and records maintained.**
C	☐	**1.4.16 An alkaline or acid based detergent is used for washing glassware/labware**
		1.41.5 Reagent and Reference Solution Preparation and Storage
C	☐	**1.5.1 Opened PSP ~~reference~~ standard solution (100µg/mL) is not stored.**
K	☐	~~2. PSP working standard solution (1 µg/ml) and all dilutions are prepared with dilute HCl, pH 3 water, using 'Class A' volumetric glassware (flasks and pipettes) or prepared gravimetrically.~~ 1.5.2 PSP reference solution (1µg/mL) is prepared by weight (grayimetrically) with dilute HCl, pH 3 water.
K	☐	~~3. Refrigerated storage of PSP working standard solution (1µg/ml) does not exceed 6 months and is checked gravimetrically for evaporation loss.~~ 1.5.3 Refrigerated storage of PSP reference solution (1µg/mL) in a sealed container is stored indefinitely as long as there is no evaporation loss as checked by weight. If evaporation is detected, the solution is discarded appropriately. Records are maintained.
C	☐	**1.5.4 Dilutions of the 1µg/mL reference solution are prepared by weight or volume using dilute HCl, pH 3 water.**
K	☐	4.1.5.5 PSP working dilutions(dilutions of the 1µg/mL reference solution) are discarded after use.
K	☐	5. ~~Make up water is distilled or deionized (*circle one*) and exceeds 0.5 megohm resistance or is less than 2 µ Siemens/cm conductivity at 25°C to be tested and recorded monthly for resistance or conductivity (*circle the appropriate*).~~ 1.5.6 Reagent water is distilled or deionized (*circle appropriate choice*), tested monthly and exceeds 0.5 megohm-cm resistance (2 megohms-cm in-line) or is less than 2.0 µSiemens/cm conductivity at 25°C (*circle the appropriate water quality descriptor determined*). Results are recorded and the records maintained.
O	☐	6. 1.5.7 ~~Make up~~ Reagent water is analyzed for residual chlorine monthly and is at a nondetectable level (<0.1ppm). Results are recorded and records maintained.
K	☐	7. Make up water is free from trace (< 0.5 mg/l) dissolved metals specifically Cd, Cr, Cu, Ni, Pb, and

		Zn as determined annually with total heavy metal content ≤1.0 mg/l. Records maintained.
O	☐	8.1.5.8 ~~Makeup~~ Reagent water contains ~~<1000~~ <100 CFU/mL as determined monthly using the heterotrophic plate count method. Results are recorded and records maintained.
		1.~~5~~6 Collection and Transportation of Samples
O	☐	1. ~~Shellstock are collected in clean, waterproof, puncture resistant containers.~~ 1.6.1 Shellfish are collected in clean, waterproof , loosely sealed, puncture resistant containers.
K	☐	2.1.6.2 Samples are appropriately labeled with the collector's name, harvest area, sampling station and time and date of collection.
K	☐	3. ~~Immediately after collection, shellstock samples are placed in dry storage for transport (e.g. cooler) which is maintained between 0 and 10°C. Upon receipt at the lab, samples are placed under refrigeration.~~ 1.6.3 Immediately after collection, shellfish samples are placed in dry storage (ice chest or equivalent) which is maintained between 0 and 10°C with ice or cold packs for transport to the laboratory. Upon receipt at the laboratory, samples are placed under refrigeration.
K	☐	4.1.6.4 The time from collection to completion of the bioassay should not exceed 24 hours. However, if there are significant transportation delays, then shellstock samples are processed immediately as follows (*circle the appropriate choice*): a. Washed, shucked, drained, frozen until extracted. b. Washed , shucked, drained, homogenized and frozen. c. Washed, shucked, drained, extracted, the supernatant decanted and refrigerated (**best choice**) ; or d. The laboratory has an appropriate contingency plan in place to handle samples which can't be analyzed within 24 hours due to transportation issues.
KC	☐	**5.1.6.5 Frozen, shucked product or homogenates are allowed to thaw completely and all liquid is included as part of the sample before being processed further.**
Part II – ~~EXAMINATION~~ ANALYSIS OF SHELLFISH FOR PSP TOXINS		
		2.1 Preparation of the Sample
C	☐	**1. 2.1.1 At least 12 animals (equivalent to at least 100 g of shellfish meat) are used per sample or the laboratory has a~~n appropriate~~ proven effective contingency plan for dealing with non-typical species of shellfish.**
O	☐	2. 2.1.2. The outside of the shell is thoroughly cleaned with fresh water.
O	☐	3. 2.1.3 Shellstock are opened by cutting adductor muscles.
O	☐	4. 2.1.4 The inside of the shell is rinsed with fresh water to remove sand or other foreign material.
O	☐	5. 2.1.5 Shellfish meats are removed from the shell by separating adductor muscles and tissue connecting at the hinge.
K	☐	6. 2.1.6 Damage to the body of the mollusk is minimized in the process of opening.
O	☐	7.2.1.7 Shucked shellfish are drained on a #10 mesh sieve (or equivalent) without layering for 5 minutes.
K	☐	8. 2.1.8 Pieces of shell and drainage are discarded.
C	☐	**9. ~~Drained meats or thawed homogenates are blended at high speed until homogenous (60 – 120 seconds).~~** **2.1.9 Drained meats or previously cooled/refrigerated, shucked, drained meats and their drip-loss liquid or thawed, shucked meat with its freeze-thaw liquid or thawed homogenates with their freeze-thaw liquid are blended at high speed until homogenous (60 – 120 seconds).**
		2.2 Extraction
K	☐	1. 2.2.1 100 grams of homogenized sample is weighed into a beaker.
K	☐	2. 2.2.2 An equal amount of 0.1 N/0.18 N HCl is added to the homogenate and thoroughly mixed. (*circle the appropriate normality*).

C	☐	**3. 2.2.3 The pH is checked and, if necessary adjusted to between pH 2.0 and 4.0.**
C	☐	**4. 2.2.4 Adjustment of the pH is made by the dropwise addition of either (5 N HCl) or base (0.1 N NaOH) as appropriate while constantly stirring the mixture.**
C	☐	**5. 2.2.5 The homogenate/acid mixture is promptly brought to a boil, 100 +1°C then gently boiled for 5 minutes.**
O	☐	6. 2.2.6 The homogenate/ acid mixture is boiled under adequate ventilation (i.e., fume hood).
O	☐	7. 2.2.7 The extract is cooled to room temperature.
C	☐	**8. 2.2.8 The pH of the extract is determined and adjusted if necessary to between pH 2 and 4 preferably to pH 3 with the stirred dropwise addition of 5 N HCl to lower the pH or 0.1 N NaOH to raise the pH.**
K	☐	9. 2.2.9 The extract volume~~(or mass)~~ is adjusted to 200 mL (or grams) with dilute HCl, pH 3.0 water.
K	☐	10.2.2.10 The extract is returned to the beaker, stirred to homogeneity and allowed to settle to remove particulates; or, if necessary, an aliquot of the stirred supernatant is centrifuged at 3,000 RPM for 5 minutes before ~~injection~~ being bioassayed.
K	☐	11. ~~If mice cannot be injected immediately then the supernatant should be removed from the centrifuge tubes and refrigerated for up to 24 hours.~~ 2.2.11 If the extract cannot be bioassayed or the Jellett Rapid Test (JRT) for PSP cannot be performed immediately, then the supernatant is removed from the centrifuge tubes and sealed and refrigerated for up to 24 hours.
K	☐	12. 2.2.12 Refrigerated extracts are allowed to reach ambient temperature before being bioassayed or tested by the JRT for PSP.
		2.3 Bioassay
O	☐	1. 2.3.1 A 26-gauge hypodermic needle is used for injection.
KC	☐	~~2. Healthy mice in the weight range of 17 – 23 grams (19 – 21 grams is preferable) from a stock colony are used for routine assays. Mice are not reused for the bioassay.~~ ~~Stock strain used_____ Source of the mice _____~~ **2.3.2 Healthy mice in the weight range of 17 – 23 grams (19 – 21 grams is preferable) from a stock colony are used for routine assays. Mice are not reused for the bioassay.** **Stock strain used_____ Source of the mice _____**
C	☐	**3. 2.3.3 Mice are allowed to acclimate for at least 24 hours prior to injection. In some cases up to 48 hours may be required.**
C	☐	**4. 2.3.4 A conversion factor (CF) has been determined as _____. Month and year when current CF determined _____.**
C	☐	**5. 2.3.5 CF value is checked weekly if assays are done on several days during the week, or, once each day that assays are performed if they are performed less than once per week.** **Date of most recent CF check_____** **CF verified~~/CF not verified~~: *yes / no*: (*circle the appropriate choice*).**
C	☐	**6. 2.3.6 If the CF is not verified, 5 additional mice are injected with the dilution used in the CF check to complete a group of 10 mice. Ten additional mice are also injected with this dilution to produce a second group of 10 mice. The CF is calculated for each group of 10 mice and averaged to give the CF to be used in sample toxicity calculations for the day's or week's work only. All subsequent work must make use of the original laboratory CF value unless this value continues to fail to be verified by routine CF checks.**
C	☐	**7. 2.3.7 If the CF fails to be verified, the cause is investigated and the situation**

		corrected. If the cause cannot be determined with reasonable certainty and fails >3 times per year, the bioassay is restandardized.
O	☐	8. 2.3.8 Mice are weighed to the nearest ~~0.5 gram~~ 0.1 gram .
C	☐	**9. 2.3.9 Mice are injected intrapertioneally with 1 mL of the acid extract.**
K	☐	10.2.3.10 For the CF check at least 5 mice are used.
C	☐	**11. 2.3.11 At least 3 mice are used per sample in routine assays.**
C	☐	**12.2.3.12 Elapsed time is accurately determined and recorded.**
K	☐	13. 2.3.13 If death occurs, the time of death to the nearest second is noted by the last gasping breath.
C	☐	**2.3.14 Mice are continually observed for up to 20 minutes after injection with periodic checks for a total of 60 minutes as appropriate.**
C	☐	**14. 2.3.15 If the median death time~~(2 out of 3 mice injected die)~~ is <5 minutes, a dilution is made with dilute HCl, pH 3 water, to obtain a median death time in the range of 5 to 7minutes.**
		2.4 Calculation of Toxicity
C	☐	**1. 2.4.1 The death time of each mouse is converted to mouse units (MU) using Sommer's Table (Table 6, *Recommended Procedures for the examination of Sea Water and Shellfish, Fourth*~~, 4th~~ Fourth Edition). The death time of mice surviving beyond 60 minutes is considered to be <0.875 MU.**
K	☐	2. 2.4.2 A weight correction in MU is made for each mouse injected using Table 7 in *Recommended Procedures for the Examination of Sea Water and Shellfish*, Fourth ~~4th~~ Edition.
C	☐	**3. 2.4.3 The death time of each mouse in MU is multiplied by a weight correction in MU to give the corrected mouse unit (CMU), the true death time for each mouse.**
C	☐	**4. 2.4.4 The median value of the array of corrected mouse units (CMU) is determined to give the median corrected mouse unit (MCMU), median death time.**
C	☐	**5. 2.4.5 The concentration of toxin is determined by the formula, MCMU x CF x Dilution Factor (DF) x 200.**
C	☐	**6. 2.4.6 Any value greater than 80 µg/100 grams of meat is actionable.**
PART III – JELLETT RAPID TEST (JRT) FOR PSP		
		3.1 Procedure
K	☐	3.1.1 The batch/lot numbers of the test strips and buffers, their expiration dates, date received and date used are recorded.
K	☐	3.1.2 When placed into service, test strips and buffers (PSP & Matrix) are within their respective expiration dates.
C	☐	**3.1.3 When opened, the test strip desiccant pouch is blue in color indicating its suitability for use. Test strips emerging from desiccant pouches which are pink in color are never used.**
K	☐	3.1. 4 Test strips and buffer are stored according to the manufacturer's instructions.
C	☐	**3.1.5 Negative extracts are spiked at a low level concentration (40 – 60 µg/100 grams of sample) or equivalent (a bioassayed extract) and used as a positive control for testing both new batches/lots of kits and buffers. Results are recorded and records maintained.**
C	☐	**3.1.6 Micropippettors capable of accurately delivering volumes of 100 and 400 µL are used to transfer buffer and sample extracts and to inoculate test strips with diluted extract.**
K	☐	3.1.7 Volumes delivered by the micropippettor are checked for accuracy at 100 and 400 µL monthly while in service. Results are recorded and records maintained.
C	☐	**3.1.8 400 µL of the buffer supplied with the test kits is accurately transferred to a small tube.**
C	☐	**3.1.9 100 µL of the sample extract is added to the buffer.**
K	☐	3.1.10 The sample/extract is thoroughly mixed with buffer by inserting the tip of the micropippettor into the buffer/sample extract mixture and pipetting up

		and down at least three (3) times.
C	☐	**3.1.11 100 µL of the thoroughly mixed diluted sample extract is inoculated into the test strip sample well.**
K	☐	3.1.12 Micropipettor tips are not reused.
K	☐	3.1.13 Inoculated test strips are allowed to react with the sample extract for the period of time specified by the manufacturer.
C	☐	**3.1.14 The test is interpreted according to the manufacturer's instruction card which is specific to each batch/lot of test strips.**
K	☐	3.1.15 When invalid tests are repeated, the pH of the sample extract is checked and adjusted as necessary to between pH 2.0 and pH 4.0. An aliquot of Matrix buffer and a fresh test strip is used to reassay the sample.
C	☐	**3.1.16 When a repeated JRT test for PSP gives identical invalid results, the sample contains interfering substances which require the use of the mouse bioassay for testing.**
C	☐	**3.1.17 A positive JRT for PSP is actionable.**

Revised 11 – 08 2010

REFERENCES

1. Adams, W.N. and S.A. Furfari. 1984. Evaluation of laboratory performance of the AOAC method for PSP toxin in shellfish. *J. Assoc. Off. Anal. Chem*. Vol 67, 6:1147-1148.
2. American Public Health Association. 1970. *Recommended Procedures for the Examination of Sea Water and Shellfish*, Fourth Edition. APHA, Washington, D.C.
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4. Association of Official Analytical Chemists International. 1990. *Methods of Analysis*, 15th Edition AOAC, Arlington, VA.
5. APHA/WEF/AWWA. 1992. *Standard Methods for the Examination of Water and Wastewater*, 18th Edition. APHA, Washington, D.C.
6. Title 21, Code of Federal Regulations, Part 58, Good Laboratory Practice for Nonclinical Laboratory Study. U.S. Government Printing Office, Washington, D.C.
7. National Research Council. 1996. *Guide for the Care and Use of Laboratory Animals*. National Academy Press. Washington, D.C.
8. Personal communication with USFDA Seafood Laboratory Branch, Office of Seafood, CFSAN, 1998-1999.
9. JRT Instruction Materials with specified batch/lot number instructions.
10 NELAP – National Environmental Laboratory Accreditation Conference. 2003. Chapter 252. ENVIRONMENTAL LABORATORY ACCREDITATION, 252.302. Qualifications of the Laboratory Supervisor, 252.304. Personnel Requirements.

LABORATORY:	**DATE OF EVALUATION:**

SHELLFISH LABORATORY EVALUATION CHECKLIST
SUMMARY OF NONCONFORMITIES

Page	**Item**	**Observation**	**Documentation Required**

LABORATORY STATUS	
LABORATORY:	**DATE:**
LABORATORY REPRESENTATIVE:	

PARALYTIC SHELLFISH TOXIN COMPONENT: PARTS I and II and III

A. Results:

Total # of Critical (C) Nonconformities _____
Total # of Key (K) Nonconformities _____
Total # of Other (O) Nonconformities _____
Total # of Critical, Key and Other Nonconformities **_____**

B. Criteria for Determining Laboratory Status of the PSP Component

1. **Does not Conform Status**. The PSP component of this Laboratory is not in conformity with NSSP requirements if :
   A. The total # of Critical Nonconformities is **>3 or**
   B. The total # of Key Nonconformities is **>6 or**
   C. The total # of Critical, Key and Other is **>10**

2. **Provisionally Conforms Status.** The PSP component of this Laboratory is determined to be provisionally conforming to NSSP requirements if the number of **Critical** Nonconformities is **< 3 and** the number of **Key** Nonconformities is **<6 and** the number of **Other** Nonconformities is **<4.**

3. **Conforming Status.** The PSP component of this Laboratory is determined to be conforming when it has **no Critical** Nonconformities **and < 6 Key** Nonconformities **and < 4 Other** Nonconformities.

C. Laboratory Status *(circle appropriate choice)*:
Does Not Conforn - Provisionally Conforms - Conforms

Revised 11 - 08 – 2010

Action by 2011 Laboratory Methods Review & Quality Assurance Committee	Recommended referral of Proposal 11-109 to an 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 Methods Review & Quality Assurance Committee	Recommended referral of Proposal 11-109 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 May 5, 2014	Concurred with Conference action on Proposal 11-109.
Action by 2015 Laboratory Methods Review Committee	Recommended that Proposal 11-109 be adopted as amended.

~~Laboratory Evaluation Checklist - PSP~~

~~PUBLIC HEALTH SERVICE~~ **~~U.S. FOOD AND DRUG ADMINISTRATION~~** ~~OFFICE OF FOOD SAFETY~~ ~~SHELLFISH AND AQUACULTURE POLICY BRANCH~~ **~~SHELLFISH PROGRAM IMPLEMENTATION BRANCH~~** **~~SHELLFISH SAFETY TEAM~~** **~~5100 PAINT BRANCH PARKWAY~~** **~~COLLEGE PARK, MD 20740-3835~~** **TEL. ~~240-402-2151/2055~~301-436-2151/2147 ~~FAX 301-436-2672~~**
SHELLFISH LABORATORY EVALUATION CHECKLIST
LABORATORY:
ADDRESS:
TELEPHONE: FAX: EMAIL:

~~DATE OF EVALUATION:~~	**~~DATE OF REPORT:~~**	**~~LAST EVALUATION:~~**

LABORATORY REPRESENTED BY:	**TITLE:**
LABORATORY EVALUATION OFFICER:	**~~SHELLFISH SPECIALIST:~~** **REGION:**
OTHER OFFICIALS PRESENT:	**TITLE:**

~~Items which do not conform are noted by:~~

~~C- Critical K - Key O - Other NA - Not Applicable Conformity is noted by a "√"~~

Mouse Bioassay Assay (MBA) and Scotia Rapid Test (SRT) for Paralytic Shellfish Poisoning (PSP)

PART I - Quality~~UALITY~~ Assurance~~SSURANCE~~

Code	REF	Item Description
		1.1 Quality Assurance (QA) Plan
K	5, 6, 8	1.1.1 Written Plan adequately covers all of the following: (check √ those items which~~that~~ apply) ~~1. a. Organization of the laboratory.~~ ~~2. b. Staff training requirements.~~ ~~3. c. Standard operating procedures.~~ ~~4. d. Internal quality control measures for equipment, calibration, maintenance, repair and performance.~~ ~~5. e. Laboratory safety.~~ ~~6. f. Quality assessment.~~ g~~. Proper animal care.~~
		a. Organization of the laboratory.
		b. Staff training requirements.
		c. Standard operating procedures (SOPs).
		d. Internal quality control measures for equipment, calibration, maintenance, repair, performance and rejection criteria established.
		e. Laboratory safety.
		f. Internal performance assessment.
		g. External performance assessment.
		h. Animal care.
C	**6**	**1.1.2~~.~~ The QA plan is implemented.**
		1.2 Educational/Experience Requirements
C	**State's Human Resources Department**	**1.2.1 In state/county laboratories, the supervisor meets the state/county educational and experience requirements for managing a public health laboratory.**
K	State's Human Resources Department	1.2.2 In state/county laboratories, the analyst(s) meet the state/county educational and experience requirements for processing samples in a public health laboratory.
C	**USDA Microbiology & EELAP**	**1.2.3 In commercial/private laboratories, the supervisor must have at least a bachelor's degree or equivalent in microbiology, biology, chemistry or another appropriate discipline with at least two years of laboratory experience.**
K	USDA Microbiology & EELAP	1.2.4 In commercial/private laboratories, the analyst(s) meets the state/county educational and experience requirements for processing samples in a public health laboratory.
		1.3~~2~~ Work Area
O	5, 6	1.3.1 Adequate for the workload and storage.
OO	5	1.3.2~~.~~ Clean and well lighted.
OO		1.3.3~~.~~ Adequate temperature control.
OO		1.3.4~~.~~ All work surfaces are nonporous and easily cleaned.
C	**8**	**1.3.5~~.~~ A separate, quiet area with adequate temperature control for mice acclimation and injection is maintained.**

			1.43 Laboratory Equipment
O	2		1.4.1 The pH meter has a standard accuracy of 0.1 pH units.
K	9		1.4.2. pH paper in the appropriate range (i.e. 1-514), if is used, measures accurately to a with minimum accuracy of 0.5 pH units over the covered pH range.
K	7		1.4.3. pH electrodes consist of pH half--cell and reference half--cell or equivalent combination electrode/triode (free from Ag/AgCl or contains an ion exchange barrier to prevent passage of Ag ions into the medium that may result in inaccurate pH readings).
K	6		1.4.4 pH meter is calibrated daily when in use. -or with each use. Results are recorded and Rrecords are maintained.
K	5		1.4.5. Effect of temperature has been compensated for by an ATC probe; use of a triode or by manual adjustment.
K	5		1.4.6. A minimum of two standard buffer solutions (2 & 7) is used to calibrate the pH meter. The first must be near the electrode isopotential point (pH 7). The second must be near the expected sample pH (i.e. pH 2, 4 or 11) as appropriate. Standard buffer solutions are used once and discarded.
K	6, 12		1.4.7. Electrode acceptabilityefficiency is determined daily or with each use by the following either slope or millivolt procedure or through determination of slope. (Circle method used).
K	2		1.4.8. The balances being used provides an appropriate sensitivity at the weights of use.of at least 0.1g at a load of 150 grams. a. To prepare reference solution, the balance must have a sensitivity of at least 0.1 g at a load of 1 g. b. For sample extraction, the balance must have a sensitivity of at least 0.1 g at a load of 100 g. c. For gravimetric extract volume adjustment, the balance must have a sensitivity of at least 0.1 g at a load of 200 g. d. To weigh mice for assay, the balance must have a sensitivity of at least 0.1 g at a load of 20 g.
K	4,5		1.4.9. The balance calibration is checked monthly according to the manufacturer's specifications using NIST Class S, -or-ASTM Class 1or 2 weights or equivalent. Results are recorded and records are maintained.
K	1		1.4.10. Refrigerator temperature is maintained between 0 and 4˚C.
KO	5		1.4.11. Refrigerator temperature is monitored at least once daily on workdays. Results are recorded and records are maintained.
K	4		1.4.12. Freezer temperature is maintained within manufacturer's toleranceat -20°C or below.
KO	5		1.4.13. Freezer temperature is monitored at least once daily on workdays. Results are recorded and records are maintained.
C	**10**		**1.4.14 All in-service thermometers are properly calibrated and immersed. Results are recorded and records are maintained.**
O	6		1.4.1514. All glassware is clean.
CO	**5**		**1.4.1615. With each load of labware/glassware washed, the contact surface of Once during each day of washing, several dry pieces of glassware from each loadbatch washed are tested for residual detergent (acid or alkali as appropriate) with aqueous 0.04% bromthymol blue (BTB) solution. Results are recorded and records are maintained.**
C	**9**		**1.4.17 An alkaline or acid based detergent is used for washing glassware/labware.**
			1.54 Reagents and Reference Solution Preparation and Storage
C	9		**1.5.1 Any residual (unused) STX diHCl1 standard solution is never stored after the ampule has been opened. Opened PSP reference stand solution (100 µg/ml) is**

			~~not stored.~~
K	15		~~1.5.~~2~~.~~ PSP reference~~working standard~~ solution (1 µg/mL~~l~~)~~ and all dilutions are~~ is prepared gravimetrically and~~ prepared with~~ diluted with 0.001 M HCl~~,~~ solution. ~~pH 3 water, using 'Class A' volumetric glassware (flasks and pipettes) or prepared gravimetrically.~~
K	9		~~1.5.~~3~~.~~ Prepared ~~Refrigerated storage of~~ PSP reference solution is stored under refrigeration in a sealed non-reactive container. Solution may be stored indefinitely as long as there is no detectable~~working standard solution (1µg/ml) does not exceed 6 months and is checked gravimetrically for~~ evaporation loss as determined by weight. If evaporation is detected, the solution is discarded appropriately. Records are maintained.
C	**14**		**1.5.4 All working dilutions from the PSP reference solution are prepared gravimetrically using 0.001 M HCl~~l~~.**
K	9		1.5.5~~4.~~ All~~PSP~~ working dilutions prepared from the PSP reference solution ~~-~~are discarded appropriately after use.
C~~K~~	**5**		**1.5.6~~5.~~ Reagent~~Make up~~ water is distilled or deionized (circle appropriate choice~~circle one~~), tested monthly and exceeds 0.5 megohm – cm resistance ~~(2 megohms-cm in-line)~~ or is less than 2.0 µ~~-~~Siemens/cm conductivity at 25 °C. (Circle the appropriate water quality descriptor determined). ~~to be tested and~~Results are recorded and records are maintained ~~monthly for resistance or conductivity (circle the appropriate).~~**
O~~K~~	5		1.5.7~~6.~~ Reagent~~Make up~~ water is analyzed for residual chlorine monthly and is at a non-detectable level (≤ 0.1 mg/L~~ppm~~). Results are recorded and records are maintained. Specify method of determination _____.
~~K~~			~~7. Make up water is free from trace (< 0.5 mg/l) dissolved metals specifically Cd, Cr, Cu, Ni, Pb, and Zn as determined annually with total heavy metal content ≤1.0 mg/l. Records maintained.~~
K~~O~~	5		1.5.8~~.~~ Reagent~~Makeup~~ water contains < 100~~0~~ CFU/mL~~l~~ as determined monthly using the heterotrophic plate count method. Results are recorded and records are maintained.
		1.6~~5~~ Collection and Transportation of Samples	
O	2		1.6.1~~.~~ Shellstock are collected in clean, waterproof, puncture resistant containers, loosely sealed.
K	2		1.6.2~~.~~ Shellstock samples are ~~appropriately~~ labeled with ~~the~~ collector's name, type of shellstock, the source or harvest area, sampling station, ~~and~~ time, ~~and~~ date and place (if applicable) of collection.
C~~K~~	**2**		**~~1.6.~~3~~.~~ Immediately after collection, shellstock samples are placed in dry storage ~~for transport~~ (~~e.g. cooler~~ice chest or equivalent) which is maintained between 0 and 10 °C with ice or cold packs for transport to the laboratory. ~~Upon receipt at the lab, samples are placed under refrigeration.~~**
K	15, 9		1.6.4~~.~~ T~~he t~~ime from collection to initiation~~completion~~ of the extraction~~bioassay~~ should not exceed 24 hours. However, if ~~there are~~ significant ~~transportation~~ delays are anticipated or if they occur, the laboratory has an appropriate contingency plan in place to handle these samples, ~~then shellstock samples are processed immediately~~ For samples shipped live in accordance with 1.6.3, the contingency plan ensures samples remain within allowable temperature tolerances and animals are alive upon receipt. The contingency plan also addresses field and/or laboratory processing that ensures the integrity of the sample or extract until initiation of the assay. For example, samples are washed, shucked, drained and processed as follows ~~(circle the appropriate choice)~~: a. refrigerated or frozen until extracted; b. homogenized and frozen until extracted; or; c. extracted, the supernatant decanted, and refrigerated or frozen until assayed.

			~~a. Washed, shucked, drained, frozen until extracted;~~ ~~b. Washed, shucked, drained, homogenized and frozen;~~ ~~c. Washed, shucked, drained, extracted, the supernatant decanted and refrigerated **(best choice); or**~~ d. The laboratory has an appropriate contingency plan in place to handle samples which can't be analyzed within 24 hours due to transportation issues.
C~~K~~	**14**		**1.6.5~~.~~ Frozen shucked product or homogenates are allowed to thaw completely and all liquid is included as part of the sample before being processed further.**
PART II ~~–~~ Analysis of Shellfish for PSP Toxins - MBA~~EXAMINATION OF SHELLFISH FOR PSP TOXIN~~			
			2.1 Preparation of Samples for Analysis – Homogenization
C	15, 9		**2.1.1~~.~~ At least 12 animals (or more to provide 100 g of shellfish meat) are used per sample or the laboratory has an appropriate contingency plan for dealing with non-typical species of shellfish.**
O	2		2.1.2~~.~~ The outside of the shell is thoroughly cleaned with fresh water.
O	2		2.1.3~~.~~ Shellstock are opened by cutting the adductor muscles.
O	2		2.1.4~~.~~ The inside surfaces of the shells and meats are~~is~~ rinsed with fresh water to remove sand or other foreign material.
O	2		2.1.5~~.~~ Shellfish meats are removed from the shell by separating the adductor muscles and tissue connecting at the hinge.
C~~K~~	**2**		**2.1.6~~.~~ Damage to the body of the mollusk is minimized in the process of opening.**
O	2		2.1.7~~.~~ Shucked shellfish are drained on a #10 mesh sieve ~~(~~or equivalent~~)~~ without layering for 5 minutes.
K	2		2.1.8~~.~~ Pieces of shell and drainage are discarded.
C	2		**2.1. 9~~.~~ Drained meats or previously cooled/refrigerated shucked meats and their drip loss liquid or thawed homogenates with their freeze-thaw liquid are blended at high speed until homogenous** (60 - 120 seconds).
			2.2 Preparation of Samples for Analysis – APHA/AOAC Digestion & Extraction
K	15, 9		2.2.1 Sample homogenates are extracted as soon as possible (preferably the same day) or stored in the freezer.
K	2		2.2.2~~1.~~ 100 grams of homogenized sample is weighed into a beaker.
K	2		2.2.3~~2.~~ The sample homogenate is extracted in a 1:1 weight/volume ratio by adding ~~An equal amount of~~ 0.1 M~~N~~ HCl~~1~~ or~~/~~ 0.18 M~~N~~ HCl ~~is added to the homogenate and thoroughly mixed~~ (*circle the appropriate choice ~~normality~~*).
K	2		**2.2.4 Homogenate/acid mixture is stirred thoroughly before boiling to completely mix the contents.**
C			**~~3. pH is checked and, if necessary adjusted to between pH 2.0 and 4.0.~~**
C	**2**		**2.2.5~~4.~~ To prevent toxin transformation, the pH of the homogenate/acid mixture before boiling is 3.0 ± 1.0, adjusted if necessary with ~~Adjustment of pH is made by~~ the dropwise addition of either ~~the acid (~~5 M~~N~~ HCl~~)~~ to lower the pH or ~~base (~~0.1 M~~N~~ NaOH~~)~~ to raise the pH, as appropriate, while constantly stirring the mixture.**
C	**2**		**2.2.6~~5.~~ The homogenate/acid mixture is promptly brought to its boiling point, ~~a boil, 100 ± 1°C,~~ then gently boiled at 100 ± 1 °C for 5 minutes.**
O	9		2.2.7~~6.~~ The homogenate/acid mixture is boiled under adequate ventilation (e.g.~~,~~ ~~i.e.~~ fume hood).

O	9		2.2.8~~7.~~ The homogenate/acid mixture~~extract~~ is allowed to cool~~ed~~ to room temperature.
C	**2**		**2.2.9 ~~8.~~ The pH of the cooled mixture after boiling is 3.0 ± 1.0, ~~extract is determined and~~ adjusted~~,~~ if necessary, ~~to between pH 2 and 4, preferably to pH 3~~ with the ~~stirred~~ dropwise addition of 5 M ~~N~~ HCl to lower the pH or 0.1 M ~~N~~ NaOH to raise the pH, as appropriate, while constantly stirring the mixture.**
K	2		2.2.10 The homogenate/acid mixture is adjusted gravimetrically to the pre-boiling weight using 0.001 M HC1.
~~K~~			~~9. The extract volume (or mass) is adjusted to 200 mls (or grams) with dilute HCl, pH 3 water.~~
K	2		2.2.11~~10.~~ The homogenate/acid mixture ~~extract is returned to the beaker, stirred to homogeneity and~~ is allowed to separate by gravity or by centrifugation ~~settle to remove particulates; or, if necessary, an aliquot of the stirred supernatant is~~ (e.g. centrifuged at 3,000 RPM for 5 minutes) ~~before injection~~.
K	9		2.2.12~~11.~~ If the extracted sample ~~mice~~ cannot be assayed~~injected~~ immediately, then the supernatant is decanted and stored in a sealed container under~~should be removed from the centrifuge tubes and~~ refrigeration~~ed~~ for up to 24 hours or frozen for longer storage.
K	9		2.2.13~~12.~~ Refrigerated extracts are allowed to reach ambient temperature before being bioassayed or tested by the SRT for PSP.
		2.3 Mouse Bioassay (MBA) for PSP	
K~~O~~	2		2.3.1~~.~~ A 26-gauge hypodermic needle is used for intraperitoneal injections.
C~~K~~	**2**		**2.3.2~~.~~ Healthy mice in the weight range of 17.0 -23.0 grams (19 - 21 grams is preferable) from a stock colony are used for routine assays. Previously injected ~~M~~mice are never~~ot~~ re-used for a bioassay.** **~~Stock strain: _____ Source:~~** **Stock strain used _____ Source of mice_____**
C	**9**		**2.3.~~3.~~ Mice are allowed to acclimate ~~for~~ at least 24 hours prior to injection. In some cases, ~~up to~~ 48 hours may be required.**
C	**9**		**2.3.~~4.~~ A conversion factor (CF) for the lab has been appropriately determined. ~~as _____. Month and year when current CF determined _____.~~** **Lab CF: Date CF established:**
C	**2**		**2.3.~~5.~~ The CF value is checked weekly if assays are done on one or several days during the week~~,~~ or~~,~~ once each day that assays are performed if they are performed less than once per week.** **~~Date of current CF check: _____ CF verified: yes/no (*circle choice*)~~** **~~Date of most recent CF check _____~~** **CF verified/CF not verified ~~*(Circle appropriate choice)*~~**
C	**2**		**2.3.6 If the lab CF is not verified during a check, the lab follows the appropriate procedure for establishing a temporary CF to use for the day/week.**
~~C~~			~~6. If the CF is not verified, 5 additional mice are injected with the dilution used in the CF check to complete a group of 10 mice. Ten additional mice are also injected with this dilution to produce a second group of 10 mice. The CF is calculated for each group of 10 mice and averaged to give the CF to be used in sample toxicity calculations for the day's or week's work only. All subsequent work must make use of the original laboratory CF value unless this value continues to fail to be verified by routine CF checks.~~
C	**2, 9**		**2.3.~~7.~~ If the lab CF fails to be verified, the cause is investigated and the situation is**

			corrected. If the cause cannot be determined with reasonable certainty and the lab CF fails to be verified > three~~3~~ times in a~~per~~ year, the lab CF~~bioassay~~ is recalculated through a restandardization~~ed~~ procedure.
K~~O~~	9		2.3.8~~.~~ Mice are weighed to the nearest 0.1~~5~~ g~~ram~~.
C	2		2.3.9~~.~~ Mice are injected intraperi~~t~~ioneally with 1 m~~L~~l of ~~the acid~~ extracted sample.
K	2		2.3.10~~.~~ For ~~the~~ CF checks, ~~at least 5~~five mice are injected~~used~~.
K~~C~~	9		2.3.11~~.~~ For routine assays, three~~At least 3~~ mice (two when both survive) are injected~~used~~ per sample ~~in routine assays~~.
C	2		2.3.~~12.~~ Elapsed time post-injection is accurately determined and recorded.
C~~K~~	2		2.3.13~~.~~ When~~If~~ death occurs, the time of death to the nearest second is noted at~~by~~ the last gasping breath and recorded.
C	9. 2		2.3.14 Mice are continually observed for up to 20 minutes after injection, then periodically observed for a total time of up to 60 minutes after injection.
C	2		2.3.15~~14.~~ If the median corrected mouse unit is greater than 1.92 ~~death time(2 out of 3 mice injected die) is <~~ (5 minutes), then the sample is ~~a~~ dilute~~d~~ion is made with ~~dilute~~0.001 M HCl as appropriate~~, pH 3 water,~~ to achieve~~obtain~~ a median corrected mouse unit, MCMU of 1.39-1.92 (a death time ~~in the range~~ of 5~~ to~~ 7 minutes).
		2.4 Calculation of t~~T~~oxicity for MBA	
C	2		2.4.~~1.~~ The death time for~~of~~ each mouse is converted to mouse units (MU) using Sommer's Table ~~(Table 6 *Recommended Procedures, 4th edition)*~~ and recorded. Any~~The death time of~~ mice surviving beyond 60 minutes are~~is considered to be recorded as~~ < 0.875 MU.
C~~K~~	2		2.4.2~~.~~ The~~A~~ weight for each mouse is correct~~ed~~ion to mouse units ~~in MU~~ using the table of weights in ~~is made for each mouse injected using Table 7 in~~ Recommended Procedures (Table 7) and interpolated for weights not listed.~~, 4th edition.~~
C	2		2.4.~~3.~~ The ~~death time of each mouse in MU is multiplied by a weight correction in MU to give the C~~corrected M~~m~~ouse U~~u~~nit (CMU) for each mouse injected is calculated as follows:~~.~~ Death time in MU x Weight correction in MU=CMU
C	2		2.4.~~4.~~ The ~~m~~Median Corrected Mouse Unit (MCMU) for each sample is calculated and used in the final toxicity calculation for that sample. ~~value of the array of corrected mouse units (CMU) is determined to give the median corrected mouse unit (MCMU).~~
C	2		2.4.~~5.~~ ~~The concentration of toxin is determined by the formula, MCMU x CF X Dilution Factor X 200.~~ The toxicity of each sample is calculated as follows: µg STX eq/100 g of sample = MCMU x CF x DF-x 200 except when less than 100 grams of sample is used for analysis. In this case an adjustment for sample weight must be made such that the formula for calculating sample toxicity becomes: µg STX eq/100 grams of sample = MCMU x CF x DF x 200/Adjusted weight of the acidified sample x 200. Where: MCMU=Median Corrected Mouse Unit for the sample CF=Laboratory Conversion Factor DF=Dilution Factor (e.g. 1:1 dilution, DF=2)
C	11		2.4.6~~6.~~ Any value equal to or greater than 80 µg STX eq/l00 g~~rams~~ of sample~~meat~~ is actionable.
PART III – Examination of Shellfish for PSP Toxins – SRT			
		3.1 Screening by Scotia Rapid Test (SRT)	

K	9		3.1.1 Before beginning any screening, the following items are recorded for the SRT kit in use. a. Date received. b. Batch/lot numbers for all kit components (test strip and PSP AOAC buffer). c. Expiration dates for all kit components. d. Date opened and/or used.
K	13		3.1.2 When placed into service, all kit components are within the accepted expiration dates.
C	**13**		**3.1.3 The desiccant pouch inside the test strip wrapping is blue in color, indicating suitability for use. Any test strip wrapping containing a pink desiccant pouch is discarded.**
K	13		3.1.4 All kit components are stored according to the manufacturer's recommendations.
C	**9**		**3.1.5 A positive control of 80 µg STX eq/100 g of sample is used to test new kit lots and buffers. Results are recorded and records maintained.**
C	**9**		**3.1.6 Micropipettes with appropriate ranges for the volumes being measured are used.**
K	9		3.1.7 All micropipettes are maintained and calibrated according to manufacturer's instructions. Results are recorded and records maintained.
C	**13**		**3.1.8 400 µL of buffer solution is accurately transferred to a small tube.**
C	**13**		**3.1.9 100 µL of sample extract is accurately added to the buffer.**
K	13		3.1.10 The buffer/sample mixture is carefully mixed by inserting the tip of the micropipette into the mixture and pipetting up and down at least three times.
C	**13**		**3.1.11 100 µL of the thoroughly mixed solution is added to the test strip sample well.**
K	9		3.1.12 Micropipette tips are not reused.
K	13		3.1.13 Inoculated test strips are allowed to react with the sample mixture for the period of time recommended by the manufacturer.
C	**13**		**3.1.14 The test strip result is interpreted according to the instruction card provided by the manufacturer, which is specific to each batch/lot of test strips. Results are recorded and records are maintained.**
K	13		3.1.15 If a test result is interpreted as invalid, the pH of the sample extract is checked and adjusted as needed to fall between pH 2.0 – 4.0. Fresh PSP AOAC buffer is used to re-test the sample on a new test strip.
C	**13**		**3.1.16 If the same sample is interpreted as invalid on two different test strips, then the sample is assumed to contain interfering substances, and an alternative test method is used.**
C	**11**		**3.1.17 Any positive result on a SRT is actionable.**

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Personal communication with USFDA Washington Seafood Laboratory Branch, Office of Seafood, CFSAN, 1998-1999.

LABORATORY:	DATE OF EVALUATION:

SHELLFISH LABORATORY EVALUATION CHECKLIST

SUMMARY OF NONCONFORMITIES

Page	Item	Observation	Documentation Required

LABORATORY STATUS

LABORATORY	**DATE**
LABORATORY REPRESENTATIVE:	

PARALYTIC SHELLFISH POISON COMPONENT: PARTS I, II, ~~and~~ III

A. Results	
Total # of Critical (C) Nonconformities	_____
Total # of Key (K) Nonconformities	_____
Total # of Critical, Key and Other (O) N~~n~~onconformities	_____

B. Criteria for Determining Laboratory Status of the PSP, MBA and/or SRT Component

1. Conforms Status; The PSP, MBA and/or SRT component of this Laboratory is in conformity with NSSP requirements if all of the following apply.

   a. No Critical nonconformities.
   b. and <6 Key nonconformities.
   c. and <12 Total Nonconformities.

2. Provisionally Conforms Status: The PSP, MBA and/or SRT component of this Laboratory is determined to be provisionally conforming to NSSP requirements if all of the following apply.

   a. the number of Critical nonconformities is > 1 but < 4,
   b. and <6 Key nonconformities.
   c. and <12 Total Nonconformities.

3. **Does Not Conform Status:** The PSP, MBA and/or SRT component of this L~~l~~aboratory is not in conformity with NSSP requirements when any of the following apply. ~~if:~~

   a. The total # of Critical nonconformities is >4.
   b. or total # of Key nonconformities is > 6.
   c. or the total # of Critical, Key and Others is > 12.

~~A. The total # of Critical nonconformities is ≥ 3 or~~

~~B. The total # of Key nonconformities is ≥ 6 or~~

~~C. The total # of Critical, Key and Other is ≥ 10~~

~~2. **Provisionally Conforms Status:** The PSP component of this laboratory is determined to be~~

~~provisionally conforming to NSSP requirements if the number of critical nonconformities is ≥ 1 but < 3~~

C. Laboratory Status (*circle appropriate*)

Does Not Conform - Provisionally Conforms - Conforms

Acknowledgement by Laboratory Director/Supervisor:

All corrective Action will be implemented and verifying substantiating documentation received by the Laboratory Evaluation Officer on or before

_____

Laboratory Signature:

_____ Date:_____

LEO Signature:

_____ Date:_____

~~NSSP Form Lab-100 Rev. 2005~~

Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 11-109.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 11-109.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 11-109.

Proposal Subject	Addition to the Requirements for the Authority During a Suspected Shellfish Related Outbreak
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management
Text of Proposal/ Requested Action	@.01 Outbreaks of Shellfish-Related Illness 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	
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 referral of Proposal 11-115 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.
Action by 2015 Shellfish Reconditioning Committee	Recommended adding a new section as follows: Chapter II. Risk Assessment and Risk Management @ .01 Outbreaks J. Molluscan shellfish products that as a result of illnesses associated with V.v. & V.p. may be reconditioned. Validated reconditioned processes include subjecting products to validated PHPs or placing product into

approved, conditionally approved, conditionally restricted, or restricted growing areas for an appropriate period of time, not less than fourteen (14) days, with appropriate controls and documentation to be determined by the State Shellfish Control Authority (SSCA).

Action by 2015 Task Force I

Recommended adoption of Proposal 11-115 as amended.

Add a new section as follows:
Chapter II. Risk Assessment and Risk Management
@ .01 Outbreaks

J. Molluscan shellfish product~~s~~ that is recalled as a result of illness~~es~~ outbreak associated with *V.v.* & *V.p.* may be reconditioned. Validated reconditioned processes include subjecting product~~s~~ to validated PHPs or placing product into approved, conditionally approved, conditionally restricted, or restricted growing areas for an appropriate period of time, not less than fourteen (14) days, with appropriate controls and documentation to be determined by the State Shellfish Control Authority (SSCA).

Action by 2015 General Assembly

Adopted recommendation of Task Force I on Proposal 11-115.

Action by FDA January 11, 2016

Concurred with Conference action on Proposal 11-115.

Proposal Subject	Sources of Seed for Aquaculture
Specific NSSP Guide Reference	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	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.
Action by 2015 Aquaculture Facility Inspection Committee	Recommended the following: (1) Referral of Proposal 13-107 back to Committee as appointed by the Conference Chair. (2) The charge of the Committee be expanded to include updating and revising the Aquaculture Chapter of the Model Ordinance to reflect current practices and methods and submit proposals for the next Annual Meeting.
Action by 2015 Task Force I	Recommended adoption of Aquaculture Facility Inspection Committee recommendations on Proposal 13-107.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 13-107.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-107.

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
Text of Proposal/ Requested Action	4. Approved Limited Use Methods for Marine Biotoxin Testing 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	Each 96 well plate costs ~$500.
Action by 2013 Laboratory Method and Quality Assurance Review Committee	Recommended referral of Proposal 13-109 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.

Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-109 to an appropriate committee as determined by the Conference Chair until data that supports the use of the Abraxis ELISA beyond the use of the onboard procedure is made available.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-109.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 13-109.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-109.

Proposal Subject	Immunoassay Method for Detection of Saxitoxin (PSP) from Shellfish
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	2. Approved Methods for Marine Biotoxin Testing and 4. Approved Limited Use Methods for Marine Biotoxin Testing. 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 reduces 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 makes the laboratories able to provide rapid warning. References attached.
Cost Information	Approximate cost for the basic set up of the method is $3600.
Action by 2013 Laboratory Methods and Quality Assurance Review Committee	Recommended referral of Proposal 13-110 to an appropriate committee as determined by the Conference Chairman and directs 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.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-110 to the appropriate committee as determined by the Conference Chair until additional data are received.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-110.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 13-110.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-110.

Proposal Subject	DSP PPIA Kit for Determination of Okadaic Acid Toxins Group (OA, DTX1, DTX2) in Molluscan Shellfish
Specific NSSP Guide Reference	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 Diarrheic 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	Refer to Para D.1. of the Checklist
Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chairman and directed 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 Laboratory Methods 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.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chair until additional data are received.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-111.
Action by 2015 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-111.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-111.

Proposal Subject	Reveal 2.0 ASP
Specific NSSP Guide Reference	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	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.
Action by 2015 Laboratory Methods	Recommended no action on Proposal 13-112. Rationale: No data has been received and submitter has indicated no plans to submit data at this time.

Review Committee Action by 2015 Task Force I	Recommended adoption of Laboratory Method Review Committee recommendation on Proposal 13-112.
Action by 2015 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-112.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-112.

Proposal Subject	Reveal 2.0 DSP
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas
Text of Proposal/ Requested Action	.11 Approved NSSP Laboratory Tests 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. Version1. http://www.aesan.msps.es/en/CRLMB/web/procedimientos_crlmb/crlmb_standard_operating_procedures.shtml
Cost Information	Approximately $17.00 per test. Reader based assay – approximate cost of Reader $1995.
Action by 2013 Laboratory Method and Quality Assurance Review Committee	Recommended referrals of Proposal 13-113 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.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-113 to an appropriate committee as determined by the Conference Chair until additional data are received.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-113.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 13-113.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-113.

Proposal Subject	Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas . 11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	4. Approved Limited Use Methods for Marine Biotoxin Testing 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 (3H-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 3H-STX is removed and the remaining labeled toxin is measured with a scintillation counter. The amount of remaining 3H-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	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 Methods 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 recommendation 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.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-114 to an appropriate committee as determined by the Conference Chair until additional data for oyster matrix are received.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-114.
Action by 2015 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-114.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-114.

Proposal Subject	Paralytic Shellfish Poisoning (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	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.

PUBLIC HEALTH SERVICE
U.S. FOOD AND DRUG ADMINISTRATION
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COLLEGE PARK, MD 20740-3835
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SHELLFISH LABORATORY EVALUATION CHECKLIST

LABORATORY:		
ADDRESS:		
TELEPHONE:	FAX:	EMAIL:
DATE OF EVALUATION:	DATE OF REPORT:	LAST EVALUATION:

LABORATORY REPRESENTED BY:	TITLE:
LABORATORY EVALUATION OFFICER:	SHELLFISH SPECIALIST:
	REGION:
OTHER OFFICIALS PRESENT:	TITLE:

Items which do not conform are noted by:

C – Critical K - Key O - Other NA - Not Applicable Conformity is noted by a "√"

PART I – QUALITY ASSURANCE			
Code			Item Description
			1.1 Quality Assurance (QA) Plan
K			1.1.1 Written Plan adequately covers all the following: (check √ those that apply) a. Organization of the laboratory. b. Staff training requirements. c. Standard operating procedures. d. Internal quality control measures for equipment, calibration, maintenance, repair and performance. e. Laboratory safety. f. Internal performance assessment g. External performance assessment
C			1.1.2 QA Plan is implemented.
			1.2 Work Area
O			1.3.1 Adequate for workload and storage.
O			1.3.2 Clean and well lighted.
O			1.3.3 Adequate temperature control.
O			1.3.4 All work surfaces are nonporous and easily cleaned.
			1.3 Laboratory Equipment.
O			1.4.1 The pH meter has a standard accuracy of 0.1 unit.
K			1.4.2 pH paper in the appropriate range (i.e. 1-4) is used with minimum accuracy of 0.5 pH units.
K			1.4.3 pH electrodes consist of pH half cell and reference half cell or equivalent combination electrode (free from Ag/AgCl or contains an ion exchange barrier to prevent passage of Ag ions into the medium that may result in inaccurate pH readings).
K			1.4.4 pH meter is calibrated daily or with each use. Records maintained.
K			1.4.5 Effect of temperature has been compensated for by an ATC probe or by manual adjustment.
K			1.4.6 A minimum of two standard buffer solutions (2 & 7) are used to calibrate the pH meter. Standard buffer solutions are used once and discarded.
K			1.4.7 Electrode efficiency is determined daily or with each use following either slope or millivolt procedure.
K			1.4.8 The balance provides a sensitivity of at least 0.0001 g at a load of 5 grams.
K			1.4.9 The balance calibration is checked monthly using NIST class S, ASTM class 1 or 2 weights or equivalent. Records maintained.
K			1.4.10 Refrigerator temperature is maintained between 0 and 4ºC.
K			1.4.11 Refrigerator temperature is monitored at least once daily. Records maintained.
K			1.4.12 Freezer temperature is maintained at -20ºC or below.
O			1.4.13 Freezer temperature is monitored at least once daily. Records maintained.
O			1.4.14 All glassware is clean.
K			1.4.15 High performance liquid chromatography system equipped with the following: a. Low dead-volume, b. binary solvent system delivering a pulse-free flow of 0.5-2.0 mL/min, c. solvent degasser, d. autosampler with loop suitable for 5-30 µL injections, e. temperature controlled column compartment capable of controlling temperature between 10 – 50ºC, and f. fluorescence detector able to achieve the required sensitivity at excitation

			λ=330nm and emission λ=390nm.
K			1.4.16 Post-column reaction system equipped with the following: a. Reactor module capable of maintaining 85ºC, b. dual reagent pumps capable of delivering accurate flows of 0.4 mL/min, and c. knitted reaction coil, 1 mL volume, 5 m x 0.5 mm.
K			1.4.17 Autopipettors are calibrated annually. Records maintained.
K			1.4.18 Boiling water bath with sufficient volume to cover sample/acid mixture.
K			1.4.19 Centrifuge capable of holding 50 mL polypropylene tubes and generating ~ 3000 RCF.
K			1.4.20 Microcentrifuge capable of generating ~16000 RCF.
			1.4 Reagents and Reference Solution Preparation and Storage
O			1.5.1 All solvents and reagents used are analytical or LC grade materials.
K			1.5.2 Water is distilled or deionized and exceeds 0.5 megaohm resistance or is less than 2 µSiemens/cm conductivity at 25ºC to be tested and recorded monthly for resistance or conductivity.
O			1.5.3 Water is analyzed for residual chlorine monthly and is at a nondetectable level (≤0.1 ppm) Records maintained.
K			1.5.4 Water is free from trace (< 0.5 mg/l) dissolved metals specifically, Cd, Cr, Cu, Ni, Pb, and Zn as determined annually with total heavy metal content < 1.0 mg/l. Records maintained.
O			1.5.5 Water contains < 1000 CFU/ml as determined monthly using the heterotrophic plate count method. Records maintained.
O			1.5.6 Reagents are properly stored and labeled with the date of receipt and date opened.
C			1.5.7 0.5 M 1-heptane sulphonate is prepared the day of use or refrigerated.
C			1.5.8 pH of mobile phases and oxidant are as follows and records maintained: a. GTX/STX toxins mobile phase A&B is 7.1, b. C toxins mobile phase A is 5.8, and c. Oxidant is 7.8.
K			Mobile phases and post-column reagents are filtered through 0.2 µm nylon filter membrane before use.
C			1.5.9 Only certified reference materials are used for standard solutions. Source of the reference standard: _____
K			1.5.10 All primary standards are stored appropriately as per supplier recommendations.
K			1.5.11 Standards are prepared gravimetrically using "Class A" glassware.
K			1.5.12 Intermediate mixes of primary standards are made up in 0.003 M HCl (GTX/STX toxins) or Milli-Q water (C toxins), and stored appropriately.
K			1.5.13 Working standards are made up from primary standard mixes by dilution with toxin-free, deproteinated mussel or oyster extract (GTX/STX toxins) or Milli-Q water (C toxins).
K			1.5.14 Working standards are stored in the refrigerator at 4°C.
			1.5 Collection and Transportation of Samples
O			1.6.1 Shellstock are collected in clean, waterproof, puncture resistant containers.
K			1.6.2 Samples are appropriately labeled with the collector's name, type of shellstock, the source, the harvest area, time, date and place (if market sample) of collection.
K			1.6.3 Immediately after collection, shellstock samples are placed in dry storage between 0 and 10ºC until analyzed.
K			The time from collection to completion of the assay should not exceed 24 hours.However, if there are significant transportation delays, then shellstock samples are processed immediately as follows (circle the appropriate choice): a. Washed, shucked, drained, frozen until extracted;

			b. Washed shucked, drained, homogenized and frozen; c. Washed, shucked drained, extracted, the supernatant decanted and refrigerated (best choice); or d. The laboratory has an appropriate contingency plan in place to handle samples which can't be analyzed within 24 hours due to transportation issues.
			1.6.4 Frozen shucked product or homogenates are allowed to thaw completely and all liquid is included as part of the sample before being processed futher.
PART II – EXAMINATION OF SHELLFISH FOR PSP TOXINS			
			2.1 Preparation of Sample
C			2.1.1 At least 12 animals are used per sample or the laboratory has an appropriate contingency plan for dealing with non-typical species of shellfish.
O			2.1.2 The outside of the shell is thoroughly cleaned with fresh water.
O			2.1.3 Shellstock are opened by cutting the adductor muscles.
O			2.1.4 The inside surfaces of the shells are rinsed with fresh water to remove sand and other foreign materials.
O			2.1.5 Shellfish meats are removed from the shell by separating the adductor muscles and tissue connecting at the hinge.
K			2.1.6 Damage to the body of the mollusk is minimized in the process of opening.
O			2.1.7 Shucked shellfish are drained on a #10 mesh sieve or equivalent without layering for 5 minutes.
K			2.1.8 Pieces of shell and drainage are discarded.
C			2.1.9 Drained meats or thawed homogentates are blended at high speed until homogenous (60-120 seconds).
			2.2 Digestion of Sample
K			2.2.1 Sample homogenates are extracted as soon as possible (same day) or stored in the freezer.
K			2.2.2 Sample homogenate is extracted in a 1:1 w/v ratio with 0.1 M HCl, preferably 5g tissue in 5mL acid
K			2.2.3 Homogenate/acid mixture is vortexed thoroughly before boiling to completely mix the contents.
C			2.2.4 To prevent toxin transformation, the pH of the homogentate/acid mixture before boiling is 3.0 ± 1.0, adjusted if necessary with 5M HCl or 0.1 M NaOH.
C			2.2.5 Samples are extracted in a boiling water bath for 5 minutes, in capped 50mL polypropylene centrifuge tubes.
K			2.2.6 The pH of the cooled mixture after boiling is 3.0 ± 1.0, adjusted if necessary with 5M HCl. Any sample with a pH of less than 2.0 is discarded and extracted again.
K			2.2.7 The homogenate/acid mixture is allowed to separate by gravity or by centrifugation at 2500 *g* for 10 minutes. Supernatant is then decanted into a scintillation vial.
			2.3 Deproteination
C			2.3.1 Extract is deproteinated with 30% trichloroacetic acid (50 µL TCA per 1000 µL aliquot of supernatant), vortexed thoroughly and centrifuged at 16,000 *g* for 5 minutes.
C			2.3.2 The pH of the deproteinated extract is adjusted to 3.0 ± 1.0 with 1.0 M NaOH (70 µL NaOH per 1000 µL aliquot of supernatant), vortexed thoroughly and centrifuged at 16,000 *g* for 5 minutes.
K			2.3.3 An aliquot of the deproteinated, pH-adjusted supernatant is filtered through a 0.2 µm filter into two 2 mL autosampler vials (one vial for GTX/STX analysis and one vial for C-Toxins analysis).

			2.4 Assay
C			2.4.1 A calibration is performed upon initial instrument set up, following any major hardware maintenance activity, or when the continuing calibration verification (CCV) indicates significant drift (> 30% for individual toxin) from the calibration. Records maintained.
K			2.4.2 For GTX/STX toxins, no more than ten samples should be made between standard analyses. For C toxins, no more than five samples injections should be made between standard analyses.
K			2.4.3 10 µL is injected for GTX/STX toxins and 5 µL is analyzed for C-toxins.
K			2.4.4 Samples are stored in the sample compartment at 4°C during analysis.
O			2.4.5 A column heater is used in the analysis.
O			2.4.6 The appropriate analytical column is used. a. GTX/STX Toxins: Zorbax Bonus-RP column, 4.6 mm x 150 mm, 3.5 µm, Agilent catalog number 863668-901 or equivalent. b. C Toxins: BetaBasic 8, 4.6 mm x 250 mm, 5 µm, Fisher catalog number 71405-254630 or equivalent.
			2.5 System Suitability
K			2.5.1 The correlation coefficient for the linear regression (r^2) must be ≥ 0.990 for each individual toxin.
K			2.5.2 Resolution and Retention Time Criteria. GTX/STX Toxins. a. Matrix peak must be at least 70% baseline resolved between GTX3 and GTX2. b. GTX5 must be at least 40% baseline resolved between dcGTX3 and dcGTX2. c. dcSTX and STX must be at least 70% baseline resolved. d. GTX4 retention time should be between 5 and 7 minutes. C Toxins. e. C1 and C2 must be at least 70% baseline resolved. f. C1 retention time should be between 5 and 8 minutes.
			2.6 Calculation of Toxicity
C			2.6.1 The toxicity of the individual toxins is calculated as follows: $$\mu gSTXdiHCleq/100g = \mu M \times \frac{372.2}{1000mL} \times \frac{Fvol}{Ext.vol} \times \left(\frac{Wt + Vol}{Wt}\right) \times ReTx \times 100$$ Where: µM = Concentration of toxin in the extract, in µM; Fvol = Final volume of the deproteinized extract (1120 µL); Ext.vol = Volume of crude extract used (1000 µL); Wt = Weight of sample used; Vol = Volume of acid extractant used (e.g. 5 mL); and ReTx = Relative toxicity of toxin vs. Saxitoxin.

Relative Toxicity Values

Toxin	ReTx	Toxin	ReTx
GTX1	0.9940	NEO	0.9243
GTX2	0.3592	STX	1.0000
GTX3	0.6379	dcSTX	0.5131
GTX4	0.7261	C1	0.0060

				GTX5	0.0644	C2	0.0963	
				dcGTX2	0.1538	C3	0.0133	
				dcGTX3	0.3766	C4	0.0576	
C			2.6.2 The individual toxicities for each toxin are summed to obtain the overall sample toxicity in µg STX equivalents/100 g (µg/100 g)					
			2.6.3 Any value greater than 80 µg STX equivalents /100 g of meat is actionable.					

REFERENCES

1. AOAC Official Methods of Analysis (2011). AOAC Official Method 2011.02 Paralytic Shellfish Toxins in Mussels, Clams, Oysters, and Scallops Post-Column Oxidation (PCOX) Method.
2. Adams, W.N. and S.A. Furfari. 1984. Evaluation of laboratory performance of the AOAC method for PSP toxin in shellfish. *J. Assoc. Off. Anal. Chem.* Vol 67, 6:1147-1148.
3. American Public Health Association. 1970. *Recommended Procedures for the Examination of Sea Water and Shellfish*, 4th Edition. APHA, Washington, D.C.
4. American Public Health Association. 192. *Standard Methods for the Examination of Dairy Products*, 16th Edition. APHA, Washington, D.C.
5. Assocation of Official Analytical Chemists International. 1990. *Methods of Analysis*, 15th Edition. AOAC, Arlington, VA.
6. APHA/WEF/AWWA. 1992. *Standard Methods for the Examination of Water and Wastewater*, 18th Edition. APHA, Washington, D.C.
7. Title 21, Code of Federal Regulations, Part 58, *Good Laboratory Practice for Nonclinical Laboratory Study*. U.S. Government Printing, Washington, D.C.
8. National Research Council. 1996. *Guide for the Care and Use of Laboratory Animals*. National Academy Press, Washington, D.C.
9. Personal communication with USFDA Washington Seafood Laboratory Branch, Office of Seafood, CFSAN, 1998-1999.

LABORATORY:			**DATE OF EVALUATION:**
SHELLFISH LABORATORY EVALUATION CHECKLIST **SUMMARY OF NONCONFORMITIES**			
Page	**Item**	**Observation**	**Documentation Required**

LABORATORY STATUS	
LABORATORY	**DATE**
LABORATORY REPRESENTATIVE:	
PARALYTIC SHELLFISH POISON COMPONENT: PARTS I AND II	
A. Results Total # of **Critical (C)** Nonconformaties Total # of Key (K) Nonconformaties Total # of Critical, Key, and Other (O) Nonconfomaties	_____ _____ _____

B. Criteria for Determining Laboratory Status of the PSP Component

1. **Does Not Conform Status** The PSP component of this laboratory is not in conformity with NSSP requirements if:
   a. The total # of Critial nonconformities is ≥ **3 or**
   b. The total # of Key nonconformities is ≥ **6 or**
   c. The total # of Critical, Key, or Other is > **10**

   d. **Provisionally Conforms Status** The PSP component of this laboratory is determined to be provisionally conforming to NSSP requirements if the number of critical nonconformities is ≥ 1 by <3.

C. Laboratory Status (*circle appropriate)*

Does Not Conform – Provisionally Conforms – Conforms

Acknowledgement by Laboratory Director/Supervisior:

All corrective Action will be implemented and verifying substantiating documentation received by the Laboratory Evaluation Officer on or before _____.

Laboratory Signature: _____ Date:_____

LEO Signature:_____ Date: _____

Action by 2013 Laboratory Methods and Quality Assurance Review Committee	Recommended referral of Proposal 13-115 to an appropriate committee as determined by the Conference Chairman.
Action by 2013 Task Force I	Recommended adoption of 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.
Action by 2015 Laboratory Methods Review Committee	Recommended adoption of Proposal 13-115 as amended.

Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-115.
Action by 2015 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-115.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-115.

Proposal Subject	Shellfish Quarantine Guidance Document
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.04 Marine Biotoxin Control Section IV. Guidance Documents Chapter II. Growing Areas .02 Guidance for Developing Marine Biotoxin Contingency Plans
Text of Proposal/ Requested Action	Model Ordinance Chapter IV. Shellstock Growing Areas @.04 Marine Biotoxin Control Section 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. 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:

(2) May receive properly tagged shellfish from eligible aquaculturists only as indicated in the Authority's authorization email;
(3) 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];
(4) 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.
(5) Must allow the Authority to take two (2) random samples [minimum of twenty (20) shellfish per each sample] from each lot and deliver to the approved laboratory for approved mouse bioassay;
(6) 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;
(7) 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;
(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

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.

Action by 2015 Biotoxin Committee

Recommended adoption of Proposal 13-116 with substitute language as follows:

(4) The plan may include agreements or memoranda of understanding, between the

Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting in designated parts of a state growing area while other parts of the same ~~the~~ growing area are placed in the closed status. Such controlled harvesting shall be conducted with strict assurances of safety. In state growing areas or designated portions of state growing waters that are closed, the authority may allow for harvesting if an end product testing program is developed and~~, such as by batch release of shellfish lots only after~~ samples of each lot are tested and found to be below the action levels specified in Section C.

The program must include at a minimum:

i. Establishment of appropriate pre-harvest screening levels;
ii. Establishment of appropriate screening and end product testing methods;
iii. Establishment of appropriate laboratories/analysts to conduct screening and end product testing methods;
iv. Establishment of representative sampling plan for both i. and ii. above; and
v. Other controls as necessary to ensure that shellstock are not released prior to meeting all requirements of the program.

Should the above amended proposal be adopted by the conference, then the Biotoxin Committee should develop a Guidance Document that includes guidance for development of end-product testing programs to address biotoxins in closed state waters.

Action by 2015 Task Force I	Recommended adoption of Biotoxin Committee recommendation on Proposal 13-116.
Action by 2015 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-116.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-116.

Proposal Subject	Certification of State Shellfish Laboratory Evaluation Officers
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas
Text of Proposal/ Requested Action	.12 Evaluation of Laboratories By State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists

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 with checklists to FDA and 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	N/A
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 2013 Task Force I on Proposal 13-117.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-117.
Action by 2015 Laboratory Methods	Recommended adoption of Proposal 13-117 as amended.

Review Committee

.12 Evaluation of Laboratories By State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists

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~~ Thee 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 with checklists to FDA and 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.~~

Action by 2015 Task Force I	Recommended adoption of Laboratory Method Review Committee recommendation on Proposal 13-117.
Action by 2015 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-117.
Action by FDA January 11, 2016	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	.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:

(1) 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 should be used considering at a minimum the most recent two years of flow records. The larger of the WWTP design flow rate or actual monthly flows should be used when actual monthly flows reach 85% of the design flow for three consecutive months. Actual monthly flows can be used when they have not reached 85% of the design flow for two consecutive years. These flow values are appropriate when establishing a minimally sized prohibited zone when the WWTP is considered to be operating under normal operating conditions. Additionally, peak hourly flow rates within the most recent two years of records should be evaluated to determine if the design flow of the WWTP is exceeded with periodic frequency. In the absence of supporting data, the conditional area should be closed when the peak 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 peak 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.

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 peak hourly rate shall be considered when determining the size of the prohibited zone. The peak hourly flow to be considered shall be determined as the maximum peak hourly flow based on (at a minimum) the most recent two consecutive years of flow records.

(2) 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. The accepted NSSP level of 1.4 x 106 FC/100ml found for disinfection failures requires a 100,000:1 dilution to dilute the non-disinfected 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.

(3) 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.

(4) 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.

(5) 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).

(6) Waste waters 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).

(7) Time of waste transport to the shellfish harvest site: The peak current flows at or near the outfall during ebb tide and flood tide shall be used for determining transport speed of effluent during possible upset conditions. 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.

(8) 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 even though no existing or identified shellfish resources are in the immediate area of the outfall.

(9) 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. 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 threshold value may be appropriate for situations in which superior 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 the WWTP at the shellfish growing area may be used provided that they are based on sound, scientific principles 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	
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 2013 Task Force I on Proposal 13-118.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-118.

Action by 2015 Growing Area Classification Committee

Recommended adoption of Proposal 13-118 with substitute language as follows:

Determining Appropriately Sized Prohibited Areas Associated with Wastewater Treatment Plants

Introduction

The original National Shellfish Sanitation Program (NSSP) principles have proved effective in controlling bacterial illness associated with shellfish harvested from polluted waters. These principles, namely a robust sanitary survey, regular water and shellfish monitoring using bacterial indicators, controlled harvest times and labelling the origin of shell stock remain applicable as the primary preventative food safety control measures for 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, Pouillot et al. 2015).

(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 2010; Iwamoto et al 2010; Scallan et al. 2011; Batz et al. 2012; Hall et al 2012). NoV genogroups I, II and IV and HAV are typically associated with ill-individuals 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.
In addition to the risk of enteric viruses WWTP effluents may also contain other chemicals and deleterious substances including pharmaceuticals, nanoparticles, and other contaminants of emerging concern. Establishment of a prohibitive area in proximity to WWTP discharges is an effective strategy to reduce the risk posed by both enteric viruses and other contaminants found in WWTP effluents. This guide provides information on the recommended dilution rates with respect to enteric viruses to ensure WWTP effluent does not cause a significant viral food safety risk within shellfish growing areas. The guide also considers the factors that should be used to assess a WWTP.

Delineation of the Prohibited Zone around a Wastewater Treatment Plant

The NSSP Model Ordinance Section II, Chapter IV. @.03 (2) (b) and @.03 E(5) 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 must 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 microbiological 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 each prohibited zone:

(1) The area 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 that relate to the WWTPs effectiveness in reducing enteric viruses in sewage.

Below is not an exhaustive list but serves as examples of situations that could occur and are critical for Shellfish Control Authorities (SCAs) on evaluating each WWTP when developing Conditional Area Management Plan (CAMP):

<u>Bypassing stage of treatment</u>

A plant may be considered operating outside of normal operation if a treatment stage such as primary or secondary treatment is bypassed which may result in an increased load of solids in the disinfection step and reduce the effectiveness of disinfection. An additional example would be when a WWTP experiences a loss in disinfection and thus the ability to effectively treat the final effluent. SCAs should determine the significance of these types of events and make appropriate provisions in the CAMP.

<u>Operating outside design specifications/other types of failures or events</u>

It is not uncommon for a WWTP to periodically experience mechanical failures of equipment that could alter the treatment of sewage. Additionally, a WWTP may also need to periodically perform routine maintenance to the various stages of treatment and may need to temporarily take a portion of a treatment stage off-line for cleaning. Other unexpected maintenance may need to occur for example bio-fouling of filters or membranes used in treatment. SCAs should be informed by WWTP operators of these events to determine if any additional temporary action is needed if not addressed in the CAMP.

<u>Operating above design flow</u>

Some WWTPs may operate above its design flow and not necessarily bypass any particular stage of treatment. During these events it is typical for WWTP operators to adjust the operation of the WWTP which may include reducing the treatment time in the aeration stage and/or solids separation/settling stage of

treatment. Under some circumstances this could lead to a significant reduction in the effectiveness of disinfection. SCAs may consider assessing the efficiency of WWTPs to determine the significance of these type of events and if additional provisions should be made in the CAMP.

WWTP permit violations

If a WWTP is exceeding the permitted bacterial indicator levels in the final effluent this indicates that effectiveness of the disinfection step has been reduced. Other measured parameters in the effluent (e.g. TSS, BOD) may also indicate a reduction in treatment efficiency as occurred. SCAs may consider assessing the efficiency of WWTPs to determine the significance of these type of events and if additional provisions should be made in the CAMP.

Situations where compliance with permit but risk to shellfish growing area.

There could be situations in which a particular WWTP could be in compliance with a permit, and could still pose a risk to the shellfish harvest area. For example, a WWTP may have permit conditions to allow for flow blending during high flow periods where a portion of the sewage may receive full treatment but a portion of the sewage may only be partially treated and "blended" in the final disinfection step. Although this may be an acceptable practice under a permit it could result in conditions in which the efficiency of the WWTP to remove enteric viruses is considerably reduced. SCAs may consider assessing the efficiency of WWTPs to determine the significance of these type of events and if additional provisions should be made in the CAMP.

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

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

Additional considerations

It is critical for SCAs to communicate with WWTP operators and ensure that there is no confusion over how SCAs define "outside of normal operation" in a Conditional Area Management Plan (CAMP) which may differ from how "malfunctions" or "violations" are defined in a permit. The SCAs also need to ensure that the WWTP operators understand the CAMP and that shellfish growing areas may close based on conditions of the CAMP even though the WWTP is operating in compliance within permitted conditions. Thus, it is important to communicate with WWTP operators to ensure that when shellfish closures occur and are reported that SCAs are using terminology that is understood by both parties.

Guidelines for Dilution, Dispersion, and Time of Travel of Effluent

Dilution refers to the dilution of effluent that occurs when the effluent is subjected to a number of physical processes in the receiving waters including turbulent mixing of the effluent in the vicinity of the outfall and at further distances primarily through tidal action, wind, and density stratification. Dispersion refers to the spread, location, and shape of the effluent discharge plume with time as it leaves the WWTP outfall. Time of travel refers to the time it takes effluent to reach the shellfish harvest site starting from the point of discharge.

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 which are the current indicator microorganisms used to assess treatment efficiency. In contrast, many human enteric viruses are not inactivated by functioning WWTP treatment and disinfection systems, hence the need for an adequate dilution zone between the outfall and the shellfish resource.

It is important to consider not only the WWTP discharge, but also overflow points on the collection system such as those from pumping stations. While a malfunctioning WWTP may provide partial treatment, the discharge from a collection system is untreated and may be a more common failure point in the overall system.

When determining if a WWTP or collection system discharge within the watershed or catchment area draining to a shellfish estuary potentially impacts a shellfish growing area, in the absence of a performance history of the treatment and collection system, and a database of influent and effluent quality, the NSSP recommends that a worst case raw sewage discharge be assumed. In this circumstance, if a level of 1.4 x 10^6 FC/100ml is assumed for a raw sewage release, a 100,000:1 dilution would be required 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. Different dilution ratios may be applied depending on the known concentration of sewage, provided that the water quality objective of the downstream harvest area is met.

In areas where the required WWTP discharge dilution is less than 100,000:1 and/or a raw sewage release results in FC levels in the growing area of >14 FC/100 ml a conditional management may be considered. However, conditional management is only recommended for, highly efficient WWTPs that are well monitored to detect malfunctions and changes in effluent quality and when the shellfish authority has the resources to effectively administrate and patrol the conditions of the growing area management plan.

In all cases the FDA recommends the minimum of a 1000:1 dilution around a WWTP outfall to mitigate the impact of viruses on shellfish growing areas.

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 and collection system overflows.

Scientific Rationale for 1000:1 Dilution Guidance

In 1995 the FDA determined the 1000:1 dilution was necessary using the most relevant the scientific literature available at that time (Kohn, et al. 1995; Havelaar et al. 1993; Kapikian et al. 1990; Liu et al. 1966). 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 technical advances to assess the 1995 1000:1 dilution recommendation. The Mobile Bay study confirmed that this level of dilution was appropriate to mitigate the risk of viruses discharged in treated wastewater effluent.

Since the 2008 Mobile Bay study there have been major advances in the detection and enumeration of NoV in wastewater and shellfish and fluorometer technologies have enabled more sophisticated hydrographic dye study methods. Using these advances, FDA has now conducted numerous dye studies supplemented with the testing of shellfish sentinels for enteric viruses and their surrogates. The 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 chlorination, and when operating under normal conditions.

While evaluating the 1000:1 dilution level Male Specific Coliphage (MSC) results in shellfish from the 2008-2015 studies were evaluated. These collaborative studies with State Shellfish Control Authorities and Industry were conducted in the Gulf, Mid-Atlantic, East and West Coast, and under varying hydrographic and meteorological conditions. Various additional factors were considered such as type of wastewater treatment and disinfection technology, seasonal conditions, and shellfish species etc. and are represented in the data collected. In some cases, data was collected during a period of which the WWTP was considered to be operating outside of "normal" operating conditions. In other cases, the WWTP was considered not suitable for conditional area management due to design/poor performance even during routine/normal operation. Focus was given to the MSC threshold of 50 PFU/100 grams of shellfish tissue which is the level 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 (Model Ordinance (Section II, Chapter IV, @.03 A(5)(C)(ii))). From the 2008-2015 studies, a total 216 samples were assessed including conditions when the WWTPs were considered operating normally as well as under a bypass or degraded operation conditions. In summary, 216 samples were analyzed for MSC of which 176 samples (81%) were positive for MSC; 118 samples (67%) contained MSC levels > than 50 PFU/100 grams; and 43 samples (20%) had MSC levels > 50 PFU/100 grams and wastewater effluent dilution was greater than 1000:1. These results are shown in Figure 1 and Table 1 below.

Figure 1: Comparison of dilution in receiving water and MSC levels in shellfish – all conditions

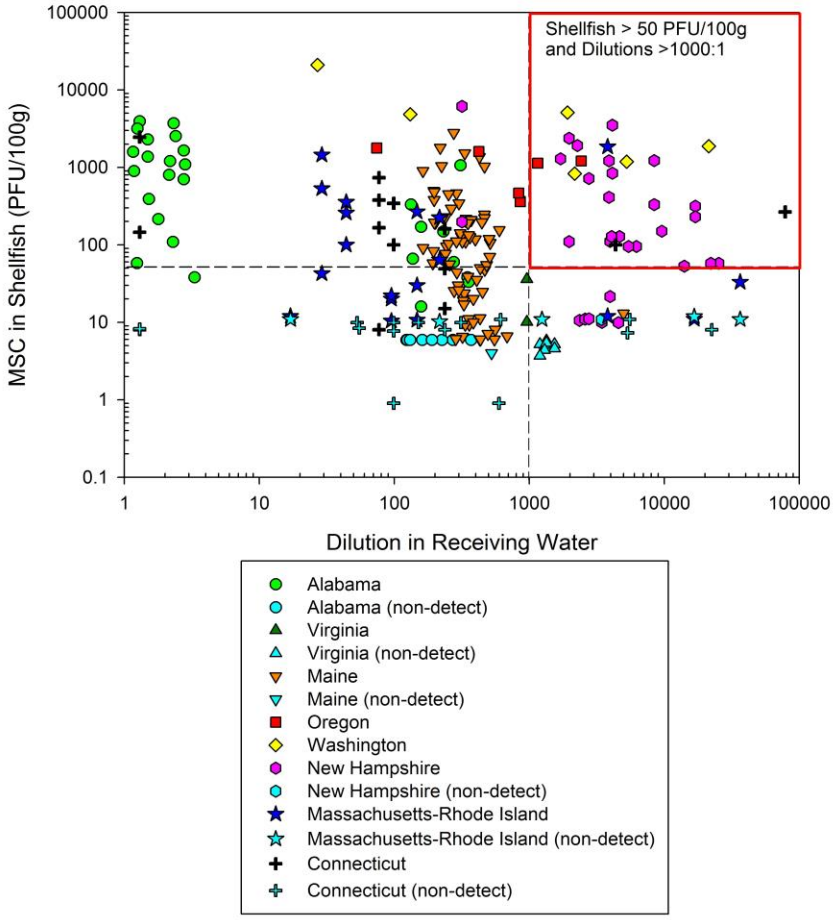


Table 1: MSC in shellfish operating under "normal" and outside of normal operation

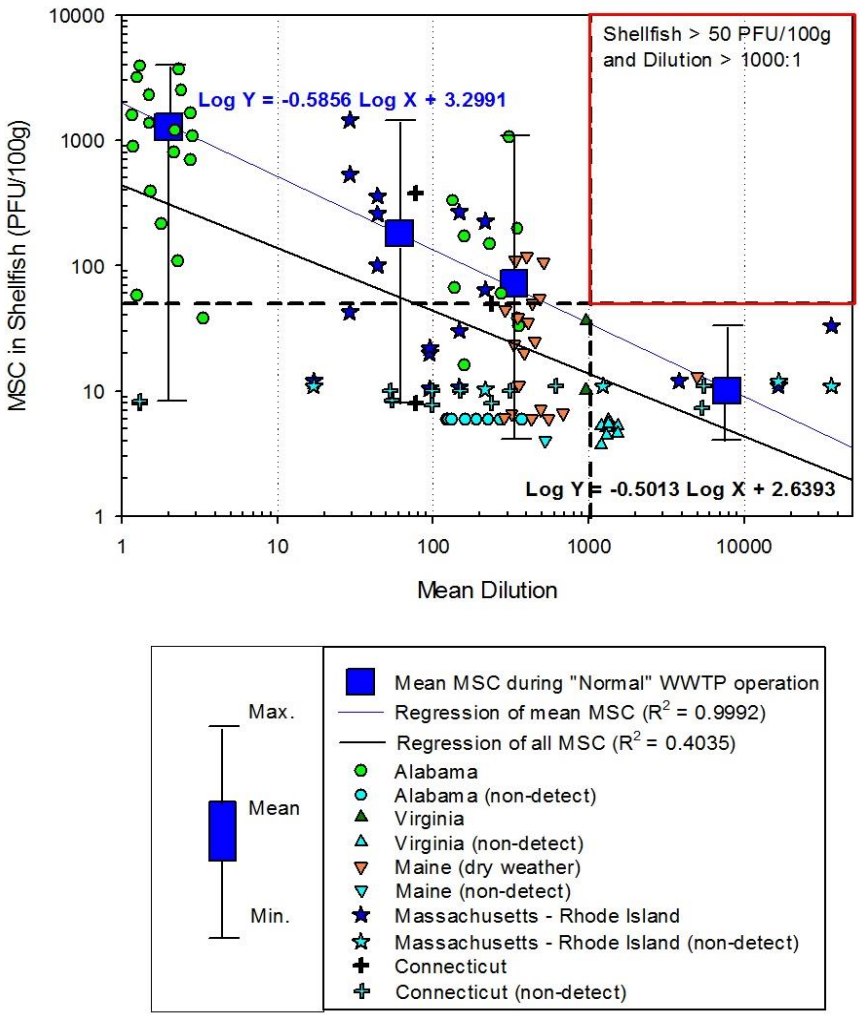
MSC Results	**All Conditions (n=216)**	**Normal Operating Conditions (n=129)**
MSC detectable	81% (176)	62% (80)
MSC levels >50 pfu/100g	67% (118)	36% (46)
MSC levels >50 pfu/100g and Dilution in Growing Area >1000:1	20% (43)	0% (0)

In separating the data attributed to "normal" operation from other conditions, 129 of the 216 total samples were considered to be attributed to "normal" WWTP operation, also shown on Table 1. Eighty seven (87) samples were removed as they were attributed to conditions of WWTP malfunction or situations considered not suitable for conditional area management. From the 87 samples, 80 were associated with degraded WWTP performance or malfunction of which 6 were associated with a primary bypass, 13 were associated within a period of a WWTP upgrade during which the WWTP reportedly was operating an extended period (weeks) without disinfection, 31 were associated with degraded treatment quality because of rainfall/flows exceeding the WWTP design capacity, and 30 were attributed to a WWTP with no secondary treatment and operated frequently with flows exceeding the design capacity. Of the remaining 7 samples, 6

were associated with a WWTP utilizing unconventional disinfection technology (membrane filtration) and demonstrated poor performance in removing viruses compared to other conventional technologies during normal operating conditions, and 1 sample was attributed to a potential point source sewage discharge other than the WWTP.

When considering the remaining 129 samples attributed to "normal" WWTP operating conditions there were no samples that were above 50 PFU/100 grams when dilution was greater than 1000:1. In comparison, of the 87 samples attributed to malfunction or unsuitable conditions, 43 samples exceeded 50 PFU/100 grams when dilution was greater than 1000:1. These results are shown in Figure 2 below.

Figure 2: Comparison of dilution in receiving water and MSC levels in shellfish under normal operation



Comparing MSC with NoV sample results, out of the 216 samples analyzed for MSC, 161 samples were also analyzed for NoV. Of the 161 samples tested for NoV, 66 were positive (41% of total) were positive for NoV. Out of the 66 NoV positive samples, 62 (94% of total) were also positive for MSC and 53 (85% of total) had levels greater than

50 PFU/100 grams. There were only 4 cases where NoV was positive but MSC was not detected. However, in these cases, 3 of the sample results were near the Limit of Detection (LOD) for NoV enumeration. In one case it is suspected that both MSC and NoV may have been present but not likely viable as the WWTP utilized UV disinfection and was operating under normal conditions. These results are shown in Figure 3 and Table 2 below:

Figure 3: Comparison of MSC and NoV results

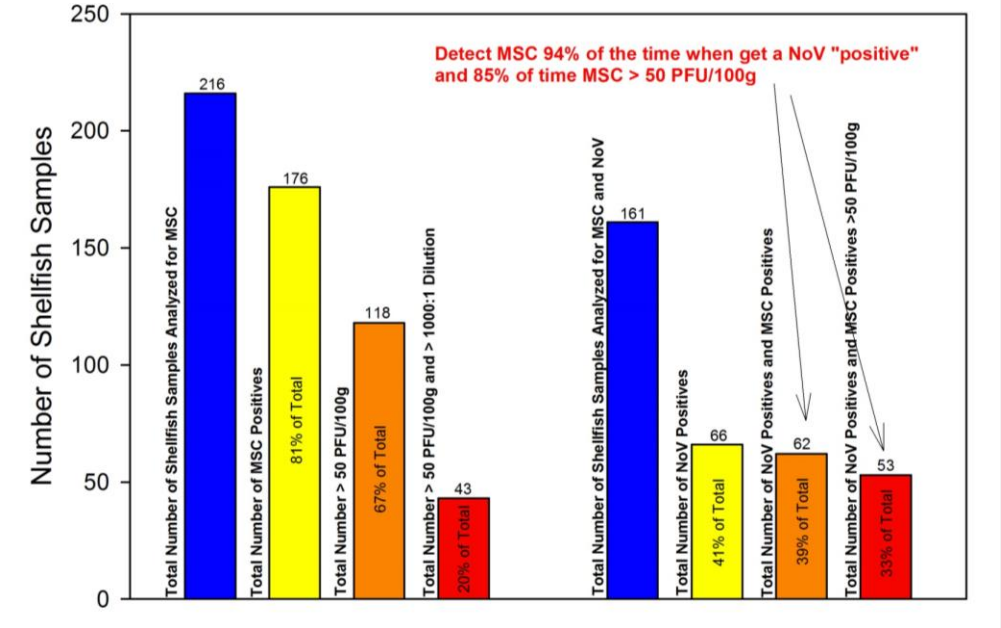


Table 2: Comparison of MSC and NoV Results in shellfish

MSC and NoV Results	
NoV detected in shellfish	41% (66 of 161)
MSC detectable	39% (62 of 161)
MSC negative when NoV detected (MSC<10 pfu/100g)	7% (4 of 66)*
MSC present when NoV detected (MSC>10 pfu/100g)	94% (62 of 66)
MSC present when NoV detected (MSC>50 pfu/100g)	85% (53 of 66)

*NoV detected at LOD of Assay

The overall results of FDA's field 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. These results also emphasize the critical need for sufficient notification time, meaning travel time from the WWTP discharge in the 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. Furthermore, this analysis demonstrates the need to individually assess each WWTP, to assess their performance to remove enteric viruses.

In addition to the FDA field studies, as part of a Joint United States-Canada Norovirus in Bivalve Molluscan Shellfish Risk Assessment, a Meta-Analysis of the Reduction of NoV and MSC Concentrations by Wastewater Treatment was conducted (Pouillot, 2015). The meta-analysis included previously unpublished surveillance data from the United States and Canada and relevant data reported in the literature (2,943 measurements in total).

For WWTPs with mechanical systems and chlorine disinfection, mean log10 reductions were 2.4 log10 gc/liter, for NoV GI, 2.7 log10 gc/liter, for NoV GII, and 2.9 log10 PFU per liter for MSCs. Comparable values for WWTPs with lagoon systems and chlorine disinfection were 1.4 log10 gc/liter for NoV GI, 1.7 log10 gc/liter for NoV GII, and 3.6 log10 PFU per liter for MSCs. WWTPs with ultra-violet (UV) disinfection demonstrated slightly higher mean log10 reductions with 3.0 log10 gc/liter, for NoV GI, 3.3 log10 gc/liter, for NoV GII, and 4.3 log10 PFU per liter for MSCs. The results of the reduction of NoV and MSC are shown in Table 3 below:

Table 3: Log reduction in NoV and MSC in treated wastewater with disinfection

Wastewater Treatment and Disinfection	**Log_{10} NoV GI Reduction**	**Log_{10} NoV GII Reduction**	**Log_{10} MSC Reduction**
Mechanical with Chlorine Disinfection	2.4	2.7	2.9
Lagoon with Chlorine Disinfection	1.4	1.7	3.6
Mechanical with UV Disinfection	3.0	3.3	4.3

This meta-analysis also demonstrated that Chlorine Disinfection had little effect on the mean reductions of the NoV and MSC. The mean log10 reduction that occur due to mechanical and biological treatment of the facility (prior to disinfection) were 2.2 log10 gc/liter, for NoV GI, 2.5 log10 gc/liter, for NoV GII, and 2.4 log10 PFU per liter for MSCs which varied little from mean log reduction after disinfection. In addition, a strong correlation, 0.8, existed between the reductions of NoV GII and MSC that occurred following treatment at the same WWTP indicating that MSCs could be useful in evaluating the efficiency of a WWTP.

Alternate Options

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. However, at this time FDA does not have reliable data to justify specific dilution levels associated with environmental variables. It is recognized that such criteria could be determined by SCAs on a case by case basis, where factors of WWTP performance, disinfection method, tidal flushing, shellfish species and seasonal impacts may vary.

For example, in consideration of a raw sewage discharge, a lower dilution level than a 100,000:1 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 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).

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, tertiary treatment and operating under optimum design flow conditions. Regardless of the technology employed any proposed alternative minimum level of

dilution for conditional management other than 1000:1 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. 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. If MSC is selected as an alternative option for calculating the size of the prohibited zone of a WWTP discharge, the authority should select an MSC criteria that adequately protects shellfish growing areas from virological effects and should be based on the most recent data and regional studies.

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Action by 2015 Task Force I	Recommended adoption of Growing Area Classification Committee recommendation on Proposal 13-118.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 13-118.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-118.

Proposal Subject	Definition of Laboratory Method Types
Specific NSSP Guide Reference	Section I. Definitions
Text of Proposal/ Requested Action	Add the following new definitions in Section I. Definitions: **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 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. **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 criteria in Procedure XVI. of the ISSC Constitution, Bylaws, and Procedures are provided.
Public Health Significance	These terms are used in Chapter III. and in the ISSC Constitution, Bylaws, and Procedures and should be defined.
Cost Information	
Action by 2015 Task Force I	Recommended adoption of the following substitute language to be included in both Section I. Definitions and Section 9, Subdivisions a and b of Procedure XVI of the ISSC Constitution Bylaws and Procedures. **Approved NSSP Methods.** Approved NSSP Methods are the primary/core methods used in the NSSP~~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 described in scientific or other peer-reviewed professional publications; have been used historically or are used throughout the NSSP and elsewhere to effectively detect or quantify and have been extensively evaluated and the performance characteristics for specific applications in the NSSP determined as~~long used in the NSSP or have completed the Single Laboratory Validation Method Protocol to show that the method is~~ fit for purpose through long use in the NSSP and/or Single Laboratory Validation (SLV) testing and/or collaborative study..

Approved Limited Use Methods. Approved Limited Use Methods are permanent 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 include new methods, alternative methods or screening 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. These methods have been evaluated and the performance characteristics for specific applications in the NSSP have been determined through the Single Laboratory Validation Method Protocol (SLV) to be fit for purpose within the NSSP. These methods are referred to as being of limited use within the NSSP either because of their status as newly adopted methods with little corroborating data beyond the SLV or because the application for which the method can be or is used within the NSSP is limited in scope with little laboratory participation within the NSSP and little to no subsequent corroborating data or because of the nature of the test method itself and/or restrictions that have been placed on its use that limit its usefulness within the NSSP. ~~Approved Limited Use Methods can include screening, provisional, or methods with limitations as defined by the LMRC evaluation of the method.~~

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 criteria in Procedure XVI. of the ISSC Constitution, Bylaws, and Procedures are provided.

Action by 2015 General Assembly

Adopted recommendation of Task Force I on Proposal 15-100.

Action by FDA January 11, 2016

Concurred with Conference action on Proposal 15-100.

Proposal Subject	Monthly Laboratory Grade Water Testing
Specific NSSP Guide Reference	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 analysis 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) 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.

E. Laboratory Grade Water, AKA Reagent Water Microbiologically Suitable Water, Type 1 Water. For the required monthly testing of the laboratory's reagent grade water for microbiological contamination, the following may be used:

(1) An AOAC, BAM, or EPA approved method;

(2) Heterotrophic plate count equivalent methods as described in *Standard Methods for the Examination of Water and Wastewater or Compendium of Methods for the Microbiological Examination of Foods.*

Public Health Significance	Although this is a monthly requirement, there are currently no approved NSSP methods that specifically address reagent water. For labs that support multiple Federal programs with this requirement, adding this would provide clearer guidance while allowing each lab to choose the method that best conforms to the analysis they routinely perform. The savings of time and money allows resources to be used to protect public health more wisely.
Cost Information	Cost will be determined by each lab dependent on method used.
Action by 2015 Laboratory Methods Review Committee	Recommended no action on Proposal 15-101. Rationale: This test is for internal laboratory use so the method of analysis used is at the discretion of the laboratory. The only requirement is that the test method chosen be recognized as fit for purpose.
Action by 2015 Task Force I	Recommended adoption of the 2015 Laboratory Method Reviews Committee recommendation on Proposal 15-101.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-101.

Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-101.

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	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas
Text of Proposal/ Requested Action	@.01 Sanitary Survey. A. General. (1) The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of: (a) A shoreline survey; (b) A survey of the ~~bacteriological~~ microbiological quality of the water and in growing areas adjacent to wastewater system discharges the State Shellfish Control Authority may utilize MSC results from analysis of shellfish meat samples and the analysis of the data will be included in the sanitary survey report; (c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area; (d) An analysis of the data from the shoreline survey, the bacteriological and the hydrodynamic, meteorological and geographic evaluations; (e) A determination of the appropriate growing area classification. B. Sanitary Survey Required… C. Sanitary Survey Performance. (5) On an annual basis, the sanitary survey shall be updated to reflect changes in the conditions in the growing area. The annual reevaluation shall include: (a) A field observation of the pollution sources which may include: (i) A drive-through survey; (ii) Observations made during sample collection; and (iii) Information from other sources. (b) Review, at a minimum, of the past year's water quality sample results by adding the year's sample results to the data base collected in accordance with the requirements for the bacteriological standards and sample collection required in Section .02; (c) Review of available inspection reports and effluent samples collected from pollution sources; (d) Review of available performance standards for various types of discharges that impact the growing area; ~~and~~ (e) A brief report which documents the findings of the annual reevaluation; ~~.~~ and (f) The SSCA may use MSC meat sampling data and/or MSC waste water sampling data in the annual reevaluation of (5) (b), (c), and (d) above to evaluate the viral contributions of the

performance standards of waste water system discharge (WWSD) impacts on shellfish growing areas.

(g) If MSC meat and/or water data is being used, the SSCA shall conduct annual sample collection and analysis in determining performance standards.

D. Shoreline Survey Requirements…

@.02 ~~Bacteriological~~ Microbiological Standards.

Note: The NSSP allows for a growing area to be classified using either a total or fecal coliform standard. The NSSP further allows the application of either standard to different water bodies within the state. The NSSP also allows for two (2) sample collection strategies for the application of the total or fecal coliform standard: adverse pollution condition and systematic random sampling. The 1992 Task Force II recommended that this portion of the Ordinance be codified in two (2) ways: a total coliform strategy and a fecal coliform strategy so that the state may choose sampling plans on a growing area basis. Within each strategy, provisions would appear for use of both systematic and adverse pollution condition sample collection. The Ordinance has been recodified in this manner. For maximum flexibility, a state may wish to adopt the use of both standards and both sampling strategies for each standard. This codification represents the fecal coliform standards. Additionally, states may choose to use MSC sample data in conjunction with total or fecal coliform data to evaluate areas impacted by waste water system discharges.

A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area. The SSCA may utilize MSC data in conjunction with bacteriological data to evaluate waste water system discharge (WWSD) impacts on shellfish growing areas.
B. Water Sample Stations…
C. Exceptions…
D. Standards for the Approved Classification of Growing Areas in the Remote Status…
E. Standard for the Approved Classification of Growing Areas Affected by Point Sources…
F. Standard for the Approved Classification of Growing Areas Affected by Nonpoint Sources…
G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration…
H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration…

@.03 Growing Area Classification.

A. General…
    (1) Emergency Conditions…
    (2) Classification of All Growing Areas…
    (3) Boundaries…
    (4) Revision of Classifications…
    (5) Status of Growing Areas…
        (a) Open Status…
        (b) Closed Status...

(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:

(i) The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of contaminant levels in the shellstock to pre-closure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on coliform levels in the water; or

(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 after contamination has ceased and from representative locations in each growing area potentially impacted; or

(iii) The requirements for Biotoxins or conditional area management plans as established in Section .04 and Section .03, respectively, are met; and

(iv) Supporting information is documented by a written record in the central file.

(d) Inactive Status…

(e) Remote Status…

(f) Seasonally Remote/Approved Status…

B. Approved Classification…

C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:

(1) Survey Required. The sanitary survey meets the following criteria:

(a) The area will be in the open status of the conditional classification for a reasonable period of time. The factors determining this period are known, are predictable, and are not so complex as to preclude a reasonable management approach;

(b) Each potential source of pollution that may adversely affect the growing area is evaluated;

(c) ~~Bacteriological~~ Microbiological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area; and

(d) For SSCAs utilizing MSC meat sample data, this data correlates with environmental conditions or other factors affecting the distribution and persistence of viral contaminants into the growing area.

(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) 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;

(b) For management plans based on pollution sources other than waste water treatment plants:
(i) Performance standards that reliably predict when criteria for conditional classification are met; and
(ii) Discussion and data supporting the performance standards.

(c) For management plans based on waste water system discharge ~~treatment plant~~ function or pollution sources other than waste water system discharge ~~treatment plants~~, criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum criteria are:
(i) Performance standards of the plan are fully met;
(ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;
(iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. The study may establish criteria for reopening based on coliform levels in the water; ~~and~~
(iv) For Conditional Management Plans based on waste water system discharge performance and for SSCAs utilizing MSC, sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of viral levels in the shellstock. Analytical sample results shall not exceed background levels or a level of 50 MSC per 100 grams. The study may establish criteria for reopening based on viral levels in the shellfish meats or the area must be in the closed status until the event is over and twenty-one (21) days have passed; and
(v) Shellstock feeding activity is sufficient to achieve

~~coliform~~ microbial reduction.

(d) For management plans based on a risk assessment made in accordance with Chapter II. Risk Assessment and Risk Management, criteria that reliably determine when the growing area may be placed in the open status and shellfish may be harvested;

(e) For management systems based on marine Biotoxins, the procedures and criteria that reliably determine when the growing area may be placed in the open status;

(f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;

(g) Provisions for patrol to prevent illegal harvest; and

(h) Procedures to immediately place the growing area in the closed status in 24 hours or less when the criteria established in the management plan are not met.

(3) Reevaluation of Conditional Classification…

(4) Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management Plan by All Parties Involved…

(5) Conditional Area Types…

(6) Conditionally Approved Classification…

(7) Conditionally Restricted Classification...

D. Restricted Classification…

E. Prohibited Classification.

(1) Exception…

(2) General…

(3) Sanitary Survey…

(4) Risk Assessment…

(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; The SSCA may utilize MSC wastewater sample data in the determination of the performance of the sewage treatment plant;

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

(iii) The wastewater's dispersion and dilution, 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.

NOTE: All references in Section II. Model Ordinance Chapter IV. Shellstock

Growing Areas will be changed to Waste Water System Discharge (WWSD).

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 105 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.

A better assessment of the risk of viral contamination at a particular location in an adjacent growing area can be ascertained directly using MSC assays of the shellstock. Performing and evaluating dye studies on waste water treatment plant outfall discharges, although effective, 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. There are advantages of using this specialty viral indicator to assess the overall impact of a municipal wastewater treatment system on a particular growing area.

The ISSC held an MSC meeting in Charlotte on August 18-19, 2014 to discuss the available MSC science and knowledge. A panel of MSC experts provided MSC information and consensus regarding usage of MSC in the NSSP. (Click here to view, download, or print the MSC meeting report)

Cost Information

The use of MSC is not a requirement; rather, it is an option for States to use, so there would be no cost to States who do not choose to use it. For States that do choose to use MSC, the cost is discussed in the ISSC MSC Meeting Report, August 18-19, 2014, where it states: The MSC assay for shellfish is relatively easy to perform and the cost is roughly equivalent to that of performing fecal coliform testing. The initial cost to prepare laboratory to perform analysis, depends on the lab, and may be approximately $8000 to $10,000, if additional equipment is needed. There may also be cost associated with sample collection.

Action by 2015 Task Force I

Recommended adoption of Proposal 15-102 as amended.

@.01 Sanitary Survey.

A. General.

(1) The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of:

(a) A shoreline survey;

(b) A survey of the microbiological quality of the water and in growing areas adjacent to wastewater system discharges the State Shellfish Control Authority may utilize MSC results from analysis of shellfish meat samples and the analysis of the data will be included in the sanitary survey report;

(c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area;

(d) An analysis of the data from the shoreline survey, the bacteriological and the hydrodynamic, meteorological and geographic evaluations;
(e) A determination of the appropriate growing area classification.

B. Sanitary Survey Required…

C. Sanitary Survey Performance.
(5) On an annual basis, the sanitary survey shall be updated to reflect changes in the conditions in the growing area. The annual reevaluation shall include:
(a) A field observation of the pollution sources which may include:
(i) A drive-through survey;
(ii) Observations made during sample collection; and
(iii) Information from other sources.
(b) Review, at a minimum, of the past year's water quality sample results by adding the year's sample results to the data base collected in accordance with the requirements for the bacteriological standards and sample collection required in Section .02;
(c) Review of available inspection reports and effluent samples collected from pollution sources;
(d) Review of available performance standards for various types of discharges that impact the growing area;
(e) A brief report which documents the findings of the annual reevaluation; and
(f) The SSCA may use MSC meat sampling data and/or MSC waste water sampling data in the annual reevaluation of (5) (b), (c), and (d) above to evaluate the viral contributions of the performance standards of waste water system discharge (WWSD) impacts on shellfish growing areas.
(g) If MSC meat and/or water data is being used, the SSCA shall conduct annual sample collection and analysis in determining performance standards.

D. Shoreline Survey Requirements…

@.02 Microbiological Standards.

Note: The NSSP allows for a growing area to be classified using either a total or fecal coliform standard. The NSSP further allows the application of either standard to different water bodies within the state. The NSSP also allows for two (2) sample collection strategies for the application of the total or fecal coliform standard: adverse pollution condition and systematic random sampling. The 1992 Task Force II recommended that this portion of the Ordinance be codified in two (2) ways: a total coliform strategy and a fecal coliform strategy so that the state may choose sampling plans on a growing area basis. Within each strategy, provisions would appear for use of both systematic and adverse pollution condition sample collection. The Ordinance has been recodified in this manner. For maximum flexibility, a state may wish to adopt the use of both standards and both sampling strategies for each standard. This codification represents the fecal coliform standards. Additionally, states may choose to use MSC sample data in conjunction with total or fecal coliform data to evaluate areas

impacted by waste water system discharges.

A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area. The SSCA may utilize MSC data in conjunction with bacteriological data to evaluate waste water system discharge (WWSD) impacts on shellfish growing areas.
B. Water Sample Stations…
C. Exceptions…
D. Standards for the Approved Classification of Growing Areas in the Remote Status…
E. Standard for the Approved Classification of Growing Areas Affected by Point Sources…
F. Standard for the Approved Classification of Growing Areas Affected by Nonpoint Sources…
G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration…
H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration…

@.03 Growing Area Classification.

A. General…
   (1) Emergency Conditions…
   (2) Classification of All Growing Areas…
   (3) Boundaries…
   (4) Revision of Classifications…
   (5) Status of Growing Areas…
      (a) Open Status…
      (b) Closed Status...
      (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:
         (i) The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of contaminant levels in the shellstock to pre-closure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on coliform levels in the water; or
         (ii) For emergency 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 or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions from shellfish samples collected no sooner

than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted~~,~~ or until the event is over and 21 day have passed; or

(iii) The requirements for Biotoxins or conditional area management plans as established in Section .04 and Section .03, respectively, are met; and

(iv) Supporting information is documented by a written record in the central file.

(d) Inactive Status…

(e) Remote Status…

(f) Seasonally Remote/Approved Status…

B. Approved Classification…

C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:

(1) Survey Required. The sanitary survey meets the following criteria:

(a) The area will be in the open status of the conditional classification for a reasonable period of time. The factors determining this period are known, are predictable, and are not so complex as to preclude a reasonable management approach;

(b) Each potential source of pollution that may adversely affect the growing area is evaluated;

(c) Microbiological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area; and

(d) For SSCAs utilizing MSC meat sample data, this data correlates with environmental conditions or other factors affecting the distribution and persistence of viral contaminants into the growing area.

(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) 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;

(b) For management plans based on pollution sources other than waste water treatment plants:

(i) Performance standards that reliably predict when criteria for conditional classification are met; and

(ii) Discussion and data supporting the performance

standards.

(c) For management plans based on waste water system discharge function or pollution sources other than waste water system discharge, criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum criteria are:

(i) Performance standards of the plan are fully met;

(ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;

(iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. The study may establish criteria for reopening based on coliform levels in the water;

(iv) For Conditional Management Plans based on waste water system discharge performance and for SSCAs utilizing MSC, sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of viral levels in the shellstock. Analytical sample results shall not exceed ~~background levels or~~ a level of 50 MSC per 100 grams or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions. These studies~~y~~ may establish criteria for reopening based on viral levels in the shellfish meats or the area must be in the closed status until the event is over and twenty-one (21) days have passed; and

(v) Shellstock feeding activity is sufficient to achieve microbial reduction.

(d) For management plans based on a risk assessment made in accordance with Chapter II. Risk Assessment and Risk Management, criteria that reliably determine when the growing area may be placed in the open status and shellfish may be harvested;

(e) For management systems based on marine Biotoxins, the procedures and criteria that reliably determine when the growing area may be placed in the open status;

(f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;

(g) Provisions for patrol to prevent illegal harvest; and

(h) Procedures to immediately place the growing area in the closed status in 24 hours or less when the criteria established in the management plan are not met.

(3) Reevaluation of Conditional Classification…

(4) Understanding of and Agreement With the Purpose of the

Conditional Classification and Conditions of Its Management Plan by All Parties Involved…
(5) Conditional Area Types…
(6) Conditionally Approved Classification…
(7) Conditionally Restricted Classification...

D. Restricted Classification…
E. Prohibited Classification.
(1) Exception…
(2) General…
(3) Sanitary Survey…
(4) Risk Assessment…
(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; The SSCA may utilize MSC wastewater sample data in the determination of the performance of the sewage treatment plant;
(ii) The decay rate of the contaminants of public health significance in the wastewater discharged;
(iii) The wastewater's dispersion and dilution, 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.

NOTE: All references in Section II. Model Ordinance Chapter IV. Shellstock Growing Areas will be changed toWaste Water System Discharge (WWSD).

Action by 2015 General Assembly

Adopted recommendation of Task Force I on Proposal 15-102 with referral to an appropriate committee as determined by the Conference Chair to develop a draft guidance document which will be presented to the ISSC Executive Board at the 2016 spring meeting for interim approval.

Action by FDA January 11, 2016

Concurred with Conference action on Proposal 15-102.

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas
Text of Proposal/ Requested Action	@.01 Sanitary Survey. A. General. (1) The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of: (a) A shoreline survey; (b) A survey of the bacteriological quality of the water; (c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area; and ~~(d) An analysis of the data from the shoreline survey, the bacteriological and the hydrodynamic, meteorological and geographic evaluations; and~~ (~~e~~d) A determination of the appropriate growing area classification. (2) The sanitary survey shall be periodically updated through the triennial reevaluation and the annual review in accordance with Section C. to assure that data is current and that conditions are unchanged. (3) The documentation supporting each sanitary survey shall be maintained by the Authority. For each growing area, the central file shall include all data, results, and analyses from: (a) The sanitary survey; (b) The triennial reevaluation; and (c) The annual review. (4) Wherever possible, the Authority shall provide the necessary information to Federal, State, or local agencies which have the responsibility to minimize or eliminate pollution sources identified in the sanitary survey. (5) The Authority shall maintain a current comprehensive, itemized list of all growing areas, including maps showing the boundaries and classification of each shellstock growing area.
Public Health Significance	This section is redundant and confusing. It does not add anything. Whatever would be included here should be addressed by analyses conducted during efforts to meet the Chapter IV. @.01 A. (1) (a) requirement for shoreline survey to be conducted according to the instructions provided in Chapter IV. @.01 D., Chapter IV. A. (1) (c) requirement for evaluating the effects of various factors impacting the area, and the Chapter IV. @.01 A. (1) (d) requirement for determining the appropriate growing area classification.
Cost Information	
Action by 2015 Task Force I	Recommended adoption of Proposal 15-103 as submitted.
Action by 2015	Adopted recommendation of Task Force I on Proposal 15-103.

General Assembly

Action by FDA
January 11, 2016

Concurred with Conference action on Proposal 15-103.

Proposal Subject	Sanitary Survey Report Format
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @01. Sanitary Survey and Section IV. Guidance Documents Chapter II. Growing Areas .04 Sanitary Survey and the Classification of Growing Waters.
Text of Proposal/ Requested Action	Model Ordinance Chapter IV. Shellstock Growing Areas @.01 Sanitary Survey

(C) Sanitary Survey Performance

(1) A sanitary survey of each growing area shall be performed at least once every twelve (12) years and shall include the components in Section A. (1.) in the following outline:

A. Executive Summary

B. Description of Growing Area

(1) Location map or chart showing growing area

(2) Description of area and its boundaries

(3) History of growing area classification

(i) Date of last sanitary survey

(ii) Previous classification(s) map(s)

C. Pollution Source Survey

(1) Summary of Sources and Location

(i) Information gathered under the shoreline survey requirements outlined in (D).

(ii) Map or chart showing the location of major sources of actual or potential pollution in the survey area including a table of sources of pollution cross-referenced to the survey area map.

(2) Detailed description, identification, evaluation, and determination of impact of all actual and potential pollution sources identified during the shoreline survey on water quality throughout the growing area.

D. Hydrographic and Meteorological Characteristics

(1) Tides (type and amplitude), and currents (velocity and direction)

(2) Rainfall and/or snowmelt

(i) Amount

(ii) When (e.g. time of year)

(iii) Frequency of significant rainfalls

(iv) Winds (Seasonality and effects on pollution dispersion)

(3) River discharges (volume and seasonality)

(4) Discussion concerning effects of pollution distribution and hydrographic factors (dilution, dispersion, and time of travel) on water quality throughout the growing area

(i) Salinity, depth, and stratification characteristics

(ii) Computer model verification if used for classification.

E. Water Quality Studies

(1) Map of sampling stations

(2) Sampling plan and justification

(i) Adverse condition sampling; and/or

(ii) Random sampling

(3) Sample Data Analysis and Presentation: Tables containing

the basic NSSP statistics (number of samples, median or geometric mean, and the respective variability factors)

(i) Station by station monitoring data array collected under the adverse condition or systematic random sampling monitoring strategy

(ii) Daily sampling results and number of samples collected for survey

(iii) Overall compliance with NSSP criteria

(iv) Sorting of data by environmental pollution, seasonal, and/or meteorological condition

(v) Classification assigned to each station

F. Interpretation of Data in Determining Classification to Be Assigned to Growing Area: A discussion of how actual or potential pollution sources, wind, tide, rainfall, etc. affect or may affect water quality, that will address the following:

(1) Effects of meteorological and hydrographic conditions on bacterial loading

(2) Variability in the bacteriological data and causes

G. Conclusions

(1) Map or chart showing classification assigned to growing area(s) (closure lines, boundary lines separating various classifications)

(2) Legal description of growing area boundaries

(3) Management plan for growing area if in the conditionally approved or conditionally restricted classification meeting the requirements in (C.)

(4) Recommendations for sanitary survey improvement

(i) Changes in monitoring schedules, addition of sampling stations or station relocation, etc.

H. Comments

Guidance Documents Chapter II. Growing Areas
.04 Sanitary Survey and the Classification of Growing Waters

~~**Minimum Requirements of the Sanitary Survey Report**~~

~~The following outline contains the minimum requirements for the written growing area sanitary survey report required in the NSSP Model Ordinance.~~

~~A. Executive Summary~~

~~B. Description of Growing Area~~

~~(1) Location map or chart showing growing area~~

~~(2) Description of area and its boundaries~~

~~(3) History of growing area classification~~

~~* Date of last sanitary survey~~

~~* Previous classification(s) map(s) C. Pollution Source Survey~~

~~(1) Summary of Sources and Location~~

~~* Information gathered under the shoreline survey procedures outlined above.~~

~~* Map or chart showing the location of major sources of actual or potential pollution in the survey area.~~

~~* Table of sources of pollution cross-referenced to the survey area map.~~

~~(2) Identification and evaluation of pollution sources~~
~~* Domestic wastes (discussion and maps)~~
~~* Storm water~~
~~* Agricultural waste (farms, feedlots, & slaughterhouse operations)~~
~~* Wildlife areas~~
~~* Industrial wastes~~
~~D. Hydrographic and Meteorological Characteristics~~
~~(1) Tides (type and amplitude), and currents (velocity and direction)~~
~~(2) Rainfall~~
~~* Amount~~
~~* When (e.g. time of year)~~
~~* Frequency of significant rainfalls~~
~~* Winds (Seasonality and effects on pollution dispersion)~~
~~(3) River discharges (volume and seasonality)~~
~~(4) Discussion concerning effects of pollution distribution and hydrographic factors (dilution, dispersion, and time of travel) on water quality throughout the growing area~~
~~* Salinity, depth, and stratification characteristics~~
~~* Computer model verification if used for classification.~~
~~E. Water Quality Studies~~
~~(1) Map of sampling stations~~
~~(2) Sampling plan and justification~~
~~* Adverse condition sampling~~
~~* Random sampling~~
~~(3) Sample Data Analysis and Presentation: Tables containing the basic NSSP statistics~~ ~~(number of samples, median or geometric mean, and the respective variability factors)~~
~~* Station by station monitoring data array collected under the adverse condition or systematic random sampling monitoring strategy~~
~~* Daily sampling results and number of samples collected for survey~~
~~* Overall compliance with NSSP criteria~~
~~* Sorting of data by environmental pollution condition~~
~~* Classification assigned to each station~~
~~F. Interpretation of Data in Determining Classification to Be Assigned to Growing Area: A discussion of how actual or potential pollution sources, wind, tide, rainfall, etc. affect or may affect water quality, that will address the following:~~
~~(1) Effects of meteorological and hydrographic conditions on bacterial loading~~
~~(2) Variability in the bacteriological data and causes~~
~~G. Conclusions~~
~~(1) Map or chart showing classification assigned to growing area(s) (closure lines, boundary lines separating various classifications)~~
~~(2) Legal description of growing area boundaries~~
~~(3) Management plan for growing area if in the conditionally approved or conditionally restricted classification~~
~~(4) Recommendations for sanitary survey improvement~~
~~* Changes in monitoring schedules, addition of sampling stations or station relocation, etc.~~
~~* Comments~~

Public Health — The Model Ordinance Guidance Documents contain the outline of the minimum

Significance	requirements for the written sanitary survey report based on the requirements of the Model Ordinance. The guidance represents the ISSC's (state, federal, and industry) current thinking on the requirements for a sanitary survey, other reports, and the classification of growing areas. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, and the Guide for the Control of Molluscan Shellfish. The requirement should not be in Guidance, but in the compliance language portion of the Model Ordinance. The primary responsibility of the State Shellfish Control Authority is to ensure the public health safety of the shellfish growing areas through compliance with the NSSP Model Ordinance. The Authority must perform a sanitary survey that collects and evaluates information concerning actual and potential pollution sources that may adversely affect the water quality in each growing area. Based on the sanitary survey information, the authority determines what use can be made of the shellstock from the growing area and assigns the growing area classification. Experience has shown that the minimum sanitary survey components required in this guidance are necessary for a reliable sanitary survey and since the State Shellfish Control Authorities are evaluated for conformance with the minimum requirements, the language should be moved to the satisfactory compliance section.
Cost Information	N/A
Action by 2015 Task Force I	Recommended no action on Proposal 15-104. Rationale: This is already adequately addressed in the Guidance Documents.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-104.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-104.

Proposal Subject	Opening Growing Areas Closed to Biotoxins
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas
Text of Proposal/ Requested Action	@.04 Marine Biotoxin Control C. Closed Status of Growing Areas (4) The closed status shall remain in effect until the Authority has data to show that the toxin content of the shellfish in the growing area is below the level established for closing the area. A minimum of two (2) consecutive shellfish samples must be collected at least three (3) days apart and the toxin levels must be below the regulatory limit(s) to reopen an area. At the discretion of the Authority, an additional sample may be required before the area is reopened if the toxin levels are just below the regulatory limit.
Public Health Significance	There is growing evidence that toxic algal blooms have been increasing over the last 20 years and not only are becoming more frequent, but more intense, occurring in new places and with longer durations. See, e.g., R.M. Kudela et al. 2015. Harmful Algal Blooms: A Scientific Summary for Policy Makers IOC/UNESCO, Paris (IOC/INF-1320). Because Biotoxins from algae bioaccumulate in shellfish, human and animal consumers of shellfish are at risk from Biotoxin poisoning. Human illnesses caused by consumption of contaminated shellfish include paralytic shellfish poisoning ("PSP"), diarrheic shellfish poisoning and amnesic shellfish poisoning. These illnesses manifest in human victims via symptoms including gastrointestinal disorders and neurologic and muscular problem, including paralysis of the chest and abdominal muscles possibly leading to death (PSP). See Raymond RaLonde (1996), Paralytic Shellfish Poisoning: The Alaska Problem, Alaska's Marine Resources Vol. 8, No. 2. There are no antidotes available to counteract Biotoxin poisoning and victims need immediate medical support. The only reliable means of protecting against the harvest and consumption of Biotoxin-contaminated shellfish is frequent sampling of harvest areas followed by qualified laboratory analysis and quick regulatory action. The presence of Biotoxins in shellfish at harmful or fatal levels cannot be detected by simple observation; affected shellfish do not differ in odor or appearance from shellfish that are safe to consume. Thus in States such as Alaska, where subsistence and recreational harvest of shellfish from unregulated beaches is common; there is a high incidence of PSP illness and even death. Between 1993 and 2014, there were 117 reported cases of PSP poisoning in Alaska, with fatalities occurring in three of those years (1994, 1997 and 2010). Further, because Biotoxin sampling results can vary significantly between lethal and safe levels in just a matter of days, it is unsafe to base a re-opening decision on a single sampling event. For example, geoduck clams sampled in Alaska's Steamboat harvest area on March 9, 2014 returned a paralytic shellfish toxin ("PST") level of 206 ug/100 grams while geoduck sampled from the same area on March 16, 2014 returned a PST level of 57 um/100 grams. With the March 16 sample showing levels below the 80 ug/100 gram closure threshold, Alaska opened the Steamboat area to harvest on March 20, 2014. Just three days later, on March 23, 2014, sampling showed PST levels back to above the closure threshold, at 118 ug/100 grams. The Steamboat area then vacillated between open and closed status weekly until May 10, then remained open until the May 31 PST sample yielded a concentration of 528 ug/100 grams. However, the Steamboat

area reopened on June 7 when the results of one sample were returned at 46 ug/100 grams.

The high volatility of Biotoxin concentrations in shellfish sampled in the same harvest areas can be seen in the attached spreadsheet, which summarizes results of shellfish harvest area PST testing performed by the Alaskan Department of Environmental Conservation ("ADEC") in 2014. Requiring two below-regulatory level Biotoxin tests before re-opening of shellfish harvesting areas will increase confidence that Biotoxin(s) are cleared from the harvest area and that the shellfish are once again safe for human consumption. While this likely will not have a significant impact on growing areas that have fairly consistent PST levels, this will require additional testing in states that reopen areas based on a single test result in growing areas with high degrees of PST variability.

Requiring two below-regulatory limit shellfish samples prior to re-opening an area closed due to Biotoxins will also increase international confidence in the safety of U.S. shellfish, avoiding future potential international bans and sanctions. For example, the proposed PSP testing standards could have avoided certain concerns raised by the Chinese government in 2013.

The Middle Gravina Island growing area in Alaska was implicated in China's 2013 ban of U.S. geoduck. ADEC identifies Middle Gravina Island as an area that consistently exceeds PSP thresholds; in fact, sampling of this area in 2014 showed an average PST level of 312 ug/100 grams. However, commercial geoduck shellfish harvest for human consumption and export occurred in this harvest area in 2013 based on a sub-80 ug/100 gram sample on October 5. The previous week's sample had returned a PST level of 388 ug/100 grams, and the subsequent two samples were 385 ug/100 gram and 528 ug/100 gram, respectively. See ADEC 2013/2014 PSP Lab Results (June 10, 2014). In fact, the only PST sample below regulatory threshold for Middle Gravina Island between September 28 and December 8, 2013 was the October 5 sample.

In summary, increasing the number of tests required before harvest re-opens following a Biotoxin event will reduce public health risks associated with the shellfish industry, boost international confidence in the safety of shellfish products, and minimize the potential that single anomalous readings could authorize the harvest of potentially unhealthy and dangerous shellfish product.

The purpose of the proposal is to set a uniform minimum threshold for State Authority PSP testing. It appears that most State Authorities already meet or exceed the standards proposed herein. In those circumstances, the proposal would not change or alter such regulations.

Cost Information

Although costs will vary by Shellfish Authority, the costs are believed to be minimal. Most ISSC member states and provinces currently use the suggested reopening criteria or one that is already more stringent to manage Biotoxin events. Any costs associated with additional testing would be mitigated by reducing the likelihood of extensive, expensive and time-consuming recalls, international sanctions, and/or the potential repercussions in consumer confidence after illnesses occur.

Action by 2015 Task Force I

Recommended referral of Proposal 15-105 to the appropriate committee as determined by the Conference Chairman.

Action by 2015 General Assembly	Recommended no action on Proposal 15-105. Rationale: The concerns outlined in this proposal are adequately addressed in the NSSP Guide for the Control of Molluscan Shellfish.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15.105 with the following comments and recommendations. Although the ISSC voted no action on Proposal 15-105, discussion of the Proposal raised concerns regarding the adequacy of state Biotoxin sampling strategies. While FDA supports establishment of minimum NSSP sampling requirements for reopening growing areas closed to harvest as a result of unacceptable Biotoxin levels, Proposal 15-105 as submitted was not in keeping with existing NSSP Guidance. Proposal 15-105 proposed reopening an area based on a minimum of two samples collected at least three (3) days apart to demonstrate the return of toxicity levels to below regulatory limits. Existing NSSP Guidance in Section IV. Guidance Documents, Chapter II. Growing Areas .02 Guidance for Developing Marine Biotoxin Contingency Plans recommends, as an example for PSP, collection of three (3) samples over a minimum two (2) week period to demonstrate the return to acceptable toxin levels and to establish a continuing detoxification curve. During discussion of Proposal 15-105, both prior to and during Task Force I, it was apparent that differing opinions and approaches are in play regarding how States manage the reopening of a growing area following a Biotoxin closure. Chapter IV. of the NSSP Model Ordinance requires that closures remain in effect until the Authority has data to show that toxin levels have returned to acceptable levels, but does not include specific sample collection requirements. On the other hand, current NSSP Guidance recommends the development of reopening criteria and outlines the type of criteria that should be integrated, including a sufficient number of samples to establish detoxification curves to levels below regulatory standards and, as stated above, offers a recommended sampling strategy. However, as guidance, those recommendations are not Model Ordinance requirements. To address sampling concerns and needs, the ISSC and FDA should immediately begin discussion regarding establishment of minimum requirements for sample collection and analysis for safely reopening areas following Biotoxin closures. Development of specific reopening criteria is critical to achieving a consistent approach nationally and to enhance the level of safety afforded by the NSSP. Toward that end FDA requests that the ISSC Executive Board further review this issue and take action to consider appropriate NSSP requirements. This effort should include examination of existing practices and the level of safety they provide.

Proposal Subject	Using Male-Specific Coliphage as a Tool to Determine Viral Quality during Shellstock Relaying
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter V. Shellstock Relaying
Text of Proposal/ Requested Action	@.01 General. The Authority shall assure that: A. The shellstock used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted; 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~~total coliform, fecal coliform.~~; and~~ ~~If~~For shellstock harvested from areas impacted by wastewater system discharges, MSC may be used as a measure for viral reduction, or poisonous or deleterious substances that may be present in shellstock to occur.~~; and~~ D. If shellstock are relayed in containers: (1) The containers are: (a) Designed and constructed so that they allow free flow of water to the shellstock; and (b) Located so as to assure the contaminant reduction required in Section C.; and (2) The shellstock are washed and culled prior to placement in the containers. @.02 Contaminant Reduction. A. The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached. B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The study report shall demonstrate that, after the completion of the relay activity: (1) The ~~bacteriological~~ microbiological quality of each shellfish species is the same ~~bacteriological~~ microbiological quality as that of the same species already present in the approved or conditionally approved area; or (2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA tolerance levels. (3) When the source growing area is impacted by wastewater system discharge, the viral quality of each shellfish species meets the male-specific coliphage standard od 50 PFU/100gm. C. The authority may waive the requirements for a contaminant reduction study if: (1) Only microbial contaminants need to be reduced; and (2) The shellstock are relayed from a conditionally approved, restricted, or

conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per Chapter IV. @.02 G. and Chapter IV. @.02 H.; and

(3) The treatment period exceeds sixty (60) days.

D. The time period shall be at least fourteen (14) consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequate.

E. When container relaying is used and the Authority allows a treatment time of less than fourteen (14) days, the Authority shall require more intensive sampling including:

(1) Product sampling before and after relay; and

(2) Monitoring of critical environmental parameters such as temperature and salinity~~.~~; and/or

(3) Male-specific coliphage monitoring before and after relay for shellstock relay from areas impacted by wastewater system discharge.

F. The Authority shall establish the time period during the year when relaying may be conducted.

Public Health Significance

The ISSC held a MSC meeting in Charlotte on August 18-19, 2014, and discussed the available MSC science and knowledge. A panel of MSC experts provided MSC information and consensus regarding the use of MSC in the NSSP. (Click here to view, download, or print the MSC meeting report) Male-specific Coliphage (MSC) is a RNA virus of E. coli present in high numbers in raw sewage (on the order of 105 PFU/100gm). MSC is a good surrogate or marker for norovirus and hepatitis A viruses, which are the viral pathogens of concern in sewage.

The ISSC Growing Area Classification Committee acknowledged that MSC should be considered by the ISSC as an indicator for contaminant reduction studies for relaying.

Cost Information

The use of MSC is not a requirement; rather, it is an option for States to use, so there would be no cost to States who do not choose to use it. For States that do choose to use MSC, the cost is discussed in the ISSC MSC Meeting Report, August 18-19, 2014, where it states: The MSC assay for shellfish is relatively easy to perform and the cost is roughly equivalent to that of performing fecal coliform testing. The initial cost to prepare laboratory to perform analysis, depends on the lab, and may be approximately $8000 to $10,000, if additional equipment is needed. There may also be cost associated with sample collection.

Action by 2015 Task Force I

Recommended adoption of Proposal 15-106 as amended:

@.01 General.

The Authority shall assure that:

A. The shellstock used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted;

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 total coliform,

fecal coliform. For shellstock harvested from areas impacted by wastewater system discharges, MSC may be used as a measure for viral reduction, or poisonous or deleterious substances that may be present in shellstock to occur.

D. If shellstock are relayed in containers:
   (1) The containers are:
      (a) Designed and constructed so that they allow free flow of water to the shellstock; and
      (b) Located so as to assure the contaminant reduction required in Section C.; and
   (2) The shellstock are washed and culled prior to placement in the containers.

@.02 Contaminant Reduction.

A. The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached.

B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The study report shall demonstrate that, after the completion of the relay activity:
   (1) The microbiological quality of each shellfish species is the same microbiological 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) When the source growing area is impacted by wastewater system discharge, the viral quality of each shellfish species meets the male-specific coliphage standard od 50 PFU/100gmor pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions.

C. The authority may waive the requirements for a contaminant reduction study if:
   (1) Only microbial contaminants need to be reduced; and
   (2) The shellstock are relayed from a conditionally approved, restricted, or conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per Chapter IV. @.02 G. and Chapter IV. @.02 H.; and
   (3) The treatment period exceeds sixty (60) days.

D. The time period shall be at least fourteen (14) consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequate.

E. When container relaying is used and the Authority allows a treatment time of less than fourteen (14) days, the Authority shall require more intensive sampling including:
   (1) Product sampling before and after relay; and
   (2) Monitoring of critical environmental parameters such as temperature and salinity; and/~~or~~
   (3) For SSCA using Male-specific coliphage monitoring before and after relay for shellstock relay from areas impacted by wastewater system discharge.

F. The Authority shall establish the time period during the year when relaying may be

	conducted.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-106.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-106.

Proposal Subject	Ineffective Model Ordinance Requirement
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VI. Shellfish Aquaculture
Text of Proposal/ Requested Action	@ .02 Seed Shellstock. ~~A. The Authority shall establish the submarket size for each species of shellfish in accordance with Section .01 B. and Section .01 C.~~ ~~B.~~ All sources of seed shall be sanctioned by the Authority. .01 Exceptions. ~~The following~~ Hatchery activities are exempt~~ed~~ from these requirements.~~:~~ ~~A. Hatcheries;~~ ~~B. Nursery products which do not exceed ten (10) percent of the market weight; and~~ ~~C. Nursery products which are six (6) months or more growing time from market size.~~ .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~~;~~; and ~~B. Seed from growing areas or growing areas in the restricted or prohibited classification have acceptable levels of poisonous or deleterious substances; and~~ ~~C~~B. Seed from growing areas or growing areas in the prohibited classification are cultured for a minimum of six (6) months. .05 Land Based Aquaculture. A. Operational Plan. Each land based aquaculture facility shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include: (1) A description of the design and activities of the culture facility; (2) The specific site and boundaries in which shellfish culture activities will be conducted; (3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters; (4) The species of shellfish to be cultured and harvested; (5) If appropriate, the source and species of other organisms to be cultured in any polyculture systems; (6) Procedures to assure that no poisonous or deleterious substances are introduced into the activities; (7) A program of sanitation, maintenance, and supervision to prevent contamination of the final shellfish products; (8) A description of the water source, including the details of any water treatment process or method, if necessary; (9) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored shall be the same as used for monitoring growing areas; ~~(10) Collection of information on the microbial and chemical quality of shellfish harvested from the aquaculture site;~~ (1~~1~~0) Collection of data concerning the quality of food production (algae or

other) used in the artificial harvest system;
(1~~2~~1) Maintenance of the required records; and
(1~~3~~2) How shellstock will be harvested, processed if applicable, and sold.

Public Health Significance

Chapter VI. @.02 A.:
This requirement to establish the submarket size of shellfish does not make sense with regard to its linked requirement to establish submarket size in accordance with 01.B and 01.C which provide exemptions for nursery products. As written, this is an unclear requirement and has no purpose in this Chapter.

Chapter VI. .01 B. and C.:
It is impossible to get this information and to verify for each facility this is very ineffective.

Chapter VI. .03 B.:
No acceptable level of poison.

Chapter VI. .05 A. (10):
Requirement already addressed by other requirements. The contaminant level of the shellfish has already been controlled in accordance with requirements that seed shellfish not be contaminated with poisonous and deleterious substances and the that requirement for aquaculture sites to be controlled for poisonous and deleterious substances and the requirement that the aquaculture site water quality be maintained.

Cost Information

Action by 2015 Task Force I

Recommended adoption of Proposal 15-107 as amended:

@ .02 Seed Shellstock.
A. The Authority shall establish the submarket size for each species of shellfish.
~~A.~~B. All sources of seed shall be sanctioned by the Authority.

.01 Exceptions.
Hatchery activities are exempt from these requirements.

.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; and
B. Seed from growing areas or growing areas in the prohibited classification are cultured for a minimum of six (6) months.

.05 Land Based Aquaculture.
A. Operational Plan. Each land based aquaculture facility shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:
(1) A description of the design and activities of the culture facility;
(2) The specific site and boundaries in which shellfish culture activities will be conducted;
(3) The types and locations of any structures, including rafts, pens, cages, nets,

tanks, ponds, or floats which will be placed in the waters;
(4) The species of shellfish to be cultured and harvested;
(5) If appropriate, the source and species of other organisms to be cultured in any polyculture systems;
(6) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;
(7) A program of sanitation, maintenance, and supervision to prevent contamination of the final shellfish products;
(8) A description of the water source, including the details of any water treatment process or method, if necessary;
(9) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored shall be the same as used for monitoring growing areas;

(10) Collection of data concerning the quality of food production (algae or other) used in the artificial harvest system;
(11) Maintenance of the required records; and
(12) How shellstock will be harvested, processed if applicable, and sold.

Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-107.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-107.

Proposal Subject	PCOX Method Status
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved Laboratory Tests
Text of Proposal/ Requested Action	This request is for a change in the status of the PCOX method for determining paralytic shellfish poisoning (PSP) toxins from "Approved Limited Use" to "Approved". This change would be reflected by: 1. Adding the PCOX method to NSSP Section IV Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests, Table 2. Approved Methods for Marine Biotoxin Testing with Biotoxin Type: Paralytic Shellfish Poisoning (PSP), Application: Growing Area Survey & Classification, Sample Type: Shellfish, and Application: Controlled Relaying Sample Type: Shellfish; and 2. Deleting the PCOX method from NSSP Section IV Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests, Table 4. Approved Limited Use Methods for Marine Biotoxin Testing. The PCOX method for paralytic shellfish poisoning toxins (PSTs) was developed by the Canadian Food Inspection Agency (CFIA) and National Research Council Canada (NRCC) using post-column oxidation and fluorescence detection (PCOX). This method was optimized, tested, and used extensively in the authors' laboratory before the formal validation process was initiated to ensure that it could perform in the "real-life" setting of a regulatory monitoring laboratory. The method performed well, and was subjected to a single-laboratory validation (SLV) study [1]. The data generated in the SLV study was used to support proposal 09-104 to the Interstate Shellfish Sanitation Conference (ISSC) to approve the PCOX method for official use; the result of this proposal was that the method was approved as a Type IV method. The PCOX method was implemented for screening PST levels in shellfish at the Canadian Food Inspection Agency Dartmouth Laboratory in November, 2009, following ISSC approval; all samples were analysed using the PCOX method, and results leading to regulatory action were confirmed by mouse bioassay (MBA), AOAC OMA 959.08[2]. The method was next subjected to an international collaborative inter-laboratory study [3]. This collaborative study was successful, and the results were used to support the approval of the PCOX method as an AOAC official method of analysis (OMA), First Action status – OMA 2011.02 [4]. All MBA analyses for PSTs were eliminated in CFIA laboratories when the PCOX method was granted OMA, First Action status in April, 2011, and the PCOX method was considered a quantitative, regulatory method, without the need for MBA confirmation of results. The PCOX method was promoted to AOAC OMA, Final Action status in 2013 in response to positive method performance feedback from users. The PCOX method has been used to analyse almost 50,000 shellfish samples since it was implemented in Canada in November, 2009, with the Canadian Food Inspection Agency (CFIA) Dartmouth Laboratory completing almost 19,000 of those tests. This large dataset from CFIA laboratories provides an opportunity to verify performance characteristics with routine use over an extended period of time. A summary of QC performance at the CFIA Dartmouth Laboratory is shown in Table 1 below. These data demonstrate excellent precision (CV of <10% for average total PSTs) and accuracy (102 ± 17% for total PSTs) in method performance examined over a span of five and a half years, including multiple instruments, multiple analysts, and numerous batches of reagents.

Additional data from other CFIA laboratories reveal similar results for >1500 additional QC points. The performance characteristics of the method were also evaluated and confirmed as part of a ring study on PSTs in oyster tissue organized by a laboratory in the United Kingdom [5]. Accuracy has also been evaluated through successful participation in CFIA and international proficiency testing programs by all three CFIA laboratories using the PCOX method. These performance characteristics exceed those specified by Codex [6] for quantitative chemical methods; recovery guidelines at these concentration are 80-110% with ≤44% RSD and repeatability guidelines for these concentration are <15% RSD.

Table 1: CFIA Dartmouth Laboratory summary of QC performance from November, 2009 – June, 2015

		GTX1	GTX3	STX	TOTAL PST
In-house reference material 1	n	520			
	Average	24[b]	29[b]	139[b]	264[b]
	Standard Deviation	3.3	2.3	11.9	17.0
	% RSD	13%	8%	9%	6%
In-house reference material 2	n	504			
	Average	45[b]	50[b]	62[b]	244[b]
	Standard Deviation	3.4	2.3	6.2	12.8
	% RSD	8%	5%	10%	5%
SPIKE RECOVERY (%)	n	1024			
	Average	100%[a]	100%	98%	102%
	Standard Deviation	38%[a]	10%	15%	17%
	Concentration Range [b,c]	3-11[a]	7-10	28-61	57-92[d]

[a] higher variability is observed because spiking levels are below the method LOD
[b] µg STXdiHCl eq/100g
[c] multiple spiking solutions were used over time; range reflects minimum and maximum spiking levels
[d] including only individual toxins that were above the method LOD

The method is also being used outside of Canada. The Norwegian School of Veterinary Science (NSVS) completed a validation study before implementing the PCOX method for all samples in January, 2013. Again, the performance of the method in the Norwegian laboratory was consistent with results from the collaborative study. It is also worth noting that all CFIA laboratories and the NSVS are accredited to ISO 17025 and maintain the PCOX method on their scope of accreditation. Within the United States, Maine has completed validation studies and been approved to use the PCOX method for regulatory samples since April, 2014, and Alaska has completed validation studies [7] and is currently awaiting final FDA approval to implement the method for regulatory testing (but currently uses the method for non-regulatory samples). Oregon has recently expressed interest in the method as well. Chilean laboratories at the University of Chile plan to validate the PCOX method and transition from MBA to the PCOX method in the near future. The method is also being used for non-routine or research purposes in New Zealand (Cawthron Laboratory), the United Kingdom (CEFAS laboratory), Ireland (Marine Institute), Chile (University of Chile), the United States (e.g., Alaska Environmental Health Laboratory, US FDA), and Canada (NRCC).

Training has been requested and delivered to groups in the United States (2010) and Europe (2012), and scientists from the Maine Department of Marine Resources and Bigelow Laboratory for Ocean Sciences were hosted for training at the CFIA Dartmouth Laboratory (2012). There was also interest in a training course organized by the China Section of AOAC International, but logistical difficulties have prevented the course from taking place thus far.

Feedback from participants in the collaborative study was very positive, and most laboratories experienced no problems with the method; however, like all methods, there are limitations and weaknesses. One weakness of the method is that it cannot resolve neosaxitoxin (NEO) from decarbamoylneosaxitoxin (dcNEO), or gonyautoxin-6 (GTX6) from gonyautoxin-4 (GTX4). The inability to resolve these toxins is an issue for samples contaminated by *Gymnodinium catenatum*, in which dcNEO and GTX6 are often present. This challenge is being examined, and the European Union Reference Laboratory for Marine Biotoxins has expressed interest in collaborating to overcome it. Another weakness of the method is the LC column, which suffers from a short lifespan. An alternative column has been proposed, but research continues to find a more suitable replacement. A weakness of all chemical PST methods is the unavailability of analytical standards for some toxins (such as GTX6, and C3/C4). The unavailable toxins are uncommon in North American toxin profiles (these toxins are common in samples contaminated by *Gymnodinium catenatum*) and have very low toxicity. These challenges are included here to provide a complete description of the method, and also to highlight that these issues are not serious enough to prevent implementation of the method. Research will continue to improve the robustness and flexibility of the method to make it easier to implement in different laboratories.

The PCOX method is more sensitive than the MBA, and can be used to provide earlier warning of rising PST levels in shellfish. This earlier warning capacity can be used to focus additional sampling and increase the probability of detecting toxin levels before they exceed the regulatory limit [8], resulting in increased food safety, and fewer product recalls for industry.

The ISSC terminology describing method status has been updated since the PCOX method was approved in 2009, and the PCOX method status is currently "Approved Limited Use"; however, there are currently no clear statements of what "limited use" means for this method. The method has been successfully implemented for regulatory samples in multiple accredited laboratories for several years, and performance data from these laboratories agree with those generated during the original inter-laboratory study. The status of this method should be changed to "Approved" to reflect the fact that this method is no longer in limited use, and no critical limitations to the method have been identified. This change would also be consistent with the changes resulting from adoption of Proposal 13-309, which recognizes AOAC OMA status when considering proposed methods that are demonstrated as fit-for-purpose.

1. Van de Riet, J.M., et al., *Liquid Chromatographic Post-Column Oxidation Method for Analysis of Paralytic Shellfish Toxins in Mussels, Clams, Scallops,and Oysters: Single-Laboratory Validation.* Journal of AOAC International, 2009. **92**(6): p. 1690-1704.
2. INTERNATIONAL, A., *Method **959.08***, in *Official Methods of Analysis, 19th Ed.* 2012, AOAC INTERNATIONAL: Gaithersburg, MD.

3. Van de Riet, J., et al., *Liquid Chromatography Post-Column Oxidation (PCOX) Method for the Determination of Paralytic Shellfish Toxins in Mussels, Clams, Oysters, and Scallops Collaborative Study.* Journal of AOAC International, 2011. **94**(4): p. 1154-1176.
4. INTERNATIONAL, A., *Method **2011.02***, in *Official Methods of Analysis, 19th Ed.* 2012, AOAC INTERNATIONAL: Gaithersburg, MD.
5. Turner, A.D., et al., *Interlaboratory Comparison of Two AOAC Liquid Chromatographic Fluorescence Detection Methods for Paralytic Shellfish Toxin Analysis through Characterization of an Oyster Reference Material.* Journal of AOAC International, 2014. **97**(2): p. 380-390.
6. Commission, C.A., *Procedural Manual, 23rd edition.* 2015.
7. Hignutt, J.E., *Suitability of Postcolumn Oxidation Liquid Chromatography Method AOAC 2011.02 for Monitoring Paralytic Shellfish Toxins in Alaskan Shellfish—Initial Pilot Study versus Mouse Bioassay and In-House Validation.* Journal of AOAC International, 2014. **97**(2): p. 293-298.
8. Rourke, W.A. and C.J. Murphy, *Animal-Free Paralytic Shellfish Toxin Testing—The Canadian Perspective to Improved Health Protection.* Journal of AOAC International, 2014. **97**(2): p. 334-338.

Public Health Significance	The detection limit for PSTs by the MBA method is 40 µg STX diHCl eq/100g, while that of the sum of individual PSTs are significantly lower using the PCOX method - <10 µg STX diHCl eq/100g. This lower detection limit improves food safety and minimizes closures in southwestern New Brunswick, Canada, where PST levels in the Bay of Fundy are chronically high and can change very rapidly. Since the PCOX method has been implemented, the local CFIA office has determined that harvest sites with PST levels >35 µg STX diHCl eq/100g should be sampled a second time in the same week instead of waiting to sample the site the following week; by contrast, those same samples would show no toxin by the MBA method and sampling would be delayed until the regularly scheduled sample the following week. This delay potentially leaves harvest areas with increasing PST levels open over the weekend and beginning of the following week; this could lead to illnesses, food safety investigations, and product recalls that are now prevented because of the lower detection limits of the PCOX method. This information has been used to maintain harvest areas in an open status longer – an advantage for the shellfish harvesting industry - and simultaneously close the harvest areas before toxin levels exceed the regulatory limits. This change in sampling frequency has resulted in fewer food safety investigations and product recalls and was not possible before the PCOX method was implemented because the MBA method does not have enough sensitivity to detect low levels of PSTs.
Cost Information	There should be no direct cost implications to this change. It may make the transition from the MBA to the PCOX method slightly easier for laboratories not currently using the latter, or for those gearing up for PST testing for the first time. The PCOX method is less expensive than the MBA if capital purchases (LC systems) are averaged over the life of the equipment.
Action by 2015 Laboratory Method Review Committee	Recommended adoption of Proposal 15-108 as submitted.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Method Review Committee recommendation on Proposal 15-108.

Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-108.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-108.

Proposal Subject	PSP HPLC-PCOX Species Expansion
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	4. Approved Limited Use Methods for Marine Biotoxin Testing PCOX This submission presents data to support the use of PCOX method for Quahogs (M. mercenaria and A. icelandica), Surf Clams (S. solidissima), Geoducks (P. generosa), Butter Clams (S. giganteus), Little Neck Clams (P. stamineais), and Razor Clams (S. patula) for regulatory paralytic shellfish toxin (PST) testing. Results of the 2009 Interstate Shellfish Sanitation Conference (ISSC) proposal 09-104 concluded the PCOX method approved for official use as a Type IV method; subsequently after single laboratory validation (SLV) and collaborative studies, ISSC proposal 13-309 accepted PCOX method as an AOAC official method of analysis (OMA) in 2013. Currently PCOX is an "Approved for Limited Use" method for mussel, clam, oyster and scallop. SLV work will be presented for quahogs, surf clams, geoducks, butter clams, little neck clams, and razor clams that demonstrates comparable performance characteristics for these species as with mussels, clams, oysters, and scallops using the PCOX method. The cost and challenges associated with maintaining both the MBA and PCOX methods for these species are high; differing laboratory skill sets are required and state laboratories have limited budgets and staff resources. Additionally, the recent shortage of the NIST saxitoxin standard used for MBA proficiencies is of concern if laboratories are expected to maintain MBA for verification purposes for these species. The requested action is being made and data presented for the purpose of inclusion of quahogs, surf clams, geoducks, butter clams, little neck clams, and razor clams as approved species (by addition to the footnote that includes mussels, clams, oysters, and scallops or as the ISSC deems appropriate) within the NSSP Guide Section IV Guidance Documents Chapter II. Growing Areas .11 Laboratory Tests Methods Table, Methods for Marine Biotoxin Testing with Biotoxin Type: Paralytic Shellfish Poisoning (PSP), Application: Growing Area Survey & Classification Sample Type: Shellfish, And Application: Controlled Relaying Sample Type: Shellfish.
Public Health Significance	The PCOX method was developed to provide a rapid, high throughput chemical assay that would eliminate the need to sacrifice animals, AOAC mouse bioassay (MBA), for toxin detection. There is a worldwide move to replace assays that use live animals as test subjects. Laboratories currently using PCOX for regulatory PST testing have found that the lower detection limits of the PCOX method allow for better early warning therefore better management of PST closures and significantly improved public health decision-making. The addition of the proposed species will allow regulatory laboratories to move away from the costliness of maintaining MBA and eliminate the need to sacrifice animals as well as improve management of species specific closure decision–making.
Cost Information	Total consumable costs for the analysis is estimated at $10/sample. A chemistry laboratory will usually be equipped with an LC system and a post column reactor to carry out the analysis. Total capital costs for the instrumentation required for the analysis is approximately $120,000. Although the upfront investment for instrumentation is high, the removal of care, maintenance, and cost of mice quickly offsets this expenditure.

Action by 2015 Laboratory Method Review Committee	Recommended referral of Proposal 15-109 to an appropriate committee as determined by the Conference Chair for evaluation of data and until additional data are received.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Method Review Committee recommendation on Proposal 15-109.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-109.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-109.

Proposal Subject	Laboratory Method for *Vibrio parahaemolyticus (V.p.)* Enumeration and Detection through MPN and Real-Time PCR
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	This method was developed by William A. Glover (Washington State Public Health Laboratories) and is being submitted by the ISSC Executive Board. The Executive Board granted interim approval to this method on March 13, 2015. The Executive Board is submitting this proposal to comply with Article V. Section 1. of the ISSC Constitution, Bylaws, and Procedures. Submitted by method developer William A. Glover (Washington State Public Health Laboratories)

5. Approved Methods for Vibrio Enumeration

	Vibrio Indicator Type:	Application: PHP Sample Type: Shucked
EIA[1]	*Vibrio vulnificus (V.v.)*	X
MPN[2]	*Vibrio vulnificus (V.v.)*	X
SYBR Green 1 QPCR-MPN[5]	*Vibrio vulnificus (V.v.)*	X
MPN[3]	*Vibrio parahaemolyticus (V.p.)*	X
PCR[4]	*Vibrio parahaemolyticus (V.p.)*	X
MPN and PCR[6]	*Vibrio parahaemolyticus (V.p.)*	X

Footnotes:

[1] EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992.
[2] MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, followed by confirmation using biochemical analyses or by the DNA -alkaline phosphatase labeled gene probe (vvhA).
[3] MPN format with confirmation by biochemical analysis, gene probe methodology as listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.
[4] PCR methods as they are listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.
[5] *Vibrio vulnificus*, ISSC Summary of Actions 2009. Proposal 09-113, Page 123.
[6] William A. Glover, II, Ph.D. D9ABMM), MT(ASCP) Food and Shellfish Bacteriology Laboratory (FSBL) at the Washington State Public Health Laboratories (WAPHL)

Public Health Significance	The purpose of this method is to provide laboratories supporting the NSSP the ability to rapidly quantify *Vibrio parahaemolyticus (V.p.)* from oysters using a high throughput real-time PCR protocol. The Food and Shellfish Bacteriology Laboratory (FSBL) at the Washington State Public Health Laboratories (WAPHL) tests on average over 200 oyster samples per year for *Vibrio parahaemolyticus (V.p.)*Culture based assays for the enumeration of *V.p.* take four days or longer and require the Kanagawa test (media based) to detect pathogenicity. Due to

	the large number of samples and need for accurate and timely results, the FSBL at the WAPHL has tested Pacific oysters (Crassostrea gigas) for (*V.p.*) using a MPN based real-time PCR assay for over 10 years. The real-time PCR assay utilized by the FSBL at the WAPHL has gone through redesigns and improvements by various scientists at the WAPHL based on new published literature, clinical *V.p.* case data, experiences in WA State over the course of a season or seasons, and requests from the Office of Shellfish & Water Protection for enhanced detection of pathogenic *V.p.* strains and additional surveillance capabilities. The real-time PCR assay redesigned and implemented in 2009 and utilized through the 2013 *V.p.* monitoring season (June – September) was designed to detect *V.p.* using the species-specific thermolabile hemolysin gene (tlh) and virulent *V.p.* using the thermostable direct hemolysin gene (tdh). This assay was designed for high throughput in a 384-well based format. Additionally, the tlh and tdh targets were redesigned yielding amplicons between 50-150 base pairs. This is optimal for real-time PCR and is known to produce consistent results1. Validation of the assay and concept of a "molecular MPN" was conducted using FERN guidelines and was compared to the FDA BAM method. This assay served as the backbone for which further improvements and redesigns were made in 2013.
Cost Information	
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 15-110 to an appropriate committee as determined by the Conference Chair to await completed SLV data.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Methods Review Committee recommendation on Proposal 15-110.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-110.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-110.

Proposal Subject

MPN-Real-Time PCR for Pathogenic *V.p.*

Specific NSSP Guide Reference

Section IV. Guidance
Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests

Text of Proposal/ Requested Action

This method was developed by Jessica Jones (FDA Gulf Coast Seafood Laboratory) and is being submitted by the ISSC Executive Board. The Executive Board granted interim approval to this method on March 13, 2015. The Executive Board is submitting this proposal to comply with Article V. Section 1. of the ISSC Constitution, Bylaws, and Procedures.

Submitted by method developer Jessica Jones (FDA Gulf Coast Seafood Laboratory)

5. Approved Methods for Vibrio Enumeration

	Vibrio Indicator Type:	Application: PHP Sample Type: Shucked	Application: Reopening
EIA[1]	*Vibrio vulnificus (V.v.)*	X	
MPN[2]	*Vibrio vulnificus (V.v.)*	X	
SYBR Green 1 QPCR-MPN[5]	*Vibrio vulnificus (V.v.)*	X	
MPN[3]	*Vibrio parahaemolyticus (V.p.)*	X	
PCR[4]	*Vibrio parahaemolyticus (V.p.)*	X	
MPN-Real Time PCR[6]	*tdh+ and trh+ Vibrio parahaemolyticus (V.p.)*	X	X

Footnotes:

[1] EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992.
[2] MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, followed by confirmation using biochemical analyses or by the DNA -alkaline phosphatase labeled gene probe (vvhA).
[3] MPN format with confirmation by biochemical analysis, gene probe methodology as listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.
[4] PCR methods as they are listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.
[5] *Vibrio vulnificus*, ISSC Summary of Actions 2009. Proposal 09-113, Page 123.
[6] MPN-real time PCR method for the *tdh* and *trh* genes for total *V. parahaemolyticus* as described in Kinsey et al., 2015.

Public Health Significance

The current NSSP method for enumeration of *tdh+ Vp* requires a minimum of four days from receipt of sample to results reporting. Currently, there is no NSSP-approved method for enumeration of *trh+ V.p.* At the 2013 conference, proposal 13-202 was adopted which requires testing for the presence of *tdh* and *trh* prior to reopening of growing areas closed as a result of *V.p.* illnesses [Chapter II @.01.F(5)]. This proposed MPN-real-time PCR method provides results in as little as 24h from receipt of sample. Availability of this more rapid method will facilitate reopening decision making.

Cost Information

This method costs ~$120 per sample for laboratory consumables, supplies, and reagents.

	Most equipment needed for testing is standard microbiology equipment, but purchase of a heat block (~$400) and/or centrifuge (~$2,500) may be necessary. Purchase of a real-time PCR instrument will be required ($30,000-$45,000). Additional costs for a laboratory would vary based on their operational overhead and labor.
Action by 2015 Laboratory Method Review Committee	Recommended that Proposal 15-111 be adopted and direct the Executive Office to request the submitter revise the SOP so that the BAM MPN calculator be used for determination of MPN values.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Methods Review Committee recommendation on Proposal 15-111.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-111.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-111.

Proposal Subject	Direct Plating Method for trh
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	This method was developed by Jessica Jones (FDA Gulf Coast Seafood Laboratory) and is being submitted by the ISSC Executive Board. The Executive Board granted interim approval to this method on March 13, 2015. The Executive Board is submitting this proposal to comply with Article V. Section 1. of the ISSC Constitution, Bylaws, and Procedures. Submitted by method developer Jessica Jones (FDA Gulf Coast Seafood Laboratory) 5. Approved Methods for Vibrio Enumeration

	Vibrio Indicator Type:	Application: PHP Sample Type: Shucked	Application: Reopening
EIA[1]	*Vibrio vulnificus (V.v.)*	X	
MPN[2]	*Vibrio vulnificus (V.v.)*	X	
SYBR Green 1 QPCR-MPN[5]	*Vibrio vulnificus (V.v.)*	X	
MPN[3]	*Vibrio parahaemolyticus (V.p.)*	X	
PCR[4]	*Vibrio parahaemolyticus (V.p.)*	X	
Direct Plating[6]	*trh+ Vibrio parahaemolyticus (V.p.)*	X	X

Footnotes:

[1] EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992.
[2] MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, followed by confirmation using biochemical analyses or by the DNA -alkaline phosphatase labeled gene probe (vvhA).
[3] MPN format with confirmation by biochemical analysis, gene probe methodology as listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.
[4] PCR methods as they are listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.
[5] *Vibrio vulnificus*, ISSC Summary of Actions 2009. Proposal 09-113, Page 123.
[6] Direct plating method for *trh* as described in Nordstrom et al., 2006.

Public Health Significance	Scientific evidence suggests that the presence of the *trh* gene in *V. parahaemolyticus (V.p.)* is correlated with higher virulence. Additionally, at the 2013 conference, proposal 13-202 was adopted which requires testing for the presence of trh prior to reopening of growing areas closed as a result of *V.p.* illnesses [Chapter II @.01.F(5)]. Currently, there are no NSSP approved methods for enumeration of *trh*. This method is a needed option for testing following *V.p.* illness closures.
Cost Information	This method costs ~$5 per test for laboratory consumables, supplies, and reagents. Most equipment needed for testing is standard microbiology equipment, but purchase of a

	specialized water bath or environmental chamber may be necessary at a cost of ~$3,000-$5,000. Additional costs for a laboratory would vary based on their operational overhead and labor.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 15-112 to an appropriate committee as determined by the Conference Chair to further review the data submitted.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Methods Review Committee recommendation on Proposal 15-112.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-112.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-112.

Proposal Subject

MPN-Real-Time PCR for Total *V.p.*

Specific NSSP Guide Reference

Section IV. Guidance Documents
Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests

Text of Proposal/ Requested Action

This method was developed by Jessica Jones (FDA Gulf Coast Seafood Laboratory) and is being submitted by the ISSC Executive Board. The Executive Board granted interim approval to this method on March 13, 2015. The Executive Board is submitting this proposal to comply with Article V. Section 1. of the ISSC Constitution, Bylaws, and Procedures.

Submitted by method developer Jessica Jones (FDA Gulf Coast Seafood Laboratory)

5. Approved Methods for Vibrio Enumeration

	Vibrio Indicator Type:	Application: PHP Sample Type: Shucked	Application: Reopening
EIA[1]	*Vibrio vulnificus (V.v.)*	X	
MPN[2]	*Vibrio vulnificus (V.v.)*	X	
SYBR Green 1 QPCR-MPN[5]	*Vibrio vulnificus (V.v.)*	X	
MPN[3]	*Vibrio parahaemolyticus (V.p.)*	X	
PCR[4]	*Vibrio parahaemolyticus (V.p.)*	X	
MPN-Real Time PCR[6]	*Vibrio parahaemolyticus (V.p.)*	X	X

Footnotes:

[1] EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992.
[2] MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, followed by confirmation using biochemical analyses or by the DNA -alkaline phosphatase labeled gene probe (vvhA).
[3] MPN format with confirmation by biochemical analysis, gene probe methodology as listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.
[4] PCR methods as they are listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.
[5] *Vibrio vulnificus*, ISSC Summary of Actions 2009. Proposal 09-113, Page 123.

[6] MPN-real time PCR method for the *tlh* gene for total *V. parahaemolyticus* as described in Kinsey et al., 2015.

Public Health Significance

The current NSSP method for enumeration of *Vp* requires a minimum of four days from receipt of sample to results reporting. The MPN-real-time PCR method provides results in as little as 24h from receipt of sample. At the 2013 conference, proposal 13-202 was adopted which requires testing prior to reopening of growing areas closed as a result of *Vp* illnesses [Chapter II @.01.F(5)]. Availability of this more rapid method will facilitate reopening decision making.

Cost Information	This method costs ~$100 per sample for laboratory consumables, supplies, and reagents. Most equipment needed for testing is standard microbiology equipment, but purchase of a heat block (~$400) and/or centrifuge (~$2,500) may be necessary. Purchase of a real-time PCR instrument will be required ($30,000-$45,000). Additional costs for a laboratory would vary based on their operational overhead and labor.
Action by 2015 Laboratory Methods Review Committee	Recommended adoption of Proposal 15-113 as submitted and direct the Executive Office to request the submitter revise the SOP so that the BAM MPN calculator be used for determination of MPN values.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Methods Review Committee recommendation on Proposal 15-113.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-113.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-113.

Proposal Subject	Pre-Proposal for Male-Specific Coliphage Enumeration in Wastewater by Direct Double-Agar Overlay Method
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	The submitter of the pre-proposal requests approval to submit a full proposal to the ISSC for approval of the analytical method for use in the NSSP. Submitted by the developer Kevin Calci (FDA Gulf Coast Seafood Laboratory) Proposed Use of the Method: This method is applicable for the enumeration of MSC wastewater influent, effluent and sewage contaminated surface waters. The method will directly determine the quantity of MSC in wastewater to provide information of the viral reduction efficiencies of wastewater treatment plants. Method is also applicable for the analysis of surface source waters as part of a shoreline survey. Description of Method: This method employs E. coli HS (pFamp) RR as a male-specific coliphage host in a direct double agar overlay for the quantification of plaque forming units. All sample volumes are plated in triplicate. Briefly, 2.5ml of sample is mixed with 2.5ml of soft agar and 0.2ml of Famp host and then poured onto bottom agar petri plate. One ml of the sample is serially diluted down to 1:10 and 1:100. Those two dilutions are then plated by placing 2.5ml of sample is mixed with 2.5ml of soft agar and 0.2ml of Famp host and then poured onto bottom agar petri plate. The plates are incubated at 35-37°C for 16-20 h. Under indirect light the plaque forming units are counted. The working range of the 9 plate method would be 14pfu/1OOml to 1.0 x 106 pfu/1 OOml.
Public Health Significance	Scientific consensus at the MSC informational meeting supported the use of MSC to evaluated wastewater treatment plant viral reduction efficiency to better inform the SSCA's conditional management plans impacted by wastewater treatment plant operations. This method would identify a consistent and accurate measure of MSC load in wastewater influent, effluent and surface waters.
Cost Information	
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 15-114 to an appropriate committee as determined by the Conference Chair to await SLV data.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Methods Review Committee recommendation on Proposal 15-114.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-114.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-114.

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

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

Action by FDA May 5, 2014	Concurred with Conference action on Proposal 09-231.
Action by 2015 PHP Committee	Recommended approval of the following recommendations: 1. The title of Chapter XVI should be changed to Processes and Procedures for Pathogen Reduction. A new section @.01 Processes and Procedures Involving Labeling Claims should be added to the existing chapter between the Title and A (see proposal 15-223). A new section @.02 Processes and Procedures Not Involving Labeling Claims should be added to Chapter XVI 2. The contents of the new section @.02 should be as indicated in proposal 15-223. 3. The subcommittee concluded that the development of blanket target levels and validation protocols for all possible processes for pathogen reduction would be complex without knowing what the processes are. The committee recommends an alternate approach as follows: (a) A new committee be established to serve as a resource to the ISSC to assist with evaluation of specific processes designed to reduce pathogens to determine target levels and recommend specific validation and verification protocols. (b) The Committee should be a standing committee and would develop target levels and validation and verification protocols as needed to support the NSSP. These recommendations are addressed in Proposal 15-302.
Action by 2015 Task Force II	Recommended no action on Proposal 09-231. Rationale: This proposal is addressed by new proposals.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 09-231.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 09-231.

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

@. 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.~~

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

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

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

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

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

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

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

~~(5) Identification and preparation for implementation of required post harvest processing capacity of 50% of all oysters intended for the raw, half-shell market during the months of May through September, harvested from a Source State, which shall be implemented should the 40 percent illness~~

reduction goal not be achieved by December 31, 2006. The percentage of post harvest processing will include the capacity of all operational plants and the capacity of plants under construction. In the alternative, the state may utilize the control measures, or equivalent control measures, listed in @.04, (C), (6) (a), (b), (c), and (d) below for such periods of time which, in combination with post harvest processing, will provide equivalent outcomes. This portion of the plan shall be completed no later than December 31, 2005; and

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

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

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

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

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

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

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

Effective January 1, 2012:

@.04 *Vibrio vulnificus* Risk Management for Oysters

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

B. The Source State's *Vibrio vulnificus* Risk Management Plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish

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

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

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

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

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

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

@05 Vibrio vulnificus Control Plan

A. Risk Evaluation

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

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

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

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

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

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

C. All States not currently implementing a *Vibrio vulnificus* Control Plan shall develop and implement a *Vibrio vulnificus* Control Plan should the risk evaluation indicate two (2) or more etiologically confirmed, and epidemiologically linked *Vibrio vulnificus* septicemia illnesses from the consumption of commercially harvested raw or undercooked oysters that originated from the growing waters of that state within the previous ten (10) years

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

(1) Any etiologically confirmed shellfish-borne *Vibrio vulnificus* illness from the growing waters of that State but the number of cases does not reach the threshold established in @.04 C; and
(2) Information on Levels of *Vibrio vulnificus*, if available in the growing waters or in shellfish that is reasonably likely to cause an illness;

E. Control Plan

(1) The *Vibrio vulnificus* Control Plan shall include the following:
(a) Identification of triggers which address factors that affect risks. The triggers will be used to indicate when control measures are needed. One or more of the following triggers will be used:
(i) The water temperatures in the area; and
(ii The air temperatures in the area; and
(iii) Salinity in the area; and
(iv) Harvesting techniques in the area; and
(v) Other factors which affect risk which can be used as a basis for reducing risk.
(b) Implementation of one or more of the following control measures to reduce the risk of *Vibrio vulnificus* illness:
(i) Labeling oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 70~~5~~°F.
(ii) Subjecting all oysters intended for the raw, half-shell market to Authority approved post-harvest processing when the Average Monthly Maximum Water Temperature exceeds 70~~5~~°F.
(iii) ~~Labeling oysters, "For shucking by a certified dealer", during the months of April through November, inclusive.~~
~~(iv) Subjecting oysters intended for the raw, half-shell market to Authority approved post-harvest processing during the months of April through November, inclusive.~~
(iiiv) Reducing time of exposure to ambient air temperature prior to delivery to the initial certified dealer based on modeling or sampling, as determined by the Authority in consultation with FDA. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. When this control measure is selected, State *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 water temperature exceeds 80°F. Authority approved Best Management Practices (BMPs) will be applied to minimize *V.v.* growth to the extent possible when water temperature exceeds 70°F but is less than 80°F. BMPs will ensure that when the water temperature exceeds 70°F but is less than 75°F risk is minimized to less than 1.75 illnesses per 100,000 servings and when water temperatures exceed 75°F but are less than 80°F the risk will not exceed 2.5 illnesses per 100,000 servings. These risks per serving will be determined using the FDA developed *Vibrio vulnificus* calculator.
(ivvi) The State Authority may implement other comparable to that will reduce the risk per servings alternative controls that will reduce the risk to a level comparable to the risk per serving identified above in @.05 E. (1) (b) (iii) when water temperatures exceed 70°F.

(2) Control Plan Evaluation

(a) In consultation with FDA the Authority will evaluate the implementation and effectiveness of their Control Plan.
(i) Changes in the annual number of *Vibrio vulnificus* cases associated with the State's growing waters.
(ii) Environmental changes which could affect total *Vibrio vulnificus* in shellfish pre and post-harvest.
(iii) Industry compliance with existing controls.
(iv) The Authorities enforcement of industries implementation of the controls.
(b) The Control Plan shall be modified when the evaluation shows the Plan is ineffective, or when new information or more effective technology is available as determined by the Authority.

F. Contingency Plan
(1) The Contingency Plan shall include a detailed plan outlining the regulatory steps that will be implemented should the number of illnesses reach the threshold established for development and implementation of a *V.v.* Control Plan.
(2) Contingency Plan Evaluation
In consultation with FDA the Authority will evaluate the adequacy of their Contingency Plan.

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

Guidance Documents, Chapter IV. Naturally Occurring Pathogens

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

~~In general, shellfish-borne vibrio infections have tended to occur in coastal areas in the summer and fall when the water was warmer and vibrio counts were higher (Bonner, 1983; Morris, 1985; Joseph, 1982). *V. parahaemolyticus* and non-01 *V. cholerae* are commonly reported as causing diarrhea illness associated with the consumption of seafood including shellfish (Bonner, 1983; Blake, 1979; Morris, 1985; Joseph, 1982; Baross and Liston, 1970; Morris, 1981). In contrast, *V. vulnificus* has been related to two distinct syndromes: wound infections, often with tissue necrosis and bacteria, and primary septicemia characterized by fulminant illness in individuals with severe chronic illnesses such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy (Bonner *et al.*, 1983; Tacket, 1984). Increasing evidence shows that~~

~~individuals with such chronic diseases are susceptible to septicemia and death from raw seafood, especially raw oysters (Bonner *et al.*, 1983; Blake, 1979; Morris, 1985; Rodrick, 1982; Bachman, 1983; Blake, 1980; Oliver, 1983; NIH, 1984; Tacket, 1984; Oliver 1982; FDA, 1985). Shellfish-borne vibrio infections can be prevented by cooking seafood thoroughly, keeping them from cross contamination after cooking, and eating them promptly or storing them at hot (60°C or higher) or cold (4°C or lower) temperatures. If oysters and other seafood are to be eaten raw, consumers are probably at lower risk to vibrio infection during months when seawater is cold than when it is warm (Blake, 1983 and 1984).~~

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

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

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

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

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

~~The *Vv* subcommittee members will include, at a minimum, balanced representation from industry and state shellfish control authorities from *Vibrio vulnificus* Illness Source States California, Florida, Louisiana and Texas, FDA, NOAA, EPA, CDC, state epidemiologists; as well as industry and shellfish control representatives from other regions. *Vibrio vulnificus* Illness Source States are those states reporting two (2) or more~~

~~etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state. Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met.~~

~~Recognizing the increasing importance and roles for the Committee, leadership will be expanded and structured in a similar manner as stated in the ISSC By-Laws for Task Forces (reference: ISSC By-Law, Article I Task Forces). The VMC Chair shall alternately be selected from a state shellfish control authority and from industry. The Board Chairman, with approval of the Board, shall appoint a VMC Chair and Vice-Chair. If the VMC Chair represents a state shellfish control authority, the Vice-Chair shall be an industry representative. At the end of the VMC Chair's term of office, the Vice Chair will become Chairman and a new Vice Chair will be appointed who represents the same segment of the Conference as the outgoing VMC Chair. A VMC Chair and Vice Chair should be appointed before October 1, 2001 in order to be consistent with plans for annual VMC meetings and with the effective date of *Vibrio vulnificus* Risk Management Plans. Likewise, the term of office shall be for (2) years.~~
~~The VMC will meet at least annually to develop and approve annual VMC work plans for *Vibrio vulnificus* illness reduction and review progress. A series of work plans, each covering a one-year period shall be adopted. The first work plan and progress review period will cover a seventeen-month period from August 1, 2001 to December 31, 2003 followed subsequently by annual work plans. Work plans will include goals, tasks, performance measures and assessment methods to track and achieve progress towards the illness reduction goals. The work plans will be developed by the VMC and approved by the VMC membership. The chair of the VMC will deliver a written annual progress report, including a summary of the previous year's progress made in the education program, to the ISSC March executive board meeting. The report shall be made available to the general membership. The annual work plan structure, outlined below, provides adaptive management and assures consistent progress towards the illness reduction goals. If annual assessment of progress towards achieving the illness rate reduction goals show inadequate progress the VMC shall incorporate actions into current and subsequent work plans to assure success in achieving those goals. In addition, if annual review shows inadequate progress the VMC will develop issues for deliberation at the 2005 biennial meeting to consider actions such as:~~

- ~~increased educational efforts,~~
- ~~limited harvest restriction,~~
- ~~reduction in time from harvest to refrigeration,~~
- ~~phased-in post-harvest treatment requirements, or~~
- ~~other equivalent controls.~~

~~Work plans developed by the VMC shall include the following elements and shall define the administrative procedures and resources necessary for accomplishment (i.e. establishment and maintenance):~~

~~(a) An ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* infection. The Education Program's objectives will be 1) to increase the target audience's awareness that eating raw, untreated oysters can be life-threatening to them, and; 2) to change the at-risk group's oyster-eating behavior, i.e., to reduce or stop eating raw, untreated oysters. The ISSC Vibrio Management Committee and the *Vibrio vulnificus* Education Subcommittee will evaluate Year 2001 survey results and compare them with the Year~~

~~2003 or 2004 survey results to determine the effectiveness in meeting the two objectives of the *Vv* education effort: (1) Show 40% increase in awareness of risk from *Vv*; and (2) Show 15% increase in at-risk consumers no longer eating raw oysters while minimizing impacts to non-at-risk consumer raw oyster consumption.~~

~~(i) The Consumer Education Program will focus educational efforts in California, Florida, Louisiana and Texas. The Education Program will make educational materials available to additional states upon request.~~

~~(ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures deemed effective such as the USDA Physician Notification Program.~~

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

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

~~(c) Creation of a working group to work cooperatively with local, state, and federal agencies and programs to assist in the collection of environmental and epidemiological data to further expand on the current information available. A coordinator may be utilized to facilitate the activities of this working group to develop standardized collection of environmental and epidemiological information from harvest to consumer.~~

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

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

~~1. Each case that is considered must be reported on a Center for Disease Control and Prevention Cholera and Other *Vibrio* Illness Surveillance Report (COVIS) Form CDC 52.79.~~

~~2. Each case must also be listed be on the FDA database (NSSP Guide for the Control of Molluscan Shellfish Guidance Documents Chapter IV .02).~~

~~3. The ISSC committee to review reported *Vv* illnesses to determine the appropriateness of inclusion into the database used for illness reduction calculations must have access to the COVIS form for each case (patient names and other necessary information appropriately redacted). The ISSC addendum form is also provided, where available. This access to the COVIS form is critical for adequate interpretation of the data collected during the state epidemiological investigation.~~

~~4. The ISSC *Vv* Illness Review Committee will complete the following criteria table for each case. These tables serve as documentation.~~

~~5. For cases to be included in illness reduction calculations the following criteria must be met:~~

- ~~Item 1-4 and 5a must be answered yes.~~
- ~~Should the COVIS form include information that suggests other exposures that may be responsible for the Vv illness further investigation may occur. Consultation with State Shellfish Control Authorities and Epidemiologist from the state is~~

encouraged to determine which exposure should be recorded as the cause of illness. Should oyster consumption not be determined to be the cause of illness the case will not be counted. Should there be disagreements with the inclusion of a case; the disagreeing party may request a review. The request must include a rationale for the review and should be addressed to the Executive Board Chairman.

- If 5b is no, other exposures should be considered. If no other exposures exist, the case will not be counted.
- Should the only exposure be consumption of cooked oysters or unknown 5b will be checked yes.

Vibrio vulnificus Criteria Table

Case Identifier / Number	**Criteria Status Determination**		
Criteria	**Yes**	**No**	**Unknown**
1. Etiologically Confirmed	☐	☐	☐
2. Septicemia Illness	☐	☐	☐
3. Reporting State (CA, FL, LA, TX)	☐	☐	☐
4. Commercial Harvest from US Production	☐	☐	☐
5. Exposures			
a. Onset Consistent with Consumption of Oysters	☐	☐	☐
b. Raw or undercooked oysters	☐	☐	☐
6. Traceback Information			
a. Were shipping tags available or was 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.

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

~~chilling and other emerging technologies.~~

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

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

~~(h) Provision for VMC compilation and review of the data on rates of illness, which will be made available to the ISSC at the ISSC Biennial meeting following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC membership. In the event there is no Biennial meeting scheduled for a certain year, the VMC shall meet and review the data when it becomes available and issue a compilation report which will be made available to the entire membership.~~

~~(i) Provision for a VMC evaluation of the effectiveness of reduction efforts, which will be conducted at the end of the fifth year (December 31, 2006). The evaluation will determine whether the 40 percent, 5-year goal to reduce the rate of illness or education/consumer intervention or post harvest controls performance measures set forth in prior work plans have been achieved. Should the VMC evaluation indicate the 40 percent, 5-year goal has not been accomplished, the committee will identify additional harvest controls in the 2007 - 2008 work plan to assure achievement of the 60 percent reduction in the rate of illness goal by the close of the seventh year. In addition, the VMC will evaluate the requirements in Section 04.C. with the possibility of changing the controls to achieve remaining illness reduction goals.~~

~~(j) Should a disagreement arise between FDA and the Authority on the equivalency of a control as described in .04(C), the V.v. Subcommittee will be requested to provide guidance.~~

~~(k) In 2006 the Executive Board directed the elimination of the Vv & Vp subcommittees. The VMC assumed all responsibilities of the subcommittees as outlined in the Vibrio vulnificus Management Guidance Document. Representation on the VMC Committee will be consistent with all guidance (VMC and Vv subcommittee) outlined in the Vibrio vulnificus Management Guidance Document.~~

~~(l) Shellstock Harvested in Source States Harvesters must include on the tag of all product harvested for restricted use the statement "for shucking by a certified dealer" and/or "For PHP Only." Harvesting controls must be provided by the Authority to ensure that restricted use shellstock is not diverted to retail or food service. Dealers must establish a restricted use shellstock Critical Limit as part of their HACCP Plan for receiving. A shipping Critical Control Point must include a restricted use shellstock~~

~~disposition step. Restricted use shellstock is not intended for retail or food service.~~
~~Should a disagreement arise between FDA and the Authority on the equivalency of a control as described in .04(C), the V.v. Subcommittee will be requested to provide guidance.~~
~~In 2006 the Executive Board directed the elimination of the Vv & Vp subcommittees. The VMC assumed all responsibilities of the subcommittees as outlined in the Vibrio vulnificus Management Guidance Document. Representation on the VMC Committee will be consistent with all guidance (VMC and Vv subcommittee) outlined in the Vibrio vulnificus Management Guidance Document.~~
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.0~~1~~3 *Vibrio parahaemolyticus* Control Plan
.0~~2~~4 Post Harvest Processing Validation Verification Interim Guidance for *Vibrio vulnificus* and *Vibrio parahaemolyticus*
.0~~3~~5 Guidance for Demonstrating the Effectiveness of Time to Temperature Reduction Criteria for *Vibrio vulnificus* and *Vibrio parahaemolyticus*

Public Health Significance

The level of *V.v.* in oysters at the time of harvest can cause illness in immuno compromised individuals with increased susceptibility. This risk ranges from approximately .06 to 3.33 illnesses per 100,000 servings depending upon water temperature. The controls presently required by State *Vibrio vulnificus* Control Plans, if properly implemented, can reduce growth and reduce *Vibrio vulnificus* levels after harvest.

Changes will provide additional options for managing the risks associated with *Vv.* These options will not require Post-Harvest Processing (PHP) controls which are presently not economically feasible. The RTI Economic Study suggested that it would take 2 to 3 years to implement PHP and, even with that time for implementation, would create a significant economic burden.

References:
(1) VMC Committee Reports (Al Rainosek's updated illness rate Calculations);
(2) RTI International Report Project Number 0211460.008
(3) "Analysis of How Post-harvest processing Technologies for Controlling Vibrio vulnificus Can Be Implemented"; Dr. Steve Otwell, Laura Garrido,Victor Garrido and Dr.Charlie Sims report "Sensory Assessment Study for Post -Harvest Processed (PHP) Oysters

Cost Information	
Action by 2011 Task Force II	Recommended adoption of Vibrio Management Committee Substitute Proposal 11-201-A as amended. Additionally, Task Force II recommended: That a committee be established to consider options for water temperature determinations which can be used in the implementation of Proposal 11-201-A. That a Committee be established to develop criteria for verifying reduction in harvest for raw consumption and the percentage of post-harvest processed product on a monthly basis for those States required to have a *Vibrio vulnificus* Control Plan. An implementation date of January 1, 2012 for Proposal 11-201-A. Recommended referral of Proposal 11-201-B to an appropriate committee with representation from all regions to develop Model Ordinance language changes to support the time temperature requirements of the State's *Vibrio* Management Plans. This committee will be appointed and approved by the Executive Board at its closing Board meeting. The committee will be expected to meet within two (2) weeks of the close of the Conference. After its initial meeting, the committee shall meet by teleconference biweekly prior to an Executive Board meeting until the proposal is completed and at least once subsequent to the dissemination of the proposal and prior to an Executive Board meeting. The draft proposal that is to be considered by the Executive Board shall be disseminated to the ISSC membership a minimum of three (3) weeks prior to the next Executive Board meeting and posted on the ISSC web site. The Committee is directed to make recommendations to the Executive Board for interim approval with an effective date prior to the 2012 *Vibrio* season. The State's Authorities are requested to begin advising and educating their industries of these changes. Additionally, the committee will develop guidance for implementation of these controls.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force II on Proposal 11-201 Part A. Adopted recommendation of 2011 Task Force II on Proposal 11-201 Part B.
Action by USFDA February 26, 2012	FDA concurred with Conference action on Proposal 11-201 Part B but did not concur with Conference action on Proposal 11-201 Part A. FDA comments and recommendations in response to Proposal 11-201 Part A: In October of 2009, the Food and Drug Administration (FDA) informed the Interstate Shellfish Sanitation Conference (ISSC) of its intention to reformulate the Agency's policy regarding implementation of the Seafood HACCP Regulation with the intent that post-harvest processing (PHP) or equivalent measures be implemented for the control of *Vibrio vulnificus (V.v.).* The new policy would require that oysters harvested from the Gulf of Mexico and intended for the raw half shell market be post-harvest processed during those months when illness from *V.v.* is reasonably likely to occur. Given that PHP can largely eliminate *V.v.* while preserving the sensory qualities of raw untreated product FDA remains committed to this approach as the most prudent means of reducing the risk of illness from *Vv.* The efficacy of PHP is evidenced by the fact that since 2003, when the State of California banned the sale of untreated Gulf oysters harvested between April

and October, there has been only one *V.v.* illness in the State. Prior to 2003 California reported on average six *V.v.* related illnesses per year.

In November 2009, having heard from elected State and Federal representatives, the oyster industry and State regulatory officials regarding the feasibility of implementing PHP or other equivalent controls, FDA acknowledged the need to further examine the process and timing of industry adoption of PHP technology and placed in abeyance the Agency's intent to change its policy for controlling *V.v.* while taking steps to complete an independent study to assess how PHP controls can be implemented. In the interim, FDA has expressed its intention to continue working cooperatively with the ISSC to implement alternate controls which would reduce illnesses and meet the goals adopted by the ISSC in Proposal 00-201. Since adoption of Proposal 00-201 FDA has repeatedly expressed concerns relative to its implementation by the ISSC, including failure to consider national illness numbers and the lack of success in achieving the 60% illness rate reduction goal. FDA reiterated its concerns during ISSC deliberation of Proposal 11-201 at the October 2011 biennial meeting and those concerns were not adequately addressed by Conference action on Proposal 11-201. It is the position of FDA that Proposa111-201 deviates from current FDA policy in that it weakens the control measures adopted by the ISSC in Proposal 00-201. Therefore, FDA cannot concur with Proposal11-201 without further Conference action. FDA requests that the ISSC address the following issues and concerns.

ISSC adoption of Proposal 00-201 in 2001 established a 60% illness rate reduction goal. Although FDA no longer considers this the most appropriate goal given the efficacy of PHP, FDA has continued to recognize and support ISSC efforts to achieve this level of illness reduction. However, the level of reduction reported by the ISSC *Vibrio* Management Committee (VMC) indicates only marginal success in moving toward that goal.

Proposal 00-201 included specific control measures to be taken by the *V.v.* Source States if the 60% goal was not met. Those measures, intended for all oysters harvested during periods of risk included; closing shellfish growing areas to harvest, labeling oysters for shucking by a certified dealer, and subjecting oysters to PHP. Although the 60% illness rate reduction goal has not been achieved, none of these control measures have been implemented. Disagreement by States and the ISSC to pursue these more effective control measures has been a significant concern to FDA. That concern is further exacerbated by the fact that Source States, with ISSC support, have now adopted a policy that focuses control efforts toward more stringent time to temperature controls, for which compliance by industry is proving difficult. Section @.05 E. (1) (b) (iii) ofProposal11-201 establishes risk per serving standards for States using time/temperature controls and Section @.05 E. (1) (b) (iv) allows for alternative controls that achieve those same risk per servings standards. The risk per serving standards in Proposal11-201 are based on controls that were derived from the FDA developed *V.v.* calculator. These controls have not yet been demonstrated to achieve a 60% illness rate reduction. The FDA maintains that until these risk per serving standards are demonstrated to achieve the intended 60% illness rate reduction, evaluation of their effectiveness is imperative. Guidance needs to be developed for how to evaluate State programs to determine if risk per serving standards are being achieved. Section @.05 E. (2) (a) ofProposal11-201 States that the State Authority in conjunction with FDA will evaluate the implementation and effectiveness of these controls. As written, FDA would consider a State to be in non-compliance when there is ineffective implementation due to industry noncompliance or

when the controls are determined ineffective in achieving the risk per serving standards. FDA would expect a State to discontinue the use of the time/temperature control measures and implement other control options outlined in @.05 E. (1) (b) should the State evaluation indicate that the State is not meeting the risk per serving standards.

Proposal 11-201, based on temperature modeling using the *V.v.* calculator, establishes risk per serving standards that are intended to achieve a 60% illness rate reduction. Determining the ability of the ISSC control strategy, based on implementing risk per serving standards, will focus on the number of nationally reported illnesses associated with oysters from the Source States. FDA expects that if the risk per serving standards established in Proposal 11-201 prove to be effective, the number of nationally reported *V.v.* illnesses associated with Gulf oysters will be reduced by 60%.

The Source States have generically incorporated as part of their risk reduction measurement a 10% reduction in harvest attributed to stricter time/ temperature controls and a 15% reduction attributed to product diversion to PHP. Actual percentages are certain to vary from State to State and year to year, making it necessary that each State provide data supporting the use of these assumptions.

FDA is concerned that efforts to assess the effectiveness of time/temperature controls in achieving risk per serving standards will be difficult. Given the small number of illnesses associated with oysters from an individual State, annual fluctuation of those numbers, and fluctuations in oyster production from year to year, calculating achievement of risk per serving numbers using national illness data and oyster production data from each *V.v.* Source State will be challenging.

Beginning with the April2012 *V.v.* season, FDA will be evaluating State *V.v.* Control Plans, industry compliance, and State enforcement. While FDA is developing guidance regarding what Shellfish Specialists should consider when conducting *V.v.* evaluations, presently neither FDA nor the ISSC has developed specific criteria for determining compliance with State *V.v.* plan goals. FDA requests that an ISSC committee be appointed to work with FDA to develop State evaluation criteria. FDA requests development of:

Evaluation criteria for determining proper and effective use of the *V.v.* calculator;

Evaluation criteria for determining State *V.v.* control plan compliance with NSSP requirements;

Evaluation criteria for determining the effectiveness of State regulatory efforts to ensure industry compliance with State *V.v.* Control Plan requirements;

A formula for calculating State compliance with risk per serving standards; and

Actions and sanctions should a State be found out of compliance. In this regard FDA envisions that the established ISSC noncompliance process would be followed, which could result in advising receiving States of issues of noncompliance and recommending that shipments of oysters intended for raw consumption from non-compliant States not be accepted.

FDA remains committed to addressing *V.v.* illnesses associated with consumption of raw

	Gulf oysters. As stated, FDA considers these illnesses to be preventable utilizing PHP technology. FDA will continue to support ISSC efforts to better control the risk of *V.v.* until the obstacles associated with full implementation of PHP are addressed. In the interim, however, FDA cannot support Conference action to change existing *V.v.* control requirements in such a way that they are less likely to achieve the existing 60% illness rate reduction goal. As adopted, FDA considers Proposal 11-201 a less effective approach to preventing *V.v.* illnesses.
Action by FDA October 10, 2012	Food and Drug Administration concurred with adoption of the Conference's Proposal 11-201Part A to initiate a new plan to reduce illnesses and deaths resulting from *Vibrio vulnificus* in raw oysters and looks forward to cooperating with ISSC members to put the plan in effect.
Action by 2013 Vibrio Management Committee	Recommended adoption of the following Vibrio Management Committee (VMC) recommendations: 1. Develop a database to input the *V.v.* Illness Review Committee information. 2. Develop criteria for verifying reduction in harvest for raw consumption and the percentage of post-harvest processed product. Executive Office has had very little success in identifying approaches for obtaining this kind of information and the VMC had no suggestions on how to achieve this either.
Action by 2013 Task Force II	Recommended adoption of VMC recommendation No. 1 to develop a database to input the *V.v.* Illness Review Committee information. Recommended no action on recommendation No. 2 to develop criteria for verifying reduction in harvest for raw consumption and the percentage and refer to ISSC Executive Office. Rationale: The Executive Office has had very little success in identifying approaches for obtaining this kind of information and the VMC had no suggestions on how to achieve this.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 11-201 Part A.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-201 Part A.
Action by 2015 Vibrio Management Committee	Recommended no action on Proposal 11-201-A. Rationale: At the 2013 Biennial Meeting the Voting Delegates directed the development of a *V.v.* database. The database has been developed and is in use. No additional action by Task Force II is required.
Action by 2015 Task Force II	Recommended adoption of VMC recommendation of no action on Proposal 11-201-A. Rationale: At the 2013 Biennial Meeting the Voting Delegates directed the development of a *V.v.* database. The database has been developed and is in use. No additional action by Task Force II is required.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 11-201-A.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 11-201-A.

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

Action by 2015 Task Force II	Recommended no action on Proposal 01-206. Rationale: Charges of the VMC related to this proposal have already been addressed.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 11-206.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 11-206.

Proposal Subject	Reducing the Risk of Vibrio Illnesses
Specific NSSP Guide Reference	NSSP Guide for the Control of Molluscan Shellfish
Text of Proposal/ Requested Action	A Vibrio workshop was held in Dauphin Island, Alabama in November 2012 to discuss possible solutions for addressing illness risks. State Shellfish Control Authority representatives, Vibrio researchers, and the USFDA participated in the two-day workshop. The participants identified several topics (listed below) that are related to Vibrio controls. These topics should be addressed by the collective participants of the ISSC. The purpose of this proposal is to request the ISSC Executive Board work collaboratively with the USFDA to address the information gaps that are obstacles to identifying effective control strategies for reducing the risk of illness associated with Vibrioses. Requested Action Items: 1. Rewrite Chapter II. Risk Assessment *V.p.* (section 05). 2. Incorporate salinity (and other environment factors?) into *V.v.* and *V.p.* risk calculators. 3. Develop protocol for validating the effectiveness of non-labeling PHPs 4. Develop protocol for ensuring that growing/harvest/handling (production) practices do not increase risk of Vibrio illness. 5. Request FDA to develop sampling protocol for closing versus reopening growing areas after outbreaks including the development of resources to sustain the present capabilities 6. Develop new labeling/tagging system for oysters produced under conditions achieve equivalent levels as validated PHP (for labeling), including validation protocol 7. ISSC request FDA to reexamine risk assessments and risk calculators (*V.p.* and *V.v.*) 8. ISSC request FDA to reexamine illness and landings data to determine observed risk per serving 9. Develop the process for using local data to refine calculators to more accurately reflect risk in the region or state 10. Determine how best to estimate national consumption patterns for molluscan bivalves 11. Mega study 12. ISSC request FDA technical assistance for enhancing state vibrio programs (data management, laboratory support, think tank, BMPs, evaluation of effectiveness of new controls, statistical support) 13. States request FDA assistance with developing approved method(s) to temper clams 14. Draft proposal for acceptance of laboratory methods validated by other accrediting bodies
Public Health Significance	The ISSC continues to struggle with identifying practical cost effective strategies for reducing the risk of Vibrio illnesses associated with the consumption of molluscan shellfish. This proposal identifies information needs that are obstacles to the development of control strategies.

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

FDA concurs with ISSC referral of Proposal 13-200 to Committee. As appropriate, FDA will provide support to the Committee via participation of Agency Vibrio research and risk assessment experts to assist in addressing Committee charges as set forth in Proposal 13-200. The Agency will look to the Conference to advance recommendations made by the Committee for purposes of implementing appropriate controls to reduce the Vibrio risk. Results of ISSC actions in response to Proposal 13-204 will be integral to answering key questions associated with the Committee's charges.

Action by 2015 Vibrio Management Committee

Recommended the following action on Proposal 13-200:

1. That the ISSC recognize the new *V.v.* and *V.p.* calculators as a tool available to calculate the actual risk and assess the effectiveness of state controls.

2. Continue to monitor the activities addressed in items 2 & 3 and report annually to the VMC regarding progress.

3. That a workgroup be formed to evaluate the effectiveness of existing NSSP regulations to reduce risk of Vibrio illnesses caused by improper handling, storing, or transportation of shellstock; to identify areas within the NSSP needing improvement; and make recommendations to the ISSC. The workgroup will consist of FDA, state and industry representatives.

Action by 2015 Task Force II

Recommended adoption of VMC recommendations 2. And 3. with referral of Proposal 13-200 to an appropriate committee with a recommendation that States be allowed to pilot the new *V.v.* and *V.p.* calculators and to provide input to the FDA and report back to VMC prior to the next ISSC meeting.

Action by 2015 General Assembly

Adopted recommendation of Task Force II on Proposal 13-200.

Action by FDA January 11, 2016

Concurred with Conference action on Proposal 13-200.

Proposal Subject	Vibrio Control Plans
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. @ .05 *Vibrio vulnificus* Control Plan Chapter II. @ .06 *Vibrio parahaemolyticus* Control Plan
Text of Proposal/ Requested Action	@.05 *Vibrio ~~vulnificus~~* Control Plan ~~(Effective January 1, 2012)~~

A. Risk Evaluation

Each shellfish producing State that is not currently implementing a *Vibrio ~~vulnificus (V.v.)~~* control plan for purposes of controlling the risk of *Vibrio vulnificus (V.v.)* and/or *Vibrio parahaemolyticus (V.p.)* shall conduct a *Vibrio ~~vulnificus~~* risk evaluation annually. The evaluation ~~shall~~should consider factors deemed appropriate by the State Authority for effectively assessing whether or not~~each of the following factors, including seasonal variations in the factors, in determining~~ the risk of *Vibrio vulnificus* or *Vibrio parahaemolyticus* infection from the consumption of shellfish harvested from the State's growing waters is reasonably likely.

(1) In conducting the risk evaluation the State Authority may ~~will at a minimum~~ consider any number of factors, for example~~the following~~:

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

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

(c) Levels of tdh+ and trh+ *Vibrio parahaemolyticus* in the growing area to the extent that such data exists; and

(d) The water temperatures in the growing area; and

(e) The air temperatures in the growing area; and

(f) Salinity in the growing area; and

(g) Harvesting techniques in the growing area; and

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

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

(1) Any etiologically confirmed shellfish-borne *Vibrio vulnificus* or *Vibrio parahaemolyticus* illness from the growing waters of that State but the number of cases does not reach the illness threshold established in Chapter II @.05 D or E; and

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

BC. States which have previously met the illness threshold for *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* requiring a *Vibrio ~~vulnificus~~* Control Plan will continue to maintain and implement a *Vibrio ~~vulnificus~~* Control Plan~~.~~

CD. All States not currently implementing a *Vibrio ~~vulnificus~~* Control Plan shall develop and implement a *Vibrio ~~vulnificus~~* Control Plan should the risk evaluation indicate two (2) or more etiologically confirmed, and epidemiologically linked *Vibrio vulnificus* septicemia illnesses from the consumption of commercially harvested raw or undercooked

oysters that originated from the growing waters of that state within the previous ten (10) years.

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

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

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

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

EF. *Vibrio* Control Plan

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

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

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

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

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

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

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

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

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

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

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

~~Reducing time of exposure to ambient air temperature prior to delivery to the initial certified dealer based on modeling or sampling, as determined by the Authority in consultation with FDA. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. When~~

~~this control measure is selected, State *V.v.* plans will include controls when water temperature promotes *V.v.* levels and risk of illness increases. The controls will minimize risk to less than three (3) illnesses per 100,000 servings when Average Monthly Maximum Wwater Ttemperature exceeds 80°F. Authority approved Best Management Practices (BMPs) will be applied to minimize *V.v.* growth to the extent possible when Average Monthly Maximum Water temperature exceeds 70°F but is less than or equal to 80 °F. BMPs will ensure that when the water temperature exceeds 70°F but is less than or equal to 75°F risk is minimized to less than 1.75 illnesses per 100,000 servings and when water temperature exceeds 75°F but is less than or equal 80 °F the risk will not exceed 2.5 illnesses per 100,000 servings. These risks per serving will be determined using the FDA developed *Vibrio vulnificus* calculator.~~

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

(2) Control Plan Evaluation

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

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

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

(iii) Industry compliance with existing controls.

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

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

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

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

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

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

a. Did the risk evaluation indicate the need for a Contingency Plan?
b. Does the plan include the regulatory steps to be implemented should the number of illnesses reach the illness threshold requiring implementation of a Vibrio Control Plan?

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

FG. Contingency Plan

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

(2) Contingency Plan Evaluation

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

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

~~A. Risk Evaluation.~~

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

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

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

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

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

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

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

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

~~B. Control Plan~~

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

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

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

~~(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and~~

~~south): 81°F.~~

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(c) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk~~

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

~~(d) Evaluate the effectiveness of the Plan.~~
~~(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.~~
~~(f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.~~

~~C. The Time When Harvest Begins For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.~~

Public Health Significance

While *Vibrio parahaemolyticus* and *Vibrio vulnificus* Control plans (VPCP and VVCP) rely primarily on time and temperature controls to reduce post-harvest vibrio growth, the controls implemented vary widely from state to state. States requiring *V.v.* controls generally must implement more restrictive harvest controls than states which only require *V.p.* control plans. Additionally, risk per serving standards associated with VVCP require corrective actions that are absent in VPCP. This disparity creates an economic advantage for industry in states with less stringent requirements and favors higher production of more risky product. This may partially explain the increases in reported *V.v.* illnesses in recent years while *V.v.* cases have remained relatively static over this same period. Post-harvest growth increases the risk of *V.p.*, *V.v.* and likely other Vibrio spp. and shall be prevented by any reasonable means. Enforcement of current time and temperature controls is problematic as it is difficult to determine when the product was harvested. Immediate cooling would prevent any vibrio growth and maintain the vibrio levels at harvest providing enhanced public health protection relative to the current control plans. Immediate cooling would also facilitate enforcement and improve compliance. This approach is consistent with Codex Guidance for bivalve mollusks and industry cooling practices with other seafood products that are inherently less risky. Environmental monitoring with the current capabilities and capacity is not an effective means for mitigating vibrio risk. While immediate cooling is not as effective as Post-Harvest Processing (PHP) or closures, it is far less disruptive to industry than these approaches. Acceptance of this proposal would unify and simplify the control approach used for *V.p.* and *V.v.* and provide a level playing field for industry.

FDA intends to provide additional information in support of this Proposal in advance of the ISSC 2013 Biennial Meeting.

Cost Information

Action by 2013 Task Force II

Recommended adoption of Proposal 13-204 as substituted.

The ISSC Executive Board is tasked to work with states to seek and obtain funding for the purpose of assessing the efficacy of time and temperature controls on post-harvest Vibrio growth. Efforts shall be directed at developing robust science to define the combination(s)

of prevention and post-harvest time and temperature controls that, when fully implemented, will minimize post-harvest Vibrio growth. The ISSC Executive Director, ISSC Chair, in consultation with an appropriate work group including some members of the Vibrio Management Committee shall provide guidance and administrative oversight to promote a coordinated effort among states, industry and the FDA to:

1. Assess regional and environmental differences that may better define the combination(s) of post-harvest time and temperature controls that will be most effective for a given region or state and;
2. Ensure that the results of research efforts will be fully considered by the membership of the ISSC.

In addition to new research activities directed at scientifically defining effective time and temperature controls, the Executive Office shall request that states and industry submit to the VMC data and information relative to efforts in their respective state associated with time and temperature assessment and control activities. This work shall be conducted over the next one to two years and the science that is generated and compiled shall be used to compose an ISSC Proposal for consideration at the 2015 biennial meeting of the ISSC for controlling the post-harvest growth of Vibrios. The Executive Board shall be briefed at each of its semiannual meetings regarding all ongoing work associated with this effort.

Additionally FDA requested that the remaining Vibrio Proposals be debated as submitted.

Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 13-204.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-204.
Action by 2015 Vibrio Management Committee	Recommended no action on Proposal 13-204. Rationale: The final reports from the ISSC funded studies have not been finalized and submitted to the ISSC. The final reports, when available, will be shared with VMC. The VMC will make recommendations to Task Force II to address Proposal 13-204 at that time.
Action by 2015 Task Force II	Recommended deferring action on Proposal 13-204. Rationale: The final reports from the ISSC funded studies have not been finalized and submitted to the ISSC. The final reports, when available, will be shared with VMC. The VMC will make recommendations to Task Force II to address Proposal 13-204 at that time.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 13-204.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-204.

Proposal Subject	Re-submerging of Shellstock
Specific NSSP Guide Reference	Section I. Purpose and Definitions Section II. Model Ordinance Chapter V. Shellstock Relaying
Text of Proposal/ Requested Action	Chapter I. Purpose and Definitions Add new definition (92) Re-submerging means the process of short term submersion of shellstock in an approved growing area following initial harvest for purposes of reducing naturally occurring bacterial pathogens to background levels. Renumber existing definitions 92 through 121. Chapter V. Shellstock Relaying and Re-submerging @.01 General The Authority shall assure that: (3) The shellstock: (1) U~~u~~sed in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted; (2) Used in re-submerging activities is harvested from growing areas classified as approved or conditionally approved; (4) The level of contamination in the shellstock can be reduced to levels safe for human consumption; (5) 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 (6) If shellstock are relayed in containers: ~~a.~~(a) The containers are: • Designed and constructed so that they allow free flow of water to the shellstock; and • Located so as to assure the contaminant reduction required in Section C.; and (2) The shellstock are washed and culled prior to placement in the containers. @.02 Contaminant Reduction. A. The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached. B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The study report shall demonstrate that, after the completion of

the relay activity:

(1) The bacteriological quality of each shellfish species is the same bacteriological quality as that of the same species already present in the approved or conditionally approved area; or

(2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA tolerance levels.

(3)

Public Health Significance

Cost Information

Action by 2013 Task Force II

Recommended referral of Proposal 13-209 to an appropriate committee as determined by the Conference Chair.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force II on Proposal 13-209.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 13-209.

Action by 2015 Shellstock Resubmerging Committee

Recommended adoption of the following substitute language.

Re-submerging means the process of short term submersion of shellstock following exceedance of the time temperature requirements of a vibrio control plan. The purpose of resubmerging is to allow shellstock harvested under conditions that are not compliant with Vibrio time temperature controls to return to background levels.

Wet Storage means the storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater at any permitted land-based activity or facility. Wet Storage can only be used for shellstock that is harvested under conditions that are compliant with the time temperature controls included in Chapter VIII. @.02.

Chapter V. Shellstock Relaying and Resubmerging

Add a new section Resubmerging. Renumber existing sections as appropriate.

@.02 Resubmerging

A. General. The Authority shall assure that:

(1) The shellstock used in re-submerging activities is harvested from growing areas classified as approved, conditionally approved, restricted or conditionally restricted;

(2) The level of contamination in the shellstock can be reduced to levels safe for human consumption;

(3) The shellstock are held in growing areas classified as approved or

conditionally approved, restricted, or conditionally restricted for a sufficient time under adequate environmental conditions so as to allow reduction of naturally occurring pathogens such as Vibrio spp. that may be present in shellstock to occur; and

B. Natural Pathogen Reduction

(1) The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached.

(2) The effectiveness of species-specific contaminant reduction shall be determined based on a study. The Authority shall retain the written study report indefinitely. The study report shall demonstrate that, after the completion of the submerging activity. The level of naturally occurring pathogens (Vibrio spp.) in each shellfish species is the same level of naturally occurring pathogens as that of the same species already present in the approved, conditionally approved, restricted or conditionally restricted area.

(3) A study will not be required if shellstock remains in the growing area for a time period of at least fourteen (14) consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequate.

Action by 2015 Task Force II	Recommended referral of Proposal 13-209 to an appropriate committee as determined by the Conference Chairperson.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 13-209.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-209.

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

Committee	C. The Authority shall inspect commercial land-based and floating aquaculture systems facilities at least every six months annually. The Authority shall at a minimum inspect operator records to verify that appropriate permits are up to date and operational plans are being implemented as written. Delete the following due to duplication: @.03 A. ~~The Authority shall inspect commercial land-based and floating aquaculture systems facilities at least every six months.~~
Action by 2015 Task Force II	Recommended adoption of Aquaculture Facility Inspection Committee recommendation on Proposal 13-210 as amended. @.01 General C. The Authority shall inspect commercial land-based and floating aquaculture systems facilities at least annually. The Authority shall at a minimum inspect operator records to verify that appropriate permits are up to date and operational plans required in @ .03 B. are being implemented ~~as written~~.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 13-210.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-210.

Proposal Subject	Tagging Requirements for Wet Stored Shellstock
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers
Text of Proposal/ Requested Action	Section II. Model Ordinance Chapter X. General Requirements B. Tags. (2) The dealer's tag shall contain the following indelible, legible information in the order specified below: (a) The dealer's name and address. (b) The dealer's certification number as assigned by the Authority. (c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required. (d) The harvest date; or if depurated, the date of depuration processing, or if wet stored, the original harvest date, the dealers lot designation, the letter "W" and the final harvest date which is the date removed from wet storage. Section IV. Guidance Documents Chapter III. Harvesting, Handling, Processing, and Distribution .04 Shellstock Tagging. Except for shellstock that originated from a depuration-processor, shellstock transported across State lines and placed in wet storage must include the following information on its shipping tag after removal from wet storage: • All information required on a dealer's tag as specified above; and • The statement that "THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO AND WAS REMOVED FROM WET STORAGE ON (DATE)"
Public Health Significance	Having multiple dates on the dealer's tag has proven to be confusing to the customers. The CFIA has chosen to avoid this confusion by listing date of removal from wet storage and listing that as the harvest date. This is the most efficacious method of clarifying the issue of when the shellfish comes out of the water which determines the shelf life of the product. Trace back is still dependent upon the Dealer's inventory control and the ability of the wet storage operator to distinguish which lots of shellfish came from which harvest area on certain dates and which lots went to which customers on which ship dates. This information trail is still vital to the trace back and will still be required. This will make Canadian CFIA wet storage tagging requirements consistent with those of the ISSC and maintain true equivalence between the two programs. This is important since products from both countries compete directly in the marketplace.
Cost Information	Trace back will still be dependent on the wet storage operator's ability to maintain accurate inventory records demarcating which lots from which harvest areas and dates were shipped to which customers on which dates. Requiring this information on the tags

	as well only adds a layer of complexity and confuses the customers.
Action by 2013 Task Force II	Recommended referral of Proposal 13-212 to an appropriate Committee as determined by the Conference Chairman with instructions to the Committee to try and find ways to increase foreign compliance on this issue.
Action by 2013 General Assembly	Adopted recommendation of Task Force II on Proposal 13-212.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-212.
Action by 2015 Wet Storage Tagging Committee	Recommended no action on Proposal 13-212. Rationale: There is no need for any revisions to the Model Ordinance. This is adequately addressed in the Model Ordinance.
Action by 2015 Task Force II	Recommended adoption of the Wet Storage Tagging Committee of no action on Proposal 13-212.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 13-212.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-212.

Proposal Subject	PHP Validation and Verification Costs
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XVI. Post-Harvest Processing
Text of Proposal/ Requested Action	In 2003 the Interstate Shellfish Sanitation Conference (ISSC) acknowledged the public health benefits of Post-Harvest Processing (PHP) to reduce *Vibrio vulnificus (V.v.)* levels in shellfish. The Conference has continued to support the voluntary adoption of PHP by the shellfish industry. In subsequent years the Conference adopted validation and verification procedures for dealers utilizing PHP. The cost of validation and verification continues to be an obstacle for many smaller dealers. The procedure should be reviewed to identify ways to reduce costs while continuing to provide a reasonable level of public health protection.
Public Health Significance	See Requested Action.
Cost Information	
Action by 2013 Task Force II	Recommended referral of Proposal 13-220 to an appropriate committee as determined by the Conference Chairman.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 13-220.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-220.
Action by 2015 PHP Committee	Recommended no action on Proposal 13-220. Rationale: It has been determined that the current costs of PHP validation and verification is not an obstacle to the voluntary expansion of PHP.
Action by 2015 Task Force II	Recommended adoption of the PHP Committee recommendation of no action on Proposal 13-220.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 13-220.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-220.

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

A. Risk Evaluation.
Every State from which oysters are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)
   (1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters commercially harvested from the State; and
   (2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and
   (3) The water temperatures in the area; and
   (4) The air temperatures in the area; and
   (5) Salinity in the area; and
   (6) Harvesting techniques in the area; and
   (7) The quantity of harvest from the area and its uses i.e. shucking, half-shell, PHP.

B. Control Plan
   (1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or
   (2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:
      (a) Waters bordering the Pacific Ocean: 60°F.
      (b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81°F.
      (c) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.
         (i) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section;
         (ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish

that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or

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

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

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

(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include: (i) Post-harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and a three (3) log reduction for the Pacific Coast oysters;

(i) Closing the area to oyster harvest,

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

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

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

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

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

(d) Evaluate the effectiveness of the Plan.

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

ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.

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

C. ~~The Time When Harvest Begins~~ For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.

D. States implementing a *Vibrio parahaemolyticus* Control Plan shall determine the level of protection afforded by calculating the observed risk per serving based on the number of annual illnesses attributed to shellfish harvested from the state and the state's annual oyster and/or hard clam production. Modify the Control Plan when the observed risk per serving is greater than one (1) illness per 100,000 servings.

Public Health Significance

In the absence of a requirement for states to determine the observed risk per serving, it is not possible to verify that the level of protection offered by state Control Plans is consistent with the level of protection (≤1 illness per 100,000 servings) intended by time and temperature controls as defined by the *Vibrio parahaemolyticus* risk calculator. Requiring states to determine the observed risk per serving using annual illness data and annual production data will allow the ISSC to gauge the success of state control plans and engage states in developing additional controls where necessary. During periods of unacceptable risk, further restrictions on time and temperature controls, or other equivalent measures, should be considered to reduce risk to an acceptable level.

Cost Information

Action by 2013 Task Force II

Recommended referral of Proposal 13-223 to an appropriate committee as determined by the Conference Chairman.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force II on Proposal 13-223.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 13-223.

Action by 2015 Vibrio Management Committee

Recommended adoption of Proposal 13-223 as amended.

States implementing a *Vibrio parahaemolyticus* control plan shall determine the level of protection afforded by calculating the observed risk per serving based on the number of ~~annual~~ illnesses attributed to shellfish harvested from the state and the state's ~~annual~~ oyster and/or hard clam production for the state's identified risk period. Modify the control plan when the observed risk per serving over a five year period is greater than 1 illness per 100,000 servings.

Action by 2015 Task Force II

Recommended no action on Proposal 13-223. Rationale: This is adequately covered in the Model Ordinance.

Action by 2015 General Assembly

Adopted recommendation of Task Force II on Proposal 13-223.

Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-223.

Proposal Subject	Shellfish Related Illnesses Associated with *V.p.*
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment & Risk Management @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)*
Text of Proposal/ Requested Action	Amend Model Ordinance Chapter II. Risk Assessment & Risk Management @.02 A. (4) (a) to provide clarification regarding closures associated with sporadic cases that do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day. Two (2) options are offered below that could provide needed clarification.

Option 1:

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

A. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and the span of time as follows.

(1) When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall:

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

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

(c) ~~The Authority will m~~Make reasonable attempts to ensure compliance with the existing Vibrio Management Plan.

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

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

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

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

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

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

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

(c) Promptly initiate a voluntary industry recall consistent with the

Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products.

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

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

(a) The area will remain closed for a minimum of seven (7) days when sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves four (4) or less cases occurring within a thirty (30) day period from the implicated area in which no two (2) cases occurred from a single harvest date from the implicated area.

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

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

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

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

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

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

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

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

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

Option 2:

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

A. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and the span of time as follows.

(1) When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. The Authority will make reasonable attempts to ensure compliance with the existing Vibrio Management Plan.

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

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

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

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

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

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

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

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

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

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

~~(a) The area will remain closed for a minimum of seven (7) days when sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves four (4) or less cases occurring~~

~~within a thirty (30) day period from the implicated area in which no two (2) cases occurred from a single harvest date from the implicated area.~~

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

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

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

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

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

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

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

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

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

Public Health Significance

Following the adoption of Proposal 13-202 at the 2013 Biennial Meeting, the Executive Board was asked to clarify the language of the proposal associated with sporadic cases that do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day.

To address this concern, the Executive Board, with FDA concurrence, took interim action to delay the implementation of the closure requirement associated with @.02 A. (4) (a). The intent of this Board action was to allow the ISSC to discuss the intent of @.02 A. (4) (a).

Cost Information

Action by 2015 Task Force II	Recommended adoption of Proposal 15-201 Option 2 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-201.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-201.

Proposal Subject	Shellfish Related Illness Associated with *Vibrio parahaemolyticus(V.p.)*
Specific NSSP Guide Reference	Section II Model Ordinance Chapter II. Section @.02. A. (4)
Text of Proposal/ Requested Action	@.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)*

A. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and the span of time as follows.

(1) When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. The Authority will make reasonable attempts to ensure compliance with the existing Vibrio Management Plan.

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

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

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

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

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

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

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

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

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

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

~~(a) The area will remain closed for a minimum of seven (7) days when sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves four (4) or less cases occurring~~

~~within a thirty (30) day period from the implicated area in which no two (2) cases occurred from a single harvest date from the implicated area.~~

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

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

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

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

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

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

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

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

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

Public Health Significance	Model Ordinance Chapter II. @.02 was adopted by the ISSC Voting Delegates at the 2013 meeting. Subsequent discussion revealed an inconsistency in that reopening criteria were adopted for a tier that does not specify a required closure. This amendment is intended to eliminate this point of confusion.
Cost Information	None.
Action by 2015 Task Force II	Recommended no action on Proposal 15-202. Rationale: This proposal was adequately addressed in Proposal 15-201.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-202
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-202.

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

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas
Text of Proposal/ Requested Action	.04 Wet Storage in Artificial Bodies of Water (Land-Based)

A. General

(1) If the dealer chooses to practice wet storage in artificial bodies of water, the dealer shall meet the requirements of Chapter VII. .01 and .02.

(2) For the purpose of permitting, each wet storage site or activity shall be evaluated in accordance with @.01. B. The evaluation shall include a review of the plan and operating procedures for conducting land-based wet storage activity as submitted by the dealer.

~~(3) Prior to commencing construction, all plans for construction or remodeling of wet storage facilities shall be reviewed and authorized by the Authority.~~

(~~4~~3) The wet storage facility evaluation shall include a review of:

(a) The purpose of the wet storage activity, such as holding, conditioning or increasing the salt content of shellstock;

(b) Any species specific physiological factors that may affect design criteria; and

(c) The plan giving the design of the land-based wet storage facility, source and quantity of process water to be used for wet storage, and details of any process water treatment (disinfection) system.

B. Operation Specifications.

(1) General. Each land-based wet storage activity shall meet the following design, construction, and operating requirements.

(a) Effective barriers shall be provided to prevent entry of birds, animals, and vermin into the area.

(b) Storage tanks and related plumbing shall be fabricated of safe material and shall be easily cleanable. This requirement shall include:

(i) Tanks constructed so as to be easily accessible for cleaning and inspection, self-draining and fabricated from nontoxic, corrosion resistant materials; and

(ii) Plumbing designed and installed so that it can be cleaned and sanitized on a regular schedule, as specified in the operating procedures.

(c) Storage tank design, dimensions, and construction are such that adequate clearance between shellstock and the tank bottom shall be maintained.

(d) Shellstock containers, if used, shall be designed and constructed so that the containers allow the free flow of water to all shellstock within a container.

~~(2) Buildings. When a building is used for the wet storage activity:~~

~~(a) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of Chapter XI.; and~~

~~(b) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of Chapter XI.~~

(~~3~~2) Outdoor Tank Operation. When the wet storage activity is outdoors or in a structure other than a building, tank covers shall be used. Tank covers shall:

(a) Prevent entry of birds, animals or vermin; and

(b) Remain closed while the system is in operation except for periods of tank loading and unloading, or cleaning.

Public Health Significance	These requirements are not necessary.
Cost Information	
Action by 2015 Task Force II	Recommended adoption of Proposal 15-204 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-204.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-204.

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting
Text of Proposal/ Requested Action	@.01 Control of Shellstock Growing Areas

B. Patrol of Growing Areas.

(3) Exceptions.

(a) Patrol is not required under the following conditions:

(i) There is no shellfish productivity, as demonstrated by one of the following methods:

a. pH, salinity, temperature, or turbidity are not favorable to the growth of shellfish; or

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

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

~~(ii) Harvest from the area is not economically feasible (i.e., the cost of harvesting exceeds the market value of the product);~~

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

a. The area is unclassified;

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

~~c. Known points of pollution do not exist; and~~

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

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

(i) Description of the area;

(ii) Classification of the area;

(iii) Description of adjacent growing areas;

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

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

(c) If the area is geographically remote, sparsely populated and has limited access (e.g., no or very poor roads) such that the potential for marketing the shellfish is severely restricted:

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

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

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

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

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

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

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

harvestable days.

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

.02 Shellstock Harvesting and Handling.

D. Disposal of Human Sewage from Vessels.

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

~~(2) The Authority shall educate all licensed harvesters and shellstock dealers concerning the public health significance of discharging human sewage overboard.~~

(~~3~~2) As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.

(~~4~~3) Portable toilets shall:

(a) Be used only for the purpose intended;

(b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage;

(c) Be emptied only into a sewage disposal system; (d) Be cleaned before being returned to the boat; and

(e) Not be cleaned in equipment used for washing or processing food.

(~~5~~4) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are:

(a) Constructed of impervious, cleanable materials and have tight fitting lids; and

(b) Meet the requirements in Section D. (3).

Public Health Significance

Chapter VIII. @.01 B. (3) (ii):

More appropriate for industry to determine whether something is "economically feasible" or not.

Chapter VIII. @.01 B. (3) (iii) (c):

To maintain the pollution source requirement means that areas that are completely void of shellfish would still have to be patrolled if a pollution source exists.

Chapter VIII. .02 D. (2):

This is a Requirement for the Authority and should not appear in a section containing Requirements for Harvesters

Cost Information

Action by 2015 Task Force II

Recommended adoption of Proposal 15-205 as amended.

@.01 Control of Shellstock Growing Areas

B. Patrol of Growing Areas.

(3) Exceptions.

(a) Patrol is not required under the following conditions:

(i) There is no shellfish productivity, as demonstrated by one of the following methods:

a. pH, salinity, temperature, or turbidity are not

favorable to the growth of shellfish; or

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

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

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

a. The area is unclassified;

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

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

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

(i) Description of the area;

(ii) Classification of the area;

(iii) Description of adjacent growing areas;

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

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

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

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

and include at least the following:

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

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

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

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

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

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

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

.02 Shellstock Harvesting and Handling.

D. Disposal of Human Sewage from Vessels.

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

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

(3) Portable toilets shall:
  (a) Be used only for the purpose intended;
  (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage;
  (c) Be emptied only into a sewage disposal system; (d) Be cleaned before being returned to the boat; and
  (e) Not be cleaned in equipment used for washing or processing food.

(4) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are:
  (a) Constructed of impervious, cleanable materials and have tight fitting lids; and
  (b) Meet the requirements in Section D. (3).

Action by 2015 General Assembly

Adopted recommendation of Task Force II on Proposal 15-205.

Action by FDA January 11, 2016

Concurred with Conference action on Proposal 15-205.

Proposal Subject	Harvester Training Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting and Chapter X. General Requirements for Dealers
Text of Proposal/ Requested Action	Chapter VIII. Requirements for Harvesters. .01 General.

A. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities.

~~NOTE: The provisions in Section B. below will take effect January 1, 2014.~~

B. Prior to licensing each harvester shall obtain Authority approved training ~~every two (2) years~~ at an interval to be determined by the Authority. The training shall include required harvest, handling, and transportation practices as determined by the Authority. A harvester shall be allowed ninety (90) days following initial licensing to obtain the required education.
   (1) A harvester shall obtain proof of completion of the required training. Proof of training obtained by the harvester ~~within the past two (2) years~~ shall be presented to the Authority prior to certification, recertification, or licensing.
   (2) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training.
   (3) The harvester shall maintain record of the completed training.

C. Persons who are working in a boat crew under the supervision of a licensed harvester need not have a valid harvester's license.

D. In the case of riparian or leased land, unless the riparian owner or lessee employs a licensed harvester, the riparian owner or lessee shall be licensed as a harvester prior to harvesting his shellstock. A licensed riparian owner or lessee may employ unlicensed harvesters to work his property or lease.

Chapter X. General Requirements for Dealers
.04 Certification Requirements.

A. General.
   (1) No person shall act as a dealer prior to obtaining certification.
   (2) Any person who wants to be a dealer shall:
      (a) Make application to the Authority for certification;
      (b) Have and implement a HACCP Plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the *Federal Register* of December 18, 1995, except for the requirement for harvester identification on a dealer's tag.

      ~~NOTE: Requirement (c) below effective January 1, 2014.~~

      (c) Obtain Authority approved training at an interval to be determined by the Authority. ~~every two (2) years.~~ The training shall include required processing, handling, and transportation practices as determined by the Authority. A

dealer shall be allowed ninety (90) days following initial licensing to obtain the required education.

(i) A dealer shall receive proof of completion of the required training. Proof of training obtained by the dealer ~~within the past two (2) years~~ shall be presented to the Authority prior to certification, recertification, or licensing.

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

(iii) The dealer shall maintain the record of the completed training.

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

Public Health Significance

Approved training every two (2) years may not be necessary in some situations. The Authority should be allowed to determine the most appropriate interval for training.

Cost Information

Action by 2015 Task Force II

Recommended adoption of Proposal 15-206 as amended.

Chapter VIII.
Requirements for Harvesters.
.01 General.

A. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities.

B. ~~Prior to licensing~~Each harvester shall obtain Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required harvest, handling, and transportation practices as determined by the Authority. A harvester shall be allowed ninety (90) days following initial licensing to obtain the required education.

(1) A harvester shall obtain proof of completion of the required training. Proof of training obtained by the harvester shall be presented to the Authority prior to certification, recertification, or licensing.

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

(3) The harvester shall maintain record of the completed training.

C. Persons who are working in a boat crew under the supervision of a licensed harvester need not have a valid harvester's license.

D. In the case of riparian or leased land, unless the riparian owner or lessee employs a licensed harvester, the riparian owner or lessee shall be licensed as a harvester prior to harvesting his shellstock. A licensed riparian owner or lessee may employ unlicensed harvesters to work his property or lease.

Chapter X. General Requirements for Dealers
.04 Certification Requirements.

A. General.

(1) No person shall act as a dealer prior to obtaining certification.

(2) Any person who wants to be a dealer shall:

(a) Make application to the Authority for certification;

(b) Have and implement a HACCP Plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the *Federal Register* of December 18, 1995, except for the requirement for harvester identification on a dealer's tag.

(c) Obtain Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required processing, handling, and transportation practices as determined by the Authority. A dealer shall be allowed ninety (90) days following initial licensing to obtain the required education.

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

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

(iii) The dealer shall maintain the record of the completed training.

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

Action by 2015 General Assembly

Adopted recommendation of Task Force II on Proposal 15-206.

Action by FDA January 11, 2016

Concurred with Conference action on Proposal 15-206.

Proposal Subject	Onboard Waste Receptacles
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting Section .02 Shellstock Harvesting and Handling D. (5) (a) and (b)
Text of Proposal/ Requested Action	D. Disposal of Human Sewage from Vessels. (1) Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock, or from vessels which buy shellstock while the vessels are in growing areas. (2) The Authority shall educate all licensed harvesters and shellstock dealers concerning the public health significance of discharging human sewage overboard. (3) As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage. (4) Portable toilets shall: (a) Be used only for the purpose intended; (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage; (c) Be emptied only into a sewage disposal system; (d) Be cleaned before being returned to the boat; and (e) Not be cleaned in equipment used for washing or processing food. (5) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are: (a) Constructed of impervious, cleanable materials and have tight fitting lids; ~~and~~ (b) Indelibly labeled "Human Waste" in contrasting letters at least three (3) inches in height; and (c) ~~(b)~~ Meet the requirements in Section D. (4). ~~(3).~~
Public Health Significance	Labeling a bucket intended for human waste indicates that the bucket is dedicated to that sole use and assures that a generic unlabeled bucket will not be used for another purpose. It also makes the boat inspection clear in that the Officer inspecting the boat that will know that the bucket is truly a waste bucket and that it is appropriately secured to prevent spillage. The change in (5) (c) is an editorial clean up since there are no requirements to meet in D. (3)
Cost Information	The cost is negligible.
Action by 2015 Task Force II	Recommended adoption of Proposal 15-207 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-207.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-207.

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

(4) Any person who repacks shucked shellfish shall be certified as a shucker-packer or repacker;

(5) Any person who repacks shellstock shall be certified as a shellstock shipper, shucker- packer, or repacker;

(6) A repacker shall not shuck shellfish.

(d) A repacker shall not repack shucked shellfish received in ROP containers.

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

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

.06 Shucked Shellfish Labeling

A. Shellfish Labeling

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

(2) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section of the regulation. When returnable containers are used, the shipment shall be accompanied by a transaction record containing:

(a) The original shucker-packer's name and certification number;

(b) The shucking date; and

(c) The quantity of shellfish per container and the total number of containers.

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

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

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

(6) The dealer shall label each individual package containing less than 64 fluid ounces of fresh or fresh frozen shellfish with the following:

(a) The words "SELL BY" or "BEST IF USED BY" followed by a reasonable date when the product would be expected to reach the end of its shelf life;

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

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

(7) The dealer shall label each individual package containing 64 fluid ounces or more of fresh or fresh frozen shellfish with the following:

(a) The words "DATE SHUCKED" followed by the date shucked located on both the lid and sidewall or bottom of the container;

(b) The date shall consist of either the abbreviation for the month and number of the day of the month or in Julian format (YDDD), the last digit of the four digit year and the three digit number corresponding the day of the year; and

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

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

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

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

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

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

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

Chapter XI. Shucking and Packing
.01 Critical Control Points

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Chapter XIV. Reshipping

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits.

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

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

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

(c) Adequately iced the shellstock; or **[C]**
(d) Shipped the shellstock in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; or **[C]**
(e) Cooled the shellstock to an internal temperature of 50°F (10°C) or less. **[C]**
(f) Shipped shucked meats packed in ROP containers below an ambient air temperature of 38ºF (3.3ºC) or covered in ice. **[C]**
(g) Shipped shucked meats packed in ROP containers with an appropriately attached and activated TTI that indicates the temperature was maintained below 38ºF (3.3ºC) throughout transit. **[C]**

D. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall:
(1) ~~s~~Store shucked shellfish at an ambient temperature of 45°F (7.2°C) or less. **[C]**
(2) Store shucked shellfish packed into ROP containers below an ambient air temperature of 38ºF (3.3ºC) or covered in ice. **[C]**

Public Health Significance

Available upon request.

Cost Information

Action by 2015 Task Force II

Recommended no action on Proposal 15-208. Rationale: Not recognized as a public health issue that warrants attention for shucked shellfish at this time.

Action by 2015 General Assembly

Recommends referral of Proposal 15-208 to an appropriate committee as determined by the Conference Chair.

Action by FDA January 11, 2016

Concurred with Conference action on Proposal 15-208 with the following comments and recommendations.

FDA applauds and concurs with action by the ISSC voting delegates to refer Proposal 15-208 to an appropriate committee.

The recommendation from Task Force II to the voting delegates was to take "No Action" on Proposal 15-208, stating that Clostridium botulinum (C. botulinum) is not recognized as a public health issue associated with Reduced Oxygen Packaging (ROP) of molluscan shellfish. A "No Action" vote by the ISSC would have created a difficult situation for FDA and ultimately the ISSC. Present FDA policy, set forth in the Fish and Fishery Products Hazards and Controls Guidance and which supports Federal Regulation CFR 21 Part 123, identifies C. botulinum as a hazard for raw oysters, clams and mussels when reduced oxygen packaged (e.g. mechanical vacuum, steam flush, hot-filled, modified atmosphere packaging, CAP, hermetically sealed or packed in oil). FDA could not have concurred with a Conference vote of "No Action" and the Agency would have been obligated to consider other regulatory options. However, ISSC action to refer Proposal 15-208 to committee provides an opportunity for further consideration and joint resolution by ISSC and FDA. A number of issues surrounding ROP will need to be examined as part of the committee's deliberative process, including identification of the packing types that would be affected, the cost of changing packaging practices and meeting new critical limits, whether existing NSSP requirements provide control or inhibit C. botulinum

growth, and identification of other alternatives for C. botulinum control.

FDA is prepared to offer assistance to the ISSC to address the ROP concern, including subject matters experts regarding the science and control of C. botulinum and associated packaging issues and technologies. With a coordinated effort among state and federal health authorities, industry representatives and subject matter experts, FDA is confident that a reasonable approach can be developed to ensure that C. botulinum is effectively addressed by the NSSP.

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers
Text of Proposal/ Requested Action	.01 General HACCP Requirements

F. Corrective Actions.

(1) Whenever a deviation from a critical limit occurs, a dealer shall take corrective action either by:

(a) Following a corrective action plan that is appropriate for the particular deviation, or

(b) Following the procedures in Section .01 F. (3).

(2) Dealers may develop written corrective action plans, which become part of their HACCP plans in accordance with Section .01 C. (5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(a) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(b) The cause of the deviation is corrected.

(3) When a deviation from a critical limit occurs and the dealer does not have a corrective action plan that is appropriate for that deviation, the dealer shall:

(a) Segregate and hold the affected product~~, at least~~ until: ~~the requirements of Section .01 F. (3) (b) and (c) are met;~~

~~(b) Perform or obtain~~

(i) There is a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with Section .01 I.; and

~~(c) Take corrective action,~~

(ii) Corrective action is taken when necessary~~, with respect to the affected product~~ to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.~~;~~

~~(d) Take corrective action, when necessary, to correct the cause of the deviation;~~

(~~e~~b) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Section .01 I., to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(4) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Section .01 G. and the record keeping requirements of Section .01 H.

.04 Certification Requirements

A. General.
(1) No person shall act as a dealer prior to obtaining certification.
(2) Any person who wants to be a dealer shall:
(a) Make application to the Authority for certification;
(b) Have and implement a HACCP Plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the *Federal Register* of December 18, 1995, except for the requirement for harvester identification on a dealer's tag.
~~NOTE: Requirement (c) below effective January 1, 2014~~
(c) Obtain Authority approved training every two (2) years. The training shall include required processing, handling, and transportation practices as determined by the Authority. A dealer shall be allowed ninety (90) days following initial licensing to obtain the required education.

Public Health Significance

Chapter X. .01 F. (3) (d):
Remove rewording to eliminate repetitiveness.

Chapter X. .04 A. (2) (b):
The stated effective date has passed and the note no longer serves any purpose.

Cost Information

Action by 2015 Task Force II

Recommended adoption of Proposal 15-209 as submitted.

Action by 2015 General Assembly

Adopted recommendation of Task Force II on Proposal 15-209.

Action by FDA January 11, 2016

Concurred with Conference action on Proposal 15-209.

Proposal Subject	Dealer Tagging
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers
Text of Proposal/ Requested Action	05. Shellstock Identification A. General (1) The dealer shall keep the harvester's tag affixed to each container of shellstock until the container is: (a) Shipped with his/her dealer tag affixed to each container of shellstock; or (b) Emptied to wash, grade, or pack the shellstock. (2) When the dealer is also the harvester and he elects not use a harvester tag, the dealer shall affix his dealer tag to each container of shellstock prior to shipment.
Public Health Significance	As written, there is no requirement for a dealer to affix his/her dealer tag to each container of shellstock prior to shipment. The language for affixing tags to each container is currently for harvesters who are also dealers. The NSSP requires that the product be identified with certain information showing that the shellfish were harvested by licensed diggers and shipped and processed by certified dealers. This information assists in tracing the product back through the distribution system to the growing area in the event the shellfish are associated with a disease outbreak. Additionally, the Federal Food, Drug and Cosmetic Act requires that food labels provide an accurate statement which includes the name and address of either the manufacturer, packer, or distributor; the net amount of food in the package; the common or usual name of the food; and the ingredients, unless the product conforms to standard of identity requirements. Foods shipped in interstate commerce having labels that do not meet these requirements are deemed misbranded and in violation of Section 405 of the Food, Drug and Cosmetic Act.
Cost Information	Dealers are already adding tags; no additional cost.
Action by 2015 Task Force II	Recommended adoption of Proposal 15-210 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-210.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-210.

Proposal Subject	Shucked Shellfish Labeling
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers
Text of Proposal/ Requested Action	.06 Shucked Shellfish Labeling. A. Shellfish Labeling. (1) The dealer shall maintain… (7) The dealer shall label each individual package containing 64 fluid ounces or more of fresh or fresh frozen shellfish with the following: (a) The words "DATE SHUCKED" or "USE BY" or "SELL BY" followed by the same information located ~~date shucked~~ ~~located~~ on both the lid and sidewall or bottom of the container; (b) The date shall consist of either the abbreviation for the month and number of the day of the month or in Julian format (YDDD), the last digit of the four digit year and the three digit number corresponding the day of the year; and (c) For fresh frozen shellfish, the year shall be added to the date(for non-Julian format)
Public Health Significance	Control of naturally occurring Vibrios.
Cost Information	
Action by 2015 Task Force II	Recommended referral of Proposal 15-211 to an appropriate committee as determined by the Conference Chairperson.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-211.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-211.

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

Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-212.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-212.

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

	matrix specifies "Maximum Hours from Exposure to Receipt at a Dealer's Facility." NSSP Guide for the Control of Molluscan Shellfish Section IV, Chapter III, Guidance Documents .07 indicates, "All shellstock obtained from a licensed harvester shall be placed in a storage area maintained at 45°F (7.2°C) or less within two (2) hours of receipt." However, language in a Section IV. Guidance Documents is not satisfactory compliance language unless it is referenced as such in Model Ordinance language and the subject language is not so referenced. Also, the purpose of the Model Ordinance format is to provide language a State or other jurisdiction can adopt in order to provide a legal basis for controlling molluscan shellfish. If a State adopts the language of the 2013 Model Ordinance without adding a clear requirement pertaining to how long a dealer has to place shellstock under temperature control after receiving from harvesters the State may not have the legal authority to require any particular time to temperature control. In fact, if the 2013 Model Ordinance language is taken literally it certainly will not.
Cost Information	Cost will be the same as it was before the referenced 2009 Model Ordinance requirement was removed.
Action by 2015 Task Force II	Recommended referral of Proposal 15-213 to an appropriate committee as determined by the Conference Chairperson.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-213.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-213.

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

impervious materials **[O]**.

~~(6) Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:~~

~~(a) Rodent attraction and harborage; and~~ **~~[O]~~**

~~(b) Inadequate drainage.~~ **~~[O]~~**

Public Health Significance	Requirements recommended for deletion are either not critical to the safety of shellfish product or already addressed by one or more of the eight sub-sections at .02 Sanitation.
Cost Information	
Action by 2015 Task Force II	Recommended no action on Proposal 15-214. Rationale: Proposal is adequately addressed in Model Ordinance.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-214.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-214.

Proposal Subject	Program Element Evaluation Criteria
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing, Chapter XII. Repacking of Shucked Shellfish, Chapter XIII. Shellstock Shipping, and Chapter XIV. Reshipping
Text of Proposal/ Requested Action	.03 Other Model Ordinance Requirements. C. Utilities. ~~(1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. [S~~ ~~*C/K*~~]~~ ~~(2)~~ The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[S$^{C/K}$]**
Public Health Significance	Requirements recommended for deletion are either not critical to the safety of shellfish product or already addressed by one or more of the eight sub-sections in @.02 Sanitation.
Cost Information	
Action by 2015 Task Force II	Recommended no action on Proposal 15-215. Rationale: Proposal is adequately addressed in the Model Ordinance.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-215.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-215.

Proposal Subject	Program Element Evaluation Criteria
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing, Chapter XII. Repacking of Shucked Shellfish, Chapter XIII. Shellstock Shipping, and Chapter XIV. Reshipping
Text of Proposal/ Requested Action	Chapter XI. .03 Other Model Ordinance Requirements ~~D. Disposal of Other Wastes.~~ ~~(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]~~ ~~(2) Shell and other non-edible materials shall be promptly and effectively removed from the shucking bench or table. [O]~~ ~~(3) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; and [O]~~ Chapter XII., Chapter XIII., and Chapter XIV. .03 Other Model Ordinance Requirements ~~D. Disposal of Other Wastes.~~ ~~(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]~~ ~~(2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; [O]~~
Public Health Significance	Requirements recommended for deletion are either not critical to the safety of shellfish product or already addressed by one or more of the eight sub-sections at .02 Sanitation.
Cost Information	
Action by 2015 Task Force II	Recommended no action on Proposal 15-216. Rationale: Proposal is adequately addressed in the Model Ordinance.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-216.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-216.

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

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

Action by 2015 General Assembly

Adopted recommendation of Task Force II on Proposal 15-217.

Action by FDA January 11, 2016

Concurred with Conference action on Proposal 15-217.

Proposal Subject	Program Element Evaluation Criteria
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing, Chapter XII. Repacking of Shucked Shellfish, Chapter XIII. Shellstock Shipping, and Chapter XIV. Reshipping
Text of Proposal/ Requested Action	.03 Other Model Ordinance Requirements. H. Supervision. (1) A reliable, competent individual shall be designated to supervise general plant management and activities; **[K]** (2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. **[K]** (3) All supervisors shall be: (a) Trained in proper food handling techniques and food protection principles; and **[K]** (b) Knowledgeable of personal hygiene and sanitary practices **[K]** (4) The dealer shall require: (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. **[K]** (b) Supervisors to assure that proper sanitary practices are implemented, including: (i) Plant and equipment clean-up; **[K]** (ii) Rapid product handling; and **[K]** (iii) Shellfish protection from contamination. **[K]** (c) Supervisors shall not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. **[K]** (d) Employees shall ~~:(i) B~~be trained in proper food handling and personal hygiene practices~~, and~~ **[K]** ~~(ii) Report any symptoms of illness to their supervisor. [K]~~
Public Health Significance	Requirements recommended for deletion are either not critical to the safety of shellfish product or already addressed by one or more of the eight sub-sections at .02 Sanitation.
Cost Information	
Action by 2015 Task Force II	Recommended adoption of Proposal 15-218 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-218.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-218.

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

Cost Information

Action by 2015 Task Force II

Recommended adoption of Proposal 15-219 as amended.

.02 Sanitation

B. Condition and Cleanliness of Food Contact Surfaces

(1) Equipment and utensil construction for food contact surfaces.
- (a) The dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guides*. **[K]**
- (b) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are:
  - (i) Constructed in a manner and with materials that can be cleaned, and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; **[K]**
  - (ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and **[K]**
  - (iii) Fabricated from food grade materials. **[K]**
- (c) The dealer shall assure that all joints on food contact surfaces
  - (i) Have smooth easily cleanable surfaces; and **[K]**
  - (ii) Are welded. **[K]**
- (d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI. .02 B. (1) (a), (b), and (c). **[K]**
- (e) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:
  - (i) Is easily accessible for cleaning and inspection; **[K]**
  - (ii) Is self-draining; and **[K]**
  - (iii) Meets the requirements for food contact surfaces. **[K]**

C. Prevention of Cross Contamination

(1) Protection of shellfish.
- (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. **[S$^{C/K}$]**
- (b) Shellfish shall be protected from contamination. [SC/K]
- (c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. **[K]**
- (d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[S$^{K/O}$]**

Action by 2015 General Assembly

Adopted recommendation of Task Force II on Proposal 15-219.

Action by FDA January 11, 2016

Concurred with Conference action on Proposal 15-219.

Proposal Subject	Shellfish Storage and Handling
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIII. Shellstock Shipping
Text of Proposal/ Requested Action	.03 Other Model Ordinance Requirements F. Shellfish Storage and Handling. (1) The dealer shall: (a) Assure that shellstock is: (i) Alive; **[K]** (ii) Reasonably free of sediment **[O]**; and (iii) Culled.~~;~~ **[K]** (2) The dealer shall inspect incoming shipments and shall reject dead or inadequately protected shellstock.~~;~~ **[K]** (3) A dealer ~~whose activity consists of trucks or docking facilities only~~ shall: (a) Have a permanent business address at which records are maintained and inspections can be performed in a timely fashion; and **[K]** (b) Not repack shellstock or be the original shipper of shellstock received from a harvester if their facility consists of trucks or docking facilities only. **[K]**
Public Health Significance	Control of naturally occurring Vibrios.
Cost Information	
Action by 2015 Task Force II	Recommended referral of Proposal 15-220 to an appropriate committee as determined by the Conference Chair with instruction to committee to review requirements for reshipping and shipping for consistency. Committee is directed to develop criteria for evaluating the adequacy of trucks and conveyances as storage facilities.
Action by 2015 General Assembly	Recommends no action on Proposal 15-220. Rationale: Facilities consisting of trucks or docking facilities only should not be restricted from being the original shipper of shellstock.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-220.

Proposal Subject	Reshipping Shucked and In-shell Product Receiving Critical Limit
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIV. Reshipping .01 Critical Control Points
Text of Proposal/ Requested Action	A. Receiving Critical Control Point - Critical Limits. (1) The dealer shall reship only shellfish obtained and transported from a dealer who has: (a) Identified the shellstock with a tag as outlined in Chapter X. .05, identified the in-shell product with a tag as outlined in Chapter X. .07, and/or identified the shucked shellfish with a label as outlined in Chapter X. .06; and **[C]** (b) Provided documentation as required in Chapter IX. .04 and .05; and **[C]** (c) Adequately iced the shellstock; or **[C]** (d) Shipped the shellstock in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; or **[C]** (e) Cooled the shellstock to an internal temperature of 50°F (10°C) or less; **[C]** or (f) Shipped the shucked shellfish and/or in-shell product iced or in a conveyance at or below 45°F (7.2°C) ambient air temperature; **[C]**
Public Health Significance	The subject requirement appeared in the 2009 Model Ordinance but was inadvertently removed when the ISSC Executive Board adopted new time to temperature controls on an interim basis prior to the 2011 Conference.
Cost Information	Cost will be the same as it was before the requirement was removed.
Action by 2015 Task Force II	Recommended adoption of Proposal 15-221 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-221.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-221.

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XV. Depuration
Text of Proposal/ Requested Action	.01 Critical Control Points A. Receiving Critical Control Point - Critical Limits. ~~(1) The dealer shall receive and depurate only shellstock which is obtained from a licensed harvester who has:~~ ~~(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; **[C]** and~~ ~~(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; **[C]** and~~ ~~(c) Harvested the shellstock in compliance with the time/temperature requirements of Chapter VIII. @.02 A. (1), (2) or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) **[C].**~~ ~~(2) The dealer shall receive and depurate only shellstock obtained and transported from a dealer who has:~~ ~~(a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05 or transaction record with each bulk shipment as outlined in Chapter VIII. .02 F. (8); **[C]** and~~ ~~(b) Provided documentation as required in Chapter IX. .04 and .05; and **[C]**~~ ~~(c) Adequately iced the shellstock, or **[C]**~~ ~~(d) Shipped the shellstock in a conveyance maintained at or below 45° F (7.2° C) ambient air temperature; or **[C]**~~ ~~(e) Cooled the shellstock to an internal temperature of 50° F (10° C) or less. **[C]**~~ ~~(3) Should a dealer receive shellstock from a dealer who is shipping shellstock harvested in accordance with Chapter VIII. @.02 A. (3) or restricted use shellstock that has not been cooled to an internal temperature of 50° F (10° C), the shellstock must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. This product can be received without meeting the receiving requirements of Chapter XIII. .01 A. (2) (c), (d) or (e). Shipments of four (4) hours or less will not be required to have a time/temperature device. **[C]**~~ ~~(4)~~ The dealer shall receive and depurate only shellstock obtained from a special licensed harvester who has: (1~~a~~) Harvested or supervised the harvest of shellstock from a Restricted or Conditionally Restricted area in the open status; **[C]** and (2~~b~~) Identified the shellstock by transaction records which include the harvest area, the special-licensed harvester's name, harvester license number(s), the harvest date, and the amount of shellstock shipped in each lot. **[C]**
Public Health	This practice should not be permitted under the NSSP since product from approved or

Significance	conditionally approved waters (in the open status) can be harvested and sold without depuration. Permitting this practice suggests that the growing area classification section of the NSSP is not adequate.
Cost Information	
Action by 2015 Task Force II	Recommended no action on Proposal 15-222. Rationale: This proposal was previously addressed in Proposal 01-206.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-222.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-222.

Proposal Subject	Post-Harvest Processing
Specific NSSP Guide Reference	Section II Model Ordinance Chapter XVI. Post-Harvest Processing
Text of Proposal/ Requested Action	Chapter XVI. ~~Post-Harvest Processing~~ Processes and Procedures for Pathogen Reduction

.01 Processes and Procedures Involving Labeling Claims.

A. If a dealer elects to use a process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concern in shellfish, and wishes to make labeling claims regarding the reduction of pathogens, the dealer shall:

(1) Have a HACCP plan approved by the Authority for the process that ensures that the target pathogen(s) are at safe levels for the at risk population in product that has been subjected to the process. The HACCP Plan shall include:

(a) Process controls to ensure that the end point criteria are met for every lot; and

(b) A sampling program to periodically verify that the end point criteria are met.

(c) Analytical results used for validation and verification of a PHP shall come from an analytical laboratory that is evaluated by the State and/or FDA and found to be in compliance with applicable NSSP laboratory requirements.

(2) Validate the process by demonstrating that the process will reliably achieve the appropriate reduction in the target pathogen(s). The process shall be validated by a study as outlined in Guidance Documents Chapter IV., Naturally Occurring Pathogens, Section .02 and be approved by the Authority, with concurrence of FDA.

(a) The dealer must demonstrate that the process reduces the level of Vibrio vulnificus and/or Vibrio parahaemolyticus in the process to non-detectable (<30MPN/gram) and the process achieves a minimum 3.52 log reduction. Determination of V. vulnificus and/or V. parahaemolyticus levels must be done using the MPN protocols described in Guidance Documents, Chapter IV., Naturally Occurring Pathogens, Section .02 followed by confirmation using methods approved for use in the NSSP.

(b) For processes that target other pathogens the dealer must demonstrate that the level of those pathogens in processed product has been reduced to levels below the appropriate FDA action level, or, in the absence of such a level, below the appropriate level as determined by the ISSC.

(3) Conduct verification sampling to verify that the validated process is working properly. Verification sampling shall be at least equivalent to the verification protocol found in Guidance Documents, Chapter IV., Naturally Occurring Pathogens, Section .02 as determined by the Authority and shall be reviewed annually by the Authority.

(4) Package and label all shellfish in accordance with all requirements of this Ordinance. This includes labeling all shellfish which have been subject to the process but which are not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter X. .05 and X. .06.

(5) Keep records in accordance with Chapter X. .07.

B. A dealer who meets the requirements of this section may label product that has been subjected to the reduction process as:
   (1) "Processed for added safety", if the process reduces the levels of all pathogens of public health concern to safe levels for the at risk population;
   (2) "Processed to reduce [name of target pathogen(s)] to non-detectable levels," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or
   (3) "Processed to reduce [name of target pathogen(s)] to non-detectable levels for added safety," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or
   (4) A term that describes the type of process applied (e.g., "pasteurized," "individually quick frozen," "pressure treated") may be substituted for the word "processed" in the options contained in B. (1) - (3).

C. For the purpose of product temperature the receiving and storage critical control points of Chapter XI., shall apply to shellstock prior to PHP processing. Following PHP processing, if the product is dead, the product shall be treated as in-shell or shucked product. If the product is live, the product shall be treated as shellstock.

.02 Processes and Procedures Not Involving Labeling Claims.

A. If a dealer elects to use a post-harvest process(es) to reduce the levels of a naturally occurring pathogen(s) of public health concern in shellfish, the dealer shall:
   (1) Have a HACCP plan (approved by the Authority) for the control(s) that reduces the target pathogen(s).
      (a) The dealer must validate that the post-harvest process(es) reduces naturally occurring pathogen(s). The validation study must be approved by the State Shellfish Control Authority with FDA concurrence.
      (b) The ability of the post-harvest process(es) to reliably achieve the appropriate reduction in the target pathogen(s) shall be verified at a frequency determined by the State Shellfish Control Authority.
   (2) Package and label all shellfish in accordance with the requirements of this Ordinance.
   (3) Keep records in accordance with Chapter X. 07.

Public Health Significance

The changes recommended by the proposal provide added opportunities for shellfish dealers to meet the required State Control Plans for naturally occurring pathogens.

Cost Information

Action by 2015 Task Force II

Recommended adoption of Proposal 15-223 as submitted.

Action by 2015 General Assembly

Adopted recommendation of Task Force II on Proposal 15-223.

Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-223.

Proposal Subject	Ineffective Model Ordinance Requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XVI. Post-Harvest Processing
Text of Proposal/ Requested Action	B. A dealer who meets the requirements of this section may label product that has been subjected to the reduction process as: (1) "Processed for added safety", if the process reduces the levels of all pathogens of public health concern to safe levels for the at risk population; (2) "Processed to reduce [name of target pathogen(s)] to non-detectable levels," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or ~~(3) "Processed to reduce [name of target pathogen(s)] to non-detectable levels for added safety," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or~~ (~~4~~3) A term that describes the type of process applied (e.g., "pasteurized," "individually quick frozen," "pressure treated") may be substituted for the word "processed" in the options contained in B. (1) - (~~3~~2).
Public Health Significance	Chapter XVI. B. (2) and Chapter XVI. B. (3) are duplicate requirements and one should be removed.
Cost Information	
Action by 2015 Task Force II	Recommended no action on Proposal 15-224. Rationale: Proposal is adequately addressed in the Model Ordinance.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-224.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-224.

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

keep a record of compliance with the pre-chilling requirement; this record is not intended to be a HACCP record for the shipping dealer.

All shipments of shellstock shall be accompanied with a documentation record indicating the time of shipment and that all shipping containers were pre-chilled. The documentation required in Chapter IX. .05 must include the time of shipment, the means of cooling, and indicate the temperature to which the conveyance was pre-chilled if mechanical refrigeration was the means of cooling (This documentation is not intended to be a HACCP record for the shipping dealer). In situations when the dealer chooses to ship product not harvested under a State Vibrio Plan that has

not achieved the internal temperature of 50°F (10°C), the shipping documentation must provide notice to the receiving dealer that the product was shipped prior to achieving an internal temperature of 50°F (10°C). Additionally, the shipment shall be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. The documentation stating the time of shipment will accompany the bill of lading and will be used by the receiving dealer to determine the length of shipment.

This control will allow product to be shipped while cooling is occurring. Should the receiving dealer choose not to further ship the shellstock with a time/temperature recording device, the dealer must cool and document that the product has reached an internal temperature of 50°F (10°C) prior to reshipping.

Conveyances Used to Transport Shellstock Directly to Retail

Dealers shipping shellstock directly to retail should comply with state laws governing retail foods. In many cases these laws require the shellstock to be at an internal temperature of 45°F (7.2°C) or less at receipt. A dealer could be in compliance with the shipping and documentation requirements of Chapter IX. .04 and .05 and the shellstock fail to meet retail food requirements.

The documentation requirements of Chapter IX. .05 are to provide receiving dealers with information necessary to meet the receiving critical limit requirements included in Chapters XI., XII., XIII., XIV., and XV. Receiving requirements for retailer and food service operators are outlined in the USFDA Food Code and State Retail Food regulations and the information included in the documentation required in Chapter IX. .05 is not necessary for retailers and food services operators to comply with the receiving requirements for retail food. Therefore, the documentation requirement in Chapter IX. .05 does not apply for shipments to retailers and food service operators.

Public Health Significance	The additional language is needed for clarification involving shipments of shellstock directly to retail.
Cost Information	
Action by 2015 Task Force II	Recommended adoption of Proposal 15-225 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-225.

Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-225.

Proposal Subject	*V.p.* Illness Response Guidance Document
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter V. Illness Outbreaks and Recall Guidance
Text of Proposal/ Requested Action	Add new section:

.03 *V.p.* Illness Response Guidance Document

I. Introduction

Chapter II @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*) is intended to address three (3) distinct *V.p.* illness situations as follows:

A. Traditional sporadic cases from a State in which single cases occur that most often do not involve a single growing area and occur weeks or months apart. The occurrences of these types of illnesses have historically been considered as an acceptable risk in the National Shellfish Sanitation Program (NSSP) and have not involved closures or recalls.

B. Frequent sporadic cases which often begin when water temperatures reach a level which supports reproduction of *V.p.* to levels which can cause illness. The illness risk usually persists until the environmental conditions no longer support *V.p.* levels of illness causing potential. This illness situation involves clusters of sporadic cases in multiple individual growing areas or may be limited to a single growing area when the environmental conditions are favorable for the persistence of illness causing levels of *V.p.*

C. A true outbreak with multiple cases with multiple harvest areas and varying routes of transportation indicates a more widespread contamination of a growing area. The outbreak may be characterized by a high attack rate. In this situation, a single growing area is usually involved with multiple cases of illness occurring from a single harvest day or from a relatively short harvest time frame.

The strains of *V.p.* associated with these different illness situations are not the same. The attack rates are very different and the reported illnesses reflect the differences in attack rates. Although strain identification is time consuming, knowing the strain aids the Shellfish Control Authority in addressing the problem.

II. Illness Investigation

When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and the span of time.

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

III. Risk per Serving Determinations

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

IV. Regulatory Response

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

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

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

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

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

The notification is intended to facilitate the reporting of other illnesses that may have occurred associated with the implicated harvest area. Although the State is

not required to report this information to the Interstate Shellfish Sanitation Conference (ISSC), if requested, the ISSC will assist the States with notification.

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

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

V. Closure Periods

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

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

VI. Reopening of Closed Areas

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

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

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

C. Implicated areas that have been closed when the risk exceeds one (1) illness per

100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area do not require sampling or review of environmental conditions prior to reopening.

VII. Harvesting From Closed Areas

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

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

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

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

VIII. Laboratory

All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish Laboratory Evaluation Office or FDA certified State Shellfish Laboratory Evaluation Officer in accordance with the requirements established under the NSSP.

IX. Approved Laboratory Methods

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

The Approved NSSP Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI. of the Constitution, Bylaws and Procedures of the ISSC and/or cited in the NSSP Guide for the Control of Molluscan Shellfish Section IV Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests.

Public Health Significance

The purpose of this document is to provide guidance to States in implementing the requirements of Chapter II. @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)*.

Cost Information

Action by 2015 Task Force II

Recommended referral of Proposal 15-226 to an appropriate committee as determined by the Conference Chair with instruction to remove this section from the NSSP Guide as interim guidance.

Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-226.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-226.

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

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

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

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

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

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

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

Public Health Significance

The purpose of this document is to provide guidance to State Shellfish Control Authorities (SSCAs) in determining scope of closures and recalls in response to illness outbreaks.

Cost Information

Action by 2015 Task Force II

Recommended adoption of Proposal 15-227 as amended.

.03. Determining the Size of Closed Area as a Result of Illnesses
A. Barriers that would inhibit pathogen and toxin distribution within the growing area (based on documented data/information in the sanitary survey considering the following, as applicable:
(1) Salinity
(2) Temperature
(3) Stratification
(4) Circulation
(5) Hydrographic patterns and bathymetry
B. Water movement (based on documented information in sanitary survey) considering the following, as applicable:
(1) Tidal influence and range

(2) Flows
(3) Precipitation
(4) Wind

C. Laboratory results and/or field measurements and/or other relevant information or data.

D. Closure boundaries
(1) Must be enforceable.
(2) May be part of one area, a whole area, or all or parts of multiple areas depending on size of areas and pattern of harvest-related illnesses.
(3) Configuration of area may change over time as more information is available, or water quality/tissue samples show no exceedance.
~~(4) In the absence of information to the contrary, the entire harvest area should be closed.~~

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

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

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

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

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

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

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

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

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

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

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

Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-227.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-227.

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
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	
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.
Action by 2015 NSSP Evaluation Criteria Committee	Recommended that draft standards be developed for each program element. These draft standards will be developed using the standards from other programs and the FDA draft. (Available upon request) It is further recommended that the ISSC identify volunteer states to pilot the standards once developed. The committee will review results from the pilot and submit a proposal for conference consideration.
Action by 2015 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-310.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 11-310.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 11-310.

Proposal Subject	Program Element Evaluation Criteria
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program
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	
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.
Action by 2015 NSSP Evaluation Criteria Committee	Recommended creating a new Chapter I @ .03 Procedure For Evaluation of Shellfish Sanitation Program Elements. Existing evaluation criteria language from Chapter III, Chapter VIII, Guidance Document Chapter I .03 and the ISSC Constitution, Bylaws and Procedures will be moved to the new @ .03 section of Model Ordinance Chapter I. This change will not result in any modification to existing criteria. This change will be made for the sole purpose of moving all evaluation criteria to one location. @.03 Evaluation of Shellfish Sanitation Program Elements

A. The goal of shellfish program evaluation shall be to monitor program implementation and work with states to determine where problems may exist and how to address them.

(1) Shellfish program evaluation methodologies shall:
- (a) Monitor state program implementation;
- (b) Assess state program effectiveness; and
- (c) Evaluate the validity of the elements of the NSSP Guide for the Control of Molluscan Shellfish.

(2) The minimum components of shellfish program evaluation shall include:
- (a) A description of the program activity;
- (b) A comparison of FDA observations with state observations; and
- (c) A measurement of conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish.

(3) The focus of data collection shall be on measuring conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish.

(4) The types of data collected shall include the following:
- (a) Program records;
- (b) Direct observation made by the evaluator;
- (c) Data and information from the Authority or other pertinent sources.

B. Criteria for evaluation of shellfish sanitation program elements shall be as follows:

(1) Laboratory
- (a) 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.
  - (i) Conforms. In order to achieve or maintain conforms status under the NSSP, a laboratory must meet the following laboratory evaluation criteria:
  - (ii) 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
  - (iii) Not more than twelve (12) key nonconformities in the microbiological component or five (5) in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA

Shellfish Laboratory Evaluation Checklist; and

(iv) 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 for 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

(v) 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 be deemed provisionally conforming under the NSSP, a laboratory must meet the following laboratory evaluation criteria:

(i) Not more than three (3) critical nonconformities in the microbiological component or two (2) in the marine Biotoxin (PSP or NSP) component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and

(ii) Not more than twelve (12) key nonconformities in the microbiological component or five (5) in the 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 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 key nonconformity has been identified in the microbiological or marine Biotoxin component under evaluation in consecutive evaluations using the appropriate FDA Shellfish Laboratory Checklist.

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

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

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

(iii) More than seventeen (17) critical, key, and other nonconformities in total in the microbiological component or more than 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; 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.

(d) Time Limit on Laboratory Status.

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

(e) 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 be assigned the following status for the laboratory component(s) in question:

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

(ii) 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 will no longer be acceptable for use in support of the NSSP for the laboratory component in question.

(f) Nonconformance.

(i) 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 nonconformities 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 continue to be nonconforming; and as a result, data being generated by the laboratory for this/these laboratory components will continue to be unacceptable for use in support of the NSSP.

(ii) When a laboratory is found to be nonconforming in either the microbiological or marine Biotoxin component or in both components for failure to successfully implement the required corrective action, or for having repeated critical or key nonconformities in consecutive evaluations, the Authority 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.

(iii) For each laboratory component evaluated, the laboratory will be reevaluated either on-site or through a thorough desk audit as determined by the FDA Shellfish Laboratory Evaluation Officer and the FDA certified State Shellfish Laboratory Evaluation Officer 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.

NOTE: This section is being moved from Model Ordinance Chapter III. Laboratory @.01 Quality Assurance Sections D. and E.

Delete Model Ordinance Chapter III. Laboratory @.01 Quality Assurance Sections D. and E.

(2) Growing Areas

Requirements for evaluation of the shellfish growing area program element shall include at a minimum:

(a) Records audit of sanitary survey;
(b) Bacteriological standards;
(c) Growing area classification;
(d) Marine Biotoxin control;
(e) Marinas.

(3) Patrol

(a) Legal Penalties – Chapter VIII. @.01 A. (2) (c) Are there penalties in place to address illegal harvest?

Compliance Criteria: The patrol element will be deemed in compliance if laws and regulations exist that provide penalties for controlling harvest from harvest restricted areas. **[Critical]**

(b) Notification of Harvest Restricted Areas – Chapter VIII. @.01 A. (2) (d)

Is the industry notified of the boundaries of Harvest Restricted Areas? – Chapter VIII. @.01 E. (2)

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the appropriate State Authority demonstrates that the industry has been notified of the boundaries. **[Critical]**

(c) Comprehensive Listing of Harvest Restricted Areas – Chapter VIII. @ .01

Does the Patrol Agency have a comprehensive listing of Harvest Restricted areas?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when it is determined that the State Authority has a comprehensive listing of all Harvest Restricted areas. **[Critical]**

(d) Patrol Policy Document – Chapter VIII. @.01 B. (7).

(i) Does the Patrol Agency have a patrol policy document?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the State Authority provides a patrol policy document. **[Key]**

(ii) Is the patrol policy document complete?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when it is determined that the patrol policy document includes all items in Chapter VIII. @.01 B. (7) listed below. **[Key]**

a. Citation of the law providing the legal basis for enforcement authority

b. Citation of the laws and regulations, including penalties, which are directly related to effective control of illegal harvest activities;

(iii) The organizational structure of the unit responsible for patrol activities, including;

a. Patrol unit(s) name, address, and phone number;

b. The roster and chain of command;

c. Area assignments that support the frequencies of patrol delineated in B. (2); and

d. A listing of specific vessels, vehicles, and equipment that support the frequencies of

patrol delineated in B. (2);

(iv) Summaries of training in shellfish patrol techniques;

(v) The methods used to inform officers of growing area classifications and status, and of any special activities licensed in the area;

(vi) A listing of growing areas where patrol is required;

(vii) An identification of any patrol problems;

(viii) The type and frequency of reporting by patrol personnel;

(ix) Copy of agreements with other agencies responsible for shellfish control activities; and

(x) Citations/summons for the past year. If available, this information may include:

a. The number of convictions or dismissals;

b. Fines in dollar amount;

c. Equipment or property confiscations and forfeitures;

d. License suspensions or revocations; and

e. Jail sentences; and

f. Written warnings.

(xi) Is the patrol policy document updated annually?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the State Authority can determine that the patrol policy document is updated every calendar year. **[Key]**

(e) Officer Training – Chapter VIII. @.01 B. (6)

Has the Patrol Agency met the NSSP patrol training requirements?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Patrol Agency can demonstrate that all officers have met or are scheduled for the training requirements of Chapter VIII. @.01 B. (6) before assuming their patrol duties **[Key]**

(i) Basic law enforcement training, before assuming their patrol duties;

(ii) Training on shellfish control regulations within the jurisdiction of the patrol agency, before assuming independent patrol duties;

(iii) In-service training on the shellfish control regulations within the jurisdiction of the patrol agency, when the regulations change.

(f) Patrol Frequency – Chapter VIII. @.01 B. (2).

(i) Has the agency determined risk categories for all harvest restricted areas? – Chapter VIII. @.01 B. (4)?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the State Authority assigns risk categories for each

harvest restricted area and provides a listing of those categories. **[Critical]**

(ii) Does a risk management plan exist if required? – Chapter VIII. @.01. B. (3) (c) and (d)
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Patrol Authority has conducted a Risk Management Plan for
all areas that are not patrolled at the frequency required in Chapter VIII. @.01 B. (2).
[Critical]

(iii) Has the patrol frequency requirement been met in all areas? – Chapter VIII. @.01 B. (3) (b), (c), and (d)
Compliance Criteria: The patrol element will be deemed in compliance as follows:

a. When the State Authority achieved 95-100 percent of required patrols in all harvest restricted areas the program is considered to be in conformance with NSSP patrol frequency requirements.

b. When the State Authority achieved 80 – 94 percent of required patrols in all harvest restricted areas the program is considered to be in non- conformance with NSSP patrol frequency requirements. **[Key]**

c. When the State Authority achieved <80 percent of required patrols in all harvest restricted areas the program is considered to be in major non- conformance with NSSP patrol frequency requirements. **[Critical]**

(g) Memorandum of Understanding/Agreements Chapter VIII. @.01 B. (5). If enforcement of shellfish regulations is shared with another agency(s), is there a formalized MOU/MOA with the other agency(s)?
Compliance Criteria: The patrol element will be deemed in compliance when the authority has developed a Memorandum of Understanding/Agreement with all Authorities which have delegated patrol responsibilities. **[Key]**

(h) The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above patrol evaluation criteria.

(i) The overall Patrol Program element will be assigned one of the following designations: (a) **Conformance:** The program is in compliance with all of the criteria listed above.

a. **Conformance with Deficiencies:** The program only has minor deficiencies associated with a key compliance item.

b. **Non-Conformance:** The program has:

i. at least one (1) critical

deficiency;

ii. two (2) or more key deficiencies; or

iii. a repeat **[Key]** deficiency from the previous evaluation.

c. **Major Non-Conformance:** The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest in harvest restricted waters.

(ii) During the closeout meeting for patrol evaluation, the Shellfish Specialists shall identify any patrol deficiency to the state patrol agency;

(iii) Within thirty (30) days of the closeout meeting, the Shellfish Specialist shall provide a written Program Element Evaluation Report (PEER), including supporting documentation, to the State patrol agency;

(iv) Within thirty (30) days of receiving the PEER, the State patrol agency shall provide a written response that indicates:

(i) The item(s) was corrected;

(ii) A correction plan has been developed with a completion date; or,

(iii) The reasons why the State disagrees with FDA's finding(s).

(v) Within fifteen (15) days of receipt FDA shall review the State response, and respond to the State;

(vi) Any CRITICAL item deficiency shall be corrected within thirty (30) days of acceptance by FDA of the correction plan;

(vii) Any KEY item deficiency shall be corrected within one (1) year of acceptance by FDA of the correction plan.

(viii) FDA shellfish specialists shall be responsible for monitoring the progress of state action plans.

(ix) Patrol Program recommendations addressing improvements not associated with the criteria included in Section I or recommendations addressing improvements beyond the requirements of the Model Ordinance should be submitted to the State Authority in correspondence

NOTE: This section is being moved from Guidance Documents Chapter I. General Section .03 Patrol Evaluation Guidance.

Delete Guidance Document Chapter I. General Section .03 Patrol Evaluation Guidance.

(4) Plants

Requirements for evaluation of the shellfish plant inspection program element shall include at a minimum:

(a) Records audit of past shellfish processing facility inspections;

(b) Direct observation of current shellfish processing facility conditions;

(c) Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program.

(d) Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria:

(i) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.

(ii) 95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish.

(iii) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.

(iv) States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the State.

(v) All critical deficiencies have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.

(e) Plant Evaluation Criteria

(i) Legal Authority – Chapter VIII. @ .01 A. (2) (c).
The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer Certification requirements listed in Chapter I @ .01 and @ 02. **[Critical]**

(ii) Initial Certification – Chapter I @ 02 B.
The Plant Sanitation Element will be deemed in compliance with this requirement when all plants are certified in accordance with criteria listed below:

a. HACCP requirements:
   i. A HACCP plan accepted by the Authority
   ii. No critical deficiencies;
   iii. Not more than 2 key deficiencies;
   iv. Not more than 2 other deficiencies.

b. Sanitation and additional Model Ordinance Requirements:
   i. No critical deficiencies;
   ii. Not more than 2 key deficiencies;
   iii. Not more than 3 other deficiencies.

(iii) Inspection frequency – Chapter I @ .02 F. and G.

The Plant Sanitation Element will be deemed in compliance with this requirement when one or less plants inspected doesn't meet the required inspection frequency.

(iv) Compliance schedules.

The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated are found to be without schedules.

(v) Follow-Up.

The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that they have performed proper follow-up for compliance schedules for 90% of dealers evaluated and if the compliance schedules were not met that administrative action was taken.

(vi) Deficiency Follow-up.

The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that all critical deficiencies have been addressed.

(vii) In-Field Plant Criteria.

The In-Field Plant Sanitation Element will be deemed in compliance with this requirement when the plant meets the following criteria:

a. Shucker/packers and repackers HACCP requirements:

i. A HACCP plan accepted by the Authority;
ii. No critical deficiencies;
iii. Not more than 4 key deficiencies;
iv. Not more than 4 other deficiencies.

b. Shucker/packers and repackers sanitation and additional Model Ordinance requirements:

i. No critical deficiencies;
ii. Not more than 4 key deficiencies;
iii. Not more than 6 other deficiencies.

c. Shellstock shippers and reshippers HACCP requirements:

i. A HACCP plan accepted by the authority;
ii. No critical deficiencies;
iii. Not more than 3 key deficiencies;
iv. Not more than 3 other deficiencies.

d. Shellstock shippers and reshippers sanitation and additional Model Ordinance requirements

i. No critical deficiencies;
ii. Not more than 3 key deficiencies;
iii. Not more than 5 other deficiencies.

(f) The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria:

(i) The overall Plant Sanitation Program element will be assigned one of the following designations:

a. Conformance: The program is in compliance with all of the criteria listed above.

b. Conformance with Deficiencies:
The program is in compliance with Procedure XV. Section F. (2) (e) (i), (ii), (iii), (iv), (v), and (vii) and has 25% or less of plants with deficiencies associated with key or other compliance items in Procedure XV. Section F. (2) (e) (vii).

c. Non-Conformance:
The program is in compliance with Procedure XV. Section F. (2) (e) (i), but, does not meet the criteria in Procedure XV. Section F. (2) (e) (ii) or (iii) or (iv) or (v) or (vi) has greater than 25% (but less than 51%) of plants with deficiencies associated with key or other compliance items Procedure XV. Section F. (2) (e) (vii).

d. Major Non-Conformance:
The program has multiple deficiencies. It is non-compliant with Procedure XV. Section F. (2) (e) (ii) or (iii) or (iv) or (v) or (vi) or 51% or greater of plants with deficiencies associated with Procedure XV. Section F. (2) (e) (vii).

(3) Evaluation of shellfish laboratories:
(a) Records audit of laboratory operations;
(b) Direct observation of current laboratory operating conditions;
(c) Information collection from the Authority and other pertinent sources concerning laboratory operations.

(4) Evaluation of shellfish growing area patrol:
(a) Records audit of past patrol activities;
(b) Direct observation of current patrol activities;
(c) Information collection from the Authority and other pertinent sources.

C. FDA will follow the current compliance program for communication with the State agencies.

Action by 2015 Task Force III

Recommended adoption of the NSSP Evaluation Committee recommendations on Proposal 13-300.

Action by 2015 General Assembly

Adopted recommendation of Task Force III 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	
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.
Action by 2015 NSSP Evaluation Criteria Committee	Recommended: 1) The following criteria be used in evaluating the State Growing Area classification element 1. Written Sanitary Survey (A) Is there a written Sanitary Survey for each growing area that is classified other than prohibited? (B) Is the Sanitary Survey complete? A. Executive Summary B. Description of Growing Area C. Pollution Source Survey D. Hydrographic and Meteorological Characteristics E. Water Quality Studies F. Interpretation of Data in Determining Classification to Be Assigned to Growing Area:

A discussion of how actual or potential pollution sources, wind, tide, rainfall, etc. affect or may affect water quality, that will address the following:
G. Conclusions

(C) Is the Sanitary Survey current?
A. Annual
B. Triennial
C. 12 Year)

2. Shoreline Survey
(A) Does Shoreline Survey include identification and evaluation of all actual and potential sources of pollution
(B) Does Shoreline Survey include boundaries?
(C) Does Shoreline Survey include unique designation?
(D) Does Shoreline Survey include required maps?
(E) Does Shoreline Survey include a summary of survey findings?

3. Adequate Sampling
(A) Are the number and location of sampling stations adequate to effectively evaluate all pollution sources.
(B) Were adequate samples collected for each area consistent with the classification and type of sampling approach used (i.e. Remote, Adverse Pollution, Systematic Random Sampling)?
(C) Were samples collected under appropriate conditions consistent with the type of sampling approach?

4. Data to support Classification
(A) The assigned classifications are based on data/information supporting the classification and performance standards?
(B) Is appropriate data/information available to support the classification within each designated growing area?

5. Proper Classification
(A) Are all growing areas properly classified?
(B) Does SSCA have appropriate MOU(s) with appropriate parties for each area classified as conditional?

2) The subcommittee will develop a scoring system which assigns appropriate significance to the criteria and establishes compliance standards which can be used to assign compliance designations as outlined in the other NSS elements.
3) Field testing of the complete evaluation criteria including compliance designation will be field tested in one state in each ISSC region. The results will be reviewed by the NSSP Evaluation Committee, modified as appropriate and presented to the ISSC as a proposal.

Action by 2015 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendations on Proposal 13-301.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-301.

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	Section 6. Requirements for evaluation of shellfish sanitation program elements shall include, at a minimum: Subdivision a. Evaluation of growing area classification; Subdivision i. Records audit of sanitary survey; Subdivision ii. Bacteriological standards; Subdivision iii. Growing area classification; Subdivision iv. Marine Biotoxin control; Subdivision v. Marinas. Subdivision b. Evaluation of shellfish plant inspection program; Subdivision i. Records audit of past shellfish processing facility inspections; Subdivision ii. Direct observation of current shellfish processing facility conditions; Subdivision iii. Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program. Subdivision iv. Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria: Subdivision (a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish. Subdivision (b) 95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish. Subdivision (c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules. Subdivision (d) States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance

			schedules were not met, that proper administrative action was taken by the State.
		Subdivision (e)	All critical deficiencies have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.
	Subdivision v.	Plant Evaluation Criteria	
		Subdivision (a)	Legal Authority – Chapter VIII. @ .01 A. (2) (c). The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer Certification requirements listed in Chapter I @ .01 and @ .02. [Critical]
		Subdivision (b)	Initial Certification – Chapter I @ .02 B. The Plant Sanitation Element will be deemed in compliance with this requirement when all plants are certified in accordance with criteria listed below: HACCP requirements: (i) A HACCP plan accepted by the Authority (ii) No critical deficiencies; (iii) Not more than 2 key deficiencies; (iv) Not more than 2 other deficiencies. Sanitation and additional Model Ordinance Requirements: (i) No critical deficiencies; (ii) Not more than 2 key deficiencies; (iii) Not more than 3 other deficiencies.
		Subdivision (c)	Inspection frequency – Chapter I @ 02 F and G.

	The Plant Sanitation Element will be deemed in compliance with this requirement when no more than one plant inspected doesn't meet the required inspection frequency.
Subdivision (d)	Compliance schedules. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated are found to be without schedules.
Subdivision (e)	Follow-Up. The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that they have performed proper follow-up for compliance schedules for 90% of dealers evaluated and if the compliance schedules were not met that administrative action was taken.
Subdivision (f)	Deficiency Follow-up. The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that all critical deficiencies have been addressed.
Subdivision (g)	In-Field Plant Criteria. The in-field Plant Sanitation Element will be deemed in compliance with this requirement when the plant meets the following criteria: (i) Shucker/packers and repackers HACCP requirements: a. A HACCP plan accepted by the Authority; b. No critical deficiencies; c. Not more than 4 key

deficiencies;
d. Not more than 4 other deficiencies.

Sanitation and additional Model Ordinance Requirements
a. No critical deficiencies except when the State demonstrates that all critical deficiencies have been addressed prior to the completion of the inspection of that facility;
b. Not more than 4 key deficiencies;
~~c. Not more than 4 other deficiencies.~~

(ii) Shellstock shippers and reshippers HACCP requirements:
a. A HACCP plan accepted by the authority;
b. No critical deficiencies;
c. Not more than 3 key deficiencies;
d. Not more than 3 other deficiencies.

Sanitation and additional Model Ordinance Requirements
a. No critical deficiencies except when the State demonstrates that all critical deficiencies

have been addressed prior to the completion of the inspection of that facility:;

b. Not more than 3 key deficiencies;

~~c. Not more than 5 other deficiencies.~~

Subdivision vi. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria.

Subdivision (a) The overall Plant Sanitation Program element will be assigned one of the following designations:

(i) Conformance: The program is in compliance with all of the criteria listed above.

(ii) Conformance with Deficiencies: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision v. (a), (b), (c), (d), (e), and (f) and has 25% or less of plants with deficiencies associated with key ~~or other~~ compliance items in Procedure XV. Section 6. Subdivision (b) Sub-division (v) (g).

(iii) Non-Conformance: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision (v) (a), but, does not meet the criteria in Procedure XV. Section 6. Subdivision (b)

Subdivision (v) Sub-division (b) or (c) or (d) or (e) or (f) has greater than 25% (but less than 51%) of plants with deficiencies associated with key ~~or other~~ compliance items Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g).

(iv) Major Non-Conformance: The program has multiple deficiencies. It is non-compliant with Procedure XV. Section 6. Subdivision (b) Subdivision (v) Sub-division (b) or (c) or (d) or (e) or (f) or 51% or greater of plants with deficiencies associated with Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g).

FDA will follow the current compliance program for communication with the State agencies.

Subdivision c.	Evaluation of shellfish laboratories;	
	Subdivision i.	Records audit of laboratory operations;
	Subdivision ii.	Direct observation of current laboratory operating conditions;
	Subdivision iii.	Information collection from the Authority and other pertinent sources concerning laboratory operations.
Subdivision d.	Evaluation of shellfish growing area patrol;	
	Subdivision i.	Records audit of past patrol activities;
	Subdivision ii.	Direct observation of current patrol activities;
	Subdivision iii.	Information collection from the Authority and other pertinent sources.

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

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.

Action by 2015 NSSP Evaluation Criteria Committee

Recommended adoption of Proposal 13-308 as amended.

Section 6. Requirements for evaluation of shellfish sanitation program elements shall include, at a minimum:

Subdivision a. Evaluation of growing area classification;
- Subdivision i. Records audit of sanitary survey;
- Subdivision ii. Bacteriological standards;
- Subdivision iii. Growing area classification;
- Subdivision iv. Marine Biotoxin control;
- Subdivision v. Marinas.

Subdivision b. Evaluation of shellfish plant inspection program;
- Subdivision i. Records audit of past shellfish processing facility inspections;
- Subdivision ii. Direct observation of current shellfish processing facility conditions;
- Subdivision iii. Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program.
- Subdivision iv. Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria:

Subdivision (a) All dealers are required to

			be certified in accordance with the Guide for the Control of Molluscan Shellfish.
		Subdivision (b)	95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish.
		Subdivision (c)	Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.
		Subdivision (d)	States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the State.
		Subdivision (e)	All critical deficiencies have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.
	Subdivision v.	Plant Evaluation Criteria	
		Subdivision (a)	Legal Authority – Chapter VIII. @ .01 A. (2) (c). The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer Certification requirements listed in Chapter I @ .01 and @ .02. [Critical]
		Subdivision (b)	Initial Certification – Chapter I @ .02 B. The Plant Sanitation Element will be deemed in compliance with this requirement when all plants

		are certified in accordance with criteria listed below: HACCP requirements: (i) A HACCP plan accepted by the Authority (ii) No critical deficiencies; (iii) Not more than 2 key deficiencies; (iv) Not more than 2 other deficiencies. Sanitation and additional Model Ordinance Requirements: (i) No critical deficiencies; (ii) Not more than 2 key deficiencies; (iii) Not more than 3 other deficiencies.
	Subdivision (c)	Inspection frequency – Chapter I @ 02 F and G. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than one plant inspected doesn't meet the required inspection frequency.
	Subdivision (d)	Compliance schedules. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated are found to be without schedules.
	Subdivision (e)	Follow-Up. The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that they have performed proper follow-up for compliance schedules for 90% of dealers evaluated and if the compliance schedules were not met that administrative action was taken.
	Subdivision (f)	Deficiency Follow-up. The Plant Sanitation

Element will be deemed in compliance with this requirement when the state demonstrates that all critical deficiencies have been addressed.

Subdivision (g) In-Field Plant Criteria.

~~The in-field Plant Sanitation Element will be deemed in compliance with this requirement when the plant meets the following criteria~~Certified Plants will be evaluated to determine compliance with the criteria listed below.~~:~~

(i) Shucker/packers and repackers HACCP requirements:
   a. A HACCP plan accepted by the Authority;
   b. No critical deficiencies;
   c. Not more than 4 key deficiencies;
   d. ~~Not more than 4 other deficiencies.~~

Sanitation and additional Model Ordinance Requirements
   a. No critical deficiencies ;
   b. Not more than 4 key deficiencies;
   ~~c. Not more than 4 other deficiencies.~~

(ii) Shellstock shippers and reshippers HACCP requirements:
   a. A HACCP plan accepted by the authority;
   b. No critical deficiencies;
   c. Not more than

3 key deficiencies;
d. ~~Not more than 3 other deficiencies.~~

Sanitation and additional Model Ordinance Requirements
a. No critical deficiencies~~.~~;
b. Not more than 3 key deficiencies;
~~c. Not more than 5 other deficiencies.~~

Subdivision vi. ~~The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria~~

~~Subdivision (a)~~ The overall Plant Sanitation Program element will be assigned one of the following conformance designations~~:~~ based on compliance with the criteria listed in Subdivision v.

(i) Conformance: The program is in compliance with all of the criteria listed above and all plants evaluated are in compliance with Procedure XV Section 6 Subdivision (b) Subdivision (v) (g).

(ii) Conformance with Deficiencies: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision v. (a), (b), (c), (d), (e), and (f) and has 25% or less of plants with deficiencies associated with ~~key or other compliance items in~~ Procedure XV. Section 6. Subdivision (b) Sub-

division (v) (g).

(iii) Non-Conformance: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision (v) (a), but, does not meet the criteria in Procedure XV. Section 6. Subdivision (b) Subdivision (v) Subdivision (b) or (c) or (d) or (e) or (f) has greater than 25% (but less than 51%) of plants with deficiencies associated with ~~key or other compliance items~~ Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g).

(iv) Major Non-Conformance: The program has multiple deficiencies. It is non-compliant with Procedure XV. Section 6. Subdivision (b) Subdivision (v) Subdivision (b) or (c) or (d) or (e) or (f) or 51% or greater of plants with deficiencies associated with Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g).

Subdivision (vii) FDA will follow the current compliance program for communication with the State agencies.

NOTE: All deficiencies observed by FDA while conducting the in-plant inspection portion of the evaluation will be documented and included in the compliance determination outlined in Section 6 Subdivision (b) Subdivision (v) (g).

Action by 2015 Task Force III	Recommended adoption of NSSP Evaluation Criteria Committee recommendations on Proposal 13-308.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 13-308.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-308.

Proposal Subject	Name of Organization
Specific NSSP Guide Reference	ISSC Constitution Bylaws and Procedure Article I. Organization
Text of Proposal/ Requested Action	**ARTICLE I. ORGANIZATION** Section 1. The name of the organization shall be the "Interstate Shellfish ~~Sanitation Conference~~Safety Congress", hereinafter referred to as the ~~Conference~~ Congress. Section 2. The ~~Conference~~ Congress shall be directed by and shall be under the control of the various states, federal agencies and shellfish industry that join together to form the ~~Conference~~Congress. The word "Conference" shall be changed to "Congress" throughout the ISSC Constitution Bylaws and Procedures
Public Health Significance	The present name is misleading regarding the primary function of SSC which is to establish guidelines to foster and improve the sanitation of shellfish in the United States. The change would more clearly define the organization as a deliberative body and would encourage more participation by stakeholders.
Cost Information	
Action by 2015 Task Force III	Recommended no action on Proposal 15-300. Rationale: FDA indicated a name change would require the development of a new Memorandum of Understanding which would require a great deal of time and effort for both FDA and ISSC. Additionally, the present Agency requirements for a MOU would most likely result in a very different document.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 15-300.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-300.

Proposal Subject	*Vibrio Vulnificus* Illness Review Committee and Laboratory Committee
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, & Procedures Article IV. Executive Board, Officers, Committees
Text of Proposal/ Requested Action	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 Chairperson. 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; • Model Ordinance Effectiveness Review; • Patrol; • Proposal Review; • Research Guidance; • Resolutions; • Shellfish Restoration; ~~and~~ • *Vibrio Management*; • *Vibrio Vulnificus* Illness Review; and • Laboratory 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 Annual Meeting. Section 16. The Executive Board Chairperson shall appoint a Laboratory Committee. The Committee will review and make recommendations that are presented to the ISSC for approval. Additionally, the Committee will be requested to provide recommendations regarding laboratory related matters. "Laboratory Methods Review Committee" shall be changed to "Laboratory Committee" throughout the ISSC Constitution, Bylaws, and Procedures and the NSSP Guide for the Control of Molluscan Shellfish.
Public Health Significance	These committees have charges that are stated in the ISSC Constitution, Bylaws, and Procedures and should be standing committees.
Cost Information	
Action by 2015 Task Force III	Recommended adoption of Proposal 15-301 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 15-301.

Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-301.

Proposal Subject	Study Design Guidance Committee
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, & Procedures
Text of Proposal/ Requested Action	ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES Section 10. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairperson. 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; • Model Ordinance Effectiveness Review; • Patrol; • Proposal Review; • Research Guidance; • Resolutions; • Shellfish Restoration; ~~and~~ • *Vibrio* Management~~.~~; and • Study Design Guidance. 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 Annual Meeting. **Section 16.** The Executive Board shall appoint a Study Design Guidance Committee. The Committee will develop guidance to assist States and the industry in establishing target levels and developing protocols for studies to determine the effectiveness of post-harvest processes.
Public Health Significance	Presently the NSSP requires that States conduct studies to (1) demonstrate the effectiveness of post-harvest processes and practices intended to reduce pathogen levels; or (2) to ensure that processes and practices do not result in unintended growth of pathogens. The NSSP offers no guidance for conducting these studies nor does the NSSP provide recommended pathogen target levels. This committee would serve as technical expertise for developing guidance.
Cost Information	
Action by 2015 Task Force III	Recommended adoption of Proposal 15-302 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 15-302.

Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-302.

Proposal Subject	Proposal Submission Procedure
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Article XIII. Procedure for the Submission of Proposals
Text of Proposal/ Requested Action	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. Proposals that lack required information will be deemed incomplete and returned to the submitter. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid. (Moved from Article XIII. Section 10.) ~~Section 10. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid.~~
Public Health Significance	The purpose of this change is to encourage submitters to review and edit proposals for accuracy.
Cost Information	
Action by 2015 Task Force III	Recommended adoption of Proposal 15-303 as amended. 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. Proposals that lack required information will be deemed incomplete and returned to the submitter ~~.~~for completion. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid. (Moved from Article XIII. Section 10.)
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 15-303.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-303.

Proposal Subject	Proposal Submission
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Article XIII. Procedure for the Submission of Proposals
Text of Proposal/ Requested Action	Add a new Section 8. To Article XIII. as follows: Section 8. Proposals that are deemed technical in nature may be submitted to a committee for review. The committee will provide a recommendation to the appropriate Task Force(s).
Public Health Significance	Historically, technical, complex, and lengthy proposals have been referred to committee because of the difficulty of fully debating these types of proposals in Task Force. This change would allow a more thorough and meaningful review of the proposal.
Cost Information	
Action by 2015 Task Force III	Recommended adoption of Proposal 15-304 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 15-304.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-304.

Proposal Subject	Unresolved Issue Procedure
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Procedure IX. Procedures for Handling Complaints and Challenges Regarding the Adequacy of Certification Controls
Text of Proposal/ Requested Action	Section 2. When an FDA field inspection or an overall program evaluation indicates a state program is not meeting the minimum requirements of the NSSP Model Ordinance, the following actions shall be taken: Subdivision a. FDA shall provide written notification to the state shellfish control authority of the item(s) requiring action with supporting documentation and recommendations as appropriate. Subdivision b. The state shall investigate the item(s) and provide a written response within thirty (30) days that it has been corrected, that a corrective action plan has been developed and will be implemented within a specific time frame, or that it disagrees with FDA's finding. The state shall provide supporting documentation regarding any disagreements. FDA shall review the materials submitted by the state and respond to the state within thirty (30) days. Subdivision c. When a state does not disagree with FDA findings, but does disagree with an FDA report, the state shall provide written notification to FDA of the areas of disagreement with supporting documentation and recommendations as appropriate. FDA shall review the information submitted and provide a written response within thirty (30) days that it agrees and the report has been corrected, that it agrees but the report cannot be corrected, or that it disagrees with the state. FDA shall provide supporting documentation regarding any inability to correct a report or any disagreement. The state shall review the materials submitted by FDA and respond to FDA within thirty (30) days. Subdivision d. If corrective action is taken by the state or by the FDA or a mutually agreed upon action plan is developed and implemented, no action by the Conference will be necessary. Subdivision e. If FDA considers the action (or lack of action) taken by the state to be inadequate to resolve the item(s), FDA shall notify the ISSC Executive Director of ~~or if the state disagrees with FDA's findings or response, it shall be considered~~ an unresolved issue. If the State disagrees with FDA's findings or response, the State may pursue one of the following actions: Subdivision i. The State may request consultation from the Consultation Subcommittee of the ISSC Unresolved Issues Committee. The purpose of this consultation will allow the State the

	opportunity to seek guidance from the Consultation Subcommittee regarding program requirements and FDA findings; or Subdivision ii. The State shall notify the ISSC Executive Director of an unresolved issue. Subdivision f. Upon notification of an unresolved issue, ~~FDA or the state shall notify~~ the ISSC Executive Director ~~who~~ shall consult with both the state and FDA and prepare recommendations, which will be submitted to the Board with the unresolved issue. The referred unresolved issue shall be handled according to Procedure IX., Section 3. FDA may also take any actions it considers appropriate to deal with any adulterated product.
Public Health Significance	Procedure IX. of the ISSC Constitution, Bylaws, and Procedures does not offer a simple remedy for a State to disagree with an FDA finding in a State evaluation. The proposed language would offer such a remedy.
Cost Information	
Action by 2015 Task Force III	Recommended adoption of Proposal 15-305 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 15-305.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-305.

Proposal Subject	Critical Deficiencies
Specific NSSP Guide Reference	ISSC Constitution Bylaws & Procedures Procedure XV. Section 6. Subdivision vi.
Text of Proposal/ Requested Action	Subdivision vi. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria Subdivision (a) The overall Plant Sanitation Program element will be assigned one of the following designations: (i) Conformance: The program is in compliance with all of the criteria listed above. (ii) Conformance with Deficiencies: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision v. (a), (b), (c), (d), (e), and (f) and has 25% or less of plants with deficiencies associated with critical, key or other compliance items in {Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g)}. (iii) Non-Conformance: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Sub-division (v) (a), but, does not meet the criteria in Procedure XV. Section 6. Subdivision (b) Subdivision (v) Sub-division (b) or (c) or (d) or (e) or (f) has greater than 25% (but less than 51%) of plants with deficiencies associated with critical, key or other compliance items {Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g)}. (iv) Major Non-Conformance: The program has multiple deficiencies. It is non-compliant with Procedure XV. Section 6. Subdivision (b) Subdivision (v) Subdivision (b) or (c) or (d) or (e) or (f) or 51% or greater of plants with ~~deficiencies associated with Procedure XV~~ critical, key or other compliance items {Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g)}. FDA will follow the current compliance program for communication with the State agencies.
Public Health Significance	Presently Procedure XV. is unclear regarding how observed criticals identified during the in-plant evaluation will be used in assigning overall plant sanitation program designations. The in-field plant criteria in Section 6. Subdivision g. includes critical deficiencies; however, Subdivision vi. does not include any reference to critical deficiencies.
Cost Information	

Action by 2015 Task Force III	Recommends no action on Proposal 15-306. Rationale: Proposal is resolved by action on Proposal 13-308.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 15-306.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-306.

Proposal No. 15-307

Proposal Subject	ISSC Annual Meeting
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Article XI. Rules of Annual Conference Meetings
Text of Proposal/ Requested Action	ARTICLE XI. Rules of Biennial ~~Annual~~ Conference Meetings Except for special meetings, as provided for in Article V., Section 5. of this Constitution, the Conference will convene a meeting biennially during odd numbered years ~~annually~~ and will rotate it among the different Regions of the country. If adopted, all other references to Annual in the ISSC Constitution, Bylaws, and Procedures will be changed to Biennial.
Public Health Significance	The Conference has functioned well with biennial meetings since 1999. The costs and time commitment for meeting do not justify meeting annually. Two (2) concerns not addressed during deliberations at the 2013 meeting: 1. FDA may not be able to provide a small conference grant every year; and 2. The new revisions of the NSSP Guide will most likely not be available for proposal submission.
Cost Information	
Action by 2015 Task Force III	Recommended adoption of Proposal 15-307 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 15-307.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-307.

Resolution Subject	Dr. Alvin P. Rainosek
Text of Resolution	***Whereas,*** Dr. Alvin P. Rainosek was born on October 30, 1937, El Campo, Texas and died 77 years later on January 12, 2015, in Mobile, Alabama. Alvin was a nationally and internationally recognized statistician who received wide acclaim, numerous awards, and recognition for his knowledge and skills in mathematics, statistics, and regulatory concepts. ***Whereas,*** Dr. Rainosek became the first statistics professor hired at the University of South Alabama in 1970 and spent 44 years building the University's statistics program and creating its first undergraduate degree in statistics. In 1991 he was named "Outstanding Professor of the Year" by the University's Alumni Association and later retired from the university in 2014. ***Whereas,*** In 1980, Dr. Rainosek became a consultant and advisor to the National Oceanic and Atmospheric Agency's National Marine Fisheries Service and the National Seafood Inspection Laboratory. During this time he represented the National Marine Fisheries Service to FDA, EPA, DOD, USDA, CDC, NIH, nearly every state food safety regulatory agency, and the ISSC. ***Whereas,*** Dr. Rainosek served internationally and made significant contributions in furthering food safety standards globally as a member of the USA delegations representing the National Marine Fisheries Service before the World Health Organization/Food and Agricultural Organization International Codex Alimentarius Food Standards Programme, the International Standards Organization, and the European Union during numerous meetings and conferences. ***Whereas,*** Dr. Rainosek was well known as a forward thinker and constantly created new ways to communicate complex concepts in creative ways to be easily understood and implemented by his peers. ***Be It Therefore Resolved,*** that the Interstate Shellfish Sanitation Conference extends its gratitude for Dr. Rainosek's leadership and lasting contributions to global food safety and the organization; and ***Be It Further Resolved***, that the Interstate Shellfish Sanitation Conference acknowledge his contributions by a letter to that effect to his family.
Action by 2015 Resolutions Committee	Recommended adoption of Resolution 15-001 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Resolutions Committee on Resolution 15-001.
Action by FDA January 11, 2016	Concurred with Conference action on Resolution 15-001.

Resolution Subject	Resolution of Appreciation
Text of Resolution	*Whereas,* the twenty-sixth meeting of the Interstate Shellfish Sanitation Conference convened October 24 – 29, 2015, at The Sheraton Hotel in Salt Lake City, Utah, 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: *Ameripure* *John Tesvich* *Franklin, LA* *H.M. Terry & Company* *Wec Terry* *Willis Wharf, VA* *Jeri's Seafood* *Tracy Woody, General Manager* *Smith Point, Texas* *The Gulf Oyster Industry Council* *Chris Nelson* *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 2015 Resolutions Committee	Recommended adoption of Resolution 15-002 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Resolutions Committee on Resolution 15-002.
Action by FDA January 11, 2016	Concurred with Conference action on Resolution 15-002.

Resolution No. 15-003

Resolution Subject	Resolution of Appreciation
Text of Resolution	*Whereas,* the twenty-sixth meeting of the Interstate Shellfish Sanitation Conference convened October 24 – 29, 2015, at The Sheraton Hotel in Salt Lake City, Utah, and *Whereas,* the following industry sponsors, companies, and individuals were instrumental in contributing to the outstanding success of the Interstate Shellfish Sanitation Conference 2015 Biennial Meeting. *Be It Therefore Resolved* that the Interstate Shellfish Sanitation Conference goes on record expressing appreciation to: The Staff of The Sheraton Hotel, particularly, Jason Ford, General Manager Nicole Bears, Assistant Director of Sales Leah Brucker, Event Manager Mary Stott, Banquet Manager Emma Tuitavuki, Banquet Captain Zach Schafer, Banquets Andrea Marks, Banquets Yadira Lopez, Banquets Nicholas Schultz, Banquets Simona Lopez, Banquets Dirk Hooley, AV Director Brant Adams, AV Technician Brandon Bryner, Executive Chef Dennis Hovet, Sous Chef The Sheraton Front Desk Staff The Volunteer ISSC Staff William J. Eisele, Office Manager Quincy Boyce Alexandra Mathews Utah Department of Agriculture Erin Butler, Maryland Department of Health & Mental Hygiene *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 2015 Resolutions Committee	Recommended adoption of Resolution 15-003 as submitted.
Action by 2015 General Assembly	Adopted recommendation of Resolutions Committee on Resolution 15-003.
Action by FDA January 11, 2016	Concurred with Conference action on Resolution 15-003.