

# **Interstate Shellfish Sanitation Conference 2017 Biennial Meeting**

## ***Task Force I Report***



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**October 14 - 19, 2017**  
**Sheraton Hotel**

Submitter	Joanne Jellett
Affiliation	Jellett Rapid Testing Ltd.
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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	<p>Procedure for Acceptance and Approval of Analytical Methods for the NSSP</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Subdivision i. Meets immediate or continuing need;</p> <p>Subdivision ii. Improves analytical capability under the NSSP as an alternative to other approved or accepted method(s)</p>

	<p>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.</p> <p>Please see attached additional information.</p> <p>Suggested wording: Section II, Chapter III Laboratory @.02 Methods</p> <p>C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:</p> <ol style="list-style-type: none"> <li>(1) The current AOAC and APHA methods used in bioassay for paralytic shellfish poisoning toxins; and</li> <li>(2) The current APHA method used in bioassay for <i>Karemia breve</i> toxins.</li> <li><u>(3) The Jellett Rapid Extraction Method may be used for extracting PSP and ASP toxins from Shellfish by regulatory and industry laboratories.</u></li> </ol>
<p>Public Health Significance</p>	<p>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.</p> <p>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.</p> <p>Possible applications for The Jellett Rapid Extraction Method for PSP and ASP include:</p> <ul style="list-style-type: none"> <li>• as a supplement to analytical methods of screening out negative samples in shellfish regulatory labs;</li> <li>• 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;</li> <li>• 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);</li> <li>• as a supplement to analytical methods for water classification for Biotoxins; and</li> <li>• as a supplement to analytical methods for broad scale ecological monitoring.</li> </ul>

	<p>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.</p> <p>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.</p> <p>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</p>
<p>Cost Information</p>	<p>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.</p>
<p>Action by 2005 Laboratory Methods Review Committee</p>	<p>Recommended referral of Proposal 05-111 to the appropriate committee as determined by the Conference Chairman.</p>
<p>Action by 2005 Task Force I</p>	<p>Recommended adoption of the Laboratory Methods Review Committee recommendation of Proposal 05-111.</p>
<p>Action by 2005 General Assembly</p>	<p>Adopted recommendation of 2005 Task Force I.</p>
<p>Action by USFDA</p>	<p>Concurred with Conference action.</p>
<p>Action by 2007 Laboratory Methods Review Committee</p>	<p>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.</p>
<p>Action by 2007 Task Force I</p>	<p>Recommended referral of Proposal 05-111 to an appropriate committee as determined by the Conference Chairman.</p>
<p>Action by 2007 General Assembly</p>	<p>Adopted recommendation of 2007 Task Force I.</p>
<p>Action by</p>	<p>December 20, 2007</p>

<p>USFDA</p>	<p>Concurred with Conference action with the following comments and recommendations for ISSC consideration.</p> <p>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.</p> <p>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.</p>
<p>Action by 2009 Laboratory Methods Review Committee</p>	<p>Recommended no action on Proposal 05-111. Rationale: Requested additional information has not been submitted.</p>
<p>Action by 2009 Task Force I</p>	<p>Recommended adoption of Laboratory Methods Review Committee recommendation of Proposal 05-111.</p>
<p>Action by 2009 General Assembly</p>	<p>Referred Proposal 05-111 to the Laboratory Methods Review Committee.</p>
<p>Action by USFDA 02/16/2010</p>	<p>Concurred with Conference action on Proposal 05-111.</p>
<p>Action by 2011 Laboratory Methods Review Committee</p>	<p>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.</p> <p>The Laboratory Methods Review Committee further recommends:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> </ol>

	<p>3. No action on the requested language change in Proposal 05-111 for the Model Ordinance Section II, Chapter III Laboratory @.02 Methods.</p> <p>Section II, Chapter III Laboratory @.02 Methods  C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:</p> <p>(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 <i>Karenia brevis</i> toxins.  (3) <del>The Jellett Rapid Extraction Method may be used for extracting PSP and ASP toxins from Shellfish by regulatory and industry laboratories.</del></p>
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	<p>Recommended the following:</p> <p>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).</p> <p>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.</p> <p>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.</p>
Action by 2015 Task Force I	<p>Recommended adoption of the Laboratory Methods Review Committee on Proposal 05-111 with the following amendments:</p> <ol style="list-style-type: none"> <li>1. Remove “and ASP” and change “toxins” to “toxin” throughout the proposal and adopt the Laboratory Method Review Committee recommendation 1</li> <li>2. Refer Proposal 05-111 to appropriate committee as determined by Conference Chair.</li> <li>3. No action on recommendation 3 as this is covered by the proposal as amended by the Task Force.</li> </ol>
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.
Action by 2017 Laboratory Committee	Recommended no action on Proposal 05-111. Rationale: The submitter does not intend to pursue this proposal at this time.
Action by 2017 Task Force I	Recommends adoption of the Laboratory Committee on Proposal 05-111.

Submitter	Thomas L. Howell
Affiliation	Spinney Creek Shellfish, Inc.
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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.  <u>(4) Exception.</u> <u>If the Male-specific Coliphage indicator is used for supplemental process verification using an end-point meat standard of &lt; 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.</u>
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.



<p>Action by 2013 Growing Area Classification Committee</p>	<p>Recommend referral of Proposal 11-103 to the appropriate committee as determined by the Conference Chairman.</p> <p>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.</p> <p>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.</p>
<p>Action by 2013 Task Force I</p>	<p>Recommended adoption of Growing Area Classification Committee action on Proposal 11-103.</p>
<p>Action by 2013 General Assembly</p>	<p>Adopted recommendation of 2013 Task Force I on Proposal 11-103.</p>
<p>Action by FDA May 5, 2014</p>	<p>Concurred with Conference action on Proposal 11-103.</p>
<p>Action by 2015 Growing Area Classification Committee</p>	<p>Recommended referral of Proposal 11-103 to appropriate committee as determined by the Conference Chair.</p>
<p>Action by 2015 Task Force I</p>	<p>Recommended adoption of Growing Area Classification Committee recommendation on Proposal 11-103.</p>
<p>Action by 2015 General Assembly</p>	<p>Adopted recommendation of Task Force I on Proposal 11-103.</p>
<p>Action by FDA January 11, 2016</p>	<p>Concurred with Conference action on Proposal 11-103.</p>
<p>Action by 2017 Growing Area Committee</p>	<p>Recommended adoption of Proposal 11-103 as amended.</p> <p>Add a new section as follows:  Chapter XV. Depuration  .03 Other Model Ordinance requirements</p> <p><u><a href="#">K. Supplemental Requirements for Depuration using MSC Viral Controls for Shellstock Harvested from Conditionally Restricted Growing Areas Impacted by Wastewater System Discharge (WWSD).</a></u></p> <p><u><a href="#">If the conditionally restricted growing area from which the shellstock is being depurated is impacted by wastewater treatment system discharge (generally that section of the conditionally restricted growing area located within the 300:1 to 1000:1 dilution lines), then supplemental requirements for depuration using MSC viral controls may be required. Depuration using MSC viral controls may be seasonally limited and may be species and depuration facility specific. Contaminant reduction studies as described in (1) below are recommended unless the SSCA and the Depuration Facility Operator have significant experience with the depuration process using MSC viral controls.</a></u></p> <p><u><a href="#">(1) Male-specific coliphage may be used in addition to fecal coliform for species-specific, growing area-specific, and depuration system-specific contaminant reduction studies. These contaminant reduction studies should demonstrate that:</a></u></p>

	<p><u>(a) Predictable periods of time exist when male-specific coliphage levels are less than 1,000 PFU/100gm in shellfish meats,</u></p> <p><u>(b) Male-specific coliphage and fecal coliform can be consistently reduced below end-point requirements, and</u></p> <p><u>(c) Critical limits of season, process water temperature and salinity, and system design and operation limitations can be assessed and determined</u></p> <p><u>(d) Species-specific operating protocols may be developed from the contaminant reduction studies for each conditionally restricted growing area that includes:</u></p> <ul style="list-style-type: none"> <li><u>(i) Calendar dates when depuration shall be permitted,</u></li> <li><u>(ii) Water temperature and salinity limitations,</u></li> <li><u>(iii) Minimum processing time,</u></li> <li><u>(iv) Sampling requirements and release criteria, and</u></li> <li><u>(v) Operating Protocol.</u></li> </ul> <p><u>(2) All requirements of Chapter XV shall be followed,</u></p> <p><u>(3) A single 0-day MSC shellfish meat sample is required.</u></p> <p><u>(4) The MSC end-point requirement for depuration is 50 PFU/100gm. If the single 0-day sample exceeds 50 PFU/100gm, then triplicate samples are required prior to release of product.</u></p> <p><u>(5) The geometric mean of the triplicate samples used for product release must not exceed 50PFU/100gm and no single sample over 100 PFU/100gm.</u></p> <p><u>(6) Extended depuration may be permitted to achieve end-point requirements.</u></p> <p><u>(7) Evaluation of male-specific coliphage samples shall be performed in an NSSP conforming laboratory.</u></p>
<p>Action of 2017 Task Force I</p>	<p>Recommends adoption of Growing Area Classification recommendation on Proposal 11-103.</p>

Submitter	Robert Rheault
Affiliation	East Coast Shellfish Growers Association
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Proposal Subject	Sources of Seed for Aquaculture
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VI. Shellfish Aquaculture
Text of Proposal/ Requested Action	<p>.03 Seed Shellstock</p> <p>Seed may come from any growing area, or from any growing area in any classification, provided that:</p> <ul style="list-style-type: none"> <li>A. The source of the seed is sanctioned by the Authority</li> <li>B. Seed from growing areas <del>or growing areas</del> in the restricted or prohibited classification have acceptable levels of poisonous or deleterious substances; and</li> <li>C. Seed from growing areas <del>or growing areas</del> in the prohibited classification are cultured for a minimum of <del>six (6) months</del> <u>one month</u> <u>while average daily water temperatures are above 50 degrees F.</u></li> </ul>
Public Health Significance	<p>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).</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>References Cited: Richards, G. (1988), Microbial Purification of Shellfish: A Review of Depuration and Relaying, J. Food Protection 51(3)218-251.</p> <p>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)</p>
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.
Action by 2017 Aquaculture Facilities Inspection Committee	<p>Recommended adoption of Proposal 13-107 as substituted.</p> <p>Section I. Definitions            Replace definition 9. in Section I of the Model Ordinance as follows:</p> <p><u>9. Aquaculture means cultivating shellfish in controlled conditions for human consumption. Cultivation includes propagation and growing of shellfish. These activities may occur in natural or man-made water bodies. These activities include seed production, cultivation in natural water bodies when shellfish are held off the bottom such as the use of racks, bags, or cages, and when shellfish are held in man-made water bodies such as the use of tanks, ponds, or raceways. These activities do not include depuration, wet storage or the broadcasting of spat or seed shellfish being left to mature the same as wild shellfish.</u></p> <p>Modify definition 93. in Section I of the Model Ordinance as follows:</p> <p>(93) Prohibited means a classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering <u>or nursery culture</u> of seed for aquaculture, is not permitted.</p> <p>Section IV. Chapter IV. Shellstock Growing Areas            Change @03 E. (2)(a) to read:            (2) General. The Authority shall:            (a) Not permit the harvest of shellstock from any area classified as prohibited, except for the harvest of shellstock for the gathering of seed <u>or nursery culture</u> for aquaculture or the depletion of the areas classified as prohibited; and</p> <p>Replace Chapter VI. Aquaculture in its entirety as follows:</p> <p><u>Chapter VI. Aquaculture Requirements for the Authority</u></p> <p><u>[Note: The Authority must meet the requirements of this section even if the</u></p>

Authority does not formally adopt this section in regulation.]  
@ .01 General.

A. Activities which have been determined to pose a significant public health concern and need regulation outlined in this Chapter include, but are not limited to:

- (1) Seed production in waters classified as Prohibited or Unclassified;
- (2) Aquaculture that attracts birds or mammals; and
- (3) Land based aquaculture

B. The Authority shall:

- (1) Approve the written operational plan for operations as outlined in @.01A above.
- (2) Inspect operations outlined in @.01A above at least annually; and
- (3) At a minimum inspect operator records to verify that appropriate permits are up to date and operational plans required in @ .01 A(1). are being implemented.
- (4) Consistent with Chapter IV @ .01 (D)(1)(e) when aquaculture as defined in the Model Ordinance attracts birds or mammals their presence should be considered for possible adverse effects on growing area water quality

@ .02 Seed Shellstock.

A. The Authority shall establish the maximum seed size for each species of shellfish that can be produced in prohibited waters. In determining the maximum seed size Authorities shall establish sizes that require a minimum of 120 days of growing to reach market size.

B. The Authority shall establish appropriate corrective actions for when seed exceeds the maximum seed size when it has been produced in waters classified as prohibited.

C. All sources of seed produced or collected in prohibited waters shall be sanctioned by the Authority.

Requirements for the Harvester/Dealer

.01 Exceptions.

Hatcheries and nurseries rearing larvae and/or seed that are located in:

A. Approved or conditionally approved growing areas are exempt from these requirements.

B. Restricted or Conditionally Restricted would be exempt from these requirements but subject to relay requirements in Chapter V for seed that exceeds the maximum seed size established by the Authority.

.02 General.

A. Any person who performs aquaculture as defined in the Model Ordinance or operates an aquaculture facility to raise shellfish for human consumption shall obtain:

- (1) A permit from the Authority for the activity and functioning of his facility;
- (2) A harvester's license; and

	<p><u>(3) Certification as a dealer, where necessary.</u></p> <p><u>B. Shellfish aquaculture as defined in the Model Ordinance shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the operator’s written operational plan.</u></p> <p><u>C. Prior to beginning his activity, an operator shall obtain the permission of the Authority for use of his facility.</u></p> <p><u>D. Any shellfish seed raised in aquaculture that exceeds the maximum seed size established by the Authority shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:</u></p> <ul style="list-style-type: none"> <li><u>(1) The closed status of the conditionally approved classification;</u></li> <li><u>(2) The restricted classification;</u></li> <li><u>(3) The open status of the conditionally restricted classification; or</u></li> </ul> <p><u>E. Only drugs sanctioned by the FDA shall be used for shellfish treatment.</u></p> <p><u>F. Harvesting, processing, storage, and shipping requirements for shellfish raised in a land-based aquaculture facility or a seed rearing facility or system that exceeds the maximum seed size established by the Authority shall be the same as the requirements for shellfish specified in Chapters V., VII., VIII., IX., X., XI., XII., XIII. and XIV.</u></p> <p><u>G. Complete and accurate records shall be maintained for at least two (2) years by the operator of the aquaculture facility and shall include the:</u></p> <ul style="list-style-type: none"> <li><u>(1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved or conditionally approved classification;</u></li> <li><u>(2) Water source, its treatment method, if necessary, and its quality in land based systems.</u></li> </ul> <p><u>.03 Seed Production in Water Classified as Prohibited or Unclassified.</u></p> <p><u>Seed may come from any growing area, or from any growing area in any classification, provided that:</u></p> <p><u>A. The source of the seed if from waters classified as prohibited or unclassified is sanctioned by the Authority; and</u></p> <p><u>B. Operational Plan. Each aquaculture site that cultures seed in waters classified as prohibited or unclassified shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:</u></p> <ul style="list-style-type: none"> <li><u>(1) A description of the design and activities of the culture facility;</u></li> <li><u>(2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;</u></li> <li><u>(3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;</u></li> <li><u>(4) The species of shellfish to be cultured and harvested;</u></li> <li><u>(5) Procedures to assure that no poisonous or deleterious substances are introduced from the seed production activities;</u></li> <li><u>(6) Corrective actions for addressing seed exceeding the maximum seed size as defined by the Authority.</u></li> </ul> <p><u>.04 Aquaculture that attracts birds or mammals.</u></p>
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A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk 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 aquaculture activities will be conducted;
- (3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;
- (4) The species of shellfish to be cultured and harvested;
- (5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities;
- (6) Maintenance of the required records

.05 Land Based Aquaculture.

A. Operational Plan. Each facility shall have a written operational plan. The facility must obtain approval from 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) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;
- (6) A program of sanitation, maintenance, and supervision to prevent contamination of the shellfish products;
- (7) A description of the water source, including the details of any water treatment process or method;
- (8) 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;
- (9) If applicable, collection of data concerning the quality of food production (algae or other) used in the artificial harvest system; and
- (10) Maintenance of the required records.

B. Each land-based facility conducting aquaculture as defined by the Model Ordinance shall maintain the following records while the aquaculture activity continues.

- (1) Construction and remodeling plans for any permitted aquaculture facility;
- (2) Aquaculture operational plans; and
- (3) Aquaculture permits.

C. Water Systems.

	<p><u>(1) If the land-based aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.</u></p> <p><u>D. Water Quality.</u></p> <p><u>(1) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size shall meet the requirements for water quality and testing in Chapter VII C. .04 (3) (a), (b), (c), and (d) may be used in direct marketing.</u></p> <p><u>(2) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size and does not meet the requirements of Section D. (1) shall be relayed or depurated consistent with Chapter IV prior to direct marketing.</u></p> <p><u>.06 Polyculture Systems.</u></p> <p><u>A polyculture system shall:</u></p> <p><u>A. Meet all requirements in Section .05 Land Based Systems;</u></p> <p><u>B. Provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested;</u></p> <p><u>C. Include in its operational plan requirements to:</u></p> <p><u>(1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and</u></p> <p><u>(2) Subject all harvested shellstock to relaying or depuration if human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances exist at levels of public health significance.</u></p> <p><u>Move Chapter VI Section .07 to a new Chapter:</u></p> <p><u>Chapter XVII Shellfish Gardening</u></p> <p><u>@ .01 Shellfish Gardening.</u></p> <p><u>If a State recognizes shellfish gardening the Authority:</u></p> <p><u>A. Shall permit or register shellfish gardening activities.</u></p> <p><u>B. Shall establish permit or registration conditions and determine classification of waters where shellfish gardening can take place prior to its implementation.</u></p> <p><u>C. Shall provide information to the shellfish gardener on the risk of consuming shellfish from private docks, piers, and shellfish floats attached to piers or docks and from waters not classified and open to harvest for direct consumption.</u></p> <p><u>D. May require that the shellfish gardener maintain records on the disposition of the shellfish product and provide these records to the Authority.</u></p>
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	<p><u>@ . 02 Requirements for the Shellfish Gardener.</u></p> <p><u>A. Shellfish gardening shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the oyster/shellfish gardening activity.</u></p> <p><u>B. Shellfish gardeners shall document that they understand the risks associated with consumption for shellfish grown from docks or private piers.</u></p> <p><u>C. If required by the Authority, shellfish gardeners shall keep accurate records on the fate or final destination of all shellfish grown at their shellfish garden site and provide these records to the Authority upon request.</u></p>
<p>Action by 2017 Task Force I</p>	<p>Recommends adoption of Aquaculture Committee recommendation on Proposal 13-107 as amended.</p> <p>Section I. Definitions          Replace definition 9. in Section I of the Model Ordinance as follows:</p> <p>9. Aquaculture means cultivating shellfish in controlled conditions for human consumption. Cultivation includes propagation and growing of shellfish. These activities may occur in natural or man-made water bodies. These activities include seed <u>collection</u>, production, cultivation in natural water bodies when shellfish are held off the bottom such as the use of racks, bags, or cages, and when shellfish are held in man-made water bodies such as the use of tanks, ponds, or raceways. These activities do not include depuration <del>or</del>, wet storage, <del>or the broadcasting of spat or seed shellfish being left to mature the same as wild shellfish.</del></p> <p>Modify definition 93. in Section I of the Model Ordinance as follows:</p> <p>(93) Prohibited means a classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering or nursery culture of seed for aquaculture, is not permitted.</p> <p>Section IV. Chapter IV. Shellstock Growing Areas          Change @03 E. (2)(a) to read:          (2) General. The Authority shall:          (a) Not permit the harvest of shellstock from any area classified as prohibited, except for the harvest of shellstock for the gathering of seed or nursery culture for aquaculture or the depletion of the areas classified as prohibited; and</p> <p>Replace Chapter VI. Aquaculture in its entirety as follows:          Change @03 E. (2)(a) to read:          (2) General. The Authority shall:              (a) Not permit the harvest of shellstock from any area classified as prohibited, except for <del>the harvest of shellstock for</del> the gathering of seed or nursery culture for aquaculture or the depletion of the areas classified as prohibited; and</p> <p>Chapter VI. Aquaculture          Requirements for the Authority          [Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]</p>

	<p>@ .01 General.</p> <p>A. <del>Aquaculture</del> Activities which <del>may have been determined to</del> pose a significant public health concern and <del>are regulated</del> <del>need regulation outlined</del> in this Chapter include, but are not limited to:</p> <ol style="list-style-type: none"> <li>(1) Seed production in waters classified as Prohibited or Unclassified;</li> <li>(2) Aquaculture <del>structures</del> that attracts birds or mammals; and</li> <li>(3) Land based aquaculture</li> </ol> <p>B. The Authority shall:</p> <ol style="list-style-type: none"> <li>(1) Approve the written operational plan for operations as outlined in @.01A above.</li> <li>(2) Inspect operations outlined in @.01A above at least annually; and</li> <li>(3) At a minimum inspect operator records to verify that appropriate permits are up to date and operational plans required in @ .01 A(1) are being implemented.</li> <li>(4) Consistent with Chapter IV @ .01 (D)(1)(e) when aquaculture as defined in the Model Ordinance attracts birds or mammals their presence should be considered for possible adverse effects on growing area water quality</li> </ol> <p>@ .02 Seed Shellstock.</p> <p>A. The Authority shall establish the maximum seed size for each species of shellfish that can be produced in prohibited waters. In determining the maximum seed size Authorities shall establish sizes that require a minimum of 120 days of growing to reach market size.</p> <p>B. The Authority shall establish appropriate corrective actions for when seed exceeds the maximum seed size when it has been produced in waters classified as prohibited.</p> <p>C. All sources of seed produced or collected in prohibited waters shall be sanctioned by the Authority.</p> <p>Requirements for the Harvester/Dealer</p> <p>.1 Exceptions.</p> <p>Hatcheries and nurseries rearing larvae and/or seed that are located in:</p> <ol style="list-style-type: none"> <li>A. Approved or conditionally approved growing areas are exempt from these requirements.</li> <li>B. Restricted or Conditionally Restricted would be exempt from these requirements but subject to relay requirements in Chapter V for seed that exceeds the maximum seed size established by the Authority.</li> </ol> <p>.2 General.</p> <p>A. Any person who performs aquaculture as defined in the Model Ordinance or operates an aquaculture facility to raise shellfish for human consumption shall obtain:</p> <ol style="list-style-type: none"> <li>(1) A permit from the Authority for the activity and functioning of his facility;</li> <li>(2) A harvester's license; and</li> <li>(3) Certification as a dealer, where necessary.</li> </ol> <p>B. Shellfish aquaculture as defined in the Model Ordinance shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the operator's written operational plan.</p> <p>C. Prior to beginning his activity, an operator shall obtain the permission of the Authority for use of his facility.</p> <p>D. Any shellfish seed raised in aquaculture that exceeds the maximum seed size</p>
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	<p>established by the Authority shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:</p> <ol style="list-style-type: none"> <li>(1) The closed status of the conditionally approved classification;</li> <li>(2) The restricted classification;</li> <li>(3) The open status of the conditionally restricted classification; or</li> </ol> <p>E. Only drugs sanctioned by the FDA shall be used for shellfish treatment.</p> <p>F. Harvesting, processing, storage, and shipping requirements for shellfish raised in a land-based aquaculture facility or a seed rearing facility or system that exceeds the maximum seed size established by the Authority shall be the same as the requirements for shellfish specified in Chapters V., VII., VIII., IX., X., XI., XII., XIII. and XIV.</p> <p>G. Complete and accurate records shall be maintained for at least two (2) years by the operator of the aquaculture facility and shall include the:</p> <ol style="list-style-type: none"> <li>(1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved or conditionally approved classification;</li> <li>(2) Water source, its treatment method, if necessary, and its quality in land based systems.</li> </ol> <p>.3 Seed Production in Water Classified as Prohibited or Unclassified. Seed may come from any growing area, or from any growing area in any classification, provided that:</p> <p>A. The source of the seed if from waters classified as prohibited or unclassified is sanctioned by the Authority; and</p> <p>B. Operational Plan. Each aquaculture site that cultures seed in waters classified as prohibited or unclassified shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:</p> <ol style="list-style-type: none"> <li>(1) A description of the design and activities of the culture facility;</li> <li>(2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;</li> <li>(3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;</li> <li>(4) The species of shellfish to be cultured and harvested;</li> <li>(5) Procedures to assure that no poisonous or deleterious substances are introduced from the seed production activities;</li> <li>(6) Corrective actions for addressing seed exceeding the maximum seed size as defined by the Authority.</li> </ol> <p>.4 Aquaculture that attracts birds or mammals.</p> <p>A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:</p> <ol style="list-style-type: none"> <li>(1) A description of the design and activities of the culture facility;</li> <li>(2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;</li> <li>(3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;</li> </ol>
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	<ul style="list-style-type: none"> <li>(4) The species of shellfish to be cultured and harvested;</li> <li>(5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities;</li> <li>(6) Maintenance of the required records</li> </ul>
.5	Land Based Aquaculture.
A.	<p>Operational Plan. Each facility shall have a written operational plan. The facility must obtain approval from the Authority prior to its implementation and shall include:</p> <ul style="list-style-type: none"> <li>(1) A description of the design and activities of the culture facility;</li> <li>(2) The specific site and boundaries in which shellfish culture activities will be conducted;</li> <li>(3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters;</li> <li>(4) The species of shellfish to be cultured and harvested;</li> <li>(5) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;</li> <li>(6) A program of sanitation, maintenance, and supervision to prevent contamination of the shellfish products;</li> <li>(7) A description of the water source, including the details of any water treatment process or method;</li> <li>(8) 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;</li> <li>(9) If applicable, collection of data concerning the quality of food production (algae or other) used in the artificial harvest system; and</li> <li>(10) Maintenance of the required records.</li> </ul>
B.	<p>Each land-based facility conducting aquaculture as defined by the Model Ordinance shall maintain the following records while the aquaculture activity continues.</p> <ul style="list-style-type: none"> <li>(1) Construction and remodeling plans for any permitted aquaculture facility;</li> <li>(2) Aquaculture operational plans; and</li> <li>(3) Aquaculture permits.</li> </ul>
C.	<p>Water Systems.</p> <ul style="list-style-type: none"> <li>(1) If the land-based aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.</li> </ul>
D.	<p>Water Quality.</p> <ul style="list-style-type: none"> <li>(1) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size shall meet the requirements for water quality and testing in Chapter VII C. .04 (3) (a), (b), (c), and (d) may be used in direct marketing.</li> <li>(2) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size and does not meet the requirements of Section D. (1) shall be relayed or depurated consistent with Chapter IV prior to direct marketing.</li> </ul>

.6 Polyculture Systems.

A polyculture system shall:

- A. Meet all requirements in Section .05 Land Based Systems;
- B. Provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested;
- C. Include in its operational plan requirements to:
  - (1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and
  - (2) Subject all harvested shellstock to relaying or depuration if human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances exist at levels of public health significance.

Move Chapter VI Section .07 to a new Chapter:

Chapter XVII Shellfish Gardening

@ .01 Shellfish Gardening.

If a State recognizes shellfish gardening the Authority:

- A. Shall permit or register shellfish gardening activities.
- B. Shall establish permit or registration conditions and determine classification of waters where shellfish gardening can take place prior to its implementation.
- C. Shall provide information to the shellfish gardener on the risk of consuming shellfish from private docks, piers, and shellfish floats attached to piers or docks and from waters not classified and open to harvest for direct consumption.
- D. May require that the shellfish gardener maintain records on the disposition of the shellfish product and provide these records to the Authority.

@ . 02 Requirements for the Shellfish Gardener.

- A. Shellfish gardening shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the oyster/shellfish gardening activity.
- B. Shellfish gardeners shall document that they understand the risks associated with consumption for shellfish grown from docks or private piers.
- C. If required by the Authority, shellfish gardeners shall keep accurate records on the fate or final destination of all shellfish grown at their shellfish garden site and provide these records to the Authority upon request.

Recommends a committee be appointed by the Conference Chair to review and revise existing guidance documents related to the Aquaculture Chapter.

Submitter	Executive Office
Affiliation	Interstate Shellfish Sanitation Conference (ISSC)
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	<p>4. Approved Limited Use Methods for Marine Biotxin Testing</p> <p>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.</p> <p>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</p>
Public Health Significance	<p>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.</p>
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.
Action by 2017 Laboratory Committee	Recommended no action on Proposal 13-109. Rationale: The committee concluded there is no need or interest in expanding the Abraxis Shipboard ELISA for PSP at this time.
Action by 2017 Task Force I	Recommends adoption of the Laboratory Committee recommendation on Proposal 13-109.

Submitter	Byungchul Kim
Affiliation	Beacon Analytical Systems, Inc.
Email	<a href="mailto:bkim@beaconkits.com">bkim@beaconkits.com</a>
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.
Action by 2017 Laboratory Committee	Recommended no action on Proposal 13-110. Rationale: Method submitter does not intend to pursue this proposal at this
Action by 2017 Task Force I	Recommends adoption of Laboratory Committee recommendation on Proposal 13-110.



Submitter	David C. Deardorff
Affiliation	Abraxis LLC
Email	<a href="mailto:ddeardorff@abraxiskits.com">ddeardorff@abraxiskits.com</a>
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 Diarrhetic 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.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	Recommends adoption of Laboratory Committee recommendation on Proposal 13-111.

Submitter	Jennifer Rice
Affiliation	Neogen Corporation
Email	<a href="mailto:jrice@neogen.com">jrice@neogen.com</a>
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. <a href="http://www.aesan.msps.es/en/CRLMB/web/procedimientos_crlmb/crlmb_standard_operating_procedures.shtml">http://www.aesan.msps.es/en/CRLMB/web/procedimientos_crlmb/crlmb_standard_operating_procedures.shtml</a>
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 201 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.
Action by 2017 Laboratory Committee	Recommended no action on Proposal 13-113. Rationale: Method submitter does not have adequate data at this time and has asked for the method to be withdrawn from further review.
Action by 2017 Task Force I	Recommends adoption of Laboratory Committee recommendation on 13-113.

Submitter	Darcie Couture
Affiliation	Resource Access International
Email	darcie.couture@att.net
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	<p>4. Approved Limited Use Methods for Marine Biotxin Testing</p> <p>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.</p> <p>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.</p> <p>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 Biotxin Testing.</p>
Public Health Significance	<p>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.</p>

<p>Cost Information</p>	<p>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.</p>
<p>Action by 2013 Laboratory Methods and Quality Assurance Review Committee</p>	<ol style="list-style-type: none"> <li>1. Recommended approval of this method as an alternative to the mouse bioassay for PSP in mussels.</li> <li>2. Recommended approval of this method for Limited Use for clams and scallops for the purpose of screening and precautionary closure for PSP.</li> <li>3. Recommended referral of this proposal to an appropriate committee as determined by the Conference Chairman to address this method in oysters.</li> <li>4. Recommended Executive Office sends 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.</li> </ol>
<p>Action by 2013 Task Force I</p>	<p>Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-114.</p>
<p>Action by 2013 General Assembly</p>	<p>Adopted recommendation of 2013 Task Force I on Proposal 13-114.</p>
<p>Action by FDA May 5, 2014</p>	<p>Concurred with Conference action on Proposal 13-114.</p>
<p>Action by 2015 Laboratory Methods Review Committee</p>	<p>Recommended referral of Proposal 13-114 to an appropriate committee as determined by the Conference Chair until additional data for oyster matrix are received.</p>
<p>Action by 2015 Task Force I</p>	<p>Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-114.</p>
<p>Action by 2015 General Assembly</p>	<p>Adopted the recommendation of Task Force I on Proposal 13-114.</p>
<p>Action by FDA January 11, 2016</p>	<p>Concurred with Conference action on Proposal 13-114.</p>
<p>Action by 2017 Laboratory Committee</p>	<p>Recommended referral of Proposal 13-114 to an appropriate committee as determined by the Conference Chair.</p>
<p>Action by 2017 Task Force I</p>	<p>Recommends adoption of Laboratory Committee recommendation on Proposal 13-114.</p>

Submitter	Florida Department of Agriculture and Consumer Services
Affiliation	Florida Department of Agriculture and Consumer Services
Email	<a href="mailto:Kimberly.Norgren@freshfromflorida.com">Kimberly.Norgren@freshfromflorida.com</a>
Proposal Subject	Shellfish Quarantine Guidance Document
Specific NSSP Guide Reference	<p>Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.04 Marine Biotoxin Control</p> <p>Section IV. Guidance Documents Chapter II. Growing Areas .02 Guidance for Developing Marine Biotoxin Contingency Plans</p>
Text of Proposal/ Requested Action	<p>Model Ordinance Chapter IV. Shellstock Growing Areas</p> <p>@.04 Marine Biotoxin Control</p> <p>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.</p> <p>Guidance Documents Chapter II. Growing Areas .02 Guidance for Developing Marine Biotoxin Contingency Plans.</p> <p>Text of the proposed guidance is as follows:</p> <p><u>Example Protocol for Quarantine Harvest of Shellfish from Aquaculture Leases During <i>Karenia brevis</i> Closures:</u></p> <p><u>A. Closure of an entire shellfish growing area due to <i>Karenia brevis</i> shall be in accordance with Model Ordinance Chapter IV. @.04 C. (1).</u></p> <p><u>B. When a shellfish growing area is closed due to <i>Karenia brevis</i>, 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 <i>Karenia brevis</i>. Zone is defined as an Authority delineated geographic area within a Conditionally Approved or Approved classified shellfish growing area.</u></p> <p><u>Controlled quarantine conditions:</u> <u>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:</u></p>

- (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;



	<p>(7) <u>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;</u></p> <p>(8) <u>Must cease this activity if any Authority collected red tide cell counts in the specific zone exceeds 200,000 cells per liter of <i>Karenia brevis</i>; and</u></p> <p>(9) <u>Must document all of the requirements listed above in the approved facility HACCP plan.</u></p> <p>C. <u>If cell counts in all water samples fall to 5,000 cells/L or less <i>Karenia brevis</i> 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 &lt;20 MU/100g.</u></p> <p>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 <i>Karenia brevis</i>.</p> <hr/> <p>Signed _____ Date _____</p>
<p>13. Public Health Significance</p>	<p>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 <i>Karenia brevis</i> 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 <i>Karenia brevis</i> 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 <i>Karenia brevis</i>. 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 <i>Karenia brevis</i> 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 <i>Karenia brevis</i> could reference this protocol in the Guidance Document and use it to effectively manage NSP closures.</p>

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 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	<p>Recommended adoption of Proposal 13-116 with substitute language as follows:</p> <p>(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 <u>state</u> growing area while other parts of <u>the same</u> <del>the</del> growing area are placed in the closed status. Such controlled harvesting shall be conducted with strict assurances of safety. <u>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, <del>such as by batch release of shellfish lots only after</del> samples of each lot are tested and found to be below the action levels specified in Section C.</u></p> <p><u>The program must include at a minimum:</u></p> <ul style="list-style-type: none"> <li><u>i. Establishment of appropriate pre-harvest screening levels;</u></li> <li><u>ii. Establishment of appropriate screening and end product testing methods;</u></li> <li><u>iii. Establishment of appropriate laboratories/analysts to conduct screening and end product testing methods;</u></li> <li><u>iv. Establishment of representative sampling plan for both i. and ii. above; and</u></li> <li><u>v. Other controls as necessary to ensure that shellstock are not released prior to meeting all requirements of the program.</u></li> </ul> <p>Should the above amended proposal be adopted by the conference, then the Biotoxin Committee develop a Guidance Document that includes guidance for development of end-product testing programs to address biotoxins in closed state waters.</p>
Action by 2015 Task Force I	Recommended adoption of Biotoxin Committee recommendation on Proposal 13-116.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-116.
Action by 2017 Task Force I	Recommends 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.

Submitter	Growing Area Classification Committee
Affiliation	Interstate Shellfish Sanitation Conference (ISSC)
Email	<a href="mailto:issc@issc.org">issc@issc.org</a>
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	<p>@.01 Sanitary Survey.</p> <p>A. General.</p> <p>(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:</p> <ul style="list-style-type: none"> <li>(a) A shoreline survey;</li> <li>(b) A survey of the <del>bacteriological</del> <u>microbiological</u> quality of the water <u>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;</u></li> <li>(c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area;</li> <li>(d) An analysis of the data from the shoreline survey, the bacteriological and the hydrodynamic, meteorological and geographic evaluations;</li> <li>(e) A determination of the appropriate growing area classification.</li> </ul> <p>B. Sanitary Survey Required...</p> <p>C. Sanitary Survey Performance.</p> <p>(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:</p> <ul style="list-style-type: none"> <li>(a) A field observation of the pollution sources which may include: <ul style="list-style-type: none"> <li>(i) A drive-through survey;</li> <li>(ii) Observations made during sample collection; and</li> <li>(iii) Information from other sources.</li> </ul> </li> <li>(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;</li> <li>(c) Review of available inspection reports and effluent samples collected from pollution sources;</li> <li>(d) Review of available performance standards for various types of discharges that impact the growing area; <del>and</del></li> </ul>

- (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.

	<p>(c) For management plans based on waste_water system <del>discharge treatment plant</del> function or pollution sources other than waste_water <u>system</u> discharge <del>treatment plants</del>, 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:</p> <ul style="list-style-type: none"> <li>(i) Performance standards of the plan are fully met;</li> <li>(ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;</li> <li>(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; <del>and</del></li> <li><u>(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</u></li> <li><u>(v) Shellstock feeding activity is sufficient to achieve <del>coliform</del> microbial reduction.</u></li> </ul> <p>(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;</p> <p>(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;</p> <p>(f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;</p> <p>(g) Provisions for patrol to prevent illegal harvest; and</p> <p>(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.</p>
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	<ul style="list-style-type: none"> <li>(3) Reevaluation of Conditional Classification...</li> <li>(4) Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management Plan by All Parties Involved...</li> <li>(5) Conditional Area Types...</li> <li>(6) Conditionally Approved Classification...</li> <li>(7) Conditionally Restricted Classification...</li> </ul> <p>D. Restricted Classification...</p> <p>E. Prohibited Classification.</p> <ul style="list-style-type: none"> <li>(1) Exception...</li> <li>(2) General...</li> <li>(3) Sanitary Survey...</li> <li>(4) Risk Assessment...</li> <li>(5) Wastewater Discharges. <ul style="list-style-type: none"> <li>(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.</li> <li>(b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria: <ul style="list-style-type: none"> <li>(i) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the microbiological quality of the effluent; <u>The SSCA may utilize MSC wastewater sample data in the determination of the performance of the sewage treatment plant;</u></li> <li>(ii) The decay rate of the contaminants of public health significance in the wastewater discharged;</li> <li>(iii) The wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and</li> <li>(iv) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.</li> </ul> </li> </ul> </li> </ul> <p>NOTE: All references in Section II. Model Ordinance Chapter IV. Shellstock Growing Areas will be changed to Waste Water System Discharge (WWSD).</p>
<p>13. Public Health Significance</p>	<p>Male-specific Coliphage (MSC) is a RNA virus of E. coli present in high numbers in raw sewage (on the order of 10<sup>5</sup> 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.</p> <p>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</p>



	<p>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.</p> <p>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. (<a href="#">Click here to view, download, or print the MSC meeting report</a>).</p>
<p>14. Cost Information</p>	<p>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.</p>
<p>Action by 2015 Task Force I</p>	<p>Recommended adoption of Proposal 15-102 as amended.</p> <p>@.01 Sanitary Survey.</p> <p>A. General.</p> <p>(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:</p> <ul style="list-style-type: none"> <li>(a) A shoreline survey;</li> <li>(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;</li> <li>(c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area;</li> <li>(d) An analysis of the data from the shoreline survey, the bacteriological and the hydrodynamic, meteorological and geographic evaluations;</li> <li>(e) A determination of the appropriate growing area classification.</li> </ul> <p>B. Sanitary Survey Required...</p>

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 (WWSO) 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

	<ul style="list-style-type: none"> <li>(viii) Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with Section E. Prohibited Classification;</li> <li>(b) For management plans based on pollution sources other than waste water treatment plants:             <ul style="list-style-type: none"> <li>(i) Performance standards that reliably predict when criteria for conditional classification are met; and</li> <li>(ii) Discussion and data supporting the performance standards.</li> </ul> </li> <li>(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:             <ul style="list-style-type: none"> <li>(i) Performance standards of the plan are fully met;</li> <li>(ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;</li> <li>(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;</li> <li>(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 <del>background levels or</del> a level of 50 MSC per 100 grams <u>or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions.</u> These <del>studies</del> 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</li> <li>(v) Shellstock feeding activity is sufficient to achieve microbial reduction.</li> </ul> </li> </ul>
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	<ul style="list-style-type: none"> <li>(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;</li> <li>(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;</li> <li>(f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;</li> <li>(g) Provisions for patrol to prevent illegal harvest; and</li> <li>(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.</li> </ul> <ul style="list-style-type: none"> <li>(3) Reevaluation of Conditional Classification...</li> <li>(4) Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management Plan by All Parties Involved...</li> <li>(5) Conditional Area Types...</li> <li>(6) Conditionally Approved Classification...</li> <li>(7) Conditionally Restricted Classification...</li> </ul> <p>D. Restricted Classification...</p> <p>E. Prohibited Classification.</p> <ul style="list-style-type: none"> <li>(1) Exception...</li> <li>(2) General...</li> <li>(3) Sanitary Survey...</li> <li>(4) Risk Assessment...</li> <li>(5) Wastewater Discharges.             <ul style="list-style-type: none"> <li>(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.</li> <li>(b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria:                 <ul style="list-style-type: none"> <li>(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;</li> <li>(ii) The decay rate of the contaminants of public health significance in the wastewater discharged;</li> <li>(iii) The wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and</li> <li>(iv) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.</li> </ul> </li> </ul> </li> </ul>
	<p>NOTE: All references in Section II. Model Ordinance Chapter IV. Shellstock Growing Areas will be changed to Waste Water System Discharge (WWSD).</p>

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.
Action by 2017 Task Force I	Recommends no action on Proposal 15-102. Rationale: The MSC Committee developed MSC guidance which was submitted as Proposal 17-113.

Submitter	Alison Sirois and Jackie Knue
Affiliation	Department of marine Resources and Alaska State Environmental Health Laboratory
Email	Alison.Sirois@maine.gov and Jacqueline.Knue@alaska.gov
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	<p>4. Approved Limited Use Methods for Marine Biotoxin Testing PCOX</p> <p>This submission presents data to support the use of PCOX method for Quahogs (<i>M. mercenaria</i> and <i>A. icelandica</i>), Surf Clams (<i>S. solidissima</i>), Geoducks (<i>P. generosa</i>), Butter Clams (<i>S. giganteus</i>), Little Neck Clams (<i>P. stamineais</i>), and Razor Clams (<i>S. patula</i>) 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.</p> <p>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.</p> <p>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 &amp; Classification Sample Type: Shellfish And Application: Controlled Relaying Sample Type: Shellfish.</p>
Public Health Significance	<p>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.</p>



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.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 15-109 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	Recommends adoption of Laboratory Committee recommendation on Proposal 15-109.

Submitter	Executive Board																					
Affiliation	Interstate Shellfish Sanitation Conference (ISSC)																					
Email	issc@issc.org																					
Proposal Subject	Laboratory Method for <i>Vibrio parahaemolyticus</i> (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	<p>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.</p> <p>Submitted by method developer William A. Glover (Washington State Public Health Laboratories)</p> <p>5. Approved Methods for Vibrio Enumeration</p> <table border="1" data-bbox="495 730 1317 1073"> <thead> <tr> <th></th> <th>Vibrio Indicator Type:</th> <th>Application: PHP Sample Type: Shucked</th> </tr> </thead> <tbody> <tr> <td>EIA<sup>1</sup></td> <td><i>Vibrio vulnificus</i> (V.v.)</td> <td>X</td> </tr> <tr> <td>MPN<sup>2</sup></td> <td><i>Vibrio vulnificus</i> (V.v.)</td> <td>X</td> </tr> <tr> <td>SYBR Green 1 QPCR-MPN<sup>5</sup></td> <td><i>Vibrio vulnificus</i> (V.v.)</td> <td>X</td> </tr> <tr> <td>MPN<sup>3</sup></td> <td><i>Vibrio parahaemolyticus</i> (V.p.)</td> <td>X</td> </tr> <tr> <td>PCR<sup>4</sup></td> <td><i>Vibrio parahaemolyticus</i> (V.p.)</td> <td>X</td> </tr> <tr> <td><u>MPN and PCR<sup>6</sup></u></td> <td><u><i>Vibrio parahaemolyticus</i> (V.p.)</u></td> <td><u>X</u></td> </tr> </tbody> </table> <p>Footnotes:</p> <p><sup>1</sup> EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992.</p> <p><sup>2</sup> 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).</p> <p><sup>3</sup> 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.</p> <p><sup>4</sup> 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.</p> <p><sup>5</sup> <i>Vibrio vulnificus</i>, ISSC Summary of Actions 2009. Proposal 09-113, Page 123.</p> <p><sup>6</sup> <u>William A. Glover, II, Ph.D. D9ABMM), MT(ASCP) Food and Shellfish Bacteriology Laboratory (FSBL) at the Washington State Public Health Laboratories (WAPHL)</u></p>		Vibrio Indicator Type:	Application: PHP Sample Type: Shucked	EIA <sup>1</sup>	<i>Vibrio vulnificus</i> (V.v.)	X	MPN <sup>2</sup>	<i>Vibrio vulnificus</i> (V.v.)	X	SYBR Green 1 QPCR-MPN <sup>5</sup>	<i>Vibrio vulnificus</i> (V.v.)	X	MPN <sup>3</sup>	<i>Vibrio parahaemolyticus</i> (V.p.)	X	PCR <sup>4</sup>	<i>Vibrio parahaemolyticus</i> (V.p.)	X	<u>MPN and PCR<sup>6</sup></u>	<u><i>Vibrio parahaemolyticus</i> (V.p.)</u>	<u>X</u>
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<p>Public Health Significance</p>	<p>The purpose of this method is to provide laboratories supporting the NSSP the ability to rapidly quantify <i>Vibrio parahaemolyticus</i> (<i>V.p.</i>) from oysters using a high throughput real-time PCR protocol.</p> <p>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 <i>Vibrio parahaemolyticus</i> (<i>V.p.</i>) Culture based assays for the enumeration of <i>V.p.</i> 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 (<i>Crassostrea gigas</i>) for (<i>V.p.</i>) 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 <i>V.p.</i> case data, experiences in WA State over the course of a season or seasons, and requests from the Office of Shellfish &amp; Water Protection for enhanced detection of pathogenic <i>V.p.</i> strains and additional surveillance capabilities.</p> <p>The real-time PCR assay redesigned and implemented in 2009 and utilized through the 2013 <i>V.p.</i> monitoring season (June – September) was designed to detect <i>V.p.</i> using the species-specific thermolabile hemolysin gene (<i>tlh</i>) and virulent <i>V.p.</i> using the thermostable direct hemolysin gene (<i>tdh</i>). This assay was designed for high throughput in a 384-well based format. Additionally, the <i>tlh</i> and <i>tdh</i> targets were redesigned yielding amplicons between 50-150 base pairs. This is optimal for real-time PCR and is known to produce consistent results<sup>1</sup>. 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.</p>
<p>Cost Information</p>	
<p>Action by 2015 Laboratory Method Review Committee</p>	<p>Recommended referral of Proposal 15-110 to an appropriate committee as determined by the Conference Chair to await completed SLV data.</p>
<p>Action by 2015 Task Force I</p>	<p>Recommended adoption of 2015 Laboratory Methods Review Committee recommendation on Proposal 15-110.</p>
<p>Action by 2015 General Assembly</p>	<p>Adopted recommendation of Task Force I on Proposal 15-110.</p>
<p>Action by FDA January 11, 2016</p>	<p>Concurred with Conference action on Proposal 15-110.</p>
<p>Action by 2017 Laboratory Committee</p>	<p>Recommended no action on Proposal 15-110. Rationale: Submitter has indicated they will not be submitting additional information</p>
<p>Action by 2017 Task Force I</p>	<p>Recommends adoption of Laboratory Committee recommendation on Proposal 15-110.</p>

Submitter	Executive Board																												
Affiliation	Interstate Shellfish Sanitation Conference (ISSC)																												
Email	issc@issc.org																												
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	<p>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.</p> <p>Submitted by method developer Jessica Jones (FDA Gulf Coast Seafood Laboratory)</p> <p>5. Approved Methods for Vibrio Enumeration</p> <table border="1" data-bbox="469 722 1421 1098"> <thead> <tr> <th></th> <th>Vibrio Indicator Type:</th> <th>Application: PHP Sample Type: Shucked</th> <th><u>Application: Reopening</u></th> </tr> </thead> <tbody> <tr> <td>EIA<sup>1</sup></td> <td><i>Vibrio vulnificus (V.v.)</i></td> <td>X</td> <td></td> </tr> <tr> <td>MPN<sup>2</sup></td> <td><i>Vibrio vulnificus (V.v.)</i></td> <td>X</td> <td></td> </tr> <tr> <td>SYBR Green 1 QPCR-MPN<sup>5</sup></td> <td><i>Vibrio vulnificus (V.v.)</i></td> <td>X</td> <td></td> </tr> <tr> <td>MPN<sup>3</sup></td> <td><i>Vibrio parahaemolyticus (V.p.)</i></td> <td>X</td> <td></td> </tr> <tr> <td>PCR<sup>4</sup></td> <td><i>Vibrio parahaemolyticus (V.p.)</i></td> <td>X</td> <td></td> </tr> <tr> <td><u>Direct Plating<sup>6</sup></u></td> <td><u><i>trh+ Vibrio parahaemolyticus (V.p.)</i></u></td> <td><u>X</u></td> <td><u>X</u></td> </tr> </tbody> </table> <p>Footnotes:</p> <p><sup>1</sup> EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992.</p> <p><sup>2</sup> 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).</p> <p><sup>3</sup> 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.</p> <p><sup>4</sup> 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.</p> <p><sup>5</sup> <i>Vibrio vulnificus</i>, ISSC Summary of Actions 2009. Proposal 09-113, Page 123.</p> <p><sup>6</sup> <u>Direct plating method for trh as described in Nordstrom et al., 2006.</u></p>		Vibrio Indicator Type:	Application: PHP Sample Type: Shucked	<u>Application: Reopening</u>	EIA <sup>1</sup>	<i>Vibrio vulnificus (V.v.)</i>	X		MPN <sup>2</sup>	<i>Vibrio vulnificus (V.v.)</i>	X		SYBR Green 1 QPCR-MPN <sup>5</sup>	<i>Vibrio vulnificus (V.v.)</i>	X		MPN <sup>3</sup>	<i>Vibrio parahaemolyticus (V.p.)</i>	X		PCR <sup>4</sup>	<i>Vibrio parahaemolyticus (V.p.)</i>	X		<u>Direct Plating<sup>6</sup></u>	<u><i>trh+ Vibrio parahaemolyticus (V.p.)</i></u>	<u>X</u>	<u>X</u>
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Public Health Significance	Scientific evidence suggests that the presence of the <i>trh</i> gene in <i>V. parahaemolyticus (V.p.)</i> is correlated with higher virulence. Additionally, at the 2013 conference, proposal 13-202 was adopted which requires testing for the presence of <i>trh</i> prior to reopening of growing areas closed as a result of <i>V.p.</i> illnesses [Chapter II @.01.F(5)]. Currently, there are no NSSP approved methods for enumeration of <i>trh</i> . This method is a needed option for testing following <i>V.p.</i> 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.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 15-112 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	Recommends adoption of Lab Committee recommendation on Proposal 15-112

Submitter	Executive Board
Affiliation	Interstate Shellfish Sanitation Conference (ISSC)
Email	issc@issc.org
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	<p>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.</p> <p>Submitted by the developer Kevin Calci (FDA Gulf Coast Seafood Laboratory)</p> <p>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.</p> <p>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/100ml to 1.0 x 10<sup>6</sup> pfu/1 00ml.</p>
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.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 15-114 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	Recommends adoption of Laboratory Committee recommendation on Proposal 15-114.

Submitter	J. Michael Hickey
Affiliation	Massachusetts Division of Marine Fisheries
Email	Michael.hickey@state.ma.us
Proposal Subject	Marina Definition
Specific NSSP Guide Reference	Section I Purposes and Definitions B. Definition of Terms (71) Marina
Text of Proposal/ Requested Action	<p><b>(71) Marina</b> means any water area with a structure (docks, basin, floating docks, etc.) which is:</p> <ul style="list-style-type: none"> <li>(a) Used for docking or otherwise mooring vessels <u>to a dock or pier</u>; and</li> <li>(b) Constructed to provide temporary or permanent docking space for more than ten boats.</li> </ul>
Public Health Significance	<p>There has been ever increasing pressure to include mooring areas which are not defined in the Model Ordinance into the Marina Proper; Section II- Chapter IV @ <b>.05 Marinas</b>. When the criteria were developed to deal with the classification of Marinas as defined, and the determination of a buffer zone in adjacent waters; mooring areas were purposely not included. It was left to the discretion of the SSCA to determine, classification criteria that could be different from the marina calculations depending on local circumstances and local knowledge. FDA is now interpreting anchors, chains and mooring blocks as “structures “and as such is requiring that mooring areas be treated as Marinas. Structure in the Marina definition means “(docks, basin, floating docks, etc.)” not anchors and chains.</p> <p>There are many different kinds of marinas, some essentially parking lots with no overnight occupancy and others that are destination mooring areas. Some states have outstanding boat pump out programs and large areas, if not the entire state, that are federal No Discharge Areas, in addition to local well enforced no discharge and occupancy regulations or by-laws.</p> <p>SSCAs should be allowed to assess the pollution impact of mooring areas based on actual circumstances and data not just an assumed risk.</p>
Cost Information	NONE, Possible savings to SSCAs.
Action By 2017 Task Force I	Recommends referral of 17-100 to an appropriate committee as determined by the Conference Chair.

Submitter	Debra Barnes
Affiliation	New York State Department of Environmental Conservation
Email	<a href="mailto:debra.barnes@dec.ny.gov">debra.barnes@dec.ny.gov</a>
Proposal Subject	Parking lot mooring/anchoring areas in EPA-approved vessel no discharge zones
Specific NSSP Guide Reference	Section I Purposes and Definitions B. Definition of Terms (72) Marinas
Text of Proposal/ Requested Action	<p><b>(72) Marina</b> means any water area with a structure (docks, basin, floating docks, etc.) which is:</p> <ul style="list-style-type: none"> <li>(a) Used for docking or otherwise mooring vessels; and</li> <li>(b) Constructed to provide temporary or permanent docking space for more than ten boats</li> </ul> <p><u>Exemption: Mooring areas located within EPA-approved “vessel no discharge zones” are excluded from this definition where the requirement that a vessel’s capacity to discharge is disabled by locking or wiring shut the discharge valve of a vessel’s marine sanitation device and is enforced by the SSCA’s law enforcement/patrol program or by uniformed local/municipal law enforcement (bay constables, harbormasters, marine police, etc.)</u></p>
Public Health Significance	Boat mooring/anchoring areas located within EPA-approved vessel no discharge zones that are enforced by the SSCA’s patrol program or other state or municipal uniformed local law enforcement officials present no significant threat to public health. Having such areas designated as closed to harvest, seasonally or year-round, requires the SSCA to patrol those areas to enforce the closures. This requirement also draws enforcement resources away from other closed areas with actual water quality problems of public health significance.
Cost Information	\$ 0.00
Action By 2017 Task Force I	Recommends no action on Proposal 17-101. Rationale: Proposal 17-101 is resolved by Task Force I action on Proposal 17-100.



Submitter	US Food & Drug Administration (FDA)
Affiliation	US Food & Drug Administration (FDA)
Email	Melissa.Abbott@fda.hhs.gov
Proposal Subject	Update definition of “replicate”
Specific NSSP Guide Reference	Section I Purposes and Definitions B. Definition of Terms (101) Replicate
Text of Proposal/ Requested Action	<b>(101) Replicate</b> is defined as two (2) <u>laboratory analyses conducted from the same sample filters for thermostable direct hemolysin (tdh) analysis from the same homogenate</u> at the same dilution.
Public Health Significance	The current definition of “replicate” is specific for one type of laboratory analysis conducted infrequently in the NSSP. The proposed change provides the same intent for the definition of “replicate”, but makes it more broadly applicable.
Cost Information	None.
Action by 2017 Laboratory Committee	Recommended adoption of Proposal 17-102 as amended.  <b>(101) Replicate</b> is defined as two (2) <u>, or more,</u> laboratory analyses conducted from the same sample at the same dilution <u>using the same method.</u>
Action by 2017 Task Force I	Recommends adoption of the Laboratory Committee recommendation.

Submitter	US Food & Drug Administration (FDA)
Affiliation	US Food & Drug Administration (FDA)
Email	Melissa.Abbott@fda.hhs.gov
Proposal Subject	Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) Method for the Determination of Diarrhetic Shellfish Poisoning (DSP) Toxins in Shellfish.
Specific NSSP Guide Reference	Section IV. (Guidance Documents), Chapter II. (Growing Areas), Section .14 (Approved Laboratory Tests), Table 2 (Approved Methods for Biotoxin Testing) and Table 4 (Approved Limited Use Methods for Marine Biotoxin Testing)
Text of Proposal/ Requested Action	The intention is for this method to be an Approved Method for Marine Biotoxin Testing for clams and that it should appear in Section IV. (Guidance Documents), Chapter II. (Growing Areas), Section .14 (Approved Laboratory Tests), Table 2 (Approved Methods for Marine Biotoxin Testing) under the new heading: Biotoxin Type: Diarrhetic Shellfish Poisoning (DSP), and the applications should be (1) Growing Area Survey and Classification and (2) Controlled Relaying with the sample type of Shellfish for both. In addition, the method should also be included in Table 4 (Approved Limited Use Methods for Biotoxin Testing) for mussels and oysters. Additional validation will be submitted later in order to move mussels and oysters also to Table 2.
Public Health Significance	Method will be used to control hazard from Diarrhetic Shellfish Poisoning (DSP) in shellfish. No methods for DSP are currently listed in the NSSP yet shellfish harvesting closures have occurred due to these toxins in Texas since 2008, in the Pacific Northwest since 2011, and in the New England region since 2015. Regulatory laboratories in these regions are currently using best available science of LC-MS/MS according to the EU reference SOP for LC-MS/MS determination of lipophilic shellfish toxins.
Cost Information	Capital equipment purchases: \$500,000. Consumable cost per sample: \$10.00
<b>Research Needs Information</b>	
a. Proposed specific research need/ problem to be addressed	No methods are currently approved for use to control DSP hazard under the NSSP. The EU has adopted LC-MS/MS as the reference method for all of the lipophilic shellfish toxins, including DSP. This method is a modified version of the EU LC-MS/MS method optimized specifically for DSP.
b. Explain the relationship between proposed research need and program change recommended in the proposal	The proposal will provide full SLV data for the detection of DSP toxins in clams. Therefore it would be considered an Approved Method for clams (Table 2). Based on the immediate need for this method, it was felt that the submission should be made with the available data for clam with the intention of subsequent validation for mussels and oysters, for which only preliminary data is provided here. Therefore, the method should be considered for Approved Limited Use at this time for mussel and oyster and be included in Table 4 for these matrices.
c. Estimated cost	\$10,000
d. Proposed sources of funding	FDA internal funding
e. Time frame anticipated	Submission of all materials in order to be reviewed prior to the 2017 bi-annual ISSC meeting.
<b><i>For Research Guidance Committee Use Only</i></b>	Relative priority rank in terms of resolving research need <input type="checkbox"/> Immediate <input type="checkbox"/> Required <input type="checkbox"/> Valuable <input type="checkbox"/> Important <input type="checkbox"/> Other

Action by 2017 Laboratory Committee	Recommended the following: 1) Adoption of Proposal 17-103 as an Approved Method for clams 2) Referral of Proposal 17-103 to an appropriate committee as determined by the Conference Chair to determine the appropriateness of the method for mussels and oysters.
Action by 2017 Task Force I	Recommends adoption of Laboratory Committee recommendations on Proposal 17-103.

Submitter	US Food & Drug Administration (FDA)
Affiliation	US Food & Drug Administration (FDA)
Email	Melissa.Abbott@fda.hhs.gov
Proposal Subject	Guidance for verifying the performance of a quantitative single laboratory validated (SLV) method of analysis being transferred from the originating laboratory/submitter to the implementing laboratory before being placed in service by the implementing laboratory.
Specific NSSP Guide Reference	Section IV Guidance Documents – Chapter II. Growing Areas
Text of Proposal/ Requested Action	<p>Section IV Guidance Documents – Chapter II. Growing Areas <u><a href="#">.20 Quantitative Analytical Method Verification</a></u></p> <p><u><a href="#">This guidance is provided to verify the performance of a quantitative single laboratory validated (SLV) method of analysis being transferred from the originating laboratory/submitter to the implementing laboratory before being placed in service by the implementing laboratory. The following performance criteria are to be verified: recovery, precision (repeatability or intermediate precision), linear range, limit of detection (LOD), limit of quantitation (LOQ), measurement uncertainty and comparability when applicable to a new or modified method used as a substitute/alternative to an established (NSSP) method.</a></u></p> <p><u><a href="#">Recovery is the fraction or percentage of an analyte(s)/measurand(s)/organism(s) of interest recovered after sample analysis.</a></u></p> <p><u><a href="#">Precision is the closeness of agreement between independent test results obtained under the stipulated conditions of repeatability (same laboratory, same analyst) or intermediate precision (same laboratory, different/multiple analysts).</a></u></p> <p><u><a href="#">Linear Range is the range within the working range where the results are proportional to the concentration of the analyte(s)/measurand(s)/organism(s) of interest present in the sample.</a></u></p> <p><u><a href="#">Limit of Detection (LOD) is the minimum concentration at which the analyte(s)/measurand(s)/organism(s) of interest can be identified under the conditions of the test.</a></u></p> <p><u><a href="#">Limit of Quantitation (LOQ) is the minimum concentration of analyte(s)/measurand(s)/ organism(s) of interest that can be quantified with an acceptable level of precision and accuracy under the conditions of the test.</a></u></p> <p><u><a href="#">Measurement Uncertainty is a single parameter (usually a standard deviation or confidence interval) expressing the possible range of values around the measured result within which the true value is expected to be with a stated degree of probability. It takes into account all recognized effects operating on the result including overall precision of the complete method, the method and laboratory bias and matrix effects.</a></u></p> <p><u><a href="#">Comparability is the acceptability of a new or modified method as a substitute/alternative for an established (NSSP) method.</a></u></p>

**Suggested Test Procedure: Shellfish**

Use samples free of the target analyte(s)/measurand(s)/organism(s) of interest. For each shellfish type of interest use a minimum of 12 shellfish per sample and prepare as a homogenate. For each sample take a minimum of six aliquots of the homogenate appropriately sized for the work and spike five of the six aliquots with five different concentrations of the target analyte(s)/measurand(s)/organism(s) of interest spanning 50-150% of the working range/range of interest for the method under study. Do not spike the sixth aliquot of each sample as this is the sample blank. Process each aliquot including the sample blank to determine the concentration of the target analyte(s)/measurand(s)/organism(s) of interest. Do three replicates for each aliquot excluding the sample blank. Do only one blank per sample. Repeat this process with a minimum of three samples for each shellfish type of interest collected from different growing areas, the same growing area harvested on different days or from different process lots. Use the same spike level for each sample analyzed.

**Suggested Test Procedure: Comparability Testing of Shellfish for Methods Used as a Substitute/Alternative for an Established (NSSP) Method**

For each shellfish type of interest use a minimum of 12 shellfish per sample and prepare as a homogenate. For each sample take two aliquots and analyze one by the established (NSSP) method and the other by the substitute/alternative method. Naturally contaminated (incurred) samples having a variety of concentrations spanning the range of the intended application of the method should be used in the comparison. Analyze a minimum of eight paired samples from different growing areas, the same growing area harvested on different days, from different process lots and covering different seasons as necessary. In case the target analyte(s)/measurand(s)/organism(s) of interest are intermittently present, spiked samples may be used as described above.

**Suggested Test Procedure: Water (growing water, wastewater, etc.)**

Use samples free of the target analyte(s)/measurand(s)/organism(s) of interest. For each sample take a minimum of six aliquots of the sample appropriately sized for the work and spike five of the six aliquots with five different concentrations of the target analyte(s)/measurand(s)/organism(s) of interest spanning 50-150% of the working range/range of interest for the method under study. Do not spike the sixth aliquot of each sample as this is the sample blank. Process each aliquot including the sample blank to determine the concentration of the target analyte(s)/measurand(s)/organism(s) of interest. Do three replicates for each aliquot excluding the sample blank. Do only one blank per sample. Repeat this process with a minimum of three samples choosing samples from different growing areas/wastewater plants, etc. Use the same spike level for each sample analyzed.

**Suggested Test Procedure: Comparability Testing of Water for Methods Used as a Substitute/Alternative for an Established (NSSP) Method**

For each sample take two aliquots and analyze for the target analyte(s)/measurand(s)/organism(s) of interest by both the established (NSSP) method and the substitute/alternative method. Naturally contaminated (incurred) samples having a variety of concentrations spanning the range of the intended application of the method should be used in the comparison. Analyze a minimum of eight paired samples from different growing areas/wastewater plants, etc. covering different seasons as necessary. In case the target

analyte(s)/measurand(s)/organism(s) of interest are intermittently present, spiked samples may be used as described above.

**Suggested Data Handling;** For microbiological methods use log transformed data.

Calculate the percent recovery by comparing the average recovery of the method to the average spike concentration.

Calculate the precision (repeatability, same laboratory, same analyst or intermediate precision, same laboratory, multiple/different analysts) by determining the coefficient of variation of the test data.

Calculate the linear range by plotting the test data versus the spike concentration and determining the correlation coefficient.

Calculate the limit of quantitation (LOQ) by plotting the coefficient of variation for the triplicates of each of five concentrations used per sample versus the spike concentration. There will be fifteen data points to be plotted. Using the equation of the line ( $y = mx + b$ ) where  $m$  is the slope and  $b$  is the y-intercept, calculate the LOQ by setting  $y = 10\%$  (0.1) and solving the equation for  $x$  (the LOQ).

Calculate the limit of detection (LOD) by dividing the limit of quantitation (LOQ) by 3.3 or by using the equation of the line and setting  $y = 33\%$  (0.33) and solving the equation for  $x$  (the LOD).

Calculate the measurement uncertainty by subtracting the test results from the spike concentration that produced the result and determining the two-sided 95% confidence interval of these differences. This range represents the measurement uncertainty of the test data.

Calculate the two-sided 95% confidence interval estimate for the regression line (as a whole) relating the established (NSSP) method and the substitute/alternative method.

**Suggested Method Acceptance:** Compare the performance criteria calculated in the method verification study with the values obtained in the original single laboratory validation (SLV) submission by calculating the two-sided 95% confidence interval for the laboratory's mean recovery, estimated LOD and LOQ. If the ranges calculated for the recovery, LOD, LOQ and measurement uncertainty encompass (intersect) the values for the mean recovery, LOD, LOQ and measurement uncertainty obtained from the original SLV and the data is linear over the working range/range of interest with a precision/coefficient of variation which does not exceed that obtained in the original SLV, then it can be concluded that the method (which does not also require comparability testing) has been successfully transferred. For methods that also require comparability testing, the two-sided 95% confidence interval of the regression line relating the established (NSSP) method and the substitute/alternative method should encompass the slope of the regression line relating the two methods in the original SLV. This requirement in addition to the substitute/alternative method meeting the requirements for recovery, LOD, LOQ, measurement uncertainty, precision and linearity are necessary in order to conclude that the method has been successfully transferred.

Public Health Significance	With the number of new analytical methods being adopted for use in the NSSP, it is necessary to have a standardized approach to verify the successful transfer of the method from the originating laboratory/SLV submitter to the implementing laboratory before the method is placed in service.
Cost Information	Not Available
Action By 2017 Laboratory Committee	<p>Recommended adoption of Proposal 17-104 as amended.</p> <p>Section IV Guidance Documents – Chapter II. Growing Areas .20 Quantitative Analytical Method Verification</p> <p>This guidance is provided to <u>aid laboratories</u> verifying the performance of an <u>NSSP Approved Method or Approved Limited Use Method</u> <del>quantitative single laboratory validated (SLV) method</del> of analysis being transferred from the originating laboratory/submitter to the implementing laboratory before being placed in service by the implementing laboratory. <u>When a laboratory implements an NSSP method for the first time, the method</u> <del>The following</del> performance <u>must be verified in that laboratory. The following performance</u> criteria are to be verified: recovery, <u>measurement uncertainty</u>, precision (repeatability <del>or</del> <u>and</u> intermediate precision), linear range, limit of detection (LOD), limit of quantitation (LOQ), <u>measurement uncertainty</u> and comparability <del>when applicable to a new or modified method used as a substitute/alternative to an established (NSSP) method.</del></p> <p><b><u>Recovery and Measurement Uncertainty.</u></b> <u>Recovery</u> is the fraction or percentage of an analyte(s)/<del>measurand(s)</del>/organism(s) of interest recovered after sample analysis. <u>Measurement uncertainty expresses the possible range of values around the measured result within which the true value is expected to be with a stated degree of probability.</u></p> <p><b><u>Precision</u></b> is the closeness of agreement between independent test results obtained under <del>the</del> stipulated conditions <del>of repeatability (same laboratory, same analyst) or intermediate precision (same laboratory, different/multiple analysts).</del> <u>There are multiple components of precision: repeatability and intermediate precision. Repeatability is the measure of agreement of replicate tests carried out on the same sample in the same laboratory by the same analyst within short intervals of time. Intermediate precision reflects within-laboratory precision obtained under variable conditions, such as different days, different analysts, and/or different instrumentation.</u></p> <p><b><u>Linear Range, Limit of Detection, and Limit of Quantitation.</u></b> <u>Linear range</u> is the range within the working range where the results are proportional to the concentration of the analyte(s)/<del>measurand(s)</del>/organism(s) <del>of interest</del> present in the sample. <u>The Limit of Detection (LOD) is the minimum concentration at which the analyte(s)/ organism(s) can be identified. LOD is matrix and analyte dependent. The Limit of Quantitation (LOQ)</u></p> <p><b><u>Limit of Detection (LOD)</u></b> <del>is the minimum concentration at which the analyte(s)/measurand(s)/organism(s) of interest can be identified under the conditions of the test.</del></p> <p><b><u>Limit of Quantitation (LOQ)</u></b> <del>is the minimum concentration of</del> analyte(s)/<del>measurand(s)</del>/ organism(s) <del>of interest</del> that can be quantified with an</p>

acceptable level of precision and accuracy under the conditions of the test.

**Measurement Uncertainty** is a single parameter (usually a standard deviation or confidence interval) expressing the possible range of values around the measured result within which the true value is expected to be with a stated degree of probability. It takes into account all recognized effects operating on the result including overall precision of the complete method, the method and laboratory bias and matrix effects.

**Comparability** is the acceptability of a new or modified method as a substitute/alternative for an established (NSSP) method.

**Suggested Test Procedure: Shellfish**

Use samples free of the target analyte(s)/~~measurand(s)~~/organism(s) of interest. For each shellfish type of interest use a minimum of 10-12 animals~~shellfish~~ per sample and prepare as a homogenate. For each sample take a minimum of six aliquots of the homogenate appropriately sized for the work and spike five of the six aliquots with five different concentrations of the target analyte(s)/~~measurand(s)~~/organism(s) of interest spanning 50-150% beyond the desired~~of the~~ working range/range of interest for the method under study and including levels half, at, and twice the action level (or analytical level of interest). Do not spike the sixth aliquot of each sample; ~~as~~ this is the sample blank. Process each aliquot including the sample blank to determine the concentration of the target analyte(s)/~~measurand(s)~~/organism(s) of interest. ~~Do three replicates for~~ For each aliquot, excluding the sample blank, sub-aliquot for three replicate analysis. ~~Do only one blank per sample.~~ Repeat this process for each shellfish type of interest with a minimum of three samples ~~for each shellfish type of interest~~ collected from different growing areas, the same growing area harvested on different days or from different process lots. Use the same spike levels for each sample analyzed.

Comparability is the acceptability of a new or modified method as a substitute/alternative for an established (NSSP) method. (Should be included if intended as an alternative or a substitute for an established method accepted by the NSSP.)

**Suggested Test Procedure: Comparability Testing of Shellfish for Methods Used as a Substitute/Alternative for an Established (NSSP) Method**

For each shellfish type of interest use a minimum of 10-12 shellfish per sample and prepare as a homogenate. For each sample take two aliquots and analyze one by the established (NSSP) method and the other by the substitute/alternative method. Naturally ~~contaminated~~ (incurred) samples having a variety of concentrations spanning the range of the intended application of the method should be used in the comparison. Analyze a minimum of eight paired samples from different growing areas, the same growing area harvested on different days, from different process lots and covering different seasons as necessary. In cases where the occurrence of the target analyte(s)/~~measurand(s)~~/organism(s) of interest are is intermittently present, spiked samples may be used as described above.

**Suggested Test Procedure: Water (growing water, wastewater, etc.)**

Use samples free of the target analyte(s)/~~measurand(s)~~/organism(s) of interest. For each sample take a minimum of six aliquots of the sample appropriately sized for



the work and spike five of the six aliquots with five different concentrations of the target analyte(s)/measurand(s)/organism(s) of interest spanning 50-150% of the working range/range of interest for the method under study. Do not spike the sixth aliquot of each sample as this is the sample blank. Process each aliquot including the sample blank to determine the concentration of the target analyte(s)/measurand(s)/organism(s) of interest. Do three replicates for each aliquot excluding the sample blank. Do only one blank per sample. Repeat this process with a minimum of three samples choosing samples from different growing areas/wastewater plants, etc. Use the same spike level for each sample analyzed.

**Suggested Test Procedure: Comparability Testing of Water for Methods Used as a Substitute/Alternative for an Established (NSSP) Method**

For each sample take two aliquots and analyze for the target analyte(s)/measurand(s)/organism(s) of interest by both the established (NSSP) method and the substitute/alternative method. Naturally contaminated (incurred) samples having a variety of concentrations spanning the range of the intended application of the method should be used in the comparison. Analyze a minimum of eight paired samples from different growing areas/wastewater plants, etc. covering different seasons as necessary. In case the target analyte(s)/measurand(s)/organism(s) of interest are intermittently present, spiked samples may be used as described above.

**Suggested Data Handling;** For microbiological methods use log transformed data.

Calculate the percent recovery by comparing the average recovery of the method to the average spike concentration.

Calculate the precision (repeatability, same laboratory, same analyst or intermediate precision, same laboratory, multiple/different analysts) by determining the coefficient of variation of the test data.

Calculate the linear range by plotting the test data versus the spike concentration and determining the correlation coefficient.

Calculate the limit of quantitation (LOQ) by plotting the coefficient of variation for the triplicates of each of five concentrations used per sample versus the spike concentration. There will be fifteen data points to be plotted. Using the equation of the line ( $y = mx + b$ ) where  $m$  is the slope and  $b$  is the  $y$  intercept, calculate the LOQ by setting  $y = 10\%$  (0.1) and solving the equation for  $x$  (the LOQ).

Calculate the limit of detection (LOD) by dividing the limit of quantitation (LOQ) by 3.3 or by using the equation of the line and setting  $y = 33\%$  (0.33) and solving the equation for  $x$  (the LOD).

Calculate the measurement uncertainty by subtracting the test results from the spike concentration that produced the result and determining the two-sided 95% confidence interval of these differences. This range represents the measurement uncertainty of the test data.

Calculate the two-sided 95% confidence interval estimate for the regression line (as a whole) relating the established (NSSP) method and the substitute/alternative

	<p><del>method.</del></p> <p><b>Suggested Method Acceptance:</b> Compare the performance criteria calculated in the method verification study with the values obtained in the original single laboratory validation (SLV) submission by calculating the two-sided 95% confidence interval for the laboratory’s mean recovery, estimated LOD and LOQ. If the ranges calculated for the recovery, LOD, LOQ and measurement uncertainty encompass (intersect) the values for the mean recovery, LOD, LOQ and measurement uncertainty obtained from the original SLV and the data is linear over the working range/range of interest with a precision/coefficient of variation which does not exceed that obtained in the original SLV, then it can be concluded that the method (which does not also require comparability testing) has been successfully transferred. For methods that also require comparability testing, the two-sided 95% confidence interval of the regression line relating the established (NSSP) method and the substitute/alternative method should encompass the slope of the regression line relating the two methods in the original SLV. This requirement in addition to the substitute/alternative method meeting the requirements for recovery, LOD, LOQ, measurement uncertainty, precision and linearity are necessary in order to conclude that the method has been successfully transferred.</p>
<p>Action By 2017 Task Force I</p>	<p>Recommends adoption of the Laboratory Committee recommendation on Proposal 17-104.</p>

Submitter	Blaine N. Rhodes
Affiliation	Washington State Department of Health
Email	blaine.rhodes@doh.wa.gov
Proposal Subject	High Pressure Liquid Chromatography (HPLC) test method for Domoic Acid (Amnesic Shellfish Poison)
Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter II. Growing Areas, 4. Approved Limited Use Methods for Marine Biotoxin Testing, HPLC entry for Biotoxin Type: Amnesic Shellfish Poisoning (ASP), p. 263 The method reference is in the footnote of the Approved Limited Use Methods for Marine Biotoxin Testing table that includes use of HPLC to detect ASP in shellfish references the method used by M.A. Quilliam, et al, to publish the Technical Report, “Rapid Extraction and Cleanup Procedure for the Determination of Domoic Acid in Tissue Samples” in 1991. At the time of publication, however, the Report did not include a full operating procedure.
Text of Proposal/ Requested Action	The Washington State Shellfish Biotoxins Laboratory proposes to perform a Single Laboratory Validation (SLV) for the detection of ASP by the HPLC method that was developed at the WA Public Health Laboratories (WAPHL) in 1991, modified in 1996 and which is currently used in the Laboratory, running the CFSAN recommended method (Quilliam et. al 1991) in tandem with the WAPHL method.
Public Health Significance	<p>Marine biotoxins are poisons that are produced by certain kinds of microscopic algae (a type of phytoplankton) that are naturally present in marine waters, normally in amounts too small to be harmful. Molluscan shellfish (shellfish with hinged shells such as oysters, clams, and mussels) are filter feeders and ingest any particles, both good and bad, that's in the surrounding water. Algae is a food source for them, and HABs create a plentiful food supply. When shellfish eat toxin producing algae, the toxin remains in their system; large amounts of algae means more toxin can concentrate in their tissue. Biotoxins don't harm shellfish, but they can accumulate in shellfish to levels that can cause illness or death in humans and other mammals that eat them.</p> <p>Domoic Acid, the agent responsible for Amnesic Shellfish Poisoning, is a naturally occurring shellfish biotoxin. It is one of several potent neurotoxins that acts as agonists to glutamate, a neurotransmitter in our central nervous systems.</p> <p>It is imperative that modern, rapid and accurate laboratory testing methods be developed or refined to assure that adequate monitoring programs are in place to protect public health.</p>
Cost Information	There is no significant difference in cost between the two methods.
<b>Research Needs Information</b>	
a. Proposed specific research need/ problem to be addressed	<p>Between the 1991 time of publication and adoption of the CFSAN procedural interpretation of this particular method by the ISSC in 2014 most state laboratories that needed to screen for Amnesic shellfish Poisoning have developed their own in house HPLC methods, which were roughly based on the Quilliam report. Over time, the methods have been updated with minor changes and modernizations in the technology which has increased sensitivity and throughput of the method. Because of the increased speed and accuracy of the WAPHL method, protection of public health will be increased as compared with the CFSAN recommended method.</p> <p>The FDA is now insisting that all laboratories standardize on the CFSAN Procedure,</p>

	<p>which has demonstrated lower sensitivity and longer sample cycle times than the current method used by the proposing laboratory. Changing to the CFSAN method at this time, while there are increased ASP concentrations on the Pacific Coast and therefore higher sample loads at the laboratory is viewed as detrimental to public health in Washington State.</p> <p>CFSAN needs to be satisfied that the methods in place at the labs testing for ASP are robust and may not need reversion to 25-year old technology and the ISSC SLV is the proper mechanism for this demonstration. Unfortunately there is currently no Proficiency Testing program offered by CFSAN for biotoxins which would also lend itself to demonstrating the comparability of the different methods.</p>
<p>b. Explain the relationship between proposed research need and program change recommended in the proposal</p>	<p>The SLV is the mechanism by which the laboratories of the ISSC can demonstrate new methodology and technologies. The Washington State Shellfish Biotoxins Laboratory feels the method they have used since 1996 is superior to the CFSAN procedural interpretation of Quilliam’s 1991 work. Furthermore, the CFSAN recommended procedure has not undergone a published ISSC SLV and its adoption by the FDA seems premature.</p>
<p>c. Estimated cost</p>	<p>The cost of this study will be borne by the Washington State Public Health Laboratories.</p>
<p>d. Proposed sources of funding</p>	<p>N/A</p>
<p>e. Time frame anticipated</p>	<p>2 years</p>
<p><b><i>For Research Guidance Committee Use Only</i></b></p>	<p>Relative priority rank in terms of resolving research need</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Immediate</li> <li><input type="checkbox"/> Required</li> <li><input type="checkbox"/> Valuable</li> <li><input type="checkbox"/> Important</li> <li><input type="checkbox"/> Other</li> </ul>
<p>Action by 2017 Task Force I</p>	<p>This Proposal was not debated by Task Force I. The proposal was ruled invalid prior to referral to Task Force I.</p>

Submitter	Pacific Rim Shellfish Sanitation Association
Affiliation	Sitka Tribe of Alaska
Email	michael.jamros@sitkatriben-sns.gov
Proposal Subject	Matrix Expansion for the Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination to Allow Use with Geoduck
Specific NSSP Guide Reference	Section IV, Chapter II.14 -- NSSP Approved Laboratory Tests (p. 261 Table 2. Approved Methods for Marine Biotxin Testing -- footnote 2, and/or p. 263 Table 4. Limited Use Methods for Marine Biotxin Testing -- footnote 5)
Text of Proposal/ Requested Action	<p>This submission presents the ‘Matrix Expansion for the Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination to Allow Use with Geoduck’ for consideration as an NSSP Approved Method for Marine Biotxin Testing for PSP in Geoduck. 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.</p> <p>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.</p> <p>The RBA has undergone AOAC single and multi-laboratory validation and is designated through AOAC as an Official Method of Analysis (OMA 2011.27). The RBA is currently an NSSP Approved Method for Marine Biotxin Testing for PSP in mussels as well as a NSSP approved for Limited Use Method for clams and scallops for the purpose of screening and precautionary closure for PSP (ISSC 2015 Summary of Actions Proposal 13-114). Here we provided results from a single laboratory validation study for use of RBA with the matrix geoduck (<i>Panopea</i>) viscera for submission for the RBA to be considered for approval as an NSSP Approved Method for Marine Biotxin Testing for PSP.</p>
Public Health Significance	<p>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</p>

	<p>Approved Method for Marine Biotxin Testing for PSP toxicity determination in geoduck (<i>Panopea</i>) 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.</p>
<p>Cost Information</p>	<p>For the assay:          The estimated cost per 96-well plate assay is ~\$95.00. Including standards and samples with triplicate measurements (as well as three dilutions per sample [ranging from 3.5-600 µg STX eq 100 g<sup>-1</sup>] to ensure the unknown samples fall within linear range of assay), the cost per sample for quantitation would be ~\$13.60. If running multiple plates or in screening mode, sample costs would be reduced.          (Van Dolah 2013)</p> <p>For proposal:          The cost of RBA work for geoduck matrix expansion is covered by an existing grant awarded to the Sitka Tribe of Alaska. Naturally contaminated samples from Washington and Alaska are pulled from regular samples tested by the respective state agencies that are part of routine shellfish testing. Therefore, there is no additional cost or funding necessary for the proposal.</p>
<p>Research Needs Information</p>	
<p>a. Proposed specific research need/ problem to be addressed</p>	<p>Paralytic shellfish poisoning (PSP) is a foodborne illness caused by ingestion of contaminated shellfish. The paralytic shellfish toxin, saxitoxin (STX), and its analogs are potent neurotoxins responsible for PSP. Marine dinoflagellates and freshwater cyanobacteria produce STX. The STX can accumulate in filter-feeding bivalve mollusks to levels that are toxic to humans. Symptoms of PSP include: tingling and numbness of the perioral area and extremities, drowsiness, incoherence, loss of motor control, and following high dose consumption, respiratory paralysis.</p> <p>In 1965 the mouse bioassay (MBA) was adopted as an official AOAC method for STX determination. The MBA has been the only method available for PSP testing for the last five decades. Both North American and European regulatory agencies have expressed the desire to transition to a more humane PSP testing method that does not require the use of live animals and is not subject to the matrix effects documented for the MBA (Turner 2012). Recently, the NSSP approved a post-column oxidation liquid chromatographic (PCOX) method and a receptor binding assay (RBA) as alternatives to the MBA. The PCOX method is approved for full use; whereas, the RBA is approved for limited use (the RBA is only approved for shellfish matrices evaluated in the single lab and multi-lab validation studies). Both the PCOX and RBA are sensitive quantitative assays for STX detection, and they do not require the use of live animals.</p> <p>The RBA is approved for regulatory testing of mussels as an alternative to the MBA and is approved for limited use as a screening tool for clams and scallops, but is not yet approved for use with geoduck (<i>Panopea</i>) due to a lack of data. Geoduck are a major commercial product, with large dive fisheries in Southeast Alaska and the Puget Sound that require STX testing. This proposal requests consideration for the NSSP RBA approval to be expanded to include geoduck. The proposal provides data from a single laboratory validation (SLV) of the RBA for geoduck testing as support for this request.</p>

<p>b. Explain the relationship between proposed research need and program change recommended in the proposal</p>	<p>This method is intended for use as an NSSP Approved Limited Use Method for screening for PSP toxicity in shellfish. The RBA serves as an alternative to the MBA in these applications, offering a measure of composite toxicity with high throughput and the elimination of live animal testing. (Van Dolah 2013) This application is for the addition of geoduck to the list of matrices approved for use with the RBA.</p> <p>There is an acknowledged need for this method in NSSP. A significant portion of the Washington and Alaska state shellfish industries are comprised of the harvest of geoduck. Approval of the RBA for use with geoduck would provide an alternative to (1) the MBA, which uses live animals, and (2) the PCOX HPLC method, which requires costly equipment and skilled personnel and offers low throughput. Acceptance of the RBA as an NSSP Approved Method for Marine Biotoxin Testing for PSP toxicity determination in geoduck 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.</p> <p><b>References:</b></p> <p>Van Dolah 2013. ISSC application: Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination.</p> <p>Van Dolah et al. 2012. Determination of paralytic shellfish toxins in shellfish by receptor binding assay: collaborative study. J AOAC Int. May-Jun;95(3):795-812.</p> <p>Van Dolah et al. 2009. Single-laboratory validation of the microplate receptor binding assay for paralytic shellfish toxins in shellfish. J AOAC Int. Nov-Dec;92(6):1705-13.</p> <p>Ruberu et al. 2012. Evaluation of variability and quality control procedures for a receptor-binding assay for paralytic shellfish poisoning toxins. Food Addit Contam Part A Chem Anal Control Expo Risk Assess.29(11):1770-9.</p> <p>Turner et al. 2012. Investigations into matrix components affecting the performance of the official bioassay reference method for quantitation of paralytic shellfish poisoning toxins in oysters. Toxicol : official journal of the International Society on Toxicology 59, 215-230.</p> <p>OMA 2011.27. AOAC Official Method 2011.27 Paralytic shellfish toxins (PSTs) in shellfish, receptor binding assay. In Official Methods of Analysis of AOAC International. <a href="http://www.eoma.aoac.org">http://www.eoma.aoac.org</a>.</p>
<p>c. Estimated cost</p>	
<p>d. Proposed sources of funding</p>	<p>This research was performed by the Sitka Tribe of Alaska using funds from an ANA ERE grant</p>
<p>e. Time frame anticipated</p>	

<p><i>For Research Guidance Committee Use Only</i></p>	<p>Relative priority rank in terms of resolving research need</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Immediate</li> <li><input type="checkbox"/> Required</li> <li><input type="checkbox"/> Valuable</li> <li><input type="checkbox"/> Important</li> <li><input type="checkbox"/> Other</li> </ul>
<p>Action By 2017 Laboratory Committee</p>	<p>Recommended referral to an appropriate committee as determined by the Conference Chair.</p>
<p>Action By 2017 Task Force I</p>	<p>Recommends adoption of the 2017 Laboratory Committee recommendation on Proposal 17-106.</p>



Submitter	Leanne J. Flewelling
Affiliation	Florida Fish and Wildlife Conservation Commission
Email	leanne.flewelling@myfwc.com
Proposal Subject	ISSC Method Application and Single Lab Validation of an Enzyme-linked Immunosorbent Assay (ELISA) method for the determination of Neurotoxic Shellfish Poisoning (NSP) toxins in hard clams, sunray venus clams, and oysters.
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas. 14 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	<p>This submission proposes that the MARBIONC brevetoxin ELISA be approved for limited use in NSP testing such that samples with negative results by ELISA (<math>\leq 1.6</math> ppm in hard clams and sunray venus clams and <math>\leq 1.80</math> ppm in oysters) would pass, while samples with positive results by ELISA (greater than these levels) would require additional testing by an Approved Method. Samples passing by ELISA would enable the same management actions as samples passing by NSP mouse bioassay (i.e., Growing Area closing or re-opening, controlled relay, and end product testing of controlled harvest as permitted within a State Authority's marine biotoxin contingency program). Samples failing by ELISA would either require additional testing by an Approved Method or could support the same management actions as samples failing by an Approved Method. ELISA could also be used as a screening method to initiate precautionary closures.</p> <p>Requested changes:</p> <p>Section IV. Guidance Documents Chapter II. Growing Areas. 14 Approved NSSP Laboratory Tests</p> <p>4. Approved Limited Use Methods for Marine Biotoxin Testing Biotoxin Type: Neurotoxic Shellfish Poisoning (NSP)</p> <p>Add columns for Biotoxin Type: Neurotoxic Shellfish Poisoning (NSP) and for Application: Controlled Harvest end product testing</p> <p>Add MARBIONC brevetoxin ELISA to table for all applications except Dockside Testing with the following footnote:</p> <p style="padding-left: 40px;">MARBIONC Brevetoxin ELISA, MARBIONC Development Group, LLC. Method can be used in place of an Approved Method for oysters, hard clams, and sunray venus clams within these parameters:</p> <p style="padding-left: 80px;">a. A negative result (<math>\leq 1.6</math> ppm in hard clams and sunray venus clams and <math>\leq 1.80</math> ppm in oysters) can substitute for testing by an Approved Method for the purposes of controlled relaying, controlled harvest end-product testing, or to re-open a previously closed area.</p> <p style="padding-left: 80px;">b. A positive result (<math>&gt; 1.6</math> ppm in hard clams and sunray venus clams and <math>&gt; 1.80</math> ppm in oysters) requires additional testing by an Approved Method or could support the same management actions as samples failing by an Approved Method.</p> <p>See attached proposed revisions to Table 4. Approved Limited Use Methods for Marine Biotoxin Testing</p>

<p>Public Health Significance</p>	<p>Brevetoxins produced by <i>K. brevis</i> are toxic to humans. Filter-feeding bivalves accumulate brevetoxins during blooms, and ingestion of contaminated shellfish can cause NSP in humans. Symptoms of NSP typically begin three to six hours after ingestion and may include nausea, diarrhea, tingling of lips or tongue, muscle ache, lack of coordination, temperature reversal, and vertigo. In severe cases, a feeling of constriction in the throat may occur. Individuals with NSP may require hospitalization but usually recover within days. To prevent NSP, shellfish harvesting areas are closed when <i>K. brevis</i> concentrations exceed 5,000 cells/L and are re-opened once <i>K. brevis</i> levels decrease and testing demonstrates that shellfish are no longer toxic. However, the APHA mouse bioassay - the only approved method for NSP testing - has many drawbacks, and the delays caused by the time required to analyze samples (two days) and low sample throughput compound economic losses. To mitigate economic harm to the shellfish industry and ensure the continued protection of public health, rapid alternative methods for NSP testing are needed.</p>
<p>Cost Information</p>	<p>Kit reagents are sold in bulk. The cost of reagents is currently \$2,400 for 15 plates and \$1,000 for 5 plates. The cost of additional consumables and reagents not included is approximately \$20 per plate. Therefore cost per sample is \$36-44 for full quantitation (5 samples per plate) and less than \$6 per sample for qualitative screening (40 samples per plate).</p>
<p>Action By 2017 Laboratory Committee</p>	<p>Recommended adoption of Proposal 17-107 as submitted.</p>
<p>Action By 2017 Task Force I</p>	<p>Recommends adoption of Proposal 17-107 as amended:</p> <p>This submission proposes that the MARBIONC brevetoxin ELISA be approved for limited use in NSP testing such that samples with negative results by ELISA (<math>\leq 1.6</math> ppm in hard clams and sunray venus clams and <math>\leq 1.80</math> ppm in oysters) would pass, while samples with positive results by ELISA (greater than these levels) would require additional testing by an Approved Method. Samples passing by ELISA would enable the same management actions as samples passing by NSP mouse bioassay (i.e., Growing Area closing or re-opening, controlled relay, and end product testing of controlled harvest as permitted within a State Authority's marine biotoxin contingency program). Samples failing by ELISA would either require additional testing by an Approved Method <u>to support management actions</u> or <del>could support the same management actions as samples failing by an Approved Method.</del> ELISA could also be used as a screening method to initiate precautionary closures. <u>A positive result (<math>&gt;1.6</math> ppm in hard clams and sunray venus clams and <math>&gt;1.8</math> ppm in oysters) requires additional testing by an approved method to support management actions.</u></p> <p>Requested changes:</p> <p>Section IV. Guidance Documents Chapter II. Growing Areas. 14 Approved NSSP Laboratory Tests</p> <p>4. Approved Limited Use Methods for Marine Biotoxin Testing Biotoxin Type: Neurotoxic Shellfish Poisoning (NSP)</p> <p>Add columns for Biotoxin Type: Neurotoxic Shellfish Poisoning (NSP) and for Application: Controlled Harvest end product testing</p>

	<p>Add MARBIONC brevetoxin ELISA to table for all applications except Dockside Testing with the following footnote:</p> <p>MARBIONC Brevetoxin ELISA, MARBIONC Development Group, LLC. Method can be used in place of an Approved Method for oysters, hard clams, and sunray venus clams within these parameters:</p> <p>a. A negative result (<math>\leq 1.6</math> ppm in hard clams and sunray venus clams and <math>\leq 1.80</math> ppm in oysters) can substitute for testing by an Approved Method for the purposes of controlled relaying, controlled harvest end-product testing, or to re-open a previously closed area.</p> <p>b. A positive result (<math>&gt; 1.6</math> ppm in hard clams and sunray venus clams and <math>&gt; 1.80</math> ppm in oysters) requires additional testing by an Approved Method or <u>to support management actions</u><del>could support the same management actions as samples failing by an Approved Method.</del></p> <p>See attached proposed revisions to Table 4. Approved Limited Use Methods for Marine Biotxin Testing</p>
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Submitter	Titan Fan, Ph.D
Affiliation	Beacon Analytical Systems, Inc.
Email	titan@beaconkits.com, holly@beaconkits.com
Proposal Subject	Detection of ASP biotoxins in <i>Mytilus edulis</i> (Blue Mussel) shellfish by ELISA for Domoic Acid
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas, Table 2.
Text of Proposal/ Requested Action	SLV Proposal supporting the use of Beacon Domoic Acid Plate Kit as fit for purpose as an Approved NSSP Method for quantification of ASP toxins in Marine Biotoxin Monitoring Programs.
Public Health Significance	<p>Shellfish consumption can pose a mammal and bird health risk (1) when toxins produced by cyanobacteria present in water and shellfish growing areas, concentrate in shellfish meat due to their filter feeding system. A Closed Status for any growing areas with shellfish tissue levels of ASP of 2 mg/100 g (20 ppm) or more have been established to protect the consumer from exposure (2). The most common clinical signs of acute toxicity are gastrointestinal distress, confusion and neurological symptoms, disorientation, memory loss, coma and death (3).</p> <p>(1). M.Fernanda, F, Mazzillo, C. Pomeroy, J.Kuo, P. Ramondi,R. Prado, M.Silver. 2010. Aquatic Biol. 9:1-12.</p> <p>(2). NSSP Guide for the Control of Molluscan Shellfish: 2015 Rev. Sec.IV Chp. II., p 231.</p> <p>(3). Kathi A. Lefebvre, Alison Robertson, Toxicon, Vol. 56, Issue 2, 15 Aug. 2010, p. 218-230.</p>
Cost Information	The price per sample is eight to nine dollars dependent upon the number of samples tested during one ELISA run, and/or the volume of kits purchased. There is an ELISA Plate Reader requirement. They can range in price from a low cost unit at approximately \$2,600 to a higher cost of \$15,000 USD unit depending upon complexity.
Action By 2017 Laboratory Committee	Recommended referral of Proposal 17-108 to an appropriate committee as determined by the Conference Chair.
Action By 2017 Task Force I	Recommends adoption of the Laboratory Committee on Proposal 17-108

Submitter	U.S. Food and Drug Administration
Affiliation	U.S. Food and Drug Administration
Email	<a href="mailto:Melissa.abbott@fda.hhs.gov">Melissa.abbott@fda.hhs.gov</a>
Proposal Subject	Domoic Acid (Amnesic Shellfish Poisoning) HPLC Method Laboratory Evaluation Checklist
Specific NSSP Guide Reference	Section IV Guidance Documents Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
Text of Proposal/ Requested Action	The requested action is to adopt the text of the attached checklist for the HPLC method for detecting domoic acid and to append the checklist to the list of NSSP Laboratory Evaluation Checklists at the end of .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.
Public Health Significance	Currently, there is no checklist adopted by the ISSC for the method approved under the NSSP for domoic acid. The attached checklist provides the quality assurance and method requirements that laboratory evaluation officers will use to evaluate laboratories implementing the HPLC method for domoic acid to support the NSSP. The checklist documents the number of critical, key or other nonconformities and how overall laboratory status for the method is determined.
Cost Information	
Action By 2017 Laboratory Committee	Recommended adoption of Proposal 17-109 as amended (attached). Available upon request (9 page document).
Action By 2017 Task Force I	Recommends adoption of Laboratory Committee recommendation on Proposal 17-109.

Submitter	U.S. Food and Drug Administration (FDA)
Affiliation	FDA
Email	Melissa.abbott@fda.hhs.gov
Proposal Subject	Alkaline Phosphatase Probe Method for <i>Vibrio vulnificus</i> and <i>Vibrio parahaemolyticus</i> Detection in Oysters - Laboratory Evaluation Checklist
Specific NSSP Guide Reference	Section IV Guidance Documents Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
Text of Proposal/ Requested Action	The requested action is to adopt the text of the attached checklist for the probe method for detecting <i>Vibrio vulnificus</i> (Vv) and <i>Vibrio parahaemolyticus</i> (Vp) in oysters and to append the checklist to the list of NSSP Laboratory Evaluation Checklists at the end of .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.
Public Health Significance	Currently, there is no checklist adopted by the ISSC for the probe method for detecting Vv and Vp in oysters. The attached checklist provides the quality assurance and method requirements that laboratory evaluation officers will use to evaluate laboratories implementing this method in support of the NSSP. The checklist documents the number of critical, key or other nonconformities and how overall laboratory status for the method is determined.
Cost Information	NA
Action By 2017 Laboratory Committee	Recommended Proposal 17-110 be referred to an appropriate committee as determined by the Conference Chair
Action By 2017 Task Force I	Recommends adoption of the Laboratory Committee recommendation on Proposal 17-110.

Submitter	U.S. Food and Drug Administration (FDA)
Affiliation	FDA
Email	<a href="mailto:Melissa.abbott@fda.hhs.gov">Melissa.abbott@fda.hhs.gov</a>
Proposal Subject	MPN Real-Time PCR Method for <i>Vibrio vulnificus</i> and <i>Vibrio parahaemolyticus</i> Detection in Oysters - Laboratory Evaluation Checklist
Specific NSSP Guide Reference	Section IV Guidance Documents Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
Text of Proposal/ Requested Action	The requested action is to adopt the text of the attached checklist for the MPN real-time PCR method for detecting <i>Vibrio vulnificus</i> (Vv) and <i>Vibrio parahaemolyticus</i> (Vp) in oysters and to append the checklist to the list of NSSP Laboratory Evaluation Checklists at the end of .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.
Public Health Significance	Currently, there is no checklist adopted by the ISSC for the MPN real-time PCR method for detecting Vv and Vp in oysters that is approved in the NSSP for Vibrio enumeration. The attached checklist provides the quality assurance and method requirements that laboratory evaluation officers will use to evaluate laboratories implementing this method in support of the NSSP. The checklist documents the number of critical, key or other nonconformities and how overall laboratory status for the method is determined.
Cost Information	NA
Action By 2017 Laboratory Committee	Recommended adoption of Proposal 17-111 as amended (attached). Available upon request (13 page document).
Action By 2017 Task Force I	Recommends adoption of Laboratory Committee recommendation on Proposal 17-111.

Submitter	US Food & Drug Administration (FDA)
Affiliation	US Food & Drug Administration (FDA)
Email	Melissa.Abbott@fda.hhs.gov
Proposal Subject	Requirements for certification of State Shellfish Laboratory Evaluation Officers (LEOs).
Specific NSSP Guide Reference	Section IV Guidance Documents – Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
Text of Proposal/ Requested Action	<p>Section IV Guidance Documents – Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists amend language.</p> <p>General Provisions</p> <ol style="list-style-type: none"> <li>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).</li> <li>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.</li> <li>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 <u>Regional</u>-Shellfish Specialist.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>7. To qualify for certification, the prospective State Shellfish LEO <del>should</del><u>must</u> <del>be:</del> <ol style="list-style-type: none"> <li>a. <del>A</del><u>Be a</u> state employee;</li> <li>b. Have <u>a minimum of two years of</u> shellfish laboratory experience or a laboratory background; <u>with three to five years of bench level experience with the specific methods that will be evaluated;</u></li> <li>c. <del>Preferably h</del><u>Have laboratory evaluation</u>-experience <u>performing laboratory evaluations or supervising a laboratory;</u> and,</li> <li>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.</li> </ol> </li> <li>8. If the prospective or current State Shellfish LEO is employed by the laboratory supporting the NSSP, that laboratory must be fully conforming to</li> </ol>



NSSP requirements or the individual will not be certified and if currently certified, certification will be revoked.

Responsibilities of the FDA National Laboratory Standard

1. The FDA National Laboratory Standard/s will be responsible for standardizing all LEOs.
2. The FDA National Laboratory Standard will conduct certifications/recertifications. The Standardization evaluation process will consist of a minimum of two (2) practice evaluations in areas under consideration for certification and one (1) formal standardization evaluation. The evaluation will be checklist specific and the State Shellfish LEO will be standardized to evaluate the methods only for which they have been certified.
3. FDA Standard Operating Procedure for Laboratory Evaluations will be provided to every LEO candidate for the purpose of evaluation standardization.

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.
3. The Authority will provide, or ensure adequate opportunity for, State Shellfish LEOs to maintain communication with FDA LEOs, as needed, to provide guidance and updates relevant to the NSSP laboratory evaluation program and any changes to their State programs.

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 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.

State Shellfish Laboratory Evaluation Officer’s Responsibilities

1. Conduct on-site laboratory evaluations at least every three (3) years. However, more frequent evaluations are strongly encouraged and may be 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.
2. Provide appropriate post-evaluation follow-up for each laboratory evaluated, (i.e., monitoring corrective actions and resolutions of all nonconformities).
3. Prepare ~~timely~~ narrative evaluation reports within 30 days 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 ~~to~~ on the analytical results. Completed corrective actions should be included in the narrative report only if they were completed on-site. Recommendations for corrective action or, if applicable, suggestions to enhance laboratory operations should also be included in the narrative report.
4. Distribute completed evaluation reports with checklists to FDA LEOs and to the appropriate FDA ~~Regional~~ Shellfish Specialist.
5. Inform FDA Shellfish ~~Laboratory Evaluation Officers~~ LEOs when a laboratory has been found to be in nonconforming status immediately upon closeout. A letter informing FDA National Laboratory Standard of upgraded status by way of a separate Completed Corrective Action Memo will be sent, should one be necessary.
6. Coordinate proficiency testing at least yearly for all laboratories in the State supporting the microbiology component of the NSSP.
7. Prepare annually (in December) a summary list of all laboratories, ~~and~~ qualified analysts, and methods performed in each NSSP laboratory and transmit it to the FDA Shellfish LEOs.

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)~~ vibrio detection and/or marine ~~B~~ biotoxin components of the NSSP depending on their qualifications and the needs of the state shellfish sanitation program, ~~and at the discretion of FDA.~~ 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 course and field standardization.

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 a~~ minimum of two practice and one final onsite evaluations with ~~an~~ the FDA National Laboratory Standard. ~~Shellfish Laboratory Evaluation Officer and preparation of the corresponding narrative evaluation reports.~~ For the final standardization assessment, the onsite evaluation, all “Critical” nonconformities cited, or lack thereof, must be in agreement between the FDA National Laboratory Standard and the State LEO candidate. Additionally, for “Key” and “Other” nonconformities, the evaluation checklists completed by the prospective State Shellfish LEO candidate and the FDA National Laboratory Standard should be in 90% agreement.
- ~~2.3.~~ During all joint field evaluations the State Shellfish LEO Candidate will be the lead evaluator. He or she will be responsible for requesting documents, assessing records, and conducting the evaluation. FDA Standard Operating Procedure for inspection will be followed regarding assessment requests. The Candidate shall also conduct the "exit" interview and discuss all significant findings with management.
- ~~3.4.~~ The narrative evaluation report must be prepared by the State Shellfish LEO candidate for each joint but independent evaluation conducted. 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~~ to the analytical results. Recommendations for corrective action, or if applicable, suggestions to enhance laboratory operations should be included in this narrative report(s).
- ~~4.5.~~ Final ~~F~~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 30 ~~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~~ National Laboratory Standard.
- ~~5.6.~~ Field standardization is based on a pass/fail system.
- ~~6.7.~~ After successfully completing the Field Standardization Exercise, the State

Shellfish LEO Candidate will be granted the title of Laboratory Evaluation Officer. A certificate recognizing that accomplishment will be forwarded to the State Shellfish LEO Candidate, along with formal notification to the State Shellfish LEO Candidate's supervisor, within thirty (30) days.

Certification

- ~~1. Certification is dependent upon the perspective State Shellfish LEO satisfying~~
- ~~2. 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.~~
- ~~3. 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.~~
- ~~4. 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; including attending the Shellfish Program Laboratory Methods and Evaluation Procedures Course. If the LEO candidate is unsuccessful in his/ her final standardization attempt he/ she must repeat the two (2) practice evaluations and one (1) final standardization evaluation. If failure continues after the second attempt, the candidate will not be eligible for a third attempt at standardization without the expressed permission of the National Laboratory Standard.
3. The requesting Authority may withdraw the prospective State Shellfish LEO from consideration.

Recertification

1. Recertification normally occurs every ~~five (5)~~ six (6) 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

	<p>narrative evaluation report to the FDA <u>National Laboratory Standard</u> <del>ee-evaluator for review and comment for each of the laboratories jointly evaluated.</del></p> <p>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.</p> <p>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 <u>Regional</u> Shellfish Specialist. A copy of this letter will be sent to the State Shellfish Control Authority and appropriate <u>Regional</u> Shellfish Specialist.</p> <p>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.</p> <p><u>Standardization Maintenance</u></p> <ol style="list-style-type: none"> <li>1. <u>Maintenance will be provided in the form of updated Laboratory Evaluation Officer courses, updated field standardization guides, and other guidance/technical assistance activities on an as needed basis.</u></li> <li>2. <u>State Shellfish LEOs will be required to attend the Shellfish Program Laboratory Methods and Evaluation Procedures Course every three years or when it is offered by FDA</u></li> </ol> <p>Revocation of Certification</p> <ol style="list-style-type: none"> <li>1. State Shellfish LEOs who fail to meet any of the certification/recertification, employment, or performance criteria listed above will have their certification revoked.</li> <li>2. Certification may be voided when state shellfish sanitation programs no longer have a need for the services of a State Shellfish LEO.</li> <li>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.</li> <li>4. Revoked certifications will not normally be restored.</li> <li>5. <u>The National Laboratory Standard will document the reason(s) for revocation of the LEO certification. This information shall be forwarded to the Candidate's supervisor and a copy shall be placed in the FDA file. All evidence and conclusions reached by the FDA shall be documented in writing by the Standard and shall be retained for three (3) years in accordance with the Freedom of Information Act.</u></li> </ol>
Public Health Significance	The updated/revised requirements for certifying State Shellfish LEOs will help to ensure a more objective, standardized approach to the certification process.
Cost Information	Costs associated with activities for certification of State Shellfish LEOs are the responsibility of the State Shellfish Control Authority. However, it is anticipated that costs specifically associated with attendance at the Shellfish Program Laboratory Methods and Evaluation Procedures Course would be funded by FDA.
Action By 2017 Laboratory Committee	Recommended adoption of Proposal 17-112 as amended. Section IV Guidance Documents – Chapter II Growing Areas .15  General Provisions

	<ol style="list-style-type: none"> <li>1. If the State Shellfish Control Authority (Authority) uses the analytical services of private/commercial/fee for services laboratories to support the NSSP, then <del>the Authority</del> <del>he/she should</del> <u>must</u> select a qualified individual to become certified as a State Shellfish Laboratory Evaluation Officer (State Shellfish LEO).</li> <li>2. If the Authority uses the analytical services of multiple public laboratories (state, county, parish town, etc.) to support the NSSP, then <del>the Authority</del> <del>he/she</del> may select a qualified individual to become a State Shellfish LEO.</li> <li>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 <del>Regional</del> Shellfish Specialist.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>7. To qualify for certification, the prospective State Shellfish LEO <del>should</del> <u>must</u> be:             <ol style="list-style-type: none"> <li>a. <del>A</del> <u>Be</u> a state employee;</li> <li><del>b. Have a minimum of two years of</del> shellfish laboratory experience or a laboratory background; <u>with a minimum of three years bench level experience with the methods types that will be evaluated e.g. mouse bio-assays, fermentation tube MPNs, HPLC, ELISAs, Functional Assays;</u></li> <li>c. <del>Preferably h</del> <u>Have laboratory evaluation</u> experience <u>performing laboratory evaluations or supervising a laboratory;</u> and,</li> <li>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.</li> </ol> </li> <li>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.</li> </ol> <p><u>Responsibilities of the FDA National Laboratory Standard</u></p> <ol style="list-style-type: none"> <li>4. <u>The FDA National Laboratory Standard/s will be responsible for standardizing all LEOs.</u></li> <li>5. <u>The FDA National Laboratory Standard will conduct certifications/recertifications. The Standardization evaluation process will consist of a minimum of <del>two (2)</del> one (1) practice evaluations in areas under consideration for certification and one (1) formal standardization evaluation.</u></li> </ol>
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The evaluation will be checklist specific and the State Shellfish LEO will be standardized to evaluate the methods only for which they have been certified.

6. FDA Standard Operating Procedure for Laboratory Evaluations will be provided to every LEO candidate for the purpose of evaluation standardization.

Responsibilities of the State Shellfish Control Authority

3.4. 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.

4.5. 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.

6. The Authority will provide, or ensure adequate opportunity for, State Shellfish LEOs to maintain communication with FDA LEOs, as needed, to provide guidance and updates relevant to the NSSP laboratory evaluation program and any changes to their State programs.

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 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.

State Shellfish Laboratory Evaluation Officer’s Responsibilities

9. Conduct on-site laboratory evaluations at least every three (3) years.

However, more frequent evaluations are strongly encouraged and may be 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.

10. Provide appropriate post-evaluation follow-up for each laboratory evaluated, (i.e., monitoring corrective actions and resolutions of all nonconformities).
11. Prepare ~~timely~~ narrative evaluation reports within 30 days 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 ~~to~~ on the analytical results. Completed corrective actions should be included in the narrative report only if they were corrected/completed during the evaluation on-site. Recommendations for corrective action or, if applicable, suggestions to enhance laboratory operations should also be included in the narrative report.
12. Distribute completed evaluation reports with checklists to FDA LEOs and to the appropriate FDA ~~Regional~~ Shellfish Specialist.
13. Inform FDA Shellfish ~~Laboratory Evaluation Officers~~ LEOs when a laboratory has been found to be in nonconforming status the same day immediately upon as the evaluation is completed/closed out. A letter informing FDA National Laboratory Standard of upgraded status by way of a separate Completed Corrective Action Memo will be sent, should one be necessary.
14. Coordinate proficiency testing at least yearly for all laboratories in the State supporting the microbiology component of the NSSP.
15. Prepare annually (in December) a summary list of all laboratories, ~~and~~ qualified analysts, and methods performed in each NSSP laboratory and transmit it to the FDA Shellfish LEOs.

Certification Process

Certification of qualified individuals 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)~~ vibrio detection and/or marine ~~B~~ biotoxin components of the NSSP depending on their qualifications and the needs of the state shellfish sanitation program, ~~and at the discretion of FDA.~~ Certification is dependent upon the prospective 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 course and field standardization.

Field Standardization



~~7.8.~~ 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.

~~9.~~ Field standardization consists of one or several joint but independent a minimum of two one practice and one final onsite evaluations with an the FDA National Laboratory Standard. Shellfish Laboratory Evaluation Officer and preparation of the corresponding narrative evaluation reports. For the final standardization assessment, the onsite evaluation, all "Critical" nonconformities cited, or lack thereof, must be in agreement between the FDA National Laboratory Standard and the State LEO candidate. Additionally, for "Key" and "Other" nonconformities, the evaluation checklists completed by the prospective State Shellfish LEO candidate and the FDA National Laboratory Standard should be in 90% agreement.

~~8.10.~~ During all joint field evaluations the State Shellfish LEO Candidate will be the lead evaluator. He or she will be responsible for requesting documents, assessing records, and conducting the evaluation. FDA Standard Operating Procedure for inspection will be followed regarding assessment requests. The Candidate shall also conduct the "exit" interview and discuss all significant findings with management.

~~9.11.~~ The narrative evaluation report must be prepared by the State Shellfish LEO candidate for each joint but independent evaluation conducted. 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 to the analytical results. Recommendations for corrective action, or if applicable, suggestions to enhance laboratory operations should be included in this narrative report(s).

~~10.12.~~ Final F-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 30 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 National Laboratory Standard.

~~11.13.~~ Field standardization is based on a pass/fail system.

~~12.14.~~ After successfully completing the Field Standardization Exercise, the State Shellfish LEO Candidate will be granted the title of Laboratory Evaluation Officer. A certificate recognizing that accomplishment will be forwarded to the State Shellfish LEO Candidate, along with formal notification to the State Shellfish LEO Candidate's supervisor, within thirty (30) days.

### Certification

~~1.~~ Certification is dependent upon the perspective State Shellfish LEO satisfying

	<p><del>all the following performance criteria:</del></p> <ul style="list-style-type: none"> <li><del>Demonstration of good familiarity with evaluation requirements.</del></li> <li><del>Demonstration of a thorough knowledge of the evaluation methods and documents.</del></li> <li><del>Demonstration of the technical knowledge/familiarity with the analytical procedures being used.</del></li> <li><del>Ability to communicate effectively both orally and in writing.</del></li> </ul> <p>e. <del>Successful completion of both training and field standardization.</del></p> <p>2. <del>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.</del></p> <p><del>12-2. 3. Certification is normally valid for up to five (5) years unless revoked or voided.</del></p> <p>Failure to be Certified</p> <ol style="list-style-type: none"> <li>4. If a prospective State Shellfish LEO fails to satisfy any of the performance criteria listed above, he/she will not be certified.</li> <li>5. <u>As resources permit and at the discretion of FDA</u>, the prospective State Shellfish LEO may receive additional training to better prepare him/her to be certified; <u>including attending the Shellfish Program Laboratory Methods and Evaluation Procedures Course. If the LEO candidate is unsuccessful in his/ her final standardization attempt he/ she must repeat the two (2) practice evaluations before attempting the and one (1) final standardization evaluation again. If failure continues after the second attempt, the candidate will not be eligible for a third attempt at standardization without the expressed permission of the National Laboratory Standard.</u></li> <li>6. The requesting Authority may withdraw the prospective State Shellfish LEO from consideration.</li> </ol> <p>Recertification</p> <ol style="list-style-type: none"> <li>5. Recertification normally occurs every <del>five (5)</del> <u>six (6)</u> years and is contingent upon the continuing need in the state shellfish sanitation program for the services of a State Shellfish LEO.</li> <li>6. Recertification is based on the State Shellfish LEO satisfactorily meeting the following employment and performance criteria.             <ol style="list-style-type: none"> <li>d. 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.</li> <li>e. The individual must demonstrate continued competence in the evaluation of NSSP laboratories by performing <del>one to several joint</del> evaluations with an FDA Shellfish Laboratory Evaluation Officer and providing an appropriate narrative evaluation report to the FDA <u>National Laboratory Standard</u>. <del>eo-evaluator for review and comment for each of the laboratories jointly evaluated.</del></li> <li>f. 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.</li> </ol> </li> <li>7. State Shellfish LEOs who successfully complete recertification will be issued a letter of recertification by FDA and be cleared to distribute the completed</li> </ol>
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	<p>report(s) to the appropriate <u>Regional</u> Shellfish Specialist. A copy of this letter will be sent to the State Shellfish Control Authority and appropriate <u>Regional</u> Shellfish Specialist.</p> <p>8. 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.</p> <p><u>Standardization Maintenance</u></p> <p><del>2.3.</del> <u>Maintenance will be provided in the form of updated Laboratory Evaluation Officer courses, updated field standardization guides, and other guidance/technical assistance activities on an as needed basis.</u></p> <p><u>4. State Shellfish LEOs will be required to attend the Shellfish Program Laboratory Methods and Evaluation Procedures Course every three years <del>or</del> if <del>when</del> it is offered by FDA</u></p> <p>Revocation of Certification</p> <p>6. State Shellfish LEOs who fail to meet any of the certification/recertification, employment, or performance criteria listed above will have their certification revoked.</p> <p>7. Certification may be voided when state shellfish sanitation programs no longer have a need for the services of a State Shellfish LEO.</p> <p>8. 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.</p> <p>9. Revoked certifications will not normally be restored.</p> <p>10. <u>The National Laboratory Standard will document the reason(s) for revocation of the LEO certification. This information shall be forwarded to the Candidate's supervisor and a copy shall be placed in the FDA file. All evidence and conclusions reached by the FDA shall be documented in writing by the Standard and shall be retained for three (3) years in accordance with the Freedom of Information Act.</u></p>
Action by 2017 Task Force I	Recommends adoption of Laboratory Committee recommendation on Proposal 17-112.

Submitter	ISSC Male-Specific Coliphage Committee
Affiliation	Interstate Shellfish Sanitation Conference
Email	issc@issc.org
Proposal Subject	Classification of Shellfish Growing Areas Adjacent to Waste Water Treatment Plants
Specific NSSP Guide Reference	Section IV Guidance Documents Chapter II. Growing Areas .19 Determining Appropriately Sized Prohibited Areas Associated with Wastewater Treatment Plants
Public Health Significance	In 2015, the ISSC adopted proposal 15-102 which incorporated the use of Male Specific Coliphage into the NSSP. The ISSC voting delegates directed the development of a guidance document to provide clarification for the use of MSC. This guidance document provides guidance regarding the use of MSC in the classification of shellfish growing areas adjacent to waste-water treatment plants. The classification guidance provides details and clarification that shellfish Authorities should find very helpful.
Cost Information	
Action By 2017 Task Force I	Recommends adoption of Proposal 17-113 as submitted.
NOTE: Due to the length of this proposal, the full text is not included. You are requested to refer to the 2017 <u>Proposals for Consideration</u> either in printed version or the on the ISSC website at <a href="http://www.issc.org/17-113">http://www.issc.org/17-113</a> .	

Submitter	U.S. Food and Drug Administration (FDA)
Affiliation	FDA
Email	<a href="mailto:Melissa.abbott@fda.hhs.gov">Melissa.abbott@fda.hhs.gov</a>
Proposal Subject	National Shellfish Sanitation Program Quality System - Laboratory Evaluation Checklist
Specific NSSP Guide Reference	Section II Model Ordinance - Chapter I Shellfish Sanitation Program @.03 Evaluation of Shellfish Sanitation Program Elements And Section IV Guidance Documents Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
Text of Proposal/ Requested Action	<p><b>Section II Model Ordinance - Chapter I Shellfish Sanitation Program @.03 Evaluation of Shellfish Sanitation Program Elements</b></p> <p>B. Criteria for evaluation of shellfish sanitation program elements shall be as follows:</p> <p>1. Laboratory</p> <p style="padding-left: 20px;">a. Requirements for evaluation of shellfish laboratories shall include at a minimum:</p> <p style="padding-left: 40px;">i. Records audit of laboratory operations: <u>both Quality Systems and Technical methods;</u></p> <p style="padding-left: 40px;">ii. Direct observation of current laboratory operating conditions; and</p> <p style="padding-left: 40px;">iii. Information collection from the Authority and other pertinent sources concerning laboratory operations.</p> <p style="padding-left: 20px;">b. 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 .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.</p> <p style="padding-left: 40px;"><u>i. Quality System Evaluation.</u></p> <p style="padding-left: 60px;"><u>(a) This checklist includes a conforming and nonconforming status only. All nonconformities must be reconciled prior to scheduling an onsite evaluation of technical methods in NSSP laboratories. As this part of the evaluation specifically refers to the Quality manual and SOPs and other documentation considered the basis for data defensibility, this documentation must be in order prior to further LEO scheduling. The Quality Systems evaluation is performed as a desk audit and is in accordance with checklist found in Chapter II.</u></p> <p style="padding-left: 40px;"><u>ii. Technical Evaluation:</u> Conforms. In order to achieve or maintain conforming status under the NSSP, a laboratory must meet the following laboratory evaluation criteria:</p> <p style="padding-left: 60px;"><u>iii(a)</u> No critical nonconformities in the microbiological or marine Biotoxin component under evaluation have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and</p> <p style="padding-left: 60px;"><u>iii(b)</u> Not more than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine Biotoxin components have been identified using the</p>

	<p>appropriate FDA Shellfish Laboratory Evaluation Checklist; and</p> <p><del>iv</del>(c) Not more than eighteen (18) critical, key, and other nonconformities in total in the microbiological component, twelve (12) critical, key and other nonconformities in total for the PSP component, or ten (10) critical, key and other nonconformities in total for the NSP component 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</p> <p><del>v</del>(d) 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.</p> <p><del>e</del>-iii. <b>Technical Evaluation:</b> Provisionally Conforms. In order to be deemed provisionally conforming under the NSSP, a laboratory must meet the following laboratory evaluation criteria:</p> <p><del>i</del>(a) Not more than three (3) critical nonconformities in the microbiological component, four (4) in the PSP component, or three (3) in the NSP component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and</p> <p><del>ii</del>(b) Not more than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine Biotoxin component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and</p> <p><del>iii</del>(c) Not more than eighteen (18) critical, key and other nonconformities in total in the microbiological component, or twelve (12) critical, key and other nonconformities in total in the PSP component or ten (10) critical, key and other nonconformities in total in the NSP component 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</p> <p><del>iv</del>(d) 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.</p> <p><del>e</del>-iv. <b>Technical Evaluation:</b> Nonconformance. When a laboratory exceeds the following criteria, it will be determined to be in nonconformance:</p> <p><del>i</del>(a) More than three (3) critical nonconformities in the microbiological component or four (4) in the PSP component, or three (3) in the NSP component have been identified using the appropriate FDA Shellfish Laboratory Checklist; or</p> <p><del>ii</del>(b) More than thirteen (13) key nonconformities in the</p>
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	<p>microbiological component or six (6) in the marine Biotoxin component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist;</p> <p><del>iii</del>(c) More than eighteen (18) critical, key, and other nonconformities in total in the microbiological component, or more than twelve (12) critical, key and other nonconformities in total in the PSP component, or more than ten (10) critical, key, and other nonconformities in total in the NSP component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; or</p> <p><del>iv</del>(d) 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.</p> <p><del>e</del>-c. <u>Corrective Actions for</u> Conforming Status. A laboratory found to be in conforming status for <del>either the microbiological or marine Biotoxin component or for both components</del> <u>technical checklists, other than the Quality Systems checklist</u>, 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.</p> <p><del>f</del>-d. <u>Corrective Actions for</u> Provisionally Conforming Status. A laboratory found to be in provisionally conforming status for <del>either the microbiological or marine Biotoxin component or for both components</del> <u>technical methods checklists</u> 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:</p> <ol style="list-style-type: none"> <li>i. Conforms if all the critical and key nonconformities have been successfully corrected in each provisionally conforming component evaluated; or</li> <li>ii. Nonconforming if any critical or key nonconformities remain to be successfully corrected in each provisionally conforming component evaluate, <u>or if the lab is not able to be evaluated because of a nonconforming Quality System</u>. 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.</li> </ol> <p><del>g</del>-e. Nonconformance.</p> <ol style="list-style-type: none"> <li>i. Upon a determination of nonconforming status in <u>any of the either the microbiological or marine Biotoxin component or in both technical method</u> 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</li> </ol>
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	<p>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.</p> <p><u>ii. Upon a determination of nonconformance for the Quality Systems component, the laboratory will have to successfully implement a quality system prior to the onsite technical evaluation. Once all nonconformities are reconciled successfully, a technical evaluation for NSSP methods using the appropriate method specific FDA Shellfish Laboratory Evaluation Checklist will be scheduled with the laboratory.</u></p> <p><del>ii</del>iii. When a laboratory is found to be nonconforming in either the <del>microbiological or marine Biotxin</del> <u>technical or quality</u> 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.</p> <p>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.</p> <p><b>Section IV Guidance Documents Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists</b></p> <p>The requested action is to adopt the text of the attached checklist for the Quality System of NSSP Laboratories and to append the checklist to the list of NSSP Laboratory Evaluation Checklists at the end of .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.</p>
<p>Public Health Significance</p>	<p>A Quality System is critical to the successful defense of laboratory data. A defensible laboratory quality results in data accuracy, reliability, and minimization of laboratory errors. Laboratory quality assurance operations must be reliable, and quality control well documented. The management of the system is critical to its success to ensure it is maintained. Without oversight and documentation of the steps a laboratory takes to ensure the highest level of laboratory quality management, the data generates is indefensible. Whether the data is challenged in a court of law or during an audit for customer or quality, a Quality System provides a level of assurance upon which data can be relied. Additionally, with time and resources for State and Federal Programs at premium, Quality Systems are an element that can successfully be evaluated remotely and ensure laboratories have continued contact with Federal partners. Once quality system essentials are in place, an onsite audit may proceed; thus, resources are conserved and laboratories</p>



	<p>are fully prepared. NSSP laboratories are producing excellent data and must be as defensible as laboratories held to accreditation standards.</p> <p>Currently, there is no checklist adopted by the ISSC and no standardized evaluation method for the NSSP to determine defensibility of the Quality System adopted by the NSSP. The attached checklist provides the metric by which laboratory evaluation officers will evaluate quality management, quality assurance and quality control elements of NSSP laboratory Quality Systems. The checklist documents whether items are present or not present, noting the labs conformance or nonconformity. If the lab fails to maintain a quality system an onsite evaluation will not be scheduled until such time as the nonconformities are rectified.</p>
<p>Cost Information</p>	<p>There will not be an additional immediate cost as this would be the first step in the routine triennial evaluation cycle.</p>
<p>Action 2017 Laboratory Committee</p>	<p>Recommended adoption of Proposal 17-114 as amended (checklist attached).  <b>Section II Model Ordinance - Chapter I Shellfish Sanitation Program @.03 Evaluation of Shellfish Sanitation Program Elements</b>          B. Criteria for evaluation of shellfish sanitation program elements shall be as follows:          1. Laboratory              a. Requirements for evaluation of shellfish laboratories shall include at a minimum:                  i. Records audit of laboratory operations both Quality Systems and Technical methods;                  ii. Direct observation of current laboratory operating conditions; and                  iii. Information collection from the Authority and other pertinent sources concerning laboratory operations.              b. 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 .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.                  i. Quality System Evaluation.                      (a) This checklist includes a conforming and nonconforming status only. All nonconformities must be reconciled prior to scheduling an onsite evaluation of technical methods in NSSP laboratories. As this part of the evaluation specifically refers to the Quality manual and SOPs and other documentation considered the basis for data defensibility, this documentation must be in order prior to further LEO scheduling. The Quality Systems evaluation is performed as a desk audit and is in accordance with checklist found in Chapter II.                  . ii. Technical Evaluation: Conforms. In order to achieve or maintain conforming status under the NSSP, a laboratory must meet the following laboratory evaluation criteria:                      (a) No critical nonconformities in the microbiological or marine Biotoxin component under evaluation have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and</p>

	<p>(b) Not more than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine Biotoxin components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and</p> <p>(c) Not more than eighteen (18) critical, key, and other nonconformities in total in the microbiological component, twelve (12) critical, key and other nonconformities in total for the PSP component, or ten (10) critical, key and other nonconformities in total for the NSP component 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</p> <p>(d) 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.</p> <p>iii. Technical Evaluation: Provisionally Conforms. In order to be deemed provisionally conforming under the NSSP, a laboratory must meet the following laboratory evaluation criteria:</p> <p>(a) Not more than three (3) critical nonconformities in the microbiological component, four (4) in the PSP component, or three (3) in the NSP component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and</p> <p>(b) Not more than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine Biotoxin component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and</p> <p>(c) Not more than eighteen (18) critical, key and other nonconformities in total in the microbiological component, or twelve (12) critical, key and other nonconformities in total in the PSP component or ten (10) critical, key and other nonconformities in total in the NSP component 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</p> <p>(d) 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.</p> <p>iv. Technical Evaluation: Nonconformance. When a laboratory exceeds the following criteria, it will be determined to be in nonconformance:</p> <p>(a) More than three (3) critical nonconformities in the microbiological component or four (4) in the PSP component, or three (3) in the NSP component have been identified using the appropriate FDA Shellfish Laboratory</p>
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	<p>Checklist; or</p> <p>(b) More than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine Biotoxin component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist;</p> <p>(c) More than eighteen (18) critical, key, and other nonconformities in total in the microbiological component, or more than twelve (12) critical, key and other nonconformities in total in the PSP component, or more than ten (10) critical, key, and other nonconformities in total in the NSP component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; or</p> <p>(d) 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.</p> <p>c. Corrective Actions for Conforming Status. A laboratory found to be in conforming status for technical checklists, other than the Quality Systems checklist, 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.</p> <p>d. Corrective Actions for Provisionally Conforming Status. A laboratory found to be in provisionally conforming status for technical methods checklists 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:</p> <p>i. Conforms if all the critical and key nonconformities have been successfully corrected in each provisionally conforming component evaluated; or</p> <p>ii. Nonconforming if any critical or key nonconformities remain to be successfully corrected in each provisionally conforming component evaluate, or if the lab is not able to be evaluated because of a nonconforming Quality System. 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.</p> <p>e. Nonconformance.</p> <p>i. Upon a determination of nonconforming status in any of the technical method 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</p>
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	<p>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.</p> <p>ii. Upon a determination of nonconformance for the Quality Systems component, the laboratory will have to successfully implement a quality system prior to the onsite technical evaluation. Once all nonconformities are reconciled successfully, a technical evaluation for NSSP methods using the appropriate method specific FDA Shellfish Laboratory Evaluation Checklist will be scheduled with the laboratory.</p> <p>iii. When a laboratory is found to be nonconforming in either the technical or quality 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.</p> <p>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.</p> <p><b>Section IV Guidance Documents Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists</b></p> <p>The requested action is to adopt the text of the attached checklist for the Quality System of NSSP Laboratories and to append the checklist to the list of NSSP Laboratory Evaluation Checklists at the end of .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.</p> <p>Checklist available upon request (12 page document).</p>
<p>Action By 2017 Task Force I</p>	<p>Recommends adoption of Laboratory Committee recommendations on Proposal 17-114.</p>

Submitter	J. Michael Hickey Margaret Barette David Fyfe
Affiliation	Massachusetts Division of Marine Fisheries Pacific Coast Shellfish Growers Association NWIFC Treaty Tribes
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Proposal Subject	Reconditioning of Recalled Shellfish Implicated in a Norovirus Outbreak
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment & Risk Management @.01 Outbreaks of Shellfish Related Illness.
Text of Proposal/ Requested Action	<p>J. Molluscan shellfish product that is recalled as a result of an illness outbreak associated with <u>V.v.</u>, <u>V.p.</u>, or <u>Norovirus</u> may be reconditioned.</p> <p><u>1. Validated reconditioning processes for V.v. and V.p. include subjecting product to validated PHPs or placing 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).</u></p> <p><u>2. Product associated with a Norovirus outbreak may be reconditioned by returning the product, within three (3) days of the recall, to the growing area from which it was harvested for an appropriate period of time. The period of time shall not be less than twenty-one (21) days. The Authority shall ensure appropriate controls and provide documentation of the activity.</u></p>
Public Health Significance	A twenty-one (21) day submergence period is consistent with the amount of time required at Section II. Chapter IV. A. (5) (b) (ii) and C. (2) (c) (iii), Shellstock Growing Areas.
Cost Information	No substantial increased cost to SSCAs and to the shellfish industry. would constitute a cost saving
Action By 2017 Task Force I	Recommends referral of Proposal 17-115 to an appropriate committee as determined by the Conference Chair.

Submitter	U.S. Food and Drug Administration (FDA)
Affiliation	U.S. Food and Drug Administration (FDA)
Email	Melissa.abbott@fda.hhs.gov
Proposal Subject	Sanitary Control of Molluscan Shellfish Harvested From Federal Waters
Specific NSSP Guide Reference	Section I Purposes & Definitions Section II Model Ordinance Chapter IV Shellstock Growing Areas Section II Model Ordinance Chapter VI Shellfish Aquaculture
Text of Proposal/ Requested Action	<p>Insert the following definition for Federal Waters in Section I Purposes &amp; Definitions as follows:</p> <p><u><b>Federal Waters means the waters that fall outside of State and local jurisdiction but within U.S. sovereignty (typically 3-200 nautical miles offshore). Federal waters include the territorial sea and exclusive economic zone.</b></u></p> <p>Insert the language below for Section II Model Ordinance Chapter IV Shellstock Growing Areas</p> <p>@.01 Sanitary Survey.  <u>E. Sanitary surveys for Federal waters will be the responsibility of FDA. Sanitary surveys will be conducted in accordance with Chapter IV @.01, as applicable.</u></p> <p>@.03 Growing Area Classification.  <u>F. FDA is responsible for the classification of growing areas in Federal waters. Federal waters are classified as Approved for shellfish harvesting unless such areas are known to be polluted (i.e., microbiological, chemical, and marine biotoxin hazards) and involve commercial shellfish resources .</u></p> <p>Insert the language below for Section II Model Ordinance Chapter VI Shellfish Aquaculture just after the text in @.03and prior to Shellfish Gardening</p> <p><u>@.04 Aquaculture in Federal Waters</u>  <u>A. Federal Agency Responsibilities. Once the appropriate permits for the construction of the aquaculture facility have been obtained,</u>  <u>(1) NOAA is responsible for establishing a contract, in consultation with FDA, with the aquaculture facility describing requirements of the NSSP including (a) the frequency with which NOAA will audit the aquaculture facility and vessels, (b) testing requirements of the aquaculture facility, and (c) the generation of product identification for traceability (i.e., tag numbers); and</u>  <u>(2) FDA is responsible for reviewing the aquaculture facility operational plan prior to the start of operations, as well as the annual inspection of records, to ensure adherence to NSSP requirements. FDA is also responsible for the classification of the growing area(s) associated with the aquaculture facility.</u></p> <p>@.0405 Shellfish Gardening</p> <p>Insert the language below for Section II Model Ordinance Chapter VI Shellfish</p>

	<p>Aquaculture just after .07</p> <p><u>.08 Requirements for the Harvester in Aquaculture in Federal Waters</u></p> <p><u>A. Prior to beginning any aquaculture activities, the person who performs aquaculture or operates an aquaculture facility to raise shellfish in Federal waters for human consumption shall obtain the appropriate permission(s) from Federal agencies as described in @.04.</u></p> <p><u>B. Operational Plan. Each aquaculture facility shall have a written operational plan as described for Land Based Aquaculture in Section II Chapter VI .05(A). The operational plan shall also include:</u></p> <ul style="list-style-type: none"> <li><u>(1) Description of harvest, tagging, handling, storage, transportation, and landing procedures;</u></li> <li><u>(2) Description of a marine biotoxin management and contingency plan (Section II Chapter IV @.04) to include marine biotoxin sampling consistent with Section II Chapter IV @.04(a)(5) and ensure product segregation and control until biotoxin results confirm the shellfish do not contain biotoxins equal to or exceeding criteria established in Section IV Chapter II .08.;</u></li> <li><u>(3) Description of a contingency in the event of an emergency situation or condition (e.g., sewage or oil spills); and</u></li> <li><u>(4) Procedures for implementing product recalls.</u></li> </ul> <p><u>C. Each aquaculture facility obtain review from the FDA to ensure adherence to NSSP requirements prior to its implementation. If the aquaculture facility makes changes to the operational plan, they shall obtain a new review from the FDA to ensure adherence to the NSSP requirements.</u></p>
Public Health Significance	<p>Currently, the NSSP Guide does not explicitly cover requirements for the sanitary control of molluscan shellfish harvested from U.S. Federal waters. The lack of standards for this activity has impeded the harvest of shellfish, notably aquaculture, from Federal waters to date. FDA’s policy on the classification of growing areas in offshore Federal waters as described in Verber 1977 was followed in drafting the Proposal. Adding specific language to the Model Ordinance on the appropriate requirements for this activity will facilitate safe and sanitary access to additional shellfish resources.</p>
Cost Information	N/A
Action By 2017 Task Force I	<p>Recommends adoption of Proposal 17-116 on an interim basis with a sunset date of November 1, 2021 and that during this period a committee be appointed to evaluate aquaculture activities in federal waters.</p>

Submitter	ISSC Male-Specific Coliphage Committee
Affiliation	Interstate Shellfish Sanitation Conference
Email	issc@issc.org
Proposal Subject	Utilizing Male-Specific Coliphage in Growing Areas
Specific NSSP Guide Reference	<p>Section I. Purpose and Definitions</p> <p>Section II. Model Ordinance</p> <p>Chapter IV. Shellstock Growing Area and Chapter V. Shellstock Relaying</p>
Text of Proposal/ Requested Action	<p><b>Section I. Purpose and Definitions</b></p> <p>Add new definitions:</p> <p><u>Wastewater Treatment Plant (WWTP) means a facility that treats or removes contaminants from sanitary and industrial sewage through a combination of processes to a point where it can be discharged to the environment or reclaimed for other purposes.</u></p> <p><u>Wastewater Collection System means a collection system which may comprise of sanitary sewer pipes, or a combination of sanitary sewer pipes and stormwater pipes, and pump stations to ensure that disposed wastewater is delivered to the wastewater treatment plant to be treated.</u></p> <p><u>Wastewater Treatment Plant Design Flow means the flow that the WWTP is designed to discharge over a specified time period (such as hourly, daily, monthly, or annually) and typically expressed as a daily or hourly average with the expectation of meeting permit requirements</u></p> <p><b>Section II. Model Ordinance</b> <b>Chapter IV. Shellstock Growing Areas</b></p> <p><b>@.02 Microbiological Standards.</b></p> <p>A. General...</p> <p>B. Water Sample Stations...</p> <p>C. Exceptions...</p> <p>D. Standard for the Approved....</p> <p>E. Standard for the Approved Classification of Growing Areas Affected By Point Sources. (1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2).</p>



- (2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed fourteen (14) per 100 ml, and not more than ten (10) percent of the samples shall exceed an MPN or MF(mTEC) of:
- (a) 43 MPN per 100 ml for a five-tube decimal dilution test; (b) 49 MPN per 100 ml for a three-tube decimal dilution test;
  - (c) 28 MPN per 100 ml for a twelve-tube single dilution test; or
  - (d) 31 CFU per 100 ml for a MF (mTEC) test.
  - (e) For SSCA utilizing MSC data in conjunction with bacteriological data to evaluate waste water system discharge (WWSD) impacts, the MSC level shall not exceed fifty (50) MSC per hundred (100) grams.
- (3) Required Sample Collection.
- (a) A minimum of five (5) samples shall be collected annually under adverse pollution conditions from each sample station in the growing area.
  - (b) A minimum of the most recent fifteen (15) samples collected under adverse pollution conditions from each sample station shall be used to calculate the median or geometric mean and percentage to determine compliance with this standard.
  - (c) Sample station locations shall be adjacent to actual or potential sources of pollution.
- F. Standard for the Approved...
- G. Standard for the Restricted...
- H. Standard for the Restricted...

**@.03 Growing Area Classification.**

- A. General. Each growing area shall be correctly classified as approved, conditionally approved, restricted, conditionally restricted, or prohibited, as provided by this Ordinance.
- (1) Emergency Conditions..
  - (2) Classification of All Growing Areas...
  - (3) Boundaries...
  - (4) Revision of Classifications...
  - (5) Status of Growing Areas... The status of a growing area is separate and distinct from its classification and may be open, closed or inactive for the harvesting of shellstock.
    - (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

	<p>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</p> <p>(i) For emergency closures of harvest areas caused by the occurrence of raw untreated sewage discharged from a large community sewage collection system or Waste Water System Discharge (WWSO), the analytical sample results shall not exceed <del>the a-levels established in Chapter IV @ 02. E of fifty (50) male specific coliphage per 100 grams</del> 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 days have passed; or</p> <p>(iii) The requirements for Biotoxins or conditional area management plans as established in Section .04 and Section .03, respectively, are met; and</p> <p>(iv) Supporting information is documented by a written record in the central file.</p> <p>(d) Inactive Status...</p> <p>(e) Remote Status...</p> <p>(f) Seasonally Remote/Approved Status...</p> <p>B. Approved Classification...</p> <p>C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:</p> <p>(1) Survey Required...</p> <p>(2) Management Plan Required. For each growing area, a written management plan shall be developed and shall include:</p> <p>(a) For management plans based on wastewater treatment plant function, performance standards that include:</p> <p>(i) Peak effluent flow, average flow, and infiltration flow;</p> <p>(ii) Microbiological quality of the effluent;</p> <p>(iii) Physical and chemical quality of the effluent;</p> <p>(iv) Conditions which cause plant failure;</p> <p>(v) Plant or collection system bypasses;</p> <p>(vi) Design, construction, and maintenance to minimize mechanical failure, or overloading;</p> <p>(vii) Provisions for monitoring and inspecting the waste water treatment plant; and</p> <p>(viii) Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with Section E. Prohibited Classification;</p> <p>(b) For management plans based on pollution sources other</p>
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	<p>than waste water treatment plants:</p> <ul style="list-style-type: none"> <li>(i) Performance standards that reliably predict when criteria for</li> <li>(ii) Discussion and data supporting the performance standards.</li> </ul> <p>(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:</p> <ul style="list-style-type: none"> <li>(i) Performance standards of the plan are fully met;</li> <li>(ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;</li> <li>(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. The SSCA may utilize <u>MSC levels to establish that sufficient time has elapsed to allow the water quality to return to acceptable levels</u> in growing areas adjacent to waste water system discharge. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of viral levels in the shellstock. Analytical sample results shall not exceed <u>the MSC levels established in Chapter IV @02 E. a level of 50 MSC per 100 grams</u> or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions. These studies 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</li> <li>(iv) Shellstock feeding activity is sufficient to achieve microbial reduction.</li> </ul> <p>(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;</p> <p>(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;</p> <p>(f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;</p>
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	<p>(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.</p> <p>(3) Reevaluation of Conditional Classification...  (4) Understanding of and Agreement With...  (5) Conditional Area Types...  (6) Conditionally Approved Classification...  (7) Conditionally Restricted Classification...</p> <p>D. Restricted Classification...  E. Prohibited Classification...</p> <p><b>Chapter V. Shellstock Relaying</b>  <b>@.02 Contaminant Reduction.</b></p> <p>A. The Authority shall ...  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:</p> <p>(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 waste water system discharge, the viral quality of each shellfish species meets the male-specific coliphage <u>(MSC) levels established in Chapter IV @02.E. standard of 50 PFU/100 gm</u> or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions.</p> <p>C. The authority may...  D. The time period...  E. When container relaying...  F. The Authority shall...</p>
Public Health Significance	<p>In 2015, the ISSC adopted proposal 15-102 which incorporated the use of Male Specific Coliphage into the NSSP. The ISSC voting delegates directed the development of a guidance document to provide clarification for the use of MSC. In the development of the guidance document, the MSC Committee concluded to changes were needed in Chapter IV for clarification and consistency. The proposed changes do not change the requirements of Chapter IV.</p>
Cost Information	
Action By 2017 Task Force I	<p>Recommends adoption of Proposal 17-117 as submitted.</p>

Submitter	Thomas Dameron BK Rastogi Chris Shriver
Affiliation	Surfside Foods Atlantic Capes Fisheries LaMonica Fine Foods Bumble Bee Foods
Email	tdameron@surfsidefoods.com brastogi@surfsidefoods.com cshriver@atlanticcapes.com
Proposal Subject	Marine Biotxin Control / Memorandums of Understanding
Specific NSSP Guide Reference	Section II. Model Ordinance, Chapter IV. Shellstock Growing Areas,@.04 Marine Biotxin Control A. Contingency Plan (5)
Text of Proposal/ Requested Action	<p>(5) Prior to allowing the landing of shellfish harvested from federal waters closed due to periodic toxic algal blooms associated with PSP, and where routine monitoring of saxitoxin levels is not conducted, the State Authority in the landing State, in cooperation with appropriate Federal agencies, shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. <u>Any properly permitted shellfish harvester or individual shellfish dealer may request an agreement or memoranda of understanding and the Authority shall provide the requirements for the application for an agreement or memoranda of understanding within 10 business days. The Authority will respond to all applications, originals and resubmittals, for agreements or memoranda of understandings within 30 business days of receipt with either an approval of the application for an agreement or memoranda of understanding or a denial complete with the rational for the denial.</u> The agreements or memoranda of understanding shall provide strict safety assurances. At a minimum agreements or memoranda of understanding shall include provisions for:</p>
Public Health Significance	<p><b>The Problem</b> – State Shellfish Control Authorities are under no obligation to enter agreements with properly permitted, out of state shellfish harvesters within any specific time. An Authorities’ refusals to enter discussions or agreements with out of State firms is improperly burdening or discriminating against interstate commerce and has public health ramifications as indicated below.</p> <p>The MOU 225-84-2003 between the FDA and ISSC states, "The purpose of the ISSC is to provide a formal structure wherein State regulatory authorities can establish updated guidelines, and <i>procedures for the uniform application of those guidelines</i>, for sanitary control of the shellfish industry." The use of timeframes where agreements or memoranda of understanding must move forward will provide regulatory uniformity and cooperation for <b>all harvesters or individual shellfish dealers</b> wanting to land shellfish harvested from the open portion of Georges Bank. Significant amounts of time and energy is being needlessly wasted when an Authority can wait indefinitely to respond to requests. This proposed update to the Model Ordinance will streamline an unnecessarily burdensome requirement and allow industry to work in as efficient a manner as possible, to maintain product quality and protect public health.</p>

	<p><b>Public Health Significance</b> – The current NSSP Guidelines allow the indefinite delay of an agreement. This prohibits organizations from offloading shellfish in the closest port to the open portion of Georges Bank, when a state doesn’t respond to requests for agreements. As an example – a Surfside Foods harvest vessel has been seeking an Agreement with Massachusetts for 14 months. The harvest vessel will experience an additional 13 hours of travel to New Jersey, a State where a written Agreement had been established in a timely manner, to harvest from Georges Bank. Additional travel time by the harvest vessel increases the time until the shellfish are under continuous cooling and it adds to the degradation of the product and the bacterial load.</p>
<p>Cost Information</p>	<p>As an example: the cost to Surfside Foods, LLC due to the refusal of the Massachusetts SSCA to act on our request for an agreement or memoranda of understanding has been significant. We submitted all documentation requested to the MA SSCA more than 13 months prior to this proposal submittal and we have yet to receive a response to our request, in the affirmative or negative. Since then we have submitted additional requests, one more than two months prior to this writing by certified mail and have gotten no response. We have secured dockage and then lost it to other vessels because we were not able to utilize it. We have missed a full season fishing Georges Bank and it appears we will miss another one.</p>
<p>Action By 2017 Task Force I</p>	<p>Recommends no action on Proposal 17-118. Rationale: This would involve the Conference in the internal affairs of States.</p>

Submitter	U.S. Food and Drug Administration (FDA)
Affiliation	U.S. Food and Drug Administration (FDA)
Email	Melissa.abbott@fda.hhs.gov
Proposal Subject	Update the Control of Marine Biotoxins in Federal Waters
Specific NSSP Guide Reference	<p>Section II Model Ordinance Chapter IV Shellstock Growing Areas @.04 Marine Biotoxin Control A(5)</p> <p>Section IV Guidance Documents Chapter II Growing Areas .06 Protocol for the Landing of Shellfish from Federally Closed Waters Due to PSP</p>
Text of Proposal/ Requested Action	<p>Update the language as indicated below for Section II Model Ordinance Chapter IV Shellstock Growing Areas @.04 Marine Biotoxin Control A. Contingency Plan</p> <p>(5) Prior to allowing the landing of shellfish harvested from <del>£</del>Federal waters <del>closed due to periodic toxic algal blooms associated with PSP, and</del> where routine monitoring of <del>saxi</del>toxin levels is not conducted, <u>in addition to following all other requirements in the Model Ordinance</u>, the State Authority in the landing State, in cooperation with appropriate Federal agencies, shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The agreements or memoranda of understanding shall provide strict safety assurances. At a minimum agreements or memoranda of understanding shall include provisions for:</p> <ul style="list-style-type: none"> <li>(a) Harvest permit requirements.</li> <li>(b) Training for individuals conducting onboard toxicity screening using NSSP methods.</li> <li>(c) Vessel monitoring;</li> <li>(d) Identification of shellfish for each harvesting trip to include: <ul style="list-style-type: none"> <li>(i) Vessel name and owner</li> <li>(ii) Captain’s name</li> <li>(iii) Person conducting onboard screening tests</li> <li>(iv) Port of departure name and date</li> <li>(v) Port of landing name and date</li> <li>(vi) Latitude and longitude coordinates of designated harvest area</li> <li>(vii) Onboard screening test results (viii)Volume and species of shellfish harvested</li> <li>(ix) Intended processing facility name, address and certification number</li> <li>(x) Captain’s signature and date</li> </ul> </li> <li>(e) Pre-harvested (onboard) sampling that includes a minimum of five (5) samples from the intended harvest area be tested for <del>saxi</del>toxins <u>that are likely to be present</u>. Harvesting shall not be permitted if any of the pre-harvested samples contain <del>saxi</del>toxin levels in excess of <u>half of the established criteria listen in Chapter IV @.04©(1) (e.g., 44 µg/100 g when using a quantitative test or a positive at a limit of detection of 40 µg/100 g for the qualitative screening test for PSP toxins)</u>.</li> <li>(f) Submittal of onboard screening homogenates and test results to the authority in the state of landing.</li> </ul>

- (g) The collection ~~and saxitoxin level testing~~ of a minimum of seven (7) dockside samples by the SSCA or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming Laboratory.

The SSCA may require more samples based on the size of the vessel and the volume of shellfish harvested.

- (h) Holding and providing separation until dockside samples verify that ~~saxi~~toxins levels are below the established criteria (e.g., 80 µg/100 g for PSP toxins).
- (i) Disposal of shellfish ~~when should~~ dockside test results meet or exceed the established criteria in Chapter IV@.04(c)(1) (e.g., 2 mg domoic acid 80 µg/100 g for ASP toxins).
- (j) Notification prior to unloading.
- (k) Unloading Schedule.
- (l) Access for Dockside Sampling.
- (m) Record Keeping.
- (n) Early Warning/Alert System.

NOTE: The plan may include other requirements, as deemed necessary by the authority in the state of landing, to ensure adequate public health protection under the NSSP.

Update the language as indicated below for Section IV Guidance Documents  
 Chapter II Growing Areas  
 .06 Protocol for the Landing of Shellfish from Federally ~~Closed~~ Waters Due to PSP

~~When the h~~Harvest of molluscan shellfish ~~is closed~~ in Federal Waters not routinely monitored for toxins in shellfish (such as the Federal waters on Georges Bank closed due to ~~Paralytic Shellfish Poison-(PSP) risks~~; ~~exceptions to the prohibitions~~ may be authorized provided the Authority in the State of landing in cooperation with appropriate Federal agencies shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. Theis following guidance provides descriptions of the specific information to be included in the protocol.

A. Harvest Permit Requirements

~~The Authority in the landing state will only allow the landing of shellfish~~ If harvesting from ~~Federal waters closed due to PSP toxins, the Authority in the landing state will only allow the landing of shellfish from vessels in possession of an appropriate Exempted Fishing Permit (EFP) issued by the National Marine Fisheries Service (NMFS) by vessels participating in the Federal Vessel Monitoring Systems (VMS). The NMFS shall receive concurrence from the SSCA in the State of landing. Vessels operating in open Federal waters will also need applicable permits.~~

B. Training

The Authority shall ensure that all shipboard persons conducting onboard ~~sampling~~ testing have been trained by a U.S. Food and Durg



~~Administration (FDA) National Shellfish Sanitation Program (NSSP) Laboratory Evaluation Officer (LEO) or an US Food and Drug Administration (FDA) marine B~~ Administration (FDA) National Shellfish Sanitation Program (NSSP) Laboratory Evaluation Officer (LEO) or an US Food and Drug Administration (FDA) marine B ~~biotoxin expert to conduct onboard PSP-toxin screening using an NSSP recognized method(s). Shipboard persons conducting onboard toxin testing must receive refresher training every 3 years. A designee of the FDA LEO or FDA marine biotoxin expert may be appointed in writing to provide the training and/or refresher training.~~ biotoxin expert to conduct onboard PSP-toxin screening using an NSSP recognized method(s). Shipboard persons conducting onboard toxin testing must receive refresher training every 3 years. A designee of the FDA LEO or FDA marine biotoxin expert may be appointed in writing to provide the training and/or refresher training.

C. Vessel Monitoring

The Authority shall ~~ensure that~~ monitor the harvesting location(s) of each landing vessel. ~~has been appropriately monitored. This requirement may be met by the vessel participating in the Federal Vessel Monitoring System (VMS).~~

D. Identification of Shellfish

Prior to landing, each vessel Captain or Mate shall provide the Authority with a Harvest Record, which may be electronic provided that it is made available to the authorized individual at dockside, for each harvesting trip ~~record~~ identifying each lot of shellfish as follows: ~~For each harvesting trip the Captain or Mate shall record the following information on a “Harvest Record.” Electronic logging of this information may be permitted provided it is made available to the authorized individual at dockside~~

1. Vessel name and Federal Fishing Permit number
2. Name and telephone number of the vessel Captain and vessel owner
3. Date(s) of harvest
4. Number of lots and volume of catch per lot or number of containers per lot
5. Location(s) of harvest (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds)
6. Identification of each harvest lot, including cage tag numbers for surf clams and ocean quahogs, and container numbers or identification codes for other shellfish species
7. Location (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds) of each PSP toxin screening sample
8. Results of each PSP-toxin screening test
9. Destination(s) and purchaser(s) of each lot and amount of each lot to each destination

The Captain or Mate shall sign the “Harvest Record.” The “Harvest

Record<sup>2</sup> shall be checked by the individual authorized to sample the harvested shellfish. Failure to provide complete and accurate information will result in revocation or suspension of the NMFS EFP and rejection of the entire lot(s) of harvested shellfish. Four (4) copies of the “Harvest Record<sup>2</sup> shall be prepared. One (1) copy shall remain with the vessel, one (1) copy shall be provided to the SSCA in the state of landing, one (1) copy shall accompany the catch to the processing firm(s), and one (1) copy shall be retained by the laboratory authorized to conduct lot sample analyses.

Container Labeling:

Each container of shellfish shall be clearly labeled (indelible and legible) with the following NSSP required information at the time of harvest:

1. ~~For s~~ Surf clams and ocean quahogs existing NMFS tagging requirements.
2. ~~For a~~ All other molluscan shellfish (including Stimpson clams also known as Arctic surf clams) using durable, waterproof, Authority sanctioned prior to use Tyvek-tags:
  - a. Vessel name;
  - b. Type and quantity of shellfish;
  - c. Date of harvest; and
  - d. Harvest lot area defined by GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds.

E. Pre-Harvest Sampling

Prior to ~~commercial~~ harvesting of molluscan shellfish, a minimum of five (5) screening samples shall be collected within each area of intended harvest (lot area) and tested for ~~PSP~~ marine biotoxins that are likely to occur in accordance with an NSSP recognized ~~screening~~ method. Each screening sample shall be collected during a separate and distinct gear tow. Screening sample tows shall be conducted in a manner that evenly distributes the five (5) samples throughout the intended harvest area for each area of intended harvest (see Section H.). Only shipboard officials trained by an FDA LEI or FDA marine biotoxin expert (or their designee as expressly indicated in writing) in the use of the designated NSSP ~~screening~~ method may conduct these tests. Each of the five (5) samples must test negative for ~~PSP~~ toxins (i.e., below half of the established criteria in Chapter IV). A positive result from any one (1) sample shall render the “lot area” unacceptable for harvest. The harvest vessel ~~e~~Captain shall immediately report all positive screening test results, by telephone or email, to the SSCA within the intended state of landing, the FDA Shellfish Specialist, and the ~~processor~~ NMFS. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area (s). The Captain should also notify other permitted harvest vessels of the positive screening test and advise them to avoid the questionable area.

For each screening test, whether positive and-or negative, the remaining

sample material (homogenate) shall be maintained under refrigeration for later use should the SSCA in the State of landing request confirmatory testing using ~~an~~ NISSP recognized ~~test~~ method.

Each screening sample shall be comprised of at least twelve (12) whole animals with the exception of mussels and “whole” or “roe-on” scallops. For mussels each sample shall be comprised of thirty (30) animals. For “whole” scallops each sample shall be comprised of twenty (20) scallop viscera and gonads. For “roe-on” scallops each sample shall be comprised of twenty (20) scallop gonads.

F. Submittal of Onboard Screening Homogenates and Test Results

All screening results shall be recorded on the “Harvest Record” as stipulated in Section D. of this Protocol. Upon landing of the harvest vessel, the “Harvest Record” and screening homogenates shall be provided to the SSCA or designee and the testing of those samples for toxins using an NISSP method by an NISSP conforming laboratory authority in the State of landing ~~authorized to sample the harvested shellfish~~ as described in Section G. of this Protocol.

G. Dockside Sampling

After dockside samples are collected by the SSCA or designee, molluscan shellfish may be processed while awaiting ~~PSP analytical~~ toxin results. Each lot must be identified and segregated during storage while awaiting dockside sample test results. Under no circumstances will product be released from the processor prior to receiving satisfactory ~~paralytic shellfish toxin test~~ results that demonstrate that toxin levels are below the established criteria in Chapter IV@.04(c)(1).

The dockside sampling protocol for molluscan shellfish shall be as follows:

1. For each lot of molluscan shellfish, a minimum of seven (7) composite samples, each comprised of at least twelve (12) whole animals, shall be taken at random by the individual authorized by the SSCA to sample, with the following exceptions:
  - a. For each lot of mussels, a minimum of seven (7) composite samples, each comprised of at least thirty (30) whole animals, shall be taken at random by the individual authorized to sample.
  - b. For each lot of “whole” scallops, a minimum of seven (7) composite samples, each comprised of twenty (20) scallop viscera and gonads, shall be taken at random by the individual authorized to sample.
  - c. For each lot of “roe-on” scallops, a minimum of seven (7) composite samples, each comprised of twenty (20) scallop gonads, shall be taken at random by the individual authorized to sample.
2. Shellfish samples collected in accordance with G.1 shall be

tested for the presence of ~~paralytic shellfish~~ toxins using an NSSP recognized methods.

3. Laboratory test results for each lot of shellfish shall be forwarded to the SSCA in the state in which the shellfish is being held prior to the product being released by the SSCA in the state of landing, or if processed in another state, the SSCA in the state of processing.

H. Holding and Lot Separation

A harvest lot is defined as all molluscan shellfish harvested during a single period of uninterrupted harvest activity within a geographic area not to exceed three (3) square miles. Once harvesting has ceased and the harvest vessel moves to another location, regardless of the distance, a new harvest lot will be established. Any harvest vessel containing more than one lot shall clearly mark and segregate each lot while at sea, during off loading, and during transportation to a processing facility. Prior to harvesting in Federal waters, each harvest vessel shall submit to the NMFS a written onboard lot segregation plan. The SSCA in the intended state of landing and the FDA ~~Regional~~ Shellfish Specialist must approve the proposed lot segregation plan.

I. Disposal of Shellfish

If test results of any one (1) of the seven (7) samples collected in accordance with G.1 equal or exceed the established criteria in Chapter IV @.04(c)(1) (e.g., 80 µg of paralytic shellfish toxins/100 g for PSP toxins) of shellfish tissue (n=7, c=0), the entire lot must be discarded or destroyed at the cost of the harvester under the supervision of the SSCA in accordance with state laws and regulations except when:

A lot of “whole” or “roe-on” scallops equals or exceeds the established criteria in Chapter IV @.04(c)(1) 80 µg paralytic shellfish toxins/100 g of tissue, the adductor muscle may be shucked from the viscera and/or gonad and marketed. The remaining materials (viscera and/or gonad) must be discarded or destroyed under supervision of the SSCA in accordance with state laws and regulations.

Dockside toxin testing Confirmatory PSP analyses shall be according to NSSP recognized methods and shall be conducted by laboratories ~~certified~~ evaluated in accordance with NSSP guidelines. Private laboratories may be used if ~~certified~~ evaluated by ~~an Federal or state shellfish Laboratory Evaluation Officer (LEO)~~ in accordance with NSSP guidelines.

J. Notification Prior to Unloading

Prior to the issuance of an EFP, the harvester shall be responsible for notifying the SSCA in the state of landing and in a manner approved by the SSCA that molluscan shellfish is being harvested for delivery to the intended receiving processor.

Each vessel shall give at least twelve (12) hours' notice to the individual authorized to sample prior to unloading shellfish. Notice of less than twelve (12) hours may be approved by the authorized individual at his/her discretion. SSCAs may ~~approve industry~~ appoint a designee in writing for sampling and sample transport to the NSSP certified testing laboratory in accordance with the practices and procedures used by the SSCA under the NSSP. The procedures, as well as training and certification records, must be available for evaluation. ~~Such procedures may be approved by the SSCA only when sample collection and sample transport training is provided by the SSCA.~~

Shellfish from a ~~federally closed~~ Federal water harvest area(s) must be kept separate and not sold until so authorized by the SSCA in the state of landing or, if processed in another state, the SSCA in the state of processing.

Failure to comply with the provisions of this Protocol will result in the suspension or revocation of the vessel's EFP permits through the NMFS.

K. Unloading Schedule

Unloading shall take place between 7:00 A.M. and 5:00 P.M. Monday through Friday, unless otherwise mutually agreed upon by the individual authorized to sample, the processing plant manager, the harvest vessel captain, and the SSCA in the state of landing, ~~sample testing, and processing.~~

L. Access for Dockside Sampling

Individuals authorized to sample shall be provided access to the catch of shellfish.

M. Record Keeping

Record keeping requirements shall be as follows:

1. The vessel shall maintain Harvest Records for at least one (1) year.
2. The processor(s) shall maintain Harvest Records for at least one (1) year or two (2) years if the product is frozen.
3. The SSCA in the State of landing shall retain Harvest Records for at least two (2) years.

N. Early Warning/Alert System

	<p><del>PSP sample Toxin</del> data acquired as a result of onboard screening and dockside testing shall be transmitted to <del>a central data register to be maintained by</del> the FDA. These data, both screening and <del>confirmatory dockside</del>, shall be transmitted to the FDA by the NSSP certified laboratory conducting <del>PSP analyses</del> <u>toxin testing</u> of the sampled lot(s) within one <u>(1)</u> week of the completion of the <del>PSP toxin</del> analyses. The data provided shall include the following:</p> <ol style="list-style-type: none"> <li>1. Shellfish species;</li> <li>2. Harvest location name and coordinates (GPS or latitude/longitude);</li> <li>3. Harvest date;</li> <li>4. Onboard screening test method, date, and results; <u>and</u></li> <li>5. Laboratory test date, <u>test method</u>, and test results <u>for dockside samples</u>.</li> </ol> <p>Results of all samples having acceptable levels of <del>paralytic shellfish</del> toxins (e.g., &lt;80 µg/100 g <u>for PSP toxins</u>) shall immediately be reported to the SSCA in the state of landing. If the results of any one (1) sample equal or exceed <u>the established criteria in Chapter IV @.04(c)(1)</u> <del>80 µg/100 g</del> the testing laboratory shall immediately notify the FDA <del>Regional</del> Shellfish Specialist, the SSCA, and the processor by telephone. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area(s).</p> <p>NOTE: Due to the resources necessary to meet the requirements of this Protocol, State Shellfish Control Authorities (SSCAs) may find it necessary to require industry to fund associated costs. These costs may include sample collection, screening, transportation, analysis, inspection, enforcement, and other related expenses.</p>
Public Health Significance	<p>The protocol adopted by the ISSC in 2011 to allow the harvest of surf clams and ocean quahogs from Federal waters closed due to the risk of paralytic shellfish poisoning (PSP) toxins has granted access to valuable shellfish resources with measures in place to protect public health. While the protocol, referred to as onboard screening dockside testing, was designed for surf clam and ocean quahog harvests on Georges Bank, its success has demonstrated its applicability to other Federal waters where routine monitoring for marine biotoxins is not feasible.</p> <p>The goal of this proposal and the requested updates to the language in the Model Ordinance and Guidance Documents is to broaden the application of this successful protocol to other regions and for other toxins as they emerge into the regions of interest, thereby safely expanding access to shellfish resources in Federal waters.</p>
Cost Information	N/A
Action By 2017 Task Force I	Recommends adoption of Proposal 17-119 as submitted.

Submitter	Paul D. Golden
Affiliation	PacRim
Email	paul.golden@dfw.wa.gov
Proposal Subject	Risk Category Reductions for Monitoring and Control of Surveillance Activities
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting, @.01 Control of Shellstock Growing Areas, B. Patrol of Growing Areas (4)(e)
Text of Proposal/ Requested Action	<p>(e) The following criteria should be used to adjust the rating, if warranted:</p> <p>(i) If a community-policing program is in place, the subtotal may be reduced by up to 0.25 points. If such a program leads to frequent citations, the subtotal may be reduced by up to 0.5 points. Community policing may include but is not limited to telephone hot lines, out-reach programs, financial incentives, local law enforcement activities not covered by B. (5), or private security arrangements.</p> <p>(ii) If specialized equipment is available to the patrol agency, the subtotal may be reduced by up to 0.40 points. The actual reduction should be dependent upon the type of equipment that is available and its frequency of use. For example, frequent use of an aircraft can warrant a 0.4 point reduction, and frequent use of night vision or periodic use of aircraft can warrant a 0.2 point reduction.</p> <p><u>(iii) If the patrol agency implements a strategy for comprehensive monitoring and control of surveillance activities, the subtotal may be reduced by up to 1 point. Activities include airport, dock, border, truck, wholesale and retail inspections. The actual reduction should be dependent on the frequency and extent of the activities.</u></p> <p><del>(iii)</del>(iv) If a growing area is conditionally managed or is poorly marked, the subtotal may be increased by up to 0.2 point. Adding or subtracting the appropriate adjustment(s) calculates the total score.</p>
Public Health Significance	<p>Agencies with units responsible for patrol activities vary throughout the country with respect to their statutory authority and primary mission. While some agencies operations are primarily limited to surveillance of growing areas, others extend beyond the harvest area to include shippers and additional receivers and buyers. Patrol agencies that implement broad monitoring, control, and surveillance strategies monitor variations in fishing effort, control harvest and sales through regulatory restrictions, and conduct surveillance and enforcement activities through the various stages of seafood transfer. Agencies with units responsible for patrol activity that conduct inspections and investigations of seafood both on the harvest grounds and beyond have opportunities to intercept illegal product at chokepoints where seafood is transferred, processed, shipped, and sold. Additionally, health authorities and natural resource agencies throughout the country are more frequently facing expanding responsibilities and competing priorities, while at the same time they are facing shrinking budgets and funding that is earmarked for narrowly defined activities. Agency managers and officers must prioritize their limited resources to make the most impact to deter illegal harvest. Widespread presence in the seafood harvest and supply chain protects seafood consumers and legitimate seafood businesses.</p>
Cost Information	none

<p>Action By 2017 Task Force I</p>	<p>Recommends adoption of Proposal 17-120 as amended:</p> <p>Section II. Model Ordinance Chapter VIII. @.01 B.(4)(e)</p> <p>(e) The following criteria should be used to adjust the rating, if warranted:</p> <p>(i) If a community-policing program is in place, the subtotal may be reduced by up to 0.25 points. If such a program leads to frequent citations, the subtotal may be reduced by up to 0.5 points. Community policing may include but is not limited to telephone hot lines, out-reach programs, financial incentives, local law enforcement activities not covered by B. (5), or private security arrangements.</p> <p>(ii) If specialized equipment is available to the patrol agency, the subtotal may be reduced by up to 0.40 points. The actual reduction should be dependent upon the type of equipment that is available and its frequency of use. For example, frequent use of an aircraft can warrant a 0.4 point reduction, and frequent use of night vision or periodic use of aircraft can warrant a 0.2 point reduction.</p> <p>(iii) If the patrol agency implements a strategy for comprehensive monitoring and control of surveillance activities, the subtotal may be reduced by up to 1 point. Activities include, <u>but are not limited to</u>, airport, dock, border, truck, wholesale and retail inspections. The actual reduction should be dependent on the frequency and extent of the activities.</p> <p><del>(iii)</del>(iv) If a growing area is conditionally managed or is poorly marked, the subtotal may be increased by up to 0.2 point. Adding or subtracting the appropriate adjustment(s) calculates the total score.</p>
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Submitter	US Food & Drug Administration (FDA)
Affiliation	US Food & Drug Administration (FDA)
Email	Melissa.Abbott@fda.hhs.gov
Proposal Subject	Disposal of Human Sewage and Bodily Fluids
Specific NSSP Guide Reference	<p>Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting Requirements for Harvesters .02 Shellstock Harvesting and Handling.</p> <p>Section II. Model Ordinance Chapter IX. Transportation Requirements for Harvesters          .01 Conveyances Used to Transport Shellstock to the Original Dealer and          .02 Conveyances Used to Transport Shellstock from Dealer to Dealer</p>
Text of Proposal/ Requested Action	<p>Chapter VIII. .02 Shellstock Harvesting and Handling</p> <p>D. Disposal of Human Sewage <u>and Bodily Fluids</u><del>from Vessels</del>.</p> <p>(1) Human sewage <u>and bodily fluids</u> shall not be discharged overboard from <del>any vehicle or</del> vessel used in the harvesting of shellstock, or from <u>vehicles or</u> vessels which buy shellstock while the <u>vehicles or</u> vessels are in growing areas.</p> <p>(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 <u>vehicle or</u> vessel to contain human sewage <u>and bodily fluids</u>.</p> <p>(3) Portable toilets shall:</p> <p>(a) Be used only for the purpose intended;</p> <p>(b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage;</p> <p>(c) Be emptied only into a sewage disposal system;</p> <p>(d) Be cleaned before being returned to the <u>vehicle or vessel</u><del>boat</del>; and</p> <p>(e) Not be cleaned in equipment used for washing or processing food.</p> <p>(4) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are:</p> <p>(a) Constructed of impervious, cleanable materials and have tight fitting lids;</p> <p>(b) Indelibly labeled “Human Waste” in contrasting letters at least three (3) inches in height; and</p> <p>(c) Meet the requirements in Section D. (3).</p> <p>Chapter IX. .01 Conveyances Used to Transport Shellstock to the Original Dealer</p> <p><u>G. Disposal of Human Sewage and Bodily Fluids</u></p> <p><u>(1) Human sewage and bodily fluids shall not be discharged overboard from any vehicle or vessel used in the harvesting of shellstock, or from vehicles or vessels which buy shellstock while the vehicles or vessels are in growing areas.</u></p> <p><u>(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 vehicle or vessel to contain human sewage and bodily fluids. Portable toilets shall meet the requirements of VIII. .02. D. (3).</u></p>

	<p>Chapter IX. 02 Conveyances Used to Transport Shellstock from Dealer to Dealer</p> <p><u>C. Disposal of Human Sewage and Bodily Fluids</u></p> <p><u>(1) Human sewage and bodily fluids shall not be discharged overboard from any vehicle or vessel used in the harvesting of shellstock, or from vehicles or vessels which buy shellstock while the vehicles or vessels are in growing areas.</u></p> <p><u>(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 vehicle or vessel to contain human sewage and bodily fluids. Portable toilets shall meet the requirements of VIII. 02. D. (3).</u></p>
<p>Public Health Significance</p>	<p>During evaluations, harvesters and certified dealers buying trucks are observed within harvesting areas and aquaculture lease site areas. The vehicles are often there for hours while harvesting, husbandry, and purchasing activities are taking place. In many areas, there are no nearby toilet facilities to accommodate emergency (or non-emergency) needs for toilet facilities to accept human digestive waste or vomit, putting the area at risk of foodborne illness, e.g. norovirus, hepatitis A, etc. The requirement for marine sanitation devices should not only pertain to vessels in order to protect the public health.</p>
<p>Cost Information</p>	<p>~\$5.00 for a five (5) gallon bucket with a lid.</p>
<p>Action By 2017 Task Force I</p>	<p>Recommends referral of Proposal 17-121 to an appropriate committee as determined by the Conference Chair.</p>

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Email	issc@issc.org
Proposal Subject	Marine Biotoxin Control
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.01 A. Chapter IV. Shellstock Growing Area @.04
Text of Proposal/ Requested Action	<p><b>Section II. Model Ordinance</b></p> <p><b>Chapter II. Risk Assessment and Risk Management</b></p> <p><b>@.01 Outbreaks of Shellfish-Related Illness.</b></p> <p>A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one or more persons in the case of <del>paralytic shellfish</del><u>shellfish toxicity</u> poisoning <u>associated with marine biotoxins</u> <del>[PSP]</del>), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:</p> <ol style="list-style-type: none"> <li>(1) Each consumer's food history;</li> <li>(2) Shellfish handling practices by the consumer and/or retailer;</li> <li>(3) Whether the disease has the potential or is known to be transmitted by shellfish; and</li> <li>(4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.</li> </ol> <p><b>Chapter IV. Shellstock Growing Areas Management</b></p> <p><b>@.04 Marine Biotoxin Control.</b></p> <p>A. Contingency Plan.</p> <p><u>(1) The Authority shall develop and adopt a marine Biotoxin contingency plan for all marine and estuarine shellfish growing areas <b>addressing the management of PSP, ASP, NSP, DSP and AZP in the event of the emergence of a toxin-producing phytoplankton that has not historically occurred or an illness outbreak caused by marine biotoxins.</b></u></p> <p>(2) The plan shall define the administrative procedures and resources necessary to accomplish the following:</p> <ol style="list-style-type: none"> <li>(a) Initiate an emergency shellfish sampling and assay program;</li> <li>(b) Close growing areas and embargo shellfish;</li> <li>(c) Prevent harvesting of contaminated species;</li> <li>(d) Provide for product recall;</li> <li>(e) Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent states, shellfish industry, and local health agencies; <del>and</del></li> <li><u>(f) Coordinate control actions taken by Authorities and federal agencies; and-</u></li> <li><u>(g) Establish reopening criteria including the number of samples over what period of time.</u></li> </ol> <p><del>(3) Except that the Authority shall classify as prohibited any growing areas where shellfish are so highly or frequently affected</del></p>

~~by marine Biotoxins that the situation cannot be safety managed, the presence of marine Biotoxins shall not affect the classification of the shellfish growing area under Section @.03. The Authority may use the conditionally approved classification for areas affected by marine Biotoxins.~~

~~(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 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 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:~~

- ~~(a) Establishment of appropriate pre harvest screening levels;~~
- ~~(b) Establishment of appropriate screening and end product testing methods;~~
- ~~(c) Establishment of appropriate laboratories/analysts to conduct screening and end product testing methods;~~
- ~~(d) Establishment of representative sampling plan for both (a) and (b) above; and~~
- ~~(e) Other controls as necessary to ensure that shellstock are not released prior to meeting all requirements of the program.~~

~~(5) Prior to allowing the landing of shellfish harvested from federal waters closed due to periodic toxic algal blooms associated with PSP, and where routine monitoring of saxitoxin levels is not conducted, the State Authority in the landing State, in cooperation with appropriate Federal agencies, shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The agreements or memoranda of understanding shall provide strict safety assurances. At a minimum agreements or memoranda of understanding shall include provisions for:~~

- ~~(a) Harvest permit requirements.~~
- ~~(b) Training for individuals conducting onboard toxicity screening using NSSP methods.~~
- ~~(c) Vessel monitoring;~~
- ~~(d) Identification of shellfish for each harvesting trip to include:~~
  - ~~(i) Vessel name and owner~~
  - ~~(ii) Captain's name~~
  - ~~(iii) Person conducting onboard screening tests~~
  - ~~(iv) Port of departure name and date~~
  - ~~(v) Port of landing name and date~~
  - ~~(vi) Latitude and longitude coordinates of designated harvest area~~
  - ~~(vii) Onboard screening test results~~
  - ~~(viii) Volume and species of shellfish harvested~~
  - ~~(ix) Intended processing facility name, address and certification~~

- number
- (x) Captain's signature and date
- (e) Pre harvested (onboard) sampling that includes a minimum of five (5) samples from the intended harvest area be tested for saxitoxins. Harvesting shall not be permitted if any of the pre-harvested samples contain saxitoxin levels in excess of 44 µg/100 g when using a quantitative test or a positive at a limit of detection of 40 µg/100 g for the qualitative screening test.
- (f) Submittal of onboard screening homogenates and test results to the authority in the state of landing.
- (g) The collection and saxitoxin level testing of a minimum of seven (7) dockside samples. The SSCA may require more samples based on the size of the vessel and the volume of shellfish harvested.
- (h) Holding and providing separation until dockside samples verify that saxitoxin levels are below 80 µg/100 g.
- (i) Disposal of shellfish should dockside test results exceed 80 µg /100 g.
- (j) Notification prior to unloading.
- (k) Unloading schedule.
- (l) Access for Dockside Sampling.
- (m) Record Keeping.
- (n) Early Warning/Alert System.

NOTE: The plan may include other requirements, as deemed necessary by the authority in the state of landing, to ensure adequate public health protection under the NSSP.

B. Marine Biotxin ~~Monitoring~~ Management Plan .

In those areas that have been implicated in an illness outbreak or where toxin-producing forming phytoplankton organisms are known to occur periodically and the toxins are prone to accumulate in shellfish, and when appropriate at those times when marine B<sub>1</sub> biotoxins can be reasonably predicted to occur, representative samples of the water may be collected and/or shellfish shall be collected during harvest periods. The samples shall be collected from indicator stations at intervals determined by the Authority. Water samples will may be assayed for the presence of toxin-producing forming organisms phytoplankton and shellfish meat samples shall be assayed for the presence of toxins.

(1) The Authority shall develop and adopt a marine biotoxin management plan for all marine and estuarine shellfish growing areas if there is a history of biotoxin closures related to PSP, ASP, NSP, DSP, or AZP; if toxin-producing phytoplankton are known to occur in the growing area; or a reasonable likelihood that biotoxin closures could occur.

	<p><u>(2) The plan shall define the administrative procedures and resources necessary to accomplish the following:</u></p> <ul style="list-style-type: none"> <li><u>(a) Maintain a routine shellfish sampling and assay program including:</u> <ul style="list-style-type: none"> <li><u>i. Establishment of appropriate shellfish screening levels;</u></li> <li><u>ii. Establishment of appropriate shellfish screening and testing methods;</u></li> <li><u>iii. Establishment of appropriate laboratories/analysts to conduct shellfish screening and testing methods;</u></li> <li><u>iv. Establishment of a sampling plan for both (i) and (ii) above; and</u></li> <li><u>v. Other controls as necessary to ensure that shellstock are not harvested when levels of marine biotoxins meet or exceed the established criteria in Section C.</u></li> </ul> </li> <li><u>(b) Close growing areas and embargo shellfish;</u></li> <li><u>(c) Prevent harvesting of contaminated species;</u></li> <li><u>(d) Provide for product recall;</u></li> <li><u>(e) Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent states, shellfish industry, and local health agencies;</u></li> <li><u>(f) Coordinate control actions taken by Authorities and federal agencies; and</u></li> <li><u>(g) Establish reopening criteria.</u></li> </ul> <p><u>(3) The Authority may use precautionary closures based on screening or water sample results as defined in their marine biotoxin management program. Precautionary closures may be lifted immediately if confirmatory testing using an approved method shows toxin-producing phytoplankton in the growing waters and/or the level of biotoxin present in shellfish meats are not equal to or above established criteria in Section C.</u></p> <p><u>(4) Except that the Authority shall classify as prohibited any growing areas where shellfish are so highly or frequently affected by marine biotoxins or so remote that adequate sampling cannot be achieved and thus the situation cannot be safely managed, the presence of marine biotoxins shall not affect the classification of the shellfish growing area under Section @.03. The Authority may use the conditionally approved classification for areas affected by marine biotoxins.</u></p> <p><u>(5) 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 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 samples of each lot are tested and found to be below the action levels specified in Section C.</u></p>
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	<p><u>The program must include at a minimum:</u></p> <ul style="list-style-type: none"> <li><u>(a) Establishment of appropriate pre-harvest screening levels;</u></li> <li><u>(b) Establishment of appropriate screening and end product testing methods;</u></li> <li><u>(c) Establishment of appropriate laboratories/analysts to conduct screening and end product testing methods;</u></li> <li><u>(d) Establishment of representative sampling plan for both (a) and (b) above;</u></li> <li><u>(e) Disposal of shellfish should end product test results meet or exceed established criteria specified in Section C.</u></li> <li><u>(f) Other controls as necessary to ensure that shellstock are not released prior to meeting all requirements of the program.</u></li> </ul> <p><u>(6) Prior to allowing the landing of shellfish harvested from federal waters closed due to periodic toxic algal blooms associated with PSP, and where routine monitoring of saxitoxin levels is not conducted, the State Authority in the landing State, in cooperation with appropriate Federal agencies, shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The agreements or memoranda of understanding shall provide strict safety assurances. At a minimum agreements or memoranda of understanding shall include provisions for:</u></p> <ul style="list-style-type: none"> <li><u>(a) Harvest permit requirements.</u></li> <li><u>(b) Training for individuals conducting onboard toxicity screening using NSSP methods.</u></li> <li><u>(c) Vessel monitoring;</u></li> <li><u>(d) Identification of shellfish for each harvesting trip to include:</u> <ul style="list-style-type: none"> <li><u>(i) Vessel name and owner</u></li> <li><u>(ii) Captain's name</u></li> <li><u>(iii) Person conducting onboard screening tests</u></li> <li><u>(iv) Port of departure name and date</u></li> <li><u>(v) Port of landing name and date</u></li> <li><u>(vi) Latitude and longitude coordinates of designated harvest area</u></li> <li><u>(vii) Onboard screening test results</u></li> <li><u>(viii) Volume and species of shellfish harvested</u></li> <li><u>(ix) Intended processing facility name, address and certification number</u></li> <li><u>(x) Captain's signature and date</u></li> </ul> </li> <li><u>(e) Pre-harvested (onboard) sampling that includes a minimum of five (5) samples from the intended harvest area be tested for saxitoxins. Harvesting shall not be permitted if any of the pre-harvested samples contain saxitoxin levels in excess of 44 µg/100 g when using a quantitative test or a positive at a limit of detection of 40 µg/100 g for the qualitative screening test.</u></li> <li><u>(f) Submittal of onboard screening homogenates and test results to the authority in the state of landing.</u></li> </ul>
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- (g) The collection and saxitoxin level testing of a minimum of seven (7) dockside samples.
- The SSCA may require more samples based on the size of the vessel and the volume of shellfish harvested.
- (h) Holding and providing separation until dockside samples verify that saxitoxin levels are below 80 µg/100 g.
- (i) Disposal of shellfish should dockside test results exceed 80 µg /100 g.
- (j) Notification prior to unloading.
- (k) Unloading schedule.
- (l) Access for Dockside Sampling.
- (m) Record Keeping.
- (n) Early Warning/Alert System.

NOTE: The plan may include other requirements, as deemed necessary by the authority in the state of landing, to ensure adequate public health protection under the NSSP.

C. Closed Status of Growing Areas.

(1) A growing area, or portion(s) thereof as provided in Section A.(4), shall be placed in the closed status for the taking of shellstock when the Authority determines that the number of toxin-forming organisms in the growing waters and/or the level of Biotoxin present in shellfish meats is sufficient to cause a health risk. The closed status shall be established based on the following criteria:

- (a) PSP - ~~cells/L n/a~~; 80 µg saxitoxin equivalents/100 grams
- (b) NSP - 5,000 cells/L or 20 MU/100 grams (0.8 mg brevetoxin-2 equivalents/kg)
- (c) AZP - ~~cells/L n/a~~; 0.16 mg azaspiracid-1 (AZA-1) equivalents/kg (0.16 ppm)
- (d) DSP – ~~cells/L n/a~~; 0.16 mg okadaic acid (OA) equivalents/kg (0.16 ppm)
- (e) ASP - ~~cells/L n/a~~; 2 mg domoic acid/100 grams (20 ppm)
- ~~(f) The concentration of paralytic shellfish poison (PSP) equals or exceeds 80 µg per 100 g of edible portion of raw shellfish; or~~
- ~~(g) For neurotoxic shellfish poisoning (NSP), the harvesting of shellstock shall not be allowed when:~~
  - ~~(i) The concentration of NSP equals or exceeds 20 mouse units per 100 grams of edible portion of raw shellfish; or~~
  - ~~(ii) The cell counts for *Karenia brevis* organisms in the water column exceed 5,000 per liter; or~~
  - ~~(h) For domoic acid, the toxin concentration shall not be equal to or exceed 20 ppm in the edible portion of raw shellfish.~~
  - ~~(i) For azaspiracid shellfish poisoning (AZP), the concentration of azaspiracids shall not be equal to or exceed 0.16 mg/kg (AZA-1 equiv.) in the edible portion of raw shellfish.~~
  - ~~(j) For diarrhetic shellfish poisoning (DSP), the concentration of DSP toxins shall not be equal to or exceed 0.16 mg/kg (OA equiv.) in the edible portion of raw~~



~~shellfish.~~

(2) For any marine Biotoxin producing organism for which criteria have not been established under this Ordinance, either cell counts in the water column or Biotoxin meat concentrations may be used by the Authority as the criteria for not allowing the harvest of shellstock.

(3) When sufficient data exist to establish that certain shellfish species can be safely exempted from the marine ~~B~~biotoxin ~~management~~contingency plan, the closed status for harvesting may be applied selectively to some shellfish species and not others.

(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.

(5) The determination to return a growing area to the open status shall consider whether toxin levels in the shellfish from adjacent areas are declining.

(6) The analysis upon which a decision to return a growing area to the open status is based shall be adequately documented.

D. Heat Processing. If heat processing is practiced, a control procedure shall be developed. This procedure shall define the following:

- (1) Toxicity limits for processing;
- (2) Controls for harvesting and transporting the shellstock to processor;
- (3) Special marking for unprocessed shellstock;
- (4) Scheduled processes; and
- (5) End product controls on the processed shellfish.

E. Records. The Authority shall maintain a copy of all of the following records.

- (1) All information, including monitoring data, relating to the levels of marine Biotoxins in the shellfish growing areas;
- (2) Copies of notices placing growing areas in the closed status;
- (3) Evaluation reports; and
- (4) Copies of notices returning growing areas to the open status.

<p>Public Health Significance</p>	<p>In response to the ISSC 2015 Summary of Actions, the USFDA requested the ISSC and FDA begin discussion regarding establishment of minimum requirements for sample collection and analysis for safely reopening areas following Biotoxin closures. This effort should include examination of existing practices and the level of safety they provide.</p> <p>In response to this request, the ISSC Executive Board agreed to host a Biotoxin meeting to discuss the Biotoxin issues listed above. States that are frequently involved in Biotoxin closures and reopenings were invited to discuss present state efforts to implement the NSSP Model Ordinance requirements for biotoxin management. The participants agreed that changes should be made to the Model Ordinance and existing biotoxin guidance. These proposed changes were provided to the Biotoxin Committee for comments. This proposal reflects the recommendation developed from that review process.</p>
<p>Cost Information</p>	
<p>Action By 2017 Task Force I</p>	<p>Recommends adoption of Proposal 17-122 as amended.          Note: The only amended language is as follows:</p> <p><b>Chapter IV. Shellstock Growing Areas Management</b>  <b>@.04 Marine Biotoxin Control.</b>          B. Marine Biotoxin Management Plan          (3) The Authority may use precautionary closures based on screening or <del>phytoplankton</del><del>water</del> sample results as defined in their marine biotoxin management program. Precautionary closures may be lifted immediately:</p> <ul style="list-style-type: none"> <li>a) if confirmatory testing using an approved method shows <del>toxin-producing phytoplankton in the growing waters</del> and/or the level of biotoxin present in shellfish meats <del>is are</del> not equal to or above established criteria in Section C; <u>or</u></li> <li><u>b) when screening or phytoplankton sample results indicate that the precautionary closure was not necessary.</u></li> </ul>

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Email	issc@issc.org
Proposal Subject	Marine Biotoxin Control Guidance
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II .02
Text of Proposal/ Requested Action	<p><b>Chapter II. Growing Areas</b>  <b>.02 Guidance for Developing Marine Biotoxin Contingency Plans.</b></p> <p>NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, <u>which includes the requirements of the program and summaries of the requirements for that component.</u> NSSP <i>Model Ordinance</i> requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.</p> <p><b>Introduction</b>  <u>Shellfish are filter feeders and, therefore, they have the ability to concentrate <del>toxigenic dinoflagellates</del>toxic phytoplankton</u> from the water column when present in shellfish growing waters. The toxins produced by <del>these dinoflagellates</del><u>certain species of phytoplankton</u> can cause illness and death in humans. Toxins are accumulated in the viscera and/or other tissues of shellfish and <del>are transferred to</del> humans <u>exposure occurs</u> when the shellfish are eaten (Gordan <i>et al.</i>, 1973). These toxins are not normally destroyed by cooking or processing and cannot be detected by taste. <del>Most of these toxins are detected through animal testing. However, some involve the use of instrument based or biochemical analyses for detection. Since the dinoflagellates are naturally occurring, their</del><u>The presence of toxic phytoplankton</u> in the water column or traces of their toxin in shellfish meat does not necessarily constitute a health risk, as toxicity is dependent on concentration (dose) in the shellfish. To protect the consumer, the Authority must evaluate the concentration of toxin present in the shellfish or the <del>dinoflagellate</del><u>toxic phytoplankton</u> concentration in the water column against the levels established in the NSSP Model Ordinance to determine what action, if any, should be taken.</p> <p><u>There are a wide range of methodologies developed for screening and confirmation of toxic phytoplankton and their toxins. Only methods adopted into the NSSP can be implemented for the purpose of confirming toxin concentration levels and making decisions to close or reopen growing areas. Additionally, some screening methods have been evaluated by the ISSC and found fit for purpose for the NSSP, thereby providing confidence in their use for specific screening purposes. Toxin methods fall into two categories in the NSSP: Approved Methods for Marine Biotoxin Testing (Section IV. Guidance Documents Chapter II Growing Areas .14 Table 2.) and Approved Limited Use Methods for Marine Biotoxin Testing (Section IV. Guidance Documents Chapter II Growing Areas .14 Table 4.). These methods range from mouse bioassays to immunochromatography and other antibody based platforms to chemical analytical methods such as high performance liquid chromatography (HPLC). Information available in the referenced Tables above provides references for the methods and, as applicable, what limitations are placed on the use of the method within the NSSP. For toxins that have no method adopted into the NSSP, best available science is employed.</u></p>

There are ~~three (3)~~ five (5) types of shellfish poisonings which are specifically addressed in the NSSP Model Ordinance: Paralytic Shellfish Poisoning (PSP), Neurotoxic Shellfish Poisoning (NSP), ~~and~~ Amnesic Shellfish Poisoning (ASP), also known as Domoic Acid poisoning, Diarrhetic Shellfish Poisoning (DSP) and Azaspiracid Shellfish Poisoning (AZP). ~~All three (3)~~ Of these five (5) types of shellfish poisoning, PSP, NSP and ASP are the most dangerous toxins, and PSP and ASP or domoic acid can cause death at sufficiently high exposure concentrations. In addition, ASP can cause lasting neurological damage. PSP is caused by saxitoxins produced by the dinoflagellates of the genus *Alexandrium* (formerly *Gonyaulax*). The dinoflagellate *Pyrodinium bahamense* is also a producer of saxitoxins. NSP is caused by brevetoxins produced by the dinoflagellates of the genus *Karenia* (formerly *Gymnodinium*). ASP is caused by domoic acid and is produced by diatoms of the genus *Pseudonitzschia*. Certain *Dinophysis* spp. and *Prorocentrum* spp. produce okadaic acid and dinophysis toxins that cause DSP. *Azadinium* spp. is the producer of azaspiracids, which cause AZP.

Both *Alexandrium* and *Karenia* can produce "red tides", i.e. discolorations of seawater caused by blooms of the algae; however, they may also reach concentrations that cause toxic shellfish without imparting any water discoloration. Toxic blooms of these dinoflagellates can occur unexpectedly or follow predictable patterns. The unpredictability in occurrence of toxic blooms was demonstrated in New England in 1972 when shellfish suddenly became toxic in a previously unaffected portion of the coastline and resulted in many illnesses (Schwalm, 1973). Historically, *Alexandrium* blooms have occurred between April and October along the Pacific coasts from Alaska to California and in the Northeast from the Canadian Provinces to Long Island Sound (U.S. Public Health Service, 1958); but these patterns may be changing. The blooms generally last only a few weeks and most shellfish (with the exception of some species of clams and scallops which retain the toxin for longer periods) clear themselves rapidly of the toxin once the bloom dissipates. Occurance of *Karenia* blooms NSP, which is less common, has occurred extends from the Carolinas south and extends throughout the Gulf Coast states. It shows no indication of regular recurrence and shellfish generally take longer to eliminate the toxin (Liston, 1994). DSP and AZP cause similar symptoms mostly related to diarrhea and abdominal pain. DSP toxin-producing phytoplankton have been documented to occur off the coasts of Washington (Trainer et al. 2013) and Texas (Deeds et al. 2010) as well as off the coast in the Northeast (e.g., Massachusetts [Tong et al. 2015]). While AZP has occurred in the U.S., the contaminated shellfish was imported (Klontz et al. 2009). Harvesting closures in the U.S. have not been documented due to AZP toxins.

The minimum concentration of PSP toxin that will cause intoxication in susceptible persons is not known. Epidemiological investigations of PSP in Canada, however, have indicated 200 to 600 micrograms of PSP toxin will produce symptoms in susceptible persons. A death has been attributed to the ingestion of a probable 480 micrograms of PSP toxin. Investigations indicate that lesser amounts of the toxin have no deleterious effects on humans. Shellfish growing areas should be closed at a PSP toxin level, which provides an adequate margin of safety, since in many instances PSP toxicity levels can change rapidly.

The NSSP Model Ordinance requires that growing areas be placed in the closed status when the PSP toxin concentration is equal to or exceeds the action level of 80 micrograms per 100 grams of ~~edible portion of~~ raw shellfish (FDA, 1977; FDA, 1985).

In shellfish growing areas where low levels of PSP toxin routinely occur, harvesting for thermal processing purposes may be an alternative to consider. Thermal processing as defined by applicable FDA regulations (21 CFR 113) will reduce ~~but not entirely destroy~~ the PSP toxin concentration content of the shellfish via dilution, not destruction. If thermal processing is practiced, the Authority must develop and implement procedures to control the harvesting and transportation of the affected shellfish to the processing plant.

In Gulf coast areas, toxicity in shellfish has been associated with red tide outbreaks caused by massive blooms of the toxic dinoflagellate, *Karenia brevis*. The most common public health problem associated with *Karenia* blooms is respiratory irritation; however, neurotoxic shellfish poisonings associated with *Karenia brevis* blooms have been reported in Florida (Center for Disease Control, 1973 [a] and [b]). Uncooked clams from a batch eaten by a patient with neurotoxic symptoms were found to contain 118 mouse units per 100 grams of shellfish meat. The NSSP Model Ordinance mandates that growing areas be placed in the closed status when any NSP toxin is found in shellfish meat at or above 20 MU per 100 grams of shellfish, or when the cell counts for members of the genus *Karenia* in the water column equal or exceed 5,000 cells per liter of water.

ASP is caused by domoic acid, which is produced by diatoms of the genus *Pseudo-nitzschia*. Blooms of *Pseudo-nitzschia* are of relatively short duration varying intensity, duration and extent. ~~However, during the~~ 1991-1992 incident in Washington and a 2015 event on the west coast from Washington to California, high toxin levels persisted for several months (Liston, 1994; McCabe et al. 2016). There was also an extensive event in the Northeast from Maine to Rhode Island in 2016, with different regions showing varying toxicity and species dominance within the bloom. The event started in late September in eastern Maine and ended in October; however, Rhode Island experienced another bloom in February of 2017. The NSSP Model Ordinance requires that growing areas be placed in the closed status when the domoic acid concentration is equal to or exceeds 20 parts per million in ~~the edible portion of~~ raw shellfish.

The suitability of some growing areas for shellfish harvesting is periodically influenced by the presence of marine biotoxins such as those responsible for PSP, NSP, domoic acid, ASP, DSP and AZP ~~or other marine Biotoxins~~. The occurrence of these toxins is often unpredictable, and the potential for them to occur exists along most coastlines of the United States and other countries having shellfish sanitation Memoranda of Understanding (MOU) agreements with the United States. As a result, states or countries with MOUs with the U.S. need to have management plans and/or make contingency plans to address shellfish-borne intoxications.

**Controlling Marine Biotoxins in Shellfish**

There are two types of plans defined in the NSSP MO for the control of marine biotoxins. A contingency plan is developed by an Authority that has no history or reason to expect toxin-producing phytoplankton in their growing areas. A marine biotoxin management plan is developed by an Authority that has historic occurrence of toxin-producing phytoplankton and toxicity in shellfish from their growing areas.

The Contingency Plan

The contingency plan is primarily for reactive management to an illness outbreak or an emergence of a toxin-producing phytoplankton in a growing area that has not historically occurred before. The contingency plan must describe administrative procedures, laboratory support, sample collection procedures, ~~and~~ patrol procedures to be implemented on an emergency basis ~~and reopening criteria in the event of the occurrence of shellfish toxicity~~ (Wilt, 1974). The contingency plan is only appropriate for a shellfish Authority that has no history or reason to expect toxin-producing phytoplankton in their growing areas. The primary goal of ~~this planning the contingency plan~~ should be to ensure that maximum public health protection is provided. To achieve this goal the following ~~objectives~~ elements should be ~~met~~ included:

- A process for immediate precautionary closures;
- A sampling plan that considers water samples to evaluate the extent and intensity of the toxic phytoplankton distribution;
- A sampling plan that considers species-specific shellfish sampling;
- Access to biotoxin tests: both screening and approved methods;
- Trained staff to carry out sample collection and testing if necessary; and
- A reopening criteria.

~~\*An early warning system should be developed and implemented.~~

~~\*Procedures should be established to define the severity of occurrences.~~

~~\*The state or MOU country should be able to respond effectively to minimize illness.~~

~~\*Adequate intelligence and surveillance information should be gathered and evaluated by the Authority.~~

~~\*Procedures should be instituted to return the Biotoxin-contaminated areas to the open status of their growing area classification.~~

Under the certification provisions of the NSSP, FDA and receiver states should have the assurance that shellfish producing states or MOU countries are taking and can take adequate measures to prevent harvesting, shipping, and consumption of toxic shellfish. To provide this assurance, the NSSP requires the Authority to develop and adopt a marine Biotoxin contingency plan for all marine and estuarine shellfish growing areas. The Authority's plan should specify how each of the objectives listed above will be accomplished. This document provides recommended guidelines to be used in preparing a plan to meet these objectives.

### The Marine Biotxin Management Plan

The marine biotoxin management plan is primarily for proactive management of marine biotoxins for growing areas with a history of toxin-producing phytoplankton and toxicity in shellfish and/or a previous illness event or outbreak. The management plan must describe an early warning system, administrative procedures, laboratory support, sample collection procedures, patrol procedures to be implemented and reopening criteria (Wilt, 1974). A management plan is required for a shellfish Authority that has a history of toxin-producing phytoplankton, toxicity in shellfish and/or an illness event or outbreak attributed to their growing areas. A shellfish Authority might have a management plan for certain marine biotoxins like PSP toxins but a contingency plan for toxins like AZP toxins. The primary goal of the management plan should be to prevent illnesses from toxic shellfish and ensure that maximum public health protection is provided. To achieve this goal the following elements should be included:

- An early warning system should be developed and implemented.
- Procedures should be established to define the severity of occurrences.
- The Authority should be able to respond effectively to minimize risk of illness.
- Adequate intelligence and surveillance information should be gathered and evaluated by the Authority.
- Procedures should be instituted to return the biotoxin contaminated areas to the open status of their growing area classification.

### **Recommended Contingency Plan Guidelines**

*\* Provide an early warning system:*

1. Communication procedures should be established with other appropriate agencies to rapidly report to the Authority any abnormal environmental phenomenon that might be associated with shellfish growing areas such as bird or fish kills, water discoloration or abnormal behavior of shellfish or marine scavengers.
2. The Authorities should establish procedures for health agencies to report any toxin-like illnesses.
3. An early warning phytoplankton and/or shellfish-monitoring program should be implemented.

These monitoring programs should use the "keyprimary station" (for both phytoplankton and shellfish monitoring) and "critical species" concepts (for shellfish monitoring).

\* Sampling stations (primary stations) should be located at sites where past experience has shown toxin is most likely to appear first.

\* When monitoring shellfish, samples should be collected of species which are most likely to reveal the early presence of toxin and which are most likely to show the highest toxin levels (critical species). For example, mussels have been found to be useful for early PSP detection. Sampling design should always consider what species are present in the growing area and commercially harvested.

\* The frequencies and ~~periods~~geographic distribution for collection of samples should be established recognizing the randomness of PSPtoxic algal blooms. This assumes several years of baseline data in order to establish stations and sampling plans.

\* Frequency and geographic distribution of sampling should be adequate to monitor for fluctuations in coastal phytoplankton populations and the influence of meteorological and hydrographic events. For example, a large rain storm may cause nutrient loading in coastal waters and trigger a toxic phytoplankton bloom or a hurricane may drive offshore phytoplankton blooms onshore.

4. Channels of communication concerning shellfish toxicity should be established with other states, countries (in the case of MOU countries), FDA, and other responsible officials. A marine Biotoxin control official should be designated by the Authority to receive and distribute all marine Biotoxin related information. Consultation with adjacent jurisdictions, marine biologists and other environmental officials ~~might also be~~is also useful (Felsing, 1966; Quayle, 1969; Prakash *et al.*, 1971).

\* *Define the severity of the problem:*

1. A procedure should be established to promptly expand the sampling program for marine Biotoxins in the event of increased toxicity/cell counts at any indicator monitoring stations identified within the plan. Sampling stations and frequencies of sampling should be increased when monitoring data or other information suggests that toxin levels are increasing. The procedure should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program.
2. Information should be available concerning the location of commercial shellfish resource areas and species present in the state.
3. Criteria should be developed to define the circumstances under which growing areas will be placed in the closed status because of marine Biotoxin contamination. The criteria should integrate public health, conservation, and economic considerations. Principal items of concern include consideration of the rapidity with which toxin levels can increase to excessive levels, the inherent delays in sample collection and results, the number of samples required to initiate action, the size of the area to be closed (including a safety zone), and the type of harvesting restrictions to be invoked (all species or specific species). It may be appropriate to close harvesting areas adjacent to known toxic areas until increased sampling can establish which areas are toxin free and that toxin levels have stabilized.
4. Procedures should be established to promptly identify which shellfish products or lots might be potentially contaminated, and to determine the distribution of these products or lots.



*\* Respond effectively to minimize illness:*

1. A summary should be provided citing the laws and regulations in the state (or MOU country) that promptly and effectively allow the Authority to restrict harvesting, withdraw interstate shipping permits, and to embargo/recall any potentially toxic shellfish already on the market in the event of a marine B*bi*otoxin *episode* event. The plan should clearly define the timeframe involved in taking appropriate legal action.
2. The administrative procedures necessary to place growing areas in the closed status, to withdraw interstate certification of dealers, and to embargo and recall shellfish should be delineated. The timeframe necessary to accomplish these actions should also be specified.
3. A plan should be developed which will define what type of patrol program is necessary to properly control harvesting in toxin contaminated growing areas. The program should be tested to ensure prompt implementation in the event it is needed.
4. Procedures should be developed to promptly disseminate information on the occurrences of toxic phytoplankton blooms to the industry and local health agencies. It is helpful to establish relationships and procedures with other agencies such as the state CDC and Poison Control and authorities in advance of any serious biotoxin event.
5. Procedures should be established to coordinate control activities taken by state and federal agencies or departments and district, regional, or local health authorities.

*\* Gather follow-up data:*

1. Appropriate records of illnesses should be compiled and maintained by the Authority. These records should include data on the incidence of illness and appropriate case history data. This information may be important in defining the severity of the problem, as well as for a retrospective evaluation of the adequacy of the entire control program.
2. Records of shellfish sample results from toxin testing should include analysis of trends, detoxification curves, phytoplankton and water sample analyses, and pertinent environmental observations.
3. Whenever possible the Authority should archive shellfish homogenates for additional analysis.

*\* Return growing areas to the open status of their NSSP classification:*

1. Once a growing area is placed in the closed status because of marine Biotoxin contamination, a procedure should be instituted to gather data necessary to decide when the area can be returned to the open status of its classification. A system of representative samples to establish detoxification curves should be part of this procedure.

	<ol style="list-style-type: none"> <li>2. The Authority should develop a set of criteria that must be met before a growing area can be returned to the open status. These criteria should integrate public health, conservation, and economic considerations, and employ a sufficient number of samples and other environmental indices, if used, to establish that the level of toxin or cell counts are below the closure level. For example, experience has shown that appropriate reopening criteria for PSP include a minimum of three (3) samples collected over a period of at least fourteen (14) days. These samples should show the absence of PSP or levels below 80 micrograms per 100 grams of shellfish tissue.</li> <li>3. A program of consumer education should be continued as long as any area remains in the closed status because of marine Biotoxin contamination.</li> </ol> <p><b>References</b></p> <ol style="list-style-type: none"> <li>1. Center for Disease Control (a). 1973. Shellfish Poisoning - Florida. <i>Morbid. Mortal. Weekly Rep.</i>22(48):397-398.</li> <li>2. Center For Disease Control (b). 1973. Neurotoxic Shellfish Poisoning - Florida. <i>Morbid. Mortal. Weekly Rep.</i> 22(48):397-398.</li> <li>3. Felsing, W.A., Jr. 1966. Proceedings of Joint Seminar on North Pacific Clams, September 24-25,1965. U.S. Public Health Service, Washington, D.C.</li> <li>4. Food and Drug Administration. 1977. Poisonous or Deleterious Substances in Food. <i>Federal Register</i> 42(190):52814-52819.</li> <li>5. Food and Drug Administration. 1985. Action Levels For Poisonous or Deleterious Substances in Human Food and Animal Feed. U.S. Department of Health and Human Services, Public Health Service, Washington, D.C. 20204. 13 pages.</li> <li>6. Gordon, K., M.D., <i>et al.</i> 1973. Shellfish Poisoning. <i>Morbid. Mortal. Weekly Rep.</i> 22, (48):397-398.</li> <li>7. Liston, J. 1994. Association of <i>Vibrionaceae</i>, natural toxins, and parasites with fecal indicators, p.215-216. In Hackney, C.R. and M.D. Pierson (eds.), <i>Environmental Indicators and Shellfish Safety</i>. Chapman and Hall, New York, NY.</li> <li>8. Prakash, A., J.C. Medcof, and A. D. Tennant. 1971. Paralytic shellfish poisoning in easternCanada. Bulletin 177, Fisheries Research Board of Canada. Ottawa, Canada.</li> <li>9. Quayle, D.B. 1969. Paralytic shellfish poisoning in British Columbia. Bulletin 168, FisheriesResearch Board of Canada. Ottawa, Canada.</li> <li>10. Schwalm, D.J. 1973. The 1972 PSP outbreak in New England. FDA Report, Boston, MA. U.S.Food and Drug Administration, Washington, D.C.</li> <li>11. U.S. Public Health Service (PHS). 1958. Proceedings: 1957 Conference on Shellfish Poison. U.S.PHS, Washington, D.C. 125 pages.</li> <li>12. Wilt, D.S. (ed). 1974. Proceedings of Eighth National Shellfish Sanitation Workshop. January 16-18. New Orleans, LA. National Technical Information Services (PB8 6 236916/AS), U.S. Dept. of Commerce, Springfield, VA. 158 p.</li> </ol>
Public Health Significance	This proposal includes modifications to Guidance Document .02 Guidance for Developing Marine Biotoxin Contingency Plans. This proposal includes guidance document modifications to support Proposal 17-122.

<p>Cost Information</p>	
<p>Action By 2017 Task Force I</p>	<p>Recommends adoption of Proposal 17-123 as amended.            Note: The only amended language is in paragraph two (2) of the introduction section as follows:</p> <p>There are a wide range of methodologies developed for screening and confirmation of toxic phytoplankton and their toxins. Only methods adopted into the NSSP can be implemented for the purpose of confirming toxin concentration levels and making decisions to <del>close or</del> reopen growing areas. Additionally, some screening methods have been evaluated by the ISSC and found fit for purpose for the NSSP, thereby providing confidence in their use for specific screening purposes. Toxin methods fall into two categories in the NSSP: Approved Methods for Marine Biotxin Testing (Section IV. Guidance Documents Chapter II Growing Areas .14 Table 2.) and Approved Limited Use Methods for Marine Biotxin Testing (Section IV. Guidance Documents Chapter II Growing Areas .14 Table 4.). These methods range from mouse bioassays to immunochromatography and other antibody based platforms to chemical analytical methods such as high performance liquid chromatography (HPLC). Information available in the referenced Tables above provides references for the methods and, as applicable, what limitations are placed on the use of the method within the NSSP. For toxins that have no method adopted into the NSSP, best available science is employed.</p>