Interstate Shellfish Sanitation Conference

Task Force I

Proposals for Consideration

At the 2017 Biennial Meeting
October 14 – 19, 2017
Sheraton Hotel & Convention Center

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Proposal No. **05-111**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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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	Procedure for Acceptance and Approval of Analytical Methods for the NSSP Marine Biotoxins affect farmed and wild fish and shellfish, as well as having a deleterious effect on humans. Jellett Rapid Testing has designed and developed rugged tests for the presence of Paralytic Shellfish Poison, Amnesic Shellfish Poison and Diarrhetic Shellfish Poison (under development at the time of this submittal). To facilitate the use of these tests in the field (for aquaculturists, campers, regulatory officials, etc.), Jellett Rapid Testing has developed a "low-tech" rugged alternative to the standard AOAC method designed to extract the toxins in the field as well as the laboratory. The AOAC method requires the sample to be boiled in acid at low pH and the pH adjusted with strong acids. This requires a fully equipped laboratory and significant safety precautions. The JRT Rapid Extraction Method was designed for use in remote areas, with little sophisticated backup support, by average individuals with little training and education. It is faster, less labor-intensive and less expensive than the other available method. The rapid extraction method requires vinegar and rubbing alcohol to extract the toxins. A simple, rapid, safe method such as this would make rapid tests for marine Biotoxins available in remote areas, to fishermen, aquaculturists, and regulatory officials on an instant basis. The method developed by Jellett Rapid Testing Ltd has been presented to regulatory bodies over the past several years. In cooperation with individuals, governments and those organizations, the analytical method has been refined and improved. The Rapid Extraction Method is being tested in several states and foreign countries. Publications will be forthcoming. The CONSTITUTION BY-LAWS and PROCEDURES of the INTERSTATE SHELLFISH SANITATION CONFERENCE allows the ISSC, through the Laboratory Methods Review Committee, to accept analytical methods that are sufficiently validated but are not AOAC or APHA methods. This is defined in the Constitution, PROCEDURE XVI. PROCEDURE FOR ACCEPTANCE AND APPROVAL OF ANALYTICAL METHODS FOR THE NSSP. Two possible reasons for considering a method are found in Subdivisions i and ii. Subdivision i. Meets immediate or continuing need;

	Subdivision ii. Improves analytical capability under the NSSP as an alternative to other approved or accepted method(s) Currently, only the AOAC extraction for PSP and ASP are accepted. The need for a simple safe extraction method has been expressed by regulatory agencies, governmental organizations and industry for many years. The Jellett Rapid Extraction Method is being validated over a wide geographic area to demonstrate its simplicity, reliability, precision and accuracy. As a result of demonstrations of efficacy and the need that has been expressed by industry and state agencies, the Jellett Rapid Extraction Method is presented as an alternative extraction method for PSP and ASP for the NSSP as a Type III or Type IV method. Please see attached additional information. Suggested wording: Section II, Chapter III Laboratory @.02 Methods C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be: (1) The current AOAC and APHA methods used in bioassay for paralytic shellfish poisoning toxins; and (2) The current APHA method used in bioassay for *Karemia breve* toxins. (3) The Jellett Rapid Extraction Method may be used for extracting PSP and ASP toxins from Shellfish by regulatory and industry laboratories.
Public Health Significance	Currently, only the AOAC extraction for PSP and ASP analyses are accepted. Because of many significant constraints, in practical terms, this means that analyses can be conducted only in laboratories, and then under dangerous conditions. Acceptance of the Jellett Rapid Extraction Method for PSP and ASP would allow harvesters, processors, and regulatory agencies to screen for PSP and ASP with an accepted standardized method that provides valid useable data. The Jellett Rapid Extraction Method for PSP and ASP was developed over several years in answer to the oft-stated need for a rapid, reliable, rugged, simple and safe sample preparation method. The Jellett Rapid Extraction Method for PSP and ASP is not meant to be a definitive “Standard Method”, but rather to provide a supplementary extraction method that can be used in the field as well as in the lab. Possible applications for The Jellett Rapid Extraction Method for PSP and ASP include: • as a supplement to analytical methods of screening out negative samples in shellfish regulatory labs; • as a harvest management tool at aquaculture facilities or in wild shellfish harvest areas (especially near shore areas) to supplement available methods to determine if shellfish are free of PSP or ASP and safe to harvest; • as a supplement to quality control methods for shellfish processing plants, distributors and wholesalers to ensure incoming shellfish are free of PSP and ASP toxins before processing or further distribution (this test could become part of the plant's HACCP program); • as a supplement to analytical methods for water classification for

	Biotoxins; and • as a supplement to analytical methods for broad scale ecological monitoring. The rationale for using the Jellett Rapid Extraction Method for PSP and ASP is that the method provides a rapid, reliable, rugged, simple, safe and cost-effective extraction method (especially in low-volume laboratories) for PSP and ASP that can supplement accepted tests and substantially reduce the cost of analyses. Used in conjunction with other rapid methods, the Jellett Rapid Extraction Method for PSP and ASP will supplement regulatory agency efforts and help prevent the harvest of contaminated product. Having the ability to conduct tests using an accepted rapid extraction method will allow those processors who choose to use this test to demonstrate that they are truly controlling for PSP and ASP hazards in the harvested shellfish. The Jellett Rapid Extraction Method for PSP and ASP could contribute to building long-term databases on broader scales than a regulatory lab can afford and, by using an accepted standardized method, will provide consistent results. These databases could be supplemented with industry testing in areas where there is no testing currently. This would extend, augment and strengthen the current food safety system broadening and refining the food safety net by increasing the number of testing sites and generating long term data in more areas. A simple, rapid, rugged, effective, reliable, safe and cost-effective extraction method, available to all harvesters, regulators, and processors, would increase the monitoring and reduce the chance that shellfish containing ASP toxins above the regulatory limit would be harvested or marketed
Cost Information	It is difficult to determine exact costs because many government cost models do not consider capital costs. Both extraction methods are the same through puree step, the chemicals used in both cases are minimal, as is the cost of incidental equipment (blender, pipettes, etc.). However, a comparison of time required using the Rapid Extraction Method (Add rapid liquid; Filter) with the time required using the AOAC Extraction (Add HCL; Boil; Wait; Filter; Pour in tube; Check PH) shows a significant difference. Our experience shows that it takes about 22 minutes for this portion of the AOAC extraction while it takes less than 2 minutes to complete the Jellett Rapid Extraction Method. At a salary of $33 / hour, that is a savings of $11.00 per sample extract.
Action by 2005 Laboratory Methods Review Committee	Recommended referral of Proposal 05-111 to the appropriate committee as determined by the Conference Chairman.
Action by 2005 Task Force I	Recommended adoption of the Laboratory Methods Review Committee recommendation of Proposal 05-111.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force I.
Action by USFDA	Concurred with Conference action.
Action by 2007 Laboratory Methods Review Committee	Recommended no action on Proposal 05-111. Rationale – Alternative extraction method for JRT PSP should be adopted to expand utility of the test; however there are insufficient data for acceptance at this time. The submitter will send data to the Executive Office for Conference approval.
Action by 2007 Task Force I	Recommended referral of Proposal 05-111 to an appropriate committee as determined by the Conference Chairman.
Action by 2007	Adopted recommendation of 2007 Task Force I.

General Assembly	
Action by USFDA	December 20, 2007 Concurred with Conference action with the following comments and recommendations for ISSC consideration. The Conference has made considerable progress in its efforts to recognize new and developing analytical methods for the detection of indicators, pathogens, and marine toxins. Much credit goes to the Laboratory Methods Review Committee and its leadership for ensuring a scientifically defensible process for adopting analytical methods under the NSSP. At the 2007 meeting numerous analytical methods were proposed for ISSC adoption. However, many of these methods were lacking the validation and associated data needed by the Laboratory Methods Review Committee to make a final determination regarding their efficacy for use in the NSSP. As a result the General Assembly voted "No Action" on analytical method Proposals 05-107, 05-108, 05-109, 05-111, 05-113, and 05-114. It is FDA's understanding that the intent of the "No Action" vote was not to remove these Proposals from ISSC deliberation as "No Action" normally suggests, but rather to maintain them before the Conference pending submission of additional data for further consideration. The Voting Delegates, by requesting the Proposal submitters provide additional data to the Executive Office for methods approval consistent with Procedure XVI, clearly recognized the importance and utility of these methods and intended to maintain them before the Conference for possible adoption following additional data submission. FDA requests that the ISSC Executive Board confirm FDA's understanding of this outcome. FDA fully supports such a Conference action and encourages the Executive Office to pursue submission of additional data as necessary to move forward with acceptance of these methods.
Action by 2009 Laboratory Methods Review Committee	Recommended no action on Proposal 05-111. Rationale: Requested additional information has not been submitted.
Action by 2009 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation of Proposal 05-111.
Action by 2009 General Assembly	Referred Proposal 05-111 to the Laboratory Methods Review Committee.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 05-111.
Action by 2011 Laboratory Methods Review Committee	Recommended acceptance of the rapid extraction method in Proposal 05-111, specifically 70% isopropanol: 5% acetic acid 2.5:1, only for use with the Abraxis shipboard ELISA for PSP as an Emerging Method solely for use in the onboard screening dockside testing protocol in the Northeast region, including George's Bank. The Laboratory Methods Review Committee further recommends: 1. The data collected during the dockside testing study be submitted to the LMRC in the SLV Method Application Protocol within 6 months of the concurrence by FDA in the Summary of Actions. 2. The validation study conducted by the State of Maine of the Abraxis laboratory ELISA with the extraction method in Proposal 05-111 be submitted to the LMRC in the SLV Method Application Protocol within 6 months of the concurrence by FDA in the Summary of Actions.

	3. No action on the requested language change in Proposal 05-111 for the Model Ordinance Section II, Chapter III Laboratory @.02 Methods. Section II, Chapter III Laboratory @.02 Methods C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be: (1) The current AOAC and APHA methods used in bioassay for paralytic shellfish poisoning toxins; and (2) The current APHA method used in bioassay for *Karenia breve* toxins. (3) ~~The Jellett Rapid Extraction Method may be used for extracting PSP and ASP toxins from Shellfish by regulatory and industry laboratories.~~
Action by 2011 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendations on Proposal 05-111.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 05-111.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 05-111.
Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended no action on Proposal 05-111 Rationale - Proposal 05-111 is resolved by action on Proposal 13-109.
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 05-111.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 05-111.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 05-111.
Action by 2015 Laboratory Methods Review Committee	Recommended the following: 1) Change the name of the Jellett Rapid Test to Scotia Rapid Test and the Jellett Rapid Extraction to Scotia Rapid Extraction in the next revision of the NSSP Guide for the Control of Molluscan Shellfish (Section IV. Guidance Documents Chapter II Growing Areas 4. Approved Limited Use Methods for Marine Biotoxin Testing). 2) Refer Proposal 05-111 for PSP to an appropriate committee as determined by the Conference Chair and further recommended to direct the Executive Office to send a letter to the method submitter requesting additional information as detailed by the LMRC. 3) No action on the Scotia Rapid Extraction Method for ASP as there is no data nor did the submitter indicate that data would be submitted for ASP.
Action by 2015 Task Force I	Recommended adoption of the Laboratory Methods Review Committee on Proposal 05-111 with the following amendments: 1. Remove "and ASP" and change "toxins" to "toxin" throughout the proposal and adopt the Laboratory Method Review Committee recommendation 1 2. Refer Proposal 05-111 to appropriate committee as determined by Conference Chair. 3. No action on recommendation 3 as this is covered by the proposal as amended by the Task Force.
Action by 2015 General Assembly	Adopted recommendations 2. And 3. of Task Force I on Proposal 05-111. Recommendation 1. Was ruled out of order and the General Assembly did not take any action on this recommendation.
Action by FDA	Concurred with Conference action on Proposal 05-111.

January 11, 2016	

Proposal No. **11-103**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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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. (4) Exception. If the Male-specific Coliphage indicator is used for supplemental process verification using an end-point meat standard of < 50PFU/100gm and existing fecal coliform testing requirements in Chapter XV .03 J. are used, then FC water quality monitoring is not required for the restricted classification of growing areas affected by point sources such as wastewater treatment plant outfall.
Public Health Significance	Under shellfish relay, water quality requirements are not needed for the restricted classification when a contaminant reduction study is conducted and a minimum time period of two weeks is used. For depuration, the restricted classification requires water quality monitoring and standards. The reason for these upper FC limits is that FC meat indicator does not adequately reflect the viral risk and/or viral depuration kinetics. Male-specific coliphage is a viral indicator organism to be used in growing areas impacted by point source sewage contamination. MSC demonstrates significant advantages over FC alone for both the assessment of viral contamination and assessment of viral depuration kinetics. Upper FC limits were put into the NSSP to prevent shellfish with higher levels of viruses from being depurated. Several studies clearly show that conventional depuration using FC for process validation is not adequate to protect public health with respect to virus contamination in growing areas with significant wastewater treatment plant and sewage impact. Studies have also shown that viral levels in shellfish impacted by sewage and partially treated sewage detected using MSC and molecular techniques are much lower in the summer months than the winter months. Additionally, the viral depuration rate is higher in the summer with process waters >18°C. Recent studies have also shown that MSC is an appropriate viral indicator to assess viral depuration. Therefore, seasonal viral depuration using male-specific coliphage as well as FC for process verification is a superior approach to taking water samples using FC in a growing area adjacent to wastewater treatment plant outfall. Combining the bacterial indicator of FC and the viral indicator MSC for mitigation strategies that use meat scores is far more direct and effective than water quality sampling in this context.
Cost Information	The Male-specific Coliphage (MSC) method is an inexpensive double-agar pour plate method that can be run in any state-certified microbiological laboratory. A

	refrigerated centrifuge capable of 9,000G is required which costs $10K to $12K (USD). Significant cost savings and a higher level of public health protection may be realized using strategies such as seasonal coliphage depuration process validated using MSC and seasonal coliphage relay using MSC in contaminant reduction studies than requiring water quality limits using FC.
Action by 2011 Task Force I	Recommend referral of Proposal 11-103 to the appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 11-103.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-103.
Action by 2013 Growing Area Classification Committee	Recommend referral of Proposal 11-103 to the appropriate committee as determined by the Conference Chairman. It was additionally recommended that a workgroup be formed to look at current MSC data and the science behind its potential use and applicability for use in the NSSP. The workgroup will organize a summit of outside experts, academia, and scientists to present current information and science on MSC. The group will meet at least quarterly and respond back to the Growing Area Classification Committee on its findings and recommendations. Recommended that the ISSC pursue funding to facilitate scheduling a summit to bring together experts to present the current science in the use of MSC.
Action by 2013 Task Force I	Recommended adoption of Growing Area Classification Committee action on Proposal 11-103.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 11-103.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-103.
Action by 2015 Growing Area Classification Committee	Recommended referral of Proposal 11-103 to appropriate committee as determined by the Conference Chair.
Action by 2015 Task Force I	Recommended adoption of Growing Area Classification Committee recommendation on Proposal 11-103.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 11-103.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 11-103.

Proposal No. **13-107**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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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	.03 Seed Shellstock Seed may come from any growing area, or from any growing area in any classification, provided that: A. The source of the seed is sanctioned by the Authority B. Seed from growing areas ~~or growing areas~~ in the restricted or prohibited classification have acceptable levels of poisonous or deleterious substances; and C. Seed from growing areas ~~or growing areas~~ in the prohibited classification are cultured for a minimum of ~~six (6) months~~ one month while average daily water temperatures are above 50 degrees F.
Public Health Significance	Shellfish seed collected or cultured in certain growing areas that are in the prohibited classification have been shown through repeated sampling to be free of deleterious substances (John Mullen RI DOH, unpub. data, Rheault unpubl. data, Rice unpub. data, Leavitt unpub. data). A period of one month is typically adequate to purge viral and bacterial contaminants provided water temperatures are high enough to maintain active metabolic activity (above 60 degrees F or 15 degrees C) (Richards 1988). Once the Authority is satisfied that adequate sampling has demonstrated that the seed have "acceptable levels of deleterious substances", then a 30 day period of culture in open waters should be adequate to allow purging of bacterial and viral contaminants to ensure that public health is protected. The Authority retains the right to deny seed collection and culture in any area, or to require additional testing for deleterious substances, or to require longer periods to purge contaminants as necessary. The original intent of this section was to provide for purging of viral and bacterial contamination prior to harvest for consumption on the assumption that deleterious substances were at acceptable levels prior to moving the seed to grow out areas The six-month requirement was implemented as a short-hand way to ensure that seed were grown for at least one month when water temperatures exceeded 60 degrees F. It makes little sense to require relay times in excess of one month for seed that are typically more than six months from harvest size when shellstock relay times as short as two weeks are common.

	References Cited: Richards, G. (1988), Microbial Purification of Shellfish: A Review of Depuration and Relaying, J. Food Protection 51(3)218-251. Supporting Information: RI DOH metals data (oyster seed grown in Billington Cove Marina) Unpublished data from Rd. Dale Leavitt (clam seed grown in Warwick Cove Marina)
Cost Information	This change should facilitate record keeping and documentation efforts required to ensure that seed from prohibited waters do not get harvested until bacterial and viral contamination has been purged.
Action by 2013 Task Force I	Recommended referral of Proposal 13-107 to an appropriate committee as determined by the Conference Chairman.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-107.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-107.
Action by 2015 Aquaculture Facility Inspection Committee	Recommended the following: (1) Referral of Proposal 13-107 back to Committee as appointed by the Conference Chair. (2) The charge of the Committee be expanded to include updating and revising the Aquaculture Chapter of the Model Ordinance to reflect current practices and methods and submit proposals for the next Annual Meeting.
Action by 2015 Task Force I	Recommended adoption of Aquaculture Facility Inspection Committee recommendations on Proposal 13-107.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 13-107.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-107.

Proposal No. **13-109**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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

Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-109.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-109.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-109 to an appropriate committee as determined by the Conference Chair until data that supports the use of the Abraxis ELISA beyond the use of the onboard procedure is made available.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-109.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 13-109.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-109.

Proposal No. **13-110**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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Proposal Subject	Immunoassay Method for Detection of Saxitoxin (PSP) from Shellfish
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	2. Approved Methods for Marine Biotoxin Testing and 4. Approved Limited Use Methods for Marine Biotoxin Testing. Review the validation for Saxitoxin (PSP) Microtiter Plate Test Kit by the Proposal Review Committee. Single Laboratory Validation Protocol for Method Approval attached.
Public Health Significance	Rapid screening method can handle numerous samples and screen out negative samples so that it reduces the size of sample to be confirmed with regulatory methods such as mouse bioassay (MBA) or liquid chromatography with post-column oxidation (PCOX). This results in saving resources of the laboratories, and makes the laboratories able to provide rapid warning. References attached.
Cost Information	Approximate cost for the basic set up of the method is $3600.
Action by 2013 Laboratory Methods and Quality Assurance Review Committee	Recommended referral of Proposal 13-110 to an appropriate committee as determined by the Conference Chairman and directs the Executive Office send a letter to the submitter requesting additional information as requested by the Laboratory Methods Review and Quality Assurance Committee.
Action by 2013 Task Force I	Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-110.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-110.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-110.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-110 to the appropriate committee as determined by the Conference Chair until additional data are received.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-110.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 13-110.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-110.

Proposal No. **13-111**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	. a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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Proposal Subject	DSP PPIA Kit for Determination of Okadaic Acid Toxins Group (OA, DTX1, DTX2) in Molluscan Shellfish
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests Marine Biotoxin Testing
Text of Proposal/ Requested Action	The DSP PPIA kit be approved as a Marine Biotoxin Laboratory Test Method.
Public Health Significance	Okadaic acid (OA) and its analogues, DTX1, DTX2, together with their ester forms are known as the group of OA-toxins. These toxins, lipophilic and heat stable, are produced by dinoflagellates and can be found in various species of shellfish, mainly in filter feeding bivalve molluscs. The OA-toxins group causes Diarrheic Shellfish Poisoning (DSP), which is characterized by symptoms such as diarrhea, nausea, vomiting and abdominal pain. These symptoms may occur in humans shortly after consumption of contaminated bivalve molluscs such as mussels, clams, scallops or oysters. Inhibition of serine/threonine phosphoprotein phosphatases is assumed to be responsible for these toxic effects. Recently in the Pacific Northwest harvest areas, outbreaks of DSP have occurred.
Cost Information	Refer to Para D.1. of the Checklist
Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chairman and directed the Executive Office send a letter to the submitter requesting additional information as provided by the Laboratory Methods Review and Quality Assurance Committee.
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 13-111.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-111.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-111.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chair until additional data are received.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-111.
Action by 2015 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-111.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-111.

Proposal No. **13-113**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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Proposal Subject	Reveal 2.0 DSP
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas
Text of Proposal/ Requested Action	.11 Approved NSSP Laboratory Tests We request review of the validation study submission for the Reveal 2.0 DSP (okadaic acid group) test kit and consideration of the method for approval as a screening method for qualitative determination of okadaic acid group in shellfish. Add Reveal DSP to Section IV. Guidance Documents, Chapter II. Growing Areas, .11 Approved NSSP Laboratory Tests.
Public Health Significance	Toxins that cause diarrhetic shellfish poisoning (DSP) include the okadaic acid (OA) group of toxins [1, 2] OA is produced by marine dinoflagellates such as Dinophysis, and has structural analogues referred to as the dinophysistoxins (DTXs). The U.S. Food and Drug Administration action limits are 160 ppb OA equivalents (OA, DTX1, DTX2, DTX3) in shellfish. LC-MS/MS methods [3] have been accepted as quantitative reference methods in many parts of the world. Assays facilitating more rapid determination of OA toxins with simplified procedures are needed by the shellfish industry and regulatory authorities. [1] J. Sobel and J. Painter (2005), Illness caused by Marine Biotoxins. Clin. Infect. Dis. 4, 1290. [2] Van Dolah, Frances M. (2000), Marine algal toxins: origins, health effects, and their increased occurrence. Environmental health perspectives 108. Suppl 1, 133. [3]Community Reference Laboratory for Marine biotoxins (CRLMB)., Agencia Española de Seguridad Alimentaria y Nutrición (AESAN). (2009). EU Harmonised Standard Operating Procedure for determination of OA-Group Toxins by LC-MS/MS. Version1. http://www.aesan.msps.es/en/CRLMB/web/procedimientos_crlmb/crlmb_standard operating_procedures.shtml
Cost Information	Approximately $17.00 per test. Reader based assay – approximate cost of Reader $1995.
Action by 2013 Laboratory Method and Quality Assurance Review Committee	Recommended referrals of Proposal 13-113 to an appropriate committee as determined by the Conference Chairman and await data to determine if the method is fit for purpose within the NSSP.
Action by 2013	Recommended adoption of Laboratory Method Review and Quality Assurance

Task Force I	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.

Proposal No. **13-114**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	Darcie Couture
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Proposal Subject	Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas. 11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	4. Approved Limited Use Methods for Marine Biotoxin Testing This submission presents the 'Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination' for consideration as an NSSP Approved Limited Use Method. The RBA is a competition-based assay that employs radiolabeled saxitoxin (3H-STX) to compete with PSP toxins present in standards/samples for binding sites on natural receptors in the assay. Following incubation with the receptors, unbound 3H-STX is removed and the remaining labeled toxin is measured with a scintillation counter. The amount of remaining 3H-STX is inversely proportional to standard/sample toxicity. The RBA offers a high-throughput, sensitive, and quantitative alternative to the mouse bioassay (MBA), which has been the long-standing reference method for PSP toxicity. Further, the RBA eliminates the use of live animals for detection of these toxins. While the RBA still uses receptors prepared from animals, the number of animals required for analysis is significantly reduced. Using native receptors as the analytical recognition elements for the assay allows for a composite measure of overall toxicity, as opposed to toxin concentrations measured by liquid chromatographic methods that require conversion factors of equivalent toxicity to calculate the overall toxicity. The RBA has undergone AOAC single- and multi-laboratory validation and is designated through AOAC as an Official Method of Analysis (OMA 2011.27). Results from those studies, and additional data, are included in this proposal submission for the RBA to be considered for approval as an NSSP Approved Limited Use Method for Marine Biotoxin Testing.
Public Health Significance	Paralytic shellfish poisoning intoxications result from the consumption of seafood (primarily bivalve molluscs) contaminated with neurotoxins known as paralytic shellfish toxins (PSTs). This suite of toxins binds to voltage-gated sodium channels and may result in paralysis if enough toxin is consumed. In extreme cases when respiratory support is not available to the patient, the intoxication may prove fatal. Since the toxins cannot be destroyed during cooking and there is no way to remove the toxins from seafood, the best control strategy is to ensure that contaminated product never reaches the market. To protect public health, harvesting closures are implemented when toxicity exceeds the guidance level of 80 micrograms saxitoxin equivalents per 100 grams of shellfish tissue. As such,

	accurate analytical methods are needed to monitor shellfish toxicity for making decisions regarding opening and closing shellfish growing areas accordingly. Acceptance of the RBA as an NSSP Approved Limited Use Method for PSP toxicity determination would provide monitoring and management programs with an additional tool that can be used for monitoring toxin levels and making regulatory decisions. Not only does the RBA eliminate the need for live animals for PSP testing, it is also more sensitive than the MBA, thereby providing an early warning system for monitoring programs as toxin levels begin to rise.
Cost Information	The estimated cost for a full 96-well plate assay is ~$95.00. Including standards and samples with triplicate measurements (as well as three dilutions per sample to ensure the unknown samples fall within linear range of assay), the cost per sample for quantitative results would be ~$13.60. If running multiple plates or in screening mode, sample costs would be reduced. Further, the filter plates used in the RBA differ from ELISA plates in that all reagents are added to each well as needed rather than already being a component of the plate, making it more practical and cost-effective to analyze samples when there is less than a full plate.
Action by 2013 Laboratory Methods and Quality Assurance Review Committee	1. Recommended approval of this method as an alternative to the mouse bioassay for PSP in mussels. 2. Recommended approval of this method for Limited Use for clams and scallops for the purpose of screening and precautionary closure for PSP. 3. Recommended referral of this proposal to an appropriate committee as determined by the Conference Chairman to address this method in oysters. 4. Recommended Executive Office 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.
Action by 2013 Task Force I	Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-114.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-114.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-114.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-114 to an appropriate committee as determined by the Conference Chair until additional data for oyster matrix are received.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-114.
Action by 2015 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-114.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-114.

Proposal No. **13-116**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	Florida Department of Agriculture and Consumer Services
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Proposal Subject	Shellfish Quarantine Guidance Document
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.04 Marine Biotoxin Control Section IV. Guidance Documents Chapter II. Growing Areas .02 Guidance for Developing Marine Biotoxin Contingency Plans
Text of Proposal/ Requested Action	Model Ordinance Chapter IV. Shellstock Growing Areas @.04 Marine Biotoxin Control Section A. (4) describes agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting during marine Biotoxin closures under specific, controlled conditions. The State of Florida has successfully implemented such an agreement to address Neurotoxic Shellfish Poisoning (NSP) for over a decade. This pilot project, developed in consultation with FDA, has resulted in zero cases of NSP in commercially harvested shellfish from Florida waters. NSP may affect any Gulf or South Atlantic state and therefore Florida wishes to provide ISSC member states with a proven quarantine protocol template for incorporation into the Model Ordinance Section IV. Guidance Documents. Guidance Documents Chapter II. Growing Areas .02 Guidance for Developing Marine Biotoxin Contingency Plans. Text of the proposed guidance is as follows: Example Protocol for Quarantine Harvest of Shellfish from Aquaculture Leases During *Karenia brevis* Closures: A. Closure of an entire shellfish growing area due to *Karenia brevis* shall be in accordance with Model Ordinance Chapter IV. @.04 C. (1). B. When a shellfish growing area is closed due to *Karenia brevis*, the Authority may allow harvest of shellfish from selected aquaculture leases within a specific zone by authorized harvesters and subsequent controlled quarantine at a certified shucker packer or shellstock shipper. This option would not be available if any Authority collected water samples in the specific zone exceeded 200,000 cells per liter of *Karenia brevis*. Zone is defined as an

Authority delineated geographic area within a Conditionally Approved or Approved classified shellfish growing area.

Controlled quarantine conditions:

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

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

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

(1) Have written permission on file with the Authority and are on an Authority-controlled document listing current approved quarantine program processors and;

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

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

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

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

lot.

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

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

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

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

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

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

(2) May receive properly tagged shellfish from eligible aquaculturists only as indicated in the Authority's authorization email;

(3) Must upon receipt of shellfish, separate and maintain the shellfish into specific lots [A Lot is defined as shellfish of one species from no more than one day's harvest from a specific zone within a shellfish growing area];

(4) Must place shellfish under proper controls and quarantine; Proper controls and quarantine are defined by bold, clear, warning signage signaling the properly tagged and segregated shellfish within the processor's cooler are under quarantine and must not be moved until Authority permission is obtained pending outcome of laboratory testing. The signage should be such that it is clear to anyone entering the cooler (including facility employees and/or regulatory inspectors) that the affected shellfish are under quarantine. Wrapping of the entire lot with a single bright red or yellow ribbon or equivalent attached to the bold warning sign will further reinforce the warning message.

(5) Must allow the Authority to take two (2) random samples [minimum of twenty (20) shellfish per each sample] from each lot and deliver to the approved laboratory for approved mouse bioassay;

(6) Must hold all shellfish in quarantine at the approved processor's

	certified facility until receiving official written test result notice from the Authority via email or fax that the shellfish are cleared for sale; (7) Must either return shellfish to aquaculture lease(s) in the zone(s) from where harvested if any sample in a lot is 20 Mouse Units / 100 grams or greater or destroy the shellfish, both activities of which must be witnessed and documented by the Authority; (8) Must cease this activity if any Authority collected red tide cell counts in the specific zone exceeds 200,000 cells per liter of *Karenia brevis*; and (9) Must document all of the requirements listed above in the approved facility HACCP plan. C. If cell counts in all water samples fall to 5,000 cells/L or less Karenia brevis in the entire area, the Authority will collect shellfish meat samples for toxicity testing and the entire Shellfish Harvesting Area will be reopened if results of all samples are <20 MU/100g. I _____(print name) have received a copy of this quarantine protocol and I agree to abide by all terms and conditions. I understand I am bound by the terms of this agreement during the period of time that I am processing shellfish from a shellfish growing area that is currently in the closed status due to Karenia brevis. _____ Signed Date
13. Public Health Significance	Closures of shellfish growing areas due to Neurotoxic Shellfish Poisoning (NSP) may occur at any time in the Gulf of Mexico and to a lesser degree, the Atlantic coast. Well established procedures for detecting and responding to *Karenia brevis* blooms have safeguarded public health. Clear early warning signs, a cell count action level with a high factor of safety and established sampling networks provide excellent public health protection. A very real impact of *Karenia brevis* blooms is the resulting long-term closures of shellfish growing areas and severe economic impact to commercial shellfish operations. Florida addressed this issue after studying years of water quality samples and mouse bioassay results from shellfish growing areas. Hydrodynamic studies linked to water samples obtained from fixed stations over an extended period of time established clear patterns in distribution of *Karenia brevis*. Working in conjunction with harmful algal bloom researchers, shellfish growing area managers, FDA and industry, Florida developed a NSP quarantine protocol that has resulted in the retention of a shellfish industry in one of the most severely impacted HAB regions of the Gulf while protecting public health as required by the Model Ordinance. An enormous amount of data has been generated and reviewed during the years this protocol has been used. Repeated mouse bioassay testing on shellfish exposed to different levels of *Karenia brevis* has provided Florida with sufficient data to refine the protocol into a powerful management tool. Florida's experience pre-quarantine protocol was unfortunate, as several fledgling businesses failed due to repeated NSP closures. It was this economic damage that spurred the aforementioned collaborative effort between leading edge HAB researchers, shellfish growing area managers, FDA and industry. If adopted, shellfish producing states impacted by *Karenia brevis* could reference this protocol in the Guidance Document and use it to effectively manage NSP closures.

Cost Information	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	Recommended adoption of Proposal 13-116 with substitute language as follows: (4) The plan may include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting in designated parts of a state growing area while other parts of the same ~~the~~ growing area are placed in the closed status. Such controlled harvesting shall be conducted with strict assurances of safety. In state growing areas or designated portions of state growing waters that are closed, the authority may allow for harvesting if an end product testing program is developed and~~, such as by batch release of shellfish lots only after~~ samples of each lot are tested and found to be below the action levels specified in Section C. The program must include at a minimum: i. Establishment of appropriate pre-harvest screening levels; ii. Establishment of appropriate screening and end product testing methods; iii. Establishment of appropriate laboratories/analysts to conduct screening and end product testing methods; iv. Establishment of representative sampling plan for both i. and ii. above; and v. Other controls as necessary to ensure that shellstock are not released prior to meeting all requirements of the program. Should the above amended proposal be adopted by the conference, then the Biotoxin Committee should develop a Guidance Document that includes guidance for development of end-product testing programs to address biotoxins in closed state waters.
Action by 2015 Task Force I	Recommends adoption of Biotoxin Committee recommendation on Proposal 13-116.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-116.

Proposal No. **15-102**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	Growing Area Classification Committee
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Proposal Subject	Using Male-Specific Coliphage as a Tool to Refine Determinations of the Size of the Areas to be Classified as Prohibited Adjacent to Each Outfall
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas
Text of Proposal/ Requested Action	@.01 Sanitary Survey. A. General. (1) The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of: (a) A shoreline survey; (b) A survey of the ~~bacteriological~~ microbiological quality of the water and in growing areas adjacent to wastewater system discharges the State Shellfish Control Authority may utilize MSC results from analysis of shellfish meat samples and the analysis of the data will be included in the sanitary survey report; (c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area; (d) An analysis of the data from the shoreline survey, the bacteriological and the hydrodynamic, meteorological and geographic evaluations; (e) A determination of the appropriate growing area classification. B. Sanitary Survey Required… C. Sanitary Survey Performance. (5) On an annual basis, the sanitary survey shall be updated to reflect changes in the conditions in the growing area. The annual reevaluation shall include: (a) A field observation of the pollution sources which may include: (i) A drive-through survey; (ii) Observations made during sample collection; and (iii) Information from other sources.

(b) Review, at a minimum, of the past year's water quality sample results by adding the year's sample results to the data base collected in accordance with the requirements for the bacteriological standards and sample collection required in Section .02;

(c) Review of available inspection reports and effluent samples collected from pollution sources;

(d) Review of available performance standards for various types of discharges that impact the growing area; ~~and~~

(e) A brief report which documents the findings of the annual reevaluation~~.~~; and

(f) The SSCA may use MSC meat sampling data and/or MSC waste water sampling data in the annual reevaluation of (5) (b), (c), and (d) above to evaluate the viral contributions of the performance standards of waste water system discharge (WWSD) impacts on shellfish growing areas.

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

D. Shoreline Survey Requirements…

@.02 ~~Bacteriological~~ Microbiological Standards.

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

A.. General. Either the total coliform or fecal coliform standard shall be applied to a growing area. The SSCA may utilize MSC data in conjunction with bacteriological data to evaluate waste water system discharge (WWSD) impacts on shellfish growing areas.

B. Water Sample Stations…

C. Exceptions…

D. Standards for the Approved Classification of Growing Areas in the Remote Status…

E. Standard for the Approved Classification of Growing Areas Affected by Point Sources…

F. Standard for the Approved Classification of Growing Areas Affected by

Nonpoint Sources…

G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration…

H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration…

@.03 Growing Area Classification.

A. General…
   (1) Emergency Conditions…
   (2) Classification of All Growing Areas…
   (3) Boundaries…
   (4) Revision of Classifications…
   (5) Status of Growing Areas…
      (a) Open Status…
      (b) Closed Status...
      (c) Reopened Status. A growing area temporarily placed in the closed status as provided in (b) above, shall be returned to the open status only when:
         (i) The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of contaminant levels in the shellstock to pre-closure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on coliform levels in the water; or
         (ii) For emergency closures ~~(not applicable for conditional closures)~~ of harvest areas caused by the occurrence of raw untreated sewage discharged from a large community sewage collection system or wastewater treatment plant, the analytical sample results shall not exceed background levels or a level of fifty (50) male-specific coliphage per 100 grams from shellfish samples collected no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted; or
         (iii) The requirements for Biotoxins or conditional area management plans as established in Section .04 and Section .03, respectively, are met; and
         (iv) Supporting information is documented by a written record in the central file.
      (d) Inactive Status…

(e) Remote Status…
(f) Seasonally Remote/Approved Status…

B. Approved Classification…

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

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

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

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

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

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

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

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

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

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

(i) Performance standards that reliably predict when criteria for conditional classification are met; and
(ii) Discussion and data supporting the performance standards.

(c) For management plans based on waste water system discharge ~~treatment plant~~ function or pollution sources other than waste water system discharge ~~treatment plants~~, criteria that reliably predict when an area that was placed in the closed status because of failure to comply

with its conditional management plan can be returned to the open status. The minimum criteria are:

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

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

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

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

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

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

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

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

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

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

(3) Reevaluation of Conditional Classification…

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

(5) Conditional Area Types…

(6) Conditionally Approved Classification…

	(7) Conditionally Restricted Classification... D. Restricted Classification… E. Prohibited Classification. (1) Exception… (2) General… (3) Sanitary Survey… (4) Risk Assessment… (5) Wastewater Discharges. (a) An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance. (b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria: (i) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the microbiological quality of the effluent; The SSCA may utilize MSC wastewater sample data in the determination of the performance of the sewage treatment plant; (ii) The decay rate of the contaminants of public health significance in the wastewater discharged; (iii) The wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and (iv) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries. NOTE: All references in Section II. Model Ordinance Chapter IV. Shellstock Growing Areas will be changed to Waste Water System Discharge (WWSD).
13. Public Health Significance	Male-specific Coliphage (MSC) is a RNA virus of E. coli present in high numbers in raw sewage (on the order of 105 PFU/100gm). MSC is similarly resistant to chlorine disinfection as are norovirus and hepatitis A viruses, which are the viral pathogens of concern in sewage. MSC is a good surrogate or marker for these enteric viruses and is a powerful tool to assess the impact on a growing area of raw, partially treated and treated sewage on adjacent growing areas. A better assessment of the risk of viral contamination at a particular location in an adjacent growing area can be ascertained directly using MSC assays of the shellstock. Performing and evaluating dye studies on waste water treatment plant outfall discharges, although effective, is expensive and complicated. Difficulties assessing ex-filtration and leakage from the sewage collection system are well known. Few tools and less guidance are available to adequately assess the performance of a particular waste water treatment plant design and its operation with respect to virus removal. There are advantages of using this specialty viral indicator to assess the overall impact of a municipal wastewater treatment system on a particular growing area. The ISSC held an MSC meeting in Charlotte on August 18-19, 2014 to discuss the

	available MSC science and knowledge. A panel of MSC experts provided MSC information and consensus regarding usage of MSC in the NSSP. (Click here to view, download, or print the MSC meeting report).
14. Cost Information	The use of MSC is not a requirement; rather, it is an option for States to use, so there would be no cost to States who do not choose to use it. For States that do choose to use MSC, the cost is discussed in the ISSC MSC Meeting Report, August 18-19, 2014, where it states: The MSC assay for shellfish is relatively easy to perform and the cost is roughly equivalent to that of performing fecal coliform testing. The initial cost to prepare laboratory to perform analysis, depends on the lab, and may be approximately $8000 to $10,000, if additional equipment is needed. There may also be cost associated with sample collection.
Action by 2015 Task Force I	Recommended adoption of Proposal 15-102 as amended. @.01 Sanitary Survey. A. General. (1) The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of: (a) A shoreline survey; (b) A survey of the microbiological quality of the water and in growing areas adjacent to wastewater system discharges the State Shellfish Control Authority may utilize MSC results from analysis of shellfish meat samples and the analysis of the data will be included in the sanitary survey report; (c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area; (d) An analysis of the data from the shoreline survey, the bacteriological and the hydrodynamic, meteorological and geographic evaluations; (e) A determination of the appropriate growing area classification. B. Sanitary Survey Required… C. Sanitary Survey Performance. (5) On an annual basis, the sanitary survey shall be updated to reflect changes in the conditions in the growing area. The annual reevaluation shall include: (a) A field observation of the pollution sources which may include: (i) A drive-through survey; (ii) Observations made during sample collection; and (iii) Information from other sources. (b) Review, at a minimum, of the past year's water quality sample results by adding the year's sample results to the data base collected in accordance with the requirements for the bacteriological standards and sample collection

required in Section .02;

(c) Review of available inspection reports and effluent samples collected from pollution sources;

(d) Review of available performance standards for various types of discharges that impact the growing area;

(e) A brief report which documents the findings of the annual reevaluation; and

(f) The SSCA may use MSC meat sampling data and/or MSC waste water sampling data in the annual reevaluation of (5) (b), (c), and (d) above to evaluate the viral contributions of the performance standards of waste water system discharge (WWSD) impacts on shellfish growing areas.

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

D. Shoreline Survey Requirements…

@.02 Microbiological Standards.

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

A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area. The SSCA may utilize MSC data in conjunction with bacteriological data to evaluate waste water system discharge (WWSD) impacts on shellfish growing areas.

B. Water Sample Stations…

C. Exceptions…

D. Standards for the Approved Classification of Growing Areas in the Remote Status…

E. Standard for the Approved Classification of Growing Areas Affected by Point Sources…

F. Standard for the Approved Classification of Growing Areas Affected by Nonpoint Sources…

G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration…

H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration…

@.03 Growing Area Classification.

A. General…
(1) Emergency Conditions…
(2) Classification of All Growing Areas…
(3) Boundaries…
(4) Revision of Classifications…
(5) Status of Growing Areas…
(a) Open Status…
(b) Closed Status...
(c) Reopened Status. A growing area temporarily placed in the closed status as provided in (b) above, shall be returned to the open status only when:
(i) The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of contaminant levels in the shellstock to pre-closure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on coliform levels in the water; or
(ii) For emergency closures of harvest areas caused by the occurrence of raw untreated sewage discharged from a large community sewage collection system or wastewater treatment plant, the analytical sample results shall not exceed ~~background levels or~~ a level of fifty (50) male-specific coliphage per 100 grams or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions from shellfish samples collected no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted~~;~~ or until the event is over and 21 day have passed; or
(iii) The requirements for Biotoxins or conditional area management plans as established in Section .04 and Section .03, respectively, are met; and
(iv) Supporting information is documented by a written record in the central file.
(d) Inactive Status…
(e) Remote Status…

(f) Seasonally Remote/Approved Status…

B. Approved Classification…

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

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

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

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

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

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

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

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

(i) Peak effluent flow, average flow, and infiltration flow;

(ii) Microbiological quality of the effluent;

(iii) Physical and chemical quality of the effluent;

(iv) Conditions which cause plant failure;

(v) Plant or collection system bypasses;

(vi) Design, construction, and maintenance to minimize mechanical failure, or overloading;

(vii) Provisions for monitoring and inspecting the waste water treatment plant; and

(viii) Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with Section E. Prohibited Classification;

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

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

(ii) Discussion and data supporting the performance standards.

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

	are: (i) Performance standards of the plan are fully met; (ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels; (iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. The study may establish criteria for reopening based on coliform levels in the water; (iv) For Conditional Management Plans based on waste water system discharge performance and for SSCAs utilizing MSC, sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of viral levels in the shellstock. Analytical sample results shall not exceed ~~background levels or~~ a level of 50 MSC per 100 grams or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions. These studies~~y~~ may establish criteria for reopening based on viral levels in the shellfish meats or the area must be in the closed status until the event is over and twenty-one (21) days have passed; and (v) Shellstock feeding activity is sufficient to achieve microbial reduction. (d) For management plans based on a risk assessment made in accordance with Chapter II. Risk Assessment and Risk Management, criteria that reliably determine when the growing area may be placed in the open status and shellfish may be harvested; (e) For management systems based on marine Biotoxins, the procedures and criteria that reliably determine when the growing area may be placed in the open status; (f) Procedures for immediate notification to the Authority when performance standards or criteria are not met; (g) Provisions for patrol to prevent illegal harvest; and (h) Procedures to immediately place the growing area in the closed status in 24 hours or less when the criteria established in the management plan are not met. (3) Reevaluation of Conditional Classification… (4) Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management Plan by All Parties Involved…

	(5) Conditional Area Types… (6) Conditionally Approved Classification… (7) Conditionally Restricted Classification... D. Restricted Classification… E. Prohibited Classification. (1) Exception… (2) General… (3) Sanitary Survey… (4) Risk Assessment… (5) Wastewater Discharges. (a) An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance. (b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria: (i) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the microbiological quality of the effluent; The SSCA may utilize MSC wastewater sample data in the determination of the performance of the sewage treatment plant; (ii) The decay rate of the contaminants of public health significance in the wastewater discharged; (iii) The wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and (iv) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries. NOTE: All references in Section II. Model Ordinance Chapter IV. Shellstock Growing Areas will be changed toWaste Water System Discharge (WWSD).
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-102 with referral to an appropriate committee as determined by the Conference Chair to develop a draft guidance document which will be presented to the ISSC Executive Board at the 2016 spring meeting for interim approval.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-102.

Proposal No. **15-109**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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Proposal Subject	PSP HPLC-PCOX Species Expansion
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	4. Approved Limited Use Methods for Marine Biotoxin Testing PCOX This submission presents data to support the use of PCOX method for Quahogs (M. mercenaria and A. icelandica), Surf Clams (S. solidissima), Geoducks (P. generosa), Butter Clams (S. giganteus), Little Neck Clams (P. stamineais), and Razor Clams (S. patula) for regulatory paralytic shellfish toxin (PST) testing. Results of the 2009 Interstate Shellfish Sanitation Conference (ISSC) proposal 09-104 concluded the PCOX method approved for official use as a Type IV method; subsequently after single laboratory validation (SLV) and collaborative studies, ISSC proposal 13-309 accepted PCOX method as an AOAC official method of analysis (OMA) in 2013. Currently PCOX is an "Approved for Limited Use" method for mussel, clam, oyster and scallop. SLV work will be presented for quahogs, surf clams, geoducks, butter clams, little neck clams, and razor clams that demonstrates comparable performance characteristics for these species as with mussels, clams, oysters, and scallops using the PCOX method. The cost and challenges associated with maintaining both the MBA and PCOX methods for these species are high; differing laboratory skill sets are required and state laboratories have limited budgets and staff resources. Additionally, the recent shortage of the NIST saxitoxin standard used for MBA proficiencies is of concern if laboratories are expected to maintain MBA for verification purposes for these species. The requested action is being made and data presented for the purpose of inclusion of quahogs, surf clams, geoducks, butter clams, little neck clams, and razor clams as approved species (by addition to the footnote that includes mussels, clams, oysters, and scallops or as the ISSC deems appropriate) within the NSSP Guide Section IV Guidance Documents Chapter II. Growing Areas .11 Laboratory Tests Methods Table, Methods for Marine Biotoxin Testing with Biotoxin Type: Paralytic Shellfish Poisoning (PSP), Application: Growing Area Survey & Classification Sample Type: Shellfish And Application: Controlled Relaying Sample Type: Shellfish.
Public Health Significance	The PCOX method was developed to provide a rapid, high throughput chemical assay that would eliminate the need to sacrifice animals, AOAC mouse bioassay

	(MBA), for toxin detection. There is a worldwide move to replace assays that use live animals as test subjects. Laboratories currently using PCOX for regulatory PST testing have found that the lower detection limits of the PCOX method allow for better early warning therefore better management of PST closures and significantly improved public health decision-making. The addition of the proposed species will allow regulatory laboratories to move away from the costliness of maintaining MBA and eliminate the need to sacrifice animals as well as improve management of species specific closure decision–making.
Cost Information	Total consumable costs for the analysis is estimated at $10/sample. A chemistry laboratory will usually be equipped with an LC system and a post column reactor to carry out the analysis. Total capital costs for the instrumentation required for the analysis is approximately $120,000. Although the upfront investment for instrumentation is high, the removal of care, maintenance, and cost of mice quickly offsets this expenditure.
Action by 2015 Laboratory Method Review Committee	Recommended referral of Proposal 15-109 to an appropriate committee as determined by the Conference Chair for evaluation of data and until additional data are received.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Method Review Committee recommendation on Proposal 15-109.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-109.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-109.

Proposal No. **15-110**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting

a. ☒ Growing Area
b. ☐ Harvesting/Handling/Distribution
c. ☐ Administrative

Submitter	Executive Board
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Proposal Subject	Laboratory Method for *Vibrio parahaemolyticus (V.p.)* Enumeration and Detection through MPN and Real-Time PCR
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	This method was developed by William A. Glover (Washington State Public Health Laboratories) and is being submitted by the ISSC Executive Board. The Executive Board granted interim approval to this method on March 13, 2015. The Executive Board is submitting this proposal to comply with Article V. Section 1. of the ISSC Constitution, Bylaws, and Procedures. Submitted by method developer William A. Glover (Washington State Public Health Laboratories) 5. Approved Methods for Vibrio Enumeration

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

Footnotes:

[1] EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992.

[2] MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, followed by confirmation using biochemical analyses or by the DNA -alkaline phosphatase labeled gene probe (vvhA).

[3] MPN format with confirmation by biochemical analysis, gene probe methodology as listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.

[4] PCR methods as they are listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.

	[5]*Vibrio vulnificus*, ISSC Summary of Actions 2009. Proposal 09-113, Page 123. [6]William A. Glover, II, Ph.D. D9ABMM), MT(ASCP) Food and Shellfish Bacteriology Laboratory (FSBL) at the Washington State Public Health Laboratories (WAPHL)
Public Health Significance	The purpose of this method is to provide laboratories supporting the NSSP the ability to rapidly quantify *Vibrio parahaemolyticus (V.p.)* from oysters using a high throughput real-time PCR protocol. The Food and Shellfish Bacteriology Laboratory (FSBL) at the Washington State Public Health Laboratories (WAPHL) tests on average over 200 oyster samples per year for *Vibrio parahaemolyticus (V.p.)*Culture based assays for the enumeration of *V.p.* take four days or longer and require the Kanagawa test (media based) to detect pathogenicity. Due to the large number of samples and need for accurate and timely results, the FSBL at the WAPHL has tested Pacific oysters (Crassostrea gigas) for (*V.p.*) using a MPN based real-time PCR assay for over 10 years. The real-time PCR assay utilized by the FSBL at the WAPHL has gone through redesigns and improvements by various scientists at the WAPHL based on new published literature, clinical *V.p.* case data, experiences in WA State over the course of a season or seasons, and requests from the Office of Shellfish & Water Protection for enhanced detection of pathogenic *V.p.* strains and additional surveillance capabilities. The real-time PCR assay redesigned and implemented in 2009 and utilized through the 2013 *V.p.* monitoring season (June – September) was designed to detect *V.p.* using the species-specific thermolabile hemolysin gene (tlh) and virulent *V.p.* using the thermostable direct hemolysin gene (tdh). This assay was designed for high throughput in a 384-well based format. Additionally, the tlh and tdh targets were redesigned yielding amplicons between 50-150 base pairs. This is optimal for real-time PCR and is known to produce consistent results1. Validation of the assay and concept of a “molecular MPN” was conducted using FERN guidelines and was compared to the FDA BAM method. This assay served as the backbone for which further improvements and redesigns were made in 2013.
Cost Information	
Action by 2015 Laboratory Method Review Committee	Recommended referral of Proposal 15-110 to an appropriate committee as determined by the Conference Chair to await completed SLV data.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Methods Review Committee recommendation on Proposal 15-110.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-110.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-110.

Proposal No. **15-112**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting

a. ☒ Growing Area
b. ☐ Harvesting/Handling/Distribution
c. ☐ Administrative

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

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

5. Approved Methods for Vibrio Enumeration

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

Footnotes:

[1] EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992.

[2] MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, followed by confirmation using biochemical analyses or by the DNA -alkaline phosphatase labeled gene probe (vvhA).

[3] MPN format with confirmation by biochemical analysis, gene probe methodology as listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.

[4] PCR methods as they are listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State

	can demonstrate is equivalent. [5]*Vibrio vulnificus*, ISSC Summary of Actions 2009. Proposal 09-113, Page 123. [6]Direct plating method for *trh* as described in Nordstrom et al., 2006.
Public Health Significance	Scientific evidence suggests that the presence of the *trh* gene in *V. parahaemolyticus (V.p.)* is correlated with higher virulence. Additionally, at the 2013 conference, proposal 13-202 was adopted which requires testing for the presence of trh prior to reopening of growing areas closed as a result of *V.p.* illnesses [Chapter II @.01.F(5)]. Currently, there are no NSSP approved methods for enumeration of *trh*. This method is a needed option for testing following *V.p.* illness closures.
Cost Information	This method costs ~$5 per test for laboratory consumables, supplies, and reagents. Most equipment needed for testing is standard microbiology equipment, but purchase of a specialized water bath or environmental chamber may be necessary at a cost of ~$3,000-$5,000. Additional costs for a laboratory would vary based on their operational overhead and labor.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 15-112 to an appropriate committee as determined by the Conference Chair to further review the data submitted.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Methods Review Committee recommendation on Proposal 15-112.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-112
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-112.

Proposal No. **15-114**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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

Proposal No. **17-100**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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Proposal Subject	Marina Definition
Specific NSSP Guide Reference	Section I Purposes and Definitions B. Definition of Terms (71) Marina
Text of Proposal/ Requested Action	**(71) Marina** means any water area with a structure (docks, basin, floating docks, etc.) which is: (a) Used for docking or otherwise mooring vessels to a dock or pier; and (b) Constructed to provide temporary or permanent docking space for more than ten boats.
Public Health Significance	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 **@ .05 Marinas**. 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. 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. SSCAs should be allowed to assess the pollution impact of mooring areas based on actual circumstances and data not just an assumed risk.
Cost Information	NONE, Possible savings to SSCAs.

Proposal No. **17-101**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	Debra Barnes
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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	**(72) Marina** means any water area with a structure (docks, basin, floating docks, etc.) which is: (a) Used for docking or otherwise mooring vessels; and (b) Constructed to provide temporary or permanent docking space for more than ten boats 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.)
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

Proposal No. **17-102**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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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	**(101) Replicate** is defined as two (2) laboratory analyses conducted from the same sample ~~filters for thermostable direct hemolysin (tdh) analysis from the same homogenate~~ 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.

Proposal No. **17-103**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	US Food & Drug Administration (FDA)
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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
Research Needs Information	
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.

For Research Guidance Committee Use Only	Relative priority rank in terms of resolving research need ☐ Immediate ☐ Required ☐ Valuable ☐ Important ☐ Other

Proposal No. **17-104**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	US Food & Drug Administration (FDA)
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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	Section IV Guidance Documents – Chapter II. Growing Areas .20 Quantitative Analytical Method Verification 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. **Recovery** is the fraction or percentage of an analyte(s)/measurand(s)/organism(s) of interest recovered after sample analysis. **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). **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. **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. **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. **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 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

Proposal No. **17-105**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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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	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. 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. 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.
Cost Information	There is no significant difference in cost between the two methods.
Research Needs Information	
a. Proposed specific research need/ problem to be addressed	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. The FDA is now insisting that all laboratories standardize on the CFSAN Procedure, 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. 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.
b. Explain the relationship between proposed research need and program change recommended in the proposal	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.
c. Estimated cost	The cost of this study will be borne by the Washington State Public Health Laboratories.
d. Proposed sources of funding	N/A
e. Time frame anticipated	2 years
For Research Guidance Committee Use Only	Relative priority rank in terms of resolving research need ☐ Immediate ☐ Required ☐ Valuable ☐ Important ☐ Other

Proposal No. **17-106**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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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 Biotoxin Testing -- footnote 2, and/or p. 263 Table 4. Limited Use Methods for Marine Biotoxin Testing -- footnote 5)
Text of Proposal/ Requested Action	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 Biotoxin 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. The RBA offers a high-throughput, sensitive, and quantitative alternative to the mouse bioassay (MBA), which has been the long-standing reference method for PSP toxicity. Further, the RBA eliminates the use of live animals for detection of these toxins. While the RBA still uses receptors prepared from animals, the number of animals required for analysis is significantly reduced. Using native receptors as the analytical recognition elements for the assay allows for a composite measure of overall toxicity, as opposed to toxin concentrations measured by liquid chromatographic methods that require conversion factors of equivalent toxicity to calculate the overall toxicity. The RBA has undergone AOAC single and multi-laboratory validation and is designated through AOAC as an Official Method of Analysis (OMA 2011.27). The RBA is currently an NSSP Approved Method for Marine Biotoxin 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 (*Panopea*) viscera for submission for the RBA to be considered for approval as an NSSP Approved Method for Marine Biotoxin Testing for PSP.
Public Health Significance	Paralytic shellfish poisoning intoxications result from the consumption of seafood (primarily bivalve molluscs) contaminated with neurotoxins known as paralytic shellfish toxins (PSTs). This suite of toxins binds to voltage-gated sodium channels and may result in paralysis if enough toxin is consumed. In extreme cases when

	respiratory support is not available to the patient, the intoxication may prove fatal. Since the toxins cannot be destroyed during cooking and there is no way to remove the toxins from seafood, the best control strategy is to ensure that contaminated product never reaches the market. To protect public health, harvesting closures are implemented when toxicity exceeds the guidance level of 80 micrograms saxitoxin equivalents per 100 grams of shellfish tissue. As such, accurate analytical methods are needed to monitor shellfish toxicity for making decisions regarding opening and closing shellfish growing areas accordingly. Acceptance of the RBA as an NSSP Approved Method for Marine Biotoxin Testing for PSP toxicity determination in geoduck (*Panopea*) would provide monitoring and management programs with an additional tool that can be used for monitoring toxin levels and making regulatory decisions. Not only does the RBA eliminate the need for live animals for PSP testing, it is also more sensitive than the MBA, thereby providing an early warning system for monitoring programs as toxin levels begin to rise.
Cost Information	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-1] 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) For proposal: The cost of RBA work for geoduck matrix expansion is covered by and 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.
Research Needs Information	
a. Proposed specific research need/ problem to be addressed	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. 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. 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 (*Panopea*) 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.
b. Explain the relationship between proposed research need and program change recommended in the proposal	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. 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. **References**: Van Dolah 2013. ISSC application: Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP)Toxicity Determination. 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. 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. 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. 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. Toxicon : official journal of the International Society on Toxicology 59, 215-230. 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. http://www.eoma.aoac.org.
c. Estimated cost	
d. Proposed sources of funding	This research was performed by the Sitka Tribe of Alaska using funds from an ANA ERE grant
e. Time frame	

anticipated	
For Research Guidance Committee Use Only	Relative priority rank in terms of resolving research need ☐ Immediate ☐ Required ☐ Valuable ☐ Important ☐ Other

Proposal No. **17-107**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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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	This submission proposes that the MARBIONC brevetoxin ELISA be approved for limited use in NSP testing such that samples with negative results by ELISA (≤ 1.6 ppm in hard clams and sunray venus clams and ≤ 1.80 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. Requested changes: Section IV. Guidance Documents Chapter II. Growing Areas. 14 Approved NSSP Laboratory Tests 4. Approved Limited Use Methods for Marine Biotoxin Testing Biotoxin Type: Neurotoxic Shellfish Poisoning (NSP) Add columns for Biotoxin Type: Neurotoxic Shellfish Poisoning (NSP) and for Application: Controlled Harvest end product testing Add MARBIONC brevetoxin ELISA to table for all applications except Dockside Testing with the following footnote: 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: a. A negative result (≤ 1.6 ppm in hard clams and sunray venus clams and ≤ 1.80 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.

	b. A positive result (> 1.6 ppm in hard clams and sunray venus clams and > 1.80 ppm in oysters) requires additional testing by an Approved Method or could support the same management actions as samples failing by an Approved Method. See attached proposed revisions to Table 4. Approved Limited Use Methods for Marine Biotoxin Testing
Public Health Significance	Brevetoxins produced by K. brevis 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 K. brevis concentrations exceed 5,000 cells/L and are re-opened once K. brevis 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.
Cost Information	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).

Proposal No. **17-108**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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Proposal Subject	Detection of ASP biotoxins in *Mytilus edulis* (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	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). (1). M.Fernanda, F, Mazzillo, C. Pomeroy, J.Kuo, P. Ramondi,R. Prado, M.Silver. 2010. Aquatic Biol. 9:1-12. (2). NSSP Guide for the Control of Molluscan Shellfish: 2015 Rev. Sec.IV Chp. II., p 231. (3). Kathi A. Lefebvre, Alison Robertson, Toxicon, Vol. 56, Issue 2, 15 Aug. 2010, p. 218-230.
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.

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	U.S. Food and Drug Administration
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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	

Proposal No. **17-110**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	U.S. Food and Drug Administration (FDA)
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Proposal Subject	Alkaline Phosphatase Probe Method for *Vibrio vulnificus* and *Vibrio parahaemolyticus* 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 *Vibrio vulnificus* (Vv) and *Vibrio parahaemolyticus* (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

Proposal No. **17-111**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	U.S. Food and Drug Administration (FDA)
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Proposal Subject	MPN Real-Time PCR Method for *Vibrio vulnificus* and *Vibrio parahaemolyticus* 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 *Vibrio vulnificus* (Vv) and *Vibrio parahaemolyticus* (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

Proposal No. **17-112**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	US Food & Drug Administration (FDA)
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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	Section IV Guidance Documents – Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists amend language. General Provisions 1. If the State Shellfish Control Authority (Authority) uses the analytical services of private/commercial/fee for services laboratories to support the NSSP, then he/she should select a qualified individual to become certified as a State Shellfish Laboratory Evaluation Officer (State Shellfish LEO). 2. If the Authority uses the analytical services of multiple public laboratories (state, county, parish town, etc.) to support the NSSP, then he/she may select a qualified individual to become a State Shellfish LEO. 3. If the Authority chooses not to participate in the certification process, FDA can evaluate the state's public laboratories. FDA, however, does not normally evaluate private/commercial/fee for services laboratories. FDA may, under certain circumstances as resources permit, evaluate these laboratories on a case-by-case basis at the request of the Authority. This request must be in writing and made through the FDA ~~Regional~~ Shellfish Specialist. 4. State Shellfish LEOs will perform official NSSP evaluations of laboratories which have been previously evaluated by FDA and been found to fully conform to NSSP laboratory requirements. 5. State Shellfish LEOs may evaluate laboratories in a different state under a memorandum of understanding between the states involved and FDA, consistent with NSSP requirements. 6. State Shellfish LEOs may not evaluate laboratories in which they are employed or which they supervise or laboratories within the same supervisory chain of command to ensure complete objectivity in the evaluation process and avoid the appearance of a conflict of interest. 7. To qualify for certification, the prospective State Shellfish LEO ~~should~~ must ~~be~~: a. ~~A~~ Be a state employee; b. Have a minimum of two years of shellfish laboratory experience or a laboratory background~~;~~ with three to five years of bench level experience with the specific methods that will be evaluated;

c. ~~Preferably h~~ Have ~~laboratory evaluation~~ experience performing laboratory evaluations or supervising a laboratory; and,

d. Be free from any commercial, financial or other pressures or conflicts of interest that might cause or appear to cause the prospective State Shellfish LEO to act in other than an impartial or non-discriminatory manner.

8. If the prospective or current State Shellfish LEO is employed by the laboratory supporting the NSSP, that laboratory must be fully conforming to NSSP requirements or the individual will not be certified and if currently certified, certification will be revoked.

Responsibilities of the 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~~

~~all the following performance criteria.~~

~~a. Demonstration of good familiarity with evaluation requirements.~~

~~b. Demonstration of a thorough knowledge of the evaluation methods and documents.~~

~~c. Demonstration of the technical knowledge/familiarity with the analytical procedures being used.~~

~~d. Ability to communicate effectively both orally and in writing.~~

~~e. Successful completion of both training and field standardization.~~

~~2. Upon successful completion of the certification process, a letter of certification will be issued by the FDA Shellfish Laboratory Evaluation Officer and a copy will be sent to both the requesting Authority and the FDA Regional Shellfish Specialist.~~

~~3. Certification is normally valid for up to five (5) years unless revoked or voided.~~

Failure to be Certified

1. If a prospective State Shellfish LEO fails to satisfy any of the performance criteria listed above, he/she will not be certified.
2. As resources permit ~~and at the discretion of FDA~~, the prospective State Shellfish LEO may receive additional training to better prepare him/her to be certified; 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 narrative evaluation report to the FDA National Laboratory Standard. ~~co-~~

	~~evaluator for review and comment for each of the laboratories jointly evaluated.~~ c. The individual must have performed laboratory evaluations at the minimum frequency prescribed in the current edition of the Guide for the Control of Molluscan Shellfish and have all Narrative evaluation reports up to date. 3. State Shellfish LEOs who successfully complete recertification will be issued a letter of recertification by FDA and be cleared to distribute the completed report(s) to the appropriate ~~Regional~~ Shellfish Specialist. A copy of this letter will be sent to the State Shellfish Control Authority and appropriate ~~Regional~~ Shellfish Specialist. 4. If FDA is unable to conduct a recertification visit by the expiration of the individual's certification, his/her certification may be extended until such time as recertification can be completed. If requested, a letter extending the certification can be provided as appropriate. Standardization Maintenance 1. 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. 2. 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 Revocation of Certification 1. State Shellfish LEOs who fail to meet any of the certification/recertification, employment, or performance criteria listed above will have their certification revoked. 2. Certification may be voided when state shellfish sanitation programs no longer have a need for the services of a State Shellfish LEO. 3. Voided certifications may be reactivated at the discretion of FDA if the need for the analytical services of additional laboratories by the state shellfish sanitation program recurs. 4. Revoked certifications will not normally be restored. 5. 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.
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.

Proposal No. **17-113**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	ISSC Male-Specific Coliphage Committee
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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
Text of Proposal/ Requested Action	**~~19. Determining Appropriately Sized Prohibited Areas Associated with Wastewater Treatment Plants~~** ~~A.Introduction~~ ~~The original National Shellfish Sanitation Program (NSSP) principles have proved effective in controlling bacterial illness associated with shellfish harvested from polluted waters. These principles, namely a robust sanitary survey, regular water and shellfish monitoring using bacterial indicators, controlled harvest times and labelling the origin of shell stock remain applicable as the primary preventative food safety control measures for growing areas.~~ ~~However, there is now ample scientific evidence to show that the current bacterial indicators are inadequate to predict the risk of viral illness for the following reasons:~~ ~~(1) Enteric viruses are resistant to treatment and disinfection processes in a Waste Water System Discharge (WWSD) and are frequently detected in the WWTP's final effluent under normal operating conditions (Baggi et al. 2001; Burkhardt et al. 2005, Pouillot et al. 2015).~~ ~~(2) Shellfish can bioaccumulate enteric viruses up to 100 fold from surrounding water (Seraichekas et al. 1968; Maalouf et al. 2011).~~ ~~(3) Certain enteric viruses are retained by molluscan shellfish to a greater extent and for longer than the indicator bacteria currently used to classify shellfish growing areas (Sobsey et al. 1987; Dore~~

~~& Lees 1995; Love et al. 2010). It has been well documented that enteric virus detection is not indexed by levels of conventional indicator bacteria.~~

~~For several decades now viral illnesses, in particular norovirus (NoV) and Hepatitis A (HAV), have been the most common food safety problem associated with bivalve molluscan shellfish (Woods 2010; Iwamoto et al 2010; Scallan et al. 2011; Batz et al. 2012; Hall et al 2012). NoV genogroups I, II and IV and HAV are typically associated with ill individuals and transferred by the fecal oral route. Because WWTPs do not completely remove infectious enteric viruses emphasis should be placed on the importance of ensuring there is adequate dilution between a sewage source and a shellfish growing area.~~

~~In addition to the risk of enteric viruses WWTP effluents may also contain other chemicals and deleterious substances including pharmaceuticals, nanoparticles, and other contaminants of emerging concern. Establishment of a prohibitive area in proximity to WWTP discharges is an effective strategy to reduce the risk posed by both enteric viruses and other contaminants found in WWTP effluents. This guide provides information on the recommended dilution rates with respect to enteric viruses to ensure WWTP effluent does not cause a significant viral food safety risk within shellfish growing areas. The guide also considers the factors that should be used to assess a WWTP.~~

~~B.Delineation of the Prohibited Area around a Waste Water System Discharge (WWSD)~~

~~The NSSP Model Ordinance Section II, Chapter IV. @.03 (2) (b) and @.03 E(5) states that all growing areas which have a sewage treatment plant outfall or other point source outfall of public health significance within or adjacent to the shellfish growing area must have a prohibited classification established adjacent to the outfall taking account of the following factors:~~

~~(1) The volume flow rate, location of discharge, performance of the Waste Water System Discharge (WWSD) and the microbiological quality of the effluent;~~

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

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

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

~~C.Establishing the Size of Each Prohibited Area There are several important considerations for the shellfish authority to consider when establishing the size of each prohibited area:~~

(1) The area to ensure that there is adequate dilution when the WWTP is operating as normal. "Normal" means that the WWTP is operating fully within the plant's design specifications, including design flows; treatment stages; disinfection; as well as compliance with all permit conditions that relate to the WWTPs effectiveness in reducing enteric viruses in sewage.

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

(a)Bypassing stage of treatment

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

(b)Operating outside design specifications/other types of failures or events

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

(c)Operating above design flow

Some WWTPs may operate above its design flow and not necessarily bypass any particular stage of treatment. During these events it is typical for WWTP operators to adjust the operation of the WWTP which may include reducing the treatment time in the aeration stage and/or solids separation/settling stage of treatment. Under some circumstances this could lead to a significant reduction in the effectiveness of disinfection. SCAs may consider assessing the efficiency of WWTPs to determine the significance of these type of events and if additional provisions should be

made in the CAMP.

(d)WWTP permit violations

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

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

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

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

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

Additional considerations

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

~~D.Guidelines for Dilution, Dispersion, and Time of Travel of Effluent~~

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

~~It is essential to recognize that water samples collected near discharge outfalls are not useful for determining the size of prohibited areas because normal operating conditions in WWTPs can effectively reduce or even eliminate the fecal and total coliforms which are the current indicator microorganisms used to assess treatment efficiency. In contrast, many human enteric viruses are not inactivated by functioning WWTP treatment and disinfection systems, hence the need for an adequate dilution zone between the outfall and the shellfish resource.~~

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

~~When determining if a WWTP or collection system discharge within the watershed or catchment area draining to a shellfish estuary potentially impacts a shellfish growing area, in the absence of a performance history of the treatment and collection system, and a database of influent and effluent quality, the NSSP recommends that a worst case raw sewage discharge be assumed. In this circumstance, if a level of 1.4×10^6 FC/100ml is assumed for a raw sewage release, a 100,000:1 dilution would be required to dilute the sewage sufficient to meet the approved area standard of 14 FC/100ml. If dilution analysis determines that the location of the discharge is such that the dilution of effluent would be greater than 100,000:1 then the WWTP could be considered located outside the zone of influence to the shellfish growing area. Different dilution ratios may be applied depending on the known concentration of sewage, provided that the water quality objective of the downstream harvest area is met.~~

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

~~In all cases the FDA recommends the minimum of a 1000:1 dilution around~~

~~a WWTP outfall to mitigate the impact of viruses on shellfish growing areas.~~

~~A dye study can be used to measure the dilution and dispersion of the effluent during specific discharge conditions. Computer modeling programs can also be used to estimate the dispersion and dilution of the effluent plume from WWTPs and collection system overflows.~~

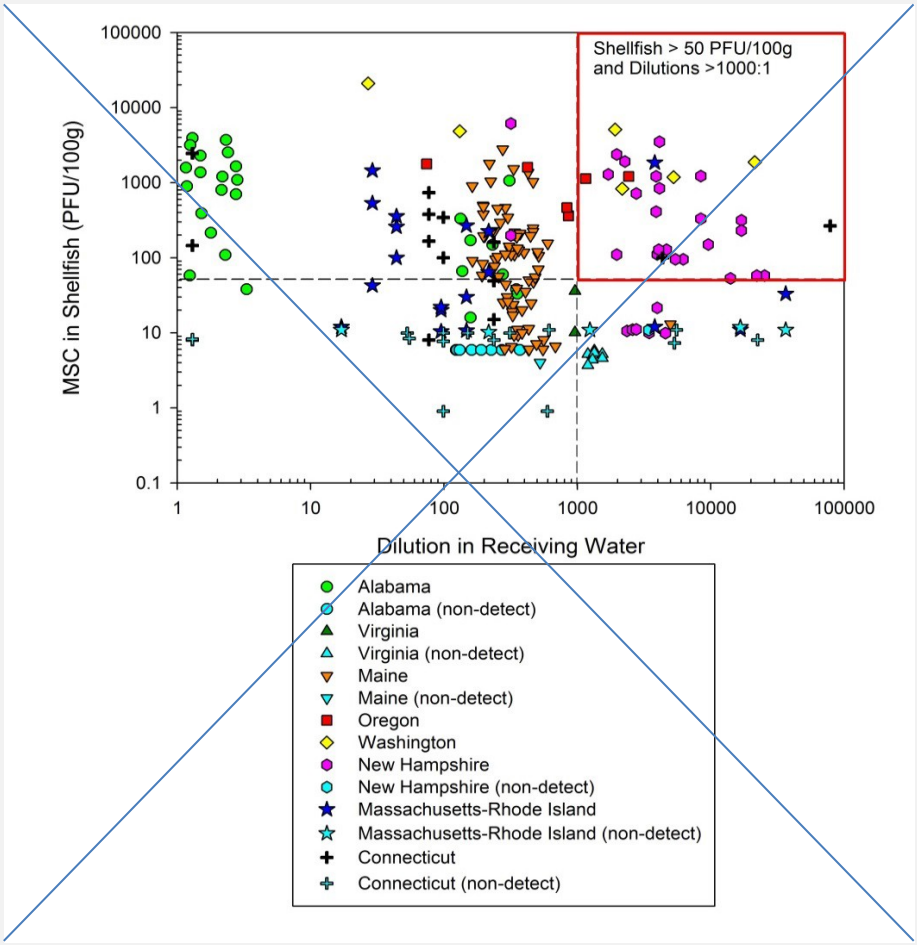
~~E.Scientific Rationale for 1000:1 Dilution Guidance~~

~~In 1995 the FDA determined the 1000:1 dilution was necessary using the most relevant the scientific literature available at that time (Kohn, et al. 1995; Havelaar et al. 1993; Kapikian et al. 1990; Liu et al. 1966). In 2008 FDA performed an investigation in the upper portion of Mobile Bay, Alabama, the results of which were published in the Journal of Shellfish Research (Goblick, et al., 2011). The article describes how FDA used technical advances to assess the 1995 1000:1 dilution recommendation. The Mobile Bay study confirmed that this level of dilution was appropriate to mitigate the risk of viruses discharged in treated wastewater effluent.~~

~~Since the 2008 Mobile Bay study there have been major advances in the detection and enumeration of NoV in wastewater and shellfish and fluorometer technologies have enabled more sophisticated hydrographic dye study methods. Using these advances, FDA has now conducted numerous dye studies supplemented with the testing of shellfish sentinels for enteric viruses and their surrogates. The findings from these studies demonstrate that achieving a steady-state 1000:1 dilution level in the requisite Prohibited area appears to be adequate for mitigating the impacts of viruses on shellfish when WWTPs have typical treatment and disinfection practices, such as secondary treatment and chlorination, and when operating under normal conditions.~~

~~While evaluating the 1000:1 dilution level Male Specific Coliphage (MSC) results in shellfish from the 2008-2015 studies were evaluated. These collaborative studies with State Shellfish Control Authorities and Industry were conducted in the Gulf, Mid-Atlantic, East and West Coast, and under varying hydrographic and meteorological conditions. Various additional factors were considered such as type of wastewater treatment and disinfection technology, seasonal conditions, and shellfish species etc. and are represented in the data collected. In some cases, data was collected during a period of which the WWTP was considered to be operating outside of "normal" operating conditions. In other cases, the WWTP was considered not suitable for conditional area management due to design/poor performance even during routine/normal operation. Focus was given to the MSC threshold of 50 PFU/100 grams of shellfish tissue which is the level used for re-opening harvest areas after an emergency closure due to raw untreated sewage discharged from a large community sewage collection system or a WWTP (Model Ordinance (Section II, Chapter IV, @.03 A(5)(C)(ii))). From the 2008-2015 studies, a total 216 samples were assessed including conditions when the WWTPs were considered operating normally as well as under a bypass or degraded operation conditions. In summary, 216 samples were analyzed for MSC of which 176 samples (81%) were~~

~~positive for MSC; 118 samples (67%) contained MSC levels > than 50 PFU/100 grams; and 43 samples (20%) had MSC levels > 50 PFU/100 grams and wastewater effluent dilution was greater than 1000:1. These results are shown in Figure 1 and Table 1 below.~~

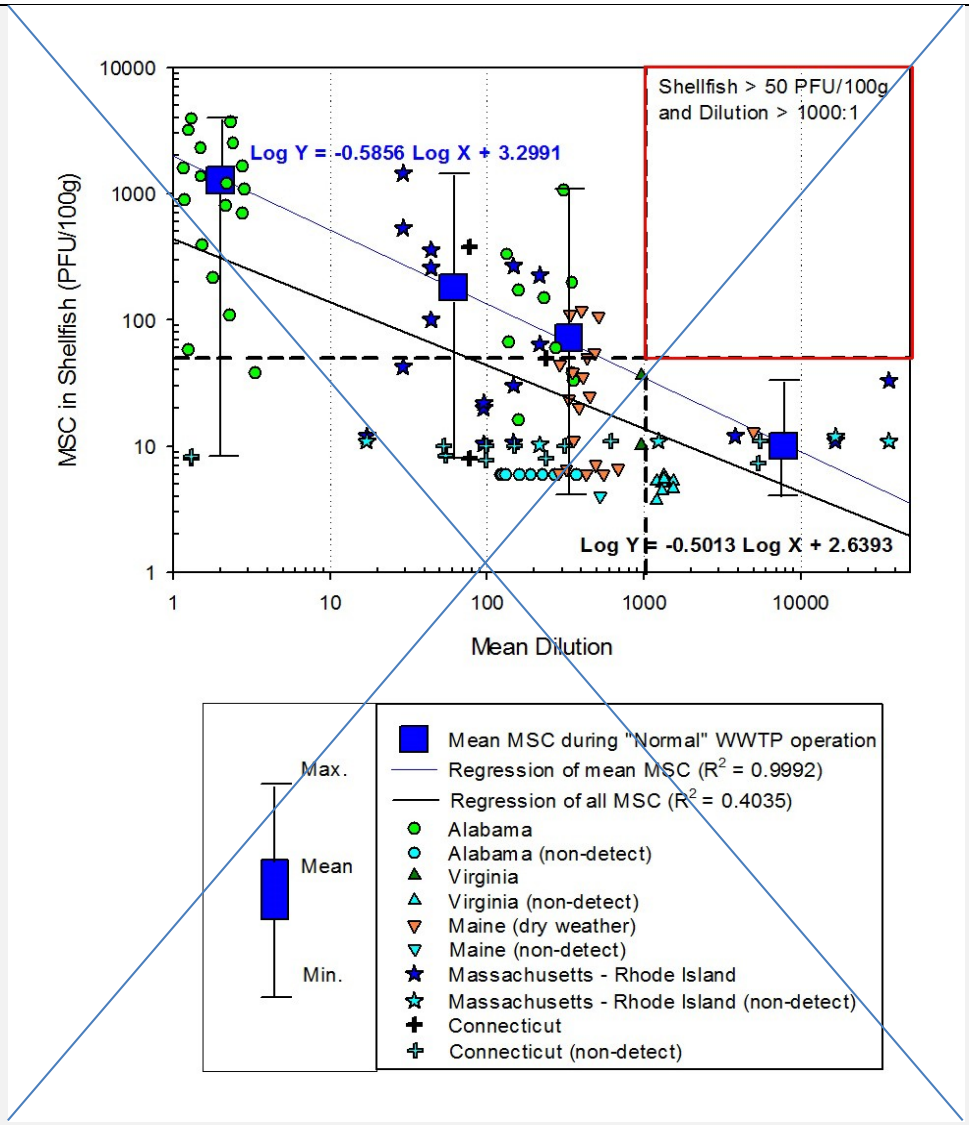


~~Figure 1: Comparison of dilution in receiving water and MSC levels in shellfish – all conditions Table 1: MSC in shellfish operating under "normal" and outside of normal operation~~

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

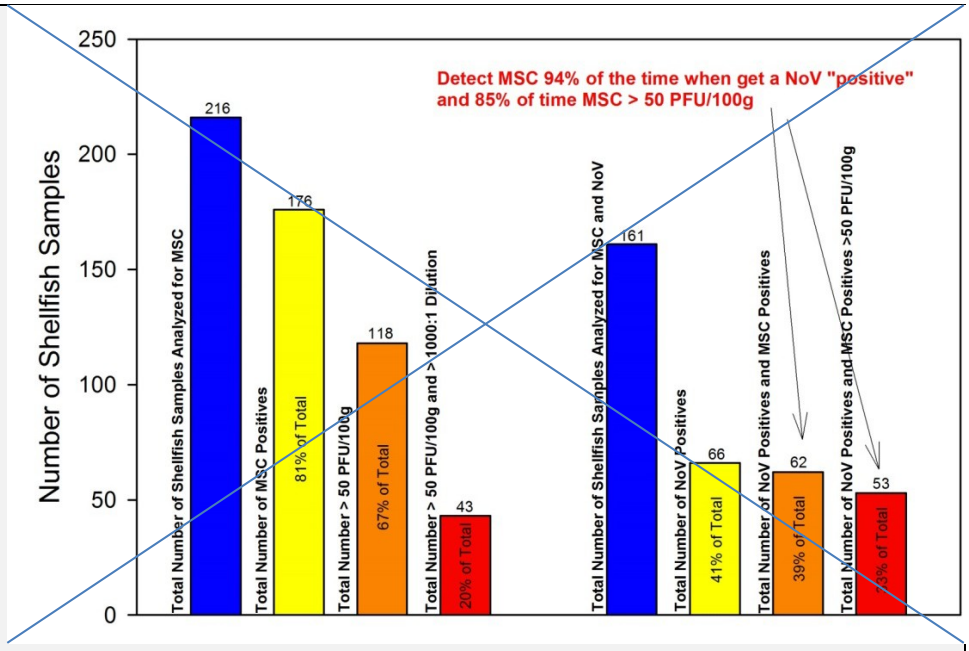
~~In separating the data attributed to "normal" operation from other conditions, 129 of the 216 total samples were considered to be attributed to~~

	~~"normal" WWTP operation, also shown on Table 1. Eighty seven (87) samples were removed as they were attributed to conditions of WWTP malfunction or situations considered not suitable for conditional area management. From the 87 samples, 80 were associated with degraded WWTP performance or malfunction of which 6 were associated with a primary bypass, 13 were associated within a period of a WWTP upgrade during which the WWTP reportedly was operating an extended period (weeks) without disinfection, 31 were associated with degraded treatment quality because of rainfall/flows exceeding the WWTP design capacity, and 30 were attributed to a WWTP with no secondary treatment and operated frequently with flows exceeding the design capacity. Of the remaining 7 samples, 6 were associated with a WWTP utilizing unconventional disinfection technology (membrane filtration) and demonstrated poor performance in removing viruses compared to other conventional technologies during normal operating conditions, and 1 sample was attributed to a potential point source sewage discharge other than the WWTP.~~ ~~When considering the remaining 129 samples attributed to "normal" WWTP operating conditions there were no samples that were above 50 PFU/100 grams when dilution was greater than 1000:1. In comparison, of the 87 samples attributed to malfunction or unsuitable conditions, 43 samples exceeded 50 PFU/100 grams when dilution was greater than 1000:1. These results are shown in Figure 2 below.~~ ~~Figure 2: Comparison of dilution in receiving water and MSC levels in shellfish under normal operation~~



~~Comparing MSC with NoV sample results, out of the 216 samples analyzed for MSC, 161 samples were also analyzed for NoV. Of the 161 samples tested for NoV, 66 were positive (41% of total) were positive for NoV. Out of the 66 NoV positive samples, 62 (94% of total) were also positive for MSC and 53 (85% of total) had levels greater than 50 PFU/100 grams. There were only 4 cases where NoV was positive but MSC was not detected. However, in these cases, 3 of the sample results were near the Limit of Detection (LOD) for NoV enumeration. In one case it is suspected that both MSC and NoV may have been present but not likely viable as the WWTP utilized UV disinfection and was operating under normal conditions. These results are shown in Figure 3 and Table 2 below:~~

~~Figure 3: Comparison of MSC and NoV results~~



~~Table 2: Comparison of MSC and NoV Results in shellfish~~

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

~~*NoV detected at LOD of Assay~~

~~The overall results of FDA's field studies demonstrate a strong relationship between increased levels of enteric viruses and MSC and decreased levels of dilution. This trend was observed in all of the studies conducted by FDA at conventional WWTPs. These results also emphasize the critical need for sufficient notification time, meaning travel time from the WWTP discharge in the prohibited area is long enough to close the shellfish growing area in the event of a malfunction. This preventative measure may necessitate the Prohibited Area be larger than the zone necessary to achieve 1000:1 dilution. Furthermore, this analysis demonstrates the need to individually assess each WWTP, to assess their performance to remove enteric viruses.~~

~~In addition to the FDA field studies, as part of a Joint United States-Canada Norovirus in Bivalve Molluscan Shellfish Risk Assessment, a Meta-Analysis of the Reduction of NoV and MSC Concentrations by~~

~~Wastewater Treatment was conducted (Pouillot, 2015). The meta-analysis included previously unpublished surveillance data from the United States and Canada and relevant data reported in the literature (2,943 measurements in total).~~

~~For WWTPs with mechanical systems and chlorine disinfection, mean log10 reductions were 2.4 log10 gc/liter, for NoV GI, 2.7 log10 gc/liter, for NoV GII, and 2.9 log10 PFU per liter for MSCs. Comparable values for~~

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

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

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

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

F. Alternate Options

The FDA studies also suggested that certain factors, such as the quality of sewage treatment or the time of year, may exert influences on the levels of viruses discharged. However, at this time FDA does not have reliable data to justify specific dilution levels associated with environmental variables. It is recognized that such criteria could be determined by SCAs on a case by case basis, where factors of WWTP performance, disinfection method, tidal flushing, shellfish species and seasonal impacts may vary.

For example, in consideration of a raw sewage discharge, a lower dilution level than a 100,000:1 could be justified provided that specific data to that particular WWTP demonstrates that a lower bacteriological level associated with a potential raw sewage discharge is supported. Additional or other site specific information also can be used to justify alternative approaches that take into account other factors (such as no prior history of raw sewage discharges or containment structures sufficiently sized to accommodate a raw sewage event preventing a discharge).

Alternative options for calculating the size of the prohibited area to mitigate the virological effects of WWTP discharges at the shellfish growing area may be used provided that they are based on sound scientific principles that can be verified. For example, it is reasonable to

~~expect a potentially higher reduction in viral load from a properly maintained wastewater treatment system employing ultraviolet (UV) disinfection, tertiary treatment and operating under optimum design flow conditions. Regardless of the technology employed any proposed alternative minimum level of dilution for conditional management other than 1000:1 would need validation. MSC could potentially be used on a case by case basis as the validation process (for example to validate treatment efficiency) if demonstrated it is a successful/feasible strategy for the given location/situation. However, when there is insufficient information available for a growing area to support the use of a lower level of dilution, the 1000:1 dilution should be employed. If MSC is selected as an alternative option for calculating the size of the prohibited area of a WWTP discharge, the authority should select an MSC criteria that adequately protects shellfish growing areas from virological effects and should be based on the most recent data and regional studies.~~

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Note: When the above document is removed from the NSSP Guide, it will be available on the ISSC website at www.issc.org/document-library.

.19 Classification of Shellfish Growing Waters Adjacent to Waste Water Treatment Plants

Note: NSSP Model Ordinance excerpts are listed in italics.

I. Introduction

One of the goals of the NSSP is to control the safety of shellfish for human consumption by preventing its harvest from contaminated growing areas. The positive relationship between sewage pollution of shellfish growing areas and disease has been demonstrated many times. Shellfish-borne infectious diseases are generally transmitted via a fecal-oral route. The pathway can become quite circuitous. The cycle usually begins with fecal contamination of the growing waters.

The primary responsibility of the State Shellfish Control Authority is to ensure the public health safety of the shellfish growing areas through compliance with the NSSP Model Ordinance. The Authority must perform a sanitary survey that collects and evaluates information concerning actual and potential pollution sources that may adversely affect the water quality in each growing area. Based on the sanitary survey information, the authority determines what use can be made of the shellstock from the growing area and assigns growing areas one (1) of five (5) classifications.

The shoreline survey (also known as the pollution source survey) is the sanitary survey component in which the actual and potential pollution sources that may adversely affect the growing area are identified. These sources may introduce infectious disease agents or poisonous and deleterious substances to the growing waters where they may be taken up and concentrated by shellfish. Detailed and accurate information concerning the pollution sources is necessary for a proper growing area classification.

The key to the accurate classification of shellfish growing areas is the sanitary survey. The principal components of a sanitary survey include: (1) an evaluation of the pollution sources that may affect the areas; (2) an evaluation of the meteorological factors; (3) a review of hydrographic factors that may affect distribution of pollutants throughout the area; and (4) an assessment of water quality.

A pollution source survey must be conducted of the shoreline area and watershed to locate direct discharges (e.g., municipal and industrial waste discharges and package treatment units) and non-point sources of pollution (e.g., septic tanks, storm water runoff and agricultural and wildlife area runoff). Municipal and industrial wastewater treatment facilities should be evaluated in terms of design capacity versus actual loading, type and concentration of pollutants discharged, and the type and effectiveness of pollution control devices.

Water samples are collected to determine if the water quality meets the water quality standards for this growing area classification. The NSSP recognizes two (2) water quality-monitoring strategies: adverse pollution condition and systematic random sampling. Presence of point sources of pollution requires the use of the adverse pollution condition monitoring

system to collect data for the application of the water quality standard. In growing areas not affected by point sources, the Authority may elect to use either system. The presence or absence of point sources of pollution and the monitoring system used dictate the frequency of samples that must be collected for application of the water quality standards.

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

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

(1) Enteric viruses are resistant to treatment and disinfection processes in a Waste Water Treatment Plant (WWTP) and are frequently detected in the WWTP's final effluent under normal operating conditions (Baggi et al. 2001; Burkhardt et al. 2005, Pouillot et al. 2015).

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

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

For several decades now viral illnesses, in particular norovirus (NoV) and hepatitis A (HAV), have been identified as common food safety problems associated with the consumption of bivalve molluscan shellfish (Woods 2010; Iwamoto et al 2010; Scallan et al. 2011; Batz et al. 2012; Hall et al 2012). NoV genogroups I, II and IV and HAV are typically associated with ill-individuals and transferred by the fecal-oral route. Because WWTPs do not completely remove infectious enteric viruses emphasis should be placed on the importance of ensuring there is adequate dilution between a sewage source and a shellfish growing area.

In addition to the risk of enteric viruses present in wastewater, WWTP effluents may also contain chemicals and other deleterious substances including pharmaceuticals, nanoparticles, and other contaminants of emerging concern. Establishment of appropriate classification based upon virus removal efficacy and proximity and

source strength of WWTP discharges is an effective strategy to reduce the risk posed by both enteric viruses and other contaminants found in WWTP effluents. NSSP requires that shellfish growing waters be classified into one of five classifications. They include:

(1) Prohibited – A classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering of seed for aquaculture, is not permitted.
(2) Restricted – A classification used to identify a growing area where harvesting shall be by special license and the shellstock, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration.
(3) Conditionally Restricted - A classification used to identify a growing area that meets the criteria for the restricted classification except under certain conditions described in a management plan.
(4) Conditionally Approved - A classification used to identify a growing area which meets the criteria for the approved classification except under certain conditions described in a management plan.
(5) Approved - A classification used to identify a growing area where harvest for direct marketing is allowed.

This guidance document provides information on the five shellfish harvest classifications and the appropriate use of these classifications impacted by WWTP effluents. A sanitary survey report is required prior to the establishment of the classifications listed above with the exception of areas classified as prohibited.

II. General Requirements for Growing Area Classification

A. Chapter IV. Shellstock Growing Areas

@.01 Sanitary Survey

A. General.
(1) The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of:
(a) A shoreline survey;
(b) A survey of the microbiological quality of the water. In growing areas adjacent to wastewater system discharges the State

Shellfish Control Authority may utilize MSC results from analysis of shellfish meat samples and the analysis of the data will be included in the sanitary survey report;

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

(d) A determination of the appropriate growing area classification.

(2) The sanitary survey shall be periodically updated through the triennial reevaluation and the annual review in accordance with Section C. to assure that data is current and that conditions are unchanged.

(3) The documentation supporting each sanitary survey shall be maintained by the Authority. For each growing area, the central file shall include all data, results, and analyses from:

(a) The sanitary survey;

(b) The triennial reevaluation; and

(c) The annual review.

(4) Wherever possible, the Authority shall provide the necessary information to Federal, State, or local agencies which have the responsibility to minimize or eliminate pollution sources identified in the sanitary survey.

(5) The Authority shall maintain a current comprehensive, itemized list of all growing areas, including maps showing the boundaries and classification of each shellstock growing area.

B. Sanitary Survey Required.

(1) A sanitary survey shall not be required to classify growing areas as prohibited. The findings of a sanitary survey, however, may result in a growing area being classified as prohibited.

(2) A sanitary survey, including the triennial reevaluation, when available, of each growing area shall be required prior to:

(a) The harvest of shellstock for human consumption; and

(b) The classification of a growing area as approved, conditionally approved, restricted, or conditionally restricted.

C. Sanitary Survey Performance.

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

(2) When a written sanitary survey report is not

	completed, the area shall be placed in the closed status. *(3) The growing area classification and the supporting data from the sanitary survey shall be reviewed at least every three (3) years.* *(a) This triennial reevaluation shall include:* *(i) A review in accordance with Section C. (5) and (6) of the water quality samples;* *(ii) Documentation of any new pollution sources and an evaluation of their effect on the growing area;* *(iii) Reevaluation of all pollution sources, including the sources previously identified in the sanitary survey, as necessary to fully evaluate any changes in the sanitary conditions of the growing area. The reevaluation may or may not include a site visit;* *(iv) A comprehensive report which analyzes the sanitary survey data and makes a determination that the existing growing area classification is correct or needs to be revised; and* *(v) If the triennial reevaluation determines that conditions have changed based on the information and data collected during the triennial review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area.* *(b) When a written triennial reevaluation report is not completed, the Authority shall place the growing area in the closed status.* *(4) The triennial reevaluation may include:* *(a) Inspection of waste water system discharges (WWSD) or collection of additional effluent samples to determine their impact on the growing area;* *(b) Hydrodynamic studies;* *(c) Additional field work to determine the actual impact of pollution sources; and* *(d) Collection of additional water samples.* *(5) On an annual basis, the sanitary survey shall be updated to reflect changes in the conditions in the growing area. The annual*

reevaluation shall include:

(a) A field observation of the pollution sources which may include:

(i) A drive-through survey;

(ii) Observations made during sample collection; and

(iii) Information from other sources.

(b) Review, at a minimum, of the past year's water quality sample results by adding the year's sample results to the data base collected in accordance with the requirements for the bacteriological standards and sample collection required in Section @.02;

(c) Review of available inspection reports and effluent samples collected from pollution sources;

(d) Review of available performance standards for various types of discharges that impact the growing area; and

(e) A brief report which documents the findings of the annual reevaluation.

(f) The SSCA may use MSC meat sampling data and/or MSC waste water sampling data in the annual revaluation 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. If MSC meat and/or water data is being used, the SSCA shall conduct annual sample collection and analysis in determining performance standards.

(6) If the annual reevaluation determines that conditions have changed based on the information and data collected during the annual review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area.

D. Shoreline Survey

Requirements.

(1) In the shoreline survey for each growing area, the Authority shall:

(a) Identify and evaluate all actual and potential sources of pollution which may affect the growing area;

(b) Determine the distance from the

pollution sources to the growing area and the impact of each source on the growing area;

(c) Assess the reliability and effectiveness of sewage or other waste treatment systems;

(d) Determine if poisonous or deleterious substances adversely affect the growing area; and

(e) Consider the presence of domestic, wild animal or resident and migrating bird populations for possible adverse effects on growing areas.

(2) The Authority shall assure that the shoreline survey meets the following minimum requirements:

(a) The boundaries, based on the area topography, of each shoreline survey area are determined by an in-field investigation which identifies only the properties with the potential to impact the shellfish waters;

(b) Each shoreline survey area is identified by a unique designation which results in identification of all data associated with each shoreline survey by the unique designation;

(c) Each shoreline survey area is investigated and pollution sources evaluated by qualified, trained personnel; and

(d) Documentation for each pollution source identified by the Authority as affecting a growing area includes:

(i) The location of the site on a comprehensive map of the survey area; and

(ii) The determination that the pollution source has a direct or indirect impact on shellfish waters: and

(e) A written summary of the survey findings.

III. Guidance for Growing Area Classification

As a result of the information gathered during the sanitary survey, the Authority is responsible for distinguishing those growing areas suitable for harvest of shellstock for direct human consumption, those growing areas where the shellfish will require treatment prior to consumption, and those

growing areas unsuitable to harvest for human consumption. The probable presence or absence of pathogenic microorganisms, marine Biotoxin or other poisonous or deleterious substances in growing area waters is important to the Authority in deciding how the shellfish obtained from the growing area should be used. The Authority's decision, based on the sanitary survey information, will place all actual and potential growing areas in one of the five possible NSSP growing area classifications.

The five (5) growing area classifications are approved, conditionally approved, restricted, conditionally restricted and prohibited. Except for an emergency situation such as conditions following a hurricane when a growing area in the approved classification may be placed temporarily in the closed status, a growing area in the approved classification is always in the open status. The remaining four growing area classifications all place some type of restriction on shellstock harvesting. For more information concerning the enforcement of these restrictions, see the NSSP Guidance Document, Growing Area Patrol and Enforcement of Growing Area Restrictions (ISSC/FDA, 2015).

IV. Prohibited Classification

A. Definition

A classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering of seed for aquaculture, is not permitted.

B. Requirements for a Prohibited Area Adjacent to a Waste Water Treatment Plant (WWTP)

(1) Model Ordinance Chapter IV. Shellstock Growing Areas

@.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. All growing areas which:

(a) Are not subjected to a sanitary survey every twelve (12) years shall be classified as prohibited;

(b) Have a sewage treatment plant outfall or other point source outfall of public health significance within or adjacent to the growing area shall have an area in the prohibited

classification established adjacent to the outfall in accordance with Section E. Prohibited Classification; and

(c) Are subjected to…

(3) Boundaries…

(4) Revision of Classifications…

(5) Status of Growing Areas…

(2) Model Ordinance Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification

E. Prohibited Classification.

(1) Exception…

(2) General…

(3) Sanitary Survey. A growing area shall be classified as prohibited if:

(a) No current sanitary survey exists;

(b) A sanitary survey determines:

(i) The growing area is adjacent to a sewage treatment plant outfall or other point source outfall with public health significance;

(ii) Pollution sources may unpredictably contaminate the growing area;

(iii) The growing area is contaminated with fecal waste so that the shellfish may be vectors of disease microorganisms;

(iv) The concentration of…

(v) The area is contaminated with poisonous or deleterious substances causing the shellfish to be adulterated.

(4) Risk Assessment. A growing area shall be classified as prohibited if a risk assessment performed in accordance with Chapter II. Risk Assessment and Risk Management indicates the shellstock are not safe for human consumption.

(5) Wastewater Discharges.

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

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

(i) The volume flow rate, location of discharge, performance of the

wastewater treatment plant and the microbiological quality of the effluent. The SSCA may utilize MSC waste water sample data in the determination of the performance of the sewage treatment plant;

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

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

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

C. Allowable Uses of Shellfish from a Prohibited Growing Area

(1) Depletion

Depletion means the removal, under the direct control of the Authority, of shellstock from a growing area classified as prohibited.

(2) Seed

Seed means shellstock which is less than market size.

D. Model Ordinance Requirements for Depletion and Gathering of Seed

(1) Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification

E. Prohibited Classification

(1) Exception…

(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 for aquaculture or the depletion of the areas classified as prohibited; and

(b) Ensure that shellstock removed from any growing area classified as prohibited is effectively excluded from human consumption unless it is seed to be cultured as outlined in the NSSP Model Ordinance Chapter VI. Shellfish

Aquaculture @.02 Seed Shellstock.

(3) Sanitary Survey…

(4) Risk Assessment…

(5) Wastewater Discharges…

(2) Chapter VI. Shellfish Aquaculture

Requirements for the Harvester/Dealer

.03 Seed Shellstock

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

A. The source of the seed is sanctioned by the Authority; and

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

E. Guidance for Determining the Size of Each Prohibited Are Adjacent to a Waste Water System Treatment Plant (WWTP)

There are several important considerations for the shellfish authority to consider when establishing the size of each prohibited area adjacent to a WWTP discharge:

(1) The area is large enough to ensure that there is adequate dilution for the type of classification that will be used adjacent to the prohibited area. If a conditional classification (either conditionally restricted or conditionally approved) is established adjacent to the prohibited area, adequate dilution should be determined when the WWTP is operating as normal. "Normal" means that the WWTP is operating fully within the plant's design specifications, including design flows; treatment stages; disinfection; as well as compliance with all permit conditions that relate to the WWTPs effectiveness in reducing enteric viruses in discharged wastewater.

Should a restricted area for the purposes of relaying or depuration be established adjacent to the prohibited area, establishing the size of the prohibited area should be based on worst case plant operating conditions. This same consideration would apply for an approved area adjacent to the prohibited area.

Below are several scenarios that could occur and are critical for Shellfish Control Authorities (SCAs) on

evaluating each WWTP when determining appropriate classifications:

(a) Bypassing stage of treatment

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

(b) Operating outside design specifications/other types of failures or events

It is not uncommon for a WWTP to periodically experience mechanical failures of equipment that could alter the treatment of sewage. Additionally, a WWTP may also need to periodically perform routine maintenance to the various stages of treatment and may need to temporarily take a portion of a treatment stage off-line for cleaning. Other unexpected maintenance may need to occur. For example cleaning of filters or membranes that have become bio-fouled.

(c) Operating above design flow

Some WWTPs may operate above its design flow and not necessarily bypass any particular stage of treatment. During these events it is typical for WWTP operators to adjust the operation of the WWTP which may include reducing the treatment time in the aeration stage and/or solids separation/settling stage of treatment. Under some circumstances this could lead to a significant reduction in the effectiveness of disinfection. SCAs may consider assessing the efficiency of WWTPs to determine the significance of these type of events.

(d) WWTP permit violations

If a WWTP is exceeding the permitted bacterial indicator levels in the final effluent this indicates that effectiveness of the disinfection step has been reduced. Other

measured parameters in the effluent (e.g. Total Suspended Solids (TSS), Biochemical Oxygen Demand (BOD)) may also indicate a reduction in treatment efficiency has occurred. SCAs may consider assessing the efficiency of WWTPs to determine the significance of these types of events.

Compliance of WWTP operation permit compliance does not necessarily eliminate the potential transmission of pathogens present in wastewater effluent to contaminating shellfish in the impacted area.

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

(2) The integrity of the collection system. Collection system malfunctions, bypasses or other factors can lead to significant leakages of untreated sewage to the marine environment.

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

F. Guidance for the Use of MSC in Shellfish Meats in determining the size of the prohibited area impacted by WWTP discharge.

MSC has been demonstrated to accurately assess enteric virus dynamics through contaminant mitigation strategies such as relay. MSC levels in shellstock from growing areas adjacent to WWTP discharge are a function of WTTP performance, seasonal persistence of viruses in the environment and the shellfish, species-specific anomalies, and distance from the outfall. The regulatory level of 50 PFU/100gm is a conservative value used for

re-opening approved growing areas (after 7 days) after a sewage spill and end point target values for viral relay. Before using MSC for these purposes, the Authority should perform preliminary studies to familiarize themselves with the seasonal viral persistence patterns, regional and species-specific anomalies.

Seasonal persistence of MSC in shellfish meats can vary greatly from warm summer months to the cooler fall, winter, and spring months. MSC levels can be 2 to 3 logs (100 to 1000) higher in the late fall, winter, and early spring months demonstrated by multiple studies from conducted in northern temperate latitudes using both MSC and molecular enumeration using PCR for enteric viruses. This dramatic tendency to accumulate virus particles by 2 to 3 logs over the winter months has species-specific implications for warm-water adapted species such as American oysters and northern quahogs, which tend to shut down as cooling water temperatures approach 10°C. Viruses and bacteria bio-accumulated in shellfish behave very differently; FC is prone to die-off in a week or two over colder months while viruses can persist at high levels under these cold water conditions for months. Cold-water adapted species such as soft-shelled clams, Pacific oysters, European oysters, and mussel all demonstrate the tendency to increase by 2 to 3 log values over the colder months.

If the Authority is interested in using MSC in shellfish meats, it is recommended that monthly samples be taken over the course of a year in multiple growing areas inside the 1000:1 line to understand these seasonal, spatial, and species-specific variations. This data can be very useful to assess the feasibility of using the conditionally restricted classification for the purpose of relay.

G. Use of MSC in Evaluating WWTP Efficiency

At a minimum, MSC may be used in conjunction with conventional bacterial indicators to conduct a comprehensive assessment of WWTP microbiological performance. The differences between influent, pre-disinfection effluent, and final effluent samples taken under normal and challenged conditions can be used to assess the viral deactivation efficiency of a specific waste water treatment process. The analysis is somewhat similar to the determination of WWTP efficacy using bacterial indicators such as E. coli, which is currently used to comply with EPA's National Pollution Discharge Elimination System (NPDES) permit requirements for municipal wastewater treatment plant discharge. Many studies have shown that deactivation of bacterial and viral indicators (and pathogens) can be significantly different in different treatment processes and under challenged conditions. There are several case studies showing that under

certain conditions, differential bacterial indicators may indicate highly effective treatment of wastewater while differential MSC samples show little deactivation efficiency.

By collecting differential wastewater samples including influent, pre-disinfection effluent, and final effluent and evaluating these samples for MSC, the viral performance of the wastewater treatment process can be determined. If a comprehensive sampling program includes sufficient samples to assess the WWTP under typical operating conditions as well as challenged condition such as high flow, the viral efficiency of the WWTP can be determined. A comprehensive assessment of WWTP microbiological performance using MSC as well as the conventional bacterial indicators can inform the SSCA on the risk associated with a growing area adjacent to a WWTP outfall. An assessment of a WWTP must demonstrate the range of effluent quality during routine operation through an appropriate sampling study and the ability to accurately predict those times when effluent microbiological quality is detrimentally impacted by challenged conditions.

H. Public Health Significance

The positive relationship between disease and consuming contaminated shellfish has been clearly established. Prevention of consumption of contaminated shellfish is the primary objective of the NSSP. The prohibited area classification is the most restrictive growing area classification and is used for areas subject to gross pollution. The use of this classification is also required for all growing areas immediately adjacent to a wastewater treatment plant and where the shellfish authority has not performed a sanitary survey. The harvesting of shellstock is not allowed for any human food use. For additional information concerning the classification of growing waters and the sanitary survey, see the NSSP Model Ordinance. Depletion and Gathering of Seed (Chapter IV @.03 E. Prohibited Classification (2) (a) & (b) and Chapter VI .03 Seed Shellstock A. & B.)

A growing area is placed in the prohibited classification when the sanitary survey or marine Biotoxin surveillance program indicates that fecal material, pathogenic microorganisms, poisonous or deleterious substances, marine Biotoxin, or radionuclides may reach the harvest area in excessive concentrations. The NSSP Model Ordinance also requires that a growing area for which there is no sanitary survey be placed in the prohibited classification as a precautionary measure. Taking shellstock from a prohibited area

for any human food purpose is not allowed.

The NSSP Model Ordinance also requires that an area classified as prohibited must be established between any sewage treatment plants or other waste discharge of public health significance and any growing area placed in the approved, conditionally approved, restricted, or conditionally restricted classification. The size of the prohibited area should be based on the effectiveness and level of sewage treatment; the location of the shellstock resource that would be affected; the classification of adjacent waters, the total time it would take for the person responsible for the operation of the sewage treatment facility to detect a failure and notify the Authority; the time it would take the Authority to issue a notice to stop shellstock harvesting, and the degree of effluent dilution. Due consideration should be given to the possibility that emergency actions might be necessary on holidays or at night.

I. Establishment of Boundaries for the Prohibited Area

The establishment of the boundary for the prohibited area is dependent upon other classification which may be adjacent to the prohibited area. Examples could include water bodies in which the Authority chose to use all five (5) classifications or a situation where the Authority only uses prohibited and approved. The decision of adjacent classifications is often based on shellfish uses for the water body or environmental control and protection efforts by State Water Control Agencies. The requirements of the classification adjacent to the prohibited area and the allowable uses in the areas will often dictate the distance the boundary line for the prohibited area is from the outfall.

Guidance for Dilution Ratios

To determine the impact of a WWTP on adjacent waters, it is imperative that the Shellfish Control Authority assess the waste water dispersal and dilution and the time of transport to the area where shellstock may be harvested. In determining the appropriate dilution for establishing the size of the prohibited area, the Shellfish Control Authority must determine the classification which will be adjacent to the prohibited area. The dilutions below outlines recommended dilution for the boundary line between prohibited and other possible classifications based on dilutions of WWTP effluent, based on initial FC values of 1.4 x 106 FC/100ml.. Each of these dilutions will be discussed in more detail in the context of each classification.

(1) Prohibited to Restricted Boundary
Minimum dilution – The SCA should determine the effluent quality based on a worst case scenario and should establish a dilution ratio that would accomplish a dilution equivalent to a MPN of 88 (or 163) which is the upper limit restricted standard for depuration and relaying without a contaminant reduction study.

(2) Prohibited to Conditionally Restricted Boundary
Minimum dilution of 320:1 based on "Critical Dilution for Toxics to Ambient (Background)" from the Clean Water Act and EPA's Regulatory Mixing Zone (RMZ).

(3) Prohibited to Conditionally Approved Boundary
Minimum dilution 1000:1 or justified by other data.

(4) Prohibited to Approved Boundary
Minimum dilution >100,000:1 dilution based on worst case scenario or justified by other data.

V. Restricted Classification.

A. Definition
A classification used to identify a growing area where harvesting shall be by special license and the shellstock, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration.

B. Requirements for Use of the Restricted Classification

(1) Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification

A. General…
B. Approved Classification…
C. Conditional Classifications…
D. Restricted Classification.
(1) General
(a) A growing area may be classified as restricted when:
(i) A sanitary survey indicates a limited degree of pollution; and
(ii) Levels of fecal pollution, human pathogens, or poisonous or deleterious substances are at such

levels that shellstock can be made safe for human consumption by either relaying, depuration or low acid-canned food processing.

(b) The Authority shall have effective controls to assure that shellfish are harvested from restricted areas only:

(i) By special license; and

(ii) Under the supervision of the Authority.

(2) Water Quality. Water quality in the growing area shall meet the bacteriological standards in Section @.02 for a growing area in the restricted classification if the growing area is used for depuration. (These standards are included later in this section.)

(3) Shellstock Quality Criteria. The Authority shall establish shellstock quality criteria for use in placing an area in the restricted classification. Depending on the treatment process to be applied to the shellstock, the criteria shall be established in accordance with:

(a) Chapter V. Shellstock Relaying; or

(b) Chapter XV. Depuration

E. Prohibited Classification…

C. Allowable Uses of Shellfish from a Restricted Growing Area

(1) Relay with a Contaminant Reduction Study

Relay means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(2) Relay without a Contaminant Reduction Study

Relay means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the

treatment process.

(3) Depuration
Depuration means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

(4) Seed
Seed means shellstock which is less than market size.

D. Model Ordinance Requirements for Relaying with a Contaminate Reduction Study

(1) Chapter V. Shellstock Relaying

@.01 General

The Authority shall assure that:

A. The shellstock used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted;
B. The level of contamination in the shellstock can be reduced to levels safe for human consumption;
C. The contaminated shellstock are held in growing areas classified as approved or conditionally approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens as measured by total coliform or fecal coliform or poisonous or deleterious substances that may be present in shellstock. For shellstock harvested from areas impacted by waste water system discharge, MSC may be used as a measure for viral reduction.
D. If shellstock are relayed in containers:
(1) The containers are:
(a) Designed and constructed so that they allow free flow of water to the shellstock; and
(b) Located so as to assure the contaminant reduction required in Section C.; and
(2) The shellstock are washed and culled prior to placement in the containers.

@.02 Contaminant Reduction.

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

B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The study report shall demonstrate that, after the completion of the relay activity:

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

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

(3) When the source growing area is impacted by waste water system discharge, the viral quality of each shellfish species meets the male-specific coliphage standard of 50 PFU/100 gm or predetermined levels established by the Authority based on studies conducted on regional species under regional conditions.

C. The authority may waive the requirements for a contaminant reduction study if:

(1) Only microbial contaminants need to be reduced; and

(2) The shellstock are relayed from a conditionally approved, restricted, or conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per Chapter IV. @.02 G. and Chapter IV. @.02 H.; and

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

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

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

(1) Product sampling before and after relay; and

(2) Monitoring of critical environmental parameters such as temperature and salinity; and

(3) For SSCAs using male-specific coliphage, monitoring before and after relay for shellstock relayed from areas impacted by waste water system discharge.

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

In addition to the requirements of Chapter IV. @.02 G. & H., restricted growing waters used for relaying without a contaminant reduction study must meet the requirements of Chapter IV. @.03 D.

E. Guidance for Restricted Classification for Relaying with a Contaminant Reduction Study

Model Ordinance Chapter IV and V do not include microbial standards for classifying growing areas as restricted that are the source of shellstock for relaying when a contaminant reduction study is required. In establishing of the boundary between prohibited and restricted classifications, the Authority must ensure that levels of fecal pollution, human pathogens, or poisonous or deleterious substances are at such levels that shellstock can be made safe for human consumption by either relaying, depuration or low acid-canned food processing.

In determining an appropriate boundary, the Authority shall consider the following factors associated with the wastewater discharge:

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

The Authority may utilize MSC waste water sample data in the determination of the performance of the sewage treatment plant;

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

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

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

A growing area may be placed in the restricted classification instead of the prohibited classification when the sanitary survey indicates a limited degree of pollution. This option may be used when the sanitary survey for the growing area indicates that the microbiological quality or poisonous or deleterious substances in the growing area are such that additional treatment through relay can render the shellstock safe for human consumption. The Authority should use the restricted classification only when sufficient relay studies have been conducted to establish raw product quality requirements at the harvest level; and when the Authority has sufficient administrative and technical resources to properly administer this classification. These resources include monitoring of pollution sources; providing coordination between state, local and industry officials; issuing special harvesting permits; and supervising the harvesting and transport of shellstock to relay sites. For a complete discussion of the supervision requirements at the harvest level, see the NSSP Guidance Document, Shellstock Relay (ISSC/FDA, 2015).

Use of the restricted classification for relaying with a contaminant reduction study requires the Authority to develop the controls necessary to assure that the shellfish are relayed prior to consumption. The criteria may vary according to the use to be made of the shellstock and the effectiveness of the relay process used to cleanse the shellstock. Process effectiveness is determined through a study, which establishes the levels of microbilogical quality indicators in shellstock at the time of harvest, and the density that can be achieved at the completion of the process. Effectiveness of the process is likely to vary between growing areas used for natural cleansing treatment in relay operations. The species of shellstock may also affect the effectiveness of the relay. For a complete discussion of relay, see the NSSP Guidance Document, Shellstock Relay (ISSC/FDA, 2015).

F. Guidance for Conducting a Contaminant Reduction Study for Relay

The use of the restricted classification for the purpose of relaying with a contaminant reduction study does not require the authority to demonstrate that the growing area meets a microbiological water quality standard. However, in determining the boundary between the prohibited area and the restricted area for relaying with a contaminant reduction study, the authority shall give consideration to the types of contamination that may be in the growing area prior to allowing the area to be in the source of shellfish for relaying. The contaminants may include:

- Pathogenic Organisms
- Poisonous or Deleterious Substances
- Marine Biotoxins
- Physical and Chemical Contaminants

Contaminant Reduction is a specified activity defined in Chapter V. Shellstock Relaying @.02. The authority shall establish species-specific critical values for water temperature, salinity and other environmental factors such as dissolved oxygen and turbidity which may affect the natural treatment process (e.g. relay process). These critical values must be monitored and the Authority shall establish the time of year when relay may be conducted. The relay process requires that shellstock are held in the receiving growing area for a sufficient time under adequate environmental conditions to allow reduction of pathogens as measured by total coliform or fecal coliform. To verify the effectiveness of a relay process, contaminant reduction studies are required. The only exception to this requirement is when water quality in the restricted growing area meets Chapter IV.@.02 G-H, only microbial contaminants need to be reduced, and the treatment period exceeds sixty (60) days. For all other relay operations, the Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the receiving growing area. The receiving waters shall be monitored with sufficient frequency to identify when limiting critical values may be approached. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The study shall demonstrates that after the completion of the relay activity, 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 contaminants levels of poisonous or deleterious substances in shellstock do not exceed NSSP tolerance levels. Based on the study, the Authority shall establish the time period during the year when relaying may be

conducted. Shellstock shall be relayed for at least fourteen 14 consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated with the contaminant reduction study to be adequate. If the shellstock are container relayed and the treatment times are less than 14 days, intensive sampling is required. This intensive sampling includes lot sampling before and after relay as well as monitoring of critical environmental parameters such as seawater temperature and salinity.

Although minimum requirements for contaminant reduction studies have not been specified in the Model Ordinance, there are certain principles of process verification studies that should be considering including; study design, sampling replicates, and data analysis providing statistical reliability. Shellstock and water samples collected during a contaminant reduction study must be analyzed in NSSP-conforming laboratories using NSSP-approved methods. Shellfish samples should be collected at regular intervals from both source and receiving growing areas over the time period of the relay and the natural cleansing process that is proposed. It is important to produce a sufficiently robust database to demonstrate the process is consistently working and the variables affecting the cleansing process are understood. All shellfish samples of 10 to 12 animals should be collected in triplicate so that the mean as well as standard deviation or standard error can be calculated. Water temperature and salinity should be measured at both source and receiving waters at the time of shellstock collection. Fecal coliform levels of shellstock already present in the receiving growing area should be collected in triplicate and evaluated for comparison to relayed shellstock microbial levels. Contaminant reduction studies are specific to species, source growing area, and receiving growing area. In states with extensive experience with relay practices, the Authority may approach contaminant reduction studies on a more regionally basis covering multiple source and receiving growing areas.

When the source growing area is adjacent to a WWTP outfall, the authority may utilize MSC in conducting the contaminant reduction study. Should the Authority utilize MSC sampling, the MSC levels in each shellfish species after the relay process must be assessed. The male-specific coliphage (MSC) standard of 50 PFU/100gm or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions are both approved for these assessments. Relay dynamics for bacterial and viral pathogens can be very different and assessing both offers more insight into the potential health risk. Seasonal persistence of bio-accumulated viral particles in

shellfish can range 1,000 times higher in the winter months verses the summer months. Depuration rates can vary from 1 log in 44 hours at receiving water temperature above 18°C to 1 log in 25 days when receiving water temperature fall below 10°C. Understanding these dynamics for each species and region is paramount to successful relay from restricted or conditionally restricted growing areas adjacent to WWTP outfall. When container relaying is considered and treatment times of less than 14 days are planned, an intensive MSC sampling program based on before and after relay samples can be utilized to assure relayed shellstock are less than the 50PFU/100gm standard or pre-determined levels established by the authority based on studies conducted on regional species under regional conditions.

G. Guidance for the use of MSC in Contaminant Reduction Studies and Process Control for Shellstock Relay

MSC has been shown to be an appropriate modeling organism for contaminant reduction studies and process verification for shellstock from growing areas impacted by a WWTP outfall. The ability of MSC to model enteric viral dynamics in relay and depuration has been demonstrated in several studies using different species in different parts of the northern temperate zone. The MSC standard of 50 PFU/100gm used in process end-point samples was shown to be conservative with respect to public health outcomes.

The conditionally restricted classification recommended for relay adjacent to WWTP outfalls where contaminant studies will be used, should have limits such as zero-hour maximum MSC limits in the shellstock from the source growing areas, seasonal limits, and receiving water temperature and salinity limits as determined by comprehensive contaminant reduction studies. This is in addition to controls to assure the continued operation of the adjacent WWTP under the management plan to keep the source growing area in the restricted status. MSC data from sampling shellstock from the source growing area may help determine those times when viral loading and/or viral persistence in the shellstock are low and viral mitigation strategies are feasible. In both viral depuration and viral relay pilot studies using soft-shelled clams in Maine, periods of time were identified using bi-weekly MSC assays of the target species to understand those times when bio-accumulated MSC levels in the shellstock were at a seasonal low (low viral persistence). Receiving waters temperatures were correspondingly high in those summer months resulting in significantly higher depuration rates, especially when water temperature exceeded 64.4°F (18°C). Studies showed the

depuration rate approached a single log reduction in 44 hours when water temperatures were above 64.4°F (18°C). In contrast, those studies also determined that as water temperature approached 41°F (5°C), it would take approximately 20 days to see a comparable single log reduction in MSC levels. The combination of seasonally low MSC levels in the soft-shelled clams and higher summertime depuration rates resulted in successful depuration consistently meeting a shellfish end-point of 50 PFU/100gm.

Species-specific and regional anomalies in persistence and relay and depuration dynamics require that comprehensive contaminant reduction studies be performed for each growing area for each relay or depuration process being considered. In planning a comprehensive contaminant reduction study, sufficient quantities of target specie(s) from the source area should be collected on a regular basis and evaluated for fecal coliform and MSC (triplicate samples of 10-12 animals), during that period of time when the restricted harvest is being considered. Background levels of MSC are not known in a new species or region, the Authority might consider collecting samples year round in the first year to understand the range of viral persistence throughout the year to understand those times when viral mitigation strategies are feasible.

Trial lots of shellstock should be evaluated monthly during the period of time when the relay is being considered. One to two bushels are adequate for relay trials. Triplicate shellfish samples of 10 to 12 animals from the approved relay site should be collected at appropriate intervals and analyzed for fecal coliform and MSC. Contaminant reduction studies should use triplicate samples so that variation as well as mean value can be assessed yielding improved statistical reliability for the contaminant reduction studies. If little is known about the depuration rates of the target species, it may be necessary to conduct a separate study using shellfish that are highly contaminated with MSC to assess the viral depuration rate in that region. The goal of contaminant reduction studies is to show those periods of time and the conditions when relay is effective.

The Authority may permit an end-point value other than 50 PFU/100gm based if pre-determined levels established by the Authority based on studies conducted on regional species in regional conditions are known.

H. Model Ordinance Requirements for Relaying without a Contaminant Reduction Study

(1) Chapter V. Shellstock Relaying

@.01 General

The Authority shall assure that:

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

B. The level of contamination in the shellstock can be reduced to levels safe for human consumption;

C. The contaminated shellstock are held in growing areas classified as approved or conditionally approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens as measured by total coliform or fecal coliform. For shellstock harvested from areas impacted by waste water system discharge, MSC may be used as a measure for viral reduction, or poisonous or deleterious substances that may be present in shellstock.

D. If shellstock are relayed in containers:

(1) The containers are:

(a) Designed and constructed so that they allow free flow of water to the shellstock; and

(b) Located so as to assure the contaminant reduction required in Section C.; and

(2) The shellstock are washed and culled prior to placement in the containers.

(2) Chapter V. Shellstock Relaying

@.02 Contaminant Reduction

C. The Authority may waive the requirements for a contaminant reduction study if:

(1) Only microbial contaminants need to be reduced; and

(2) The shellstock are relayed from a conditionally approved, restricted, or

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

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

(3) Chapter IV. Shellstock Growing Areas

@.02 Microbiological Standards

G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section G. (2).

(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 88 per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of:

(a) 300 MPN per 100 ml for a three-tube decimal dilution test;

(b) 173 MPN per 100 ml for a twelve-tube single dilution test; or

(c) 163 CFU per 100 ml for a MF (mTEC) test.

(3) Required Sample Collection. Samples shall be collected in accordance with Section E. (3).

H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration.

(1) Exception. If the tidal stage increases the fecal coliform concentration, the Authority shall use samples collected under that tidal stage to classify the area.

(2) Pollution Sources. Growing areas shall meet the requirements in Section F. (2).

(3) Water Quality. The bacteriological quality of every sample station in the growing area shall meet the fecal coliform standard in Section G. (2) or Section H. (4).

(4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed a MPN or MF (mTEC) of:

(a) 260 MPN per 100 ml for a five-tube decimal dilution test;

(b) 300 MPN per 100 ml for a three-tube decimal dilution test; or

(c) 163 CFU per 100 ml for a MF (mTEC) test.

(5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by the same method described in Section F. (5).

(6) Required Sample Collection.

(a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in Section E. (3) for application of the standard under Section G. (2).

(b) Systematic Random Sampling Standard. The Authority shall collect samples in the same intensity and frequency, and shall apply the sample results in the manner described in Section F. (6) for the application of the standard under Section H. (4).

In addition to the requirements of Chapter IV @.02 G & H., restricted growing waters used for relaying without a contaminant study must meet the requirements of Chapter IV @.03 D. (Page 12)

I. Guidance for Restricted Classification for Relay Without a Contaminant Reduction Study

The NSSP Model Ordinance provides state Authorities the option to allow relaying from a restricted area affected by a point source without a contaminant reduction study. The requirement for establishing the restricted classification for this use is different than the requirements for relay with a contaminant reduction study. The Authority must assure that the bacteriological quality of every station meets Chapter IV @.02 G (2). Additionally, the treatment period must exceed sixty (60) days. Should the Authority have viral concerns, the use of MSC sampling of the shellfish would be appropriate. The Authority could use the 50 PFU/100gm level or predetermined levels established by the Authority based on studies conducted in the area.

J. Model Ordinance Requirements for Depuration

(1) Chapter IV. Shellstock Growing Areas

@.02 Microbiological Standards.

G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section G. (2).

(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 88 per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of:

(a) 300 MPN per 100 ml for a three-tube decimal dilution test;

(b) 173 MPN per 100 ml for a twelve-tube single dilution test; or

(c) 163 CFU per 100 ml for a MF (mTEC) test.

(3) Required Sample Collection. Samples shall be collected in accordance with Section E. (3).

H. Standard for the Restricted Classification of

	Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration. *(1) Exception. If the tidal stage increases the fecal coliform concentration, the Authority shall use samples collected under that tidal stage to classify the area.* *(2) Pollution Sources. Growing areas shall meet the requirements in Section F. (2).* *(3) Water Quality. The bacteriological quality of every sample station in the growing area shall meet the fecal coliform standard in Section G. (2) or Section H. (4).* *(4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median or geometric mean MPN or MF(mTEC) of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed a MPN or MF (mTEC) of:* *(a) 260 MPN per 100 ml for a five-tube decimal dilution test;* *(b) 300 MPN per 100 ml for a three-tube decimal dilution test; or* *(c) 163 CFU per 100 ml for a MF (mTEC) test.* *(5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by the same method described in Section F. (5).* *(6) Required Sample Collection.* *(a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in Section E. (3) for application of the standard under Section G. (2).* *(b) Systematic Random Sampling Standard. The Authority shall collect samples in the same intensity and frequency, and shall apply the sample results in the manner described in Section F. (6) for the application of the*

standard under Section H. (4).

(2) Chapter XV. Depuration

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall…

(2) The dealer shall…

(3) Should a dealer…

(4) The dealer shall receive and depurate only shellstock obtained from a special licensed harvester who has:

(a) Harvested or supervised the harvest of shellstock from a Restricted or Conditionally Restricted area in the open status.

(b) Identified the shellstock…

K. Guidance for Restricted Classification for Depuration

Use of the restricted classification for depuration requires the Authority to conduct a sanitary survey of the growing area as required in Chapter IV @ 01 and establish a monitoring program to ensure the water quality requirements of Chapter IV @ 02 G & H and @03 D.

Depuration process verification described in Chapter XV. @.03 Section J. is based on conditional and approved protocols. The protocol is conditional when statistical analysis of the database containing the 10 most recent FC end point samples fails to meet prescribed species-specific indices. The intent of which is to ensure an appropriate level of testing and quality assurance, including release criteria, during those periods of time when the depuration process is being challenged. These process verification protocols are based on fecal coliform assays of shellfish meats. The requirement for adverse case sampling of the restricted growing area is to assure that water quality in the restricted harvest growing areas does not exceed a median FC score of 88/100ml (or 163 FC.100ml) and P90 requirements.

Water quality requirements for the restricted growing area used for depuration were put in place to prevent grossly contaminated shellfish from being processed. It was not the inability to depurate high FC levels from contaminated shellstock, but rather that viruses associated with grossly contaminated shellstock were

thought to not effectively depurate viruses in 44 hours. In contrast, restricted growing areas adjacent to WWTP discharges used for relay with contamination reduction studies are considered effective for viral reductions and do not require a water quality sampling program based on 14 consecutive days of relay. The inability to detect viruses using fecal coliform based process verification and the lack of any suitable viral indicator assays was the original rationale behind restricted growing areas for depuration requiring water quality limits.

L. Model Ordinance Requirements for Use of a Restricted Area as the Source of Seed

(1) Chapter VI. Shellfish Aquaculture

.03 Seed Shellstock

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

A. The source of the seed is sanctioned by the Authority; and

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

M. Seed

If a restricted growing area is used as a source for seed and the Authority requires that the shellfish must be cultured in the approved growing area for a minimum of six (6) months, the classification requirements for relay and depuration are adequate for this use.

N. Determination of the Boundaries Between Prohibited and Restricted Areas

The establishment of boundaries separating prohibited and restricted growing areas is dependent upon the uses to be allowed within the restricted growing area. MO Chapters IV and V address the classification requirements for allowable shellfish uses in the restricted classification. These uses include the following:

(1) Relay with a contaminant reduction study
(2) Relay without a contaminant reduction study
(3) Depuration

If harvesting for relay with a contaminant reduction study, the

boundary line should be based on an acceptable dilution ratio. If harvesting for relay without a contaminant reduction study or depuration, the boundary line must be based on a fecal coliform sampling program. The SCA has the option to utilize MSC.

Guidance for Dilution Ratios

Restricted areas that are the source for shellstock relaying with a contaminant reduction study are not required to meet a microbiological standard. Shellstock from restricted areas used for relaying without a contaminant reduction study or for depuration do have to meet a microbiological standard. In the absence of a microbiological standard, dilution ratios become very important to protect public health. A Shellfish Control Authority should not allow relay with a contaminant reduction study from any portion of a restricted area that does not meet a minimum dilution. The SCA should determine the effluent quality based on a worst case scenario and should establish a dilution ratio that would accomplish a dilution equivalent to a MPN of 88 (or 163) which is the upper limit restricted standard for relaying without a contaminant reduction study and for depuration. This dilution is 16,000:1. Should the Shellfish Control Authority choose to classify waters not meeting a dilution ratio equivalent to the upper limit MPN standard of 88 (or 163), the classification should be supported by fecal or MSC sampling of WWTP effluent to demonstrate a wastewater quality level less than 1.4×10^6 or the results of the contaminate reduction studies conducted over worst-case scenarios at the upstream WWTP discharge.

VI. Establishment of Conditional Classifications

The basic concept of the NSSP is to control the safety of shellfish by preventing their harvest from contaminated growing areas. In reviewing growing area classifications and sanitary surveys conducted by Shellfish Control Authorities, it appears that a common misinterpretation is the classification of an area as approved when in fact the area should have been classified as conditional. Critical investigations usually reveal that the area is subject to intermittent pollution events. Careful consideration of an intermittent pollution event, development and application of a management plan, and cooperation and compliance by all parties may also allow upgrading of an area to a conditionally approved or conditionally restricted classification instead of requiring the area to be restricted or prohibited at all times.

Intermittent pollution to shellfish growing waters has been a significant cause of shellfish-borne infectious disease outbreaks worldwide. In 1978, at least 20,000 persons were involved in an outbreak of oyster-associated gastroenteritis attributed to Norwalk virus. The investigation of the outbreak indicated that a combination of meteorological and hydrographic

events had caused inadequately treated and diluted sewage from a nearby municipal facility to reach the area. In an incident in 1982, at least 471 persons developed gastroenteritis after consumption of sewage contaminated oysters when a combination of raw sewage bypasses, high rainfall, strong winds, and abnormally low tides caused contamination of an area that was classified as approved. In both of these instances, application of the conditionally approved area concept probably could have prevented the outbreaks.

A common situation where this classification might be appropriate is when water quality is, to some degree, dependent upon the operation of a Waste Water Treatment Plant (WWTP). For example, the boundaries of an approved shellfish area might be improperly determined during a period when a WWTPSD is operating at a satisfactory level. If there is some interruption in treatment, it follows that there will be some degradation of water quality in the growing area which may require a relocation of the boundaries. The degree of relocation would depend upon such items as the distance between the pollution source and the growing area, hydrography, the amount of water, and the amount of pollution.

The first step in determining whether an area should be classified as conditionally approved or conditionally restricted is to determine whether sufficient State resources are available to manage, survey, monitor, control harvesting, affect closures, and reopen the area as required. It should be noted that sources of pollution must be routinely monitored; coordination between State, local and industry officials must be timely; performance standards must be monitored; and closures must be immediate and effective. States electing to classify areas as conditionally approved have found the public resource investment to be substantial.

The second step in determining whether an area should be placed in the conditionally approved or conditionally restricted classification is to evaluate the potential sources of pollution in terms of their effect on water quality in the area. Potential sources of pollution involving a WWTP include: bypasses and overflows within a sewage collection and treatment system.

The third step in establishing a conditionally approved or conditionally restricted area is to evaluate the source of pollution in terms of the water quality standards to be maintained, and to formulate performance standards for each pollution source having a significant effect on the sanitary quality of the area. The following is an example of performance standards that might be developed:

Performance standards or closure criteria may be based upon the bacteriological quality of effluent from sewage treatment plants. This

might be stated in terms of chlorine residual if the bacteriological quality of the effluent can be positively related to chlorine residual. The following is an example of a performance standard for an effluent discharge: "The median coliform MPN, in any one (1) month, shall not exceed 500 per 100 ml, based on not less than sixteen (16) composite samples per month, and not more than ten (10) percent of the samples shall have an MPN in excess of 10,000 per 100 ml. Determinations of the chlorine residual of the effluent should be made hourly and recorded in the permanent plant records."
A performance standard may be based upon total quality of sewage, which can be discharged from any given unit, or from a combination of units, without causing the basic water quality standards to be exceeded.

The design of a waste treatment plant and the plant effluent specifications may be critical to the designation of an area classified as conditionally approved or conditionally restricted. Design criteria which may be useful in determining the quality of sewage which can be discharged into an area without exceeding the desired water quality standards include: population equivalent (coliform) of sewage, predicted survival of coliform in seawater, effectiveness of chlorination and the total quality of clean dilution water in an area. Results of many studies on the survival of bacteria in seawater have been published.

The mechanical equipment at critical sewage treatment or pumping units should be such that interruptions will be minimized. Wherever possible, operations should be automatically recorded on charts. Requirements that might be imposed depend upon the importance of the unit's relationship to water quality. Important design features of a sanitary waste collection system that should be considered include:
Storm water should be excluded from the sanitary system. There should be stand-by equipment to insure that treatment or pumping will not be interrupted. It should be taken into account that interruptions may occur because of damage to a single unit or a power failure.

The pumps and critical units should be fitted with meters or gauges so the regulatory agency can monitor performance standards.

Installation of recording scales to indicate rate of chlorine use is helpful. Chlorine flow meters are available that integrate hydraulic flow with chlorine demand.

Liquid level recording gauges fitted with alarms and located in overflow channels of sewage treatment plants and wet wells of lift stations are useful. They can be set to indicate when overflow takes place. It is good operating procedure to date recording charts. Gauges should be calibrated and maintained so that indicated discharge rates are accurate.

Automatic devices to warn of failure or malfunctioning at self-operated pumping stations or treatment plants can be an important control.

Another factor to consider in developing a conditionally approved or conditionally restricted area is that a prohibited area must be interposed between the conditionally approved or restricted area and the source of pollution. The size of such area should be based on the total time it would take for the operating agency to detect a failure, notify the State Shellfish Control Agency, and for the latter agency to issue a notice to stop shellfish harvesting. It is recommended that the area be of such size that the flow time through the safety area is at least twice that required for the notification process to become effective. Due consideration should be given to the possibility that closure actions might be necessary on holidays or at night.

The length of time a conditionally approved or conditionally restricted area should be closed following a temporary closure will depend upon several factors including the species of shellfish, water temperature, shellfish activity and cleansing rates, presence of silt or other chemicals that might interfere with the physiological activity of the shellfish, and the degree of pollution of the area.

The conditional classifications are designed to address growing areas that are subject to intermittent microbiological pollution. These optional classifications offer the Authority an alternative to placing the area in the restricted or prohibited classification year round when during certain times of the year or under certain conditions, the shellstock from the growing area may be safely harvested. Public health protection and the control of shellfish safety in the use of the conditional classifications are afforded through the use of a management plan. The management plan for each growing area placed in a conditional classification is based on the information gathered during the sanitary survey. The plan establishes a strict set of criteria that must be met for the growing area to remain in the open status. Failure to meet the criteria automatically places the growing area in the closed status, with immediate notice to the public, the affected industry, and the plan's participants. Two (2) of the most important components of the management plan are: the acceptance of and the agreement to the conditions of the management plan by the one (1) or more Authorities involved, other local, State and Federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved; and the annual reevaluation of compliance with the plan to assure public health protection. Use of the conditional classification requires more intense monitoring and more frequent reevaluation because of the intermittent nature of the pollution event.

When the Authority has sufficient resources to manage a conditional

classification, the use of the conditional classification could allow the safe use of growing areas that might otherwise not be available to the shellfish industry. For a complete discussion of the conditional classification, see the NSSP Model Ordinance Guidance Documents: Management Plans for Growing Areas in the Conditional Classification (ISSC/FDA, 2015). For additional information concerning the classification of growing waters and the sanitary survey, see the NSSP Model Ordinance Guidance Documents: Sanitary Survey and the Classification of Growing Waters (ISSC/FDA, 2015).

A. Requirements for Conditional Area Adjacent to a Waste Water Treatment Plant (WWTP)

(1) Model Ordinance Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification.

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

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

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

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

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

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

	(2) Management Plan Required. For each growing area, a written management plan shall be developed and shall include: *(a) For management plans based on wastewater treatment plant function, performance standards that include:* *(i) Peak effluent flow, average flow, and infiltration flow;* *(ii) Microbiological quality of the effluent;* *(iii) Physical and chemical quality of the effluent;* *(iv) Conditions which cause plant failure;* *(v) Plant or collection system bypasses;* *(vi) Design, construction, and maintenance to minimize mechanical failure, or overloading;* *(vii) Provisions for monitoring and inspecting the waste water treatment plant; and* *(viii) Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with Section E. Prohibited Classification;* *(b) For management plans based on pollution sources other than waste water treatment plants:* *(i) Performance standards that reliably predict when criteria for conditional classification are met; and* *(ii) Discussion and data supporting the performance standards.* *(c) For management plans based on waste water system discharge function or pollution sources other than waste water system discharge*

	criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum criteria are: *(i) Performance standards of the plan are fully met;* *(ii)Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;* *(iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. The study may establish criteria for reopening based on coliform levels in the water. The SSCA may utilize MSC 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 a level of 50 MSC per 100 grams or pre-determined levels established by the Authority based on studies conducted on regional species under regional*

	conditions. These studies 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 *(iv) Shellstock feeding activity is sufficient to achieve microbial reduction.* *(d) For management plans based on a risk assessment made in accordance with Chapter II. Risk Assessment and Risk Management, criteria that reliably determine when the growing area may be placed in the open status and shellfish may be harvested;* *(f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;* *(g) Provisions for patrol to prevent illegal harvest; and* *(h) Procedures to immediately place the growing area in the closed status in 24 hours or less when the criteria established in the management plan are not met.* *(3) Reevaluation of Conditional Classification.* *(a) The classification shall be reevaluated at least once each year. The reevaluation shall include:* *(i) Evaluation of compliance with the management plan;* *(ii)Determination of adequacy of reporting of failure to meet performance standards;* *(iii) Review of the cooperation of the persons involved;* *(iv) Evaluation of water*

	quality in the growing area with respect to the bacteriological standards for its classification; *(v) Field inspection of critical pollution sources, where necessary; and* *(vi) Written findings, evaluations and recommendations.* *(b) Water Sample Collection.* *(i) When the conditional management plan is based on the absence of pollution from marinas for certain times of the year, monthly water samples are not required when the growing area is in the open status of its conditional classification provided that at least three of the water samples collected to satisfy the bacteriological standard for the open status are collected when the growing area is in the open status.* *(ii) When the conditional management plan is based on the operation and performance of a Waste Water System Discharge (WWSD) (s); combined sewer overflow(s); or other point sources of pollution, monthly water samples are required when the growing area is in the open status of its conditional classification.* *(iii) If a monthly sample cannot be collected due to environmental constraints, the monthly sampling requirement will be satisfied if an additional water sampling run is conducted the following month.*

	(iv) When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events, storm water runoff, and seasonal variations, a minimum of five (5) sets of water samples (when the Adverse Pollution Condition sampling regimen is used) or six (6) sets of water samples (when the Systematic Random Sampling regimen is used) are required. The samples shall be collected when the growing area is in the open status. *(v) When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events or storm water runoff, and the area is in the open status for less than six (6) months a minimum of five (5) sets of water samples are required (Adverse Pollution Condition and Systematic Random Sampling). At least one (1) sample shall be collected each month the area is placed in the open status. This sample shall be collected while the area is open. If closed status samples are used to meet the minimum sample requirements only two (2) sets of samples may be utilized and they must have been taken within five (5) days of when the Authority anticipates that the area will*

	be placed in the open status. For growing areas in the open status less than two (2) months, at least one (1) sample must be collected while the area is in the open status. Samples collected during the closed status to meet the minimum five (5) sets of water samples shall be applied to annual and triennial reevaluations of the area. *(vi) When the conditional management plan is based on the seasonal opening and closing of the area, and the area is in the open status for a predetermined period of less than six (6) months, a minimum of five (5) sets of water samples are required (Adverse Pollution Condition and Systematic Random Sampling). All samples shall be collected while the area is in the open status unless the Authority has historical water quality data to demonstrate that the area meets open status criteria while in the closed status. If closed status samples are used to meet the minimum sample requirements they must be collected within thirty (30) days prior to the area being placed in the open status.* *(4) Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management Plan by All Parties Involved.* *(a) The management plan shall be*

developed by the Authority in coordination with:

(i) The local shellfish industry;

(ii) The individuals responsible for the operation of any Waste Water System Discharge (WWSD)s involved; and

(iii) Any local or State agencies; and

(b) Failure of any one party to agree shall constitute sufficient justification to deny the application of the conditional classification to a growing area.

(5) Conditional Area Types. There are two (2) types of conditional areas:

(a) Conditionally approved; and

(b) Conditionally restricted

B. Guidance for a Conditional Area Management Plan

The management plan for a growing area in the conditionally approved or conditionally restricted classification must meet certain minimum requirements to ensure that the safety of the shellfish for human consumption is maintained. The use and success of the conditional classification depends upon a thorough and accurate management plan. Therefore, it is important that all aspects of the management plan be fully considered and implemented. The minimum requirements to be addressed are:

(1) An understanding of and an agreement to the conditions of the management plan by the one (1) or more Authorities involved, other local, state and federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved;

(2) A written management plan for the growing area being placed in the conditional classification, which includes a general description of the growing area with a map showing the area's boundaries, and which addresses all items in C. through H..

(3) A sanitary survey that shows the growing area will be in the open status of its conditional classification for reasonable periods of time. The survey must provide a description of the factors determining the growing area's suitability for being classified conditionally approved or conditionally restricted, and the supporting information and data.

(4) A description of the predictable pollution event or events that are being managed and the performance standards established for each pollution source contributing to the pollution event including:

(a) For a wastewater treatment facility, the performance standard should be based on:

(i) Peak effluent flow

(ii) Bacteriological quality of the effluent

(iii) Physical and chemical quality of the effluent

(iv) Bypasses from the treatment plant or its collection system

(v) Design, construction, and maintenance to minimize mechanical failure or overloading (i.e., the reliability of the treatment system and collection system components)

(vi) Provisions for verifying and monitoring efficiency of the wastewater treatment plant and the feedback system for addressing inadequate treatment.

(vii) Identification of conditions that lead to Waste Water Treatment Plant (WWTP) failure and closure of the conditionally approved area.

(b) For meteorological or hydrological events, the performance standard should be based on:

(i) Identification of the specific meteorological and/or hydrologic event that will cause the growing area to be placed in the closed status;

(ii) Discussion and data analyses concluding that effects on water quality from these specific meteorological and/or hydrologic events are predictable, and that the data are sufficient to establish meaningful performance standards or criteria for the establishment and implementation of a management plan for the growing area placed in the conditional classification; and

(iii) The predicted number of times, based on historical findings, that the pollution event will occur within one (1) year.

(c) For seasonal events, such as marina operation, seasonal rainfall, and waterfowl migration, the performance standard should be based on:

i. Identification of the seasonal event that will cause the growing area to be placed in the closed status, including its estimated duration; and

(ii) Discussion and data concluding that the seasonal event is predictable, and that the data are sufficient to establish meaningful performance standards or criteria for the establishment and implementation of a management plan for a growing area placed in the conditional classification;

(5) A description of the plan for monitoring water quality including numbers and frequency;

(6) A description of how the closed status for the conditional classification will be implemented, which must include:

(a) A clear statement that when the performance standards are not met, the growing area will immediately be placed in the closed status;

(b) A requirement to notify the Authority or Authorities that the

management plan performance standards have not been met, including:

(i) The name of the agency or other party responsible for notifying the Authority;

(ii) The anticipated response time between the performance standards not being met and notification of the Authority; and

(iii) The procedures for prompt notification including contingencies such as night, weekend and absences of key personnel;

(c) A description of the implementation and enforcement, including:

(i) The response time between the notification to the Authority of the failure to meet performance standards and activation of the legal closure of the growing area by the Authority;

(ii) The procedures and methods to be used to notify the shellfish industry; and

(iii) The procedures and methods to be used to notify the patrol agency (enforcement agency) including:

- The name of the responsible patrol agency;
- The anticipated response time between the Authority's legal closure of the growing area and notification of closure to the patrol agency; and
- A description of the patrol agencies anticipated activities to enforce the closed status.

(7) A description of the criteria that must be met prior to reopening a growing area in the closed status, including the need to determine that:

(a) The performance standards established in the management plan are again fully met;

(b) The flushing time for pollution dissipation is adequate;

(c) A time interval has elapsed which is sufficient to permit reduction of human pathogens as measured by the coliform indicator group in the shellstock;

(d) Where necessary, the bacteriological quality of the water must be verified; and

(e) Shellstock feeding activity is sufficient to achieve reduction of pathogens to levels present prior to the pollution event.

(8) A commitment to a reevaluation of the management plan at least annually using, at a minimum, the reevaluation requirements in the NSSP Model Ordinance

VII. Conditionally Restricted

A. Definition

A classification used to identify a growing area that meets the criteria for the restricted classification except under certain conditions described in a management plan.

B. Requirements for Conditionally Restricted Area Adjacent to a Waste Water Treatment Plant (WWTP)

(1) Model Ordinance Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification.

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

(7) Conditionally Restricted Classification. Any growing area in the conditionally restricted classification shall:

(a) Meet the requirements for:

(i) A restricted classification when the conditionally restricted classification is in the open status; and

(ii) A prohibited classification when the conditionally restricted classification is in the closed status; and

(b) Designate in its management plan whether the harvested shellstock are to be relayed or

depurated.

(2) Use of the conditionally restricted classifications by the Authority is optional. The conditionally restricted classification is designed to address growing areas that are subject to intermittent microbiological pollution. These classifications offer the Authority an alternative to placing the area in the prohibited classification year round when, under certain conditions, the shellstock from the growing area may be safely harvested for restricted purposes. The concept also applies to situations where conditions are acceptable for harvest when wastewater treatment plant operation is satisfactory, but not when a malfunction occurs. A management plan is required that describes the controls to provide public health protection in the use of the conditionally restricted classification. For a full explanation of the conditional classifications and their use, see the NSSP Guidance Document, *Management Plans for Growing Areas in the Conditional Classifications* (ISSC/FDA, 2015).

State Control Authorities that allow relaying or depuration may utilize the conditionally restricted classification adjacent to prohibited areas established as a result of a WWTP outfall. The use of the conditionally restricted classification is dependent upon the predictable factors associated with the WWTP discharge. These factors may include volume, treatment efficient, seasonality or other factors which affect the quality of the WWTP effluent. The quality concerns are bacterial, viral, toxic chemical and poisonous deleterious substances. Portions of the prohibited area that are less impacted by the WWTP outfall during predictable time periods can be classified conditional and used as a source of shellfish for relaying and depuration.

The conditionally restricted classification management plan must establish a strict set of criteria, which must be met for the growing area to remain in the restricted status. The following are examples of different types of performance standards that could be used:

(a) Performance standards might stipulate the bacteriological quality of effluent from sewage treatment plants. The

microbiological quality can be monitored in terms of disinfection residual or dosage for ultraviolet light disinfection. An example of a performance standard for an effluent discharge is:

"The median fecal coliform MPN, in any one (1) month, shall not exceed 200 per 100 ml, based on not less than sixteen (16) samples per month, and not more than ten (10) percent of the samples shall have an MPN in excess of 1,000 per 100 ml. This fecal coliform limit shall be presumed to be met if the chlorine residual in the effluent is at least 1.0 ppm and the chlorine residual in the effluent is continuously recorded on a chart by chlorine residual analyzer or is measured hourly and recorded in the daily monitoring records as required for the plant's NPDES permit."

(b) For disinfection by ultraviolet (UV) light, the disinfection is based on dosage. An example of a performance standard is, "A minimum UV dose of 37 mW-Sec/cm^2 is to be maintained. The calculation of intensity of the UV light is to include factors for effluent quality, including turbidity, suspended solids, and transmittance. The effluent factors contributing to the dose, including turbidity, suspended solids, transmittance, and flow will be continuously measured and recorded. An alarm will be activated if any of the factors are above design limits."

A detailed discussion of ways to increase the reliability of sewage treatment plants can be found in *Protection of Shellfish Waters* (USEPA, 1974) and *Design Criteria for Mechanical, Electric and Fluid System Component Reliability* (USEPA, 1974).

The fourth step is to determine the water quality, which will occur in the growing area when the performance standards are not met, and what portion of the growing area will be affected. Once these determinations are made, the Authority can select the appropriate management strategy for the portion of the growing area

that will be placed in the closed status when performance standards are not met, and can select the boundaries for the closed status. The boundaries of that portion of the growing area to be placed in the closed status would depend upon such items as the distance and travel time from the pollution source to the area, the concentration of pollutants in the discharge during the breakdown condition, amount of effluent and hydrographic factors including dilution available in the receiving water.

The use of the conditional classification where a sewage treatment plant is the pollution source being managed requires a fifth step. An area in the prohibited classification must be established between the sewage treatment plant and the growing area placed in the conditionally approved or conditionally restricted classification. The size of the prohibited area should be based on the level of sewage treatment; the total time it would take for the person responsible for the operation of the sewage treatment facility to detect a failure and notify the Authority; and the time it would take the Authority to issue a notice to stop shellstock harvesting. The size of the area in the prohibited classification should allow for an effluent travel time through the prohibited area that is at least twice that required for the notification process to become effective. Due consideration should be given to the possibility that emergency actions might be necessary on holidays or at night. A minimum effluent dilution is to be determined at the prohibited boundary and can be the controlling factor in situations where there is efficient detection and notification of breakdowns.

The length of time that a growing area should be in the closed status of its conditional classification will depend upon several factors. These factors include the degree of pollution in the growing area and flushing capacity of the estuary, the species of shellfish, water temperature, shellstock activity and cleansing rates, and presence of silt or other chemicals that might interfere with the physiological activity of the shellstock. Additional information on the natural cleansing of shellstock is provided in the NSSP Guidance Document, *Shellstock Relay* (ISSC/FDA, 2015).

C. Allowable Uses of Shellfish from a Conditionally Restricted Growing Area

(1) Allowable Uses When Area is in Restricted Status

(a) Relay without a Contaminant Reduction Study

Relay means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or

conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(b) Relay with a Contaminant Reduction Study
Relay means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(c) Depuration
Depuration means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

(d) Seed
Seed means shellstock which is less than market size.

(2) Allowable Uses When Area is in Prohibited Status

(a) Seed
Seed means shellstock which is less than market size.

D. Model Ordinance Requirements for Relay with a Contaminant Study
The Requirements for Relay with a Contaminant Study are defined in Section V. D.

E. Model Ordinance Requirements for Relay without a Contaminant Study
The Requirements for Relay without a Contaminant Study are defined in Section V. H.

F. Model Ordinance Requirements for Depuration
The Requirements for Depuration are defined in Section V.J.

G. Model Ordinance Requirements for Seed
The Requirements for Seed are defined in Section V.L.

H. Determining Boundaries for Conditionally Restricted Growing Areas

Should the Authority utilize the conditionally restricted

classification to allow relay or depuration, the area classified as conditionally restricted would be established within the portion of the prohibited area established adjacent to the WWTP. Shellfish uses allowed in the restricted classification would be allowed in the conditionally restricted area when the plant is operating within the satisfactory conditions outlined in the conditionally restricted management plan. (Chapter IV@ .03 C (2). Use of the conditionally restricted classification for relay without contaminant reductions studies and depuration requires the Authority to determine whether the growing area is impacted by additional point and non-point sources of pollution in addition to the management plan which is intended to address all potential problems with the adjacent WWTP. The bacteriological quality of every sample station in the growing area shall meet the fecal coliform standard in Chapter IV.@.02 Section G. (2) or Section H. (3) depending upon whether there is an additional point source or just non-point sources of contamination impacting the conditionally restricted growing area. Sufficient water quality samples shall be collected in accordance with Chapter IV.@.02 Section E. (3) at representative water quality sampling stations throughout the impacted restricted growing area.

The establishment of boundaries separating prohibited and conditionally restricted growing areas is dependent upon the uses to be allowed within the restricted growing area. MO Chapters IV and V address the classification requirements for allowable shellfish uses in the restricted classification. These uses include the following:

(1) Relay with a contaminant reduction study
(2) Relay without a contaminant reduction study
(3) Depuration

If harvesting for relay with a contaminant reduction study, the boundary line should be based on an acceptable dilution ratio. If harvesting for relay without a contaminant reduction study or depuration, the boundary line must be based on a fecal coliform sampling program. The SCA has the option to utilize MSC.

The use of the conditionally restricted classification should not affect other adjacent classifications such as restricted, conditionally approved or approved. The area will be considered in the prohibited status when the management plan criteria are not met.

Guidance for Dilution Ratios

For Shellfish Control Authorities that choose to establish conditionally restricted areas, the operating efficiency of the plant must be a primary consideration. A portion of what might be the standard prohibited area could be classified as conditionally restricted when the WWTP is operating efficiently. An explanation for operating efficiency is included in Section VI paged 26 of this document. Conditionally restricted areas, when meeting the NSSP requirement for the restricted classification, can be used for a source for shellstock relaying with a contaminant reduction study. These areas are not required to meet a microbiological standard. Shellstock from restricted areas used for relaying without a contaminant reduction study or for depuration do have to meet a microbiological standard. In the absence of a microbiological standard, dilution ratios become very important to protect public health.

A Shellfish Control Authority should not consider any portion of a growing area that does not meet a 320:1 dilution ratio as a source for relaying with a contaminant reduction study. The concept of a 320:1 dilution ratio was first documented in a technical paper written by Virgil Carr of FDA. The technical paper was based on studies conducted at WWTP utilizing UV for disinfection.

This study proposed that the prohibited area, could approach the size requirements for Critical Dilution for Toxics to Ambient (Background) from the Clean Water Act. Similarly, the EPA's Regulatory Mixing Zone (RMZ) is 300:1, which is approximately the transition line from near field dilution zone to far field dilution zone where most mixing has already occurred. The 320:1 dilution ratio is needed to assure that poisonous and deleterious substances are not present in high enough concentrations to present a public health concern.

From a pragmatic point of view, dilution from the outfall to the 320:1 line is a dilution factor of 320 while dilution from 320:1 to 1000:1 is a dilution factor of 3.1. This roughly equates to 100 times more dilution of the originate effluent occurring within the 320:1 dilution line than occurs from the 320:1 dilution line to the 1000:1 dilution line. This is an important factor to consider when one is attempting to understand the viral density in growing waters overlying growing areas adjacent to WWTP discharge and the associated risk.

VIII. Conditionally Approved

A. Definition

A classification used to identify a growing area which meets the criteria for the approved classification except under certain conditions described in a management plan.

B. Requirements for Conditionally Approved Area Adjacent to a Waste Water Treatment Plant (WWTP)

(1) Model Ordinance Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification.

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

(6) Conditionally Approved Classification. Any growing area in the conditionally approved classification shall:

(a) Meet the requirements for:

(i) An approved area classification when the conditionally approved classification is in the open status; and

(ii) A restricted or prohibited classification when the conditionally approved classification is in the closed status; and

(b) If the closed status meets the criteria for the restricted classification, designate in its management plan whether the shellstock may be harvested for relaying or depuration.

Growing areas are placed in the approved classification when the sanitary survey information and marine Biotoxin surveillance data indicate that fecal material, pathogenic microorganisms, poisonous, or deleterious substances are not present in the growing area in unacceptable concentrations. Shellstock harvested from these growing areas may be sold directly to the public for consumption raw or cooked.

C. Allowable Uses of Shellfish in a Conditionally Approved Growing Area

(1) Allowable Uses when the Conditionally Approved Area is in the Open Status

(a) Direct Marketing

Direct Marketing means the sale for human consumption of shellfish which:

(i) Does not require depuration or relaying prior to sale; or

(ii) Has been subjected to depuration or relaying activities

(b) Relay

Relay means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(c) Depuration

Depuration means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

(d) Seed

Seed means shellstock which is less than market size.

(e) Post-Harvest Processing

Post-Harvest Processing means any process which has been validated using NSSP validation procedures which reduces the levels of pathogenic hazards to below the appropriate FDA action level or in the absence of such a level, below the appropriate level as determined by the ISSC.

(2) Allowable Uses when the Conditionally Approved Area is in the Closed Status

(a) Relay

Relay means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(b) Depuration

Depuration means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

(c) Seed
Seed means shellstock which is less than market size.

D. Model Ordinance Requirements for Direct Marketing
There are no classification restrictions on shellfish harvested from conditionally approved areas in the open status for direct market.

E. Model Ordinance Requirements for Relay
The Requirements for Relay are defined in Section V. H.
There are no classification restrictions on shellfish harvested from conditionally approved areas in the open status for relay.

F. Model Ordinance Requirements for Depuration
There are no classification restrictions on shellfish harvested from conditionally approved areas in the open status for depuration.

(1) Model Ordinance Chapter XV. Depuration

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall receive and depurate only shellstock which is obtained from a licensed harvester who has:

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

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

(c) Harvested the shellstock in compliance with the time/temperature requirements of Chapter VIII. @.02 A. (1), (2) or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) [C].

(2) The dealer shall…
(3) Should a dealer…
(4) The dealer shall…

The Requirements for Depuration of shellfish harvested from conditionally approved areas in the closed status are defined in Section V.J.

G. Model Ordinance Requirements for Seed

The Requirements for Seed are defined in Section V.L.
There are no classification restrictions on shellfish harvested from conditionally approved areas in the open status for seed.

H. Model Ordinance Requirements for Post-Harvest Processing

There are no classification restrictions on shellfish harvested from conditionally approved areas in the open status for post-harvest processing.

I. Model Ordinance Requirements for Relay with a Contaminant Reduction Study

The Requirements for Relay with a Contaminant Reduction Study are defined in Section V.D.

J. Model Ordinance Requirements for Relay without a Contaminant Reduction Study

The Requirements for Relay without a Contaminant Reduction Study are defined in Section V.H.

K. Determining Boundaries for Conditionally Approved Growing Areas

Should the Authority utilize the conditionally approved classification to allow harvest for direct marketing, the area classified as conditionally approved would be established within the portion of the prohibited or restricted area established adjacent to the WWTP. Shellfish uses allowed in the approved classification would be allowed in the prohibited or restricted area when the plant is operating within the satisfactory conditions outlined in the conditionally approved management plan. (Chapter IV@ .03 C (2).

In addition to meeting the satisfactory conditions outline in the conditionally approved management plan, the area must also conduct a sanitary survey of the growing area as required in Chapter IV @ 01 and establish a monitoring program to ensure the water quality requirements of Chapter IV @ 02 E. The area will

be considered in the prohibited or restricted status when the management plan criteria is not met.

Guidance for Dilution Ratios

For Shellfish Control Authorities that choose to establish conditionally approved areas for harvest uses allowable within the approved classification, the operating efficiency of the plant must be a primary consideration. A portion of the prohibited or restricted area could be classified as conditionally approved when the WWTP is operating efficiently. An explanation for operating efficiency is included in Section VI page 26 of this document. The minimum dilution of 1000:1 is recommended for establishing a conditionally approved area adjacent to a WWTP. The rationale for the 1000:1 dilution rate was included in Section IV: Guidance Document Chapter II 19., which was adopted by the ISSC in 2015. Conditionally approved areas, when not in the approved status, can be used for a source for shellstock relaying with a contaminant reduction study, shellstock relaying without a contaminant reduction study and depuration. To utilize shellfish for these purposes, these areas are required to meet the Model Ordinance requirements associated with those uses (e.g. restricted water quality standard).

IX. Approved Classification

A. Definition

A classification used to identify a growing area where harvest for direct marketing is allowed.

B. Requirements for Use of the Approved Classification

(1) Model Ordinance Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification.

B. Approved Classification. Growing areas shall be classified as approved when the following criteria are met.

(1) Survey Required. A sanitary survey finds that the area is:

(a) Safe for the direct marketing of shellfish;

(b) Not subject to contamination from human or animal fecal matter at levels that, in the judgment of the Authority, presents an actual or potential public health hazard; and

(c) Not contaminated with:

	(i) Pathogenic organisms; (ii) Poisonous or deleterious substances; (iii) Marine Biotoxins; or (iv) Bacteria concentrations exceeding the bacteriological standards for a growing area in this classification. (2) Water Quality. The water quality in the growing area shall meet the bacteriological standards for an approved classification in Section @.02. **@.02 Microbiological Standards** 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). (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. (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.

C. Allowable Uses of Shellfish in an Approved Growing Area

(1) Direct Marketing

Direct Marketing means the sale for human consumption of shellfish which:

(a) Does not require depuration or relaying prior to sale; or

(b) Has been subjected to depuration or relaying activities

(2) Depuration

Depuration means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

(3) Seed

Seed means shellstock which is less than market size.

(4) Post-Harvest Processing

Post-Harvest Processing means any process which has been validated using NSSP validation procedures which reduces the levels of pathogenic hazards to below the appropriate FDA action level or in the absence of such a level, below the appropriate level as determined by the ISSC.

D. Model Ordinance Requirements for Direct Marketing

There are no classification restrictions on shellfish harvested from approved areas for direct market.

E. Model Ordinance Requirements for Depuration

The Requirements for Depuration are defined in Section XIII.F.

There are no classification restrictions on shellfish harvested from approved areas for depuration.

F. Model Ordinance Requirements for Seed

The Requirements for Seed are defined in Section V.L.

There are no classification restrictions on shellfish harvested from approved areas for seed.

G. Model Ordinance Requirements for Post-Harvest Processing

There are no classification restrictions on shellfish harvested from approved areas for post-harvest processing.

H. Determining Boundaries for Conditionally Approved Growing Areas

	In establishing boundaries between approved areas and other classifications adjacent to a WWTP, the SCA should consider dilution ratios and the approved area must meet the microbiological standards for approved growing areas. Guidance for Dilution Ratios When determining if a WWTP or collection system discharge within the watershed or catchment area draining to a shellfish estuary potentially impacts a shellfish growing area, the NSSP recommends that a worst case raw sewage discharge be assumed. In this circumstance, if a level of 1.4×10^6 FC/100ml is assumed for a raw sewage release, a 100,000:1 dilution would be required to dilute the sewage sufficient to meet the approved area standard of 14 FC/100ml. If dilution analysis determines that the location of the discharge is such that the dilution of effluent would be greater than 100,000:1 then the WWTP could be considered located outside the zone of influence to the shellfish growing area. Different dilution ratios may be applied depending on the known concentration of sewage, a performance history of the treatment and collection system and a database of influent and effluent quality, provided that the water quality objective of the downstream harvest area is met.
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	

Proposal No. **17-114**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	U.S. Food and Drug Administration (FDA)
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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	**Section II Model Ordinance - Chapter I Shellfish Sanitation Program @.03 Evaluation of Shellfish Sanitation Program Elements** 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. ~~i.~~ ii. Technical Evaluation: Conforms. In order to achieve or maintain conform~~s~~ing status under the NSSP, a laboratory must

meet the following laboratory evaluation criteria:

~~ii~~(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

~~iii~~(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

~~iv~~(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

~~v~~(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.

~~c.~~iii. Technical Evaluation: Provisionally Conforms. In order to be deemed provisionally conforming under the NSSP, a laboratory must meet the following laboratory evaluation criteria:

~~i.~~(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

~~ii~~(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

~~iii~~(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

~~iv~~(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.

~~d.~~iv. Technical Evaluation: Nonconformance. When a laboratory exceeds the following criteria, it will be determined to be in nonconformance:

~~i.~~(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

~~ii.~~(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;

~~iii.~~(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

~~iv.~~(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.

~~e.~~c. Corrective Actions for Conforming Status. A laboratory found to be in conforming status for ~~either the microbiological or marine Biotoxin component or for both components~~ 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.

~~f.~~ d. Corrective Actions for Provisionally Conform~~s~~ing Status. A laboratory found to be in provisionally conforming status for ~~either the microbiological or marine Biotoxin component or for both components~~ 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:

i. Conforms if all the critical and key nonconformities have been successfully corrected in each provisionally conforming component evaluated; or

ii. Nonconforming if any critical or key nonconformities remain to be successfully corrected in each provisionally conforming component 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.

~~g~~ e. Nonconformance.

i. Upon a determination of nonconforming status in any of the ~~either the microbiological or marine Biotoxin component or in both~~ 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 any critical or key nonconformities remain to be successfully corrected, the status of the laboratory for the laboratory component(s) in question will continue to be nonconforming; and as a result, data being generated by the laboratory for this/these laboratory components will continue to be unacceptable for use in support of the NSSP. ii. 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. ~~ii~~iii. When a laboratory is found to be nonconforming in either the ~~microbiological or marine Biotoxin~~ 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. 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. **Section IV Guidance Documents Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists** 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.
Public Health Significance	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 are fully prepared. NSSP laboratories are producing excellent data and must be as defensible as laboratories held to accreditation standards. 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.
Cost Information	There will not be an additional immediate cost as this would be the first step in the routine triennial evaluation cycle.

Proposal No. **17-115**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative
Submitter	J. Michael Hickey Margaret Barette David Fyfe
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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	J. Molluscan shellfish product that is recalled as a result of an illness outbreak associated with *V.v.*, *V.p.*, or Norovirus may be reconditioned. 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). 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.
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

Proposal No. **17-116**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
Submitter	U.S. Food and Drug Administration (FDA)
Affiliation	U.S. Food and Drug Administration (FDA)
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Address Line 2	HFS-325
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Phone	240-402-1401
Fax	301-436-2601
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	Insert the following definition for Federal Waters in Section I Purposes & Definitions as follows: **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. Insert the language below for Section II Model Ordinance Chapter IV Shellstock Growing Areas @.01 Sanitary Survey. 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. @.03 Growing Area Classification. 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 . Insert the language below for Section II Model Ordinance Chapter VI Shellfish Aquaculture just after the text in @.03and prior to Shellfish Gardening @.04 Aquaculture in Federal Waters A. Federal Agency Responsibilities. Once the appropriate permits for the construction of the aquaculture facility have been obtained, (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 (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. @.~~04~~05 Shellfish Gardening Insert the language below for Section II Model Ordinance Chapter VI Shellfish Aquaculture just after .07 .08 Requirements for the Harvester in Aquaculture in Federal Waters 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. 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: (1) Description of harvest, tagging, handling, storage, transportation, and landing procedures; (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.; (3) Description of a contingency in the event of an emergency situation or condition (e.g., sewage or oil spills); and (4) Procedures for implementing product recalls. 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.
Public Health Significance	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.
Cost Information	N/A

Proposal No. **17-117**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	ISSC Male-Specific Coliphage Committee
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Proposal Subject	Utilizing Male-Specific Coliphage in Growing Areas
Specific NSSP Guide Reference	Section I. Purpose and Definitions Section II. Model Ordinance Chapter IV. Shellstock Growing Area and Chapter V. Shellstock Relaying
Text of Proposal/ Requested Action	**Section I. Purpose and Definitions** Add new definitions: **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. **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. **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 **Section II. Model Ordinance** **Chapter IV. Shellstock Growing Areas** **@.02 Microbiological Standards.** A. General… B. Water Sample Stations... C. Exceptions... D. Standard for the Approved…. 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).

(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 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 Waste Water System Discharge (WWSD), the analytical sample results shall not exceed the ~~a~~ levels established in Chapter IV @ 02. E ~~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 days 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…

(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

(ii) Discussion and data supporting the performance standards.

(c) For management plans based on waste water system discharge function or pollution sources other than waste

water system discharge criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum criteria are:

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

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

(iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. The study may establish criteria for reopening based on coliform levels in the water. The SSCA may utilize MSC levels to establish that sufficient time has elapsed to allow the water quality to return to acceptable levels 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 the MSC levels established in Chapter IV @02 E.~~a level of 50 MSC per 100 grams~~ or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions. These studies 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

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

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

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

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

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

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

(3) Reevaluation of Conditional Classification...

(4) Understanding of and Agreement With…

(5) Conditional Area Types...

(6) Conditionally Approved Classification…

(7) Conditionally Restricted Classification...

D. Restricted Classification…

	E. Prohibited Classification… **Chapter V. Shellstock Relaying** **@.02 Contaminant Reduction.** 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: (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(MSC) levels established in Chapter IV @02.E. ~~standard of 50 PFU/100 gm~~ or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions. C. The authority may… D. The time period… E. When container relaying… F. The Authority shall…
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. 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.
Cost Information	

Proposal No. **17-118**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
Submitter	Thomas Dameron BK Rastogi Chris Shriver
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Proposal Subject	Marine Biotoxin Control / Memorandums of Understanding
Specific NSSP Guide Reference	Section II. Model Ordinance, Chapter IV. Shellstock Growing Areas,@.04 Marine Biotoxin Control A. Contingency Plan (5)
Text of Proposal/ Requested Action	(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. 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. The agreements or memoranda of understanding shall provide strict safety assurances. At a minimum agreements or memoranda of understanding shall include provisions for:
Public Health Significance	**The Problem** – 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. 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 *procedures for the uniform application of those guidelines*, 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 **all harvesters or individual shellfish**

	dealers 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. **Public Health Significance** – 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.
Cost Information	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.

Proposal No. **17-119**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	U.S. Food and Drug Administration (FDA)
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Email	Melissa.abbott@fda.hhs.gov
Proposal Subject	Update the Control of Marine Biotoxins in Federal Waters
Specific NSSP Guide Reference	Section II Model Ordinance Chapter IV Shellstock Growing Areas @.04 Marine Biotoxin Control A(5) Section IV Guidance Documents Chapter II Growing Areas .06 Protocol for the Landing of Shellfish from Federally Closed Waters Due to PSP
Text of Proposal/ Requested Action	Update the language as indicated below for Section II Model Ordinance Chapter IV Shellstock Growing Areas @.04 Marine Biotoxin Control A. Contingency Plan (5) Prior to allowing the landing of shellfish harvested from ~~f~~Federal waters ~~closed due to periodic toxic algal blooms associated with PSP, and~~ where routine monitoring of ~~saxi~~toxin levels is not conducted, in addition to following all other requirements in the Model Ordinance, 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

~~saxi~~toxins that are likely to be present. Harvesting shall not be permitted if any of the pre-harvested samples contain ~~saxi~~toxin levels in excess of half of the established criteria listen in Chapter IV @.04©(1) (e.g., 44 µg/l00 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).

(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 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~~toxin 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 Federal~~ly 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. The~~is~~ 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 ~~f~~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~~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" 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" 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 Chpater IV). A positive result from any one (1) sample shall render the "lot area" unacceptable for harvest. The harvest vessel ~~c~~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 NSSP 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 NSSP method by an NSSP 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©(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

~~PSP sample~~ Toxin data acquired as a result of onboard screening and dockside testing shall be transmitted to ~~a central data register to be maintained by~~ the FDA. These data, both screening and ~~confirmatory~~dockside, shall be transmitted to the FDA by the NSSP certified laboratory conducting ~~PSP analyses~~ toxin testing of the sampled lot(s) within one (1) week of the completion of the ~~PSP~~ toxin analyses. The data provided shall include the following:

1. Shellfish species;
2. Harvest location name and coordinates (GPS or latitude/longitude);

	3. Harvest date; 4. Onboard screening test method, date, and results; and 5. Laboratory test date, test method, and test results for dockside samples. Results of all samples having acceptable levels of ~~paralytic shellfish~~ toxins (e.g., <80 µg/100 g for PSP toxins) shall immediately be reported to the SSCA in the state of landing. If the results of any one (1) sample equal or exceed the estabished criteria in Chapter IV @.04(c)(1) ~~80 µg/100 g~~ the testing laboratory shall immediately notify the FDA ~~Regional~~ 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). 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.
Public Health Significance	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. 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.
Cost Information	N/A

Proposal No. **17-120**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	Paul D. Golden
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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	(e) The following criteria should be used to adjust the rating, if warranted: (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. (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. (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. ~~(iii)~~(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.
Public Health Significance	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.

Cost Information	none

Proposal No. **17-121**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	☒ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative

Submitter	US Food & Drug Administration (FDA)
Affiliation	US Food & Drug Administration (FDA)
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Proposal Subject	Disposal of Human Sewage and Bodily Fluids
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting Requirements for Harvesters .02 Shellstock Harvesting and Handling. 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
Text of Proposal/ Requested Action	Chapter VIII. .02 Shellstock Harvesting and Handling D. Disposal of Human Sewage and Bodily Fluids~~from Vessels~~. (1) Human sewage and bodily fluids shall not be discharged overboard from ~~a~~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. (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. (3) Portable toilets shall: (a) Be used only for the purpose intended; (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage; (c) Be emptied only into a sewage disposal system; (d) Be cleaned before being returned to the vehicle or vessel~~boat~~; and (e) Not be cleaned in equipment used for washing or processing food. (4) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are: (a) Constructed of impervious, cleanable materials and have tight fitting lids; (b) Indelibly labeled “Human Waste” in contrasting letters at least three (3) inches in height; and (c) Meet the requirements in Section D. (3). Chapter IX. .01 Conveyances Used to Transport Shellstock to the Original Dealer G. Disposal of Human Sewage and Bodily Fluids (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. (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). Chapter IX. 02 Conveyances Used to Transport Shellstock from Dealer to Dealer C. Disposal of Human Sewage and Bodily Fluids (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. (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).
Public Health Significance	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.
Cost Information	~$5.00 for a five (5) gallon bucket with a lid.

Proposal No. **17-122**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	ISSC Executive Office
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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	**Section II. Model Ordinance** **Chapter II. Risk Assessment and Risk Management** **@.01 Outbreaks of Shellfish-Related Illness.** A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one or more persons in the case of ~~paralytic shellfish~~shellfish toxicity poisoning associated with marine biotoxins ~~[PSP])~~, the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing: (1) Each consumer's food history; (2) Shellfish handling practices by the consumer and/or retailer; (3) Whether the disease has the potential or is known to be transmitted by shellfish; and (4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent. **Chapter IV. Shellstock Growing Areas Management** **@.04 Marine Biotoxin Control.** A. Contingency Plan. (1) The Authority shall develop and adopt a marine Biotoxin contingency plan for all marine and estuarine shellfish growing areas 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. (2) The plan shall define the administrative procedures and resources necessary to accomplish the following: (a) Initiate an emergency shellfish sampling and assay program; (b) Close growing areas and embargo shellfish; (c) Prevent harvesting of contaminated species; (d) Provide for product recall;

(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; ~~and~~

(f) Coordinate control actions taken by Authorities and federal agencies; and~~.~~

(g) Establish reopening criteria including the number of samples over what period of time.

~~(3) Except that the Authority shall classify as prohibited any growing areas where shellfish are so highly or frequently affected 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 Biotoxin ~~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~~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.

(2) The plan shall define the administrative procedures and resources necessary to accomplish the following:

(a) Maintain a routine shellfish sampling and assay program including;

i. Establishment of appropriate shellfish screening levels;

ii. Establishment of appropriate shellfish screening and testing methods;

iii. Establishment of appropriate laboratories/analysts to conduct shellfish screening and testing methods;

iv. Establishment of a sampling plan for both (i) and (ii) above; and

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.

(b) Close growing areas and embargo shellfish;

(c) Prevent harvesting of contaminated species;

(d) Provide for product recall;

(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;

(f) Coordinate control actions taken by Authorities and federal agencies; and

(g) Establish reopening criteria.

(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.

(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 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.

(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. 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;
(e) Disposal of shellfish should end product test results meet or exceed established criteria specified in Section C.
(f) Other controls as necessary to ensure that shellstock are not released prior to meeting all requirements of the program.

(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:

(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/l00 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.

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~~
t~~o 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.

Public Health Significance	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. 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.
Cost Information	

Proposal No. 17-123

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
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Proposal Subject	Marine Biotoxin Control Guidance
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II .02
Text of Proposal/ Requested Action	**Chapter II. Growing Areas** **.02 Guidance for Developing Marine Biotoxin ~~Contingency~~ Plans.** NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, which includes the requirements of the program ~~and summaries of the requirements for that component~~. NSSP *Model Ordinance* 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. **Introduction** Shellfish are filter feeders and, therefore, they have the ability to concentrate ~~toxigenic dinoflagellates~~toxic phytoplankton from the water column when present in shellfish growing waters. The toxins produced by ~~these dinoflagellates~~ certain species of phytoplankton can cause illness and death in humans. Toxins are accumulated in the viscera and/or other tissues of shellfish and ~~are transferred to~~ humans exposure occurs when the shellfish are eaten (Gordan *et al.*, 1973). These toxins are not normally destroyed by cooking or processing and cannot be detected by taste. ~~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~~The presence of toxic phytoplankton 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 ~~dinoflagellate~~toxic phytoplankton concentration in the water column against the levels established in the NSSP Model Ordinance to determine what action, if any, should be taken. 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.

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 Pseudonitzchia. 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).

~~I~~n 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-nitzs~~a~~chia*. Blooms of *Pseudo-nitzs~~a~~chia* are of ~~relatively short duration~~varying intensity, duration and extent.. ~~However, d~~During ~~the~~a 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 Biotoxin 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 "~~key~~primary 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 ~~PSP~~toxic 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~~biotoxin ~~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.
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.
3. A program of consumer education should be continued as long as any area remains in the closed status because of marine Biotoxin contamination.

References

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Public Health Significance	This proposal includes modifications to Guidance Document .02 Guidance for Developing Marine Biotoxin Contingency Plans. This proposal includes guidance document modifications which support Proposal 17-122.
Cost Information	