Interstate Shellfish Sanitation Conference

Summary of Actions

San Diego, CA

October 5 – 10, 2019

Proposal No. 11-103

Submitter	Thomas L. Howell Spinney Creek Shellfish, Inc. tlhowell@spineycreek.com
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.
Action by 2017 Growing Area Committee	Recommended adoption of Proposal 11-103 as amended. Add a new section as follows: Chapter XV. Depuration

.03 Other Model Ordinance requirements

K. Supplemental Requirements for Depuration using MSC Viral Controls for Shellstock Harvested from Conditionally Restricted Growing Areas Impacted by Wastewater System Discharge (WWSD).

If the conditionally restricted growing area from which the shellstock is being depurated is impacted by wastewater treatment system discharge (generally that section of the conditionally restriced growing area located within the 300:1 to 1000:1 dilution lines), then supplemental requirements for depuration using MSC viral controls may be required. Depuration using MSC viral controls may be seasonally limited and may be species and depuration facility specific. Contaminant reduction studies as described in (1) below are recommended unless the SSCA and the Depuration Facility Operator have significant experience with the depuration process using MSC viral controls.

(1) Male-specific coliphage may be used in addition to fecal coliform for species-specific, growing area-specific, and depuration system-specific contaminant reduction studies. These contaminant reduction studies should demonstrate that;

(a) Predictable periods of time exist when male-specific coliphage levels are less than 1,000 PFU/100gm in shellfish meats,

(b) Male-specific coliphage and fecal coliform can be consistently reduced below end-point requirements, and

(c) Critical limits of season, process water temperature and salinity, and system design and operation limitations can be assessed and determined

(d) Species-specific operating protocols may be developed from the contaminant reduction studies for each conditionally restricted growing area that includes;

(i) Calendar dates when depuration shall be permitted,
(ii) Water temperature and salinity limitations,
(iii) Minimum processing time,
(iv) Sampling requirements and release criteria, and
(v) Operating Protocol.

(2) All requirements of Chapter XV shall be followed,

(3) A single 0-day MSC shellfish meat sample is required.

(4) The MSC end-point requirement for depuration is 50 PFU/100gm. If the single 0-day sample exceeds 50 PFU/100gm, then triplicate samples are required prior to release of product.

(5) The geometric mean of the triplicate samples used for product release must not exceed 50PFU/100gm and no single sample over 100

PFU/100gm.

(6) Extended depuration may be permitted to achieve end-point requirements.

(7) Evaluation of male-specific coliphage samples shall be performed in an NSSP conforming laboratory,

Action of 2017 Task Force I	Recommended adoption of Growing Area Classification Committee recommendation on Proposal 11-103.
Action by FDA February 7, 2018	Did not concur with Conference action on proposal 11-103
Action by ISSC Executive Board	Referred Proposal 11-103 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Male-Specific Coliphage Committee	Committee recommended the adoption of 11-103 as amended.

K. Supplemental Requirements for Depuration using MSC Viral Controls for Shellstock Harvested from Conditionally Restricted Growing Areas Impacted by Wastewater System Discharge (WWSD). outside of a 300:1 dilution or the EPA Toxic Dilution Zone (whichever is greater) and within an area determined to be impacted by wastewater treatment system discharge. These requirements would allow harvesting in areas that would otherwise be classified as prohibited due to viral pollution concerns. The harvest area that could be considered would include the area between 300:1 dilution or the EPA Toxic Dilution (whichever is greter) and the established boundary for depuration (Chapter IV @.02 G.)

If the conditionally restricted growing area from which the shellstock is being depurated is impacted by wastewater treatment system discharge (generally that section of the conditionally restriced growing area located within the 300:1 to 1000:1 dilution lines), then supplemental requirements for depuration using MSC viral controls may be required. Depuration using MSC viral controls may be seasonally limited and may be species and depuration facility specific. CThe suplemental requirements must be included in contaminant reduction studies as described in (1) below. are recommended unless the SSCA and the Depuration Facility Operator have significant experience with the depuration process using MSC viral controls.

(1) Male-specific coliphage may shall be used in addition to fecal coliform for species-specific, growing area-specific, and depuration system-specific contaminant reduction studies. These contaminant reduction studies should demonstrate that;

(a) Predictable periods of time exist when male-specific coliphage levels are less than 1,000 PFU/100gm in shellfish meats,

(ba) Male-specific coliphage and fecal coliform can be

consistently reduced below end-point requirements, and

(~~c~~b) Critical limits of season, process water temperature and salinity, and system design and operation limitations can be assessed and determined

(~~d~~c) Species-specific operating protocols ~~may~~ shall be developed from the contaminant reduction studies for each conditionally restricted growing area that includes;

(i) Calendar dates when depuration shall be permitted,
(ii) Water temperature and salinity limitations,
(iii) Minimum processing time,
(iv) Sampling requirements and release criteria, and
(v) Operating Protocol.

(2) All requirements of Chapter XV shall be followed,

(3) A ~~single~~triplicate 0-day MSC shellfish meat sample is required.

~~(4) The MSC end-point requirement for depuration is 50 PFU/100gm. If the single 0-day sample exceeds 50 PFU/100gm, then triplicate samples are required prior to release of product.~~

(~~5~~4) The geometric mean of the triplicate samples used for product release must not exceed 50PFU/100gm and no single sample over 100 PFU/100gm

(~~6~~5) Extended depuration ~~may be permitted~~is allowable if necessary to achieve end-point requirements.

(~~7~~6) Evaluation of male-specific coliphage samples shall be performed in an NSSP conforming laboratory,

Action by 2019 Task Force I	Recommended adoption of Male Specific Coliphage Committee recommendations on Proposal 11-103.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 11-103.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 11-103.

Proposal No. 13-107

Submitter	Robert Rheault East Coast Shellfish Growers Association bob@ecsga.org
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.

Action by 2017 Aquaculture Facilities Inspection Committee

Recommended adoption of Proposal 13-107 as substituted.

Section I. Definitions
Replace definition 9. in Section I of the Model Ordinance as follows:

9. Aquaculture means cultivating shellfish in controlled conditions for human consumption. Cultivation includes propagation and growing of shellfish. These activities may occur in natural or man-made water bodies. These activities include seed production, cultivation in natural water bodies when shellfish are held off the bottom such as the use of racks, bags, or cages, and when shellfish are held in man-made water bodies such as the use of tanks, ponds, or raceways. These activities do not include depuration, wet storage or the broadcasting of spat or seed shellfish being left to mature the same as wild shellfish.

Modify definition 93. in Section I of the Model Ordinance as follows:

(93) Prohibited means a classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering or nursery culture of seed for aquaculture, is not permitted.

Section IV. Chapter IV. Shellstock Growing Areas
Change @03 E. (2)(a) to read:
(2) General. The Authority shall:
(a) Not permit the harvest of shellstock from any area classified as prohibited, except for the harvest of shellstock for the gathering of seed or nursery culture for aquaculture or the depletion of the areas classified as prohibited; and

Replace Chapter VI. Aquaculture in its entirety as follows:

Chapter VI. Aquaculture
Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]
@ .01 General.

A. Activities which have been determined to pose a significant public health concern and need regulation outlined in this Chapter include, but are not limited to:
(1) Seed production in waters classified as Prohibited or Unclassified;
(2) Aquaculture that attracts birds or mammals; and
(3) Land based aquaculture
B. The Authority shall:
(1) Approve the written operational plan for operations as outlined in @.01A above.
(2) Inspect operations outlined in @.01A above at least annually; and
(3) At a minimum inspect operator records to verify that appropriate permits are up to date and operational plans required in @ .01 A(1). are being implemented.
(4) Consistent with Chapter IV @ .01 (D)(1)(e) when aquaculture as defined in the Model Ordinance attracts birds or mammals their presence should be considered for possible adverse effects on growing area water quality

@ .02 Seed Shellstock.

A. The Authority shall establish the maximum seed size for each species of shellfish that can be produced in prohibited waters. In determining the maximum seed size Authorities shall establish sizes that require a minimum of 120 days of growing to reach market size.
B. The Authority shall establish appropriate corrective actions for when seed exceeds the maximum seed size when it has been produced in waters classified as prohibited.
C. All sources of seed produced or collected in prohibited waters shall be sanctioned by the Authority.

Requirements for the Harvester/Dealer

.01 Exceptions.

Hatcheries and nurseries rearing larvae and/or seed that are located in:
A. Approved or conditionally approved growing areas are exempt from these requirements.
B. Restricted or Conditionally Restricted would be exempt from these requirements but subject to relay requirements in Chapter V for seed that exceeds the maximum seed size established by the Authority.

.02 General.

A. Any person who performs aquaculture as defined in the Model Ordinance or operates an aquaculture facility to raise shellfish for human consumption shall obtain:
(1) A permit from the Authority for the activity and functioning of his facility;
(2) A harvester's license; and
(3) Certification as a dealer, where necessary.
B. Shellfish aquaculture as defined in the Model Ordinance shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the operator's written operational plan.
C. Prior to beginning his activity, an operator shall obtain the permission of the Authority for use of his facility.
D. Any shellfish seed raised in aquaculture that exceeds the maximum seed size established by the Authority shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:
(1) The closed status of the conditionally approved classification;
(2) The restricted classification;
(3) The open status of the conditionally restricted classification; or
E. Only drugs sanctioned by the FDA shall be used for shellfish treatment.
F. Harvesting, processing, storage, and shipping requirements for shellfish raised in a land-based aquaculture facility or a seed rearing facility or system that exceeds the maximum seed size established by the Authority shall be the same as the requirements for shellfish specified in Chapters V., VII., VIII., IX., X., XI., XII., XIII. and XIV.
G. Complete and accurate records shall be maintained for at least two (2) years by the operator of the aquaculture facility and shall include the:
(1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved or conditionally approved classification;
(2) Water source, its treatment method, if necessary, and its quality in land based systems.

.03 Seed Production in Water Classified as Prohibited or Unclassified.

Seed may come from any growing area, or from any growing area in any classification, provided that:
A. The source of the seed if from waters classified as prohibited or

unclassified is sanctioned by the Authority; and

B. Operational Plan. Each aquaculture site that cultures seed in waters classified as prohibited or unclassified shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:

(1) A description of the design and activities of the culture facility;

(2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;

(3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;

(4) The species of shellfish to be cultured and harvested;

(5) Procedures to assure that no poisonous or deleterious substances are introduced from the seed production activities;

(6) Corrective actions for addressing seed exceeding the maximum seed size as defined by the Authority.

.04 Aquaculture that attracts birds or mammals.

A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:

(1) A description of the design and activities of the culture facility;

(2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;

(3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;

(4) The species of shellfish to be cultured and harvested;

(5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities;

(6) Maintenance of the required records

.05 Land Based Aquaculture.

A. Operational Plan. Each facility shall have a written operational plan. The facility must obtain approval from the Authority prior to its implementation and shall include:

(1) A description of the design and activities of the culture facility;

(2) The specific site and boundaries in which shellfish culture activities will be conducted;

(3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters;

(4) The species of shellfish to be cultured and harvested;

(5) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;

(6) A program of sanitation, maintenance, and supervision to prevent contamination of the shellfish products;

(7) A description of the water source, including the details of any water treatment process or method;

(8) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored

shall be the same as used for monitoring growing areas;

(9) If applicable, collection of data concerning the quality of food production (algae or other) used in the artificial harvest system; and

(10) Maintenance of the required records.

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

(1) Construction and remodeling plans for any permitted aquaculture facility;

(2) Aquaculture operational plans; and

(3) Aquaculture permits.

C. Water Systems.

(1) If the land-based aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.

D. Water Quality.

(1) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size shall meet the requirements for water quality and testing in Chapter VII C. .04 (3) (a), (b), (c), and (d) may be used in direct marketing.

(2) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size and does not meet the requirements of Section D. (1) shall be relayed or depurated consistent with Chapter IV prior to direct marketing.

.06 Polyculture Systems.

A polyculture system shall:

A. Meet all requirements in Section .05 Land Based Systems;

B. Provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested;

C. Include in its operational plan requirements to:

(1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and

(2) Subject all harvested shellstock to relaying or depuration if human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances exist at levels of public health significance.

Move Chapter VI Section .07 to a new Chapter:

Chapter XVII Shellfish Gardening

@ .01 Shellfish Gardening.

If a State recognizes shellfish gardening the Authority:

A. Shall permit or register shellfish gardening activities.

B. Shall establish permit or registration conditions and determine classification of waters where shellfish gardening can take place prior to its

implementation.
C. Shall provide information to the shellfish gardener on the risk of consuming shellfish from private docks, piers, and shellfish floats attached to piers or docks and from waters not classified and open to harvest for direct consumption.
D. May require that the shellfish gardener maintain records on the disposition of the shellfish product and provide these records to the Authority.

@ . 02 Requirements for the Shellfish Gardener.

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

Action by 2017 Task Force I

Recommended adoption of Aquaculture Committee recommendation on Proposal 13-107 as amended.

Section I. Definitions
Replace definition 9. in Section I of the Model Ordinance as follows:

9. Aquaculture means cultivating shellfish in controlled conditions for human consumption. Cultivation includes propagation and growing of shellfish. These activities may occur in natural or man-made water bodies. These activities include seed collection, production, cultivation in natural water bodies when shellfish are held off the bottom such as the use of racks, bags, or cages, and when shellfish are held in man-made water bodies such as the use of tanks, ponds, or raceways. These activities do not include depuration or~~,~~ wet storage. ~~or the broadcasting of spat or seed shellfish being left to mature the same as wild shellfish.~~

Modify definition 93. in Section I of the Model Ordinance as follows:

(93) Prohibited means a classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering or nursery culture of seed for aquaculture, is not permitted.

Section IV. Chapter IV. Shellstock Growing Areas
Change @03 E. (2)(a) to read:
(2) General. The Authority shall:
(a) Not permit the harvest of shellstock from any area classified as prohibited, except for the harvest of shellstock for the gathering of seed or nursery culture for aquaculture or the depletion of the areas classified as prohibited; and

Replace Chapter VI. Aquaculture in its entirety as follows:

Change @03 E. (2)(a) to read:
(2) General. The Authority shall:

(a) Not permit the harvest of shellstock from any area classified as prohibited, except for ~~the harvest of shellstock for~~ the gathering of seed or nursery culture for aquaculture or the depletion of the areas classified as prohibited; and

Chapter VI. Aquaculture
Requirements for the Authority
[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@ .01 General.

A. Aquaculture ~~A~~a activities which may ~~have been determined to~~ pose a significant public health concern and are regulated ~~need regulation outlined~~ in this Chapter include, but are not limited to:
   (1) Seed production in waters classified as Prohibited or Unclassified;
   (2) Aquaculture structures that attracts birds or mammals; and
   (3) Land based aquaculture

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

@ .02 Seed Shellstock.

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

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

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

Requirements for the Harvester/Dealer

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

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

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

.2 General.

A. Any person who performs aquaculture as defined in the Model Ordinance or operates an aquaculture facility to raise shellfish for human consumption shall obtain:
   (1) A permit from the Authority for the activity and functioning of his

facility;
(2) A harvester's license; and
(3) Certification as a dealer, where necessary.

B. Shellfish aquaculture as defined in the Model Ordinance shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the operator's written operational plan.

C. Prior to beginning his activity, an operator shall obtain the permission of the Authority for use of his facility.

D. Any shellfish seed raised in aquaculture that exceeds the maximum seed size established by the Authority shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:
(1) The closed status of the conditionally approved classification;
(2) The restricted classification;
(3) The open status of the conditionally restricted classification; or

E. Only drugs sanctioned by the FDA shall be used for shellfish treatment.

F. Harvesting, processing, storage, and shipping requirements for shellfish raised in a land-based aquaculture facility or a seed rearing facility or system that exceeds the maximum seed size established by the Authority shall be the same as the requirements for shellfish specified in Chapters V., VII., VIII., IX., X., XI., XII., XIII. and XIV.

G. Complete and accurate records shall be maintained for at least two (2) years by the operator of the aquaculture facility and shall include the:
(1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved or conditionally approved classification;
(2) Water source, its treatment method, if necessary, and its quality in land based systems.

.3 Seed Production in Water Classified as Prohibited or Unclassified.
Seed may come from any growing area, or from any growing area in any classification, provided that:

A. The source of the seed if from waters classified as prohibited or unclassified is sanctioned by the Authority; and

B. Operational Plan. Each aquaculture site that cultures seed in waters classified as prohibited or unclassified shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:
(1) A description of the design and activities of the culture facility;
(2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;
(3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;
(4) The species of shellfish to be cultured and harvested;
(5) Procedures to assure that no poisonous or deleterious substances are introduced from the seed production activities;
(6) Corrective actions for addressing seed exceeding the maximum seed size as defined by the Authority.

.4 Aquaculture that attracts birds or mammals.

A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:
   (1) A description of the design and activities of the culture facility;
   (2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;
   (3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;
   (4) The species of shellfish to be cultured and harvested;
   (5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities;
   (6) Maintenance of the required records

.5 Land Based Aquaculture.

A. Operational Plan. Each facility shall have a written operational plan. The facility must obtain approval from the Authority prior to its implementation and shall include:
   (1) A description of the design and activities of the culture facility;
   (2) The specific site and boundaries in which shellfish culture activities will be conducted;
   (3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters;
   (4) The species of shellfish to be cultured and harvested;
   (5) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;
   (6) A program of sanitation, maintenance, and supervision to prevent contamination of the shellfish products;
   (7) A description of the water source, including the details of any water treatment process or method;
   (8) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored shall be the same as used for monitoring growing areas;
   (9) If applicable, collection of data concerning the quality of food production (algae or other) used in the artificial harvest system; and
   (10) Maintenance of the required records.

B. Each land-based facility conducting aquaculture as defined by the Model Ordinance shall maintain the following records while the aquaculture activity continues.
   (1) Construction and remodeling plans for any permitted aquaculture facility;
   (2) Aquaculture operational plans; and
   (3) Aquaculture permits.

C. Water Systems.
   (1) If the land-based aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times

shellfish are held, may be used without treatment.

D. Water Quality.
   (1) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size shall meet the requirements for water quality and testing in Chapter VII C. .04 (3) (a), (b), (c), and (d) may be used in direct marketing.
   (2) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size and does not meet the requirements of Section D. (1) shall be relayed or depurated consistent with Chapter IV prior to direct marketing.

.6 Polyculture Systems.

A polyculture system shall:

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

Move Chapter VI Section .07 to a new Chapter:

Chapter XVII Shellfish Gardening

@ .01 Shellfish Gardening.

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

@ . 02 Requirements for the Shellfish Gardener.

A. Shellfish gardening shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the oyster/shellfish gardening activity.
B. Shellfish gardeners shall document that they understand the risks

associated with consumption for shellfish grown from docks or private piers.

C. If required by the Authority, shellfish gardeners shall keep accurate records on the fate or final destination of all shellfish grown at their shellfish garden site and provide these records to the Authority upon request.

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

Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-107.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-107.
Action by 2019 Aquaculture Committee	In 2017 the Conference adopted the new language of Proosal 13-107 to modify the requirements of Chapter VI. The Conference further directed the development of guidance for Chapter VI. The Aquaculture Committee was charged with the development of a Guidance Document. That work was not completed. The Chapter VI language that was adopted in 2017 is not included in the 2019 Task Force II report. The Aquaculture Committee recommended referral of the Guidance Document request included in Proposal 13-107 to an appropriate committee as determined by the Conference Chairperson with further instruction that the committee be convened before the Spring Executive Board meeting to begin development of a guidance document for the revised Aquaculture Chapter.
Action by 2019 Task Force I	Recommended adoption of the Aquaculture Committee recommendation on Proposal 13-107.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 13-107.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 13-107.

Proposal No. 13-111

Submitter	David C. Deardorff Abraxis LLC ddeardorff@abraxiskits.com
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	Concurred with Conference action on Proposal 13-111.

January 11, 2016

Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-111.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 13-111.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-111.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-111.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 13-111.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 13-111.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 13-111.

Proposal No. 13-114

Submitter	Darcie Couture Resource Access International darcie.couture@att.net
Proposal Subject	Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas. 11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	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.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 13-114 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 13-114.

Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-114.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-114.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 13-114 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 13-114.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 13-114.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 13-114.

Proposal No. 13-116

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

possessing a valid shellfish processing plant certification license must have written permission from the Authority to engage in this activity. To be eligible for participation in the quarantine program, the certified processor must:

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) May receive properly tagged shellfish from eligible aquaculturists only as indicated in the Authority's authorization email;
(3) Must upon receipt of shellfish, separate and maintain the shellfish into specific lots [A Lot is defined as shellfish of one species from no more than one day's harvest from a specific zone within a shellfish growing area];
(4) Must place shellfish under proper controls and quarantine; Proper controls and quarantine are defined by bold, clear, warning signage signaling the properly tagged and segregated shellfish within the processor's cooler are under quarantine and must not be moved until Authority permission is obtained pending outcome of laboratory testing. The signage should be such that it is clear to anyone entering the cooler (including facility employees and/or regulatory inspectors) that the affected shellfish are under quarantine. Wrapping of the entire lot with a single bright red or yellow ribbon or equivalent attached to the bold warning sign will further reinforce the warning message.
(5) Must allow the Authority to take two (2) random samples [minimum of twenty (20) shellfish per each sample] from each lot and deliver to the approved laboratory for approved mouse bioassay;
(6) Must hold all shellfish in quarantine at the approved processor's certified facility until receiving official written test result notice from the Authority via email or fax that the shellfish are cleared for sale;

(7) Must either return shellfish to aquaculture lease(s) in the zone(s) from where harvested if any sample in a lot is 20 Mouse Units / 100 grams or greater or destroy the shellfish, both activities of which must be witnessed and documented by the Authority;

(8) Must cease this activity if any Authority collected red tide cell counts in the specific zone exceeds 200,000 cells per liter of *Karenia brevis*; and

(9) Must document all of the requirements listed above in the approved facility HACCP plan.

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

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

_____ _____

Signed Date

Public Health Significance

Closures of shellfish growing areas due to Neurotoxic Shellfish Poisoning (NSP) may occur at any time in the Gulf of Mexico and to a lesser degree, the Atlantic coast. Well established procedures for detecting and responding to *Karenia brevis* blooms have safeguarded public health. Clear early warning signs, a cell count action level with a high factor of safety and established sampling networks provide excellent public health protection. A very real impact of *Karenia brevis* blooms is the resulting long-term closures of shellfish growing areas and severe economic impact to commercial shellfish operations. Florida addressed this issue after studying years of water quality samples and mouse bioassay results from shellfish growing areas. Hydrodynamic studies linked to water samples obtained from fixed stations over an extended period of time established clear patterns in distribution of *Karenia brevis*. Working in conjunction with harmful algal bloom researchers, shellfish growing area managers, FDA and industry, Florida developed a NSP quarantine protocol that has resulted in the retention of a shellfish industry in one of the most severely impacted HAB regions of the Gulf while protecting public health as required by the Model Ordinance. An enormous amount of data has been generated and reviewed during the years this protocol has been used. Repeated mouse bioassay testing on shellfish exposed to different levels of *Karenia brevis* has provided Florida with sufficient data to refine the protocol into a powerful management tool. Florida's experience pre-quarantine protocol was unfortunate, as several fledgling businesses failed due to repeated NSP closures. It was this economic damage that spurred the aforementioned collaborative effort between leading edge HAB researchers, shellfish growing area managers, FDA and industry. If adopted, shellfish producing states impacted by *Karenia brevis* could reference this protocol in the Guidance Document and use it to effectively manage NSP closures.

Cost Information

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.
Action by 2017 Task Force I	Recommended 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 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-116.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-116.
Action by 2019 Task Force I	Recommended no action on Proposal 13-116. Rationale: The Guidance Document was developed by the Biotoxin Committee and submitted in conjunction with other recommended Model Ordinance changes as part of Proposal 19-149.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 13-116.
Action by FDA January , 2020	Concurred with Conference action on Proposal 13-116.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 13-116.

Submitter	Alison Sirois and Jackie Knue Department of marine Resources and Alaska State Environmental Health Laboratory Alison.Sirois@maine.gov and Jacqueline.Knue@alaska.gov
Proposal Subject	PSP HPLC-PCOX Species Expansion
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	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.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 15-109 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 15-109.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 15-109.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 15-109.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 15-109 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 15-109.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 15-109.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 15-109.

Proposal No. 15-112

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

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

5. Approved Methods for Vibrio Enumeration

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

Footnotes:

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

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

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

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

[5] *Vibrio vulnificus*, ISSC Summary of Actions 2009. Proposal 09-113, Page 123.

[6] Direct plating method for *trh* as described in Nordstrom et al., 2006.

Public Health Significance	Scientific evidence suggests that the presence of the *trh* gene in *V. parahaemolyticus (V.p.)* is correlated with higher virulence. Additionally, at the 2013 conference, proposal 13-202 was adopted which requires testing for the presence of trh prior to reopening of growing areas closed as a result of *V.p.* illnesses [Chapter II @.01.F(5)]. Currently, there are no NSSP approved methods for enumeration of *trh*. This method is a needed option for testing following *V.p.* illness closures.
Cost Information	This method costs ~$5 per test for laboratory consumables, supplies, and reagents. Most equipment needed for testing is standard microbiology equipment, but purchase of a specialized water bath or environmental chamber may be necessary at a cost of ~$3,000-$5,000. Additional costs for a laboratory would vary based on their operational overhead and labor.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 15-112 to an appropriate committee as determined by the Conference Chair to further review the data submitted.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Methods Review Committee recommendation on Proposal 15-112.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-112
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-112.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 15-112 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	Recommended adoption of Lab Committee recommendation on Proposal 15-112.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 15-112.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 15-112.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 15-112 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 15-112.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 15-112.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 15-112.

Proposal No. 15-114

Submitter	Executive Board Interstate Shellfish Sanitation Conference (ISSC) issc@issc.org
Proposal Subject	Pre-Proposal for Male-Specific Coliphage Enumeration in Wastewater by Direct Double-Agar Overlay Method
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	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.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 15-114 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 15-114.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 15-114.

Action by FDA February 7, 2018	Concurred with Conference action on Proposal 15-114.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 15-114 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 15-114.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 15-114.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 15-114.

Proposal No. 17-100

Submitter	J. Michael Hickey Massachusetts Division of Marine Fisheries Michael.hickey@state.ma.us
Proposal Subject	Marina Definition
Specific NSSP Guide Reference	Section I Purposes and Definitions B. Definition of Terms (71) Marina
Text of Proposal/ Requested Action	**(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.
Action By 2017 Task Force I	Recommended referral of Proposal 17-100 to an appropriate committee as determined by the Conference Chair.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-100.
Action by FDA February 7, 2018	Concurred with Conference action on proposal 17-100 with comments. (See February 7, 2018 FDA response to ISSC Summary of Actions)
Action by 2019 Marina Committee	Recommended adoption of Proposal 17-100 as amended. **Section I. Purpose & Definitions** **Definitions** (73) **Marina** means any water area with a structure (docks, basin, floating docks, etc.) which is ~~:(a) Used~~ used for docking ~~or otherwise mooring vessels;~~ and ~~(b) Constructed~~ constructed to provide temporary or permanent docking space for more than ten boats. Add new definition. **Mooring Areas** mean any water area that is used to provide temporary or permanent anchorage for more than 10 boats. Mooring areas do not include any structures for docking boats.

Section II. Model Ordinance
Chapter IV. Shellstock Growing Areas

@.05 Marinas.

A. Marina Proper. The area within any marina which is in or adjacent to a shellstock growing area shall be classified as: conditionally approved, conditionally restricted or prohibited.~~:~~

(1) Prior to the Authority establishing a classification of conditionally approved or conditionally restricted in the marina proper, a pollution assessment supporting the classification will be conducted by the authority.

(2) The assignment of a prohibited classification with the marina proper does not require a pollution assessment by the Authority.

~~(1) Conditionally approved;~~
~~(2) Conditionally restricted; or~~
~~(3) Prohibited.~~

B. Adjacent Waters. Waters adjacent to marina waters classified under Section A. may be impacted by pollution associated with the marina.

(1) A dilution analysis shall be used to determine if there is any impact to adjacent waters.

(2) The dilution analysis shall be based on the volume of water in the vicinity of the marina.

(3) The dilution analysis shall incorporate the following:

(a) A slip occupancy rate for the marina;

(b) An actual or assumed rate of boats which will discharge untreated waste;

(c) An occupancy per boat rate (i.e., number of persons per boat);

(d) A fecal coliform discharge rate of 2 x 10 fecal coliform per ninth power per day; and

(e) The assumption that the wastes are completely mixed in the volume of water in and around the marina.

(f) Documentation, verification and enforcement of Federal No Discharge Zones and locally well enforced no discharge and occupancy by-laws and regulations.

(g) Availability and documented use of pump out boats or facilities.

(4) If the dilution analysis predicts a theoretical fecal coliform loading greater than fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the marina shall be classified as:

(a) Conditionally approved;

(b) Restricted;

(c) Conditionally restricted; or

(d) Prohibited.

(5) If the dilution analyses predict a theoretical fecal coliform loading less than or equal to fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the marina may be classified as:

(a) Approved; or

(b) Conditionally approved.

(6) If the Authority chooses not to determine a specific occupancy per boat rate by investigation in specific areas or sites, the Authority shall assume a minimum occupancy rate of two (2) persons per boat.

@.06 Mooring Areas

A. Mooring Area. The area within any Public entity designated mooring area, where there is anchoring of boats, which is in or adjacent to a shellstock growing area shall be classified as, conditionally approved, conditionally restricted, restricted or prohibited.

(1) Prior to the Authority establishing a classification of, conditionally approved or conditionally restricted or restricted in the mooring area proper, a pollution assessment supporting the classification will be conducted by the authority. The assessment shall include:

(a) Boat type and usage

(b) Density of boats

(c) Accessibility to boats which could reduce likelihood of overnight occupancy.

(d) Occupancy rates

(e) Seasonal Use Pattern

(f) An actual or assumed rate of boats which will discharge untreated waste

(g) Documentation, verification and enforcement of federal No Discharge Zones, and locally well enforced no discharge and occupancy regulations or by-laws.

(h) Availability and documented use of pump out boats.

(2)The assignment of a prohibited classification with the mooring area proper does not require a pollution assessment by the Authority.

B. Adjacent Waters. Waters adjacent to open water mooring areas classified under Section A. may be impacted by pollution associated with the mooring areas. If determined a pollution source:

(1) A dilution analysis shall be used to determine if there is any impact to adjacent waters.

(2) The dilution analysis shall be based on the volume of water in the vicinity of the mooring areas.

(3) The dilution analysis shall incorporate the following:

(a) An occupancy rate for the mooring areas;

(b) An actual or assumed rate of boats which will discharge untreated waste;

(c) An occupancy per boat rate (i.e., number of persons per boat);

(d) A fecal coliform discharge rate of 2 x 10 fecal coliform per ninth power per day; and

(e) The assumption that the wastes are completely mixed in the volume of water in and around the open water mooring areas.

(4) If the dilution analysis predicts a theoretical fecal coliform loading greater than fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the mooring areas shall be classified as:

(a) Conditionally approved;

(b) Restricted;

(c) Conditionally restricted; or

(d) Prohibited.

(5) If the dilution analyses predict a theoretical fecal coliform loading less than or equal to fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the mooring areas may be classified as:

(a) Approved; or

(b) Conditionally approved.

(6) If the Authority chooses not to determine a specific occupancy per boat rate by

investigation in specific areas or sites, the Authority shall assume a minimum occupancy rate of two (2) persons per boat.

Action by 2019 Task Force I

Recommended adoption of Proposal 17-100 as amended.

Section I. Purpose & Definitions

Definitions

(73) **Marina** means any water area with a structure (docks, basin, floating docks, etc.) which is used for docking and constructed to provide temporary or permanent docking space for more than ten boats.

Add new definition.

Mooring Areas mean any water area that is used to provide temporary or permanent anchorage for more than twenty (20)~~10~~ boats. Mooring areas do not include any structures for docking boats.

Section II. Model Ordinance

Chapter IV. Shellstock Growing Areas

@.05 Marinas.

A. Marina Proper. The area within any marina which is in or adjacent to a shellstock growing area shall be classified as: conditionally approved, conditionally restricted or prohibited.

(1) Prior to the Authority establishing a classification of conditionally approved or conditionally restricted in the marina proper, a pollution assessment supporting the classification will be conducted by the authority.

(2) The assignment of a prohibited classification with the marina proper does not require a pollution assessment by the Authority.

B. Adjacent Waters. Waters adjacent to marina waters classified under Section A. may be impacted by pollution associated with the marina.

(1) A dilution analysis shall be used to determine if there is any impact to adjacent waters.

(2) The dilution analysis shall be based on the volume of water in the vicinity of the marina.

(3) The dilution analysis shall incorporate the following:

(a) A slip occupancy rate for the marina;

(b) An actual or assumed rate of boats which will discharge untreated waste;

(c) An occupancy per boat rate (i.e., number of persons per boat);

(d) A fecal coliform discharge rate of 2 x 10 fecal coliform per ninth power per day; and

(e) The assumption that the wastes are completely mixed in the volume of water in and around the marina.

(f) Documentation, verification and enforcement of Federal No Discharge Zones and locally well enforced no discharge and occupancy by-laws and regulations.

(g) Availability and documented use of pump out boats or facilities.

(4) If the dilution analysis predicts a theoretical fecal coliform loading greater than fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the marina shall be classified as:

(a) Conditionally approved;

(b) Restricted;
(c) Conditionally restricted; or
(d) Prohibited.

(5) If the dilution analyses predict a theoretical fecal coliform loading less than or equal to fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the marina may be classified as:
(a) Approved; or
(b) Conditionally approved.

(6) If the Authority chooses not to determine a specific occupancy per boat rate by investigation in specific areas or sites, the Authority shall assume a minimum occupancy rate of two (2) persons per boat.

@.06 Mooring Areas

A. Mooring Area. The area within any Public entity designated mooring area, where there is anchoring of boats, which is in or adjacent to a shellstock growing area shall be classified as, conditionally approved, conditionally restricted, restricted or prohibited.

(1) Prior to the Authority establishing a classification of, conditionally approved or conditionally restricted or restricted in the mooring area proper, a pollution assessment supporting the classification will be conducted by the authority. The assessment shall include:
(a) Boat type and usage
(b) Density of boats
(c) Accessibility to boats which could reduce likelihood of overnight occupancy.
(d) Occupancy rates
(e) Seasonal Use Pattern
(f) An actual or assumed rate of boats which will discharge untreated waste
(g) Documentation, verification and enforcement of federal No Discharge Zones, and locally well enforced no discharge and occupancy regulations or by-laws.
(h) Availability and documented use of pump out boats.

(2) After assessment determines that the mooring area is not a pollution source and it is documented in the Conditional Management Area Plan, the area can be placed in the open status.

(~~2~~3)The assignment of a prohibited classification with the mooring area proper does not require a pollution assessment by the Authority.

B. Adjacent Waters. Waters adjacent to open water mooring areas classified under Section A. may be impacted by pollution associated with the mooring areas. If determined a pollution source:

(1) A dilution analysis shall be used to determine if there is any impact to adjacent waters.

(2) The dilution analysis shall be based on the volume of water in the vicinity of the mooring areas.

(3) The dilution analysis shall incorporate the following:
(a) An occupancy rate for the mooring areas;
(b) An actual or assumed rate of boats which will discharge untreated waste;
(c) An occupancy per boat rate (i.e., number of persons per boat);

(d) A fecal coliform discharge rate of 2 x 10 fecal coliform per ninth power per day; and
(e) The assumption that the wastes are completely mixed in the volume of water in and around the open water mooring areas.

(4) If the dilution analysis predicts a theoretical fecal coliform loading greater than fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the mooring areas shall be classified as:
(a) Conditionally approved;
(b) Restricted;
(c) Conditionally restricted; or
(d) Prohibited.

(5) If the dilution analyses predict a theoretical fecal coliform loading less than or equal to fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the mooring areas may be classified as:
(a) Approved; or
(b) Conditionally approved.

(6) If the Authority chooses not to determine a specific occupancy per boat rate by investigation in specific areas or sites, the Authority shall assume a minimum occupancy rate of two (2) persons per boat.

Action by 2019 General Assembly

Adopted recommendation of Task Force I on Proposal 17-100.

Action by FDA February 21, 2020

The FDA concurred with the primary purpose of Proposal 17-100, which was to recognize potential pollution differences between marina and mooring areas. However, the FDA has identified several inconsistencies in the adopted language that must be addressed before FDA can provide concurrence.

FDA Concerns:

1. Mooring Area Definition and Chapter IV@.06A Language: The newly adopted definition for a mooring area in the Section I. Purpose & Definitions is not consistent with language included in Chapter IV@.06A and may cause confusion.

   The FDA suggests the term "Public entity," included in the new language included in Chapter IV @ .06 A, be deleted. The term, "Public entity" is limiting and not consistent with the adopted language for the definition of a mooring area. The inclusion of "Public entity" does not provide a full characterization of all mooring areas that should be considered in the classification of shellfish growing areas. The phrase "where there is anchoring of boats" is redundant and should be deleted. The classification requirements of a mooring area in Chapter IV@.06A should be consistent with the definition of a mooring area in Section I. Purpose & Definitions.

   Suggested Change to Newly Adopted Chapter IV@.06A:
   Mooring Area Proper. The area within any Public entity designated mooring area, where there is anchoring of boats, which is in or adjacent to a shellstock growing area shall be classified as,

conditionally approved, conditionally restricted, restricted or prohibited.

2. Pollution Assessment: The newly adopted language in Chapter IV@.06 requires a "pollution assessment" to be conducted prior to classifying any mooring area as Conditionally Approved, Conditionally Restricted, or Restricted. The FDA has concerns that the pollution assessment requirements are not specific enough and may cause confusion and inconsistencies during FDA evaluations. The FDA wants to ensure that the State Control Authority (Authority) is informed as to what will be expected by FDA in an acceptable pollution assessment for mooring areas. The FDA would like to clarify the following points to make sure that a complete pollution assessment is conducted.

   a) Pollution Assessment Guidance: The FDA has concerns that the "pollution assessment" language describing the new requirements in Chapter IV. @.06(1) is not specific enough given that the pollution assessment will be used to allow classifications other than prohibited. Our primary concern would be the use of Conditionally Approved in the open status. Chapter IV@,06A.(2), states that, *"(2)After assessment determines that the mooring area is not a pollution source and it is documented in the Conditional Area Management Plan, the area can be placed in the open status."* To address this, the FDA suggests providing guidance for conducting a mooring area pollution assessment through updating the 1989 FDA Guideline – Evaluation of Marinas by State Shellfish Sanitation Control Officials. This 1989 document is used as part of the FD242 Growing Area Course. This document is not presently included in the NSSP Guide. FDA would work with the Growing Area Classification Committee to update this document and submit it as a proposal for inclusion in the NSSP Guide as a guidance document.

   b) Pollution Assessment and Federal No Discharge Zone CNDZ): The NDZ is only one factor to consider in conducting a pollution assessment when classifying a growing area with a mooring area as Conditionally Approved in the open status. The FDA has concerns with the addition of Chapter IV@.06A(g), *"(g)Documentation, verification and enforcement offederal No Discharge Zones, and locally well enforced no discharge and occupancy regulations or by-laws."* The FDA is concerned that documentation of the NDZ designation may be considered by the Authority to be all that is needed for a pollution assessment and pollution control for a mooring area to be classified as Conditionally Approved in the open status. The FDA does not consider the NDZ designation to be a sufficient standalone pollution assessment, control mechanism, or justification for classifying a mooring area as Conditionally Approved in the open status. As stated in the new

language, documentation, verification and enforcement of NDZ and locally well enforced no discharge and occupancy regulations or by-laws will be necessary in the assessment and for review in FDA evaluations.

In addition, Section 312 of the Clean Water Act (CWA) contains the principal framework for domestically regulating sewage discharges from boats and is implemented jointly by the U.S. Environmental Protection Agency (EPA) and the U.S. Coast Guard (USCG). "Sewage" is defined under the CWA as "human body wastes and the waste from toilets and other receptacles intended to receive or retain body wastes" and is prohibited in a NDZ. Graywater is not defined as "sewage" and is not prohibited under the NDZ. Graywater may contain high levels of human bacteria and viruses and pose a significant human health risk when present and this too should be considered in the pollution assessment. The FDA suggests that the guidance document mentioned in a) above include guidance for assessing "No Discharge Zones."

3. Areas Where There are Twenty (20) or Less Boats Moored: The FDA interprets the newly adopted language in Chapter IV@.06 for mooring areas, defined as *"any water area that is used to provide temporary or permanent anchorage for more than twenty (20) boats,"* as a component of the overall sanitary survey requirements in Chapter IV@.01. The sanitary survey currently requires an evaluation of all actual and potential pollution sources that may impact a shellfish growing area. As a fundamental premise, FDA considers every boat (boat, houseboat, barge, etc.) within a growing area to have the potential to discharge human waste and transmit pathogens; therefore, areas where there are 20 or less boats moored, still need to be evaluated as a potential pollution source and documented in the sanitary survey.

   Any congregation of boats, including those below the number required for the mooring area definition, must be assessed. In addition, the pollution assessment of mooring areas must be conducted during time of use, e.g. weekends, holidays, and times of peak usage (summer). This guidance should also be included in the guidance document mentioned in a) above.

4. FDA has identified additional places in the NSSP MO that should be

updated to include mooring areas.

- Section II Model Ordinance - Chapter I Shellfish Sanitation Program Shellfish Sanitation Program Requirements for the Authority

  @.03 Evaluation of Shellfish Sanitation Program Elements

  B. Criteria for evaluation of shellfish sanitation program elements shall be as follows:

  2. Growing Areas

  Requirements for evaluation of the shellfish growing area program element shall include at a minimum:

  a. Records audit of sanitary survey;

  b. Bacteriological standards;

  c. Growing area classification;

  d. Marine Biotoxin control; and

  e. Marinas

  f. Mooring Areas.

- Section II Model Ordinance - Chapter IV@.03C(3)(b)(i)

  When the conditional management plan is based on the absence of pollution from marinas and/or mooring areas 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.

- Section II Model Ordinance - Chapter IV@.03E(l)

  E. Prohibited Classification

  (1) Exception. The prohibited classification is not required for harvest waters within or adjacent to marinas and/or mooring areas. The Authority, however, may use the prohibited classification for these waters.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) Method for the Determination of Diarrhetic Shellfish Poisoning (DSP) Toxins in Shellfish.
Specific NSSP Guide Reference	Section IV. (Guidance Documents), Chapter II. (Growing Areas), Section .14 (Approved Laboratory Tests), Table 2 (Approved Methods for Biotoxin Testing) and Table 4 (Approved Limited Use Methods for Marine Biotoxin Testing)
Text of Proposal/ Requested Action	The intention is for this method to be an Approved Method for Marine Biotoxin Testing for clams and that it should appear in Section IV. (Guidance Documents), Chapter II. (Growing Areas), Section .14 (Approved Laboratory Tests), Table 2 (Approved Methods for Marine Biotoxin Testing) under the new heading: Biotoxin Type: Diarrhetic Shellfish Poisoning (DSP), and the applications should be (1) Growing Area Survey and Classification and (2) Controlled Relaying with the sample type of Shellfish for both. In addition, the method should also be included in Table 4 (Approved Limited Use Methods for Biotoxin Testing) for mussels and oysters. Additional validation will be submitted later in order to move mussels and oysters also to Table 2.
Public Health Significance	Method will be used to control hazard from Diarrhetic Shellfish Poisoning (DSP) in shellfish. No methods for DSP are currently listed in the NSSP yet shellfish harvesting closures have occurred due to these toxins in Texas since 2008, in the Pacific Northwest since 2011, and in the New England region since 2015. Regulatory laboratories in these regions are currently using best available science of LC-MS/MS according to the EU reference SOP for LC-MS/MS determination of lipophilic shellfish toxins.
Cost Information	Capital equipment purchases: $500,000. Consumable cost per sample: $10.00
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.
Action by 2017 Laboratory Committee	Recommended the following: 1) Adoption of Proposal 17-103 as an Approved Method for clams 2) Referral of Proposal 17-103 to an appropriate committee as determined by the Conference Chair to determine the appropriateness of the method for mussels and oysters.
Action by 2017 Task Force I	Recommended adoption of Laboratory Committee recommendations on Proposal 17-103.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-103.

Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-103.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 17-103 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 17-103.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 17-103.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-103.

Proposal No. 17-106

Submitter	Pacific Rim Shellfish Sanitation Association Sitka Tribe of Alaska Michael.jamros@sitkatribe-nsn.gov
Proposal Subject	Matrix Expansion for the Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination to Allow Use with Geoduck
Specific NSSP Guide Reference	Section IV, Chapter II.14 -- NSSP Approved Laboratory Tests (p. 261 Table 2. Approved Methods for Marine 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	
Action By 2017 Laboratory Committee	Recommended referral to an appropriate committee as determined by the Conference Chair.
Action By 2017 Task	Recommended adoption of the Laboratory Committee recommendation on

Force I	Proposal 17-106.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-106.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-106.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 17-106 to an appropriate committee as determined by the Conference Chairperson.
Action by 2019 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 17-106.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 17-106.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-106.

Proposal No. 17-108

Submitter	Titan Fan, Ph.D Beacon Analytical Systems, Inc. titan@beaconkits.com, holly@beaconkits.com
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.
Action By 2017 Laboratory Committee	Recommended referral of Proposal 17-108 to an appropriate committee as determined by the Conference Chair.
Action By 2017 Task Force I	Recommended adoption of the Laboratory Committee on Proposal 17-108.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-108.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-108.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 17-108 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 17-108.
Action by 2019 General Assembly	Adopted recommenda`tion of Task Force I on Proposal 17-108.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-108.

Proposal No. 17-110

Submitter	U.S. Food and Drug Administration (FDA) Melissa.abbott@fda.hhs.gov
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
Action By 2017 Laboratory Committee	Recommended Proposal 17-110 be referred to an appropriate committee as determined by the Conference Chair.
Action By 2017 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 17-110.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-110.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-110.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 17-110 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 17-110.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 17-110.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-110.

Proposal No. 17-115

Submitter	J. Michael Hickey, Margaret Barette, David Fyfe Massachusetts Division of Marine Fisheries, Pacific Coast Shellfish Growers Association, NWIFC Treaty Tribes Michael.hickey@state.ma.us, margaretbarrette@pcsga.org, dfyfe@nwifc.org
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
Action By 2017 Task Force I	Recommends referral of Proposal 17-115 to an appropriate committee as determined by the Conference Chair.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-114.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-114.
Action by 2019 Shellfish Reconditioning Committee	Recommended the adoption of Proposal 17-115 as amended: **Section II. Model Ordinance** **Chapter II. Risk Assessment & Risk Management** @.01 Outbreaks of Shellfish Related Illness 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~~ten (10) days of harvest, to the area from which it was harvested for an appropriate period of time. Environmental conditions in the harvest area must be conducive for pumping and feeding. The period of time shall not be less than ~~twenty one (21)~~thirtly-one (31) days. The Authority shall ensure appropriate controls and provide documentation of the activity.

Action by 2019 Task Force I

Recommended adoption of Proposal 17-115 as amended.

Section II. Model Ordinance
Chapter II. Risk Assessment & Risk Management

@.01 Outbreaks of Shellfish Related Illness 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 ten (10) days of harvest, to the area from which it was harvested for an appropriate period of time. Environmental conditions in the harvest area must be conducive for pumping and feeding. The period of time shall not be less than ~~thirtly-one (31)~~sixty (60) days. The Authority shall ensure appropriate controls and provide documentation of the activity.

Action by 2019 General Assembly

Adopted recommendation of Task Force I on Proposal 17-115.

Action by FDA February 21, 2020

Concurred with Conference action on Proposal 17-115.

Proposal No. 17-116

Submitter	U.S. Food and Drug Administration (FDA) 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
Action By 2017 Task Force I	Recommended adoption of Proposal 17-116 on an interim basis with a sunset date of November 1, 2021 and that during this period a committee be appointed to evaluate aquaculture activities in federal waters.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-116.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-116.
Actions by 2019 Federal Waters Committee	Recommended the adoption of the following proposals: 19-202,19-203, 19-214, 19-223, 19-228, 19-229, 19-120 The Committee was provided a task list developed by the Federal Waters Subcommittee which includes a number of regulatory actions necessary to provide a framework for incorporating shellfish from Federal Waters into the NSSP.
Action by 2019 Task Force I	Recommended Proposal 17-116 be referred to an appropriate committee as determined by the Conference Chairperson with further instruction to identify the specific sanitary survey criteria requirements to be used by FDA.

Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 17-116.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-116.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
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.

Action By 2017 Task Force I

Recommended referral of Proposal 17-121 to an appropriate committee as determined by the Conference Chair.

Action by 2017 General Assembly

Adopted the recommendation of Task Force I on Proposal 17-121.

Action by FDA February 7, 2018

Concurred with Conference action on Proposal 17-121.

Action by 2019 Overboard Discharge Committee

Recommended the adoption of Proposal 17-121 as amended:

Section II. Model Ordinance

Chapter VIII. Control of Shellfish Harvesting Requirements for Harvesters

.02 Shellstock Harvesting and Handling

D. 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 or available for the vehicle operator's use for the purpose of containing ~~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; 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. Transportation Requirements for Harvesters

.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 buys 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 or available for the vehicle operator's use for the purpose of containing ~~to contain~~ human sewage and bodily fluids. Portable toilets shall meet the requirements of VIII. .02. D. (3).

.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).

Action by 2019 Task Force I	Recommended adoption of Overboard Discharge Committee recommendation for Proposal 17-121.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 17-121.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-121.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Determining Emergency Conditions
Specific NSSP Guide Reference	Section I. Purposes and Definitions Section II. Model Ordinance Chapter IV @.03 A.(1)
Text of Proposal/ Requested Action	Section I. Purposes and Definitions

New Definition:

B.(39) **Emergency Conditions** means potential or actual pollution conditions which were not specifically represented in the sanitary survey information used to establish the classification and support the status of a shellfish growing area. Emergency conditions include, but are not limited to, tropical storms, hurricanes, sewage spills, oil spills, poisonous or deleterious substance spills, excessive rainfall, and flooding events.

Chapter IV @.03 A.(1):

(1) Emergency Conditions. A growing area shall be placed in the closed status under Section @.03A. (5) when ~~pollution conditions exist which were not included in the database used to classify the area~~ emergency conditions exist. The Authority shall:

(a) Develop a written emergency conditions protocol defining the thresholds and criteria used to determine if emergency conditions exist, including defining what conditions would trigger a growing area closure, and how to reopen a growing area once the emergency conditions no longer exist. The thresholds and criteria used to determine if emergency conditions exist, shall be based on the potential or actual pollution conditions which were not specifically represented in the sanitary survey information or database used to establish the classification and support the status of a shellfish growing area. These potential or actual pollution conditions may include, but are not limited to, tropical storms, hurricanes, sewage spills, oil spills, poisonous or deleterious substance spills, excessive rainfall, and flooding events;

(b) Make a determination within 24 hours of a potential emergency condition event as to whether conditions exceed the established thresholds and criteria defined in the emergency conditions protocol and maintain a written record of the determination assessment;

(c) Notify FDA and ISSC of the determination within 24 hours;

(d) Once it is determined that an emergency condition exists, ~~If it is determined that an emergency condition or situation exists, then the growing area will be~~ immediately (within 24 hours) ~~placed in the closed status.~~ place the growing area in the closed status;

(e) If a determination cannot be made within 24 hours, notify FDA and ISSC and immediately place the growing area in the closed status;

(f) If the growing area is closed due to a precautionary closure and a determination is later made that the growing area did not experience emergency conditions based on the established protocol, the area may be immediately re-opened. The determination shall be documented in a written report and included in the sanitary survey for the area; and

~~(e)~~(g) If the growing area is closed due to emergency conditions, prior to re-

opening, conduct an assessment of the growing area based on the established protocol and field observations and document the results in a written report to be included in the sanitary survey. Field observations include, but are not limited to, observations of actual or potential pollution sources made via shoreline survey, boat survey, sample collection, and/or analysis of sample results. The assessment shall include documentation of any new pollution sources and their effect on the growing area.

Public Health Significance	Current Model Ordinance language in Chapter IV states "If it is determined that an emergency condition or situation exists…", but does not specify the circumstances under which a determination must be made by the Authority. It will not be clear to a state Authority that pollution conditions exist which were not included in the data used to classify a growing area unless the Authority decides to check the data within the sanitary survey and perform an assessment in a situation which has the potential to meet emergency conditions. Not all Authorities do this in all situations that have the potential to meet "Emergency Conditions" under NSSP MO @.03 A.(1), such as excessive rainfall events with higher rainfall totals that what's recorded in the Authority's database. Additionally, the current language for "Emergency Conditions" does not clearly define "pollution conditions" or "the database used to classify the area". The "database" could be referring to the most recent 12 year sanitary survey or to all of the data ever collected for a growing area or to the most recent 30 water quality samples – it is not clear. In some instances, this has led to disagreements between FDA and state Authorities as to when a growing area needs to be closed due to emergency conditions, such as in the event of a tropical storm with rainfall levels or river stage levels which may or may not exceed the levels in the state's database. Since emergency conditions have the potential to significantly impact the water quality of a growing area and could lead to human fecal contamination, petroleum contamination, or poisonous or deleterious substance contamination in the area and possible shellfish-borne illnesses, it is important to clarify the definition of "Emergency Conditions".
Cost Information	Minimal Cost
Action by 2019 Task Force I	Recommended no action on Proposal 19-100. Issues are already addressed in the Model Ordinance.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-100.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-100.

Proposal No. 19-101

Submitter	Michael Hickey, Jeff Kennedy, Diane Regan Michael.hickey@mass.gov
Proposal Subject	Conditionally Conforming Laboratory Status
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority @.03 B. 1. b. Section II. Model Ordinance Chapter III. Laboratory @.01 Section II. Model Ordinance Chapter XV. Depuration .03 J. (4)
Text of Proposal/ Requested Action	The requested action is to create a NSSP laboratory status of conditionally conforming. This status is based on a demonstrated proficiency of laboratory method performance. Laboratories that are found to conditionally conform for a laboratory analysis may support the NSSP.

MO Chapter 1.@.03 B. 1. b.

v. Performance Evaluation: Conditionally Conforms. Tto be deemed conditionally conforming under the NSSP, a laboratory must meet one of the following laboratory performance criteria:
(a) Complete an appropriate ISSC Accepted SLV; or
(b) Complete a Method Verification Study, Section IV. Chapter II. .20 that successfully transfers; or
(c). Successfully complete a proficiency and/or inter-laboratory study approved by the FDA Shellfish LEO or State certified Shellfish LEO.
(d) This laboratory status will remain in effect until an technical FDA Shellfish LEO or FDA certified State Shellfish LEO Evaluation occurs as in @.03 B.

MO Chapter III. @.01 Quality Assurance

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

MO Chapter XV. .03 J. (4)

(a) Are analyzed by a laboratory which has been evaluated and found to conform or conditionally conform to the NSSP pursuant to the requirements in Chapter III, using an NSSP-Approved Method;

Public Health Significance	A technical Laboratory evaluation, as outlined in MO Chapter 1.@.03B.1.b.ii, is conducted to verify that conditions are present *in the laboratory* which **should** result in the accurate outcome of method data. A performance evaluation **verifies** that the method data produced *by the laboratory and for all analysts* is accurate. A technical evaluation does not examine the quality of a laboratory's method data for validity, standardization or for individual analysts. If a laboratory has successfully passed a proficiency study, SLV or MV, and statistically confirmed method data results, the laboratory can be assumed to have technically performed the method correctly. Under current interpretation a laboratory may have completed and had accepted by the conference a method SLV with accompanying checklist yet not be able to support the NSSP with data until a FDA Shellfish LEO or FDA certified State Shellfish LEO conducts a technical inspection at their laboratory using the laboratory's own checklist. If a laboratory has proven its

ability to perform a method, then the laboratory should be able to conditionally support the NSSP with data.

A cooperative goal of the NSSP, FDA and the SSCA is to assure that a laboratory's data is accurate, verified and standardized. Method based performance evaluations confirm data which results in standardization across laboratories. Method based performance evaluations statistically verify data accuracy. Performance Evaluations therefore support the legal defensibility of the laboratory's Laboratory Quality Management System.

Cost Information	Cost of conducting SLV, MV or Proficiency Participation
Action by 2019 Laboratory Committee	Recommended no action on Proposal 19-101. Rationale: This issue is addressed by Proposal 19-301.
Action by 2019 Task Force I	Recommended adoption of Proposal 19-101 as submitted.
Action by 2019 General Assembly	Recommended referral of Proposal 19-101 to an appropriate committee as determined by the Conference Chair.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-101.

Proposal No. 19-105

Submitter	Scott Berbells Washington State Department of Health Scott.Berbells@doh.wa.gov
Proposal Subject	Laboratory approval for sample analysis with no Model Ordinance defined method or action level
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter III. Laboratory @.01 Quality Assurance (A)
Text of Proposal/ Requested Action	Chapter III. @.01 A. NSSP Conformance Required~~. for all laboratories supporting the NSSP~~. All laboratory analyses for compliance with classification requirements that require a specific method, actions level, and use defined in the Model Ordinance shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish LEO or FDA certified State Shellfish LEO in accordance with the requirements established under the NSSP.
Public Health Significance	This proposed amendment to Chapter III, @.01 (A) updates the requirement related to the use of data analyzed by a laboratory that has not been certified by the FDA Shellfish LEO or FDA certified State Shellfish LEO and potentially used for regulatory purposes. The amendment allows state shellfish authorities to use non FDA approved laboratories when methods and action levels have not been defined in the Model Ordinance. Washington state has developed an extensive array of partnerships aimed at evaluating pollution conditions around shellfish growing areas primarily related to microbiological conditions and remediating any impacts identified. Local and state government agencies, tribes, and wastewater treatment plant operators collect data that may be used by the Shellfish Authority to manage the status of shellfish harvesting areas. Sampling activities from sewage spills, agricultural manure discharges, failing septic systems, and treatment loss at wastewater treatment plants have resulted in temporary closures of harvest areas. In turn, data collected from partner agencies has been used to identify when the pollution issue has been resolved and when the growing area can be opened. All sample analysis is completed by laboratories inspected by state regulatory agencies but have not evaluated for conformance by the FDA Shellfish LEO or FDA certified State Shellfish LEO. Washington state periodically uses laboratory analysis to determine if shellfish and shellfish harvesting areas are impacted by poisonous and deleterious substances. Shellfish closures or consumption advisories may be implemented based on this data. There are currently no laboratories approved by FDA Shellfish LEO for the analysis of poisonous and deleterious substances. The proposal assures that an FDA approved laboratory is required when laboratory

methods and action levels are defined in the Model Ordinance and data may be used for regulatory action (marine water quality, marine biotoxins, Male Specific Coliphage).

This proposal will give state shellfish authorities the flexibility to adapt to ongoing environmental conditions and make appropriate public health decisions based on laboratory data.

Cost Information	
Action by 2019 Task Force I	Recommended referral of Proposal 19-105 to an appropriate committee as determined by the Conference Chair
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-105.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-105.

Proposal No. 19-106

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Delete Notification Requirement to Pollution Control Agencies
Specific NSSP Guide Reference	Section II Model Ordinance Chapter IV Shellstock Growing Areas @.01
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 microbiological quality of the water. In growing areas adjacent to waste water system discharge (WWSD)s the Authority may utilize male specific coliphage (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 are 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)~~(4) The Authority shall maintain a current comprehensive, itemized list of all growing areas, including maps showing the boundaries and classification of each shellstock growing area.
Public Health Significance	This requirement does not have public health significance.
Cost Information	
Action by 2019 Task Force I	Recommended adoption of Proposal 19-106 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-106.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-106.

Proposal No. 19-107

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Determining shoreline survey area.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.01 Sanitary Survey D.(1) and (2)(a).
Text of Proposal/ Requested Action	(1) In the shoreline survey for each growing area, the Authority shall: (f) Conduct an in-field assessment of pollution sources which may include: (i) A drive-through survey; (ii) Observations made during sample collection; and/or (iii) Information from other sources. (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~~ that shall include, but not limited to, all properties with the potential to impact the shellstock growing area based on area topography, as well as field observations, and other sources of information;
Public Health Significance	The minimum requirements of the shoreline survey include an investigation and evaluation of pollution sources by trained, qualified, personnel. The investigation must be accomplished through an in-field assessment where the surveyor identifies actual and potential sources of pollution that might influence water quality. Given the technology available today, there are mutltiple options for identifing properties with the potential to impact growing areas. The Authority can define the shoreline survey area boundry by using various data resources such as geoprapohic information such as on-line maps. Using the term “only” as it is used in the existing language is confusing and, if taken literally, limiting. Example: One property two miles from the growing contains a large wastewater treatment plant that has the potential to impact shellfish waters. Another property one- and one-half miles from the growing area between that growing area and the property with the wastewater treatment plant on it has no identifiable pollution sources on it so that it does not have potential to impact shellfish waters. If the shoreline survey area is defined as a single area that includes the property with the wastewater treatment plant, it will also include the property with no identifiable pollution sources on it. Thus, it will not be an area that has “only” the properties with potential to impact the shellfish waters in it.
Cost Information	No cost.
Action by 2019 Task Force I	Recommended adoption of Proposal 19-107 as amended. (1) In the shoreline survey for each growing area, the Authority shall: (f) Conduct an ~~in-field~~ assessment of pollution sources which may include: (i) A drive-through survey; (ii) Observations made during sample collection; ~~and/or~~ ~~(ii)~~(iii) Other in-field assessments; and/or

~~(iii)~~(iv) Information from other sources.

(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

Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-107.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-107.

Proposal No. 19-108

Submitter	Robert Rheault ECSGA bob@ECSGA.org
Proposal Subject	Aquaculture Seed Shellstock
Specific NSSP Guide Reference	Section II Model Ordinance, Chapter VI. Shellfish Aquaculture, Requirements of the Authority @.02
Text of Proposal/ Requested Action	**@ .02 Seed Shellstock** A. The Authority shall establish the maximum seed size for each species of shellfish that can be produced in prohibited waters. In determining the maximum seed size Authorities shall establish sizes that require a minimum of 60~~120~~ days of growing with water temperatures over 50 degrees F to reach market size. B. For states that have not established a minimum market size, the Authority shall establish record-keeping protocols to track seed sourced from prohibited waters to ensure seed have at least 60 days of growing with water temperatures above 50 degrees F before sale for human consumption. C. ~~B.~~ The Authority shall establish appropriate corrective actions for ~~when~~ seed that exceeds the maximum seed size when it is being cultured in ~~has been produced in~~ waters classified as prohibited. D. ~~C.~~ All sources of seed produced or collected in prohibited waters shall be sanctioned by the Authority.
Public Health Significance	Existing language does not describe how the Authority should establish maximum seed size in states that have no minimum market size. Further the existing language does not require that shellfish from prohibited waters are held in waters above 50 degrees to ensure that the animals are metabolically active. Shellfish seed collected or cultured in prohibited waters have been shown through repeated sampling not to accumulate heavy metals at levels that exceed EPA alert levels. (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 bacterial contaminants provided water temperatures are high enough to maintain active metabolic activity (above 50 degrees F or 10 degrees C) (Richards 1988). Several studies have demonstrated that viral contamination in relayed or depurated shellfish is reduced to non-detect levels in 30-40 days (McLeod et. al. 2017 and Choi and Kingsley 2016). The Authority has the option to deny seed culture in any area, or to require additional testing for deleterious substances, or to require longer purge periods as they deem necessary based on potential sources of contaminants. References Cited: Richards, G. (1988), Microbial Purification of Shellfish: A Review of Depuration and Relaying, J. Food Protection 51(3)218-251. C. McLeod et. al. (2017) Depuration and Relaying: A Review on Potential Removal of Norovirus from Oysters. Comprehensive Reviews in Food Science and Food Safety, Vol.16, pp. 692-706 Choi, C. and D. H. Kingsley. Temperature-Dependent Persistence of Human Norovirus within Oysters (Crassostrea virginica). Food and Environmental

Virology, 8:141-147. 2016.

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	Proposal would not impact the enforcement costs for the authority and would simplify management for growers.
Action by 2019 Task Force I	Recommended referral of Proposal 19-108 to an appropriate committee as determined by the Conference Chairperson.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-108.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-108.

Proposal No. 19-109

Submitter	Jill Fleiger Department of Agriculture and Consumer Services Jillian.Fleiger@freshfromflorida.com
Proposal Subject	Offshore State Water classification requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.02
Text of Proposal/ Requested Action	**@.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, an Authority may wish to adopt the use of both standards and both sampling strategies for each standard. This codification represents the fecal coliform standards. Additionally, the Authority may choose to use MSC sample data in conjunction with total or fecal coliform data to evaluate areas impacted by WWSD. A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area. The Authority may utilize MSC data in conjunction with bacteriological data to evaluate WWSD impacts on shellfish growing areas. B. Water Sample Stations. The Authority shall assure that the number and location of sampling stations is adequate to effectively evaluate all pollution sources. C. Exceptions. (1) Except for growing areas classified as prohibited, in growing areas where there are pollution sources having an impact on the water quality, a minimum of thirty (30) samples, collected under various environmental conditions, shall be required to classify any growing area not previously classified under Section @.03. (2) Except for growing areas classified as prohibited or when the systematic random sampling standard is applied, in growing areas where there are no pollution sources having an impact on the water quality, a minimum of fifteen (15) samples shall be required to classify any growing area not previously classified under Section @.03. (3) Except for offshore state waters where a sanitary survey shows that there are no pollution sources that will impact the microbiological quality of the water. Offshore state waters are classified as approved.
Public Health Significance	State waters extend 9 miles off shore of the State of Florida. If a sanitary survey can show there are no pollution impacts (ie. Rivers, WWTPs discharges) to proposed areas for aquaculture the required 30 samples to classify should not be required.
Cost Information	This would reduce the cost and burden to state authorities having to sample waters that are far removed from any potential pollution sources.

Action by 2019 Task Force I

Recommends adoption of Proposal 19-109 as amended

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, an Authority may wish to adopt the use of both standards and both sampling strategies for each standard. This codification represents the fecal coliform standards. Additionally, the Authority may choose to use MSC sample data in conjunction with total or fecal coliform data to evaluate areas impacted by WWSD.

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

B. Water Sample Stations. The Authority shall assure that the number and location of sampling stations is adequate to effectively evaluate all pollution sources.

C. Exceptions.

(1) Except for growing areas classified as prohibited, in growing areas where there are pollution sources having an impact on the water quality, a minimum of thirty (30) samples, collected under various environmental conditions, shall be required to classify any growing area not previously classified under Section @.03.

(2) Except for growing areas classified as prohibited or when the systematic random sampling standard is applied, in growing areas where there are no pollution sources having an impact on the water quality, a minimum of fifteen (15) samples shall be required to classify any growing area not previously classified under Section @.03.

(3) Except for offshore state waters greater than three (3) nautical miles from shore where a sanitary survey shows that there are no pollution sources that will impact the microbiological quality of the water. Offshore state waters greater than three (3) nautical miles from shore ~~are~~ may be classified as approved.

Action by 2019 General Assembly

Adopted recommendation of Task Force I on Proposal 19-109.

Action by FDA February 21, 2020

Concurred with Conference action on Proposal 19-109.

Proposal No. 19-110

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Point source approved standard station locations.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.02 Microbiological Standards E.(3)(c).
Text of Proposal/ Requested Action	(c) Sample station locations shall be adjacent to actual or potential sources of pollution and adequate in terms of number and spatial distribution to support the conclusion that the growing area is characterized by water quality meeting the approved classification bacteriological requirements.
Public Health Significance	Stations in waters classified as approved are frequently not adjacent to pollution sources. Stations represent a miniscule portion of points within a growing area. The stations should be located so that it is reasonable to believe that, if a station were established at any point in the area where no station currently exists, that new station would yield bacteriological data meeting the relevant bacteriological standard consistent with the classification.
Cost Information	No cost.
Action by 2019 Task Force I	Recommended referral of Proposal 19-110 to an appropriate committee as determined by the Conference Chairperson.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-110.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-110.

Submitter	Scott Berbells Washington State Department of Health Scott.Berbells@doh.wa.gov
Proposal Subject	Allowing the use of the SRS method in areas impacted by point sources
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.02E; Chapter IV. Shellstock Growing Areas @.02F; Chapter IV. Shellstock Growing Areas @.02F(2)(b); Chapter IV Shellstock Growing Areas @.02G; and Chapter IV. Shellstock Growing Areas @.02H
Text of Proposal/ Requested Action	Chapter IV, @.02 E. Standard for the Approved Classification of Growing Areas ~~Affected by Point Sources~~ when Evaluated for Adverse Pollution Conditions. Chapter IV, @.02 F. Standard for the Approved Classification of Growing Areas ~~Affected by Nonpoint Sources~~ when Evaluated for Nonpoint Sources. (1) Exception. If the tidal stage increases the fecal coliform concentration, the authority shall use sample results collected during that tidal stage to classify the area. (2) Pollution Sources. Growing areas shall be~~:~~ ~~(a)~~ Impacted only by randomly occurring, intermittent events~~; and~~ ~~(b) Not impacted by discharges from sewage treatment facilities or combined sewer overflows.~~ Chapter IV, @.02 G. Standard for the Restricted Classification of Growing Areas ~~Affected by Point Sources~~ when Evaluated for Adverse Pollution Conditions and Used as a Shellstock Source for Shellstock Depuration. Chapter IV, @.02 H. Standard for the Restricted Classification of Growing Areas ~~Affected by Nonpoint Sources~~ when Evaluated for Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration
Public Health Significance	This proposed amendment to Chapter IV, @.02 updates the conditions under which the APC and SRS methods may be used. The proposal allows the use of the SRS method in areas impacted by discharges from sewage treatment facilities or combined sewage overflows where marine water stations have been placed to monitor nonpoint pollution. The intent of this proposal is to use the sampling methodology and statistical analysis most acceptable for the purpose of the marine water sampling station. If the station is placed to monitor nonpoint pollution, the SRS methodology should be used. If the station is placed to monitor adverse pollution conditions, the APC methodology should be used. In Washington state, marine water stations located in Conditionally Approved areas

impacted by wastewater treatment plants are placed to monitor nonpoint pollution from the surrounding upland areas. The APC criterion is used to sample and evaluate data from these stations with the adverse condition defined as an upset at the treatment plant. Many wastewater treatment plants are high performing and upset conditions occur infrequently. The infrequency of the impact to the growing area does not allow for the intended use of the APC sampling strategy.

Hydrographic studies and dilution analyses are more appropriate for the evaluation of the impact area around high performing wastewater treatment plants.

Cost Information	No impact
Action by 2019 Task Force I	Recommended adoption of Proposal 19-111 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-111.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-111.

Proposal No. 19-112

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Nonpoint source approved standard station locations.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.02 Microbiological Standards F.(6)(b)(i).
Text of Proposal/ Requested Action	(i) Sample station locations ~~are~~ shall be adequate ~~to produce the data to effectively evaluate all nonpoint sources of pollution~~in terms of number and spatial distribution to support the conclusion that the growing area is characterized by water quality meeting the approved classification bacteriological requirements;
Public Health Significance	The Model Ordinance Chapter IV.@.02B indicates "The Authority shall assure that the number and location of sampling stations is adequate to effectively evaluate all pollution sources." That includes all nonpoint sources of pollution so there is no need to state that requirement within IV.@.02F. Stations represent a miniscule portion of potential points within a growing area. The stations should be located so that it is reasonable to believe that, if a station were established at any point in the area where no station currently exists, that new station would yield bacteriological data meeting the relevant bacteriological standard consistent with the classification.
Cost Information	No cost.
Action by 2019 Task Force I	Recommended referral of Proposal 19-112 to an appropriate committee as determined by the Conference Chairperson
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-112.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-112.

Proposal No. 19-113

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Authorizing unclassified areas and multiple classifications for single area.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.03 Growing Area Classification A.(2).
Text of Proposal/ Requested Action	(2) Classification of ~~All~~ Growing Areas. ~~All~~ Each growing ~~areas~~area which: (a) ~~Are~~ Is not subjected to a sanitary survey every twelve (12) years shall be classified as prohibited or, if unclassified, shall be treated as prohibited for NSSP purposes; or ~~(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~~ (b~~e~~) ~~Are~~ Is subjected to a sanitary survey shall be correctly classified based on the twelve (12) year sanitary survey, and its most recent triennial or annual reevaluation when available, as ~~only~~ one or more~~(1)~~ of the following: (i) Approved; (ii) Conditionally Approved; (iii) Restricted; (iv) Conditionally Restricted; and/or (v) Prohibited.
Public Health Significance	There is no reason to require that all growing areas be classified if the Authority is required to treat unclassified areas as prohibited areas. The current Section II. Chapter IV.@.03A.(2)(b) language is unnecessary. Requiring that each growing area be characterized by only one classification is not realistic and does not reflect common practice. There are many circumstances in which one growing area contains several classifications. Example: A 10 square mile growing area is generally classified as approved. However, there is a marina in it, so some waters associated with that marina are classified as prohibited and restricted. There is a business with a 5,000 gallon per day wastewater treatment system discharging along the shoreline so there is a prohibited zone adjacent to that point source. That circumstance literally represents violation of Chapter IV.@.03A.(2)(c) as that requirement now reads because there are multiple classifications within a single growing area.
Cost Information	No cost.
Action by 2019 Task Force I	Recommended adoption of Proposal 19-113 as amended. 2) Classification of ~~All~~ Growing Areas. Each growing area which: (a) Is not subjected to a sanitary survey every twelve (12) years shall be classified as prohibited or, if unclassified, shall be treated as prohibited for NSSP purposes; or

(~~b~~c) Is subjected to a sanitary survey shall be correctly classified based on the twelve (12) year sanitary survey, and its most recent triennial or annual reevaluation when available, as one or more of the following:

(i) Approved;
(ii) Conditionally Approved;
(iii) Restricted;
(iv) Conditionally Restricted; and/or
(v) Prohibited.

Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-113.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-113.

Proposal No. 19-114

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Emergency Conditions re-opening studies.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.03 Growing Area Classification A.(5)(c)(i).
Text of Proposal/ Requested Action	(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. When pathogens are of concern, ~~S~~studies establishing sufficient elapsed time shall document the interval necessary for reduction of ~~contaminant~~ coliform levels in the shellstock to pre-closure levels. ~~In addressing pathogen concerns, the~~ Such coliform studiesmay establish criteria for reopening based on coliform levels in the water. When poisonous or deleterious substances are the concern, studies shall establish that poisonous or deleterious substances in shellstock do not exceed FDA action levels, tolerances and/or guidance levels and/or levels that are deemed safe through risk evaluation; or
Public Health Significance	National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, Section IV Guidance Documents, Chapter II Growing Areas, .08 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood contains target levels for many poisonous or deleterious substances. Target levels for other substances can be established through risk evaluation. The 2010 Deepwater Horizon crisis provides an example of how emergency conditions involving poisonous or deleterious substances are addressed in practice. Levels of concern were established through risk evaluation then areas were re-opened based on determining that contaminant levels were below levels of concern rather than based on comparisons between pre and post closure levels.
Cost Information	Cost would potentially be reduced because studies to compare post closure levels of poisonous or deleterious substances to pre closure levels would no longer be required.
Action by 2019 Task Force I	Recommended adoption of Proposal 19-114 as amended. (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. When pathogens are of concern, studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. Such coliform studiesmay establish criteria for reopening based on coliform levels in the water. When poisonous or deleterious substances are the concern, ~~studies~~ sampling shall establish that poisonous or deleterious substances in shellstock do not exceed FDA action levels, tolerances and/or guidance levels and/or levels that are deemed safe through risk evaluation; or
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-114
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-114.

Proposal No. 19-115

Submitter	Kathy Brohawn Maryland Department of Environment Kathy.brohawn@maryland.gov
Proposal Subject	Emergency Conditions/closed status to reflect Chapter II use of harvest area
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.03 Growing Area Classification A. General (1) and (5)
Text of Proposal/ Requested Action	@.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. A growing area or a portion of a growing area (harvest area) shall be placed in the closed status under Section @.03 A. (5) when unpredicted pollution conditions exist ~~which were not included in the database used to classify the area~~. If it is determined that an emergency condition or situation exists, then the growing area or harvest area will be immediately (within twenty-four (24) hours) placed in the closed status.

(a) If the growing area or harvest area is already closed due to resource conservation under existing fishery laws or regulation, the area is considered to be in the closed status. If the authority choses to uses this approach, an MOU detailing coordination and, communication between agencies and patrol shall be required.

~~(a)~~(b) If no harvest areas are impacted by Emergency Conditions, placement into the closed status is not required.

(2)……..
(3).....
(4)……

(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. Supporting information for all changes in the status of growing areas shall be documented by a written record in the central file.

(a) Open Status. Except for an area in the prohibited classification, any correctly classified growing area is normally open for the purposes of harvesting shellstock, subject to the limitations of its classification.

(b) Closed Status. Any classified growing area or harvest area may be closed for a limited or temporary period because of:

(i) An emergency condition or situation;
(ii) The presence of biotoxins in concentrations of public health significance;
(iii) Conditions stipulated in the management plan of conditionally approved or conditionally

restricted areas;

(iv) Failure of the Authority to complete a written sanitary survey or triennial review evaluation report; or

(v) The requirements for biotoxins or conditional area management plans as established in Section @.04 and Section @.03, respectively, are met.

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

Public Health Significance	Closed status following an emergency situation can include an entire growing area or a harvest area within the growing area; This change is consistent with Chapter II where, if appropriate, only a harvest area is closed due to an outbreak and not necessarily the entire growing area. In addition, the text stating conditions that were not included in the data base makes no sense related to emergency conditions and actually state the obvious. Deletion of that statement clarifies this part of the MO.
Cost Information	There should be no need to close an area that has no shellfish resource or is already closed by existing regulation. If this proposal is accepted by the Conference, it would save money for any state that is required to post closures in the newspaper (public notice); For Maryland the cost is ~$1500, so it would represent a significant savings.
Action by 2019 Task Force I	Recommended referral of Proposal 19-115 to an appropriate committee determined by the Conference Chair
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-115.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-115.

Proposal No. 19-116

Submitter	J. Michael Hickey Massachusetts Division of Marine Fisheries Michael.hickey@mass.gov
Proposal Subject	Adding a time frame to the limited or temporary period an area can be remain under a closed status prior to being reclassified.
Specific NSSP Guide Reference	Section II, Model Ordinance Chapter IV. Shellstock Growing Areas @.03 Growing Area Classification A. (5) (b).
Text of Proposal/ Requested Action	(b) Closed Status. Any classified growing area may be closed for a limited or temporary period, not to exceed more than one year prior to a reclassification because of: (i) An emergency…; (ii) The presence…; (iii) Conditions stipulated…; (iv) Failure of…; or (v) The requirements….
Public Health Significance	The M. O. Chapter IV @.03 A. (5) (b) states that any classified growing area may be closed for a limited or temporary period because of: (i) through (vi). The time frame "limited or temporary period "is not defined in the "Guide". The authority is required by @.03 A. (1) to place a growing area in the closed status ..." under Section @.03 A. (5) when pollution conditions exist which were not included in the database used to classify the area. If it is determined that an emergency condition or situation exists, then the growing area will be immediately (within 24 hours) placed in the closed status." Once the area is in the closed status, harvesting, attempting to harvest, possession, or sale of shellfish from the closed area is prohibited. A time limit of up to but not to exceed one year from the time the area was placed in the closed status allows the authority time with defined maximum to determine the source /cause(s) of a pollution or contamination problem before initiating a reclassification while still protecting public health by virtue of the area being in a closed status. The proposed change will not lessen public health protection.
Cost Information	Does not add any cost and may actually save administrative cost by averting multiple reclassifications in the process of sorting out the final correct classification.
Action by 2019 Task Force I	Recommended referral of Proposal 19-116 to an appropriate committee as determined by the Conference Chairperson.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-116.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-116.

Proposal No. 19-117

Submitter	J. Michael Hickey Massachusetts Division of Marine Fisheries Michael.hickey@mass.gov
Proposal Subject	Shellfish cleansing studies
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.03 Growing Area Classification. C. Conditional Classifications. (2) (c) (iii)
Text of Proposal/ Requested Action	(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. If the conditional management plan is based on effects of non-point sources of pollution such as rain events and /or storm water runoff, an area can be reopened 48 hours after the water quality has met acceptable classification criteria as long as shellstock are actively feeding.
Public Health Significance	There are a number of problems related to the current M. O. language." There is no guidance or criteria in the Guide concerning what constitutes an adequate study. There are a number of study related questions: 1) How many shellfish samples of each species of shellfish and sampling stations (locations) are needed in a growing area; 2) Are studies required in every conditional area? 3) can information obtained in one growing area be applied to shellstock in another growing area? 4) The first sentence at (iii) refers "*to reducing pathogens...to acceptable levels*", what are acceptable levels of pathogens. The second sentence at (iii) refers to *reduction of coliform levels in shellstock to pre-closure levels*. Pre-closure levels in shellstock can be variable both temporally and spatially. Thus the concept of reducing coliforms to pre-closure levels is at best ambiguous. In order to obtain the required data, there is a sampling and laboratory burden. This requires time consuming shellstock sampling during open periods and again after pollution events over the year as well as increased laboratory effort to establish a data base. Shellfish samples require two lab days thus reducing lab capacity to handle water samples. In the 1980's and early 1990's Massachusetts and other states sampled shellstock one or two days after water in Conditionally Approved areas reached the criteria for an Approved classification to ensure that the shellstock was well below the then existing NSSP 230 FC market standard. Usually 150 FC or less was considered adequate to reopen because there was no actual coliform harvest standard and it made sense to only allow harvest well below the market standard. This reduction was accomplished within two days or less of the water quality returning to acceptable levels. This approach compared coliform levels in shellfish after water quality reached acceptable levels to an existing standard. When this policy was established, it was endorsed by the FDA Shellfish Specialist. \Shellstock can accumulate bacteria up to 100 times the level in the water. In theory shellstock in water at geometric mean of 10 FC per 100 ml could accumulate FC bacteria to a level of 1000 FC per 100 g. Thus opening an area at a level below the former 230 FC market standard would seem appropriate. Two day purging time is well established. Literature supports elimination of greater

	than 95% of FC bacteria from shellstock in less than 24 hours including NSSP workshop studies. Temperature is the most important factor affecting elimination of bacteria because it governs shellfish feeding activity. Naturally contaminated shellfish can eliminate fecal coliform levels in 48 hours to levels below most market standards over a range of environmental conditions (Perkins, et al, 1979). Other studies show that soft –shelled clams at MPN 10,000 FC /100 g reduced to values below 50 in 48 hours (Arcisz, et al, 1955) and oysters at MPN 39,000FC/1000g can purge to values below 50 in 48 hours.
Cost Information	Could produce significant savings to state shellfish classification programs.
Action by 2019 Task Force I	Recommended adoption of Proposal 19-117 as amended. (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. If the conditional management plan is based on effects of non-point sources of pollution such as rain events and /or storm water runoff, an area can be reopened ~~48 hours after~~when the water quality ~~has met~~meets ~~acceptable~~ classification criteria without a cleansing study.~~ as long as shellstock are actively feeding~~
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-117.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-117.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Conditional areas not based on predicting microbiological indicator levels.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.03 Growing Area Classification C.(1).
Text of Proposal/ Requested Action	(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 the~~is~~ period the growing area is in open status are known and ~~, 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) When conditional management is based at least in part on predicted changes in microbiological water quality,~~M~~microbiological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area; and (d) For Authorities utilizing MSC meat sample data, when conditional management is based at least in part on predicted changes in MSC levels, those~~is~~ data correlate~~s~~ with environmental conditions or other factors affecting the distribution and persistence of viral contaminants into the growing area.
Public Health Significance	Not all conditional management is based on predicted changes in microbiological water quality. Conditional management can be based, for example, on the operation of a wastewater treatment system that has never failed. In such a circumstance, demonstrating correlation with environmental conditions or other factors may play no role. The plan can be based completely on other means of predicting the impact of plant failure. Conditional management can also be based on changes in marina occupancy. Similarly, the Authority may use MSC data in some way to support conditional management without demonstrating correlation between MSC levels in shellfish tissues and environmental conditions or other factors.
Cost Information	No cost.
Action by 2019 Task Force I	Recommended adoption of Proposl 19-118 as amended. 1) Survey Required. The sanitary survey meets the following criteria: (a) The factors determining the~~is~~ period the growing area is in open status are known and predictable ~~and are not so complex as to preclude a reasonable management approach as determined by the Authority;~~ (b) Each potential source of pollution that may adversely affect the growing area is evaluated; (c) When conditional management is based at least in part on predicted changes in microbiological water quality,microbiological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area; and (d) For Authorities utilizing MSC meat sample data, when conditional management is based at least in part on predicted changes in MSC levels,

	those data correlates with environmental conditions or other factors affecting the distribution and persistence of viral contaminants into the growing area.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-118.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-118.

Proposal No. 19-119

Submitter	Scott Berbells Washington State Department of Health Scott.Berbells@doh.wa.gov
Proposal Subject	Reduced marine water sampling in conditionally approved areas impacted by point sources
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.03 Growing Area Classification C3. Reevaluation of Conditional Classification(b)(ii)
Text of Proposal/ Requested Action	Section II Model Ordinance Chapter IV Shellstock Growing Area @.03 Growing Area Classification C3. Reevaluation of Conditional Classification (b) Water Sample Collection (ii) When the conditional management plan is based on the operation and performance of a WWSD (s); combined sewer overflows(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 except when: (a) Hydrographic or dilution analysis has been completed to determine the impact of a performance failure; and (b) Communication requirements are documented and the WWSD operator provides immediate notification to the Shellfish Authority during a performance failure.
Public Health Significance	This proposed amendment to Chapter IV, @.03C3(b)(ii) updates the requirements related to the monthly sampling requirement in Conditionally Approved areas classified based on the operation and performance of a WWSD, combined sewer overflow, or other point source. The proposal allows the Shellfish Authority to reduce the number of marine water samples in the area from monthly to five or six times per year, based on the sampling methodology used, if additional studies and appropriate communication channels have been developed. Based on the high performance of many treatment plants, upset conditions occur infrequently and are not evaluated through the placement of permanent marine water sampling stations. Dye and drogue studies coupled with computer modelling are commonly used to determine the potential impact from a point source of pollution on the growing area and are used to calculate the dilution available throughout the area. In Washington state, all NPDES permits issued to wastewater treatment plants contain requirements for operators to provide immediate notification to the Shellfish Authority during upset conditions. Failure of the operator to respond in a timely fashion could result in a significant penalty. Upset conditions impacting Conditionally Approved shellfish growing areas in Washington State are infrequent; however, during each event the Shellfish Authority has been immediately informed. The high performance of current treatment plants, effective use of hydrographic and dilution analysis, and immediate communication during upset conditions provide more effective and efficient protection of public health in Conditionally Approved areas impacted by point sources. Upset conditions are infrequent and random which can make monthly sampling inefficient and ineffective at evaluating

impacts from the point source.

Cost Information
The reduced sampling option would be a cost savings for the Shellfish Authority.

Action by 2019 Task Force I
Recommended adoption of Proposal 19-119 as amended.

Section II Model Ordinance
Chapter IV Shellstock Growing Area @.03 Growing Area Classification C3. Reevaluation of Conditional Classification (b) Water Sample Collection

(ii) When the conditional management plan is based on the operation and performance of a WWSD (s); combined sewer overflows(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 except when:

(a) Hydrographic or dilution analysis has been completed to determine the impact of a WWSD performance failure ~~;~~ and ~~Communication~~ communication requirements are documented and the WWSD operator provides immediate notification to the Shellfish Authority during a performance failure; or

~~(a)~~(b) ~~.~~ Mooring assessment determines the mooring area is not a pollution source.

Action by 2019 General Assembly
Adopted recommendation of Task Force I on Proposal 19-119.

Action by FDA February 21, 2020
Concurred with Conference action on Proposal 19-119.

Proposal No. 19-120

Submitter	Tom Dameron Surfside Foods capttomd@gmail.com
Proposal Subject	Classification of Federal Waters
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.03 Growing Area Classification F.
Text of Proposal/ Requested Action	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, or marine biotoxin hazards) and involve commercial shellfish resources. Should FDA allow harvesting in Federal waters with known marine biotoxin hazards, the FDA will classify the harvest area in a manner equivalent to the requirements of Model Ordinance Chapter IV.
Public Health Significance	The FDA has taken the position that all Federal waters are approved unless closed. Currently shellfish harvesting is being allowed in areas with known marine biotoxin hazards. To address these hazards, harvesting restrictions are being required without the designation of appropriate harvesting classification. Currently the Model Ordinance does not include any restrictions for approved areas. Shellfish harvesting areas that have been closed are considered prohibited and harvesting for human consumption purposes is not allowed. If the FDA wants to continue to allow harvesting in Federal waters with restrictions, appropriate classification should be designated.
Cost Information	
Action by 2019 Task Force I	Recommended adoption of Proposal 19-120 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-120.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-120.

Proposal No. 19-121

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	*Karenia brevis*
Specific NSSP Guide Reference	Section II Model Ordinance Chapter IV. Shellstock Growing Areas @.04
Text of Proposal/ Requested Action	Chapter IV. Shellstock Growing Areas @.04 C. Closed Status of Growing Areas. 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 - 80 µg saxitoxin equivalents/100 grams (b) NSP - 5,000 cells/L *(Karenia brevis)* or 20 MU/100 grams (0.8 mg brevetoxin-2 equivalents/kg) (c) AZP - 0.16 mg azaspiracid-1 (AZA-1) equivalents/kg (0.16 ppm) (d) DSP – 0.16 mg okadaic acid (OA) equivalents/kg (0.16 ppm) (e) ASP – 2 mg domoic acid/100 grams (20 ppm)
Public Health Significance	The 5,000 cell count standard applies to *Karenia brevis* only
Cost Information	
Action by 2019 Task Force I	Recommended no action on Proposal 19-121. Rationale: This issue is addressed by Proposal 19-149.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-121.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-121.

Proposal No. 19-122

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Use of “growing area” rather than “harvest area” in Patrol requirements language.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.01 Control of Shellstock Growing Areas A.(2)(d), A.(3)(b), B.(2).
Text of Proposal/ Requested Action	A. General. (1) The Authority shall maintain an effective program to control shellstock growing areas and to assure that shellstock are harvested only: (a) From areas in an open status; and (b) With approval from areas classified as restricted, conditionally restricted, or prohibited, or in the closed status of the approved or conditionally approved classification. (2) This program shall include: (a) The patrol of growing areas; (b) The licensing of harvesters; (c) Enforceable legal penalties sufficient to encourage compliance; and (d) Appropriate identification of growing~~harvest~~ areas and/or portions of growing areas where shellstock harvest is not allowed. (3) At the time of issuance or renewal of a harvester's license or a dealer's certification, or an annual mail out to all licensed shellfish harvesters, the Authority shall provide each harvester or dealer with: (a) Information which explains the public health risk associated with illegal harvesting shellstock in areas classified as restricted, conditionally restricted, or prohibited or in the closed status; and (b) When requested, a current, comprehensive, itemized listing of all growing~~harvest~~ areas including their geographic boundaries and their classification. B. Patrol of Growing Areas. (1) The Authority shall assure that shellstock are harvested only as provided in this Chapter. (2) The Authority shall patrol growing~~harvest~~ areas classified as restricted, conditionally restricted, or prohibited, or conditionally approved and approved when in the closed status at sufficient intervals to deter illegal harvesting...
Public Health Significance	The NSSP Guide for the Control of Molluscan Shellfish contains definitions for “Harvest Area” and “Growing Area.” “Growing Area” is the more appropriate term for the indicated locations.
Cost Information	No cost.
Action by 2019 Task Force I	Recommended adoption of Proposal 19-122 as amended. A. General. (1) The Authority shall maintain an effective program to control shellstock growing areas and to assure that shellstock are harvested only: (a) From areas in an open status; and (b) With approval from areas classified as restricted, conditionally restricted, or prohibited, or in the closed status of the approved or conditionally approved classification. (2) This program shall include:

(a) The patrol of growing areas;
(b) The licensing of harvesters;
(c) Enforceable legal penalties sufficient to encourage compliance; and
(d) Appropriate identification of growing areas and/or portions of growing areas where shellstock harvest is not allowed.

(3) At the time of issuance or renewal of a harvester's license or a dealer's certification, or an annual mail out to all licensed shellfish harvesters, the Authority shall provide each harvester or dealer with:
(a) Information which explains the public health risk associated with illegal harvesting shellstock in areas classified as restricted, conditionally restricted, or prohibited or in the closed status; and
(b) When requested, a current, comprehensive, itemized listing of all growing areas including their geographic boundaries and their classification.

B. Patrol of Growing Areas.

(1) The Authority shall assure that shellstock are harvested only as provided in this Chapter.
(2) The Authority shall patrol growing areas or portions of growing areas classified as restricted, conditionally restricted, or prohibited, or conditionally approved and approved when in the closed status at sufficient intervals to deter illegal harvesting...

Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-122.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-122.

Submitter	Kimberly Stryker State of Alaska Department of Environmental Conservation Kimberly.stryker@alaska.gov
Proposal Subject	Marine Biotoxin Control - Public Health Reasons
Specific NSSP Guide Reference	Section III. Public Health Reasons and Explanations, Model Ordinance Chapter IV. Shellstock Growing Areas, @.04
Text of Proposal/ Requested Action	**. @.04 Marine Biotoxin Control**

Marine Biotoxins

Unlike human pathogens, marine biotoxins occur naturally in aquatic environments. Toxins are produced by certain micro-algae (also called phytoplankton), including dinoflagellates and others.

Shellfish are filter feeders and may ingest and concentrate toxic phytoplankton from the water column when present in shellfish growing waters. Toxins are accumulated in the viscera and/or other tissues of shellfish and are transferred to humans when the shellfish are eaten (Gordon et al., 1973). Marine biotoxins are a public health concern for many reasons; for example, marine biotoxins:

- May build up in shellfish in concentrations up to 100 times greater than in surrounding waters;
- Are not normally destroyed by cooking or processing;
- Cannot be detected by taste; and
- Can cause illness and death if consumed in sufficient concentrations.

In most cases, the toxin has no effect on the shellfish itself, and how long each shellfish vector remains toxic depends on the individual species in question. Additionally, there are non-traditional and emerging vectors of these toxins that also are potentially toxic foods. One example is that pufferfish, typically associated with tetrodotoxin, may also contain saxitoxin (e.g., puffers from coastal waters of Florida).

Toxic dinoflagellates or diatoms are single-cell marine plants that are indigenous to most coastal and estuarine waters on the Atlantic, Gulf, and Pacific coasts of America, as well as in many other parts of the world. Dinoflagellates and diatoms in their vegetative stage flourish (“bloom”) seasonally when water conditions are favorable. Blooms of these organisms can occur unexpectedly and rapidly, or may follow predictable patterns.

Because dinoflagellates occur naturally, their presence in the water column does not necessarily constitute a health risk. In fact, traces of their toxin in shellfish meat does not necessarily mean they are hazardous. Toxicity depends on concentration (dose) in the shellfish.

Red tide refers to the discoloration of seawater caused by blooms of marine algae. Red tides are not always red. They occur in many colors, including amber, brown, purple, red, and pink. The relationship between red tides and biotoxin poisoning is widely misunderstood, and many people mistakenly believe that shellfish are safe to eat if no red tide is visible. While red tide can be related to harmful algae, it is helpful to remember that:

- Toxic blooms may be other colors, such as blue-green;
- Marine biotoxin poisoning can happen when there is no discoloration of the water; and
- Several marine algae that pose no public health risk to humans can turn the water red.

Diseases and Outbreaks

All humans are susceptible to shellfish poisoning. A disproportionate number of shellfish-poisoning cases occur among tourists or others who are not native to the location where the toxic shellfish are harvested, and fishermen and recreational harvesters. This may be due to disregard for either official quarantines or traditions of safe consumption.

Diagnosis of shellfish poisoning is based entirely on observed symptomatology and recent dietary history. Human ingestion of contaminated shellfish results in a wide variety of symptoms, depending on the toxin(s) present, their concentrations in the shellfish, and the amount of contaminated shellfish consumed.

Marine Biotoxin Plans – Management & Contingency

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, ASP, DSP and AZP. 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.

For this reason, even when the authority has no history or reason to expect toxin-producing phytoplankton in their growing areas, every shellfish-producing authority must have a contingency plan that defines administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of shellfish toxins. For producing authorities where there is historic occurrence of toxin-producing phytoplankton and toxicity in shellfish from their growing areas, the authority must develop a management plan.

Most authorities will have a combination of management and contingency plans - management plans to address those growing areas with historic occurrence of certain toxin-producing phytoplankton, and contingency plans to address toxin-producing phytoplankton in growing areas in the event of such emergence. As an example, an authority may have statewide historical occurrence of PSP toxin-producing phytoplankton, for which it develops a management plan; however, because of a lack of illness outbreak or historical evidence of phytoplankton that produce ASP, NSP, DSP, and AZP toxins, the authority also develops a contingency plan that addresses how the authority will manage the emergence of those particular toxins.

Guidance for the development of contingency and management plans is found at Ch IV @.04.

Shellfish Meat Analyses

Laboratory methods to detect marine biotoxins in shellfish include:

- Animal bioassay;
- Biochemical;
- Rapid test kits; and
- Chemical analytical methods.

The mouse bioassay historically has been the most universally applied technique for examining shellfish toxins. Other bioassay procedures have been developed and are becoming more generally applied. In recent years, considerable effort has been appli to development of chemical analyses to replace or provide alternatives to in-vivo (liv animal) bioassays.

Marine biotoxin testing methods fall into two categories in the NSSP:

1. **Approved** (Section IV. Guidance Documents Chapter II Growing Areas .14 Table 2.)
   Approved methods are those methods that have undergone ISSC evaluation and have been adopted into the NSSP (for certain species) for regulatory decisions, including reopening a growing area after a closure.

2. **Approved Limited Use** (Section IV. Guidance Documents Chapter II Grow Areas .14 Table 4.)
   Approved limited use methods (sometimes referred to as rapid or screening methods) are testing methods that have been evaluated by the ISSC and foun fit for purpose for the NSSP, thereby providing confidence in those methods specific screening purposes. **Most limited use methods may be used for specific screening purposes, the results of which an authority may use to close a growing area; however, an approved method must be utilized to reopen an area following a closure.**

For analyses of toxins for which no method has been adopted into the NSSP, best available science is employed.

Toxin Profiles (PSP, DSP, NSP, ASP, AZP)

Paralytic Shellfish Poisoning (PSP) Toxin	
Cause	Saxitoxins are produced by the dinoflagellates of the genus *Alexandrium* (formerly *Gonyaulax*). The dinoflagellate *Pyrodinium bahamense* is also a producer of saxitoxins.
Analogs	Water-soluble alkaloid neurotoxins that are collectively referred to as saxitoxins or paralytic shellfish toxins (PSTs). To date 57 analogs have been identified, although not all are always present, and they vary greatly in overall toxicity. In addition to saxitoxin (the parent compound), monitoring laboratories typically analyze for approximately 12 other analogs that may contribute measurably to toxicity.
Occurrences	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 (US Public Health Service, 1958); but these patterns may be changing. The blooms, which may or

	may not result in discoloration of seawater, generally last only a few weeks and most shellfish (with the exceptions of some species of clams and scallops, which retain the toxin for longer periods) clear themselves rapidly of the toxin once the bloom dissipates.
Predictability	Toxic blooms of these dinoflagellates can occur unexpectedly or follow predictable patterns.
Action Level	0.8 ppm (80 µg/100 g) saxitoxin equivalents. Selective species closures are allowed under the NSSP. In shellfish growing areas where low levels of PSP routinely occur, harvesting for thermal processing purposes is allowed. Thermal processing is defined by FDA regulation 21 CFR 113. Thermal processing will not entirely destroy PSP content of the shellfish; therefore, the Authority must develop and implement procedures to control harvesting and transportation of shellfish intended to be processed.
Action Level Origin	The regulatory limit was set in the 1930s (Wekell, 2004). 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.
Monitoring	Monitoring programs for analysis of PSP toxins include: • Samples submitted by industry with a MOU. • Samples collected by shellfish authority personnel. • Sentinel species monitoring.
Shellfish Lab Methods	The mouse bioassay is still the most widely accepted detection method for the saxitoxins around the world and has been shown to adequately protect the public's health. In 2009, the Interstate Shellfish Sanitation Conference approved a post-column oxidation HPLC-PCOX method, making it the newest regulatory method available for PSP toxins in the U.S. The receptor binding assay, a competition assay whereby radiolabeled saxitoxin competes with unlabeled saxitoxin for a finite number of available receptor sites as a measure of native saxitoxin concentrations in a sample, was also approved as an official AOAC method in 2011.
Disease	Paralytic Shellfish Poisoning
Mortality	Death has been reported to occur as soon as 3 to 4 hours after consumption.
Onset	Symptoms can generally occur within 30 minutes of consuming contaminated seafood, although reports have indicated that symptoms can even ensue within a few minutes, if high enough toxin concentrations are present.
Symptoms,	Predominantly neurologic and include tingling of the lips,

Illness Course	mouth, and tongue; numbness of extremities; paresthesias; weakness; ataxia; floating/dissociative feelings; nausea; shortness of breath; dizziness; vomiting; headache; and respiratory paralysis. Medical treatment consists of providing respiratory support, and fluid therapy can be used to facilitate toxin excretion. For patients surviving 24 hours, with or without respiratory support, the prognosis is considered good, with no lasting side effects. In fatal cases, death is typically due to asphyxiation. In unusual cases, death may occur from cardiovascular collapse, despite respiratory support, because of the weak hypotensive action of the toxin.
General Food Associations	Mussels, clams, cockles, oysters, and scallops (excluding the scallop adductor muscle).
Outbreak Examples	In New England in 1972, shellfish suddenly became toxic in a previously unaffected portion of the coastline, which resulted in many illnesses (Schwalm, 1973). Despite widespread PSP closures, poisoning events still occur and are generally associated with recreational harvest. For example, in July 2007, a lobster fisherman harvested mussels from a floating barrel off Jonesport, Maine (an area that was currently open to shellfish harvesting), and he and his family ate them for dinner. All four consumers became ill with PSP symptoms, and three of them were admitted to the hospital. It was apparent that the barrel of mussels had originated further up the coast in an area that had been banned to commercial harvest (DeGrasse, 2014).
	Diarrhetic Shellfish Poisoning (DSP) Toxin
Cause	Certain *Dinophysis spp.* and *Prorocentrum spp.* produce okadaic acid and dinophysis toxins that cause DSP.
Analogs	A group of lipid-soluble polyether toxins that includes okadaic acid, the dinophysistoxins, and a series of fatty acid esters of okadaic acid and the dinophysistoxins (collectively known as DSTs) (Uchida, 2018).
Occurrence	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., 2014], Maine, and Connecticut). Known global distribution of DSTs also includes Japan, Europe, Asia, Chile, Canada, Tasmania, and New Zealand (Trainer, 2013). In 2008, a large portion of the Texas Gulf Coast was closed to the harvesting of oysters due to the presence of okadaic acid in excess of the FDA guidance level. Although no illnesses were reported in 2008, these were the first closures in the U.S. due to confirmed toxins.
Predictability	Dinoflagellates are known to thrive in stratified systems and

	Dinophysis has particular adaptive strategies to cope with freshwater plumes (Trainer, 2013).
Action Level	0.16 ppm total okadaic acid equivalents (i.e., combined free okadaic acid, dinophysistoxins, acyl-esters of okadaic acid and dinophysistoxins)
Action Level Origin	Established by FDA in 2011 for total (esterified plus non-esterified OA + DTXs (with no guidance for PTXs and YTXs) (Trainer, 2013).
Monitoring	Production of DSTs has been confirmed in several *Dinophysis* species, including *D. fortii*, *D. acuminata*, *D. acuta*, *D. norvegica*, *D. mitra*, *D. rotundata*, *D. ovum*, *D. sacculus*, *D. caudate*, *and D. tripos*, and in the benthic dinoflagellates *Prorocentrum lima*, *P. concavum* (or *P. maculosum*), *P. micans*, *P. minimum*, and *P. redfieldii*. One other *Dinophysis* species, *D. hastate*, is also suspected to produce toxins (Trainer, 2013). Precautionary closures initiated based on cell abundance are not useful, but observations show promise in providing early warning to DSP events (Trainer, 2013).
Shellfish Lab Methods	Until recently, DSP was managed by mouse bioassay and/or monitoring shellfish growing waters for the presence of *Dinophysis* organisms. Unfortunately, the dose-survival times for the DSP toxins in the mouse assay vary considerably, and fatty acids interfere with the assay, giving false-positive results. A suckling mouse assay has been developed and used for control of DSP. This assay measures fluid accumulation after injection of the shellfish extract. In 2017 an LCMS/MS method for quantifying DTXs in clams was approved in the NSSP. For other species, the best available science is recommended.
Disease	Diarrhetic Shellfish Poisoning
Mortality	This disease generally is not life-threatening.
Onset	Onset of the disease, depending on the dose of toxin ingested, may be as little as 30 minutes to 3 hours.
Symptoms, Illness Course	DSP is primarily observed as a generally mild gastrointestinal disorder; i.e., nausea, vomiting, diarrhea, and abdominal pain, accompanied by chills, headache, and fever. Symptoms may last as long as 2 to 3 days, with no chronic effects.
General Food Associations	Mussels, clams, cockles, oysters, and scallops (excluding the scallop adductor muscle).
Outbreak Examples	Although there have been numerous outbreaks of diarrhetic shellfish poisoning around the world, until recently there were no confirmed cases of DSP in the U.S. that were due to domestically harvested shellfish (Trainer, 2013). In 2011, approximately 60 illnesses occurred in British Columbia, Canada, and 3 illnesses occurred in Washington State due to consumption of DSP-contaminated mussels. Subsequent harvesting closures and product recalls were issued (Lloyd, 2013).
	Neurotoxic Shellfish Poisoning (NSP) Toxin

Cause	NSP is caused by brevetoxins produced by the dinoflagellates of the genus *Karenia* (formerly *Gymnodinium*).
Analogs	Comprised of more than 10 lipid-soluble cyclic polyethers. A number of analogs and metabolites have been identified. NSP-causing toxins in shellfish include intact algal brevetoxins and their metabolites (collectively known as NSTs). In addition to brevitoxins, numerous other *Karenia spp*. Found in the Gulf of Mexico and around the world regularly associated with blooms produce hymnodimine, karlotoxins, and other potent toxins (Watkins, 2008).
Occurrence	In Gulf coast areas, toxicity in shellfish has been associated with red tide outbreaks caused by massive blooms of the toxic dinoflagellate, *Karenia brevis* (formerly *Ptychodiscus brevis*). Naturally occurs in Gulf of Mexico, Caribbean Sea, and along New Zealand coasts; it regularly produces blooms along the coasts of Florida and Texas. Blooms may cause ocean to appear red, brown, or simply darkened and are usually accompanied by massive fish kills and mortalities in marine mammals and sea birds (Watkins, 2008). Dupuration time of brevetoxins in shellfish varies, but is typically within two to eight weeks, although reports of much longer retention (nearly one year post bloom) have been documented (Watkins, 2008).
Predictability	*Karenia* blooms show no indication of regular recurrence and shellfish generally take longer to eliminate the toxin. Blooms were once considered to be sporadic and seasonal, but historical records demonstrate these blooms have occurred in Florida almost annually in the years since the 1940s. Although more frequent in late summer and early fall, Florida blooms have been documented in almost every month of the year and may disperse in a matter of weeks, or may be present for many months at a time; in 2006, a bloom off the coast of Sarasota lasted over 12 months. Occurrence and magnitude of blooms are unpredictable.
Action Level	0.8 ppm (20 mouse units/100 g tissue or 80 µg/100 g tissue) brevetoxin-2 equivalents The cell count of members of *Karenia brevis* in the water column exceeds 5,000 cells per liter of water.
Action Level Origin	Uncooked clams from a batch eaten by a patient in Florida with NSP symptoms were found to contain 118 mouse units per 100 grams of shellfish meat. However, consumption of even a few contaminated shellfish may result in poisoning and the severity of the disease may be dependent on many factors, including dose, bodyweight, underlying medical conditions, and the age of the victim as well as possibly the toxin mixture of the particular bloom (Watkins, 2008).
Monitoring	Water cell counts and tissue samples.
Shellfish Lab Methods	Toxicity of shellfish exposed to the dinoflagellate *Karenia brevis* has been historically assessed by mouse bioassay in the

	U.S.; however, mouse bioassay is not very specific for NSP toxins (Watkins, 2008). Efforts are underway to validate *in-vitro* methods for detection of brevetoxins in shellfish. For example, rapid, sensitive ELISA test kits already are commercially available for this purpose. Biomarkers of brevetoxin contamination in shellfish have been identified by using LC/MS. Structural confirmation of these metabolites and brevetoxins in shellfish can be made by LC/MS, a method that offers high sensitivity and specificity. A method for detection, identification, and quantification of brevetoxins is HPLC-MS. Radioimmunoassay (RIA) and Receptor Binding Assay (RBA) are also under current use (Watkins, 2008). Available detection methods are not equal in their ability to measure naturally-produced brevetoxins, and most methods are hampered by the absence of specific reference standards for brevetoxin congeners (Watkins, 2008).
Disease	Neurotoxic Shellfish Poisoning
Mortality	No fatalities have been reported, but hospitalizations occur.
Onset	Onset of this disease occurs within a few minutes to a few hours. A mean time to onset of 3-4 hours has been reported in the few documented outbreaks (Watkins, 2008).
Symptoms, Illness Course	Both gastrointestinal and neurological symptoms characterize NSP, including tingling and numbness of lips, tongue, and throat; muscular aches; dizziness; diarrhea; and vomiting. Respiratory distress has been recorded. Duration is fairly short, from a few hours to several days. Recovery is complete, with few after-effects.
General Food Associations	Oysters and clams.
Outbreak Examples	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 (US Center for Disease Control, 1973). Until NSP toxins were implicated in more than 180 human illnesses in New Zealand in 1992/1993 due to consumption of cockles and green shell mussels, NSP was considered to be an issue only in the U.S. Outbreaks of NSP are rare where programs for monitoring *K. brevis* blooms and shellfish toxicity are implemented. An NSP outbreak involving 48 individuals occurred in North Carolina in 1987 (Morris, 1991). A series of NSP cases occurred along the southwest coast of Florida, in 2006, after people consumed recreationally-harvested clams from waters unapproved for shellfish harvesting (Watkins, 2008).
Amnesic Shellfish Poisoning (ASP) Toxin	
Cause	ASP is caused by domoic acid that is produced by diatoms of the genus *Pseudonitzchia*.
Analogs	The neurotoxin domoic acid is a water-soluble, non-protein,

	excitatory amino acid. Isomers of domoic acid have been reported, but are less toxic than domoic acid itself. Excitatory amino acid (EAA) analogues of glutamate.
Occurrence	During 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. During 1991 and 1992, there was a spread of domoic acid producing organisms throughout the world including the detection of high numbers of the diatom *Pseudonitzschia pseudodelcatissima* in Australia and *Pseudonitzschia pseudoseratia* in California. Domoic acid has also been recovered from shellfish in Washington and Oregon.
Predictability	Blooms of *Pseudonitzschia* are of varying intensity, duration and extent. Environmental factors associated with ASP in shellfish are currently unknown.
Action Level	20 ppm domoic acid
Action Level Origin	In 1987 in eastern Canada, DA poisonings sickened individuals, leading to Health Canada's establishment of the regulatory limit. (Wekell, 2004)
Monitoring	Monitoring programs for ASP toxin are designed around the shellfish species of interest.
Shellfish Lab Methods	The mouse bioassay for domoic acid is not sufficiently sensitive and does not provide a reliable estimate of potency. The NSSP approved regulatory method for detecting domoic acid in seafood is a reversed-phase HPLC method with ultraviolet (UV) detection. There is also an AOAC approved ELISA for the detection of domoic acid.
Disease	Amnesic Shellfish Poisoning
Mortality	All fatalities, to date, have involved elderly patients.
Onset	The toxicosis is characterized by onset of gastrointestinal symptoms within 24 hours; neurologic symptoms occur within 48 hours.
Symptoms, Illness Course	ASP is characterized by gastrointestinal disorders (vomiting, diarrhea, abdominal pain) and neurological problems (confusion, short-term memory loss, disorientation, seizure, coma). Human clinical signs of domoic acid toxicity are reported as mild gastrointestinal symptoms, from an oral dose of 0.9-2.0 mg domoic acid (DA)/kg body weight. Neurologic effects, such as seizure and disorientation, are reported from an oral dose of 1.9-4.2 mg DA/kg body weight. The toxicosis is particularly serious in elderly patients, and includes symptoms reminiscent of Alzheimer's disease.

General Food Associations	Mussels, clams, cockles, oysters, and scallops (excluding the scallop adductor muscle).
Outbreak Examples	The first human domoic acid poisoning events were reported in 1987, in Canada (Perl, 1990). While domoic acid exposure still exists, there have been no documented ASP cases since 1987, following implementation of effective seafood toxin-monitoring programs (Pulido, 2008).
Azaspiracid Shellfish Poisoning (AZP) Toxin	
Cause	*Azadinium spp*. is the producer of azaspiracids, which cause AZP.
Analogs	The lipid-soluble toxin azaspiracid and several derivatives (AZAs). More than 30 AZA analogs have been identified, with three analogs routinely monitored in shellfish (AZA1, AZA2, and AZA3).
Occurrence	Coastal regions of western Europe, as well as NW Africa and eastern Canada.
Predictability	Detected between mid-summer and mid-winter from northern/western European waters, but in certain cases, the presence of AZAs in phytoplankton does correspond to the timing of shellfish contamination, yet toxin levels in bivalves can remain elevated for 8 – 12 months following initial exposure.
Action Level	160 µ/kg shellfish meat
Action Level Origin	Estimation of consumption of a single portion of shellfish and through estimate of an Acute Reference Dose. Derived from epidemiological observations caused by a mixture of naturally occurring analogs (AZA 1, 2, and 3). Based on methods available in 2001.
Monitoring	Range of species in which AZAs have been detected includes mussels (*M. edulis; M. galloprovincialis*), oysters (*Crossostrea gigas*, *Ostrea edulis*), scallops (*Pecten maximus*), clams (*Tapes philipinarum*, *Ensis siliqua*, *Donax* spp.), and cockles (*Cerastroderma edule*). AZAs have also been found in crustaceans. Monitoring programs will benefit from major research efforts to identify the causative organism(s) because there is often, but not always, a correlation between the presence of potentially toxigenic phytoplankton species and the subsequent accumulation of toxins in shellfish.
Shellfish Lab Methods	AZAs are not routinely monitored in shellfish harvested in the U.S., but, in the EU, the mouse bioassay has been used. As for many of the lipophilic toxins, the mouse assay is not adequately sensitive or specific for public- health purposes. *In-vitro* assays and analytical methods are now available to assess the toxicity of AZA-contaminated shellfish and to confirm the presence of AZA analogs in shellfish. These methods are in various stages of validation for regulatory use around the world. LC/MS is used as a confirmatory method for AZA, providing unambiguous structural confirmation of

	AZA analogs in shellfish samples.
Disease	Azaspiracid Shellfish Poisoning
Mortality	No known fatalities to date.
Onset	Symptoms appear in humans within hours of eating AZA-contaminated shellfish.
Symptoms, Illness Course	Symptoms are predominantly gastrointestinal disturbances resembling those of diarrhetic shellfish poisoning and include nausea, vomiting, stomach cramps, and diarrhea. Illness is self-limiting, with symptoms lasting 2 or 3 days.
General Food Associations	Detected in mussels, oysters, scallops, clams, cockles, and crabs.
Outbreak Examples	The first case of AZP was detected in the Netherlands in 1995, where 8 people became ill after consuming mussels. From 1997 – 2000, approximately 80 individuals reported illnesses from mussels and scallops harvested from Ireland, Italy, France, and United Kingdom (Twiner, 2008). There have been no confirmed cases of AZP in the U.S. from domestically-harvested product. In 2008, the first recognized outbreak of AZP in the U.S. was reported, but was associated with a mussel product imported from Ireland (Klontz et al. 2009).

Resources

The 2012 version of FDA's Bad Bug Book, Foodborne Pathogenic Microorganisms and Natural Toxins, is a comprehensive resource from which a great deal of information has been used for the toxin profiles in the table above. It is accessible at https://www.fda.gov/media/83271/download

For more discussion of chemical structures and properties, methods of analysis, source organisms and habitat, occurrence and accumulation in shellfish, toxicity of toxins, prevention of intoxication, cases and outbreaks, and regulations and monitoring, see the FAO Paper 80: Marine Toxins. This may be accessed as follows:

Paralytic Shellfish Poisoning	http://www.fao.org/3/y5486e/y5486e05.htm
Diarrhetic Shellfish Poisoning	http://www.fao.org/3/y5486e/y5486e0e.htm
Neurotoxic Shellfish Poisoning	http://www.fao.org/3/y5486e/y5486e0o.htm
Amnesic Shellfish Poisoning	http://www.fao.org/3/y5486e/y5486e0n.htm
Azaspiracid Shellfish Poisoning	http://www.fao.org/3/y5486e/y5486e0p.htm
References	http://www.fao.org/3/y5486e/y5486e0t.htm

The FDA online course, Shellfish Growing Areas, introduces participants to requirements and procedures under the NSSP to ensure that shellfish are harvested from safe waters. The course contains a significant section addressing marine biotoxins. The course may be accessed at https://www.accessdata.fda.gov/ORAU/ShellfishGrowingAreas/SGA_summary.htm.

Additional information from the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR) contains illness reports related to these toxins. This may be accessed at https://www.cdc.gov/mmwr/index.html.

NIH/PubMed: Various Shellfish-Associated Toxins provides a list of research abstracts in the National Library of Medicine's MEDLINE database.

The specific seafood with which each toxin generally is associated is included in the profiles above to help readers link symptoms to potential sources. However, all shellfish (filter-feeding mollusks, as well as the carnivorous grazers that feed on these mollusks (such as whelk, snails, and, in some cases, even lobster and octopus), may become toxic in areas where the source algae are present.

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~~Marine biotoxins may be ingested by molluscan shellfish feeding on toxic dinoflagellates. Dinoflagellates in their vegetative stage flourish seasonally when water conditions are favorable. Toxic blooms of dinoflagellates or diatoms can occur unexpectedly or may follow predictable patterns. PSP, NSP and Domoic Acid poisoning, also known as ASP are the three (3) types of poisonings most commonly associated with oysters, clams, mussels and scallops in the United States.~~

~~Cases of paralytic shellfish poisoning, including several fatalities resulting from poisonous shellfish, have been reported from both the Atlantic and Pacific coasts. The minimum quantity of poison, which will cause intoxication in the susceptible person, is not known. Epidemiological investigations of paralytic shellfish poisoning in Canada have indicated 200 to 600 micrograms of poison will produce symptoms in susceptible persons. A death has been attributed to the ingestion of a probable 480 micrograms of poison. Investigations indicate that lesser amounts of the poison have no deleterious effects on humans. Growing areas should be closed at a level to provide an adequate margin of safety, since in many instances, toxicity levels will change rapidly.~~

~~A review of the literature and research dealing with the source of the poison, the occurrences, and distribution of poisonous shellfish physiology and toxicology, characteristics of the poison, and prevention and control of poisoning has been prepared.~~

~~In Gulf coast areas, toxicity in shellfish has been associated with red tide outbreaks caused by massive blooms of the toxic dinoflagellate, *Karenia brevis* (formerly *Ptychodiscus brevis*). Toxic symptoms in mice suggest a type of NSP rather than symptoms of PSP. The most common public health problem associated with *Karenia brevis* blooms is respiratory irritation; however, NSP associated with *Karenia brevis* blooms have been reported in Florida. 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.~~

~~Toxic dinoflagellates or diatoms are indigenous to most coastal and estuarine waters on the Atlantic, Gulf, and Pacific coasts of America, as well as in many other parts of the world. Blooms of these organisms can occur unexpectedly and rapidly. This phenomenon occurred in New England in 1972 when shellfish suddenly became toxic in a previously unaffected portion of the coastline and resulted in many illnesses. During 1991 and 1992, there was a spread of domoic acid producing organisms throughout the world including the detection of high numbers of the diatom *Pseudo-nitzschia pseudo-delcatissima* in Australia and *Pseudo-nitzschia pseudo-seratia* in California. Domoic acid was also recovered from shellfish in Washington and Oregon. All shellfish producing States or MOU countries must have a contingency plan that defines administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of shellfish toxins. A model State contingency plan for control of marine biotoxins is provided in the NSSP Model Ordinance Guidance~~

~~Documents, *Guidance for Developing Marine Biotoxin Contingency Plans* (ISSC/FDA, 2017).~~

~~All States or MOU countries must monitor toxin levels to establish a baseline historical reference. Thereafter, States or MOU countries where shellfish toxins are likely to occur must monitor toxin levels on a routine basis to meet the approved area requirements for direct market harvesting. Experience with monitoring for shellfish toxins suggests that an effective program should include the following:~~

~~Sampling stations should be located at sites where past experience has shown toxin is most likely to appear first.~~

~~Samples should be collected of shellfish species which are most likely to reveal the early presence of toxin and which are most likely to show the highest toxin levels. For example, mussels have been found to be useful for early PSP detection.~~

~~The frequency and period for collection of samples should be based upon historical patterns. This assumes several years of baseline data in order to establish stations and sampling plans.~~

~~An information network should be established between the health and marine resource communities and the Authority. Any toxin-like illnesses related to shellfish and environmental phenomena such as algal blooms, fish kills, or bird kills, which might indicate the early stages of an increase in toxin levels, should be rapidly communicated over the network.~~

~~Sampling stations and frequency of sampling should be increased when monitoring data or other information suggests that toxin levels are increasing.~~

~~Sample collection, sample transportation, and sample analysis procedures should be developed so that in an emergency sample results will be known within twelve (12) hours.~~

~~When monitoring data or other information indicates that toxin levels have increased to the quarantine levels, growing area closures must be immediately implemented. The determination of which growing areas should be closed should include consideration of the rapidity with which toxin levels can increase to excessive levels and the inherent delays in the State sample collection procedures. It may be appropriate to close growing areas adjacent to known toxic areas until increased sampling can establish which areas are toxin-free and that toxin levels have stabilized.~~

~~Shellfish growing areas closed because marine biotoxins have exceeded quarantine levels may be reopened for growing after a sufficient number of samples and other environmental indices, if used, have established that the level of toxin will remain below quarantine levels for an extended period. For example, experience has shown that appropriate reopening criteria 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.~~

~~**A.** Contingency Plan.~~

~~The suitability of some areas for harvesting shellstock is periodically influenced by the presence of toxigenic micro-algae. Recent increases in toxigenic micro-algae distribution dictate that a more comprehensive series of public health controls be adopted. The need exists to make contingency plans to address the contamination of a growing area by toxigenic micro-algae or a disease outbreak caused by marine biotoxin. This contingency plan must describe administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of marine biotoxin in shellstock. The primary goal of this planning should be to ensure that maximum public health protection is provided in growing areas subject to marine biotoxin contamination. For a discussion of marine biotoxin disease and its management in shellfish growing areas, see the NSSP Model Ordinance Guidance Documents: *Guidance for Developing Marine Biotoxin Contingency Plan* (ISSC/FDA, 2017).~~

~~**B.** Marine Biotoxin Monitoring.~~

~~The primary purpose of a marine biotoxin-monitoring program is to prevent illness or death among the shellfish consuming public. The monitoring program should use the "indicator station" and "critical species" concepts to develop an early warning system to prevent harvest of biotoxin contaminated shellstock. For a full discussion, see the NSSP Model Ordinance Guidance Documents: *Guidance for Developing Marine Biotoxin Contingency Plan* (ISSC/FDA, 2017).~~

~~**C.** Closed Status of Growing Areas.~~

~~In the event of a toxigenic micro-algae bloom, shellstock growing areas shall be placed in the closed status for harvesting to prevent human consumption of biotoxin contaminated shellfish. The biotoxin level governing the need to place the growing area in the closed status will vary depending on the species of toxigenic micro-algae and the species of bivalve shellfish. Since the ability to concentrate biotoxins varies among species, it is possible for one (1) species in a growing area to have safe levels of biotoxin while another species in the same growing area will have dangerous biotoxin concentrations. In this situation, the Authority may permit the harvesting of one (1) species with no adverse public health consequences while prohibiting the harvest of another species. In these situations, the Authority must closely monitor the growing area and develop a sufficient database for use in making this determination.~~

~~The Authority must develop criteria, which must be met before a growing area can be returned to the open status for harvesting. These criteria should integrate public health, conservation, and economic considerations. The criteria should also employ a sufficient number of samples and other environmental indices, if used, to establish that the level of toxin will remain, for an extended period of time, at levels safe for human consumption. For additional discussion concerning biotoxin contamination of shellstock, see the NSSP Model~~

~~Ordinance Guidance Documents: *Guidance for Developing Marine Biotoxin Contingency Plan* (ISSC/FDA, 2017).~~

~~**D.** Heat Processing.~~

~~Heat treatment can reduce the toxicity of some biotoxins. When heat treatment is used, the Authority must require that the processor provide adequate demonstration of the destruction of the biotoxin and adequate controls to assure that the end product is safe for human consumption.~~

~~**E.** Records.~~

~~Good record keeping is essential to the successful management of a Marine Biotoxin Contingency Plan. Appropriate records of monitoring data, evaluation reports, and closure and reopening notices should be compiled and~~ Recommends referral of Propossl 19-123 to an appropriate committee as esignated by the Conference Chair ~~maintained by the Authority. This information is important in defining the severity of the problem, as well as for a retrospective evaluation of the adequacy of the entire control program.~~

Public Health Significance	Marine biotoxins can cause injury, illness, or death. More clearly presented information will assist NSSP participants in understanding the public health reasons for marine biotoxin contingency and management plans.
Cost Information	None
Action by 2019 Task Force I	Recommended referral of Proposal 19-123 to an appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-123.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-123.

Proposal No. 19-124

Submitter	Kimberly Stryker State of Alaska Department of Environmental Conservation Kimberly.stryker@alaska.gov
Proposal Subject	Marine Biotoxin Control – Guidance Document
Specific NSSP Guide Reference	Section IV Guidance Documents Chapter II. Growing Areas Chapter IV. Shellstock Growing Areas .02
Text of Proposal/ Requested Action	**.02 Guidance for Developing Marine Biotoxin Contingency and Management Plans.**

Regardless of whether a growing area has a history of toxin-producing phytoplankton, being able to detect occurrences and take appropriate action to prevent contaminated product from entering commerce is an important part of marine biotoxin control.

There are two types of plans defined in the NSSP MO for the control of marine biotoxins: a *contingency plan* and a *management 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 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 the contingency plan is to detect emerging toxins and to outline response activities necessary to prevent additional illnesses (if illness has already occurred) and protect the public's health.

The *management plan* is primarily for proactive management of marine biotoxins in growing areas with a history of toxin-producing phytoplankton and toxicity in shellfish and/or a previous illness event or outbreak. 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.

General Plan Elements

Whether the authority is developing a plan to manage biotoxins, or a contingency plan for the unexpected, the plan should address the following elements:

- Statutory and/or Regulatory Authorities
- Resource/Growing Areas and Species
- Communication
- Control & Response
- Growing Area Reopening Criteria
- Recordkeeping
- Post Event Actions
- Plan Testing, Post Event Activities

Recommended General Plan Guidelines

**Statutory and/or Regulatory Authorities*

The authority should prepare a summary of the laws and regulations in the state (or MOU country) that allow the authority to promptly and effectively take actions to prevent or remove potentially toxic shellfish from commerce in the event of a marine biotoxin event, including:

1. close a growing area to harvest;
2. embargo shellfish that has not entered commerce;
3. prevent harvesting of contaminated species;
4. provide for embargo and/or recall of any potentially toxic shellfish already on the market; and
5. withdraw interstate shipping permits.

**Resource/Growing Areas and Species*

As is the case in several aspects of the NSSP MO, the plan should include a list or reference to a list of locations of classified shellfish growing areas and the species present in the area. This is especially important if the authority intends to implement species-specific biotoxin closures as part of the plan.

**Communication*

Information-sharing among government and non-government agencies is critical as part of an effective biotoxin plan, whether contingency or management. As such, the authority should establish and formalize channels of communication with appropriate partner agencies (e.g., wildlife, epidemiology, local health, public safety, public health, and environmental), research or academic organizations (e.g., marine biologists), adjacent shellfish control authorities, industry, and other similar partners in advance of any serious biotoxin event.

Information to be communicated includes that which is relevant to early warning as well as control and response, including:

1. abnormal environmental phenomenon that may be associated with a shellfish growing area (e.g., bird, fish, or marine mammal die-offs or abnormal behavior, or water discoloration);
2. occurrences of toxic phytoplankton blooms;
3. toxin-like illness reports in humans;
4. growing area closures (specifically, disseminating information on occurrences and/or toxicity in shellfish meats to adjacent states, industry, and local health agencies);
5. coordination of control activities taken by state and federal agencies or departments and district, regional, or local health authorities (e.g., patrol, legal actions); and
6. consumer educational outreach during growing area closure periods.

This aspect of the plan may include references to Memoranda of Understanding and tables that outline each partner's roles and responsibilities, and procedures that define how agencies will maintain contact lists. Model press releases, email notifications, and similar templates may also be useful.

**Control and Response Activities*

An authority's plan should include the following elements to address control and response activities:

1. Growing Area Closure Criteria

   An authority's plan (either contingency or management) should define the circumstances under which the authority will place a growing area in the closed status due to marine biotoxin contamination. The criteria should integrate public health and economic considerations. Principle considerations include

   * The rapidity with which toxin levels can increase to excessive levels;
   * 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 (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); and
   * The type of harvesting restrictions to be invoked (all species or specific species).

   The biotoxin level governing the need to place the growing area in the closed status may vary depending on the species of phytoplankton and the species of bivalve shellfish. Since the ability to concentrate biotoxins varies among species, it is possible for one species in a growing area to have safe levels of biotoxin while another species in the same growing area will have dangerous biotoxin concentrations. In this situation, the authority may allow the harvesting of one species with no adverse public health consequences while prohibiting the harvest of another species. In these situations, the authority must closely monitor the growing area and develop a sufficient database for use in making this determination.

2. Administrative Actions

   The authority should specify the administrative procedures, including timeframes, necessary to place growing areas in the closed status, identify potentially contaminated shellfish products, determine the distribution of these products, and initiate embargo and/or recall activities.

3. Other Control Activities.

   If the authority's statutes or regulation do not allow for a certain administrative action and/or the authority must seek a court order or other legal action, the authority should define the procedures and timeframes, where applicable.

   The authority should also refer to, or describe patrol activities relative to growing area closures due to marine toxins.

**Growing Area Reopening Criteria*

The authority's plan should describe how the authority determines that shellfish for commercial harvest in a growing area are safe for harvest and distribution into commerce for human consumption following an event. The protocol should reflect the

authority's consideration of the public's health, and economic consequences.

A system of representative samples and other environmental indices are typically used to establish detoxification curves indicating that the level of toxin or cell counts have decreased to acceptable levels. Several authorities require that three (3) samples collected over a period of fourteen (14) days show results below the quarantine limit before reopening the affected area.

**Routine Monitoring Program*

A routine surveillance monitoring program (also referred to as an early warning phytoplankton and/or shellfish-monitoring program) is recommended as part of a marine biotoxin control plan to detect the presence of a "bloom." In describing this program, the authority should include:

1. Geographic Distribution of Primary Sampling Stations
   For both phytoplankton and shellfish monitoring plans, primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxin is most likely to first appear, based either on past experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. For these reasons, several years of baseline data are often necessary in order to establish stations. To facilitate knowledge transfer, it is advisable that the authority describe its rationale in selecting sampling sites.
2. Determination of Species to be Sampled
   For a monitoring plan, sampling design should always take into account what commercially-harvested species are present in the growing area and samples should be collected of species which are most likely to reveal the early presence of toxin and are most likely to show the highest toxin levels. For example, mussels have been found to be useful for early detection of an event.
3. Frequency and Timing of Sample Collection
4. Just as location of sampling sites should be carefully considered, the authority should establish the frequency and period for collection of samples in order to identify an event as early as possible. Historical occurrences and fluctuations in coastal phytoplankton populations due to the influence of meteorological and hydrographic events are important considerations. 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. As well, uptake rates for various species of shellfish being tested is critical in terms of timing.
5. Sample Collection Procedures
6. Sample collection, sample transportation, and sample analysis procedures should be developed and predictable timeframes established between collection and results. The Authority should ensure that in an emergency, such as a suspected biotoxin illness, the normal timeframe can be compressed and sample results known as quickly as possible. It is important to consider emergency coverage schedules for staff and lab availability outside of normal office hours during harmful algal bloom events.
7. Identification of Laboratories/Analysts;
   Biotoxin sample results must be provided by an NSSP conforming lab that is utilizing an approved or limited use method. For checklist requirements and additional guidance regarding laboratory evaluation for conformance, see

Chapter II Growing Areas. For NSSP requirements, see Section II MO, Chapter I Shellfish Sanitation Program, @.03(B).

The Authority should consider where they can access sample processing for all biotoxins that occur or may occur within their jurisdiction, and identify alternative laboratory support, should that support become necessary.

8. Description of Testing Methods, Which May Include Approved Limited Use and Approved Methods
   To control marine biotoxins, the authority must evaluate the concentration of toxin present in the shellfish. In the case of NSP, phytoplankton must be monitored as well as shellfish. Approved and limited use methods are listed in the NSSP Guidance Documents.

9. Establishment of Appropriate Screening Levels
   Though the NSSP establishes the toxin levels in shellfish at which a growing area must be closed, many programs implementing early warning systems include phytoplankton cell counts. Additionally, shellfish toxin levels that are below the regulatory levels may trigger emergency or expanded testing, or precautionary closures. Growing areas should be closed at a level that provides an adequate margin of safety, since in many instances, toxicity levels will change rapidly and the time between sampling and results should be considered. Precautionary closures can be made in order to prevent the harvest of potentially toxic shellfish while sample results are being collected and processed.

10. Procedures to Expand Sampling if Toxin Levels or Cell Counts Indicate a Harmful Algal Bloom.
    When an early warning system detects increased toxicity/cell counts or other information suggests that toxin levels are increasing, it is important that the authority have procedures to promptly expand sampling to additional stations and/or increase the frequency of sampling for marine biotoxins. The procedure should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program.

    If a plan consists of water sampling for phytoplankton cell counts as surveillance, the authority should identify its plan to be able to initiate an emergency shellfish sampling program

**Recordkeeping*

Records generated as part of a marine biotoxin program may be important in defining the severity of an event, as well as for retrospectively evaluating the adequacy of the entire control program.

The NSSP requires certain biotoxin-related records be maintained. As such, authority's plan should define records to be generated, reviewed, and maintained. Required records include:

* Monitoring data, including shellfish and phytoplankton and water sample analyses results, relating to levels of marine biotoxins in each growing

area;
* Closure and reopening notices;
* Investigation-related documents, including sample results;
* Recall-related records, including public warnings, notification to other states involved in the recall, FDA, and ISSC, recall status reports in accordance with Section II, Chapter II Risk Assessment and Risk Management, @.01(I); and
* Evaluation reports, which may include analyses of trends and detoxification curves.

An authority may also consider maintaining
- Records of reported illnesses that include data on the incidence of illness and appropriate case history data; and
- Pertinent environmental observations.

Whenever possible, the authority's servicing laboratory should archive shellfish homogenates for additional analysis.

**Plan Testing, Post Event Activities*

The authority should test the plan periodically to ensure prompt implementation in the event it is needed. As well, the authority should routinely review data post-event to improve aspects of the authority's plan. Because historical information plays such a critical role in the authority's plan, authorities are highly encouraged to document rationale for significant changes.

Heat Processing.

In shellfish growing areas where low levels of PSP 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 the toxin concentration of certain toxins in 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; and must require that the processor provide adequate demonstration of the destruction of the biotoxin and adequate controls to assure that the end product is safe for human consumption.

~~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 . 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.~~

~~**Introductin**~~

~~Shellfish are filter feeders and, therefore, they have the ability to concentrate toxic~~

phytoplankton from the water column when present in shellfish growing waters. The toxins produced by 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 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. 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 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.

While there is a wide range of methodologies developed for screening and confirmation of toxic phytoplankton and their toxins, methods must be adopted into the NSSP if they are to be implemented for the confirmation of toxins for making decisions to reopen growing areas. Additionally, there are screening methods that have been evaluated by the ISSC and found fit for purpose for the NSSP, thereby providing confidence in those methods 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, and limitations 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 five (5) types of shellfish poisonings which are specifically addressed in the NSSP Model Ordinance: Paralytic Shellfish Poisoning (PSP), Neurotoxic Shellfish Poisoning (NSP), Amnesic Shellfish Poisoning (ASP), also known as Domoic Acid poisoning, Diarrhetic Shellfish Poisoning (DSP) and Azaspiracid Shellfish Poisoning (AZP). Of these five (5) types of shellfish poisoning, PSP, NSP and ASP are the most dangerous PSP and ASP can cause death at sufficiently high 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 may result in 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. NSP has occurred from the Carolinas and extends throughout the Gulf Coast states. It shows no indication of regular recurrence and shellfish generally take longer to eliminate the toxin (Liston, 1994). DSP and AZP cause similar symptoms mostly related to diarrhea and abdominal pain. DSP toxin-producing phytoplankton have been documented to occur off the coasts of Washington (Trainer et al. 2013) and Texas (Deeds et al. 2010) as well as off the coast in the northeast (e.g., Massachusetts [Tong et al. 2015]).While AZP has occurred in the U.S., the contaminated shellfish was imported (Klontz et al. 2009). Harvesting closures in the U.S. have not been documented due to AZP toxins.~~

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

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

~~In shellfish growing areas where low levels of PSP 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 the PSP toxin concentration 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 *Pseudonitzachia*. Blooms of *Pseudonitzachia* are of varying intensity, duration and~~

extent.. During the 1991-1992 incident in Washington and the 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 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, ASP, DSP and AZP. 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 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

The contingency plan must describe administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of shellfish toxicity (Wilt, 1974). The primary goal of this planning should be to ensure that maximum public health protection is provided. To achieve this goal the following objectives should be met:

*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.

Recommended Contingency Plan Guidelines

- The process for precautionary closures:

- A sampling plan that considers water samples to evaluate the extent and intensity of the bloom
- A sampling plan that considers species specific shellfish sampling
- Access to screening tests; both rapid and approved methods
- Trained staff to carry out sample collection and testing if necessary
- A reopening criteria

The Marine Biotoxin Management Plan

The marine biotoxin management plan is primarily for proactive management of marine biotoxins based on 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 objectives should be met:

- 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 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.

** 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 station" (for both phytoplankton and shellfish monitoring) and "critical species" concepts (for shellfish monitoring).

   * Sampling 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. For example, mussels have been found to be useful for early PSP detection.~~
~~* The frequencies and periods for collection of samples should be established recognizing the randomness of PSP blooms. This assumes several years of baseline data in order to establish stations and sampling plans.~~
~~* Frequency of sampling should be adequate to monitor for fluctuations in coastal phytoplankton populations.~~

~~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 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 Biotoxin 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.

** 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
Title 21 CFR Part 7
References

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Public Health Significance	Marine biotoxins can cause injury, illness, or death. More clearly presented guidance will assist control authorities in developing marine biotoxin contingency and management plans.
Cost Information	None
Action by 2019 Task Force I	Recommended referral of Proposal 19-124 to an appropriate committee as determined by the Conference Chairperson.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-124.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-124.

Proposal No. 19-125

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	*Karenia brevis* Guidance
Specific NSSP Guide Reference	Section IV Guidance Documents – Chapter II. Growing Areas
Text of Proposal/ Requested Action	**.02 Guidance for Developing Marine Biotoxin Plans**

Introduction

Shellfish are filter…
There are a…
There are five…
Both *Alexandrium* and…
The minimum concentration…

The NSSP Model…
In shellfish growing…
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 brevis* in the water column equal or exceed 5,000 cells per liter of water.

Public Health Significance	The 5,000 cell count standard applies to *Karenia brevis* only
Cost Information	
Action by 2019 Task Force I	Recommended adoption of Proposal 19-125 as amended.

.02 Guidance for Developing Marine Biotoxin Plans

Introduction

Shellfish are filter…
There are a…
There are five…
Both *Alexandrium* and…
The minimum concentration…

The NSSP Model…
In shellfish growing…
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 *Karenia brevis* in the water column equal or exceed 5,000 cells per liter of water.~~

Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-125.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-120.

Submitter

US Food & Drug Administration (FDA)
Melissa.Abbott@fda.hhs.gov

Proposal Subject

MPN-Real-Time PCR for Enumeration of Vibrio vulnificus in Oysters

Specific NSSP Guide Reference

Section IV. Guidance Documents, Chapter II. Growing Areas .14 Approved NSSP Laboratory Tests.

Text of Proposal/ Requested Action

5. Approved Methods for Vibrio Enumeration

	Vibrio Indicator Type:	**Application: PHP Sample Type: Shucked**	**Application: Reopening**
EIA[1]	***Vibrio vulnificus (V.v.)***	**X**	
MPN[2]	***Vibrio vulnificus (V.v.)***	**X**	
SYBR Green 1 QPCR-MPN[5]	***Vibrio vulnificus (V.v.)***	**X**	
MPN[3]	***Vibrio parahaemolyticus (V.p.)***	**X**	
PCR[4]	***Vibrio parahaemolyticus (V.p.)***	**X**	
MPN-Real Time PCR[6]	***tdh+*** and ***trh+ Vibrio parahaemolyticus (V.p.)***	**X**	**X**
MPN-Real Time PCR[7]	***Vibrio parahaemolyticus (V.p.)***	**X**	**X**
Direct Plating Method[8]	***Vibrio parahaemolyticus (V.p.)***		**X**
MPN-Real Time PCR[9]	***Vibrio vulnificus (V.v.)***	**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 gene probe for vvhA as described by Wright et al., or a method that a State can demonstrate is equivalent.

[3] MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, followed by confirmation using biochemical analyses or the DNA-alkaline phosphatase gene probe for tlh as described by McCarthy et al., or a method that a State can demonstrate is equivalent.

[4] MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, and as described in the "Direct Plating Procedure for the Enumeration of Total and Pathogenic *Vibrio parahaemolyticus* in Oyster Meats" developed by FDA, Gulf Coast Seafood Laboratory, or a method that a State can demonstrate is equivalent.

[5] *Vibrio vulnificus*, ISSC Summary of Actions 2009. Proposal 09-113, Page 123.

[6] MPN-Real Time PCR Method for the tdh and trh Genes for Total *V. parahaemolyticus* as described in Kinsey et al., 2015. ISSC 2015 Summary of Actions Proposal 15-111, Page 397.

[7] MPN-Real Time PCR Method for the *tlh* gene for total *V. parahaemolyticus* as described in Kinsey et al., 2015. ISSC 2015 Summary of Actions Proposal 15-113, Page 418

[8] Direct Plating Procedure in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, and as described in the 'Direct Plating Procedure for the Enumeration of Total and Pathogenic *Vibrio parahaemolyticus* in Oyster Meats' developed by FDA, Gulf Coast Seafood Laboratory.

[9] MPN-Real Time PCR Method for the vvh gene for total *V. vulnificus* as described in Kinsey et al., 2015.

Public Health Significance

This MPN-real-time PCR method provides results in as little as 24 h from receipt of sample. The current NSSP methods for enumeration of *Vv* have limitations: the

	traditional MPN requires a minimum of 3 days and the SYBR Green PCR is only validated on an instrument platform which is no longer supported by the manufacturer. This method provides an additional option for laboratories to maintain the same level of testing as has been maintained in the program.
Cost Information	This method costs ~$100 per sample for laboratory consumables, supplies, and reagents. Most equipment needed for testing is standard microbiology equipment, but purchase of a heat block (~$400) and/or centrifuge (~$2,500) may be necessary. Purchase of a real-time PCR instrument will be required ($30,000-$45,000). Additional costs for a laboratory would vary based on their operational overhead and labor.
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-126 as submitted.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-126.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-126.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-126.

Proposal No. 19-127

Submitter	Leanne J. Flewelling Florida Fish and Wildlife Conservation Commission leanne.flewelling@myfwc.com
Proposal Subject	Modification of the MARBIONC Brevetoxin ELISA Standard Operating Procedures
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas. 14 Approved NSSP Laboratory Tests 4. Approved Limited Use Methods for Marine Biotoxin Testing
Text of Proposal/ Requested Action	In 2017, the ISSC approved the MARBIONC Brevetoxin ELISA as a Limited Use Method under the NSSP (Proposal 17-107). The Standard Operating Procedure (SOP) for the MARBIONC Brevetoxin ELISA submitted as a part of the supporting documents for Proposal 17-107 specifies that quantification of sample dilutions is restricted to those dilutions falling within the linear portion of the standard curve, which is specified as the range of concentrations that yield 20-70% inhibition in the assay. One of the QA/QC criterion in the SOP requires that the variation (%CV) of concentrations calculated from sample dilutions falling within this range must be <20%. This proposal is to modify the MARBIONC ELISA SOP to: a) narrow the range for quantifying sample dilutions to 30%-70%, b) update the QA/QC criteria to reflect this change, and c) make minor additions and corrections to the text of the SOP. The modified SOP with proposed changes is provided in Appendix A. Data and justification for the proposed changes are provided in Appendix B.
Public Health Significance	The approval of this ELISA as a Limited Use Method for testing to support the NSSP has enabled rapid testing for NSP, which has enhanced the protection of public health by enabling more frequent NSP testing. Revising the SOP and QA/QC criteria will help to minimize avoidable QA/QC failures while still controlling for errors and protecting public health.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-127 as submitted.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-127.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-127.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-127.

Proposal No. 19-128

Submitter	Gina Olson Washington State Dept of Health Gina.olson@doh.wa.gov
Proposal Subject	Laboratory Method for *Vibrio parahaemolyticus* and *Vibrio vulnificus* Enumeration and Detection Through MPN and Real-Time PCR
Specific NSSP Guide Reference	Section IV Guidance Documents Chapter II Growing Areas .14 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	5. Approved Methods fir Vibrio Enumeration

	Vibrio Type:	**Application : PHP Sample Type:**	**Application : Reopening**
EIA[1]	***Vibrio vulnificus (V.v.)***	X	
MPN[2]	***Vibrio vulnificus (V.v.)***	X	
SYBR Green 1 QPCR-MPN[5]	***Vibrio vulnificus (V.v.)***	X	
MPN[3]	***Vibrio parahaemolyticus (V.p.)***	X	
PCR[4]	***Vibrio parahaemolyticus (V.p.)***	X	
MPN-Real Time PCR[6]	***tdh+ and trh+ Vibrio parahaemolyticus (V.p.)***	X	X
MPN-Real Time PCR[7]	***Vibrio parahaemolyticus (V.p.)***	X	X
MPN-Real Time PCR[9]	***Vibrio parahaemolyticus (V.p.)* and *Vibrio vulnificus (V.v.)***	X	X
Direct Plating Method[8]	***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 gene probe for vvhA as described by Wright et al., or a method that a State can demonstrate is equivalent.

3 MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, followed by confirmation using biochemical

analyses or the DNA-alkaline phosphatase gene probe for tlh as described by McCarthy et al., or a method that a State can demonstrate is equivalent.

[4] MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, and as described in the "Direct Plating Procedure for the Enumeration of Total and Pathogenic *Vibrio parahaemolyticus* in Oyster Meats" developed by FDA, Gulf Coast Seafood Laboratory, or a method that a State can demonstrate is equivalent.

[5]*Vibrio vulnificus*, ISSC Summary of Actions 2009. Proposal 09-113, Page 123.

[6]MPN-Real Time PCR Method for the tdh and trh Genes for Total *V. parahaemolyticus* as described in Kinsey et al., 2015. ISSC 2015 Summary of Actions Proposal 15-111, Page 397.

[7]MPN-Real Time PCR Method for the *tlh* gene for total *V. parahaemolyticus* as described in Kinsey et al., 2015. ISSC 2015 Summary of Actions Proposal 15-113, Page 418

[8]Direct Plating Procedure in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, and as described in the 'Direct Plating Procedure for the Enumeration of Total and Pathogenic *Vibrio parahaemolyticus* in Oyster Meats' developed by FDA, Gulf Coast Seafood Laboratory.

[9]MPN-Real Time PCR Method for *Vibrio parahaemolyticus* and *Vibrio vulnificus.* Washington State Department of Health, Food and Shellfish Bacteriology Laboratory.

Public Health Significance	The purpose of this method is to provide laboratories supporting the NSSP the ability to rapidly quantify *Vibrio parahaemolyticus (Vp)* and *Vibrio vulnificus (Vv)* from oysters using a high throughput real-time PCR assay. Rapid and early detection of these pathogens, complying with the required quantitative detection guidelines suggested by the ISSC, will help the shellfish industry market oysters for consumption that are within regulatory limits for these pathogens. This method once approved would add a testing method of MPN Real-Time PCR for *Vibrio vulnificus* and it would be an alternative to the *Vibrio parahaemolyticus* MPN Real-Time PCR methods already approved in the 2017 Model Ordinance.
Cost Information	The cost for this method is approx. $155 per sample. This estimate is based on recurring costs of consumables, reagents, and supplies needed for routine testing. It does not include indirect materials considered to be standard microbiology equipment such as analytical balance, PCR workstation, DNA purification system, refrigerator, pipettes, etc.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-128 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-128.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-128.
Action by FDA February	Concurred with Conference action on Proposal 19-128.

21, 2020

Proposal No. 19-129

Submitter	Leonora Porter- Spokesperson Northeast Laboratory Evaluation Officers and Managers (NELEOM) leonora.porter@dec.ny.gov
Proposal Subject	Micropipettor Verification
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, NSSP Laboratory Evaluation Checklists, 2. Shellfish Laboratory Evaluation Checklist for Mouse Bioassay (MBA) and Scotia Rapid Test for PSP.
Text of Proposal/ Requested Action	The requested action is to adopt the new text to be consistent across checklists for the NSSP MBS and Scotia Rapid Test (SRT) for PSP under Part III, Section 3.1, Screening by SRT item 3.1.7.
Public Health Significance	Quality Assurance and Standardization are integral to the validity of the NSSP laboratory. This includes verifying the measurement accuracy of pipetting instruments including micropipettors. There are no recognized references that state micropipettors must receive third party certifications. There is no indication as to what "Level" calibration should exist. The reference for this item is only **#2, Good Laboratory Practice**. Accuracy measurement assurance should be based on workload and use. Pipette calibration values on certificates obtained in a calibration laboratory (known as a controlled laboratory) do not accurately transfer to the NSSP laboratory and therefore do not provide assurance and defensibility. A pipette's measurement accuracy is influenced by its *physical uncertainty*, *environmental uncertainty* (i.e., temperature, vibration and humidity) and *operator use uncertainty*. These uncertainties will differ between laboratories. Pipette performance in the NSSP (non-controlled laboratories) is impacted by the temperature and viscosity of the fluid, the skill of the operator and choice of tip. Conducting in-house verifications for each operator, using a verified balance provides a better assessment of the actual measurement accuracy of what the pipet is delivering. When the uncertainty of measurement exceeds the stated laboratory established threshold, adjustments are made. As a component of a Laboratory's Quality Management System, the individual laboratory can institute legally defensible and measurement assurance practices appropriate for the laboratory's workload, testing and ambient conditions. Calibration Cost Information from one Pipet Manufacturer: 1. Calibration and Maintenance - Offers three "levels" of examination, with an assorted number of readings at 3 volumes, across different channel pipettors. Cost Range $30 - $225 per unit. 2. Calibration only (center channel only) - $30 - $180 if unit passed on the initial attempt. 3. Non-Operational pipette repair evaluation (no calibration and parts additional cost) starting at $28/unit.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended no action on Proposal 19-129. Rationale: The recommended new text would replace existing language that is needed.
Action by 2019 Task	Recommended adoption of Laboratory Committee recommendation on Proposal

Force	19-129.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-129.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-129.

Proposal No. 19-130

Submitter	Leonora Porter - Spokesperson Northeast Laboratory Evaluation Officers and Managers (NELEOM) leonora.porter@dec.ny.gov
Proposal Subject	Microbiology Laboratory Evaluation Checklist- Standards Thermometer
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, 1. NSSP Laboratory Evaluation Checklist for Microbiology
Text of Proposal/ Requested Action	The requested action is to adopt modified standards thermometer language to correct checklist inconsistencies in Section 1.4 Laboratory Equipment item 1.4.21.
Public Health Significance	All standards thermometers allowed for in section 1.4.23, not just mercury-in-glass thermometers, should be calibrated and traceable to NIST at the points of use.
Cost Information	Cost of calibration.
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-130 as submitted.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-130.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-130.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-130.

Proposal No. 19-131

Submitter	Leonora Porter - Spokesperson NELEOM – Northeast Laboratory Evaluation Officers and Managers leonora.porter@dec.ny.gov
Proposal Subject	NSSP Microbiology Laboratory Evaluation Checklist – Reagent Water Quality
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, 1. NSSP Laboratory Evaluation Checklist for Microbiology.
Text of Proposal/ Requested Action	The requested action is to adopt the modified text and update the reference in Section 1.7 Media Preparation for checklist item 1.7.6.
Public Health Significance	The suggested change addresses the importance of accurate information used in laboratory Quality Assurance Programs (QAPs) for recommended limits for the quality of reagent water used for microbiology testing by correcting the maximum acceptable limits for conductivity and resistivity testing based on the most current ***Standard Methods*** Edition. For 26 years, the incorrect units of measure for conductivity and resistivity have been printed in laboratory reference materials: ***Standard Methods for the Examination of Water and Wastewater***, 1992, 18th Edition; ***Standard Methods***, 2012, 22nd Edition; and ***Standard Methods***, 2017, 23rd Edition. The QA information is finally corrected in the ERRATA, dated 5/29/18 for ***Standard Methods*** 23rd Edition. The material states "In Section 9020, Table 9020:II (p. 9-14), the recommended Maximum Acceptable Limit for Conductivity Test should be "<2 µmhos/cm (µSiemens/cm) at 25°C." The incorrect "resistance" statement from the 18th Edition is removed in the 22nd and 23rd Editions of ***Standard Methods***. The resistivity (also called specific resistance) is the reciprocal of the conductivity, not resistance. A resistivity recommendation can be found in the Reagent Grade Water section.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-131 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-131.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-131.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-131.

Proposal No. 19-132

Submitter	Leonora Porter, Spokesperson NELEOM – Northeast Laboratory Evaluation Officers and Managers leonora.porter@dec.ny.gov
Proposal Subject	Microbiology Laboratory Evaluation Checklist - Working Thermometers
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, 1. NSSP Laboratory Evaluation Checklist for Microbiology
Text of Proposal/ Requested Action	The requested action is to adopt the modified text of the NSSP microbiology checklist, section 1.4 Laboratory Equipment, item 1.4.24:
Public Health Significance	The laboratory's goal is to ensure high-quality data using accepted scientific practices. The designated changes incorporate recommended best practices from a current recognized scientific publication. These types of acknowledged practices are used to develop a laboratory's Quality Assurance Program (QAP). The *verification* of working thermometers is now suitably referenced to support past and present practices in program laboratories and *recommends a rejection component (new)*. The newer/current reference material is cited to strengthen confidence in the acceptability of past practices for "checking" accuracy in working temperature monitoring devices. ***Standard Methods,*** 23rd Edition, states "Annually, or preferably semiannually, **verify** the accuracy of all working temperature-sensing devices (e.g., liquid-in-glass thermometers, thermocouples, and temperature-recording instruments) at the use temperature(s). To do this, compare each device's measurements to those of a certified NIST temperature-sensing device or one traceable to NIST and conforming to NIST specifications. Discard temperature-sensing devices that differ by >1ºC from the reference device."
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-132 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-132.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-132.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-132.

Proposal No. 19-133

Submitter	Leonora Porter - Spokesperson Northeast Laboratory Evaluation Officers and Managers (NELEOM) leonora.porter@dec.ny.gov
Proposal Subject	Microbiology & PCR Laboratory Evaluation Checklists - Working Thermometers
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, NSSP Laboratory Evaluation Checklists
Text of Proposal/ Requested Action	The requested action is to adopt modified working thermometer language for these two NSSP laboratory evaluation checklists items. The modification is to remove the word "calibrated" and add thermometer accuracy requirements.
Public Health Significance	There are currently no NSSP accuracy criteria established for Liquid-in-Glass –thermometers. This proposal establishes uncertainty requirements that should be considered prior to purchase since all thermometers and temperature recording devices are not created equally. Quality Assurance and Standardization are integral to the validity of the NSSP laboratory. For thermometers there are several factors that influence temperature readings; therefore, controlling thermometer accuracy will impact thermometer standardization across NSSP laboratories. A thermometer's accuracy is a product of its *manufacturing uncertainty*, *measurement uncertainty* and *environmental uncertainty* which all must be considered and evaluated by the purchaser. Only thermometers that are manufactured accurately and are found *fit for purpose* for the NSSP laboratory should be purchased. Some Liquid-in-Glass thermometers are manufactured with accuracies (> 0.2ºC) that are greater than the water bath temperature limit of ±0.2°C; these thermometers should not be purchased for the NSSP laboratory. As stated in Reference #4, NIST Monograph 150 "the accuracy attainable is principally limited by the characteristics of the thermometer itself." Therefore, a working thermometer's accuracy should be assessed prior to purchase. Calibration is performed post purchase. *Calibration quantifies <u>only</u> the temperature* ***measurement uncertainty*** *at the single temperature point assessed.* Calibration without also considering the ***manufacturing uncertainties*** of the thermometer is inaccurate: generating a false security for accuracy. Calibration values are only accurate at the environmental conditions found within the calibration laboratory; when total immersion thermometers are immersed to the test temperature being measured with the emergent stem at ambient temperature. In the NSSP laboratory, the emergent stem <u>is not</u> at ambient temperature. This creates ***environmental uncertainty*** which invalidates the calibration certificate and requires experience and knowledge in generating an accurate stem correction. An inaccurate stem correction compounds the degree of error in the final temperature reading. The current NSSP practice of calibrating an inappropriate thermometer against the undefined calibration standard (NIST, ASTM, Primary, Secondary, etc) and then using this thermometer incorrectly in the laboratory environment negates any

assurance received by having a calibration certificate. This practice would not be legally defensible.

NSSP Quality Assurance and Standardization would be better served to establish manufacturing accuracy requirements that only allow for the use of appropriate working thermometers. *These working thermometers will then be verified against a calibrated standards thermometer, that is traceable to NIST in section 1.4.24.*

Savings: Calibration costs per thermometer: $125 for the first point and $60 for each additional point. Most lab are locked into local calibration facilities, within driving distance of their labs, if their thermometers are mercury. Postal hazard restrictions prohibit mercury thermometers being shipped in the mail.

Cost Information	none
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-133 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-133.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-133.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-133.

Proposal No. 19-134

Submitter	J. Michael Hickey, Jeff Kennedy, Diane Regan Massachusetts Division of Marine Fisheries Michael.Hickey@mass.gov
Proposal Subject	Membrane Filtration Technique for Seawater using mEndo Agar LES 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 , NSSP Laboratory Evaluation Checklists, NSSP Laboratory Evaluation Checklist for Microbiology
Text of Proposal/ Requested Action	The Requested Action is to adopt the attached checklist for the Membrane Filtration Technique for Seawater using mEndo Agar LES and to append the NSSP Laboratory Evaluation Checklist for Microbiology found at the end of section .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists to include this checklist.
Public Health Significance	The NSSP does not have a checklist for Total Coliform analysis on UV Seawater using the NSSP approved method of Membrane Filtration with mEndo Agar LES. Checklists provide quality assurance and method support for laboratories and for Laboratory Evaluation Officers to standardize and evaluate laboratories which use approved methods in support of the NSSP. The attached checklist for this NSSP approved method provides such standardization, quality assurance and background documentation for method procedures. As a laboratory evaluation tool with critical and key codes identified it will be used for determination of laboratory conformance and compliance.
Cost Information	none
Action by 2019 Laboratory Committee	Recommended no action on Proposal 19-134. Rationale: This issue is addressed by Proposal 19-137.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-134.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-134.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-134.

Submitter	Leonora Porter, Spokesperson Northeast Laboratory Evaluation Officers and Managers (NELEOM) leonora.porter@dec.ny.gov
Proposal Subject	Microbiology Laboratory Evaluation Checklist - Sterilization
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, 1. NSSP Laboratory Evaluation Checklist for Microbiology
Text of Proposal/ Requested Action	The requested action is to adopt the modified text of the NSSP microbiology checklist, section 1.6 Sterilization and Decontamination, item 1.6.3:
Public Health Significance	The laboratory's goal is to ensure high-quality data using accepted scientific practices. The denoted information acknowledges recommended best practices used in recognized scientific publications to develop a laboratory's Quality Assurance Program (QAP) for sterilization practices at a wider range of temperature. The sterilization temperature range and the verification of working thermometers are now acceptably referenced to support past and present practices in program laboratories. The current reference material is cited to foster confidence in accepting the changes to an elevated sterilization temperature range and strengthen confidence in the acceptability of past practices for checking accuracy of working temperature monitoring devices. Most references for media sterilization simply state "121ºC for no less than 15 minutes." ***Difco***, a leading media manufacturer, states "A temperature range of 121-124ºC for 15 minutes is an accepted standard condition for sterilizing up to one liter of culture medium. The definition of "autoclave at 121ºC for 15 minutes" refers to the temperature of the contents of the container being held at 121ºC for 15 minutes, not to the temperature and time at which the autoclave has been set." ***Standard Methods,*** 23rd Edition, states "Annually, or preferably semiannually, **verify** the accuracy of all working temperature-sensing devices (e.g., liquid-in-glass thermometers, thermocouples, and temperature-recording instruments) at the use temperature(s). To do this, compare each device's measurements to those of a certified NIST temperature-sensing device or one traceable to NIST and conforming to NIST specifications. Discard temperature-sensing devices that differ by >1ºC from the reference device…..For general sterilization tasks, the recommended autoclave temperature range is 121 to 124ºC (at 200 kPa/29 PSI), although higher temperatures (≥121ºC) are acceptable for decontaminating laboratory material." *Each lab's QAP **must validate** temperature, time and pressure parameters for successful sterilization for media, reagents, supplies and spores using a verified working temperature monitoring device*.
Cost Information	No Cost. Minor adjustment during regularly scheduled sterilizer preventative maintenance service.
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-135 as amended.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-135.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-135.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-135.

Proposal No. 19-136

Submitter	US Food and Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	NSSP DSP 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 laboratory evaluation checklist for Diarrhetic Shellfish Poisoning LC-MS/MS.
Public Health Significance	The Diarrhetic Shellfish Poisoning (DSP) LC-MS/MS checklist will provide the means of assessing the competence of the laboratory to perform the test method.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-136 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-136.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-136.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-136.

Proposal No. 19-137

Submitter	US Food & Drug Administration (FDA) Melissa.abbott@fda.hhs.gov
Proposal Subject	Checklist for the Bacteriological Analysis of UV Treated Process Water Samples by Membrane Filtration (MF) using mEndo Agar LES
Specific NSSP Guide Reference	NSSP *Guide for the Control of Molluscan Shellfish*, 2017 Revision, "Guidance Documents", Chapter II. Growing Areas, .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists, 1. NSSP Laboratory Evaluation Checklists for Microbiology.
Text of Proposal/ Requested Action	Incorporate Sections 2.11 through 2.14 for the Bacteriological Analysis of UV Treated Process Water Samples by Membrane Filtration using mEndo Agar LES into the NSSP Laboratory Evaluation Checklist for Microbiology.
Public Health Significance	Incorporation of the mEndo Agar LES membrane filtration method into the Microbiology Checklist will provide the means of assessing the competence of the laboratory to perform the test method.
Cost Information	NA
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-137 as amended.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-137.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-137.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-137.

Proposal No. 19-138

Submitter	US Food and Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	NSSP Microbiology 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 modified text of four (4) NSSP microbiology checklist items in the Laboratory Equipment and Sterilization and Decontamination sections; said NSSP checklist items are 1.4.5, 1.4.21, 1.6.10, and 1.6.11.
Public Health Significance	The proposed modifications are to improve consistency in current NSSP microbiology checklist language and account for technology improvements to laboratory equipment.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-138 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-138.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-138.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-138.

Submitter	NSSP Laboratory Evaluation Officers Team FDA LEO and State LEO Team- represented by Melissa Farrell Melissa.Farrell@fda.hhs.gov
Proposal Subject	NSSP Microbiology 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 modified text of NSSP microbiology checklist item 1.4.24 in the Laboratory Equipment section and 3.2.7 in the Preparation of Shellfish for Examination section and add an additional reference to item 3.2.7.
Public Health Significance	1.4.24: One of the most basic attributes of any thermometer is its accuracy, and because a thermometer is only as valuable as the temperature it measures, accuracy is of the utmost importance. Calibration defines the accuracy by quantifying and controlling uncertainties within the measurement process. The quality of data must be known and established beyond a reasonable doubt before it can be used logically in any application; thus, calibration is an integral part of the lab's Quality Assurance. When individuals record and maintain data, proof of calibration demonstrates that the measurements performed are consistent with the "true value." An intermediate check is an action that the user takes to verify that the measuring instrument continues to be suitable for its purpose. Currently, the NSSP requires laboratories to perform intermediate checks on incubator and water bath thermometers at the temperature at which they are used. This requirement does not include refrigerator or freezer thermometers; however, NSSP Microbiology checklist items 1.4.9 and 1.4.10 require laboratories to measure and record refrigerator temperature data. When properly performed, an ice point is recommended as a “fixed point” for calibration of liquid in glass thermometers as it provides a reliable reference temperature at 0 °C with an estimated measurement uncertainty of ± 0.002 °C for determining the thermometer’s accuracy at all calibration points. The reliability and high degree of accuracy achieved by performing a proper ice point is due to the ice-water mixture stabilizing at its own “triple point.” Due to the nature of an ice point, it is the most common calibration point used for intermediate checks. 3.2.7 and reference addition: This change corrects an oversight in the current checklist regarding the role of gloves when shucking.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-139 as submitted.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-139.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-139.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-139.

Proposal No. 19-140

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	NSSP Microbiology 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 modified text of the attached checklist for Bacteriological Examination of Soft-shelled Clams and American Oysters for Male Specific Coliphage (MSC), starting at section 3.10.
Public Health Significance	The proposed modifications are to provide clarification to bench analysts and LEOs for consistent performance and evaluation of the method for the NSSP.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-140 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-140.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-140.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-140.

Proposal No. 19-141

Submitter	US Food and Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	NSSP Receptor Binding Assay for Paralytic Shellfish Poisoning (PSP) 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 laboratory evaluation checklist for the Receptor Binding Assay for Paralytic Shellfish Poisoning (PSP).
Public Health Significance	The Receptor Binding Assay for Paralytic Shellfish Poisoning (PSP) checklist will provide the means of assessing the competence of the laboratory to perform the test method.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-141 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-141.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-141.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-141.

Proposal No. 19-142

Submitter	Shelley Lankford WA DOH Public Health Laboratories Shelley.Lankford@DOH.WA.GOV
Proposal Subject	Add the use of a mechanical shaker to the water microbiology methods checklist in the sample preparation requirements section and include a reference.
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 SHELLFISH LABORATORY EVALUATION CHECKLIST PART II - SEAWATER SAMPLES 2.2 Bacteriological Examination of Seawater by the APHA MPN 2.2.3 Sample and dilutions of sample are shaken vigorously (25 times in a 12" arc in 7 seconds) before inoculation. 2.5 Bacteriological Examination of Seawater by the MA-1 Method 2.5.5 Sample and dilutions of sample are shaken vigorously (25 times in a 12" arc in 7 seconds) before inoculation. 2.9 Sample Analyses - MF using mTEC Agar 2.9.3 The sample is shaken vigorously (25 times in a 12″ arc in 7 seconds) before filtration.
Text of Proposal/ Requested Action	Adopt the text of update the shellfish laboratory evaluation microbiology checklist (attached) to include the use of a mechanical shaker for sample preparation and include a reference for the use in the checklist's lists of references.
Public Health Significance	This proposal does not have direct public health significance but directly impacts the health of laboratorians performing water microbiological testing by allowing the use of a mechanical shaker to reduce or alleviate repetitive motion injuries caused by hand shaking the water samples. Work related injuries in the laboratory due to poor ergonomics are increasing every year and are costly to the laboratory due to work related injury claims. FDA LEO's currently allow the use of this equipment but there is no mention of the use of the equipment, no guidance for use of the equipment nor any reference from a reliable source in the current microbiology checklist for allowing the use of a mechanical shaker for sample preparation purposes.
Cost Information	This proposal updates text in the NSSP Manual wherever found in the microbiology checklist if approved by the conference. Minimal costs will be incurred by the ISSC administration when the laboratory evaluation checklist development and updating occurs at the ISSC office as part of the biannual NSSP Manual update process.
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-142 as amended. .
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-142.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-142.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-142.

Proposal No. 19-143

Submitter	Leanne Flewelling Florida Fish and Wildlife Conservation Commission leanne.flewelling@myfwc.com
Proposal Subject	MARBIONC Brevetoxin (Neurotoxic Shellfish Poisoning; NSP) ELISA 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 MARBIONC Brevetoxin ELISA method 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	The MARBIONC Brevetoxin ELISA method was approved for limited use at the 2017 ISSC meeting. Currently, there is no checklist adopted by the ISSC for this method. The attached checklist provides the quality assurance and method requirements that laboratory evaluation officers will use to evaluate laboratories implementing the MARBIONC Brevetoxin ELISA method 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	N/A
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-143 as amended.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-143.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-143.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-143.

Submitter	Thomas Howell Spinney Creek Shellfish, Inc. tlhowell@spinneycreek.com
Proposal Subject	Guidance for Assessing the Viral Impact from Waste Water Treatment Plant Outfall on Adjacent Growing Areas using the Male-specific Coliphage Method on Effluent Samples.
Specific NSSP Guide Reference	Section IV Guidance Documents - Chapter II. Growing Areas - .19 Classification of the Shellfish Growing Waters Adjacent to Waste Water Treatment Plants
Text of Proposal/ Requested Action	The requested action is that an ISSC committee be formed to draft guidance language describing how to best use MSC effluent sampling techniques to assess the viral impact on adjacent growing areas. This proposed action is the result of recent collaborative work funded by New Hampshire Sea Grant. The PI's and project participants on this project included University of New Hampshire Sea Grant, Connecticut Sea Grant, Spinney Creek Shellfish, Connecticut Department of Agriculture, New Hampshire Department of Environmental Services, US Food and Drug Administration Center for Food Safety and Applied Nutrition, and US Food and Drug Administration Gulf Coast Seafood Laboratory. An optimized method to determine MSC in effluent samples, both pre-treatment (disinfection) and final effluent has been submitted to the Lab Committee for approval. Two years of field studies were recently completed which looked closely at 2 plants in CT and 4 plants in NH. Results of these field studies were reported at the 2019 NESSA meeting in Plymouth MA. By taking effluent samples from WTP's two to three times per week over an extended period, a database can be assembled including Geomean and P95 values in a strategy consistent with NSSP practices. Plotting the effluent time-series data can be used to identify times when plant performance is degraded by predictable, challenging, conditions whether they are operational or environmental. By informing dye study work with WWTF effluent analysis, much more informed decisions can be made with respect to classification of adjacent growing waters. Simply multiplying the P95 results from final effluent statistical analysis by the dilution line in question, an upper level of MSC concentration MSC in the growing waters can be estimated. An interpretation matrix for final effluent MSC time-series analysis to interpret results in a relative way is proposed.
Public Health Significance	The Public Health Significance of this proposal is substantial. Dye studies alone are protective of public health using the 1000:1 dilution line for classification purposes. However, MSC assessment of effluent samples gives a much more informed picture of how appropriate the 1000:1 line is in a particular situation. If an under-designed, problematic WWTP is not adequately deactivating viruses, a higher dilution may be required. This is an important consideration when dealing with a WWTP that does not perform to typical standards of secondary treatment with effective disinfection. However, the study has shown that many modern and advanced WWTPs can be reliably operated at sufficient performance levels to justify the 300:1 dilution line for the establishment of a prohibited classification around the WWTP outfall. As time continues and WWTPs are upgraded, this method and technique may permit increased utility of the growing area between the 300:1 and 1000:1 dilution line. In conclusion, public health can be informed and optimized while maximum commercial utilization of growing areas can be achieved.

Cost Information	The MSC method for WWTP effluent samples is inexpensive and easy to perform. Costs become more significant when one considers the personnel and travel time needed to sample the WWTP's. The state control agency can optimize this work by focusing field work during the winter months when the WWTP are likely more challenged and personnel resources are more available.
Action by 2019 Task Force I	Recommended referral of Proposal 19-144 to an appropriate committee as determined by the Conference Chairman.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-144.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-144.

Submitter	US Food & Drug Administration (FDA)
Email	Melissa.Abbott@fda.hhs.gov
Proposal Subject	Guidance on cleansing studies
Specific NSSP Guide Reference	NSSP Section IV Chapter II .19 VI B.
Text of Proposal/ Requested Action	

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 WWTP failure, a lapse in WWTP treatment leading to untreated or partially treated sewage

discharge, 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:

(a) 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;

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

(c) 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~~;~~ . Studies shall be conducted to document the time interval necessary for the reduction of coliform levels in the shellstock to pre-closure levels. The Authority shall develop and implement a study design that includes:

(i) The utilization of NSSP-conforming laboratories and NSSP-approved methods to analyze coliform in shellstock and water.

(ii) Establishing a pre-closure coliform baseline in shellstock for each species under consideration in the conditional area management plan.

(iii) If re-opening is to be based on coliform levels in the water, identify and describe an association between coliform levels in shellstock for each species under consideration in the conditional area management plan and coliform levels in growing area water.

(iv) Defining conditions under the conditional area management plan which considers various factors including water temperature, salinity, seasonality, and other environmental conditions that may affect the pumping activity of each species of shellstock under consideration.

~~(i)~~(v) A study design and data analysis approach providing statistical reliability. At a minimum, this should include consideration of:

- variability of measurements of indicator levels in replicate samples
- the likelihood or probability that a significant difference in indicator levels will be identified based on the sample outcomes if a substantial difference exists between the populations being sampled.

Irrespective of the type of study design, these considerations apply and should be used to ensure that the number of samples collected is adequate. The number of samples needed increases with increasing variability of the measurements. When there is a substantial difference between indicator levels in the populations being sampled, the study should have at least an 80% probability of identifying this as such.

~~(ii)~~(vi) Determining the time interval for post-closure coliform levels in shellstock and water to return to the pre-closure established baseline.

(d) When utilizing MSC in shellstock in growing areas subjected to suspected human sewage to reopen a closed growing area, studies (utilizing the same format as (c) above) establishing sufficient elapsed time shall document the interval necessary for reduction of viral levels in the shellstock. The utilization of NSSP-conforming laboratories and NSSP-approved methods to analyze MSC in shellstock. Analytical shellstock 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;

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

~~(e)~~(f) 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.

Public Health Significance

This language will provide state shellfish Authorities with guidance regarding establishing the elapsed time to reopen closed conditional management areas and assure that shellstock are not adulterated.

The public health significance of the proposed guidance for statistical reliability of studies used to establish an elapsed time to reopen is evident by considering an example of the effect of application of these criteria. While several different types

of study designs are suitable to identify a minimum elapsed time for pathogen reduction, a common approach is to compare mean log concentrations of fecal indicators in a group of samples collected pre-closure, and representative of baseline, to that in a group of samples collected at the candidate elapsed time post-closure. For this type of study, a two-sample one-sided t-test is typically applied to test the null hypothesis that mean log concentrations are equal. If the test statistic is statistically significant (i.e., $p<0.05$), the null hypothesis is rejected; otherwise, mean concentrations are considered equivalent and the candidate elapsed time sufficient for pathogen reduction.

To satisfy the proposed criteria of statistical reliability the sample size of the study will need to be large enough to achieve, based on expected variability of sample measurements about mean levels, an 80% probability of rejecting the null hypothesis when a minimally consequential difference in means exists. This determination of the sample size is made based on what is called the power function of the test statistic. Explicit formula and/or software to calculate sample sizes based on power functions are widely available for most commonly used hypothesis tests and test statistics. Using such calculations, it can be determined that, when the expected standard deviation of log sample measurements about mean levels is 0.5 logs, the example study design requires 13 samples per group to achieve 80% power (probability) to reject the null hypothesis when a true difference in means of 0.5 logs exists. Consequently, when a difference in means of 0.5 logs is considered consequential, a study of this type with fewer than 13 samples per group would not be considered sufficiently reliable. With an expected standard deviation of 0.5 logs, a sample size of 3 per group would have only a 27% probability of rejecting the null hypothesis when a consequential difference in means of 0.5 logs exists and an 80% probability of rejecting the null hypothesis would be achieved only when the true difference in means is equal to or greater than 1.25 logs.

Cost Information	No additional cost. This is simply providing guidance for a requirement already in place.
Action by 2019 Task Force I	Recommended referral of Proposal 19-145 to an appropriate committee as determined by the Conference Chairperson with the following instructions to develop guidance for cleansing studies and to assess scenarios where water quality sampling could be used in place of cleansing studies.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-145.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-145.

Proposal No. 19-146

Submitter	Leonora Porter - Spokesperson Northeast Laboratory Evaluation Officers and Managers (NELEOM) leonora.porter@dec.ny.gov
Proposal Subject	Micropipettor Verification
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, NSSP Laboratory Evaluation Checklists, 6. Shellfish Laboratory Evaluation Checklist for PCR Microbiology
Text of Proposal/ Requested Action	The requested action is to adopt the new text for the NSSP PCR Microbiology checklist, section 1.4 Laboratory Equipment item 1.4.24.
Public Health Significance	Quality Assurance and Standardization are integral to the validity of the NSSP laboratory. One QA component includes verifying the measurement accuracy of pipetting instruments including micropipettors. There are no recognized references that state micropipettors must receive third party certifications. There is no indication as to what "Level" calibration should exist. The reference for this item is only **#2, Good Laboratory Practice**. Accuracy measurement assurance should be based on workload and use, not calendar year. Pipette calibration values on certificates obtained in a calibration laboratory (known as a controlled laboratory) do not accurately transfer to the NSSP laboratory and therefore do not provide assurance and defensibility. A pipette's measurement accuracy is influenced by its *physical uncertainty*, *environmental uncertainty* (i.e., temperature, vibration and humidity) and *operator use uncertainty*. These uncertainties will differ between laboratories. Pipette performance in the NSSP (non-controlled laboratories) is impacted by the temperature and viscosity of the fluid, the skill of the operator and choice of tip. Conducting in-house verifications for each operator, using a verified balance provides a better assessment of the actual measurement accuracy of what the pipet is delivering. When the uncertainty of measurement exceeds the stated laboratory established threshold, adjustments are made. As a component of a Laboratory's Quality Management System, the individual laboratory can institute legally defensible and measurement assurance practices appropriate for the laboratory's workload, testing and ambient conditions. Savings: Calibration Cost Information from one Pipet Manufacturer: 1. Calibration and Maintenance - Offers three "levels" of examination, with an assorted number of readings at 3 volumes, across different channel pipettors. Cost Range $30 - $225 per unit. 2. Calibration only (<u>center channel only</u>) - $30 - $180 if unit passed on the initial attempt. Non-Operational pipette repair evaluation (no calibration and parts additional cost) starting at $28/unit.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended no action on Proposal 19-146. Rationale: The existing language is needed.
Action by 2019 Task	Recommended the adoption of Laboratory Committee recommendation on

Force I	Proposal 19-146.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-146.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-146.

Proposal No. 19-147

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Relay contaminant reduction studies.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter V. Shellstock Relaying Section @.02 Contaminant Reduction B. (2)
Text of Proposal/ Requested Action	(2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA ~~tolerance~~action levels, tolerances and/or guidance levels and/or levels that are deemed safe through risk evaluation; or
Public Health Significance	Action levels, tolerances and/or guidance levels have not been established for all poisonous or deleterious substances. When there is concern about contamination of shellstock by a poisonous or deleterious substance and no action level, tolerance, or guidance level for that substance, regulators must evaluate risk and establish a level of concern. Suggested change from "tolerance" to "action levels, tolerances, and/or guidance levels" is made to make the language consistent with the title of National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, Section IV Guidance Documents, Chapter II Growing Areas, .08 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood.
Cost Information	Possible increased cost of unknown magnitude related to time necessary to conduct risk evaluations.
Action by 2019 Task Force I	Recommended adoption of Proposl 19-147 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-147.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-147.

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Correct language of MO to reflect current checklists
Specific NSSP Guide Reference	Section II Model Ordinance – Chapter I. Shellfish Sanitation Program for the Authority @.03 Evaluation of Shellfish Sanitation Program Elements B. Criteria for evaluation of shellfish sanitation program elements shall be as follows: 1. Laboratory
Text of Proposal/ Requested Action	Section II Model Ordinance – Chapter I. Shellfish Sanitation Program for the Authority @.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 Section IV 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 Laboratory Evaluation Officer (LEO) scheduling. The Quality Systems evaluation is performed as a desk audit and is in accordance with the checklist

found in Section IV Chapter II.

ii. Technical Evaluation: Shellfish Laboratory will be technical.y evaluation and will be assigned the designation of conforms, provisionally conforms or non-confomance. The criteria used in determining the evaluation designations are included in the NSSP Shellfish Laboratory Evaluation Checklist designated for the specific type of laboratory evaluation being performed. (For more information see Section IV. Guidance Documents Chapter II. Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists

~~Conforms. In order to achieve or maintain conforming status under the NSSP, a laboratory must meet the following laboratory evaluation criteria:~~

~~(a)No critical nonconformities in the microbiological or marine biotoxin component under evaluation have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and~~

~~(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 NSSP Shellfish Laboratory Evaluation Checklist; and~~

~~(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 paralytic shellfish poisoning (PSP) and amnesic shellfish poisoning (ASP) components, or ten (10) critical, key and other nonconformities in total for the neurotoxic shellfish poisoning (NSP) component have been identifiedusing the appropriate NSSP Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and~~

~~(d) No repeat key nonconformities have been identified in the microbiological or marine~~

~~biotoxin component under evaluation in consecutive evaluations using the appropriate NSSP Shellfish Laboratory Evaluation Checklist.~~

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

~~(a) Not more than three (3) critical nonconformities in the microbiological component, four (4) in the PSP and ASP components, or three (3) in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and~~

~~(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 NSSP Shellfish Laboratory Evaluation Checklist; and~~

~~(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 and ASP components or ten (10) critical, key and other nonconformities in total in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation umber must not exceed the numerical limits established for either the critical or key criteria; and~~

~~(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 NSSP Shellfish Laboratory Checklist.~~

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

(a) ~~More than three (3) critical nonconformities in the microbiological component or four (4) in the PSP and ASP components, or three (3) in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Checklist; or~~

~~(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 NSSP Shellfish Laboratory Evaluation Checklist;~~

~~(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 and ASP components, or more than ten (10) critical, key, and other nonconformities in total in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; or~~

~~(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 NSSP Shellfish Laboratory Evaluation Checklist.~~

Public Health Significance	The goal of a laboratory evaluation is to monitor implementation of NSSP Quality Systems and Approved methods. Laboratory data is standardized as a result of this process and reciprocity of shellfish in the commercial market is protected and preserved through defensible practices and transparent requirements. As the laboratory program in the NSSP continues to develop and grow it is prudent to keep requirements in accessible documents with few deviations. Checklists are a cornerstone document for laboratories, referring to these documents ensures laboratories have access to requirements at all times. As laboratorians are the target audience, this is the most sensible place for the actual numbers of nonconformities to reside, and the reference to the checklists in the Model Ordinance ensures the checklists are part of the overarching document adopted by reference or into legislation. Multiple locations of numbers of permissible nonconformities only ensures updates will be missed. As existing structure is in place through the Lab Committee to handle checklists and edits therein, this seems the most reasonable solution.
Cost Information	No cost incurred by change. Practice is already in place.
Action by 2019 Task Force I	Recommended adoption of Proposal 19-148 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-148.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-148.

Proposal No. 19-149

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Biotoxin Guidance
Specific NSSP Guide Reference	Section II. Chapter IV Shellstock Growing Areas-
Text of Proposal/ Requested Action	In conjunction with the adoption of Proposal 13-116 at the 2017 ISSC Biennial Meeting, the voting delegates recommended the Biotoxin Committee develop a guidance document to include guidance for end product testing programs in closed state waters. In addition to proposing guidance, the committee will be making recommendations to modify the monitoring requirements of Chapter IV @.04 Marine Biotoxin Control. These proposed changes are under development. The purpose of this proposal is to advise the ISSC membership that the Biotoxin Committee will be making recommendations to modify Chapter IV @.04 as part of their committee charge from Proposal 13-116 -
Public Health Significance	The proposed changes should clarify and simplify biotoxin monitoring.
Cost Information	
Action by 2019 Biotoxin Committee	Recommended adoption of Proposal 19-149 as substituted.

Section II. 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…
   (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, controlled access in the case of biotoxins or inactive for the harvesting of shellstock. Supporting information for all changes in the status of growing areas shall be documented by a written record in the central file.
      (a) Open Status…
      (b) Closed Status…
      (c) Controlled Access Status. This status can be applied to allow harvesting in areas with biotoxin concerns where routine monitoring or pre-harvest testing is not practical.
      ~~(c)~~(d) Reopened Status...
      (e) Inactive Status…

(f) Remote Status...
(g) Seasonally Remote/Approved Status...

@.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, diarrhetic shellfish poisoning (DSP) and azaspiracid shellfish poisoning (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 and federal partners, shellfish industry, and local health agencies;
(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.

~~**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.~~

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .06~~2~~

B. Marine Biotoxin Management Plan.

In those areas that have been implicated in an illness outbreak or where toxin-producing phytoplankton ~~are known~~ have been documented to occur, ~~and~~ the toxins are prone to accumulate in shellfish, and ~~when appropriate at those~~during times when marine biotoxins ~~can be reasonably predicted~~are likely to occur, representative samples of ~~the~~ water ~~may be collected~~ and/or shellfish shall be collected during harvest periods in accordance with one or a combination of the marine biotoxin management strategies listed below in 4. and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. ~~The samples shall be collected from indicator stations at intervals determined by the Authority.~~

~~Water samples may be assayed for the presence of toxin-producing phytoplankton and shellfish meat samples shall be assayed for the presence of toxins.~~

~~**NOTE:** In situations in which the toxin of concern has an established cell count standard, such as *Karenia brevis*, water and shellfish samples would not be required. Management decisions could be made on either water or shellfish sampling results.~~

(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, and/or AZP; if toxin-producing phytoplankton ~~are known~~have been documented 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 toxin-producing phytoplankton and/or shellfish sampling as described below in (4). It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.~~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.~~i. ~~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;~~.~~ and

(h) Ensure that all shellfish harvested from growing areas or portion(s) of growing areas placed in the controlled access status meets all conditions of harvest restrictions prior to being placed in distribution. This would include all sampling, testing or product holds.

(3) The Authority may use precautionary closures based on shellfish toxicity screening or phytoplankton sample results as defined in their marine biotoxin management ~~program~~plan. Precautionary closures may be lifted immediately:

(a) if confirmatory testing using an approved method shows the level of biotoxin present in shellfish meats is not equal to or above established criteria as described below in ~~Section~~ C; or

(b) when shellfish toxicity screening or phytoplankton sample results indicate that the precautionary closure was not necessary.

(4) Marine biotoxin management strategies are as follows:~~Except that the Authority shall classify as prohibited any growing areas where shellfish are so highly or frequently affected by marine biotoxins or so remote that adequate sampling cannot be achieved and thus the situation cannot be safely managed, the presence of marine biotoxins shall not affect the classification of the shellfish growing area under Section @.03. The Authority may use the conditionally approved classification for areas affected by marine biotoxins.~~

(a) Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species known or suspected to produce marine biotoxins. This is a complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish and must be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(b) Routine shellfish toxicity monitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. Unless species specific shellfish testing is conducted, the highest risk species shall be used. This strategy may be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(c) Pre-harvest shellfish toxicity testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins in the intended harvest area specifically in advance of harvest. This strategy, if used independent of any other strategy, shall permit harvest for a short period of time following testing. This strategy may be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(d) Shellfish lot testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins on a lot basis after harvest. This strategy may be combined with a pre-harvest shellfish toxicity testing strategy, the results of which permit harvest. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.

(e) Pre-harvest shellfish toxicity screening and lot testing: this strategy requires pre-harvest shellfish toxicity screening of the intended harvest area coupled with shellfish lot testing upon landing. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(5) The marine biotoxin management plan ~~may~~ shall include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters, individual growers or individual shellfish dealers, to allow harvesting in ~~designated parts of~~ a ~~State~~ growing area ~~while other parts of the same growing area are~~that is placed in the controlled access~~closed~~ status. Such ~~controlled~~ harvesting shall be conducted with strict assurances of safety and in accordance with the marine biotoxin management strategies listed in (4).

~~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; and~~
~~(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 where routine monitoring of toxin levels is not conducted, in addition to following State 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; and~~
~~(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 toxins that are likely to be present harvesting shall not be permitted if any of the pre-harvested samples contain toxin levels in excess of half of the established criteria listed 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 of a minimum of seven (7) dockside samples by the Authority or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming laboratory; the Authority 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 toxin levels are below the established criteria (e.g., 80 µg/100 g for PSP toxins);~~
~~(i) Disposal of shellfish when dockside test results meet or exceed the established criteria in Chapter IV@.04C.(1) (e.g., 80 µg /100 g for PSP toxins);~~
~~(j) Notification prior to unloading;~~
~~(k) Unloading schedule;~~
~~(l) Access for Dockside Sampling;~~
~~(m) Record Keeping; and~~
~~(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 or Controlled Access 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 - 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 - 0.16 mg azaspiracid-1 (AZA-1) equivalents/kg (0.16 ppm)
(d) DSP – 0.16 mg okadaic acid (OA) equivalents/kg (0.16 ppm)
(e) ASP - 2 mg domoic acid/100 grams (20 ppm)
(2) For any marine biotoxin ~~producing organism~~ for which criteria have not been established under this Ordinance, either cell counts of the toxin producing organism 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 biotoxin management 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.

~~(6)~~(7) A growing area, or portion(s) thereof, shall be placed in the controlled access status for the taking of shellstock when the Authority determines that additional requirements are necessary to ensure the safe harvest of product. Controlled access status is a designation of an approved area. Additional requirements shall be included in harvest permit conditions. All shellstock harvested from growing areas in the controlled access status shall be tagged with Restricted Shellstock tags.

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.

Section IV. Guidance Documents
Chapter II. Growing Areas

.02 Guidance for Developing Marine Biotoxin Plans

Section to be added:

Marine Biotoxin Management Strategies

It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. The Authority initiating biotoxin management plans should employ sampling in accordance with the strategies below until a baseline dataset of at least 36 samples per growing area or hydrographically linked waterbodies is developed. These samples should cover representative environmental conditions and a time span of at least three years. Once this dataset is developed, the Authority may consider modifying sample numbers and frequency in the marine biotoxin management plan in accordance with the strategies below.

A. Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species documented or suspected to produce marine biotoxins. This complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish must be used in combination with other management strategies.

The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of toxin-producing phytoplankton may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies for a time span of at least three years of phytoplankton counts, comparing with the onset of shellfish toxicity when toxic phytoplankton are present, should be developed before the biotoxin monitoring plan may be modified.
Phytoplankton monitoring can be applied to all growing areas where collecting, transporting and processing water samples is logistically feasible, taking into consideration effects of zooplankton grazing and durability of various cell types to temperature and transport. This management strategy may be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible wild harvest areas and aquaculture sites in state waters or aquaculture sites in federal waters.
The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sample locations (stations),
- appropriate sampling frequency; and
- a sufficient dataset to support management decisions.

The phytoplankton monitoring strategy shall be used together with one or more of the other biotoxin management strategies. If it were used as the sole management strategy, phytoplankton monitoring would likely misrepresent the actual risk of marine biotoxins. Cell counts, as measured per liter of water, are often used to trigger additional testing of shellfish in biotoxin monitoring programs. These cell count criteria can only be established with a robust data set; therefore, new monitoring programs should employ low cell count criteria to trigger shellfish toxicity samples to establish or refine the cell concentrations responsible for toxins accumulating in shellfish.
When an early warning system such as phytoplankton monitoring detects increased toxicity/cell counts or other information suggests that toxin levels are increasing, it is important that the Authority have procedures to promptly expand sampling to additional stations and/or increase the frequency of sampling for marine biotoxins. The procedures should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program. If a plan consists of water sampling for phytoplankton cell counts as surveillance, the Authority should identify its plan to be able to initiate shellfish sampling.
Considerations should be made for how sampling is conducted such as phytoplankton net tows, filtered surface water, or whole water samples. The depth of water sampled should also be considered and evaluated for all species of phytoplankton being targeted. Some species of phytoplankton are known to display diurnal, vertical migration patterns within the water column, while other species are known to occur in dense patches.
Laboratory and field methods may include, but are not limited to light microscopy, flowcytometry, DNA fingerprinting, rapid toxin detection tests, and PCR assays.

Analysts should be trained in each method employed and consideration should be given to complimentary methods of analysis such as light microscopy with phytoplankton identification confirmed by a rapid test at least in the initial phases of the monitoring program.

An appropriate sampling plan, station location, and sampling frequency should all factor in the location and type of the resource being monitored, the species of phytoplankton anticipated or observed, and the environmental conditions that might result in a rapid bloom or trigger the production of toxicity in an existing population. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxic phytoplankton are most likely to first appear, based either on experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for collection of samples to identify an event as early as possible is an important consideration. Historical occurrences and fluctuations in coastal phytoplankton populations due to the influence of meteorological and hydrographic events are also significant. For example, a large rain storm may cause nutrient loading in coastal waters and trigger a toxic phytoplankton bloom, or a hurricane may drive an offshore phytoplankton bloom onshore. To facilitate knowledge transfer, it is advisable that the authority describe its rationale in selecting sampling sites.

B. Routine shellfish toxicity monitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. Unless species-specific shellfish testing is conducted, the highest risk species (e.g. species that metabolizes toxin most quickly) occurring in the growing area shall be used. Many biotoxin monitoring programs have found mussels to be the best sentinal species. This strategy may be used alone or in combination with other management strategies.

The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of shellfish toxicity may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies across representative environmental conditions for a span of at least three years shall be developed before the biotoxin monitoring plan may be modified. Until the Authority is confident they understand the risk posed by marine biotoxins in the growing area, sampling should be as robust as possible, and managers should consider that harmful algal blooms can change dramatically from year to year.

This management strategy can be applied to all growing areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to, easily accessible wild harvest areas and aquaculture sites in state waters or wild harvest areas and aquaculture sites in federal waters.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sample locations (stations),

- appropriate sampling frequency; and
- a sufficient dataset to support management decisions.

The routine shellfish toxicity monitoring strategy may be used independently or together with one or more of the other biotoxin management strategies. If used as the sole management strategy, predicting future toxicity levels in shellfish and the appropriate sampling frequency can be difficult. Long-term databases can provide valuable historic information on the timing of toxicity occurring in shellfish as well as toxicity depuration from shellfish. Shellfish toxin levels that are below the regulatory levels may trigger emergency or expanded testing, or precautionary closures. Growing areas should be placed in the closed status at a level that provides an adequate margin of safety, since in many instances, toxicity levels will change rapidly and the time between sampling and results should be considered. Precautionary closures can be made in order to prevent the harvest of potentially toxic shellfish while sample results are being collected and processed.
Consideration should be given to the different species of shellfish present in a growing area, the intensity and duration of harmful algal blooms and the uptake and depuration rates of specific toxins from all species of shellfish harvested from the growing areastoxins (e.g., sea scallops).
Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14. The Authority should identify laboratories that can perform approved methods for marine biotoxins and identify laboratory capacity.
An appropriate sampling plan, station location and sampling frequency should factor in the location and type of the resource being monitored, the species of shellfish harvested in the growing area and environmental conditions that might affect toxin uptake, such as water temperatures. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxin is most likely to first appear, based either on past experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for collection of samples to identify an event as early as possible is an important consideration.
Sample collection, sample transportation, and sample analysis procedures should be developed, and predictable timeframes established between collection and results. The Authority should ensure that in an emergency, such as a suspected biotoxin illness, the normal timeframe can be compressed, and sample results known as quickly as possible. It is important to consider emergency coverage schedules for staff and lab availability outside of normal office hours during harmful algal bloom events.
When an early warning system detects increased toxicity/cell counts or other information suggests that toxin levels are increasing, it is important that the Authority have procedures to promptly expand sampling to additional stations and/or increase the frequency of sampling for marine biotoxins. The procedures should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program.

C. Pre-harvest shellfish toxicity testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins in the intended harvest area specifically in advance of harvesting. This strategy, if used independent of any other strategy, shall permit harvest in specific geographic locations and for short durations. This strategy may also be used in combination with other management

strategies and should be considered as a complementary strategy while developing datasets for alternative management strategies (e.g. pre-harvest shellfish toxicity testing in combination with phytoplankton monitoring which can evolve into a robust shellfish toxicity monitoring strategy).

This strategy requires representative samples that cover the spatial distribution of the area to be harvested. The duration of permitted harvest following sampling will vary based on the species being tested and the historical database available to inform the sampling strategy. A dataset with at least 36 samples per harvest area shall be developed before the biotoxin monitoring plan may be modified. Without at least 36 samples per harvest area over the span of at least three years, the short duration of permitted harvest shall not exceed three days from the time of shellfish collection for toxicity testing to harvest. The dataset could then be used to modify the duration of permitted harvest.

This management strategy can be applied to harvest areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters. If toxicity in excess of the established threshold in C. is detected, the growing area must be either be placed in the closed or controlled access status.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency,
- a defined harvest area, and;
- appropriate duration for permitted harvesting subsequent to sampling.

This strategy is specifically for permitting harvest following shellfish testing. The duration of permitted harvesting will depend on the species being tested, the risk of increasing toxicity and the timing of additional sampling. Samples must be representative of the harvest area.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas .14.

D. Shellfish lot testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins on a lot basis after harvest. This strategy may be combined with a pre-harvest shellfish toxicity testing strategy, the results of which permit harvest. Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.

This strategy requires representative samples for each lot of harvested shellstock. Lot testing shall be permitted in growing areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests are available. A dataset with at least 36 samples per harvest area over the span of at least three years shall be developed before the biotoxin monitoring plan may be modified.

This management strategy can be applied to all growing areas where harvest

occurs. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters.
The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency, and;
- representative number of samples per lot.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14.
E. Pre-harvest shellfish toxicity screening and lot testing: this strategy requires pre-harvest shellfish toxicity screening of the intended harvest area coupled with shellfish lot testing upon landing or receipt at the initial certified dealer.
This strategy shall permit harvest in specific geographic locations from growing areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests results are available. A dataset with at least 36 samples taken monthly per harvest area spanning at least three years shall be developed before the biotoxin monitoring plan may be modified. In the absence of an adequate dataset, the initial number and frequency of pre-harvest and lot samples must be sufficient to conduct an evaluation of risk in the intended harvest area. The initial number of samples must be adequate to address the size of the growing area and the amount of shellfish harvested. Single samples are not adequate for evaluation of risk. Should initial samples indicate minimal toxin levels or the absence of toxins, sampling can be reduced but must be conducted at least monthly or as often as necessary to monitor risk.
This management strategy can be applied to all growing areas where harvest occurs. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters.
The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency,
- a defined harvest area, and;
- representative number of samples.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14.

Section IV. Guidance Documents
Chapter II. Growing Areas

.06 Protocol for the Landing of Shellfish from Federal Waters

Harvest of molluscan shellfish in Federal Waters not routinely monitored for toxins in shellfish (such as the Federal waters on Georges Bank closed due to PSP risks) 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 following guidance provides descriptions of the specific information to be included in the protocol.

A. Harvest Permit Requirements

If harvesting from Federal waters closed due to 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 System (VMS). The NMFS shall receive concurrence from the Authority 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 testing have been trained by a U.S. FDA LEO (LEO) or an FDA marine biotoxin expert to conduct onboard toxin screening using an NSSP recognized method(s). Shipboard persons conducting onboard toxin testing must receive refresher training every three (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 monitor the harvesting location(s) of each landing vessel.

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 identifying each lot of shellfish as follows:

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 toxin screening sample;
8. Results of each toxin screening test; and
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 Authority 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. Surf clams and ocean quahogs existing NMFS tagging requirements.
2. All other molluscan shellfish (including Stimpson clams also known as Arctic surf clams) using durable, waterproof, Authority sanctioned prior to use 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 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 marine biotoxins that are likely to occur in accordance with an NSSP recognized 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 LEO or FDA marine biotoxin expert (or their designee as expressly indicated in writing) in the use of the designated NSSP method may conduct these tests. Each of the five (5) samples must test negative for toxins (i.e., below half of the established criteria in Section II. Model Ordinance Chapter IV @04.C. (1)). A positive result from any one (1) sample shall render the lot area unacceptable for harvest. The harvest

vessel Captain shall immediately report all positive screening test results, by telephone or email, to the Authority within the intended State of landing, the FDA Shellfish Specialist, and the processor. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area(s). For each screening test, whether positive or negative, the remaining sample material (homogenate) shall be maintained under refrigeration for later use should the Authority in the State of landing request confirmatory testing using an NSSP recognized 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 Authority or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming laboratory 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 Authority or designee, molluscan shellfish may be processed while awaiting 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 toxin results that demonstrate that toxin levels are below the established criteria in Section II. Model Ordinance 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 Authority 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 toxins using an NSSP recognized method(s).

3. Laboratory test results for each lot of shellfish shall be forwarded to the Authority in the State in which the shellfish is being held prior to the product being released by the Authority in the State of landing, or if processed in another State, the Authority 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 (1)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 Authority in the intended State of landing and the FDA 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 Section II. Model Ordinance Chapter IV@.04 C. (1) (e.g., 80 µg /100 g for PSP toxins)(n=7, c=0), the entire lot must be discarded or destroyed at the cost of the harvester under the supervision of the Authority in accordance with State laws and regulations except when:

A lot of "whole" or "roe-on" scallops equals or exceeds the established criteria in Section II. Model Ordinance Chapter IV@.04C.(1), 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 Authority in accordance with State laws and regulations.

Dockside toxin testing shall be according to NSSP recognized methods and shall be conducted by laboratories evaluated in accordance with

~~NSSP guidelines. Private laboratories may be used if evaluated by an 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 Authority in the State of landing and in a manner approved by the Authority 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. Authorities may 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 Authority under the NSSP. The procedures, as well as training and certification records, must be available for evaluation.~~

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

~~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 Authority in the State of landing shall retain Harvest Records for at least two (2) years.~~

~~N. Early Warning/Alert System~~

~~Toxin data acquired as a result of onboard screening and dockside testing shall be transmitted to the FDA. These data, both screening and dockside, shall be transmitted to the FDA by the NSSP certified laboratory conducting toxin testing of the sampled lot(s) within one (1) week of the completion of the 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 toxins (e.g.,<80 µg/100 g for PSP toxins) shall immediately be reported to the Authority in the State of landing. If the results of any one (1) sample equal or exceed the established criteria in Chapter IV @.04(c)(1) the testing laboratory shall immediately notify the FDA Shellfish Specialist, the Authority, 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, Authorities (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.~~

Action by 2019 Task Force I

Recommended adoption of Proposal 19-149 as amended.

Section II. 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…
(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, controlled access in the case of biotoxins or inactive for the harvesting of shellstock. Supporting information for all changes in the status of growing areas shall be documented by

a written record in the central file.
(a) Open Status…
(b) Closed Status…
(c) Controlled Access Status. This status can be applied to allow harvesting in areas with biotoxin concerns where routine monitoring or pre-harvest testing is not practical.
(d) Reopened Status...
(e) Inactive Status…
(f) Remote Status...
(g) Seasonally Remote/Approved Status...

@.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, diarrhetic shellfish poisoning (DSP) and azaspiracid shellfish poisoning (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 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 and federal partners, shellfish industry, and local health agencies;
(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.

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .02

B. Marine Biotoxin Management Plan.
In those areas that have been implicated in an illness outbreak or where toxin-producing phytoplankton have been documented to occur, the toxins are prone to accumulate in shellfish, and during times when marine biotoxins are likely to occur, representative samples of water and/or shellfish shall be collected during harvest periods in accordance with one or a combination of the marine biotoxin management strategies listed below in 4. and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(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, and/or AZP; if toxin-producing phytoplankton have been documented 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 toxin-producing phytoplankton and/or shellfish sampling program as described below in (4). It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(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;

(g) Establish reopening criteria; and

(h) Ensure that all shellfish harvested from growing areas or portion(s) of growing areas placed in the controlled access status meets all conditions of harvest restrictions prior to being placed in distribution. This would include all sampling, testing or product holds.

(3) The Authority may use precautionary closures based on shellfish toxicity screening or phytoplankton sample results as defined in their marine biotoxin management plan. Precautionary closures may be lifted immediately:

(a) if confirmatory testing using an approved method shows the level of biotoxin present in shellfish meats is not equal to or above established criteria as described below in C; or

(b) when shellfish toxicity screening or phytoplankton sample results indicate that the precautionary closure was not necessary.

(4) Marine biotoxin management strategies are as follows:

(a) Phytoplankton monitoring: this strategy involves a routine program for sampling

growing area waters for the presence of phytoplankton species known or suspected to produce marine biotoxins. This is a complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish and must be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(b) Routine shellfish toxicity monitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. Unless species specific shellfish testing is conducted, the highest risk species shall be used. This strategy may be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(c) Pre-harvest shellfish toxicity testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins in the intended harvest area specifically in advance of harvest. This strategy, if used independent of any other strategy, shall permit harvest for a short period of time following testing. This strategy may be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(d) Shellfish lot testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins on a lot basis after harvest. This strategy may be combined with a pre-harvest shellfish toxicity testing strategy, the results of which permit harvest. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.

(e) Pre-harvest shellfish toxicity screening and lot testing: this strategy requires pre-harvest shellfish toxicity screening of the intended harvest area

coupled with shellfish lot testing upon landing. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(5) The marine biotoxin management plan shall include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters, individual growers or individual shellfish dealers, to allow harvesting in a growing area that is placed in the controlled access status. Such harvesting shall be conducted with strict assurances of safety and in accordance with the marine biotoxin management strategies listed in (4).

C. Closed or Controlled Access 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 - 80 µg saxitoxin equivalents/100 grams
(b) NSP - 20 MU/100 grams (0.8 mg brevetoxin-2 equivalents/kg)
(c) AZP - 0.16 mg azaspiracid-1 (AZA-1) equivalents/kg (0.16 ppm)
(d) DSP – 0.16 mg okadaic acid (OA) equivalents/kg (0.16 ppm)
(e) ASP - 2 mg domoic acid/100 grams (20 ppm)

(2) For any marine biotoxin for which criteria have not been established under this Ordinance, either cell counts of the toxin producing organism 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, 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.

(7) A growing area, or portion(s) thereof, shall be placed in the controlled access status for the taking of shellstock when the Authority determines that additional requirements are necessary to ensure the safe harvest of product. Controlled access status is a designation of an approved area. Additional requirements shall be included in harvest permit conditions. All shellstock harvested from growing areas in the controlled access status shall be tagged with Restricted Shellstock tags.

H. 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.

J. 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.

Section IV. Guidance Documents
Chapter II. Growing Areas

.02 Guidance for Developing Marine Biotoxin Plans

Section to be added:

Marine Biotoxin Management Strategies
It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. The Authority initiating biotoxin management plans should employ sampling in accordance with the strategies below until a baseline dataset of at least 36 samples per growing area or hydrographically linked waterbodies is developed. These samples should cover representative environmental conditions and a time span of at least three years. Once this dataset is developed, the Authority may consider modifying sample numbers and frequency in the marine biotoxin management plan in accordance with the strategies below.
A. Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species documented or suspected to produce marine biotoxins. This complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish must be used in combination with other management strategies.
The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of toxin-producing phytoplankton may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies for a time span of at least three years of phytoplankton counts, comparing with the onset of shellfish toxicity when toxic phytoplankton are present, should be developed before the biotoxin monitoring plan may be modified.
Phytoplankton monitoring can be applied to all growing areas where collecting, transporting and processing water samples is logistically feasible, taking into consideration effects of zooplankton grazing and durability of various cell types to temperature and transport. This management strategy may be applied to

aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible wild harvest areas and aquaculture sites in state waters or aquaculture sites in federal waters.
The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sample locations (stations),
- appropriate sampling frequency; and
- a sufficient dataset to support management decisions.

The phytoplankton monitoring strategy shall be used together with one or more of the other biotoxin management strategies. If it were used as the sole management strategy, phytoplankton monitoring would likely misrepresent the actual risk of marine biotoxins. Cell counts, as measured per liter of water, are often used to trigger additional testing of shellfish in biotoxin monitoring programs. These cell count criteria can only be established with a robust data set; therefore, new monitoring programs should employ low cell count criteria to trigger shellfish toxicity samples to establish or refine the cell concentrations responsible for toxins accumulating in shellfish.
When an early warning system such as phytoplankton monitoring detects increased toxicity/cell counts or other information suggests that toxin levels are increasing, it is important that the Authority have procedures to promptly expand sampling to additional stations and/or increase the frequency of sampling for marine biotoxins. The procedures should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program. If a plan consists of water sampling for phytoplankton cell counts as surveillance, the Authority should identify its plan to be able to initiate shellfish sampling.
Considerations should be made for how sampling is conducted such as phytoplankton net tows, filtered surface water, or whole water samples. The depth of water sampled should also be considered and evaluated for all species of phytoplankton being targeted. Some species of phytoplankton are known to display diurnal, vertical migration patterns within the water column, while other species are known to occur in dense patches.
Laboratory and field methods may include, but are not limited to light microscopy, flowcytometry, DNA fingerprinting, rapid toxin detection tests, and PCR assays. Analysts should be trained in each method employed and consideration should be given to complimentary methods of analysis such as light microscopy with phytoplankton identification confirmed by a rapid test at least in the initial phases of the monitoring program.
An appropriate sampling plan, station location, and sampling frequency should all factor in the location and type of the resource being monitored, the species of phytoplankton anticipated or observed, and the environmental conditions that might result in a rapid bloom or trigger the production of toxicity in an existing population. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxic phytoplankton are most likely to first appear, based either on experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for

collection of samples to identify an event as early as possible is an important consideration. Historical occurrences and fluctuations in coastal phytoplankton populations due to the influence of meteorological and hydrographic events are also significant. For example, a large rain storm may cause nutrient loading in coastal waters and trigger a toxic phytoplankton bloom, or a hurricane may drive an offshore phytoplankton bloom onshore. To facilitate knowledge transfer, it is advisable that the authority describe its rationale in selecting sampling sites.

B. Routine shellfish toxicity monitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. Unless species-specific shellfish testing is conducted, the highest risk species (e.g. species that metabolizes toxin most quickly) occurring in the growing area shall be used. Many biotoxin monitoring programs have found mussels to be the best sentinal species. This strategy may be used alone or in combination with other management strategies.

The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of shellfish toxicity may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies across representative environmental conditions for a span of at least three years shall be developed before the biotoxin monitoring plan may be modified. Until the Authority is confident they understand the risk posed by marine biotoxins in the growing area, sampling should be as robust as possible, and managers should consider that harmful algal blooms can change dramatically from year to year. This management strategy can be applied to all growing areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to, easily accessible wild harvest areas and aquaculture sites in state waters or wild harvest areas and aquaculture sites in federal waters.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sample locations (stations),
- appropriate sampling frequency; and
- a sufficient dataset to support management decisions.

The routine shellfish toxicity monitoring strategy may be used independently or together with one or more of the other biotoxin management strategies. If used as the sole management strategy, predicting future toxicity levels in shellfish and the appropriate sampling frequency can be difficult. Long-term databases can provide valuable historic information on the timing of toxicity occurring in shellfish as well as toxicity elimination ~~depuration~~ from shellfish. Shellfish toxin levels that are below the regulatory levels may trigger emergency or expanded testing, or precautionary closures. Growing areas should be placed in the closed status at a level that provides an adequate margin of safety, since in many instances, toxicity levels will change rapidly and the time between sampling and results should be

considered. Precautionary closures can be made in order to prevent the harvest of potentially toxic shellfish while sample results are being collected and processed. Consideration should be given to the different species of shellfish present in a growing area, the intensity and duration of harmful algal blooms and the uptake and elimination ~~depuration~~ rates of specific toxins from all species of shellfish harvested from the growing areastoxins (e.g., sea scallops).
Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14. or Section II Chapter III @.02 C or The Authority should identify laboratories that can perform approved methods for marine biotoxins and identify laboratory capacity.
An appropriate sampling plan, station location and sampling frequency should factor in the location and type of the resource being monitored, the species of shellfish harvested in the growing area and environmental conditions that might affect toxin uptake, such as water temperatures. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxin is most likely to first appear, based either on past experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for collection of samples to identify an event as early as possible is an important consideration.
Sample collection, sample transportation, and sample analysis procedures should be developed, and predictable timeframes established between collection and results. The Authority should ensure that in an emergency, such as a suspected biotoxin illness, the normal timeframe can be compressed, and sample results known as quickly as possible. It is important to consider emergency coverage schedules for staff and lab availability outside of normal office hours during harmful algal bloom events.
When an early warning system detects increased toxicity/cell counts or other information suggests that toxin levels are increasing, it is important that the Authority have procedures to promptly expand sampling to additional stations and/or increase the frequency of sampling for marine biotoxins. The procedures should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program.

C. Pre-harvest shellfish toxicity testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins in the intended harvest area specifically in advance of harvesting. This strategy, if used independent of any other strategy, shall permit harvest in specific geographic locations and for short durations. This strategy may also be used in combination with other management strategies and should be considered as a complementary strategy while developing datasets for alternative management strategies (e.g. pre-harvest shellfish toxicity testing in combination with phytoplankton monitoring which can evolve into a robust shellfish toxicity monitoring strategy).
This strategy requires representative samples that cover the spatial distribution of the area to be harvested. The duration of permitted harvest following sampling will vary based on the species being tested and the historical database available to inform the sampling strategy. A dataset with at least 36 samples per harvest area shall be developed before the biotoxin monitoring plan may be modified. Without at least 36 samples per harvest area over the span of at least three years, the short duration of permitted harvest shall not exceed three days from the time of shellfish collection for toxicity testing to harvest. The dataset could then be used to modify

the duration of permitted harvest.
This management strategy can be applied to harvest areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters. If toxicity in excess of the established threshold in Section II Chapter IV @.04 C. is detected, the growing area must be either be placed in the closed or controlled access status.
The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency,
- a defined harvest area, and;
- appropriate duration for permitted harvesting subsequent to sampling.

This strategy is specifically for permitting harvest following shellfish testing. The duration of permitted harvesting will depend on the species being tested, the risk of increasing toxicity and the timing of additional sampling. Samples must be representative of the harvest area.
Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas .14. or Section II Chapter III @.02 C.
D. Shellfish lot testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins on a lot basis after harvest. This strategy may be combined with a pre-harvest shellfish toxicity testing strategy, the results of which permit harvest. Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.
This strategy requires representative samples for each lot of harvested shellstock. Lot testing shall be permitted in growing areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests are available. A dataset with at least 36 samples per harvest area over the span of at least three years shall be developed before the biotoxin monitoring plan may be modified.
This management strategy can be applied to all growing areas where harvest occurs. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters.
The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency, and;
- representative number of samples per lot.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14. or Section II Chapter III @.02 C.

E. Pre-harvest shellfish toxicity screening and lot testing: this strategy requires pre-harvest shellfish toxicity screening of the intended harvest area coupled with shellfish lot testing upon landing or receipt at the initial certified dealer. This strategy shall permit harvest ~~in specific geographic locations~~ from ~~growing~~ intended harvest areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests results are available. A dataset with at least 36 samples taken monthly per harvest area spanning at least three years shall be developed before the biotoxin monitoring plan may be modified. In the absence of an adequate dataset, the initial number and frequency of pre-harvest and lot samples must be sufficient to conduct an evaluation of risk in the intended harvest area. The initial number of samples must be adequate to address the size of the intended harvest ~~growing~~ area and the amount of shellfish harvested. Single samples are not adequate for evaluation of risk. Should initial samples indicate minimal toxin levels or the absence of toxins, sampling can be reduced but must be conducted at least monthly or as often as necessary to monitor risk.

This management strategy can be applied to all growing areas where harvest occurs. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency,
- a defined harvest area, and;
- representative number of samples.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14. or Section II Chapter III @.02 C

Section IV. Guidance Documents
Chapter II. Growing Areas

Action by 2019 General Assembly: Adopted recommendation of Task Force I on Proposal 19-149.

Action by FDA February 21, 2020: Concurred with Conference action on Proposal 19-149.

Submitter	Brooke Roman Neogen Corporation broman@neogen.com
Proposal Subject	Neogen's 'Reveal 2.0 for PSP' for detection of PSP
Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter II. Growing Areas, .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	The intention is for this method to be an Approved Limited Use Method for Biotoxin testing for PSP toxins under the NSSP (for mussels and oysters) and that it should appear in Section IV (Guidance Documents), Table 4 (Approved Limited Use Methods for Biotoxin Testing). Full SLV validation data is provided for mussels and oysters.
Public Health Significance	PSP is a serious intoxication which still occurs in the USA and elsewhere. The USFDA and the European Union (EU) have established action levels for PSP toxins at 800 ppb (800 µg/kg) STX equivalents in shellfish. PCOX, has been accepted as a quantitative reference method in the USA and some other countries, although Pre-COX is also accepted by regulatory agencies in other areas of the world such as the UK, various EU countries, AU and NZ. Shellfish need to be more easily screened for toxins that cause paralytic shellfish poisoning (PSP), and they need to be screened closer to growing/harvesting areas to better protect public health. A reliable and simple screening tool for end product testing (EPT) by industry, for community-based and remote surveillance, and for screening out negative samples from the regulatory sample stream. Implementation of these approaches would broaden the food safety net and reduce outbreaks of PSP intoxication. Neogen is the only antibody-based test to detect both the STX and NEO parts of the PSP family of toxins at similar levels. No other antibody-based rapid test for PSP can detect NEO to any significant degree. Other ISSC approved "rapid" methods for PSP screening are largely limited to laboratory settings because of complexity which limits their use in EPT and community-based and remote surveillance of shellfish resources. The only ISSC-approved LFA rapid method, the Scotia LFI, has had many issues with reliability that have limited its applicability in screening for PSP, and concerns about the stability of the method have also been published [1,2,3,4,5]. The Neogen Reveal 2.0 for PSP is an excellent candidate for rapid screening of shellfish for PSP toxins in both laboratory and field situations, and is an extension of a platform used by Neogen for many reliable rapid tests in the meat, dairy and food sectors, many of which are approved for use by FDA, USFDA and/or EPA. The test has undergone SLV and ILV evaluations [5,6]and has been shown to be an accurate and reliable candidate for approval for use in the NSSP. [1] Cefas 2006 [2] Turner et al. 2015 [3] Harrison et al. 2016 [4] Dorantes-Aranda et al. 2017a [5] Jawaid et al. 2015 [6] Dorantes-Aranda et al. 2017b
Cost Information	Approximately $20 per test. Reader based assay – approximate cost of reader is $2,700.00 USD.
Action by 2019 Laboratory	Recommended referral of Proposal 19-150 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force	Recommended adoption of Laboratory Committee recommendation on Proposal 19-150.

Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-150.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-150.

Submitter	Catalina Sea Ranch, LLC (CSR) maria@catalinasearanch.com
Proposal Subject	Update the Protocol for the Landing of Shellfish from Federal Waters
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.03 Section IV. Guidance Documents Chapter II Growing Areas .06
Text of Proposal/ Requested Action	**Section II. Model Ordinance** **Chapter VI. Shellfish Aquaculture** **@.03 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) biotoxin 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.

Section IV. Guidance Documents
Chapter II. Growing Areas
.06 Protocol for the Landing of Shellfish from Federal Waters

Harvest of molluscan shellfish in Federal Waters not routinely monitored for toxins in shellfish ~~(such as the Federal waters on Georges Bank closed due to PSP risks)~~ 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 following guidance provides descriptions of the specific information to be included in the protocol.

A. Harvest Permit Requirements

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

~~Training~~

~~The Authority shall ensure that all shipboard persons conducting onboard testing have been trained by a U.S. FDA LEO (LEO) or an~~

~~FDA marine biotoxin expert to conduct onboard toxin screening using an NSSP recognized method(s). Shipboard persons conducting onboard toxin testing must receive refresher training every three (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.~~

B. Vessel Monitoring
The Authority shall monitor the harvesting location(s) of each landing vessel.

C. 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 identifying each lot of shellfish as follows:

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 toxin screening sample;
8. Results of each toxin screening test; and
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 Authority 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. Surf clams and ocean quahogs existing NMFS tagging requirements.
2. All other molluscan shellfish (including Stimpson clams also known as Arctic surf clams) using durable, waterproof, Authority sanctioned prior to use 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.

D. ~~Pre-Harvest~~Shellfish Sampling

~~Prior to 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 marine biotoxins that are likely to occur in accordance with an NSSP recognized 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 LEO or FDA marine biotoxin expert (or their designee as expressly indicated in writing) in the use of the designated NSSP method may conduct these tests. Each of the five (5) samples must test negative for toxins (i.e., below half of the established criteria in Section II. Model Ordinance Chapter IV @04.C. (1)). A positive result from any one (1) sample shall render the lot area unacceptable for harvest. The harvest vessel Captain shall immediately report all positive screening test results, by telephone or email, to the Authority within the intended State of landing, the FDA Shellfish Specialist, and the processor. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area(s). For each screening test, whether positive or negative, the remaining sample material (homogenate) shall be maintained under refrigeration for later use should the Authority in the State of landing request confirmatory testing using an NSSP recognized method.~~

Each commercial shellfish grower is required to submit at least one shellfish sample per week, per lot, to an FDA conforming laboratory for testing of ASP and PSP during all harvest periods. Sample test results will be submitted to the Authority for review and data compilation.

Harvester representatives performing sample collection must receive initial training to ensure proper collection technique from the appropriate Authority. Sample collectors must receive refresher training every three (3) years.

Location of sampling stations:
The sampling station should be centrally located in each harvest lot.

Sampling Frequency:
Samplers are required to achieve a sampling frequency of at least once sample per week during the months of May through October, and at least one sample per month during the months of November through April. When either PSP toxins or domoic acid are detected in shellfish, the frequency of sampling will double to allow better characterization of the event.

If test results of any sample collected equal or exceed 50% of the established criteria in Section II. Model Ordinance Chapter IV@.04 C. (1) (e.g., 40 µg /100 g for PSP toxins), sampling will double for all harvesters. If test results of any samples collected equal or exceed 75% of the established criteria in Section II. Model Ordinance Chapter IV@.04 C. (1) then sampling will commence for each harvest and the harvest will be held until final test results indicate toxin levels below that established criteria in Section II. Model Ordinance Chapter IV@.04 C. (1).

If test results equal or exceed that established criteria in Section II. Model Ordinance Chapter IV@.04 C. (1) then the growing area will be placed in Closed Status pursuant to Section II. Model Ordinance Chapter IV@.04 C. (1).

Testing shall be according to NSSP recognized methods and shall be conducted by laboratories evaluated in accordance with NSSP guidelines. Private laboratories may be used if evaluated by an LEO in accordance with NSSP guidelines.

Sampling Methods:

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.

~~E. Submittal of Onboard Screening Homogenates and Test Results~~
~~F.~~

~~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 Authority or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming laboratory in the State of landing authorized to sample the harvested shellfish as described in Section G. of this Protocol.~~

~~Dockside Sampling~~

~~After dockside samples are collected by the Authority or designee, molluscan shellfish may be processed while awaiting 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 toxin results that demonstrate that toxin levels are below the established criteria in Section II. Model Ordinance Chapter IV @04.C.(1).~~

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

~~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 Authority to sample, with the following exceptions:~~

~~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.~~

~~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.~~

~~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.~~

~~Shellfish samples collected in accordance with G.1 shall be tested for the presence of toxins using an NSSP recognized method(s).~~

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

~~G.~~E. 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 (1)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 Authority in the intended State of landing and the FDA Shellfish Specialist must approve the proposed lot segregation plan.

~~H.~~F. Disposal of Shellfish

If test results of any harvest held based on D. Shellfish Sampling ~~one (1) of the seven (7) samples collected in accordance with G.1~~ equal or exceed the established criteria in Section II. Model Ordinance Chapter

IV@.04 C. (1) (e.g., 80 µg /100 g for PSP toxins)(n=7, c=0), the entire lot must be discarded or destroyed at the cost of the harvester under the supervision of the Authority in accordance with State laws and regulations except when:

A lot of "whole" or "roe-on" scallops equals or exceeds the established criteria in Section II. Model Ordinance Chapter IV@.04C.(1), 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 Authority in accordance with State laws and regulations.

Dockside toxin testing shall be according to NSSP recognized methods and shall be conducted by laboratories evaluated in accordance with NSSP guidelines. Private laboratories may be used if evaluated by an LEO in accordance with NSSP guidelines.

~~I.~~G. Notification Prior to Unloading by Harvesters Under NMFS Permts

Prior to the issuance of an EFP, the harvester shall be responsible for notifying the Authority in the State of landing and in a manner approved by the Authority 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. Authorities may 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 Authority under the NSSP. The procedures, as well as training and certification records, must be available for evaluation.

Shellfish from a Federal water harvest area(s) must be kept separate and not sold until so authorized by the Authority in the State of landing or, if processed in another State, the Authority 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 permits through the NMFS.

~~J.~~H. Unloading Schedule for Harvesters Under NMS Permits

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 Authority in the State of landing.

~~K. Access for Dockside Sampling~~

~~L.~~

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

~~M.~~I. 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 Authority in the State of landing shall retain Harvest Records for at least two (2) years.

~~N.~~J. Early Warning/Alert System

Toxin data acquired as a result of ~~onboard screening and dockside~~sample testing shall be transmitted to the FDA. These data~~, both screening and dockside,~~ shall be transmitted to the FDA by the NSSP certified laboratory conducting toxin testing of the sampled lot(s) within one (1) week of the completion of the 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 unacceptable levels of toxins (e.g.,<80 µg/100 g for PSP toxins) shall immediately be reported to the Authority in the State of landing. If the results of any one (1) sample equal or exceed the established criteria in Chapter IV @.04(c)(1) the testing laboratory shall immediately notify the FDA Shellfish Specialist, the Authority, and the processor by telephone and email. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease ~~fishing~~ harvesting in the affected area(s).

Public Health Significance	This proposal provides clarification to Chapter VI. @.03 by clarifying the type of testing requirements for aquaculture facilities. Additionally, the proposal modifies Section IV. Guidance Documents for the landing of shellfish in Federal Waters. These modifications would improve and simplify the protocols for landing shellfish in Federal Waters where a biotoxin concern exists.
Cost Information	
Action by 2019 Task Force I	Recommended no action on Proposal 19-151. Rationale: This issue is addressed by Proposal 19-149.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-151.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-151.

Proposal No. 19-153

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Alternative Pre-harvest Screening
Specific NSSP Guide Reference	Section II Model Ordinance – Chapter IV. Shellstock Growing Area @.04 Marine Biotoxin Control B. Marine Biotoxin Management Plan (6)e
Text of Proposal/ Requested Action	(6) Prior to allowing the landing of shellfish harvested from Federal waters where routine monitoring of toxin levels is not conducted, in addition to following State 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; and (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 toxins that are likely to be present. Harvesting shall not be permitted if any of the pre-harvested samples contain toxin levels in excess of half of the established criteria listed in Chapter IV@.04(c)(1)As an alternative to pre-harvest (on-board) screening samples, end product (dockside) testing samples alone may be used. Should alternative be chosen, the minimum number of seven (7) dockside samples as stated in section (g) below must be expanded to ten (10). (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 of a minimum of seven (7) dockside samples by the Authority or designee and the testing of those samples for toxins using a NSSP method by a NSSP conforming laboratory; the Authority 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 toxin levels are below the established criteria (e.g., 80 µg/100 g for PSP toxins);
(i) Disposal of shellfish when dockside test results meet or exceed the established criteria in Chapter IV@.04C.(1) (e.g., 80 µg /100 g for PSP toxins);
(j) Notification prior to unloading;
(k) Unloading schedule;
(l) Access for Dockside Sampling;
(m) Record Keeping; and
(n) Early Warning/Alert System.

Public Health Significance	The ISSC Executive Board adopted the proposed language as an interim measure to address concerns with the Abraxis PSP Shipboard ELISA Kit. See attached report.
Cost Information	
Action by 2019 Task Force I	Recommended no action on 19-153.Rationale: This issue is addressed by 19-149.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-153.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-153.

Proposal No. 13-200

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

Public Health Significance

The ISSC continues to struggle with identifying practical cost effective strategies for reducing the risk of Vibrio illnesses associated with the consumption of molluscan shellfish. This proposal identifies information needs that are obstacles to the development of control strategies.

Cost Information Research Needs Information Proposed (specific research need/problem to be addressed)

1. Is total *V.v.* a valid indicator of risk?
2. Are there differential effects of validated PHP on virulent subpopulations?
3. How do environmental factors affect levels of virulent subpopulations?
4. Compile collection of *V.v.* for future virulence research.
5. Do other species react to controls the same as *V.v.* and *V.p.*?
6. Determine relative virulence of *V.p.* subpopulations.
7. What are Vibrio (total and virulent) levels at harvest (in oysters and clams)?
8. How much Vibrio (total and virulent) growth results from the current time/temperature controls (in oysters and clams)?

Priorities:

1. What information is needed to supply more tools to the "toolbox"?
2. What regional information is needed to refine risk assessments and risk calculator tools for implementation of effective control plans?
3. What is the significance of salinity to Vibrio levels in shellfish?
4. Is there a salinity/temperature matrix that determines Vibrio levels?
5. What are the key virulence factors (or combination thereof) for *V.v.* and *V.p.*?
6. Need to know dose response of different Vibrio strains and populations
7. What are the regional differences in pathogenic strains of *V.v.* and *V.p.*?
8. What is the percentage of pathogenic strains of Vibrio in growing waters?
9. Should the "viable but not culturable" state in pathogenic Vibrios be a concern?

Action by 2013 Task Force II

Recommended referral of Proposal 13-200 to an appropriate committee as determined by the Conference Chairman with instructions to the committee as follows:

1. Request that FDA reexamine its risk assessments and risk calculators (*V.p.*) and (*V.v.*) and present the results to ISSC, including the factors and methodology used to calculate risk per serving.
2. Develop a process for using local data including regional or state illness and landings information, to more accurately reflect risk in a region or state.
3. Determine how best to estimate consumption patterns, including collection data regarding the number of shellfish consumed per serving, through market research, end-point consumer data, or other information gathering methods.
4. Evaluate existing NSSP regulations to reduce risk of Vibrio illness caused by improper handling, storing, or transportation of shellstock and the effectiveness of existing enforcement mechanisms.
5. Provide recommendations to ISSC based on the results of the above study and evaluation.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force II on Proposal 13-200.

Action by FDA May 5, 2014

FDA concurred with Conference action on Proposal 13-200 with the following comments and recommendations.

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

Action by 2015 Vibrio Management Committee

Recommended the following action on Proposal 13-200:

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

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

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

Action by 2015 Task Force II

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

Action by 2015 General Assembly

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

Action by FDA January 11, 2016

Concurred with Conference action on Proposal 13-200.

Action by 2017 Vibrio Management Committee

a. Monitor the development of processes for using local data including regional or state illnesses and landings information, to more accurately reflect risk in a region or state.

   Recommendation:
   The VMC recommended the Conference support and promote the collection of production data and recommends in every case possible the data be provided in product form.

b. Monitor activities to estimate consumption patterns, including collection of data regarding the number of shellfish consumed per serving, through market research, end-point consumer data, or other information gathering methods.

   Recommendations:

1. The VMC recommended that the ISSC continue to identify funding to collect data regarding shellfish consumption patterns to include serving size and product form and also distribution patterns.

2. VMC recommended the Conference identify funding to conduct pilots in each region of the country to gather information on consumption patterns, including collection of data regarding the number of shellfish consumed per serving.

c. Evaluate the effectiveness of existing NSSP guidelines in reducing the risk of Vibrio illness caused by improper handling, storing or transportation of shellstock and effectiveness of existing enforcement mechanisms.

Recommendation:

VMC recommended no action. Rationale: This charge is part of VMC ongoing mission.

Action by 2017 Task Force II	Recommended adoption of Vibrio Management Committee recommendations on Proposal 13-200 as submitted.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 13-200.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-200.
Action by 2019 Task Force II	No Task Force Action is necessary on Proposal 13-200. This proposal was included for informational purposes only. The VMC has pending recommendations in their committee report that are included in the VMC Committee Report. These recommendations do not involve any changes to the NSSP Guide.
Action by 2019 General Assembly	No action required by General Assembly on Proposal 13-200.
Action by FDA February 21, 2020	No action required by FDA on Proposal 13-200

Proposal No. 15-226

Submitter	Executive Office Interstate Shellfish Sanitation Conference (ISSC) issc@issc.org
Proposal Subject	*V.p.* Illness Response Guidance Document
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter V. Illness Outbreaks and Recall Guidance
Text of Proposal/ Requested Action	Add new section:

.03 *V.p.* Illness Response Guidance Document

I. Introduction

Chapter II @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*) is intended to address three (3) distinct *V.p.* illness situations as follows:

A. Traditional sporadic cases from a State in which single cases occur that most often do not involve a single growing area and occur weeks or months apart. The occurrences of these types of illnesses have historically been considered as an acceptable risk in the National Shellfish Sanitation Program (NSSP) and have not involved closures or recalls.

B. Frequent sporadic cases which often begin when water temperatures reach a level which supports reproduction of *V.p.* to levels which can cause illness. The illness risk usually persists until the environmental conditions no longer support *V.p.* levels of illness causing potential. This illness situation involves clusters of sporadic cases in multiple individual growing areas or may be limited to a single growing area when the environmental conditions are favorable for the persistence of illness causing levels of *V.p.*

C. A true outbreak with multiple cases with multiple harvest areas and varying routes of transportation indicates a more widespread contamination of a growing area. The outbreak may be characterized by a high attack rate. In this situation, a single growing area is usually involved with multiple cases of illness occurring from a single harvest day or from a relatively short harvest time frame.

The strains of *V.p.* associated with these different illness situations are not the same. The attack rates are very different and the reported illnesses reflect the differences in attack rates. Although strain identification is time consuming, knowing the strain aids the Shellfish Control Authority in addressing the problem.

II. Illness Investigation

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

The Shellfish Control Authority is encouraged to coordinate the investigation and response with other appropriate State entities and the US Food and Drug Administration (FDA) to facilitate and streamline the reporting process to promote prompt and appropriate regulatory responses to illness.

III. Risk per Serving Determinations

In determining a risk per serving, the Shellfish Control Authority should use a recognized serving size and credible landing data. The period of time for evaluating the risk per serving should be consistent with the time of harvest of the shellfish that was associated with the illness (es) and should not exceed thirty (30) days

IV. Regulatory Response

When a case(s) is reported, the State Shellfish Control Authority will determine the number of cases and the time period between the harvest dates of reported cases and the extent of the implicated area.

When determining the number of illnesses in the thirty (30) day period, the harvest date will be used. When an illness occurs, the Shellfish Control Authority will determine the number of cases that have occurred during the previous thirty (30) days. Every subsequent harvest associated with a new reported case will require a review of the previous thirty (30) days.

A. Should the number of cases and the period of time result in a risk that is less than one (1) per 100,000 servings or involves at least two (2) but not more than four (4) cases in which no two of these were from a single harvest day from an implicated area, the State Shellfish Control Authority will evaluate and attempt to ensure compliance, where appropriate, with the existing Vibrio Management Plan. Regulatory response to multiple illnesses occurring from a single harvest day from an implicated area are addressed in IV. B and IV. C.

B. Should the number of cases and the period of time result in a risk that exceeds one (1) illness per 100,000 servings or if the number of cases within a thirty (30) day period from the implicated area is more than four (4) but less than ten (10) or if two (2) or more but less than four (4) cases occur from a single harvest day from the implicated area, the Shellfish Control Authority is required to:

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

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

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

The notification is intended to facilitate the reporting of other illnesses that may have occurred associated with the implicated harvest area. Although the State is not required to report this information to the Interstate Shellfish Sanitation Conference (ISSC), if requested, the ISSC will assist the States with notification.

C. Should the number of cases exceed ten (10) within a thirty (30) day period or four (4) or more cases occurred from a single harvest day from the implicated area, the Shellfish Control Authority is required to:

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

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

(3) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer

available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products; and

(4) Issue a consumer advisory for all shellfish (or species implicated in the illness). The consumer advisory shall be in the form of a news release and will be shared with the State Shellfish Control Authorities in all states receiving the implicated shellfish.

V. Closure Periods

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

B. When the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area the Shellfish Control Authority will close the implicated growing area. The area will remain closed for a minimum of twenty-one (21) days.

VI. Reopening of Closed Areas

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

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

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

C. Implicated areas that have been closed when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area do not require sampling or review of environmental conditions prior to reopening.

VII. Harvesting From Closed Areas

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

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

Coast oysters and/or hard clams;

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

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

VIII. Laboratory

All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish Laboratory Evaluation Office or FDA certified State Shellfish Laboratory Evaluation Officer in accordance with the requirements established under the NSSP.

IX. Approved Laboratory Methods

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

The Approved NSSP Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI. of the Constitution, Bylaws and Procedures of the ISSC and/or cited in the NSSP Guide for the Control of Molluscan Shellfish Section IV Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests.

Public Health Significance	The purpose of this document is to provide guidance to States in implementing the requirements of Chapter II. @.02 Shellfish Related Illnesses Associated with Vibrio parahaemolyticus (V.p.).
Cost Information	
Action by 2015 Task Force II	Recommended referral of Proposal 15-226 to an appropriate committee as determined by the Conference Chair with instruction to remove this section from the NSSP Guide as interim guidance.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 15-226.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-226.
Action by 2017 Vibrio Management Committee	The Vibrio Management Committee recommended that the Conference Chairperson appoint an appropriate workgroup to amend the *Vibrio parahaemolyticus* Illness Response guidance document to submit to the Executive Board as interim approval following the Biennial Meeting.
Action by 2017 Task Force II	Recommended adoption of Vibrio Management Committee recommendation on Proposal 15-226.

Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 15-226.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 15-226.
Action by 2019 Illness Response Committee	Recommended Proposal 15-226 be referred back to Committee by the Conference Chairperson so that any changes in Vp response requirements can be considered when developing the NSSP guidance document.
Action by Task 2019 Force II	Recommended referral of Proposal 15-226 to the appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 15-226.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 15-226.

Proposal No. 17-204

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Notices of Illness Outbreaks, Recalls and Closures
Specific NSSP Guide Reference	NSSP Guide for the Control of Molluscan Shellfish Section II. Chapter II. Risk Assessment and Risk Management @.01 Outbreaks of Shellfish-Related Illnesses
Text of Proposal/ Requested Action	@.01 Outbreaks of Shellfish-Related Illness

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

(1) Notify the FDA Regional Shellfish Specialist that a shellfish related outbreak has occurred.

(~~1~~2) Conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.

(~~2~~3) Determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated products.

C. When the investigation outlined in Model Ordinance Chapter II. @.04 B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:

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

(2) Notify ~~receiving states~~, the ISSC and the FDA Regional Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;

~~(3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and~~

(3~~4~~) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21CFR Part 7. The recall shall include all implicated products.

(4) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

(5) The ISSC will notify States and FDA Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

D. When the investigation outlined in Model Ordinance Chapter II. @.04 B. demonstrates that the illnesses are related to post- harvesting contamination or

mishandling, growing area closure is not required. However, the Authority shall:

(1) Notify ~~receiving states,~~ the ISSC and the FDA Regional Shellfish Specialist of the problem; and

(2) Initiate a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.

(3) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

(4) The ISSC will notify States and FDA Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

Public Health Significance

The proposed language in Section B. would ensure that FDA is immediately aware of shellfish related outbreaks. The proposed language changes in Section C. would more clearly outline the responsibility associated with notification to FDA and States. Currently notification requirements are not included for recalls associated with post-harvest contamination. Additionally, there are no requirements for notification to States that are not identified as a State receiving recalled product. It is important that all States be notified of recalls. In many cases the complete list of States cannot be determined by identifying the initial dealers. The proposed change would also establish an inventory of closures and recalls. Without an inventory it is difficult to assess program trends.

Cost Information

Action by 2017 Task Force II

Recommended adoption of Proposal 17-201 with recommendations to the ISSC Executive Board to appoint a committee to develop guidance which details recall and closure information sharing.

Action by 2017 General Assembly

Adopted the recommendation of Task Force II on Proposal 17-201.

Action by FDA February 7, 2018

Concurred with Conference action on Proposal 17-201.

Action by 2019 Illness Notification Committee

The committee recommended the following examples be added to Section IV, Chapter V (Illness Outbreaks and Recall Guidance):

Example Notification

NOTICE OF POTENTIAL HEALTH RISK ASSOCIATED WITH AN

IMPLICATED GROWING AREA (Ch II@.01(C)(2))

On **(DATE)**, **(NAME OF AUTHORITY)** determined that an epidemiological association between a **(NAME OF AGENT CAUSING OUTBREAK)** outbreak and **(SPECIES)** consumption existed and began an investigation of the outbreak to determine whether the illness was growing-area related or was the result of post-harvest contamination or mishandling. We have determined that this outbreak is growing-area related and this email serves to notify ISSC and the FDA Shellfish Specialist of these findings.

On **(DATE)**, the **(IMPLICATED HARVEST/GROWING AREA)** was closed to harvest and recall procedures consistent with the Recall Enforcement Policy at 21 CFR Part 7 are being initiated to recall all implicated **(SPECIES)** harvested from **(DATES OF HARVEST)**.

The Point of Contact for this matter is **(NAME OF KEY PERSON WITHIN AUTHORITY AND CONTACT INFORMATION)**.

Example Notification

DISTRIBUTION INFORMATION
RE: PRODUCT RECALL ASSOCIATED WITH OUTBREAK (Ch II@.01(C)(4))

On **(DATE)**, **(NAME OF AUTHORITY)** determined an epidemiological association between a **(NAME OF AGENT CAUSING OUTBREAK)** outbreak and **(SPECIES)** consumption, determined that this outbreak is growing-area related, and initiated recall procedures consistent with the Recall Enforcement Policy at 21 CFR Part 7 to recall all implicated **(SPECIES)** harvested **from (IMPLICATED HARVEST/GROWING AREA)** from **(DATES OF HARVEST)**. This email serves to provide distribution information to ISSC and FDA.

Recalled product was distributed to dealers and/or retailers in the following states: **(NAME OF EACH STATE)**. In accordance with Ch II@.01(I), we have notified each of the receiving states.

The Point of Contact for this matter is **(NAME OF KEY PERSON WITHIN AUTHORITY AND CONTACT INFORMATION)**.

Distribution information is as follows:

Shipping Dealer #1 **Name & ICSSL #:**								
Harvest Area	**Harvest Date**	**Receiving Dealer, Retailer, or Food Service** *(include ICSSL #, if known or applicable)*	**City, State**	**Sale Date**	**Lot No.** **or Date Shucked**	**Qty Sold**	**Product Description**	**Status** *(consumed, destroyed, returned)*

Shipping Dealer #2 **Name & ICSSL #:**								
Harvest Area	**Harvest Date**	**Receiving Dealer, Retailer, or Food Service** *(include ICSSL #, if known/applicable)*	**City, State**	**Sale Date**	**Lot No. or Date Shucked**	**Qty Sold**	**Product Description**	**Status** *(consumed, destroyed, returned)*

(include as many tables as needed, depending on number of shipping dealers involved in recall)

Attachments:

Action by 2019 Task Force II	Recommended adoption of the Illness Notification Committee recommendation on Proposal 17-201.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 17-204.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-204.

Proposal No. 17-206

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Shellfish Illness Response Associated with *Vibrio parahaemolyticus* (*V.p.*)
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.02 Shellfish Related Illnesses Associated with *V.p.*

Text of Proposal/ Requested Action

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

(1) Each consumer's food history;

(2) Shellfish handling practices by the consumer and/or retailer.

B. When the Authority has determined an epidemiological association between *V.p.* illness(es) and shellfish, including illnesses described as sporadic, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and span of time as follows:

(1) When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) ~~but not more than four (4)~~ cases occurring within a ~~thirty (30)~~seven (7) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. ~~The Authority will make reasonable attempts to ensure~~ and evaluate compliance with the ~~existing~~ State Vibrio Control ~~Management~~ Plan. If at least two (2) cases occur from a single harvest day, the Authority shall refer to @.02 B. (3).

(2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed ~~four (4)~~two (2) but not more than ~~ten (10)~~four (4) over a ~~thirty (30) day~~ time period greater than seven (7) but less than thirty (30) days, from the implicated area ~~or two (2) or more cases but less than four (4) cases occur from a single harvest day from the implicated area,~~ the Authority shall:

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

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

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

(3) When the number of cases exceeds ~~ten (10)~~ four (4) illnesses within a thirty (30) day period or two (2) illnesses within a seven (7) day period from the implicated area ~~or four (4) or more cases occurred from a single harvest date from the implicated area~~, ~~T~~the Authority shall:

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

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

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

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

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

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

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

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

(5) Prior to reopening an area closed as a result of the number of cases exceeding ~~ten (10)~~ four (4) illnesses within thirty (30) days or ~~four (4)~~ two (2) within seven (7) days or two (2) cases from a single harvest date from the implicated area, the Authority shall:

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

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

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

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

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

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

(7) Molluscan shellfish recalled as a result of *V.p.* illnesses may be reconditioned as described in Chapter II. @.01 J.

Public Health Significance

The national trend with regard to Vp illnesses has not improved over the past several years. This proposal intends to improve the effectiveness of response to Vp illnesses. This proposal retains the tiered approach for response to Vp illnesses, but requires closure of implicated areas and recall for situations where multiple illnesses occur over a short period of time, suggesting a higher risk situation.

The requirement to close for a minimum of fourteen (14) days and to collect and analyze water samples prior to re-opening is expected to decrease the numbers of *V.p.* illnesses occurring from particularly high risk growing areas.

A reference to @ .01 J has been added for clarification.

Cost Information

Action by 2017 Task Force II

Recommended referral of Proposal 17-206 to an appropriate committee as determined by the Conference Chair.

Action by 2017 General Assembly

Adopted the recommendation of Task Force II on Proposal 17-206.

Action by FDA February 7, 2018

Concurred with Conference action on Proposal 17-206.

Action by 2019 *V.p.* Illness Response Committee

Recommended:

1) the language of proposal 17-206 be replaced with substitute language presented by FDA (included below) for the purpose of referral to an appropriate committee

Section II. Model Ordinance

Chapter II. Risk Assessment and Risk Management

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

A. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and the span of time as follows
(1) lllness per 100,000 servings or….
(2) …
(3) …

(4) …
(5) …
(6) …
(7) Culture-Independent Diagnostic Test (CIDT) positive results not confirmed by reflex culture (probable case) will be considered a confirmed case **if:**
a) more than (>) 2 CIDT positive cases, with symptoms corresponding to Vp, originate from the same growing area within a 30-day period;
b) CIDT positive cases originate from areas where confirmed Vp cases are occurring within a 30-days period. If either of these scenarios present themselves, the presumptive CIDT cases will be treated as confirmed Vp cases

Vibrio parahaemolyticus Illness Attribution Committee will attribute multisource illnesses, if the Authority is unable to attribute a case to a growing area within 24 hrs of the completion of the illness investigation. This committee will assign cases and percentages of cases to state growing areas if a single source cannot be identified. State members of the committee may not vote on illnesses potentially attributed to their own state.

2) Proposal 17-206, as amended, be referred by the Conference Chairman to an appropriate committee, requesting that the committee charge and appointments be made prior to the 2020 ISSC Spring Executive Board meeting.

Action by 2019 Task Force II: Recommended adoption of substitute language of Proposal 17-206 with referral to an appropriate committee as determined by the Conference Chair.

Action by 2019 General Assembly: Adopted recommendation of Task Force II on Proposal 17-206.

Action by FDA February 21, 2020: FDA concurred with the Conference's action to refer Proposal 17-206 to committee. FDA suggests this committee be formed as soon as possible and that the Executive Board consider the committee's recommendations on appropriate changes to the June 22, 2018 Guidance which was provided to states. The critical issues that should be considered by the committee are counting of culture independent diagnostic testing (CIDT) positive cases and case attribution where multiple sources are identified. The committee would deliberate and decide on appropriate attribution. The attribution of illnesses is a great public health concern as it impacts closure and harvest controls; and thus, prevention of further illnesses. The FDA encourages the expeditious formation of the committee and looks forward to continued engagement in this process.

Proposal No. 17-207

Submitter	John A. Tesvich Louisiana Oyster Task Force jatesvich@yahoo.com
Proposal Subject	*V. vulnificus* Control Plan
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management Requirements for the Authority @.06 *Vibrio vulnificus* Control Plan (Effective January 1, 2012) E. Control Plan (1)
Text of Proposal/ Requested Action	Add Section @.06 E. (1) (c)

(c) A state has the option to implement a *Vibrio vulnificus* Control Plan that includes time-temperature harvesting controls when Average Monthly Maximum water temperatures are below 70°F. If the state implements this option, shellstock intended for raw consumption shall comply with the matrix below:

Action Level	Water Temperature	Maximum hours from Exposure to Temperature Control
Level 1	<65°F	36 hours
Level 2	65°F - 70°F (18°C – 23°C	14 hours

Public Health Significance	In the Gulf there has been no significant risk of *V.v*. illness during the coldest months, Dec-Feb. This will allow a state with a *Vibrio vulnificus* Control Plan to more effectively tailor a comprehensive harvesting time-temp control plan without a 70 degree F average maximum water temperature limit.
Cost Information	No expected increase in cost.
Action by 2017 Task Force II	Recommended referral of Proposal 17-207 to an appropriate committee as determined by the Conference Chair.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-207.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-207.
Action by 2019 Time Temperature Committee	Recommended adoption of Proposal 17-207 as amended. Add Section @.06 E. (1) (c)

(c) A state has the option to implement a *Vibrio vulnificus* Control Plan that includes time-temperature harvesting controls when Average Monthly Maximum water temperatures are below 70°F. If the state implements this option, shellstock intended for raw consumption shall comply with the matrix below:

Action Level	~~Water Temperature~~ Month	Maximum hours from Exposure to Temperature Control
Level 1	~~<65°F~~December, January, February	36 hours
Level 2	~~65°F - 70°F (18°C – 23°C~~March, November	14 hours

Action by 2019 Task Force II

Recommended adoption of Temperature Committee recommendations on Proposal 17-207 as amended

Add Section @.06 E. (1) (c)

(a) A state has the option to implement a *Vibrio vulnificus* Control Plan that includes time-temperature harvesting controls when Average Monthly Maximum water temperatures are below 70°F. If the state implements this option, shellstock intended for raw consumption shall comply with the matrix below:

Action Level	Water Temperature	Maximum hours from Exposure to Temperature Control
Level 1	<65°F	36 hours
Level 2	65°F - 70°F (18°C – 23°C	14 hours

(b) All shellstock harvested according to a Vibrio vulnificus control plan shall be cooled to an internal temperature of 55F (12.7 C) or less within 10 hours of being placed into temperature control.

Action by 2019 General Assembly

Adopted recommendation of Task Force II on Proposal 17-207.

Action by FDA February 21, 2020

Concurred with Conference action on Proposal 17-207.

Proposal No. 17-209

Submitter	John A. Tesvich Louisiana Oyster Task Force jatesvich@yahoo.com
Proposal Subject	Shellstock Time to Temperature Controls
Specific NSSP Guide Reference	Section II Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.02 Shellstock Time to Temperature Controls.
Text of Proposal/ Requested Action	A. Each shellfish producing State shall establish time to temperature requirements for the harvesting of all shellstock to ensure that harvesters shall comply with one of the following: (1) The State *Vibrio vulnificus* Control Plan as outlined in Chapter II. @.06; or (2) The State *Vibrio parahaemolyticus* Plan as outlined in Chapter II. @.07; or (3) All other shellstock shall comply with one of the ~~matrix~~ matrices below:

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

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

Public Health Significance	No adverse public health significance. Gulf states have had no significant historical bacterial based risk during cold water months Dec-Feb. This will allow states the option to have the harvest time to temperature controls based on Average Monthly Maximum water temperature instead of only Average Monthly Maximum Air Temperature, (as it was prior to 2012)
Cost Information	None
Action by 2017 Task Force II	Recommended referral of Proposal 17-209 to an appropriate committee as determined by the Conference Chair.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-209.

Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-209.
Action by 2019 Time Temperature Committee	Recommended Task Force II to take no action on Proposal 17-209. Rationale this issue is resolved by action on Proposal 17-207.
Action by 2019 Task Force II	Recommended no action on Proposal 17-209. Rationale: Adequately addressed by the action taken on Proposal 17-207.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 17-209.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-209.

Proposal No. 17-217

Submitter	Susan Ritchie New York State Department of Environmental Conservation susan.ritchie@dec.ny.gov
Proposal Subject	Removal of Harvester Tags being Shipped by Shellfish Dealers
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers .05 Shellstock Identification
Text of Proposal/ Requested Action	B. Tags (1) The dealers' tags… (2) The dealer's tag… (3) ~~When both the dealer and harvester tag appear on the container, the dealer's tag is not required to duplicate the information on the harvester's tag.~~ The harvester tag must be removed from each container prior to being shipped. The harvester tag shall be replaced with a dealer tag and shall meet the requirements in Section .05 B. (4) If the shellstock… (5) Country of origin… (6) When shellstock intended… (7) If a shellfish…
Public Health Significance	There should not be any harvester tags at restaurants because only harvesters who are also certified dealers can sell directly to retail or ship interstate making harvesters an unapproved source. When both tags are affixed to the container, there will also be a blank dealer's tag that may potentially be used by an unauthorized person. Excerpt from Shellfish Plant Sanitation Course. "Shellfish harvesters are authorized to: grow and harvest shellstock. Wash, sort, bag and tag harvested shellstock. Sell the product to certified dealers in the State, depending on the State's regulations. Only a harvester who is also a certified dealer can sell directly to retail or ship interstate." https://www.accessdata.fda.gov/ORAU/ShellfishPlantSanitation/SPS_01_000.htm
Cost Information	$0.00
Action by 2017 Task Force II	Recommended adoption of Proposal 17-217 as submitted.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-217.
Action by FDA February 7, 2018	Did not concur with Conference action on proposal 17-217. FDA recommended alternative language. (See February 7, 2018 FDA response to ISSC Summary of Actions)
Action by ISSC Executive Board	Did not accept the FDA recommended language. Referred Proposal 17-217 to an appropriate committee as determined by the Conference Chair.
Action by 2019	Recommended adoption of Proposal 17-217 as amended.

Shellfish Tagging Committee	B.	Tags
		(1) The dealers' tags…
		(2) The dealer's tag…
		(3) ~~The harvester tag must be removed from each container prior to being shipped. The harvester tag shall be replaced with a dealer tag and shall meet the requirements in Section .05 B.~~If a dual-purpose tag is used (harvester or dealer), duplicate information is not required on both sides of the tag.
		(4) If a two-tag system is used, the dealer tag shall meet the requirements in .05 B.
		(~~4~~5) If the shellstock…
		(~~5~~6) Country of origin…
		(~~6~~7) When shellstock intended…
		(~~7~~8) If a shellfish…
Action by 2019 Task Force II	Recommended adoption of Proposal 17-217 as amended.	
	B.	Tags
		(1) The dealers' tags…
		(2) The dealer's tag…
		(3) If a dual-purpose tag is used (harvester and ~~or~~ dealer), duplicate information is not required on both sides of the tag, or~~.~~
		(4) If a two-tag system is used, the dealer tag shall meet the requirements in .05 B.
		(5) If the shellstock…
		(6) Country of origin…
		(7) When shellstock intended…
		(8) If a shellfish…
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 17-217.	
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-217.	

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Hand Sanitizer
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. .02 D. (4); Section II. Model Ordinance Chapter XII. .02 D. (1) (c); Section II. Model Ordinance Chapter XIII. .02 D. (1) (b); Section II. Model Ordinance Chapter XIV. .02 D. (1) (b); and Section II. Model Ordinance Chapter XV. .02 D. (3)

Text of Proposal/ Requested Action

Chapter XI. Shucking and Packing .02 Sanitation

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

(1) Hand washing facilities…

(2) Hand washing facilities…

(3) The dealer shall…

(4) The dealer shall provide at each hand washing facility:

(a) Supply of hand cleansing soap or detergent; [K]

(b) Supply of hand sanitizer; **[K]**

(c~~b~~) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]

(d~~c~~) Easily cleanable waste receptacle; and [O]

(e~~d~~) Hand washing signs in a language understood by the employees; [O]

(5) Sewage [C] and liquid…

(6) The dealer shall provide…

Chapter XII. Repacking of Shucked Shellfish .02 Sanitation.

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

(1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C) dispensed from a hot and cold mixing or combination faucet shall be provided. [$S^{K/O}$]

(a) Hand washing facilities…

(b) The dealer shall…

(c) The dealer shall provide at each hand washing facility:

(i) Supply of hand cleansing soap or detergent; [K]

(ii) Supply of hand sanitizer; **[K]**

(i~~i~~i) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]

(iv~~ii~~) Easily cleanable waste receptacle; and [O]

(~~i~~v) Hand washing signs in a language understood by the employees; [O]

(2) Sewage [C] and liquid…

(3) The dealer shall…

Chapter XIII. Shellstock Shipping .02 Sanitation.

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

(1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C) dispensed from a hot and cold mixing or combination faucet shall be provided. [$S^{K/O}$]

(a) Handwashing facilities shall…

(b) The dealer shall provide at each handwashing facility:

(i) Supply of hand cleansing soap or detergent; [K]

(ii) Supply of hand sanitizer; **[K]**

(iii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]

(iv~~ii~~) Easily cleanable waste receptacle; and [O]

(~~i~~v) Handwashing signs in a language understood by the employees; [O]

(2) Sewage [K] and liquid…

(3) The dealer shall…

Chapter XIV. Reshipping .02 Sanitation.

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

(1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C) dispensed from a hot and cold mixing or combination faucet shall be provided. [$S^{K/O}$]

(a) Handwashing facilities shall…

(b) The dealer shall provide at each handwashing facility:

(i) Supply of hand cleansing soap or detergent; [K]

(ii) Supply of hand sanitizer; **[K]**

(iii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]

(iv~~ii~~) Easily cleanable waste receptacle; and [O]

(~~i~~v) Handwashing signs in a language understood by the employees; [O]

(2) Liquid disposable wastes…

(3) The dealer shall…

Chapter XV. Depuration .02 Sanitation

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities

(1) Hand washing facilities…

(2) Hand washing facilities…

(3) The dealer shall provide at each hand washing facility;

(a) Supply of hand cleansing soap or detergent; [K]

(b) Supply of hand sanitizer; **[K]**

(c~~b~~) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]

(dc) Easily cleanable waste receptacle; and [O]
(ed) Hand washing signs in a language understood by the employees; [O]
(4) Sewage [C] and liquid…

Public Health Significance

Current Model Ordinance language in Chapters XI-XV .02 C. Prevention of Cross Contamination, requires that employees wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility. Currently D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities addresses an adequate supply of hand cleaning soap or detergent, but does not address an adequate supply of hand sanitizer. Adding the new language in will make current language more consistent and enforceable by State inspectors.

Cost Information

Minimal cost.

Action by 2017 Task Force II

Recommended referral of Proposal 17-220 to an appropriate committee as determined by the Conference Chair.

Action by 2017 General Assembly

Adopted the recommendation of Task Force II on Proposal 17-220.

Action by FDA February 7, 2018

Concurred with Conference action on Proposal 17-220.

Action by 2019 Sanitation Committee

Recommended adoption of Proposal 17-217 as amended.

Section II.

Chapter XI. Shucking and Packing

.02 Sanitation
D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
(1) Hand washing facilities…
(2) Hand washing facilities…
(3) The dealer shall…
(4) The dealer shall provide at each hand washing facility:
(a) Supply of hand cleansing soap or detergent; [K]
(b) Supply of FDA approved hand antisepticsanitizer; **[K]**
(c) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
(d) Easily cleanable waste receptacle; and [O]
(e) Hand washing signs in a language understood by the employees; [O]
(5) Sewage [C] and liquid…
(6) The dealer shall provide…

Chapter XII. Repacking of Shucked Shellfish .02 Sanitation.
D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
(1) Hand washing facilities with warm water at a minimum temperature of

100 °F (37.8 °C) dispensed from a hot and cold mixing or combination faucet shall be provided. [$S^{K/O}$]

(a) Hand washing facilities…
(b) The dealer shall…
(c) The dealer shall provide at each hand washing facility:
(i) Supply of hand cleansing soap or detergent; [K]
(ii) Supply of FDA approved hand antiseptic~~sanitizer~~; **[K]**
(iii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
(iv) Easily cleanable waste receptacle; and [O]
(v) Hand washing signs in a language understood by the employees; [O]
(2) Sewage [C] and liquid…
(3) The dealer shall…

No changes will be made to Chapters XIII, XIV, or XV

Action by 2019 Task Force II

Recommended adoption of Proposal of 17-220 as amended.

17-220 Hand Sanitizer
Substitute
Text of Proposal/Requested Action
Section II – Chapter X. General Requirements for Dealers
.02 General Sanitation Requirements
A...
(4) Maintenance of hand washing, ~~hand sanitizing~~, and toilet facilities, hereinafter referred to as:
Maintenance of Hand Washing, ~~Hand Sanitizing~~ and Toilet Facilities;

Section II – Chapter XI. Shucking and Packing
.02 Sanitation
C. Prevention of Cross Contamination.
(3) Employee practices.
(b) The dealer shall require all employees to wash their hands thoroughly with soap and water ~~and sanitize their hands~~ in an adequate hand washing facility:

D. Maintenance of Hand Washing~~, Hand Sanitizing~~ and Toilet Facilities.

Section II - Chapter XII. Repacking of Shucked Shellfish
.02 Sanitation
C. Prevention of Cross Contamination.
(b) The dealer shall require all employees to wash their hands thoroughly with soap and water ~~and sanitize their hands~~ in an adequate hand washing facility:

D. Maintenance of Hand Washing~~, Hand Sanitizing~~ and Toilet Facilities.

Section II – Chapter XIII. Shellstock Shipping
.02 Sanitation

(C) Prevention of Cross Contamination
(2) Employee practices. (a) The dealer shall require all employees to wash their hands thoroughly with
soap and water ~~and sanitize their hands~~ in an adequate handwashing facility:

D. Maintenance of Hand Washing~~, Hand Sanitizing~~ and Toilet Facilities.

Section II. XIV. Reshipping
.02 Sanitation
(C) Prevention of Cross Contamination
(2) Employee practices. (a) The dealer shall require all employees to wash their hands thoroughly with soap and water ~~and sanitize their hands~~in an adequate handwashing facility:

D. Maintenance of Hand Washing~~, Hand Sanitizing~~ and Toilet Facilities.

Section II. Chapter XV. Depuration
.02 Sanitation
(C) Prevention of Cross Contamination
(3) Employee practices. (a) The dealer shall require all employees to wash their hands thoroughly with soap and water ~~and sanitize their hands~~ in an adequate hand washing facility:

D. Maintenance of Hand Washing~~, Hand Sanitizing~~ and Toilet Facilities.

Section III. Public Health Reasons and Explanations – Chapters XI., XII., XIII., and XIV. Shellfish Processing
and Handling
Requirements for Dealers

.02 General Sanitation Requirements
General Sanitation Requirements apply to Chapters XI., XII., XIII., XIV., and XV. as appropriate to the activity being conducted and as required in the NSSP Model Ordinance: (1) Safety of Water for Processing and Ice Production; (2) Condition and Cleanliness of Food Contact Surfaces; (3) Prevention of Cross Contamination; (4) Maintenance of Hand Washing~~, Hand Sanitizing~~, and Toilet Facilities; (5) Protection from Adulterants; (6) Proper Labeling, Storage, and Use of Toxin Compounds; (7) Control of Employees with Adverse Health Conditions; (8) Exclusion of Pests.

D. Maintenance of Hand Washing~~, Hand Sanitizing~~, and Toilet Facilities.
Hand washing by employees is an important public health measure. Providing convenient, properly constructed and plumbed facilities, supplied with soap and towels encourages employees to wash hands frequently and correctly. Washing of hands with soap and drying with single service towels or a handdrying device improves the ~~sanitizing~~ sanitation of the hands. Disease-causing microorganisms may be present in body discharges of employees that are cases or carriers of communicable disease organisms. When sewage disposal facilities are of a satisfactory type, there is less possibility that the shellfish being processed may become contaminated with fecal material carried by flies, rodents, or by other means.

.03 Other Model Ordinance Requirements

L. Personnel. Disease producing agents may be carried on the hands of shuckers and packers unless proper hand washing is practiced. Finger cots, gloves, and shields, unless effectively sanitized periodically, will accumulate bacteria that may contaminate the shucked shellfish. ~~Employees handling shucked shellfish need to sanitize their hands as an added public health control practice.~~

Requirements for the Depuration Processor
.02 Sanitation
D. Maintenance of Hand Washing~~, Hand Sanitizing~~, and Toilet Facilities. Adequate toilet, *and* hand washing ~~and sanitizing~~ facilities must be provided. Hand washing by employees is an important public health measure. Providing convenient, properly constructed and plumbed facilities, supplied with soap and towels encourages employees to wash their hands frequently and correctly. Washing of hands with soap and drying with single service towels or a hand-drying device improves the ~~sanitizing~~ sanitation of the hands.

Section IV. Guidance Documents
Chapter III Harvesting, handling, processing, and distribution
.02 Shellfish Plant Inspection Standardization Procedures NSSP Standardized Shellfish Processing Plant Inspection Form

Chapter IV Performance Criteria for Field Standardization
INTRODUCTION
(d.) Although there will be no written report left, with the firm, if there are significant findings they will be brought to the attention of the PERSON IN CHARGE during the Exit Interview. In addition to verbal and written communication, the Candidate shall also use the inspection process to communicate and demonstrate FOOD SAFETY concepts by example. Activities such as proper hand washing~~, and sanitizing~~, insuring the thermometer is cleaned and sanitized before every use and wearing proper clean outer garments and a ~~heave~~head cover will reinforce your spoken and written communications.

Action by 2019 General Assembly — Adopted recommendation of Task Force II on Proposal 17-220.

Action by FDA February 21, 2020 — Concurred with Conference action on Proposal 17-220.

Submitter	Chris Shriver, GM and Daniel Cohen, President Atlantic Capes Fisheries, Inc. cshriver@atlanticcapes.com and dcohen@atlanticcapes.com
Proposal Subject	Clarification of Surf Clams and Ocean Quahogs Exemption from Time/Temperature Requirements whcn "intended for thermal processing".
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.02 Shellstock Time to Temperature Controls G. Section IV. Guidance Documents Chapter II. Handling, Processing, and Distributing B.
Text of Proposal/ Requested Action	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.02 Shellstock Time to Temperature Controls

G. Ocean Quahogs (*Arctica islandia*) and surf clams (*Spisula solidissima*) are exempt from this temperature control plan when these products are intended for thermal processing, which includes when a Processor represents, labels, or intends for the products to be cooked prior to consumption pursuant to the Processor's HACCP Plan as defined in FDA 21 CFR Part 123 Seafood HACCP regulations. For clarity, if Surf Clams or Ocean Quahogs are distributed live with the intention they could eaten raw, those Surf Clams and Ocean Quahogs are not exempt from this temperature control plan.

Section IV. Guidance Documents Chapter III. Handling, Processing and Distributing

B. Ocean Quahogs (*Arctica islandia*) and Surf Clams (*Spisula solidissima*) are excluded from the time to temperature controls of State Vibrio Control Plans or the matrix outlined in Chapter VIII. @.02 A. (1) (2) and (3). This exclusion applies only when these products are intended for thermal processing, which includes when a Processor represents, labels, or intends for the product to be cooked prior to consumption pursuant to the Processor's HACCP Plan as defined in FDA 21 CFR Part 123 Seafood HACCP regulations. Authorities may exclude other species when intended for thermal processing. For clarity, if Surf Clams or Ocean Quahogs are distributed live with the intention they could eaten raw, those Surf Clams and Ocean Quahogs are not exempt from this temperature control plan.

Public Health Significance	There is no adverse public health significance by this clarification of the meaning of the exemption for surf Clams and Ocean Quahogs *"intended for thermal processing"*. There will be no change from current practices, which include HACCP process controls adopted by each Processor. The additional wording merely clarifies a misinterpretation that the definition of *"intended for thermal processing"* is limited to low acid canning of 21 CFR 113.3(o). The Surf Clam and Ocean Quahog processors have been shucking surf clams and selling them in the uncooked state (both as fresh clam meats and frozen clam meats) for decades to customers with the intention that all of their customers will fully cook the Surf Clam meats and Ocean Quahogs prior to consumption. Thermal processing and cooked is not limited to only low aid canning, but also includes other forms of cooking and thermal processing as defined in the NSSP MO in Definitions (B) (94). Intended use guidance and controls

	are already established, this proposal simply clarifies and documents current practices, and aligns with common use of Surf Clams and Ocean Quahogs. As per FDA 21 CFR Part 123 Seafood HACCP regulations the Surf Clam and Ocean Quahog processors shall identify the intended use of their products. Additionally the Surf Clam and Ocean Quahog processors shall be required, consistent with their HACCP Plans, to issue annual HACCP Compliance Letters to all their customers which also identify the intended use of their products.
Cost Information	None. There will be no additional cost to industry, public, or the regulators by this clarification.
Action by 2017 Task Force II	Recommended referral of Proposal 17-225 to an appropriate committee as determined by the Conference Chair. Task Force Member Joe Jewell (Mississippi) requested the record reflect he abstained from the vote.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-225.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-225.
Action by 2019 Time Temperature Committee	Recommended Task Force II refer Proposal 17-225 back to the committee as the Subcommittee is still collecting data needed to make a recommendation.
Action by 2019 Task Force II	Recommended referral of Proposal 17-225 back to Time Temperature Committee with instruction to develop a definition for thermal processing and to request FDA to extend the exemption from the time temperature requirements until the study is completed.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 17-225.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-225..

Proposal No. 19-200

Submitter	David Fyfe[1] & Tamara Gage[2] Northwest Indian Fisheries Commission[1] & Port Gamble Tribe[2] dfyfe@nwifc.org
Proposal Subject	Impact of water quality in wet storage
Specific NSSP Guide Reference	Not Applicable
Text of Proposal/ Requested Action	There are very specific conditions associated with moving shellfish from one body of water to another for the purposes of relay or depuration. These processes 1. Always move shellfish into water that is considered better quality, from a health standpoint, and 2. Are specifically designed to reduce bacterial loads resulting from human contamination i.e. coliforms For decades now, public health concerns have increasingly focused on vibrios, which are naturally occurring, and less predictable. Wet storage, which is not designed to reduce bacterial load, is given little attention, provided that the shellfish move between Approved growing areas. Vibrios, however, could be at a higher concentration in the originating waters or where the wet storage occurs, so with time, vibrio levels may increase or decrease while in wet storage. With public health in mind, it is probably safe to assume that when shellfish are exposed to higher bacterial levels, their uptake is relatively quick and when bacterial levels are low, 'purging' is relatively slow. This is because uptake simply involves filtration and reduction involves emptying of the gut. When a vibrio illness occurs due to the consumption of shellfish that have been wet stored, both bodies of water are noted on the associated tags and thereby become associated with a vibrio problem, if not directly implicated. Shellfish which have been raised in waters with no recorded vibrio illnesses, could be wet stored in a growing area that has a history of vibrio illnesses, now implicating the former and possibly resulting in stricter harvesting and handling standards. In an extreme case, that growing area could be considered the sole source of an illness, if wet storage only occurred for a few days. This proposal asks that a committee be charged with examining this situation for the purposes of providing guidance as to how much weight should be given to the relative history of vibrios in both the growing area and the wet storage area, when implicating one or both, after an illness.
Public Health Significance	Individual subjectivity could result in low risk areas being implicated and/or high risk areas being cleared, based on perception as to how long shellfish must remain in a wet storage area in order to significantly uptake or purge vibrios. Guidance resulting from Committee deliberations, possibly including a recommendation for a multisource determination in certain circumstances, is requested.
Cost Information	
Action by 2019 Task	Recommended adoption of Proposal 19-200 as submitted.

Force II	
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-200.
Action by FDA	Concurred with Conference action on Proposal 19-200.
February 21, 2020	

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Definition of Certification Number
Specific NSSP Guide Reference	Section I. Purpose and Definitions B. Definition of Terms
Text of Proposal/ Requested Action	**(17) Certification Number** means the unique identification number issued by the Authority to each dealer for each location. Each certification number shall consist of a one (1) to five (5) digit Arabic number preceded by the two letter State abbreviation and followed by a two (2) letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with Chapter X. .04 B. The certification type will be followed by applicable permit designation as indicated in Chapter I. @.02 E.1.~~this Ordinance using the following terms:~~ ~~(a) Shellstock shipper (SS);~~ ~~(b) Shucker-packer (SP);~~ ~~(c) Repacker (RP);~~ ~~(d) Reshipper (RS); and~~ ~~(e)Depuration processor (DP).~~
Public Health Significance	The new language creates consistencies with Proposal 19-204 and includes both certification type and permit designations.
Cost Information	
Action by 2019 Task Force II	Recommended adoption of Proposal 19-201 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-201.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-201.

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Definition of Restricted Shellstock
Specific NSSP Guide Reference	Section I. Purpose and Definitions B. Definition of Terms
Text of Proposal/ Requested Action	**(105) Restricted ~~Use~~ Shellstock** means shellstock that is harvested from growing areas classified as approved or conditionally approved in the open status and under conditions that do not allow the sale of the shellstock for direct marketing for raw consumption. Restricted use shellstock is identified with a tag indicating that the shellstock ~~is intended for~~has restrictions requiring further processing or testing prior to distribution~~. to retail or food service.~~ NOTE: Should this change be adopted, it may be necessary to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.
Public Health Significance	In 2017, the US FDA submitted Proposals 17-116 and 17-119 for the purpose of integrating shellfish harvested from Federal waters into the National Shellfish Sanitation Program (NSSP). The ISSC voting delegates voted to appoint a committee to evaluate aquaculture activities in Federal waters. Since the meeting in 2017, it has become apparent that the implications of Proposals 17-116 and 17-119 are not limited to aquaculture activities. A Federal Waters Subcommittee has met and identified numerous concerns associated with integrating shellfish from Federal waters into the NSSP that were not addressed in Proposals 17-116 and 17-119. The Subcommittee is continuing to discuss necessary NSSP changes for consideration at the 2019 ISSC Biennial Meeting. As Executive Director, I am submitting several proposals that I expect the Federal Waters Committee to modify. These proposals include 19-202, 19-203, 19-214, 19-223, 19-228, and 19-229. The purpose of these proposals is to meet the notification requirements for proposals. These proposals have not been reviewed and approved by the Federal Waters Subcommittee or the Federal Waters Committee. They address topics and possible solutions that have been discussed to this point.
Cost Information	
Action by 2019 Task Force II	Recommended to adopt Proposal 19-202 as amended: **(105) Restricted Shellstock** means shellstock that is harvested from growing areas classified as approved or conditionally approved in the open status and under conditions that do not allow the sale of the shellstock for direct marketing for raw consumption. Restricted ~~use~~ shellstock is identified with a tag indicating that the shellstock has restrictions requiring further processing or testing prior to distribution. And also to refer to an appropriate committee as determined by the Conference Chair to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.

Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-202.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-202.

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Foreign Country and Federal Waters Authority
Specific NSSP Guide Reference	Section II, Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority
Text of Proposal/ Requested Action	**@.01 Administration**

A. Scope.

(1) The Authority shall establish a statewide shellfish safety and sanitation program to regulate:

(a) The classification of shellfish growing areas;
(b) The harvesting of shellfish;
(c) Shellfish processing procedures and facilities;
(d) Product labeling;
(e) Storage, handling and packing;
(f) Shellfish shipment in interstate commerce;
(g) Shellfish dealers; and
(h) Bivalve aquaculture

(2) All foreign countries shipping shellfish into the United States will have a memorandum of understanding or an equivalency agreement with the United States.

(3) The regulatory responsibility for growing area and harvest control in federal waters will be the responsibility of the FDA and NOAA.

B. State Laws and Regulations. The Authority shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of all program elements including but not limited to the elements outlined in @.01 A. Federal Agencies shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of growing area and harvest control.

C. Records. The Authority…

D. Shared Responsibilities. If more than one agency is involved in the administration of the statewide shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities. In the case of Federal Waters, if more than one agency is involved in the administration of the shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities

E. Administrative Procedures.

(1) The Authority shall have administrative procedures sufficient to:

(a) Regulate shellfish harvesting, sale, and shipment;
(b) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the State from which the shellstock are harvested or landed, unless the Authority has a memorandum of understanding with the Authority in another State to allow dealers from its State to purchase the shellstock;
(c) Detain, condemn, seize, and embargo shellfish; and

(d) Assure compliance with Shellfish Plant Inspection Standardization

(2) In the case of Federal Waters, the FDA and NOAA shall have administrative procedures sufficient to regulate growing areas and harvest control.

NOTE: Should this change be adopted, it may be necessary to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.

Public Health Significance	In 2017, the US FDA submitted Proposals 17-116 and 17-119 for the purpose of integrating shellfish harvested from Federal waters into the National Shellfish Sanitation Program (NSSP). The ISSC voting delegates voted to appoint a committee to evaluate aquaculture activities in Federal waters. Since the meeting in 2017, it has become apparent that the implications of Proposals 17-116 and 17-119 are not limited to aquaculture activities. A Federal Waters Subcommittee has met and identified numerous concerns associated with integrating shellfish from Federal waters into the NSSP that were not addressed in Proposals 17-116 and 17-119. The Subcommittee is continuing to discuss necessary NSSP changes for consideration at the 2019 ISSC Biennial Meeting. As Executive Director, I am submitting several proposals that I expect the Federal Waters Committee to modify. These proposals include 19-202, 19-203, 19-214, 19-223, 19-228, and 19-229. The purpose of these proposals is to meet the notification requirements for proposals. These proposals have not been reviewed and approved by the Federal Waters Subcommittee or the Federal Waters Committee. They address topics and possible solutions that have been discussed to this point.
Cost Information	
Action by 2019 Task Force II	Recommended adoption of Proposal 19-203 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-203.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-203.

Proposal No. 19-204

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	ICSSL Certification Type
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program for the Authority @.02 E. 1.
Text of Proposal/ Requested Action	E. Interstate Certified Shellfish Shippers List (ICSSL). (1) When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. The Authority shall include the certification type and any permit designation to be included in the ICSSL. The notice shall be in the format of FDA Form 3038.

Designations:

Certification	Permit
SP – Shucker Packer	PHP – Post-Harvest Processing
RP – Repacker	AQ – Aquaculture
SS – Shellstock Shipper	WS – Wet Storage
RS – Reshipper	
DP – Depuration	

(2) The Authority shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate or permit is:

(a) Suspended; or

(b) Revoked.

Public Health Significance	This language is intended to address an omission. Authorities currently include certification type when submitting 3038 forms.
Cost Information	
Action by 2019 Task Force II	Recommended adoption of Proposal 19-204 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-204.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-204.

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Dealer Inspection Requirements for States
Specific NSSP Guide Reference	Section II Model Ordinance Chapter I Shellfish Sanitation Program for the Authority @.02 F.
Text of Proposal/ Requested Action	F. Inspections. (1) After any person is certified, the Authority shall make unannounced inspections of the dealer's facilities: (a) During periods of activity; and (b) At the following minimum frequencies: (i) Within thirty (30) days of beginning activities if the dealer was certified on the basis of a pre-operational inspection; (ii) At least monthly for dealer facilities certified as depuration processors; (iii) At least quarterly for dealer's activities certified as shucker-packer or repacker; and (iv) At least semiannually for other dealer activities. (2) The Authority shall provide a copy of the completed inspection form to the person in-charge at the dealer's operation at the time of inspection. The inspection form shall contain a listing of deficiencies by area in the operation and inspection item with corresponding citations to this Model Ordinance. ~~(2)~~(3) The plant inspection shall be conducted by the State Shellfish Standardization Inspector using the appropriate inspection form.
Public Health Significance	Model Ordinance Chapter I @.02 A. states that certification inspections can only be conducted by a State Shellfish Standardization Inspector using the appropriate inspection form. Chapter I @.02 F., which addresses routine inspections, does not state that routine inspections must be conducted by a standardized inspector. This was probably an unintentional omission. This proposal is intended to create consistency within the program.
Cost Information	
Action by 2019 Task Force II	Recommended adoption of Proposal 19-205 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-205.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-205.

Submitter	ISSC Illness Outbreak Guidance Committee Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Illness Outbreak Response
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management
Text of Proposal/ Requested Action	**@.01 Outbreaks of Shellfish-Related Illness**

A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one (1) or more persons in the case of shellfish toxicity poisoning associated with marine biotoxins), the ~~Authority~~ determination of ~~shall determine~~ whether an epidemiological association exists between the illness and the shellfish consumption will be made by the state or local epidemiologist in the state in which the outbreak occurs. The determination will be made by reviewing:

(1) ~~Each consumer's f~~Food history;

~~(2) Shellfish handling practices by the consumer and/or retailer;~~

~~(3)~~(2) Whether the disease has the potential or is known to be transmitted by shellfish; and

~~(4)~~(3) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.

NOTE: For additional guidance refer to the International Association of Milk, Food, and Environmental Sanitarians' *Procedures to Investigate Food Borne Illness*.

B. When the state or local epidemiologist in the state in which the outbreak occurs ~~Authority~~ has determined an epidemiological association between an illness outbreak and shellfish consumption, the appropriate ~~Authority~~ Authorities shall:

(1) Notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred.

(2) ~~Conduct an investigation of the illness outbreak w~~Within twenty-four (24) hours ~~to~~ determine whether the illness is growing area related or is the result of post-harvest contamination, ~~or~~ mishandling, or illegal harvesting from a closed area. The determination of post-harvest contamination may involve multiple authorities in multiple states. The determination of the illness being growing area related will be conducted by the source state.

~~(3) Determine whether to initiate a voluntary recall by firms.~~ If ~~a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated pro~~ducts.

C. When the Authorities determine that the outbreak is not the result~~investigation outlined in Model Ordinance Chapter II. @.04 B. does not indicate~~ a post-harvest contamination problem, or illegal

harvesting from a closed area, the Authority shall:

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

(2) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;

(3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include all implicated products.

(4) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

(5) The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

D. When the appropriate Authorities determine ~~investigation outlined in Model Ordinance Chapter II. @.04 B. demonstrates~~ that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority in the state where the post-harvest contamination, mishandling or illegal harvesting from a closed area shall:

(1) Notify the ISSC and the FDA Shellfish Specialist of the problem; and

(2) ~~Initiate a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use~~ Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 when a recall is deemed appropriate by the Authority. The recall shall include all implicated products.

(3) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

(4) The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

E. When the Authority can not complete the determination outlined in Chapter II @.01 B ~~investigation outlined in Model Ordinance Chapter II. @.04 B. cannot be completed~~ within 24 hours, the Authority in the source state shall:

(1) Immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status.~~Follow the closure procedure outlined in Chapter II @.01 C.; and if the investigation does not indicate a growing area problem, the area may be immediately reopened and product recall terminated.~~

(2) Should the Authorities later determine that the illnesses are

related to post harvest contamination, or mishandling, or harvesting from a closed area, the suspected growing area can be reopened.

~~(1)~~(3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include all implicated products

~~F. Upon closing an implicated area for problems other than naturally occurring pathogens and/or biotoxins, the Authority shall review the growing area classification and determine if a growing area classification problem exists. The review shall include at a minimum:~~

~~(1) A review of the growing area classification file records;~~

~~(2) A field review of existing pollution sources;~~

~~(3) A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems; and~~

(4) ~~Examination of water quality subsequent to the illness outbreak~~.

~~G.~~F. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or biotoxins, the Authority:

(1) Shall follow an existing marine biotoxin contingency/management plan, if appropriate.

(2) Shall collect and analyze samples relevant to the investigation, if appropriate.

(3) Shall keep the area closed until it has been determined that levels of naturally occurring pathogens and/or biotoxins are not a public health concern.

(4) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.

~~H.~~G. When the growing area is determined the problem, the Authority shall:

(1) Place the growing area in the closed status until:

(a) The Authority verifies that the area is properly classified by conducting a review of the growing area to include:

(i) ~~, using~~ current data, in compliance with the NSSP Model Ordinance; ~~or~~

(ii) A field review of existing pollution sources;

(iii) A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems. If the review indicates that a previously unknown pollution source exists, the area shall be reclassified. If the previously unknown pollution source can be corrected, the closure period ~~should~~ shall be extended to allow for natural depuration following correction of the pollution source; and

~~(i)~~(iv) Examination of water quality subsequent to the illness outbreak.

(b) ~~Shellfish from the growing area are confirmed as the cause of illness but i~~It has been determined that the event which caused the contamination no longer exists and sufficient time has elapsed for natural depuration;

(2) Keep the area closed for a minimum of 21 days if the illness is consistent with viral etiology; and
(3) Develop a written report summarizing the findings of the investigation and actions taken.

~~I.~~H. Whenever an Authority or dealer initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA, ISSC and the Authorities in other States involved in the recall. The Authority shall submit periodic recall status reports to the FDA Shellfish Specialist consistent with the Recall Enforcement Policy Title 21 CFR Part 7, Subpart C, Section 7.53 (b) (1- 6) until such time that the Authority deems the recall to be completed. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market, issue public warnings if necessary to protect public health and provide periodic reports to the Authority in the State of product origin regarding recall efforts within their State until such time that the Authority in the State of product origin deems the recall to be completed. FDA will decide whether to audit or issue public warnings after consultation with the Authority/Authorities and after taking into account the scope of the product distribution and other related factors. If the FDA determines that the Authority in any State involved in the recall fails to implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate.

~~J.~~I. Molluscan shellfish product that is recalled as a result of an illness outbreak associated with *V.v.* or *V.p.* may be reconditioned. Validated reconditioning processes include subjecting product to validated post-harvest processing (PHP) or placing product into approved, conditionally approved, conditionally restricted, or restricted growing areas for an appropriate period of time, not less than fourteen (14) days, with appropriate controls and documentation to be determined by the Authority.

Public Health Significance	Following outbreaks in Maryland and Washington, the states requested clarification regarding the requirements of Chapter II. @.01 “Outbreaks from Shellfish Related Illness”. In response, the ISSC Executive Board directed the establishment of a committee to provide clarification. The committee was also tasked to develop proposals to revise Chapter II language to provide requirement clarification. The committee was also requested to address appropriate outbreak response to multi-source outbreaks.
Cost Information	
Action by 2019 Task Force II	Recommend adoption of Proposal 19-208 as amended. Task Force II requests the development of a decision tree reflecting the requirements of 19-208 to be presented at the Spring 2020 Board Meeting.

@.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 (1) or more persons in the case of shellfish toxicity poisoning associated with marine biotoxins), the determination of whether an epidemiological association exists between the illness and the shellfish consumption will be made by the state or local epidemiologist in the state in which the outbreak occurs. The determination will be made by reviewing:
   (1) Food history;
   (2) Whether the disease has the potential or is known to be transmitted by shellfish; and
   (3) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.

NOTE: For additional guidance refer to the International Association of Milk, Food, and Environmental Sanitarians' *Procedures to Investigate Food Borne Illness*.

B. When the state or local epidemiologist in the state in which the outbreak occurs has determined an epidemiological association between an illness outbreak meeting the definition of the NSSP and shellfish consumption, the appropriate Authorities shall:
   (1) Notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred.
   (2) Within twenty-four (24) hours determine whether the illness is growing area related or is the result of post-harvest contamination, mishandling, or illegal harvesting from a closed area. The determination of post-harvest contamination may involve multiple authorities in multiple states. The determination of the illness being growing area related will be conducted by the source state.

C. When the Authorities determine that the outbreak is not the result a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:
   (1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;
   (2) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;
   (3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include all implicated products.
   (4) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.
   (5) The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers

shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

D. When the appropriate Authorities determine that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority in the state where the post-harvest contamination, mishandling or illegal harvesting from a closed area shall:

(1) Notify the ISSC and the FDA Shellfish Specialist of the problem; and

(2) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 when a recall is deemed appropriate by the Authority. The recall shall include all implicated products.

(3) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

(4) The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

E. When the Authority can not complete the determination outlined in Chapter II @.01 B within 24 hours, the Authority in the source state shall:

(1) Immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status.
Should the Authorities later determine that the illnesses are related to post harvest contamination, or mishandling, or harvesting from a closed area, the suspected growing area can be reopened.

(2) ~~Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include all implicated products~~ Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority deems appropriate.

(3)
~~(2)~~ Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority can document a rationale that a recall would be effective.

~~F. .~~

~~G.~~F. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or biotoxins, the Authority:

(1) Shall follow an existing marine biotoxin contingency/management plan, if appropriate.

(2) Shall collect and analyze samples relevant to the investigation, if appropriate.

(3) Shall keep the area closed until it has been determined that levels of naturally occurring pathogens and/or biotoxins are not a

public health concern.

(4) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.

~~H.~~G. When the growing area is determined the problem, the Authority shall:

(1) Place the growing area in the closed status until:

(a) The Authority verifies that the area is properly classified by conducting a review of the growing area to include:

(i) current data, in compliance with the NSSP Model Ordinance;

(ii) A field review of existing pollution sources;

(iii) A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems. ~~If the review indicates that a previously unknown pollution source exists, the area shall be reclassified.~~ If ~~the~~ a previously unknown pollution source can be corrected, the closure period ~~should~~ shall be extended to allow for natural depuration following correction of the pollution source; and

(iv) Examination of water quality subsequent to the illness outbreak.

(b) It has been determined that the event which caused the contamination no longer exists and sufficient time has elapsed for natural depuration;

(2) Keep the area closed for a minimum of 21 days if the illness is consistent with viral etiology; and

(3) Develop a written report summarizing the findings of the investigation and actions taken.

~~I.~~H. Whenever an Authority or dealer initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA, ISSC and the Authorities in other States involved in the recall. The Authority shall submit periodic recall status reports to the FDA Shellfish Specialist consistent with the Recall Enforcement Policy Title 21 CFR Part 7, Subpart C, Section 7.53 (b) (1- 6) until such time that the Authority deems the recall to be completed. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market, issue public warnings if necessary to protect public health and provide periodic reports to the Authority in the State of product origin regarding recall efforts within their State until such time that the Authority in the State of product origin deems the recall to be completed. FDA will decide whether to audit or issue public warnings after consultation with the Authority/Authorities and after taking into account the scope of the product distribution and other related factors. If the FDA determines that the Authority in any State involved in the recall fails to implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate.

~~J.~~I. Molluscan shellfish product that is recalled as a result of an illness outbreak associated with *V.v.* or *V.p.* may be reconditioned. Validated reconditioning processes include subjecting product to validated post-harvest processing

	(PHP) or placing product into approved, conditionally approved, conditionally restricted, or restricted growing areas for an appropriate period of time, not less than fourteen (14) days, with appropriate controls and documentation to be determined by the Authority.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-208.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-208.

Submitter	ISSC Illness Outbreak Guidance Committee Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Illness Outbreak Response
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management
Text of Proposal/ Requested Action	**@.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)***

A. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area. States will not be expected to close growing areas based on *V.p.* cases that are reported more than sixty (60) days after harvest. ~~and a~~Actions taken by the Authority will be based on the number of cases and the span of time as follows.

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

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

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

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

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

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

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

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

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

all implicated products.

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

(4) When the number of cases and the span of time reach the thresholds outlined above, prior to implementing the controls above, the Authority shall conduct an investigation of the illnesses within seventy-two (72) hours of reaching any one of the thresholds of Chapter II @.02 . 1, 2 or 3 to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling such as time temperature abuse.

(5) When the investigation outlined in Model Ordinance Chapter II. @.02 A.4. demonstrates that the illnesses are related to post-harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:

(a) Notify the ISSC and the FDA Shellfish Specialist of the problem; and

(b) Determine the appropriateness of initiating a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.

(c) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish; Should closures and recalls be necessary the ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

(6) When the investigation outlined in Model Ordinance Chapter II. @.02 A.4. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:

(a) Follow the procedures outlined in Chapter II @.02 A. 1, 2 and 3.

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

(c) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;

(d) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.

(e) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

~~(e)~~(f) The ISSC will notify States and FDA Shellfish

Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

(7) When the State Authority investigating the laboratory confirmed *V.p.* cases does not provide information to identify a single growing area and multiple growing areas are implicated, the State Authorities in the states with implicated growing areas shall evaluate to determine if the illness should be attributed to the implicated area(s). Evaluations may include but are not limited to:

(a) Vibrio levels in the growing area around the time and date of harvest

(b) Comparison of other single source illnesses attributed to a growing area(s) involved in a multiple source outbreak. The purpose of this comparison would be to determine if a common growing area can be identified.

(c) Environmental conditions which could increase the risk of *V.p.* at the time of harvest. This could include conditions such as water temperature, air temperature and tidal stage.

(d) Genetic typing the implicates a common growing area or rules out implicated growing areas

(8) If conditions in (7) identify higher risk for *Vibrio parahaemolyticus* then the Shellfish Authority shall take actions outlined in A, above.

~~(4)~~(9) When a growing area has been closed as a result of *V.p.* cases, the Authority shall keep the area closed for the following periods of time to determine if additional illnesses have occurred:

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

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

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

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

on studies.

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

~~(6)~~(11) Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one (1) or more of the following controls:

(a) PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total *V.p.* for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams;

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

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

Public Health Significance

Following outbreaks in Maryland and Washington, the states requested clarification regarding the requirements of Chapter II. @.01 "Outbreaks from Shellfish Related Illness". In response, the ISSC Executive Board directed the establishment of a committee to provide clarification. The committee was also tasked to develop proposals to revise Chapter II language to provide requirement clarification. The committee was also requested to address appropriate outbreak response to multi-source outbreaks.

Cost Information

Action by 2019 Task Force II

Recommended adoption of Proposal 19-209 as amended.

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

A. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area. States will not be expected to close growing areas based on *V.p.* cases that are reported more than sixty (60) days after harvest.or when environmental parameters have changed or monitoring indicates the *V.p.* risk is reduced. Actions taken by the Authority will be based on the number of cases and the span of time as follows.

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

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

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

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

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

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

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

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

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

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

(4) When the number of cases and the span of time reach the thresholds outlined above, prior to implementing the controls above, the Authority shall conduct an investigation of the illnesses within seventy-two (72) hours of reaching any one of the thresholds of Chapter II @.02 . 1, 2 or 3 to determine whether the illness is growing area related or is the result of post-harvest ~~contamination~~ abuse or mishandling such as time temperature abuse.

(a) If the conditions in Chapter II @.02 (2) or (3) are met and the investigation cannot be completed within 72 hours, immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status.

(b) Should the Authority later determine that the illnesses are related to post harvest abuse or mishandling the implicated harvest area(s) can be immediately reopened.

(5) When the investigation outlined in Model Ordinance Chapter II. @.02 A.4. demonstrates that the illnesses are related to

post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:

(a) Notify the ISSC and the FDA Shellfish Specialist of the problem; and

(b) Determine the appropriateness of initiating a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.

(c) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish; Should closures and recalls be necessary the ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

(6) When the investigation outlined in Model Ordinance Chapter II. @.02 A.4. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:

(a) Follow the procedures outlined in Chapter II @.02 A. 1, 2 and 3.

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

~~(c)~~(b) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;

(c) ~~Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.~~If a recall is required by Chapter II @.02 A. 3

i. Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.

ii. The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

(7) When the State Authority investigating the laboratory confirmed *V.p.* cases does not provide information to identify a single growing area and multiple growing areas are implicated, the State Authorities in the states with implicated growing areas shall evaluate to determine if the illness should be attributed to the implicated area(s). Evaluations may

include but are not limited to:

(a) Vibrio levels in the growing area around the time and date of harvest

(b) Comparison of other single source illnesses attributed to a growing area(s) involved in a multiple source outbreak. The purpose of this comparison would be to determine if a common growing area can be identified.

(c) Environmental conditions which could increase the risk of *V.p.* at the time of harvest. This could include conditions such as water temperature, air temperature and tidal stage.

(d) Genetic typing of clinical isolets ~~the~~ implicates a common growing area or rules out implicated growing areas

(8) If the~~conditions~~ evaluation in (7) provides sufficient information to implicate a single area,~~identify higher risk for *Vibrio parahaemolyticus*~~ then the Shellfish Authority shall take actions outlined in A, above.

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

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

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

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

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

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

(11) Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one (1) or more of the following controls:

(a) PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total *V.p.* for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams;

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

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

Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-209.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-209.

Submitter	ISSC Illness Outbreak Guidance Committee Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Illness Investigation Response for Multi-Source Cases
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management
Text of Proposal/ Requested Action	**@.01 Outbreaks of Shellfish-Related Illness**

A. When shellfish are…
B. When the Authority…
C. When the post-harvest contamination investigation ~~i~~involving multiple sources (either harvesters/processors or growing areas) does not indicate post-harvest contamination problem or illegal harvesting from a closed area the Authorities in the source states shall immediately place the implicated portion(s) of the harvest area(s) in a precautionary closure. A specific growing area placed in a precautionary closed status under this section can be immediately re- opened when one or more of the following conditions are met:
(1) When the investigation, conducted in consultation with epidemiologist(s) in the state(s) in which the outbreak occurs, determines that the shellfish which caused the outbreak did not come from one or more of the implicated growing areas in question based on consumption data provided by victims or other relevant data provided by state investigators. This would include an additional illness(es) that matches one or more of the implicated areas and allows for a more precise identification of the growing area(s) which caused the outbreak.
(2) When an investigation, in accordance with Chapter II @ .01 H, of an implicated growing area identifies an actual or potential pollution source(s) in a specific growing area and no source(s) are identified in other implicated growing areas, the precautionary closures in other implicated growing areas can be reopened. The reopening can only occur in a growing area after the investigation referenced above does not indicate an actual or potential pollution sources that could be the cause of the outbreak.
(3) When the ~~-~~investigation, conducted in consultation with the epidemeiologists in the state(s) in which the illnesses occur and the Authorities in the state from which the shellfish were harvested, provides information that may include but shall not be limited to:
a) Volume or distribution information which would implicate a specific growing area;
b) Illness reporting from immediately adjacent growing areas;
c) Pollution source investigation in conjunction with growing area evaluation does not identify a pollution source.
d) Epidemiological tools that would link cases based on genetic similarity.
D. When precautionary closures are established to address an illness outbreak involving multiple sources, Authorities will not be required to initiate voluntary recalls until the investigations indicate a single source.

Existing C-J renumbered.

Public Health Significance	Following outbreaks in Maryland and Washington, the states requested clarification regarding the requirements of Chapter II. @.01 "Outbreaks from Shellfish Related Illness". In response, the ISSC Executive Board directed the establishment of a committee to provide clarification. The committee was also tasked to develop proposals to revise Chapter II language to provide requirement clarification. The committee was also requested to address appropriate outbreak response to multi-source outbreaks.
Cost Information	
Action by 2019 Task Force II	Recommended adoption of Proposal 19-210 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-210.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-210.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Frequency of *Vibrio vulnificus* Control Plan evaluation.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.06 *Vibrio vulnificus* Control Plan E.(2)(a).
Text of Proposal/ Requested Action	(a) The State Authority will conduct annual~~an~~ evaluations of the plan.
Public Health Significance	Current Model Ordinance language does not specify a frequency for *Vibrio vulnificus* Control Plan evaluation. II.@.06E.(2)(a)(i) requires that the evaluation include "The annual number of *Vibrio vulnificus* cases associated with the State's growing waters and the amount of shellstock sold for half shell consumption to determine risk per servings for each temperature period." However, the Authority could meet that requirement by, for example, conducting an overall evaluation once every 10 years while including information on each of the previous 10 years' cases and risk per servings estimates.
Cost Information	No cost.
Action by 2019 Task Force II	Recommended adoption of Proposal 19-211 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-211.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-211.

Proposal No. 19-212

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Restricted use language *Vibrio vulnificus* Control Plan.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.06 *Vibrio vulnificus* Control Plan E.(1)(b)(i).
Text of Proposal/ Requested Action	(i) Labeling oysters as being ~~F~~for shucking by a certified dealer~~.~~ or for approved post-harvest processing to control the *Vibrio vulnificus* hazard when the Average Monthly Maximum Water Temperature exceeds 70 °F.
Public Health Significance	Using quotes with the language "For shucking by a certified dealers" technically means that exact language must appear. States frequently use language like "For Shucking by a Certified Dealer or Post Harvest Processing" only.
Cost Information	No cost.
Action by 2019 Task Force II	Recommended adoption of Proposal 19-212 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-212.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-212.

Proposal No. 19-213

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Restricted use language *Vibrio parahaemolyticus* Control Plan.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.07 *Vibrio parahaemolyticus* Control Plan B.(4)(c).
Text of Proposal/ Requested Action	(c) Require the original dealer to cool oysters and/or hard clams to an internal temperature of 50 °F (10 °C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *V.p.* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters and/or hard clams has reached 50 °F (10 °C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering. Oysters and/or hard clams without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled as being for shucking by a certified dealer or for approved post-harvest processing to control the *Vibrio parahaemolyticus* hazard~~*only"*, or other means to allow the hazard to be addressed by further processing.~~
Public Health Significance	Using quotes with the language *"for shucking only"* technically means that exact language must appear. States frequently use language like "For shucking by a certified dealer or Post Harvest Processing" only.
Cost Information	No cost.
Action by 2019 Task Force II	Recommended adoption of Proposal 19-213 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-213.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-213.

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Permitting of Federal Waters Harvesting
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellfish Growing Areas @04 b 6 Chapter VIII. Control of Shellfish Harvesting
Text of Proposal/ Requested Action	Section II. Model Ordinance Chapter IV. Shellfish Growing Areas @04 b 6

~~(6) Prior to allowing the landing of shellfish harvested from Federal waters where routine monitoring of toxin levels is not conducted, in addition to following State 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; and~~
~~(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 toxins that are likely to be present harvesting shall not be permitted if any of the pre-harvested samples contain toxin levels in excess of half of the established criteria listed in Chapter IV@.04(1) (e.g., 44 µg/100 g when using a quantitative test or a positive at a limit of detection of 40 µg/100 g for the qualitative screening test for PSP toxins);~~
~~(f) Submittal of onboard screening homogenates and test results to the Authority in the State of landing;~~
~~(g) The collection of a minimum of seven (7) dockside samples by the Authority or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming laboratory; the Authority 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 toxin levels are below the established criteria (e.g., 80 µg/100 g for PSP toxins);~~
~~(i) Disposal of shellfish when dockside test results meet or exceed the established criteria in Chapter IV@.04C.(1) (e.g., 80 µg /100 g for PSP toxins);~~
~~(j) Notification prior to unloading;~~
~~(k) Unloading schedule;~~
~~(l) Access for Dockside Sampling;~~
~~(m) Record Keeping; and~~
~~(n) Early Warning/Alert System.~~

Section II. Model Ordinance
Chapter VIII. Control of Shellfish Harvesting

.01 General…
.02. Shellstock Harvesting and Handling…
.03. Shellstock Harvesting in Federal Waters
A. Prior to harvesting shellfish in Federal waters that have been implicated in an illness outbreak or where toxin producing phytoplankton are known to occur and the toxins are known to accumulate in shellfish and where routine monitoring of toxin levels is not conducted, the harvester shall;

(1) Obtain a harvester license from NOAA that explains the condition for harvest and includes harvest restriction
(2) Be a party to agreements or memorandum of understanding between the Authority, the landing state, NOAA and the shellfish dealers receiving the shellfish.

NOTE: Should this change be adopted, it may be necessary to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.

Public Health Significance

In 2017, the US FDA submitted Proposals 17-116 and 17-119 for the purpose of integrating shellfish harvested from Federal waters into the National Shellfish Sanitation Program (NSSP). The ISSC voting delegates voted to appoint a committee to evaluate aquaculture activities in Federal waters. Since the meeting in 2017, it has become apparent that the implications of Proposals 17-116 and 17-119 are not limited to aquaculture activities. A Federal Waters Subcommittee has met and identified numerous concerns associated with integrating shellfish from Federal waters into the NSSP that were not addressed in Proposals 17-116 and 17-119. The Subcommittee is continuing to discuss necessary NSSP changes for consideration at the 2019 ISSC Biennial Meeting. As Executive Director, I am submitting several proposals that I expect the Federal Waters Committee to modify. These proposals include 19-202, 19-203, 19-214, 19-223, 19-228, and 19-229. The purpose of these proposals is to meet the notification requirements for proposals. These proposals have not been reviewed and approved by the Federal Waters Subcommittee or the Federal Waters Committee. They address topics and possible solutions that have

	been discussed to this point.
Cost Information	
Action by 2019 Task Force II	Recommended adoption of Proposal 19-214 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-214.
Action by FDA	Concurred with Conference action on Proposal 19-214.
February 21, 2020	

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Ingredients Used in Shellstock during Wet Storage
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas .04 C.(1)(f) Chapter X. General Requirements for Dealers .05 B.(2)(k)
Text of Proposal/ Requested Action	Chapter VII. .04 C.(1): C. Wet Storage Source Water (1) General. (a) Except for wells… (b) Any well used… (c) Except when the… (d) Results of water… (e) Disinfection or other... (f) Ingredients intended to alter the taste, texture, or quality of live shellstock shall not be used in wet storage process water unless such ingredients are GRAS or otherwise authorized by the FDA for direct food use in the quantities used and are labeled on the tag in accordance with NSSP MO X. .05 B.(2)(k). (g)~~(f)~~ Disinfected process water… (h)~~(g)~~ When the laboratory… Chapter X. .05 B.(2): .05 Shellstock Identification B. Tags. … (2) The dealer's tag shall contain the following indelible, legible information in the order specified below: (a) The dealer's name… (b) The dealer's certification… (c) The original shellstock… (d) The harvest date… (e) If wet stored… (f) The most precise… (g) The type and… (h) The following statement… (i) All shellstock intended… (j) The statement "Keep … (k) The words "Added Ingredients:" and the common or usual name (not the brand name or trade name) of any ingredient and sub-ingredients unless otherwise exempt. An ingredient may be added to impart or alter the taste, flavor, texture, or quality of live shellstock via wet storage process water or otherwise added to shellstock. Additionally, ingredient labeling shall comply with applicable sections of 21 CFR 101 and the Food Allergen Labeling and Consumer Protection Act.
Public Health Significance	Current Model Ordinance language in Chapter VII addresses disinfection ~~with salt~~ or other water treatment that can leave residues, but it does not address the direct addition of ingredients, such as liquid smoke flavors or flavored salts, to wet storage

	water for the purpose of modifying the taste/quality of live molluscan shellfish. The FDA has received inquiries regarding what ingredients are permitted to be used in live molluscan shellfish and how such ingredients should be labeled. The purpose of this proposal is to address these inquiries to ensure compliance with 21 CFR 101 and 21 CFR 172-189.
Cost Information	Minimal Cost
Action by 2019 Task Force II	Recommended referral of Proposal 19-215 to an appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-215.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-215.

Proposal No. 19-216

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Storage of Toxic Compounds on Harvester Vessels
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting .02 C.(1)
Text of Proposal/ Requested Action	Chapter VIII. .02 C.(1): .02 Shellstock Harvesting and Handling C. Vessels. (1) The operator shall assure that all vessels used to harvest and transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the shellstock. (a) Decks and storage… (b) Bilge pump discharges… (c) Containers used for… (d) Boat decks and… (e) Vessels and all… (f) When necessary… (g) Toxic compounds shall be stored to prevent contamination of shellstock onboard the vessel. Such compounds include, but are not limited to, lubricants, oils, cleaners, paints, anti-freeze, and road salts.
Public Health Significance	Current Model Ordinance language in Chapter VIII .02 C.(1) addresses prevention of contamination due to bilge water, unsafe/unclean storage materials, hot sun, birds, and animals, but it does not address how to prevent contamination of shellstock due to the improper storage and use of toxic compounds frequently stored onboard harvester boats, such as oils, cleaners, paints, anti-freeze, road salts, etc. In many cases, these chemicals are stored in close proximity to shellstock onboard the vessel. There are specific requirements for dealers regarding the "Proper labeling, storage, and use of toxic compounds" (Chapter X. .02 A.(6)) in order to prevent shellstock from becoming contaminated by these chemicals in the dealer facility. On a harvester boat, the potential risk of chemical contamination (e.g., spills or leaks) is even greater, due to the movement of the boat and adverse weather conditions. By requiring toxic compounds onboard a harvester vessel to be stored in a manner that will prevent contamination of shellstock in the event of a leak or spill, this proposal will help reduce the potential risk posed by these chemicals.
Cost Information	Plastic boxes/containers can be purchased at the following costs, based on https://www.usplastic.com/: 6 Quart Plastic Box - $2.08 16 Quart Plastic Box - $5.07 18 Quart Plastic Box - $8.25 30 Quart Plastic Box - $8.53 48 Quart Plastic Box - $12.07 Harvesters would also have the option to store chemicals below deck, to elevate shellstock, or to use other means to safely store chemicals, minus the use of a box,

due to the proposed language “or otherwise stored to prevent contamination of shellstock onboard the vessel”.

Action by 2019 Task Force II	Recommended adoption of Proposal 19-216 as submitted.
Action by 2019 General Assembly	Recommended No Action on Proposal 19-216.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-216.

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Time to Temperature Controls Clarification
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting
Text of Proposal/ Requested Action	**@.02 Shellstock Time to Temperature Controls**

A. Each shellfish producing State shall establish time to temperature requirements for the harvesting of all shellstock to ensure that harvesters shall comply with one (1) of the following:
(1) The State *V.v.* Control Plan as outlined in Chapter II. @.06; or
(2) The State *V.p.* Plan as outlined in Chapter II. @.07; or
(3) All other shellstock shall comply with the matrix below:

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

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

C. The Authority shall establish the water ~~or air~~ temperature required in the vibrio plans outlined in A.(1) and A.(2) above. The authority shall establish the air temperature required in A (3) above. These temperatures shall be established ~~to be applied to the requirements above~~ for each growing area by averaging the previous five (5) years maximum monthly ~~water or air~~ temperatures.

Public Health Significance	The purpose of this proposal is to provide clarification regarding the circumstances in which air temperature and water temperature measurements are used to meet the requirements of Chapter VIII @.02 A.
Cost Information	
Action by 2019 Task Force II	Recommended adoption of Proposal 19-217 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-217.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-217.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Ice used on Harvester Vessels
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting .02 H
Text of Proposal/ Requested Action	.02 Shellstock Harvesting and Handling H. Ice production: (1) Any ice used in the storage or cooling of shellfish during harvest shall: (a) Be made from a potable water source or from a growing area in the approved classification or in the open status of the conditionally approved classification; or (b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. (c) Protected from contamination
Public Health Significance	Harvesters are using ice during harvest to meet the shellstock cooling requirements of State *Vibrio vulnificus* and *Vibrio parahaemolyticus* management plans. The source of ice used during these cooling activities is not referenced in NSSP MO Chapter VIII. NSSP MO Chapter VIII does reference that water used for washing shellfish shall be from a potable water source or from a growing area in the approved status or in the open status of the conditionally approved classification. This proposal just clarifies that water used in the production of ice must meet the same requirements of water (potable) being used to wash shellfish.
Cost Information	NA. Harvesters using ice are already purchasing or making ice. This requirement only ensures that the water used in the production of ice is potable or has come from a facility sanctioned by the Authority or the appropriate regulatory agency.
Action by 2019 Task Force II	Recommended adoption of 19-218 as amended. .02 Shellstock Harvesting and Handling H. Ice production: (1) Any ice used in the storage or cooling of shellfish during harvest shall: (a) Be made from a potable water source or from a growing area in the approved classification or in the open status of the conditionally approved classification; or (b) Come from a facility ~~sanctioned~~ approved by the Authority or the appropriate regulatory agency: and~~.~~ (c) Be ~~P~~protected from contamination
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-218.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-218.

Proposal No. 19-220

Submitter	Susan Ritchie, New York State Department of Environmental Conservation David Carey, Connecticut Department of Agriculture Kristin DeRosia-Banick, Connecticut Department of Agriculture Alissa Dragan, Connecticut Department of Agriculture State Agencies susan.ritchie@dec.ny.gov
Proposal Subject	Shipping Temperatures
Specific NSSP Guide Reference	Section II Model Ordinance Chapter IX. Transportation .04 Shipping Temperatures
Text of Proposal/ Requested Action	.04 Shipping Temperatures Shellfish dealers shall ship shellfish adequately iced; or in a conveyance ~~pre-chilled~~ maintained at or below 45°F (7.2°C) ambient air temperature. Geoduck clams (*Panopea generosa*) are exempt from these requirements.
Public Health Significance	This change from "pre-chilled" to "maintained" will provide consistency between the shellstock shipping requirements of Chapter IX. And the shellstock receiving critical control points in Chapters XI, XIII and XIV. Pre-chilling of conveyances does not provide additional health protection for shellfish consumers and directly conflicts with many States' statutes and regulations regarding idling vehicles (see attachment). Idling also wastes money by burning millions of gallons of fuel each year and risks public health by releasing thousands of tons of pollution into the air (excerpt by American Lung Association of the City of New York). The manufacturers of refrigeration units recommended that the unit be turned off during loading to avoid condensation, and to maintain optimal function of the unit. Conveyances are not designed to lower product temperature; they are designed to maintain the desired temperature of the conveyance. In order for the conveyance to maintain ambient temperatures of 45°F or less, shellstock must be cooled prior to shipping. Warm shellstock placed into a conveyance that is set to 45°F may overwhelm the ability of the conveyance to maintain that temperature and subsequently fail to achieve continuous cooling of product as required under Chapter XIII. @.01 A. (3), for VIII. @.02 A. (3) shellstock that has not been cooled to an internal temperature of 50°F (10°C). Conversely, a conveyance with a properly functioning refrigeration unit maintaining an ambient temperature of 45°F or less should be able to maintain the internal temperatures of shellstock. This proposal should be considered along with the 2019 proposal regarding Transportation Records (Section II Model Ordinance Chapter IX .05).
Cost Information	No cost will be incurred by the industry or State regulatory agencies.
Action by 2019 Task Force II	Recommended referral of Proposal 19-220 to an appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-220.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-220.

Submitter	Susan Ritchie, New York State Department of Environmental Conservation David Carey, Connecticut Department of Agriculture Kristin DeRosia-Banick, Connecticut Department of Agriculture Alissa Dragan, Connecticut Department of Agriculture State Agencies susan.ritchie@dec.ny.gov
Proposal Subject	Transportation Records
Specific NSSP Guide Reference	Section II Model Ordinance Chapter IX. Transportation .05 Transportation Records
Text of Proposal/ Requested Action	05 Transportation Records ~~All shipments of shellstock shall be accompanied with documentation indicating the time of shipment and that that all shipping conveyances comply with the requirements of Chapter IX. This documentation must include a notice of all shellstock harvested under the requirements of Chapter VIII. @02 A. (3) that has not been cooled to an internal temperature of 50°F (10°C) and indicate the presence of a time/temperature recording device.~~ A. All shipments of shellstock shall be accompanied with documentation indicating the following: (1) Date and time of shipment; and (2) The temperature of the shellstock recorded by the shipping dealer at the time of shipment. B. For shipments of shellstock harvested under the requirements of Chapter VIII. @.02 A. (3) that has not been cooled to an internal temperature of 50°F (10°C) prior to shipping and where the shipping time is greater than four (4) hours, the documentation shall also indicate the presence of a time/temperature recording device. C. Geoduck clams (*Panopea generosa*) are exempt from these requirements. If adopted, the receiving critical control points under Chapter XI. and XIII. .01 A. (2) (b) and Chapter XIV. 01 A. (2) would need to be updated to read: (2) A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c), (d) or (e). The product must be accompanied with documentation as outlined in Chapter IX. .05 A. and B. and must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature recording device or comply with Chapter XIII. 01. A. (2) (c), (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter IX. 05. A.
Public Health Significance	There is no public health significance associated with the .05 Transportation Records as originally adopted. The transportation document has been a requirement since the 2015 Model Ordinance was published and has done nothing but create problems for industry and State regulatory agencies. Rather than “a notice of shellstock that has not been cooled to an internal temperature of 50°F,” recording an actual shellstock temperature prior to shipping provides a mechanism for the receiving dealer to readily document and verify that continuous

cooling was achieved for all shipments, not only those that are shipped prior to cooling.

For the VIII. @.02 A. (3) product that has not been cooled prior to shipping, the temperature prior to shipping and the temperature recorded by the receiving dealer upon receipt, provides a verifiable value, that when considered with the TTRD data (for shipments greater than four (4) hours, allows both inspectors and dealers to readily verify the conditions that the shipment has been subject to.

This documentation will also no longer comply with the requirements of Section II Model Ordinance Chapter IX. 04 should the new 2019 proposal regarding shipping temperatures be adopted. See new 2019 Proposal regarding Shipping Temperatures (Section II Model Ordinance Chapter IX. 04).

Cost Information	No cost will be incurred by the industry or State regulatory agencies.
Action by 2019 Task Force II	Recommended adoption of Proposal 19-221 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-221.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-221.

Proposal No. 19-222

Submitter	Susan Ritchie, New York State Department of Environmental Conservation Alissa Dragan, Connecticut Department of Agriculture State Agencies susan.ritchie@dec.ny.gov
Proposal Subject	Shellstock Identification
Specific NSSP Guide Reference	Section II Model Ordinance Chapter X. General Requirements for Dealers .05 Shellstock Identification A. General.
Text of Proposal/ Requested Action	(1) The dealer shall keep the harvester's tag affixed to each container of shellstock until the container is: (a) Shipped with his/her dealer tag affixed to each container of shellstock; or (b) Emptied to wash, grade, or pack the shellstock. (2) When the dealer is also the harvester and he elects not to use a harvest tag, the dealer shall affix his dealer tag to each container of shellstock prior to shipment. (3) The dealer shall not give, receive, or possess any shellfish tag or label that belongs to another dealer, except for the tag required to be affixed to containers of shellstock that meets the requirements in Section .05 B. through E. with the following exceptions: (a) When a written MOU/MOA has been established between the State Shellfish Control Authority and the dealers to allow the possession of another dealer's tag within the State; or (b) When a written MOU/MOA has been established between State Shellfish Control Authorities to allow the possession of a dealer's tag from another State. (4) The dealer shall not give, sell or allow any person who has not been certified as a dealer in accordance with the requirement of Section .04 A. (1) to possess any shellfish dealer tag or label, except for the tag required to be affixed to containers of shellstock that meets the requirements in Section .05B through E.
Public Health Significance	If a shellfish dealer possesses a tag that belongs to another shellfish dealer, it allows opportunity for other dealers or persons to misrepresent the actual harvest location, harvest date, etc. This makes traceback nearly impossible. In the event of a shellfish related illness, the illness is reported to the shellfish authority of the state indicated on the tag along with the harvest information which may incorrectly implicate that state as the origin of the shellfish. In October 2018, a confirmed *Vv*-related death resulted from the consumption of oyster. In this case, the shellfish dealer in one state arranged for shipments of oysters from two other states to be shipped to a fourth state (the receiving state). Following a lengthy investigation, all four states conferred with each other and determined that the retagging of oysters occurred in the receiving state using tags that implicated the shellfish dealer in the state that arranged the shipments of oysters to the receiving state. An investigation by the receiving state shellfish authority revealed that the person who received the oysters and retagged them was not a certified shellfish dealer in any state. The receiving state shellfish authority was also told by the non-certified shellfish dealer that the oysters were stored in a refrigerated truck for two days. The receiving state shellfish authority managed to acquire the original tags from the non-certified shellfish dealer. The authority sent the original tags to the growing area states for further investigation.

To complicate things further, an investigation by one of the growing area states revealed that one of their certified dealers had allowed another one of their certified shellfish dealers to use their tags. The shellfish authority from this state determined that the harvest area indicated on the tag was not a harvest area that the dealer using the other dealer's tags harvests.

Following this investigation, it was then discovered that a previous unconfirmed shellfish related illness, which occurred in May 2018, involved some of the same people and states. The tags for this case had been taken at face value, and no investigation ensued.

The above incidents highlight the possible consequences of one shellfish dealer using tags that belong to another and support the addition of the proposed text.

Cost Information	No cost will be incurred by the industry or State regulatory agencies.
Action by 2019 Task Force II	Recommended referral of Proposal 19-222 to an appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-222.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-222.

Proposal No. 19-223

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Restricted Shellstock
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers .05. E.
Text of Proposal/ Requested Action	B. All restricted ~~use~~ shellstock shall include a tag containing all information required in Section .05 of Model Ordinance Chapter X. In addition, the tag will include specific language detailing the restrictions requiring further processing or testing prior to distribution.~~intended use of the shellstock until processed consistent with the stated purpose~~. NOTE: Should this change be adopted, it may be necessary to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.
Public Health Significance	In 2017, the US FDA submitted Proposals 17-116 and 17-119 for the purpose of integrating shellfish harvested from Federal waters into the National Shellfish Sanitation Program (NSSP). The ISSC voting delegates voted to appoint a committee to evaluate aquaculture activities in Federal waters. Since the meeting in 2017, it has become apparent that the implications of Proposals 17-116 and 17-119 are not limited to aquaculture activities. A Federal Waters Subcommittee has met and identified numerous concerns associated with integrating shellfish from Federal waters into the NSSP that were not addressed in Proposals 17-116 and 17-119. The Subcommittee is continuing to discuss necessary NSSP changes for consideration at the 2019 ISSC Biennial Meeting. As Executive Director, I am submitting several proposals that I expect the Federal Waters Committee to modify. These proposals include 19-202, 19-203, 19-214, 19-223, 19-228, and 19-229 . The purpose of these proposals is to meet the notification requirements for proposals. These proposals have not been reviewed and approved by the Federal Waters Subcommittee or the Federal Waters Committee. They address topics and possible solutions that have been discussed to this point.
Cost Information	
Action by 2019 Task Force II	Recommended adoption of 19-223 as submitted and Recommended that a committee as appointed by the Conference Chair to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-223.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-223.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Restricted use tag language General Requirements for Dealers.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers .05 Shellstock Identification B.7.
Text of Proposal/ Requested Action	(7) If a shellfish producing State selects to implement Chapter II. @.06 E. (1) (b) (i), ~~the~~a statement indicating that the shellstock are "~~F~~for shucking by a certified dealer" or for approved post-harvest processing to control the *Vibrio vulnificus* hazard ~~or an equivalent statement~~ shall be included on the tag. When this statement is included, the shellstock shall ultimately be sold to or processed by a certified shucker-packer or post-harvest processor for the purpose of shucking or post-harvest processing~~only~~.
Public Health Significance	The existing language allows for language equivalent to quoted language. However, States frequently use language such a "For Shucking by a Certified Dealer or Post Harvest Processing" on restricted use tags and such language may not be equivalent to "For shucking by a certified dealer."
Cost Information	No cost.
Action by 2019 Task Force II	Recommended adoption of Proposal 19-224 as amended. (7) If a shellfish producing State selects to implement Chapter II. @.06 E. (1) (b) (i), a statement indicating that the shellstock are for shucking by a certified dealer and/ or for approved post-harvest processing to control the *Vibrio vulnificus* hazard shall be included on the tag. When this statement is included, the shellstock shall ultimately be sold to or processed by a certified shucker-packer or post-harvest processor for the purpose of shucking or post-harvest processing.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-224.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-224.

Proposal No. 19-225

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Add Depuration Processor Certification
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter X. General Requirements for Dealers .04 B
Text of Proposal/ Requested Action	B. Types of Certification. (1) Shucker-packer. Any person who shucks shellfish shall be certified as a shucker-packer. (2) Repacker. (a) Any person who repacks shucked shellfish shall be certified as a shucker-packer or repacker; (b) Any person who repacks shellstock shall be certified as a shellstock shipper, shucker- packer, or repacker; (c) A repacker shall not shuck shellfish. (3) Shellstock Shipper. Any person who ships and receives shellstock in interstate commerce shall be certified as a shellstock shipper, repacker, or shucker-packer. (4) Reshipper. Any person who purchases shellstock or shucked shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers or retailers shall be certified as a reshipper. ~~(4)~~(5) Depuration Processor. Any person who harvests or receives shellstock from growing areas in the approved or conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process.
Public Health Significance	Depuration is a recognized type of certification that is currently not included in this section.
Cost Information	
Action by 2019 Task Force II	Recommended adoption of Proposal 19-225 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-225.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-225.

Proposal No. 19-226

Submitter	Jon C Strauss Colorado Dept. of Public Health and Environment jon.strauss@comcast.net
Proposal Subject	Deletion of requirement for a suitable holder for toilet paper roll.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing Chapter XII. Repacking of Shucked Shellfish Chapter XIII. Shellstock Shipping Chapter XIV. Reshipping Chapter XV. Depuration
Text of Proposal/ Requested Action	Chapter XI @.02 D

(6) The dealer shall provide:
(a) Toilet room doors that are tight fitting, self-closing, and do not open directly into a processing area; **[K]**
(b) An adequate number of conveniently located, toilets; and **[K]**
(c) Each toilet facility with an adequate supply of toilet paper **[K]** ~~in a suitable holder~~. ~~**[S$^{K/O}$]**~~

Chapter XII @.02 D

(3) The dealer shall provide:
(a) Toilet room doors that are tight fitting, self-closing, and do not open directly into a processing area; **[K]**
(b) An adequate number of conveniently located, toilets; and **[K]**
(c) Each toilet facility with an adequate supply of toilet paper **[K]** ~~in a suitable holder~~. ~~**[S$^{K/O}$]**~~

Chapter XIII @.02 D

(3) The dealer shall provide:
(a) Toilet room doors that are tight fitting, self-closing, and do not open directly into a processing area; **[K]**
(b) An adequate number of conveniently located, toilets; and **[K]**
(c) Each toilet facility with an adequate supply of toilet paper **[K]** ~~in a suitable holder~~.~~**[S$^{K/O}$]**~~

Chapter XIV @.02 D

(3) The dealer shall provide:
(a) Toilet room doors that are tight fitting, self-closing, and do not open directly into a processing area; **[K]**
(b) An adequate number of conveniently located, toilets; and **[K]**
(c) Each toilet facility with an adequate supply of toilet paper **[K]** ~~in a suitable holder~~.~~**[S$^{K/O}$]**~~

Chapter XV @.02 D

(5) The dealer shall provide:
(a) Toilet room doors that are tight fitting, self-closing, and do

not open directly into a processing area; **[K]**
(b) An adequate number of conveniently located, toilets; and **[K]**
(c) Each toilet facility with an adequate supply of toilet paper **[K]** ~~in a suitable holder~~. ~~**[S[K/O]]**~~

Public Health Significance	The Food Code and the Grade "A" Pasteurized Milk Ordinance (PMO) do not require toilet paper to be on an appropriate holder. Many inland state inspectors who work in multiple programs have noted this disparity. The authors of this proposal do not seek to limit or eliminate toilet paper holders/dispensers, nor do they advocate for facilities to forgo use of existing toilet paper holders/dispensers. The developers of the proposal only seek to eliminate citing deficiencies when one or more unwrapped toilet paper rolls are found set upon the top of the toilet paper holder or on top of the toilet, in a stall or restroom that has a suitable holder/dispenser. Accordingly, it would be a deficiency if the stall/bathroom lacked toilet paper or if the toilet paper roll(s) were stored on the floor. Based upon how this situation is treated in other food safety programs, the developers of this proposal believe it is in the best interest of the ISSC to adopt this proposal and improve uniformity between food safety programs nation-wide.
Cost Information	No cost.
Action by 2019 Task Force II	Recommended adoption of Proposal 19-226 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-226.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-226.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Proper Use of Devices to Prevent Backflow and Back Siphonage
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing Chapter XII. Repacking of Shucked Shellfish Chapter XIII. Shellstock Shipping Chapter XIV. Reshipping Chapter XV. Depuration Section IV: Guidance Documents Chapter III. Harvesting, Handling, Processing and Distribution
Text of Proposal/ Requested Action	**Chapter XI .02 Sanitation** B. Safety of Water for Processing and Ice Production. (1) Water Supply… (2) Ice Production… (3) Shellstock Washing… (4) Plumbing and Related Facilities. (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to: (i) Prevent contamination of water supplies; **[S$^{C/K}$]** (ii) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. **[S$^{C/K}$]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage, in accordance with the manufacturer's specifications. Backflow and back siphonage devices not rated for pressure shall not be subjected to continuous pressure. **[K]** **Chapter XII .02 Sanitation** A. Safety of Water for Processing and Ice Production. (1) Water Supply… (2) Ice Production… (3) Plumbing and Related Facilities. (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to: (i) Prevent contamination of water supplies and [S$^{C/K}$] (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. [S$^{C/K}$] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage, in accordance with the manufacturer's specifications. Backflow and back siphonage devices not rated for pressure shall not be subjected to continuous pressure. **[K]** **Chapter XIII .02 Sanitation**

A. Safety of Water for Processing and Ice Production.
(1) Water Supply…
(2) Ice Production…
(3) Shellstock Washing…
(4) Plumbing and Related Facilities. The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
(a) Prevent contamination of water supplies; [$S^{C/K}$]
(b) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source [$S^{C/K}$] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage, in accordance with the manufacturer's specifications. Backflow and back siphonage devices not rated for pressure shall not be subjected to continuous pressure. **[K]**

Chapter XIV .02 Sanitation

A. Safety of Water for Processing and Ice Production.
(1) Water Supply…
(2) Ice Production…
(3) Plumbing and Related Facilities. The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
(a) Prevent contamination of water supplies; **[$S^{C/K}$]**
(b) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[$S^{C/K}$]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage, in accordance with the manufacturer's specifications. Backflow and back siphonage devices not rated for pressure shall not be subjected to continuous pressure. **[K]**

Chapter XV .02 Sanitation

A. Safety of Water for Processing and Ice Production
(1) Water Supply…
(2) Ice Production…
(3) Shellstock Washing…
(4) Depuration Process Water…
(5) Plumbing and Related Facilities.
(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
(i) Prevent contamination of water supplies; **[$S^{C/K}$]** and
(ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[$S^{C/K}$]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage, in accordance with the manufacturer's specifications. Backflow and back siphonage devices not rated for pressure shall not be subjected to continuous pressure. **[K]**
(b) Depuration Plant Design and Construction. The dealer shall

ensure that:
(i) Depuration tanks, processing containers, and piping are fabricated from non-toxic corrosion-resistant materials and are easily cleanable; **[K]**
(ii) Depuration tank design, hydraulics, and typical container configuration are such that process water is evenly circulated throughout all the shellfish containers within a given tank; and **[K]**
(iii) Shellfish containers allow process water to flow freely and uniformly to all shellfish within each container. **[K]**

(6) No change.

Section IV Guidance Documents – Chapter III

VIII. Backflow Prevention

Preventing contamination of potable water supplies through proper backflow prevention is a responsibility of every shellfish dealer. Different varieties of backflow and back siphonage devices are designed for specific conditions, thus dealers should work with their plumber to select the proper device for the proper application. Simple hose bib vacuum breakers are designed to protect against back siphon only. As such, they are to be used downstream of all shut-off valves. Their manufacturer's design criteria specify they must not be subjected to continuous pressure, for example, a shut-off valve or shut-off sprayer nozzle being installed downstream from the hose bib vacuum breaker. Observation of water being randomly expelled from vents in the simple hose bib vacuum breaker provides evidence that the device is being subjected to continuous pressure and dealers should be aware the simple devices are prone to failure. The internal mechanism is not robust and will fail under continuous pressure, leading to a loss of back siphonage protection. Hose bib vacuum breakers are inexpensive and ideal for applications where a simple hose is attached to them, without a shut-off sprayer nozzle attached to the end of the hose. In contrast, dual check valve (with or without intermediate atmospheric vent) backflow preventers are specifically designed for service in continuous pressure systems. As such, they are ideal when located upstream from shut-off sprayer nozzles. Dual check valve backflow preventers are designed to protect against back siphon and pressurized backflow. Shellfish dealers have access to different, free resources for plumbing design questions. A simple query made to the manufacturer of the backflow device in question should provide the dealer with critical information, describing the proper installation, application, and maintenance of the device.

Public Health Significance

Backflow and back siphonage are easily prevented public health threats that can lead to contamination of the plant water supply. Devices used to prevent backflow and back siphonage have specific application criteria that must be adhered to, for proper operation of the devices. For example, the simple hose bib vacuum breaker is designed to prevent back siphon only and is not designed for continuous pressure, per the manufacture and the International Association of Plumbing and Mechanical Officials, American National Standard, 2018 Uniform Plumbing Code.

Cost Information	Hose bib vacuum breakers may continue to be used, provided they are not subjected to continuous pressure. For example, a simple hose attached to a hose bib, which is in turn connected to a faucet is acceptable. Cost is approximately $6. If, however, a shut-off spray nozzle is added, the hose bib should be removed and a device capable of protecting against backflow and back siphonage under pressure should be installed upstream of the faucet valve. Cost per replacement device varies. For example, a ¾" Watts® LF7R lead free dual check valve, capable of protecting against backflow and back siphonage under continuous pressure in potable water systems, whether mounted vertically or horizontally, will cost approximately $40. Addition of an atmospheric vent to the dual check valve assembly will increase the cost.
Action by 2019 Task Force II	Recommended referral of Proposal 19-227 to the appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-227.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-227.

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Harvest of Restricted Shellstock In Federal Waters
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing .01 A
Text of Proposal/ Requested Action	A. Receiving Critical Control Point - Critical Limits. (1) The dealer shall shuck and pack only shellstock obtained from a licensed harvester who has: (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and **[C]** ~~(a)~~(b) Harvested restricted shellstock from Federal waters and properly tagged with information describing the restriction. ~~(b)~~(c) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and **[C]** ~~(c)~~(d) 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].** NOTE: Should this change be adopted, it may be necessary to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.
Public Health Significance	In 2017, the US FDA submitted Proposals 17-116 and 17-119 for the purpose of integrating shellfish harvested from Federal waters into the National Shellfish Sanitation Program (NSSP). The ISSC voting delegates voted to appoint a committee to evaluate aquaculture activities in Federal waters. Since the meeting in 2017, it has become apparent that the implications of Proposals 17-116 and 17-119 are not limited to aquaculture activities. A Federal Waters Subcommittee has met and identified numerous concerns associated with integrating shellfish from Federal waters into the NSSP that were not addressed in Proposals 17-116 and 17-119. The Subcommittee is continuing to discuss necessary NSSP changes for consideration at the 2019 ISSC Biennial Meeting. As Executive Director, I am submitting several proposals that I expect the Federal Waters Committee to modify. These proposals include 19-202, 19-203, 19-214, 19-223, 19-228, and 19-229,. The purpose of these proposals is to meet the notification requirements for proposals. These proposals have not been reviewed and approved by the Federal Waters Subcommittee or the Federal Waters Committee. They address topics and possible solutions that have been discussed to this point.
Cost Information	
Action by 2019 Task Force II	Recommended adoption of Proposal 19-228 as amended. A. Receiving Critical Control Point - Critical Limits. (1) The dealer shall shuck and pack only shellstock obtained from a licensed harvester who has: (a) Harvested the shellstock from an Approved or

Conditionally Approved area in the open status as indicated by the tag; and **[C]**
(b) Harvested restricted shellstock from Federal waters and properly tagged with information describing the restriction**[C]**.
(c) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and **[C]**
(d) 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].**

Action by 2019 General Assembly — Adopted recommendation of Task Force II on Proposal 19-228.

Action by FDA February 21, 2020 — Concurred with Conference action on Proposal 19-228.

Proposal No. 19-229

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Restricted Shellstock From Federal Waters
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing .03 I. Section II. Model Ordinance Chapter XIII. Shellstock Shipping .02 I.
Text of Proposal/ Requested Action	Section II. Model Ordinance Chapter XI. Shucking and Packing .03 I. I. Restricted Shellstock from Federal Waters. The dealer shall: 1. Obtain permission from the Authority to receive restricted shellstock prior to receipt. 2. Develop agreements or memorandum of understanding between the Authority, National Oceanic Atmospheric Administration (NOAA) and the individual harvesters as necessary to comply with the biotoxin controls outlined in Chapter IV. Section II. Model Ordinance Chapter XIII. Shellstock Shipping .03 I. I. Restricted Shellstock from Federal Waters. The dealer shall: 1. Obtain permission from the Authority to receive restricted shellstock prior to receipt. 2. Develop agreements or memorandum of understanding between the Authority, National Oceanic Atmospheric Administration (NOAA) and the individual harvesters as necessary to comply with the biotoxin controls outlined in Chapter IV. NOTE: Should this change be adopted, it may be necessary to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.
Public Health Significance	In 2017, the US FDA submitted Proposals 17-116 and 17-119 for the purpose of integrating shellfish harvested from Federal waters into the National Shellfish Sanitation Program (NSSP). The ISSC voting delegates voted to appoint a committee to evaluate aquaculture activities in Federal waters. Since the meeting in 2017, it has become apparent that the implications of Proposals 17-116 and 17-119 are not limited to aquaculture activities. A Federal Waters Subcommittee has met and identified numerous concerns associated with integrating shellfish from Federal waters into the NSSP that were not addressed in Proposals 17-116 and 17-119. The Subcommittee is continuing to discuss necessary NSSP changes for consideration at the 2019 ISSC Biennial Meeting. As Executive Director, I am submitting several proposals that I expect the Federal Waters Committee to modify. These proposals include 19-202, 19-203, 19-214, 19-223, 19-228, and 19-229,. The purpose of these proposals is to meet the notification requirements for proposals. These proposals have not been reviewed and approved by the Federal Waters Subcommittee or the Federal Waters Committee.

They address topics and possible solutions that have been discussed to this point.

Cost Information

Action by 2019 Task Force II

Recommended adoption of 19-229 as amended.

Section II. Model Ordinance Chapter X~~I. Shucking and Packing .03 I.~~General Requirements for Dealers .09

~~I.~~ Restricted Shellstock from Federal Waters.

The dealer shall:

1. Obtain permission from the Authority to receive restricted shellstock prior to receipt.
2. Develop agreements or memorandum of understanding between the Authority, National Oceanic Atmospheric Administration (NOAA) and the individual harvesters as necessary to comply with the biotoxin controls outlined in Chapter IV.

~~Section II. Model Ordinance Chapter XIII. Shellstock Shipping .03 I.~~
~~I. Restricted Shellstock from Federal Waters.~~
~~The dealer shall:~~
~~1. Obtain permission from the Authority to receive restricted shellstock prior to receipt.~~
~~2. Develop agreements or memorandum of understanding between the Authority, National Oceanic Atmospheric Administration (NOAA) and the individual harvesters as necessary to comply with the biotoxin controls outlined in Chapter IV.~~

And refer to the appropriate committee as determined by the Conference Chair with instruction to make modifications to Section II. Guidance Documents Chapter II. Growing Areas .06 Protocol for the Landing of Shellfish from Federal Waters.

Action by 2019 General Assembly

Adopted recommendation of Task Force II on Proposal 19-229.

Action by FDA February 21, 2020

Concurred with Conference action on Proposal 19-229.

Proposal No. 19-230

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Shellstock Shipping facility requirements.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIII. Shellstock Shipping *Exceptions.*
Text of Proposal/ Requested Action	~~*Exceptions. Shellstock Shippers are not required to pack shellstock in a building that complies with Sections .02 and .03 of this chapter when the Authority has determined that a shellstock shipper's practices and conditions do not warrant requiring shellstock to be packed in a building.*~~ *Exceptions. Shellstock Shippers are not required to comply with the building requirements in Sections .02 and .03 of this chapter when the Authority has determined that a Shellstock Shipper's practices and conditions do not warrant requiring a building.*
Public Health Significance	This is suggested to make it clear that, depending on practices, Shellstock Shipping may not require a building complying with Section .02 and .03 requirements. Some dealer operations consist of receiving shellstock from harvesters in harvest containers then selling them immediately without handling them in any way other than unloading harvest containers from vessels and loading them onto trucks or possibly into standby coolers if necessary. They must be certified to purchase shellstock from harvesters but there is no reason to require that they have facilities required for Shellstock Shippers who wash, cull, and repack the shellstock. Allowance for dealers without buildings meeting Section .02 and .03 requirements is effectively indicated by XIII.03F, which references provisions for "A dealer whose activity consists of trucks or docking facilities only."
Cost Information	No cost.
Action by 2019 Task Force II	Recommended adoption of Proposal 19-230 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-230.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-230.

Proposal No. 19-231

Submitter	Blake Millett / Jon Strauss Utah Department of Agriculture and Food / Colorado Department of Public Health & Envm bmillett@utah.gov / jon.strauss@state.co.us
Proposal Subject	Addition of shipping CCP
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIII. Shellstock Shipping Chapter XIV. Reshipping
Text of Proposal/ Requested Action	**Chapter XIII Shellstock Shipping** **.01 Critical Control Points** D. Shellstock Shipping Critical Control Point- The dealer shall ensure that (1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock. The transaction record shall indicate the quantity of restricted use shellstock containers.**[C]** (2) All shellstock is cooled to meet the requirements outlined in .01 B. (3) and (4) above prior to shipment. The original dealer may elect to ship restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) prior to achieving the internal temperature of 50 °F (10 °C). Should the original dealer choose this option the shipment shall be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. **[C]** (3) All shellstock shipments to other certified dealers shall be accompanied by documentation in accordance with Chapter IX. .05 [C] **Chapter XIV Reshipping** **.01 Critical Control Points** E. Shellstock Shipping Critical Control Point. The dealer shall ensure that: (1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock. The transaction record shall indicate the quantity of restricted use shellstock containers. **[C]** (2) All shellstock received from a dealer which elected to ship restricted use shellstock or shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) prior to achieving the internal temperature of 50 °F (10 °C) must be cooled to an internal temperature of 50 °F (10 °C) prior to shipment. The dealer may elect to ship restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. (3) prior to achieving the internal temperature of 50 °F (10 °C). Should the dealer choose this option the shipment shall be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. **[C]** (4) All shellstock shipments to other certified dealers shall be accompanied by documentation in accordance with Chapter IX. .05[C]

Public Health Significance

When a dealer receives shellstock from another dealer, without the required time and pre-chill temperature documentation, then under Chapter XI.01.A.(2)(b), Chapter XIII.01.B, Chapter XIV.01.A.(1).(b), or Chapter XV.01.A.(2).(b), the receiving firm receives a Critical violation if that product is still present at the receiving firm during the Authority's inspection. Currently, the dealer who ships product without the required time and pre-chill temperature only receives a Key violation under Chapter IX. .04 and .05. Recall the issue that led to modifications of Chapter IX was the discovery of one or more original shippers loading shellstock into hot trailers. It is unclear how penalizing all receiving dealers, (who until the scandal broke, were unknowingly receiving product that was initially temperature abused), was a logical solution to halting a problem caused by a few original shippers. This proposal would create an equal penalty for a dealer who fails to add the required time and pre-chill temperature information to the transportation documents.

There have been recurrent, unintended consequences from Chapter IX. Receiving dealers are failing recertifications for receiving shipments that do not contain the time and pre-chill temperature on the shipping documents, if that particular shipment of shellstock is present in the facility during inspection. While it is the receiving dealer's responsibility to reject these noncompliant shipments, responsibility should fall equally on the dealer who sends out noncompliant shipments. By creating a requirement for a shipping CCP, dealers who ship product without the time and pre-chill temperature as required will receive the same Critical violation that the receiving dealer gets on their inspection.

The public health significance of this proposal is that by fairly and equally sharing the responsibility for those shipping and those receiving product, we are placing a stronger emphasis on the importance of keeping product safe during transportation from one dealer to another.

The way that the MO is currently written, with the receiving firm getting cited for a Critical deficiency and the shipping firm getting a Key, we are essentially sanctioning the passing of risk to the receiving firm. As further evidence of passing risk to the end user, FDA has gone on record to state that if the Authority's inspection discovers a receiving dealer lacks proper documentation required by Chapter IX but the live shellfish shipment in question has been shipped out to another dealer and is thus not present in the receiving dealer's facility, the Critical deficiency becomes a Key.

Proponents of the original change to Chapter IX insist the receiving firm should take responsibility and reject the product. In this way, the shipping firms would have to comply or risk shipments being rejected. History has shown that is not the case. The original change to Chapter IX, adding special shipping document requirements for shellstock to all receiving dealer CCPs, was put into place in 2011. Eight years later,

	we are still having national issues with some certified shippers not including this required documentation. This proposal will fix these issues.
Cost Information	No cost.
Action by 2019 Task Force II	Recommended referral of Proposal 19-231 to the appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-231.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-231.

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Public Health Explanation of Depuration
Specific NSSP Guide Reference	Section III Public Health Reasons and Explanations Chapter XV. Depuration
Text of Proposal/ Requested Action	**@.01 Administration** Depuration is intended to reduce the number of pathogenic organisms that may be present in shellfish harvested from moderately polluted (restricted) waters to such levels that the shellfish will be acceptable for human consumption without further processing. The process is not intended for shellfish from heavily polluted (prohibited) waters ~~nor to reduce the levels of poisonous or deleterious substances that the shellfish may have accumulated from their environment~~. The acceptability of the depuration process is contingent upon the Authority exercising very stringent supervision over all phases of the process.
Public Health Significance	This statement is not accurate.
Cost Information	
Action by 2019 Task Force II	Recommended no action on Proposal 19-232. Rationale: Submitter requests no action.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-232.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-232.

Proposal No. 19-235

Submitter	Tom Dameron Surfside Foods capttomd@gmail.com
Proposal Subject	Shellstock Receiving and Shipping
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program for the Authority @.01 E
Text of Proposal/ Requested Action	~~E.~~F. Administrative Procedures. The Authority shall have administrative procedures sufficient to: (1) Regulate shellfish harvesting, sale, and shipment; ~~(2) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the State from which the shellstock are harvested or landed, unless the Authority has a memorandum of understanding with the Authority in another State to allow dealers from its State to purchase the shellstock;~~ ~~(3)~~(2) Detain, condemn, seize, and embargo shellfish; and ~~(4)~~(3) Assure compliance with Shellfish Plant Inspection Standardization.
Public Health Significance	There is no public health significance associated with this requirement. Dealer receiving critical control points address the source of the shellfish. There is no public health reason for prohibiting a company which has a harvester license and is certified as a dealer from landing in one state and trucking shellfish to their dealer location in another state.
Cost Information	
Action by 2019 Task Force II	Recommended referral of Proposal 19-235 to an appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-235.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-235.

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Aquaculture Operational Plan for Birds and/or Mammals
Specific NSSP Guide Reference	Section II . Model Ordinance Chapter VI. Shellfish Aquaculture .04
Text of Proposal/ Requested Action	**.04 Aquaculture That Attracts Birds or Mammals** A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include: (1) A description of the design and activities of the culture facility; (2) The specific site and boundaries in which shellfish aquaculture activities will be conducted; (3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters; (4) The species of shellfish to be cultured and harvested; (5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities; and (6) An evaluation of the potential pollution impact of the birds and/or mammals. (~~6~~7) Maintenance of the required records.
Public Health Significance	As currently written section .04 does not require a pollution assessment.
Cost Information	
Action by 2019 Task Force II	Recommended adoption of proposal 19-236 as amended. **.04 Aquaculture That Attracts Birds or Mammals** A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include: (1) A description of the design and activities of the culture facility; (2) The specific site and boundaries in which shellfish aquaculture activities will be conducted; (3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters; (4) The species of shellfish to be cultured and harvested; (5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities; and (6) ~~An evaluation~~ A description of the mitigation or deterrent measures to minimize the potential pollution impact of ~~the~~ birds and/or mammals.

(7) Maintenance of the required records.

Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-236.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-236.

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Dealer Receiving Critical Control Points
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing .01 A. (2) Chapter XIII. Shellstock Shipping .01 A (2). Chapter XIV. Reshipping .01 A (1)
Text of Proposal/ Requested Action	**Chapter XI. Shucking and Packing** **.01 Critical Control Points**

B. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall…

(2) The dealer shall shuck and pack only shellstock obtained and transported from a dealer who has:

(a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05 or transaction record with each bulk shipment as outlined in Chapter VIII. .02 F. (8); and **[C]**

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

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

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

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

Chapter XIII. Shellstock Shipping

.01 Critical Control Points

B. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall…

(2) The dealer shall ship or repack only shellstock obtained and transported from a dealer who has:

(a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05; and **[C]**

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

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

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

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

Chapter XIV. Reshipping

.01 Critical Control Points

B. Receiving Critical Control Point - Critical Limits.

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

(a) Identified the shellstock with a tag as outlined in Chapter

X. .05, identified the in-shell product with a tag as outlined in Chapter X. .07, and/or identified the shucked shellfish with a label as outlined in Chapter X. .06; and **[C]**
(b) Provided documentation as required in Chapter IX. .05; and **[C]**
(c) Adequately iced the shellstock; or **[C]**
(d) Shipped the shellstock in a conveyance ~~maintained~~ at or below 45 °F (7.2 °C) ambient air temperature; ~~or~~ and **[C]**
(e) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less; **[C]** or
(f) Shipped the shucked shellfish and/or in-shell product adequately iced or in a conveyance at or below 45 ºF (7.2 ºC) ambient air temperature. **[C]**

Public Health Significance	A record to document that the temperature has been maintained would require a time/temperature recording device in all shellstock. The requirement in (2) (e) was never intended to be an option at receiving. This is a shellstock storage critical control point at
Cost Information	
Action by 2019 Task Force II	Recommended adoption of Proposal 19-237 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-237.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-237.

Submitter	ISSC Executive Office issc@issc.org
Proposal Subject	Definition of Processed Shellfish
Specific NSSP Guide Reference	Section I Definitions
Text of Proposal/ Requested Action	The National Shellfish Sanitation Program (NSSP) is the Federal/State cooperative program recognized by the U. S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption. The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and whole or roe-on scallops) moving in interstate commerce through Federal/State cooperation and uniformity of State shellfish programs. Only shellfish harvested under the NSSP is allowed for market access, whether consumed raw or transformed by further processing post-harvest (e.g. breading, canning, cooking, marinating, smoking, etc.). Shellfish subjected to further processing by which the organoleptic characteristics have been altered are beyond the scope of the NSSP controls for safe handling of raw shellfish and subject to the Seafood HACCP regulations (21CFR123). Historically the recognized purpose of the NSSP was to address shellfish as defined in Definition (112) as follows: (112) Shellfish means all species of: (a) Oysters, clams or mussels, whether: (i) Shucked or in the shell; (ii) Raw, including post-harvest processed; (iii) Frozen or unfrozen; (iv) Whole or in part; and (b) Scallops in any form, except when the final product form is the adductor muscle only. There are other definitions included in the Guide for the Control of Molluscan Shellfish that suggest that the NSSP includes certain types of processed shellfish. Below are two examples: (91) Processing means any activity associated with the handling, shucking, freezing, packing, labeling or storing of shellfish in preparation for distribution. This would include the activities of a shellstock shipper, shucker packer, repacker, reshipper, or depuration processor. (from NSSP Guide Section IV, Chapter III .01 Shellfish Industry Equipment Construction Guide) 27. Molluscan Shellfish - All edible species of oysters, clams, mussels and whole scallops or roe-on scallops (scallops are excluded when the final product is the shucked adductor muscle only). Shellfish products which may contain any material other than the meats and /or shell liquor of oysters, clams, mussels or scallops will be regarded as a ”processed food” and will not be included in the Cooperative Program. The FDA will be recommending language for inclusion in Section I. Purpose of the NSSP Guide to clearly define the shellfish product forms to which the NSSP should apply.
Public Health Significance	The purpose of this proposal is to provide consistent language throughout the NSS Guide and clarity on the types of shellfish products that the NSSP Guide is intended to cover, while giving consideration to the advances in shellfish processing that have occurred over time.
Cost Information	None
Action by 2019	Recommended adoption of Proposal 19-238 as substituted.

Task Force

NSSP Guide
Section I. Purpose and Definitions

FIRST CHANGE:
Purpose (page 2)
First paragraph
The National Shellfish Sanitation Program (NSSP) is the Federal/State cooperative program recognized by the U. S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of bivalve molluscan shellfish (hereinafter referred to as shellfish) produced and sold for human consumption. The purpose of the NSSP…

Fourth paragraph
The NSSP Guide for the Control of Molluscan Shellfish consists of a Model Ordinance, supporting guidance documents, recommended forms, and other related materials associated with the Program. The Model Ordinance includes guidelines to ensure that the shellfish produced in States in compliance with the guidelines are safe and sanitary. The Model Ordinance provides readily adoptable standards and administrative practices necessary for the sanitary control of molluscan shellfish. The Model Ordinance is intended to cover molluscan shellfish that are raw (live, fresh or fresh frozen) and molluscan shellfish subjected to post-harvest processing (PHP) as defined in this Guide. Cooked shellfish, shellfish subject to 21 CFR part 113 or 114, or raw shellfish packaged with the explicit intent that they will be cooked by the end consumer (such as breaded or marinated) are generally recognized as products that are beyond the scope of the NSSP and are subject to the Seafood HACCP regulations (21 CFR 123). However, such shellfish products intended for interstate commerce are still subject to the appropriate harvest and/or approved source controls outlined in this Guide when they are necessary to control a food safety hazard."

SECOND CHANGE:
(95) Raw means shellfish that have not been heated ~~thermally processed: (a)~~ to an internal temperature of 145 °Fahrenheit or greater for 15 seconds (or equivalent~~); or (b) altering the organoleptic characteristics~~.

THIRD CHANGE:
Section IV, Chapter III .01 Shellfish Industry Equipment Construction Guide
~~27. Molluscan Shellfish – All edible species of oysters, clams, mussels and whole scallops or roe-on scallops (scallops are excluded when the final product is the shucked adductor muscle only). Shellfish products which may contain any material other than the meats and/or shell liquor of oysters, clams, mussels or scallops will be regarded as a "processed food" and will not be included in the Cooperative Program.~~

Action by 2019 General Assembly: Adopted recommendation of Task Force II on Proposal 19-238.

Action by FDA February 21, 2020: Concurred with Conference action on Proposal 19-238.

Proposal No. 19-239

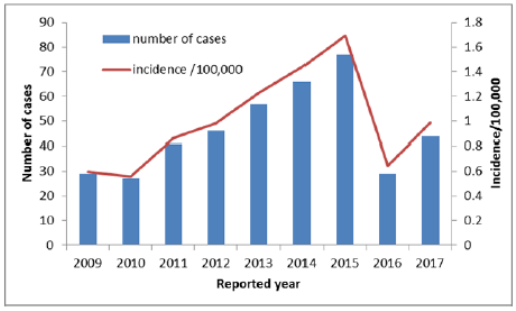
Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Updating epidemiological investigation reference.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.01 Outbreaks of Shellfish-Related Illness A NOTE.
Text of Proposal/ Requested Action	NOTE: For additional guidance refer to the International Association for Food Protection ~~of Milk, Food, and Environmental Sanitarians'~~ *Procedures to Investigate Food Borne Illness*.
Public Health Significance	The name of the organization producing the referenced publication has changed.
Cost Information	No cost.
Action by 2019 Task Force II	Recommended adoption of Proposal 19-239 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-239.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-239.

Proposal No. 19-240

Submitter	Bill Dewey Taylor Shellfish Farms billd@taylorshellfish.com
Proposal Subject	Alternative for allowing harvest for raw consumption from a growing area closed due to *V.p.*
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*), Section A. (6)
Text of Proposal/ Requested Action	(6) Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one (1) or more of the following controls: (a) PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total *V.p.* for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams; (b) Implementing a process that has been validated to achieve <100 mpn/gram total *V.p.*; ~~(b)~~(c) Restricting oyster and/or hard clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing; ~~(c)~~(d) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.
Public Health Significance	The Center for Disease control estimates 45,000 people get ill each year in the United States from *V.p.*. In an effort to reduce *V.p.* illnesses SSCAs have developed and implemented vibrio control plans and industry has diligently implemented strict temperature controls and harvest practices. Despite these efforts *V.p.* illnesses persist. There are several possible explanations for this. It could be the result of more oysters being produced for raw consumption and therefore greater exposure or because the adopted controls are ineffective or because of improper handling during retail distribution and sale at facilities beyond the authority of ISSC to control or because of increased reporting of illnesses because of improved awareness or changes in reporting procedures. Regardless of the reason, the fact is consumers continue to get ill from eating raw shellfish contaminated with *V.p.* bacteria and it is incumbent on the ISSC to consider all options for reducing *V,p.* illnesses. With this proposal we hope to enlighten ISSC participants to the apparent efficacy of utilizing a < 100 MPN/gram tlh standard to reduce V.p. illnesses and establish the standard as an option for states to use. While based in Washington State, Taylor Shellfish Farms has farms, a processing facility and oyster bar in British Columbia. Because of this we are familiar with Canadian *V.p.* regulations. Following a *V.p.* outbreak in 2015 Canada implemented a requirement for processors to reduce total V.p. (tlh) levels below 100 MPN/gram prior to sale or distribution. This new regulation appears to have been effective at reducing

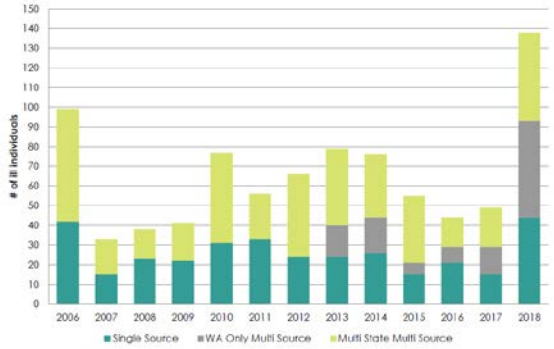
V.p. illnesses while adjacent Washington State continues to see significant *V.p.* illnesses despite a vibrio control plan updated in 2015 with stringent harvest controls and time to documented temperature reduction.

Number of cases and Incidence/100,000 of *V. parahaemoliticus* in BC, by reported year, 2009-2017



Total Vp Illnesses from Oyster Consumption

(Attributed to commercially harvested oysters & WA growing areas by year)



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On Taylor Shellfish farms in British Columbia (d.b.a. Fanny Bay Oyster) we can predictably achieve the < 100 MPN/gram Canadian standard by holding oysters in culture trays at growing densities in 12-15 C water for 5 to 7 days. In Washington, we are achieving similar results after holding shellfish in a chilled recirculating wet storage system at 15 C for 3 days.

The current Chapter II. Risk Assessment and Risk Management @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*), Section A. (6)(c) allows for harvest from areas closed due to *V.p.* with "Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority". This could provide the opportunity for a SSCA to allow the use of the < 100 MPN/gram to permit harvest. We are submitting this proposal to draw attention to the effectiveness of the < 100 MPN/gram tlh standard and clearly state that it is an option for inclusion in state vibrio control plans. As proposed, it is our understanding and intent that this would be an option and not mandatory. If adopted it would provide companies with an option to continue harvesting and distribution of a reduced risk product during V.p. closures.

The International Commission on Microbiological Standards for Foods (ICMSF) advises that < 100 MPN/gram would be of acceptable quality in live bivalve Mollusca. Other countries, including Japan for fresh/frozen fish and shellfish and Hong Kong, Australia, New Zealand in Ready to Eat (RTE) foods and Russia (for imported shellfish) have adopted the 100 MPN/gram standard. U.S. companies exporting live shellfish to countries that have adopted this standard already have to demonstrate their product achieves the standard. This is yet another reason we feel it makes sense for the U.S. to consider including it as an option in the Model Ordinance.

As a major seafood and shellfish consumer Japan has had a history of large numbers of *V.p.* illnesses. Their response warrants review as it appears to have been very effective at reducing illnesses. Following a peak in 1998 with 839 outbreaks and 12,318 cases, Japan's Ministry of Health, Labor and Welfare (MHLW) instituted a series of regulations from production through consumption including adoption of a ≤ 100 MPN/gram standard. Subsequently, the number of cases and out- breaks of *V. parahaemolyticus* infections decreased by an unprecedented 99- and 93-fold, respectively, from 1998 to 2012.

The 2014 paper: Impact of seafood regulations for *Vibrio parahaemolyticus* infection and verification by analyses of seafood contamination and infection
by Kara-Kudo and Kumagai reviews Japan's response including an explanation of how they arrived at the ≤ 100 MPN/gram tlh standard while considering various serotypes and pathogenic thermostable direct haemolysin (TDH) and/or TDH-related haemolysin (TRH)-positive strains.

Further, according to Kara-Kudo and Kumagai's review article total V. parahaemolyticus levels in seafood associated with 11 outbreaks from 1998 were analyzed. The contamination levels in 8 out of 11 outbreaks were >100 V. parahaemolyticus MPN/g food, suggesting that the regulatory level of ≤100 V. parahaemolyticus MPN/g is effective for food control.

	Taylor Shellfish Farms is confident based on recommendations from the International Commission on Microbiological Standards for Foods (ICMSF), that results seen in BC and documented in Japan that the < 100 MPN/gram tlh standard provides considerable *V.p.* illness risk reduction. So much so that we have begun construction of a 90,000 gallon chilled live holding system at our Shelton, Washington processing facility with the goal of ensuring all our shellfish destined for raw consumption meets this standard.
Cost Information	If adopted as intended, it would be optional for states to include it in their vibrio control plans and for companies to pursue validation of a process to achieve the standard. It is anticipated that the tests associated with the validation process and periodic verification would be at the expense of the participating company. The costs would only be incurred if a company opted to pursue validation of their process. It is anticipated that states would recoup the cost of the validation tests if they were performed at a state operated laboratory. Presumably SSCAs could also impose fees to cover cost associated with overseeing validation of a company's process and periodic verification. Costs incurred by companies would theoretically be recouped by having the advantage of continued sales when growing areas might otherwise be closed due to *V.p.*.
Action by 2019 Task Force II	Recommended referral of Proposal 19-240 to the appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-240.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-240.

Submitter	Centers for Disease Control and Prevention (CDC) CDC Estokes@cdc.gov
Proposal Subject	*Vibrio vulnificus* risk evaluation
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.06 *Vibrio vulnificus* Control Plan Section III. Public Health Reasons and Explanations Chapter IV. Shellstock Growing Areas @.01 Sanitary Survey ISSC Constitution, Bylaws & Procedures Procedure XVI. Procedure for *Vibrio vulnificus (V.v.)* Illness Review Committee Procedures
Text of Proposal/ Requested Action	**Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.06 *Vibrio vulnificus* Control Plan**

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

Section III. Public Health Reasons and Explanations Chapter IV. Shellstock Growing Areas @.01 Sanitary Survey

A. General.

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. Feces deposited on land surfaces can release pathogens into surface waters via runoff. Most freshwater streams eventually empty into an estuary where fecal bacteria and viruses may accumulate in sediment and subsequently can be re-suspended.

Shellfish pump large quantities of water through their bodies during the normal feeding process. During this process the shellfish also concentrate microorganisms, which may include pathogenic microorganisms. Epidemiological investigations of shellfish-caused disease outbreaks have found difficulty in establishing a direct numerical correlation between the bacteriological quality of water and the degree of hazard to health. Investigations made from 1914 to 1925 by the States and the Public Health Service, a period when disease outbreaks attributable to shellfish were more prevalent, indicated that typhoid fever or other enteric diseases would not ordinarily be attributed to shellfish harvested from water in which not more than fifty (50) percent of the one (1) cc portions of water examined were positive for coliforms (an MPN of approximately seventy [70] per 100 ml), provided the areas were not subject to direct contamination with small amounts of fresh sewage which would not be revealed by bacteriological examination.

Following the oyster-borne typhoid outbreaks during the winter of 1924-25 in the

United States, the NSSP was initiated by the States, the Public Health Service, and the shellfish industry. Water quality criteria were then stated as: (1) the area is sufficiently removed from major sources of pollution so that the shellfish would not be subjected to fecal contamination in quantities which might be dangerous to the public health, (2) the area is free from pollution by even small quantities of fresh sewage, and (3) bacteriological examination does not ordinarily show the presence of the coli- aerogenes group of bacteria in one (1) cc dilution of the growing area water. Once the standards were adopted in the United States in 1925, reliance on this three-part standard for evaluating the safety of shellfish harvesting areas has generally proven effective in preventing major outbreaks of disease transmitted by the fecal-oral route. Similar water quality criteria have been used in other countries with favorable results.

Nevertheless, some indicators and pathogens are capable of persisting in terrestrial soil, fresh and marine waters, and aquatic sediment for many days while others are even capable of growth external to a host. A small number of shellfish-borne illnesses have also been associated with bacteria of the genus Vibrio. The *Vibrio spp.* are free-living aquatic microorganisms, generally inhabiting marine and estuarine waters.
Among the marine *Vibrio spp.* classified as pathogenic are strains of non-01 *Vibrio cholerae*, *V. parahaemolyticus*, and *V. vulnificus*. All three (3) species have been recovered from coastal waters in the United States and other parts of the world. These and other *Vibrio spp.* have been detected in some environmental samples recovered from areas free of overt sewage contamination and coliform.
In general, shellfish-borne Vibrio infections have tended to occur in coastal areas in the summer and fall when the water was warmer and *Vibrio* spp. counts were higher. *V. parahaemolyticus* and non-~~01~~O1 *V. cholerae* are commonly reported as causing diarrhea illness associated with the consumption of seafood including shellfish. In contrast, *V. vulnificus* has been related to ~~two (2) distinct syndromes:~~ wound infections, invasive disease usually characterized by bacteremia, and less commonly diarrheal illness associated with the consumption of seafood. ~~often with tissue necrosis and bacteremia, and primary septicemia characterized by fulminant illness in individuals with severe chronic illnesses such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy. Increasing c~~Evidence shows that individuals with such chronic diseases such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy are susceptible to ~~septicemia~~ severe illness and death from raw seafood, especially raw oysters. Shellfish-borne Vibrio infections can be prevented by cooking seafood thoroughly, keeping them from cross contamination after cooking, and eating them promptly or storing them at hot (60 °C or higher) or cold (4 °C or lower) temperatures. If oysters and other seafood are to be eaten raw, consumers are probably at lower risk to Vibrio infection during months when seawater is cold than when it is warm.

In addition to pathogenic microorganisms, poisonous or deleterious substances may enter shellfish growing areas via industrial or domestic waste discharges, seepage from waste disposal sites, agricultural land or geochemical reactions. The potential public health hazard posed by these substances must also be considered in assessing the safety of shellfish growing areas.

The primary responsibility of the Authority is to ensure the public health safety of the shellfish growing areas through compliance with the NSSP Model Ordinance. The Authority must perform a sanitary survey that collects and evaluates information concerning actual and potential pollution sources that may adversely affect the water

quality in each growing area. Based on the sanitary survey information, the authority determines what use can be made of the shellstock from the growing area and assigns the growing area to one (1) of five (5) classifications. The survey information must be updated periodically to ensure that it remains current and must be readily accessible to both the Authority and the harvester. Experience has shown that the minimum sanitary survey components required in this chapter are necessary for a reliable sanitary survey. A more detailed explanation is provided in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2017).

ISSC Constitution, Bylaws & Procedures Procedure XVI. Procedure for *Vibrio vulnificus (V.v.)* Illness Review Committee Procedures

Section 1. Committee Charge

The *V.v.* Illness Review Committee will annually review all *V.v.* cases involving the consumption of shellfish which are reported to FDA regional specialists and the Center for Disease Control (CDC). The Committee will determine which cases meet the case definition of a National Shellfish Sanitation Program (NSSP) *V.v.* case as outlined in Model Ordinance Section II. Chapter II. @.05. All cases meeting the NSSP definition will be included in an annual report which will be presented to the Interstate Shellfish Sanitation Conference (ISSC) Executive Board and the Vibrio Management Committee. Following ISSC Executive Board approval the report will be made available to the ISSC membership and posted on the ISSC website. This data is expected to be used by USFDA, State Authorities, and the ISSC for the following purposes:

Subdivision a. Conducting annual *V.v.* Risk Evaluations;

Subdivision b. Risk per serving determinations;

Subdivision c. *V.v.* Control Plan Evaluations;

Subdivision d. *V.v.* Contingency Plan Evaluations; and

Subdivision e. Reviewing illness trends.

Section 2. Procedures.

Subdivision a. The Committee will only consider cases that are reported on a CDC and Prevention Cholera Vibrio Illness Surveillance Report (COVIS) Form CDC 52.79 or other means.

Subdivision b. FDA will coordinate the collection of cases and COVIS forms, and other information and after redacting identifying information will make this information available to the Committee.

Subdivision c. The information from the COVIS forms will be shared with the *V.v.* Illness Review Committee for review.

Subdivision d. The *V.v.* Illness Review Committee will review the cases and incorporate the appropriate information into a chart which will serve as the

Committee report.

Subdivision e. The report will be presented to the ISSC Executive Board for approval and then forwarded to the Vibrio Management Committee.

Subdivision f. The availability of the report will be announced to the ISSC membership.

A copy of the report will be posted on the ISSC website.

Section 3. Criteria and Guidelines.

The Committee will use the following criteria and guidelines in reviewing reported cases:

Subdivision a. Was the illness etiologically confirmed? In this context "etiologically confirmed "shall mean laboratory confirmation by wound, stool or blood culture. Confirmation may be by a laboratory otherthan a State laboratory."

Subdivision b. Was the illness epidemiologically linked to shellfish? Epidemiologically linked will mean "associated with" the consumption of oysters. Consumption means ingested; eaten within 7 days of onset of symptoms. Date of onset may be before hospitalization. Further information may be warranted; discretion may be exercised.

Subdivision c. Were the shellfish consumed?

Subdivision d~~e~~. Were the shellfish commercially harvested? Commercially harvested shall mean the shellfish were intended for sale or distribution in commerce. Commercial harvest will include those cases involving a foreign state.

~~Subdivision d. Were the shellfish raw or undercooked? If the victim developed *V.v.* septicemia after consumption the shellfish are considered to have been raw or undercooked.~~

Subdivision e. From what State was the shellfish harvested?

Subdivision f. ~~Did the case involve septicemia from consumption:~~

~~The following guidance will be used in determining if the case is a septicemia or a gastroenteritis case. Clinical signs and symptoms *V.v.* septicemia include:~~

A case of severe *V.v.* is defined as illness in a person who had V. vulnificus infection confirmed by bacterial culture and either of the following:

Subdivision i. *V. vulnificus* was isolated

		from blood or a site that likely indicates invasive disease (see specimen source table).~~*V.v.* bacteria isolated from blood~~.
	Subdivision ii.	Any of the following were indicated on the COVIS case report form: 1. Fever 2. Septic Shock 3. Death Any of the following sequelae: necrosis; or invasive procedure, such as surgery, amputation, skin graft, wound debridement, fasciotomy, or incision and drainage~~Fever measured as above 100 degree Fahrenheit~~.
	~~Subdivision iii.~~	~~Death as outcome (septicemia has a mortality rate of over 50% - 70%).~~
	~~Subdivision iv.~~	~~Bullae (blood filled blisters) but this also can occur after a wound infection which becomes septic.~~
	~~Subdivision v.~~	~~Shock because of the sepsis (again this can happen also because of a wound infection).~~
~~Subdivision g.~~	~~Indications case may not be *V.v.* septicemia from consumption:~~	
	~~Subdivision i.~~	~~Bacteria are only isolated from wound fluid or stool and no clinical evidence of septicemia.~~
	~~Subdivision ii.~~	~~Cellulitis. Since cellulitis is a localized or diffuse inflammation of connective tissue with severe inflammation of dermal and subcutaneous layers of the skin (bacteria entering bodies through the skin, there might be a visible wound or just a small scratch), therefore more likely a wound infection.~~
	~~Subdivision iii.~~	~~History of pre existing and~~

~~sustained wound infection (If both wound and oyster/seafood consumption is documented and happened within the incubation period, there is no way to differentiate why the patient is septic.)~~

~~Subdivision iv.~~ ~~Septicemia has a much shorter incubation period compared to gastroenteritis, according to CDC data. *V.v.* septicemia has an incubation period between 12-72 hours, although we have seen cases with shorter incubation periods.~~

Section 4. Challenges to Committee Findings.

Persons wishing to challenge the information included in the report must notify the ISSC Executive Director within sixty (60) days of the posting of the report on the ISSC website. The ISSC Executive Board will review all challenges at the next scheduled Executive Board meeting.

Section 5. *V.v.* Case Appeal Procedure

Subdivision a. Appropriate V.v. information will be provided to the reporting and source States at least 60 days prior to committee review. The States will be given 30 days from the date of receipt to respond.

Subdivision b. Following V.v. Illness Review Committee review, each source State with a countable case will be notified.

Subdivision c. Should a source State disagree with the Committee determination on a specific case, the source State will be provided thirty (30) days to file an appeal.

Subdivision d. Should the Committee, based on the information provided by the appellant, conclude that the original determination should be reversed, the appellant will be notified.

Subdivision e. Should the Committee, based on the information provided by the appellant, conclude that the original determination was appropriate; the Committee will provide the appellant an opportunity to state their position. This opportunity will be either by telephone conference call or in person. The choice of

venue will be determined by the Committee and will not exceed fifteen (15) minutes.

Subdivision f. The Committee will consider information presented by the appellant in the oral presentation. The appellant will be notified of the final decision of the Committee.

Subdivision g. The appellant will receive a final decision from the Committee no more than 30 days after the date the appeal is submitted; if a decision can NOT be made after 30 days, then an appeal extension must be granted by the committee, or the appeal will be considered denied.

Table: Specimen sources that likely reflect invasive disease

ISSC *Vibrio vulnificus* Illness Review Criteria Table

Review Date: _____

Blood: Includes plasma and blood components
Vascular: Includes heart, heart valves, aorta, blood vessels
Lymphatic: Includes lymph, lymph nodes, thymus
Spleen: Includes spleen, splenic abscesses
Bone: Includes bone, bone marrow
Placenta and products of conception: Includes fetus, cord blood
Nervous system Cerebrospinal fluid (CSF) Other nervous tissue; includes brain abscess
Pleural fluid
Peritoneal fluid
Joint: includes synovial/joint fluid
Hepatobiliary: Gallbladder, bile, liver (includes abscesses)
Pancreas: Includes pancreas, pancreatic cysts, and abscesses
Reproductive: Ovary, fallopian tube, uterus (includes cysts and abscesses in these sites), pelvic abscesses, amniotic fluid
Kidney: Includes renal and perinephric abscess

Case Identifier/Number:	Criteria Status		
Criteria	Yes	No	Unknown
1. Etiologically Confirmed? ~~Blood Stool~~			
2. Epidemiologically Linked?			
3. ~~Septicemia~~ Severe Illness?			
4. Reporting State?			
5. Commercial Harvest?			

6. Were shellfish consumed?			
a. Specify shellfish consumed:	Oysters	Clams	Specify Other
b. Date of consumption: _____			
c. Is onset consistent with consumption of shellfish? Date of onset _____			
7. Trace-back Information			
a. Were shipping tags available? If other trace-back information reported, list:			
b. State of harvest, harvest area (s), and harvest date (list all reported).			

Harvest Area	Harvest State	Harvest Date	Species	Comment

Public Health Significance

Septicemia is an outdated term no longer commonly used in medicine or public health. An alternative strategy of considering only “severe” cases to reflect the magnitude of risk from food is problematic, because 1) the severity of an illness may depend on factors other than the food, such as the patient’s age, underlying health conditions, access to healthcare, bacterial load ingested, and appropriateness of medical treatment, and 2) data collection practices, state resources, and availability of data can vary by geography and over time. This makes the reporting of “severe” cases potentially inconsistent.

Surveillance data on method of preparation can be limited and subjective. Any oyster that transmits illness can be considered insufficiently cooked; consumers may not realize they have eaten an undercooked food.

Counting all etiologically confirmed cases associated with consumption of commercially

harvested oysters is the most clear and consistent measure of *V. vulnificus* illness risk to the public.

Cost Information	NA
Action by 2019 Task Force II	Recommended to referral of Proposal 19-241 to the appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-241.
Action by FDA February 21, 2020	FDA concurred with the Conference's action to refer Proposal 19-241 to committee. FDA would like to encourage the Conference Chair to direct the *Vv* Illness Review (VvIR) committee to begin discussions on proposal 19-241 as soon as possible. Identification of more appropriate metrics to assign *Vibrio vulnificus (Vv)* cases will greatly facilitate the *VvlR* committee's standing charge. The ISSC with FDA concurrence has opted not to accept each *Vv* case that is reported but to critique the merits to determine if each case is indeed septicemia from a commercial oyster consumption illness. As the uses of *Vv* data have changed over the life of the committee, this metric has become less useful. Ifthe committee is to continue to be useful in their role, each case must be deliberated in a standardized manner, not by examining for septicemia, but determining if each case meets a clinical definition. FDA supports this CDC drafted proposal intended to eliminate the septicemia qualification from Procedure XVI when case counting for *Vv* illness review. The suggested new metric to be used would be severe illness in the form of bacteremia, not blood infection. The proposal language includes cooked oysters and eliminates the question of how well the oysters are cooked. Additionally, the language considers only clinical symptoms such as fever, shock, listed sequelae or death. This proposal includes a table of specimen sources likely to indicate invasive disease rather than discounting stool or wound specimens.

Submitter	Steve Fleetwood Bivalve Packing Company eastpointoysters@aol.com
Proposal Subject	Vv Illness Reporting
Specific NSSP Guide Reference	Not Applicable
Text of Proposal/ Requested Action	The CDC reported 493 *Vibrio vulnificus* cases for the years 2011-2014. The 493 cases resulted in 407 hospitalizations and 121 deaths. Although most illnesses are associated with persons at high risk, the outcomes are very severe. To address the illnesses associated with the consumption of raw or undercooked molluscan shellfish, the ISSC adopted control measures in an attempt to minimize *V.v.* cases associated with shellfish. Additionally the ISSC, FDA, states and the industry have developed and participated in education programs to inform at risk individuals of the risk of vibrio illness. This proposal is being presented to request the ISSC and FDA encourage the CDC and state epidemiologist to amend the current COVIS form to include a field to be used to determine if individuals who have contracted illnesses are aware of *V.v.* and the risk of illness posed to at risk individuals.
Public Health Significance	The inclusion of this request on the COVIS form would provide public health officials with information to determine if additional education programs should be developed to advise at risk consumers of all types of *V.v.* exposures.
Cost Information	N/A
Action by 2019 Task Force II	Recommended referral of Proposal 19-242 to the appropriate committee as appointed by the Conference Chair with additional instructions to encourage the conference to continue to address education efforts and specifically to consider target audiences and a needs assessment and potentially develop a data collection tool to determine existing knowledge of at risk individuals associated with *Vibriosis* illnesses.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-242.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-242.

Proposal No. 19-243

Submitter	Steve Fleetwood Bivalve Packing Company eastpointoysters@aol.com
Proposal Subject	Vp Illness Reporting
Specific NSSP Guide Reference	Not Applicable
Text of Proposal/ Requested Action	For the past several years, the CDC has reported increased *Vibrio parahaemolyticus* cases. To address the illnesses associated with the consumption of raw or undercooked molluscan shellfish, the ISSC has adopted control measures in an attempt to minimize *V.p.* cases associated with shellfish. Additionally the ISSC, FDA, states and the industry have developed and participated in education programs. This proposal is being presented to request the ISSC and FDA encourage the CDC and state epidemiologist to amend the current COVIS form to include a field to be used to determine if individuals who have contracted *V.p. have* illness conditions or are taking medications that place them at a higher risk of contracting *V.p*
Public Health Significance	The inclusion of this request on the COVIS form would provide public health officials with information to determine if additional education programs should be developed to advise consumers of *V.p.* risk.
Cost Information	N/A
Action by 2019 Task Force II	Recommended no action on Proposal 19-243. Rationale: Proposal is adequately covered by Proposal 19-242.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-243.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-243.

Proposal No. 19-152

Submitter	Catalina Sea Ranch, LLC (CSR) maria@catalinasearanch.com
Proposal Subject	Update the Protocol for Marine Biotoxin Control
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.04 B.
Text of Proposal/ Requested Action	**@.04 Marine Biotoxin Control** B. Marine Biotoxin Management Plan. In those areas that have been implicated in an illness outbreak or where toxin-producing phytoplankton are known to occur and the toxins are prone to accumulate in shellfish, and when appropriate at those times when marine biotoxins can be reasonably predicted to occur, representative samples of the water may be collected and shellfish shall be collected during harvest periods. The samples shall be collected from indicator stations at intervals determined by the Authority. Water samples may be assayed for the presence of toxin-producing phytoplankton and shellfish meat samples shall be assayed for the presence of toxins. **NOTE:** In situations in which the toxin of concern has an established cell count standard, such as *Karenia brevis,* water and shellfish samples would not be required. Management decisions could be made on either water or shellfish sampling results. (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) For Federal waters harvesters, each company is considered an Authority and must develop and adopt their own plan. (~~2~~3) The plan shall… (~~3~~4) The Authority may… (~~4~~5) Except that the… (~~5~~6) The plan may… (~~6~~7) Prior to allowing…
Public Health Significance	This proposal would expand the definition of Authority to include harvesters in the definition of Authority.
Cost Information	
Action by 2019 Task Fore II	Recommends no action on Proposal 19-152. Rationale: This proposal was addressed by Task Force action on Proposal 19-203.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-152.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-152.

Submitter	Julie Henderson Virginia Department of Health Division of Shellfish Sanitation julie.henderson@vdh.virginia.gov
Proposal Subject	Internal Authority Self-Assessment Using a National Program Standards Manual
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority
Text of Proposal/ Requested Action	@.01 Administration A. Scope… B. State Law and Regulations… C. Records… D. Shared Responsibilities… E. Administrative Procedures… F. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness… G. Commingling… H. Program Evaluation. The Authority shall conduct a self-assessment using the National Program Standards Manual and report annually to the U.S. Food and Drug Administration the results of the assessment.
Public Health Significance	The purpose of this proposal is to begin discussions on how a self-assessment can be used by Authorities to conduct a comprehensive evaluation of their ability to promote the protection of public health. An assessment conducted by an Authority may encourage continuous improvement and innovation and can assure that individual program activities provide comparability among other domestic and international shellfish programs. The evaluation can be used to assist both the FDA and shellfish Authorities in fulfilling regulatory obligations and ensuring the implementation of the requirements set forth in the NSSP Model Ordinance
Cost Information	
Action by 2011 Task Force III	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-310.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-310.
Action by 2013 NSSP Evaluation Criteria Committee	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairperson with the following instructions. Establish a workgroup to evaluate the Manufactured Food Standards and determine the applicability of and/or use of these Manufactured Standards to the National Shellfish Sanitation Model Ordinance requirements and report their findings and recommendations to the NSSP Evaluation Criteria Committee at the next ISSC Meeting. The Committee further recommended that self-assessments should be voluntary and that the

	word “shall” should be replaced with the word “may”.
Action by 2013 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-310.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 11-310.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-310.
Action by 2015 NSSP Evaluation Criteria Committee	Recommended that draft standards be developed for each program element. These draft standards will be developed using the stnadards from other programs and the FDA draft. It is further recommended that the ISSC identify volunteer states to ilot the standards once developed. The committee will review results from the pilot and submit a proposal for conference consideration.
Action by 2015 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-210.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 11-310.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 11-310.
Action by 2017 NSSP Evaluation Committee	Recommended: 1. The full committee be allowed to review the Voluntary National Shellfish Regulatory Program Standards Plant Sanitation draft report. 2. This review should take place as soon as possible so that a decision can be made in January by the NSSP Evaluation Committee via a conference call. 3. If the full committee concurs, 2-4 state can move forward with a pilot study for the program standards as determined by the sub-committee chair.
Action by 2017 Task Force III	Recommended referral of Proposal 11-310 back to the NSSP Evaluation Criteria Committee with instructions to review the Plant Sanitation Standards developed by the Standards Subcommittee. The Committee is instructed to complete the review by January 31, 2018 and present recommendations to the ISSC Executive Board for interim approval and pilot testing.
Action by 2017 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-310.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 11-310.
Action by 2019 Standards Committee	The Committee recommended Task Force III adopt the draft Voluntary National Shellfish Regulatory Program Standards (attached) for the Plant Sanitation element into Section IV Guidance Documents of the National Shellfish Sanitation Program (NSSP) Guide for the

Control of Molluscan Shellfish.

Action by 2019 Task Force III	Recommended adoption of the Standards Committee recommendation on Proposal 11-310 as follows: 1) Adopt the draft Voluntary National Shellfish Regulatory Program Standards for the Plant Sanitation element into Section IV Guidance Documents of the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish. 2) The committee complete the piloting and recommend any needed changes to the Conference at the 2021 Bieninal Meeting. 3) The committee begin the development of Program Standards for the Growing Area Classification Element for Conference consideration.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 11-310.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 11-310.

Proposal No. 13-301

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Growing Area Classification Criteria
Specific NSSP Guide Reference	To Be Determined
Text of Proposal/ Requested Action	The ISSC has adopted evaluation criteria for several program elements within the NSSP. These include laboratories, plant sanitation, and patrol. The development of these criteria has seemed to provide a better understanding of expectations, improve uniformity in State evaluations and enhance compliance. The ISSC should expand its evaluation criteria efforts to include growing area classification. Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification. Although more complex, this element of the program could benefit from the development of evaluation criteria. The purpose of this proposal is to request the Evaluation Criteria Committee be charged with the task of developing evaluation criteria for the growing area element.
Public Health Significance	Growing area classification criteria will enhance State classification efforts and ensure a high level of uniformity and effectiveness in FDA evaluations.
Cost Information	
Action by 2013 Task Force III	The submitter of Proposal 13-301 requested that the following sentence be deleted from the proposal. ~~Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification.~~ The Task Force recommended adoption of Proposal 13-301 with the amendment as requested by the submitter.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-301.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-301.
Action by 2015 NSSP Evaluation Criteria Committee	Recommended: 1) The following criteria be used in evaluating the State Growing Area classification element 1. Written Sanitary Survey (A) Is there a written Sanitary Survey for each growing area

that is classified other than prohibited?

(B) Is the Sanitary Survey complete?

A. Executive Summary
B. Description of Growing Area
C. Pollution Source Survey
D. Hydrographic and Meteorological Characteristics
E. Water Quality Studies
F. Interpretation of Data in Determining Classification to Be Assigned to Growing Area: A discussion of how actual or potential pollution sources, wind, tide, rainfall, etc. affect or may affect water quality, that will address the following:
G. Conclusions

(C) Is the Sanitary Survey current?

A. Annual
B. Triennial
C. 12 Year)

2. Shoreline Survey

(A) Does Shoreline Survey include identification and evaluation of all actual and potential sources of pollution
(B) Does Shoreline Survey include boundaries?
(C) Does Shoreline Survey include unique designation?
(D) Does Shoreline Survey include required maps?
(E) Does Shoreline Survey include a summary of survey findings?

3. Adequate Sampling

(A) Are the number and location of sampling stations adequate to effectively evaluate all pollution sources.
(B) Were adequate samples collected for each area consistent with the classification and type of sampling approach used (i.e. Remote, Adverse Pollution, Systematic Random Sampling)?
(C) Were samples collected under appropriate conditions consistent with the type of sampling approach?

4. Data to support Classification

(A) The assigned classifications are based on data/information supporting the classification and performance standards?
(B) Is appropriate data/information available to support the classification within each designated growing area?

5. Proper Classification

(A) Are all growing areas properly classified?

(B) Does SSCA have appropriate MOU(s) with appropriate parties for each area classified as conditional?

2) The subcommittee will develop a scoring system which assigns appropriate significance to the criteria and establishes compliance standards which can be used to assign compliance designations as outlined in the other NSS elements.
3) Field testing of the complete evaluation criteria including compliance designation will be field tested in one state in each ISSC region. The results will be reviewed by the NSSP Evaluation Committee, modified as appropriate and presented to the ISSC as a proposal.

Action by 2015 Task Force III — Recommended adoption of the NSSP Evaluation Criteria Committee recommendations on Proposal 13-301.

Action by 2015 General Assembly — Adopted recommendation of Task Force III on Proposal 13-301.

Action by FDA January 11, 2016 — Concurred with Conference action on Proposal 13-301.

Action by 2017 NSSP Evaluation Criteria Committee — Recommended:

1. The full committee is allowed to review the FDA proposed growing area evaluation criteria immediately.
2. Concurrence with FDA not to initiate a full pilot until the committee completes a review of the FDA proposed criteria.

Action by 2017 Task Force III — Recommended adoption of NSSP Evaluation Criteria Committee recommendation to refer Proposal 13-301 back to the NSSP Evaluation Criteria Committee with the following charge:

Review the evaluation criteria provided to the NSSP Evaluation Criteria Committee and provide recommendation for interim approval by the ISSC Executive Board at the Spring Board meeting. The Executive Board is requested to coordinate the piloting of the criteria with FDA as soon as possible.

Action by 2017 General Assembly — Adopted the recommendation of Task Force III on Proposal 13-301.

Action by FDA February 7, 2018 — Concurred with Conference action on Proposal 13-301.

Action by 2019 NSSP Evaluation Criteria — Recommended Proposal 13-301 be referred to an appropriate committee as determined by the Conference Chairperson to continue the development of the growing area classification evaluation criteria and make recommendations to the conference on proposal 13-301. The

Committee	committee will work with FDA to assure consistency and uniformity of evaluation criteria for all program elements. The committee requests the Conference Chairperson to instruct the committee to start deliberation as soon as possible.
Action by 2019 Task Force III	Recommended adoption of NSSP Evaluation Criteria Committee recommendation to refer Proposal 13-301 to the NSSP Evaluation Criteria Committee.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 13-301.

Proposal No. 17-302

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	NSSP Training Curriculum
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I Section IV. Guidance Documents Chapter I
Text of Proposal/ Requested Action	Presently the NSSP does not have a well defined training curriculum for State Shellfish Authority staff that are implementing the requirements of the NSSP. There are two (2) required courses for Authority staff and FDA provides other training on an as needed basis. In 2016, the Association of Food and Drug Officials received a cooperative program grant to support training for shellfish regulatory staff. A joint advisory group (JAG) was created to provide oversight. The lack of an established NSSP curriculum made it difficult to develop funding selection criteria. In response, the ISSC appointed a training committee which discussed available training and provided recommendations to the JAG. The purpose of this proposal is to charge the Training Committee with development of an NSSP training curriculum for inclusion into either Chapter I of the Model Ordinance or as a Guidance Document.
Public Health Significance	Adequate training of Authority staff is fundamental to successful implementation of the elements of the NSSP. A NSSP training curriculum would be a helpful tool to guide Authorities in selection of appropriate and helpful training for staff.
Cost Information	
Action by 2017 Task Force III	Recommended adoption of Proposal 17-302 as submitted.
Action by 2017 General Assembly	Adopted the recommendation of Task Force III on Proposal 17-302.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-302.
NOTE:	This Proposal appears in the 2019 Proposal Package for information only and does not require Task Force action. The Task Force addressed the recommendations of the Training Committee in Proposals 19-303 and 19-304.

Proposal No. 17-305

Submitter	Kathy Brohawn, Kathryn Busch, Robin Henderson, Debbie Rouse Maryland Department of Environment, Natural Resources & Health & Mental Hygiene, DE Division of Natural Resources & Environmental Control kathy.brohawn@maryland.gov, kathryn.busch@maryland.gov, robin.henerson@maryland.gov, debbie.rouse@state.de.us
Proposal Subject	Responsibilities of the FDA for Annual or Bi-Annual Evaluations
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures of the ISSC Procedure IV. Responsibilities of the FDA Section 3. and Model Ordinance Chapter I. @.03 (new) E.

Text of Proposal/ Requested Action

Procedures of the Interstate Shellfish Sanitation Conference
Procedure IV. Responsibilities of the FDA Section 3.

Subdivision a: FDA shall provide a description of all deficiencies/non-compliance or emerging concerns identified during the evaluation. FDA will include the specific NSSP Model Ordinance reference for each deficiency, non-compliance, or emerging concern. This can be accomplished during a close out session with state program officials or at any time during a field inspection or overall program evaluation and shall occur prior to finalizing the Program Element Evaluation Report (PEER)

Subdivision b: FDA shall allow state program officials a minimum of 30 days to correct any deficiencies/non-compliance or emerging concerns (that do not pose an imminent health hazard) identified prior to finalizing the PEER. If state program officials correct the identified deficiencies during the 30 day time frame, the final PEER will acknowledge the corrections and reflect compliance with any deficiencies identified or noted during the evaluation as in Subdivision a, above. If corrections cannot be accomplished within 30 days an agreed upon timeframe or action plan is required and should be included in the PEER.

Subdivision c: All deficiencies, non-compliance, or emerging concerns cited in a PEER will include the specific Model Ordinance references of the requirements. Once a State has corrected any non-compliance FDA shall acknowledge the correction in writing.

Model Ordinance Chapter I. @.03 (new) E.

E. When notifying the Authority of deficiencies cited as part of a Program Evaluation, the FDA will adhere to the following:

(1) FDA shall provide a description of all deficiencies/non-compliance or emerging concerns identified during the evaluation and include the specific NSSP Model Ordinance reference for each.

(2) FDA shall allow state program officials a minimum of 30 days to correct any deficiencies/non-compliance or emerging concerns (that do not pose a public health hazard) identified prior to finalizing the Program Element Evaluation Report (PEER). If State program officials correct the identified deficiencies during the 30 day time frame, the PEER will acknowledge and reflect compliance.

(3) Once a State has corrected or addressed any non-compliance, deficiencies, or emerging concerns, FDA shall acknowledge the correction in writing.

Public Health Significance	Provides a mechanism to assure consistency and encourages corrections during the evaluation process so that correctin of deficiencies occur in a timely manner. This is consistent with the existing FDA Compliance Program Guidance Manual. This language encourages the cooperative aspect of the NSSP by allowing FDA and State Authorities to work together to address problems sooner rather than later.
Cost Information	Would save time and resources for both FDA and State Regulators.
Action by 2017 Task Force III	Recommended referral of Proposal 17-305 to an appropriate committee as determined by the Conference Chairperson.
Action by 2017 General Assembly	Adopted the recommendation of Proposal 17-306 on Proposal 17-305.
Action by FDA February 7, 2018	Concurred with Conference action on proposal 17-305 with comments. (See February 7, 2018 FDA response to ISSC Summary of Actions)
Action by 2019 NSSP Evaluation Criteria Committee	Recommended that the FDA conduct a review of proposal 17-305 in conjunction with The Molluscan Shellfish Compliance Program and report back to the Regulatory Relationships Committee and the NSSP Evaluation Criteria Committee what they incorporated from the proposal, and if they did not, the justification for their decision.
Action by 2019 Task Force III	Recommended the FDA determine if the issues outlined in Proposal 17-305 can be addressed in the Molluscan Shellfish Compliance Program and advise the Regulatory Relationships Committee.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 17-305.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-305.

Proposal No. 19-300

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Executive Committee Membership
Specific NSSP Guide Reference	ISSC Constitution By-laws & Procedures Article VIII. of the Constitution entitled *Duties of the Executive Director*
Text of Proposal/ Requested Action	Section 1. The Executive Director shall serve as chief administrator of the Conference and shall serve as a non-voting member of the Executive Board and the Executive Committee. The Executive Director shall conduct the affairs of the Conference and shall implement the decisions and policies of the Board and voting delegates.
Public Health Significance	It is critical that the Executive Director be included as a non-voting member of the Executive Committee for the same reason that the Executive Director is included as a non-voting member of the Executive Board. Given the duties and responsibilities of the Executive Director, it is imperative that the Executive Director participate in Executive Board and Executive Committee discussions for the purpose of providing information necessary to conduct conference discussions.
Cost Information	
Action by 2019 Task Force III	Recommended adoption of Proposal 19-300 as submitted. The change will also result in a change to Section 9. Article IV. Executive Board, Officers and Committees.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-300.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-300.

Submitter	ISSC Laboratory Committee Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Updating and Clarifying Laboratory Evaluation Checklist Submission Requirements
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures, Procedure XV, Section 4 and Section 6
Text of Proposal/ Requested Action	Section 4., Subdivision a. All proposals shall include a completed ~~Single Laboratory Validation (SLV) Method Application and Checklist.~~ ISSC Method Application and Single Lab Validation Summary of Required Elements for Acceptance of a Method for Use in the NSSP. Submitters of AOAC and FDA methods will provide ~~a Single Laboratory Validation Method Application and Checklist~~ an ISSC Method Application and Single Lab Validation Summary of Required Elements for Acceptance of a Method for Use in the NSSP, along with the AOAC OMA or FDA Office of Foods Level 3 or 4 validations. Section 6., Subdivision a., Subdivision ii. Method documentation including: Subdivision (a) Method title, scope and references; Subdivision (b) Equipment and reagents required; Subdivision (c) Sample collection, preservation and storage requirements; Subdivision (d) Safety requirements; Subdivision (e) Step by step procedure; Subdivision (f) Specific quality control measures associated with the method; Subdivision (g) Laboratory Evaluation Checklist for use during evaluations of proper method implementation; Subdivision (~~g~~h) Cost of the method; Subdivision (~~h~~i) Sample turnaround time.
Public Health Significance	Whenever a new laboratory method is accepted for use within the National Shellfish Sanitation Program, an associated laboratory evaluation checklist to properly evaluate method implementation is necessary for laboratory evaluation officers (LEOs) to be able to fully and uniformly evaluate laboratories which have adopted the method. These checklists are often not prepared or submitted by the method developer/submitter in a timely manner, if at all, and the Laboratory Committee is often called upon instead to expend valuable time and resources preparing these checklists. Further, the method developer/submitter is the most appropriate individual for developing the technical aspects of the laboratory evaluation checklist, while the Laboratory Committee is better suited for ensuring consistency

	and uniformity with other NSSP laboratory evaluation checklists. There are a few reasons why these challenges with laboratory evaluation checklist submissions arise. First, there is often confusion among method developers between the laboratory evaluation checklist and the "ISSC Method Application and Single Lab Validation Checklist for Acceptance of a Method for Use in the NSSP," which is required to be completed when submitting a new method for adoption within the program. Developers often think that they have already fulfilled their checklist completion requirement by submitting this document. Additionally, laboratory evaluation checklists are not currently required to be prepared until after the method has been approved for use within the program, and there are no timeline standards associated with this expectation. This proposal attempts to eliminate the confusion between checklists by retitling the "ISSC Method Application and Single Lab Validation Checklist for Acceptance of a Method for Use in the NSSP" to "ISSC Method Application and Single Lab Validation Summary of Required Elements for Acceptance of a Method for Use in the NSSP," and to make laboratory evaluation checklist submission a required component of method submission for approval. The text of this proposal includes modifications to the ISSC Constitution, Bylaws, and Procedures, Procedure XV, as well as all other supporting documents that describe the process of method submission that would be available on the ISSC webpage.
Cost Information	No additional costs as laboratory evaluation checklist development is already a required part of the process, and this proposal simply changes where in the method approval process the checklist must be submitted for evaluation by the Laboratory Committee.
Action by 2019 Task Force III	Recommended adoption of Proposal 19-301 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-301.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-301.

Proposal No. 19-302

Submitter	ISSC Laboratory Committee Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Adding Matrix Extension Guidelines for Method Validation
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures, Procedure XV, Add a new Section 10.
Text of Proposal/ Requested Action	Section 10. Matrix Extensions. For methods already adopted into the NSSP, consideration of expanding a method to a new molluscan shellfish species is accomplished using the "ISSC Method Application Format for Biotoxin Methods Matrix Extension" and the "ISSC Method Application Format for Microbiology Methods Matrix Extension." The simplified, reduced approach to method validation for expanding an NSSP method to new molluscan shellfish species is visually represented in the "Matrix Extension Guidelines" schematic.
Public Health Significance	Analytical methods employed in the National Shellfish Sanitation Program (NSSP) are validated for the intended purpose within the Program. Since individual molluscan shellfish matrices may impact the performance of certain methods in their ability to identify and quantify biotoxins or microbiological contaminants, each method must be validated for each molluscan shellfish. To date, a full single laboratory validation (SLV) for each molluscan shellfish matrix has been expected. However, the Interstate Shellfish Sanitation Conference Laboratory Committee has developed simplified method validation guidelines for extending an adopted NSSP method for the use of additional species. The reduced guidelines address the critical method performance criteria that may be impacted by a change in shellfish type.
Cost Information	No additional costs. The cost to laboratories performing the validation studies would be less since this represents a reduced version of the validation guidelines for extending an NSSP method to a new molluscan shellfish matrix.
Action by 2019 Task Force III	Recommended adoption of Proposal 19-302 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-302.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-302.

Proposal No. 19-303

Submitter	ISSC Training Committee Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Definitions and Training Requirements
Specific NSSP Guide Reference	Section I. Purpose and Definitions Section II. Model Ordinance Chapter I, Shellfish Sanitation Program Requirements for the Authority Chapter IV. Shellstock Growing Areas Chapter VIII. Control of Shellfish Harvesting Section III. Public Health Reasons and Explanations Chapter I. Shellfish Sanitation Program
Text of Proposal/ Requested Action	Section I. Purpose and Definitions Definitions (120) ~~State~~ Shellfish Standardization Inspector means a person from either a state, federal or foreign authority who has met the requirements established in Chapter 1 @.01 (H.). ~~that has successfully completed the FDA standardization training course (or one deemed acceptable by the FDA and the field evaluation phase of shellfish plant inspection with either an FDA standardization officer or a state standardization officer).~~ (121) ~~State~~ Shellfish Standardization Officer means a person from either a state, federal or foreign authority who has met the requirements established in Chapter 1 @.01 (H.). ~~that has successfully completed the FDA standardization training course and the field evaluation phase of shellfish plant inspection with an FDA standardization officer.~~ Sanitary Survey Officer means a person from either a state, federal or foreign authority who has met the requirements established in Chapter 1 @.01 (H.). Laboratory Evaluation Officer means a person from either a state, federal or foreign authority who has met the requirements established in Chapter 1 @.01 (H.). Section II. Model Ordinance Chapter I, Shellfish Sanitation Program Requirements for the Authority @.01 H. Personnel training requirements for implementing the NSSP (1) Shellfish Dealer Inspections: (a) Shellfish Standardization Officer (SSO) shall successfully complete: (i) the FDA standardization training course, (ii) seafood HACCP, and;

(iii) the field evaluation by a FDA standardization officer.

(b) Shellfish Standardized Inspector (SSI) shall successfully complete:

(i) the FDA standardization training course,

(ii) seafood HACCP, and;

(iii) the field evaluation by a FDA standardization officer or the SSO.

(2) Growing Area Classification:

(a) Sanitary Survey Officer shall successfully complete:

(i) the FDA growing area course, and;

(ii) have a minimum of one (1) year of on the job experience in a NSSP growing area classification program within the shellfish sanitation program

(3) Patrol Enforcement:

(a) Officers responsible for the patrol of shellfish growing areas shall obtain the following training:

(i) basic law enforcement before assuming patrol duties,

(ii) shellfish control regulations before assuming independent patrol duties, and;

(iii) updated shellfish control regulations at an interval deemed appropriate by the Authority.

(4) Laboratory:

(a) Laboratory Evaluation Officer (LEO) shall successfully complete:

(i) the FDA Laboratory Evaluation Officer training course,

(ii). field standardization by a FDA LEO, and;

(iii) have a minimum of two (2) years of shellfish laboratory experience or a laboratory background with a minimum of three (3) years of bench level experience with the method types that will be evaluated.

Chapter IV. Shellstock Growing Areas @.01

A. General.

(1) The sanitary survey…

(2) The sanitary survey…

(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 reviewed and signed by the Sanitary Survey Officer;

(b) The triennial reevaluation; and

(c) The annual review.

Chapter VIII. Control of Shellfish Harvesting @.01

B. Patrol of Growing Areas.

(1) The Authority shall…

(2) The Authority shall…

(3) Exceptions….

(4) The Risk Category…
(5) The Authority may…
~~(6) Officers responsible for the patrol of shellfish growing areas shall obtain the following training:~~
~~(a) Basic law enforcement training, before assuming their patrol duties;~~
~~(b) Training on shellfish control regulations within the~~ jurisdiction ~~of the patrol agency, before assuming independent patrol duties~~; ~~and~~
~~(c)~~In-~~service training on the shellfish control regulations within the jurisdiction of the patrol agency, when the regulations change~~.

Section III. Public Health Reasons and Explanations

Chapter I. Shellfish Sanitation Program @.01
H. Training
Training is required for state, federal or foreign authorities implementing the NSSP. These training requirements ensure that persons in positions of responsibility understand the foundational elements of the program and demonstrate proficiency. Training is required for four elements of the program; Shellfish Dealer Inspection, Growing Area Classification, Patrol Enforcement and Laboratory. Each training requirement is linked to individuals designated as "Officers" who either sign off on reports or who enforce laws and regulations.

Public Health Significance

The modifications to the standardization definitions provide clarification regarding those required to have training.

The proposal creates a training requirement for persons responsible for developing sanitary surveys and outlines the training requirements.

The proposal creates a definition for Laboratory Evaluation Officer. The requirements are currently outlines in Chapter III.

The proposal creates a new section in Chapter I @.01 H. that would include all required program training.

Cost Information

Action by 2019 Task Force III

Recommended adoption of Proposal 19-303 as submitted.

Action by 2019 General Assembly

Adopted recommendation of Task Force III on Proposal 19-303.

Action by FDA
February 21, 2020

Concurred with Conference action on Proposal 19-303.

Proposal No. 19-304

Submitter	ISSC Training Committee Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Training Guidance
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter I. General
Text of Proposal/ Requested Action	Section IV Guidance Documents Chapter 1. General .03 Training requirements and recommendations
Public Health Significance	This guidance document will create a NSSP training curriculum. This curriculum will include required and recommended training for persons implementing the NSSP. This curriculum will be used in establishing priorities for scheduling and funding training. Currently, funding is made available to states through the FDA/AFDO Training Cooperative Agreement. The joint advisory group will use this curriculum in prioritizing funding requests.
Cost Information	
Action by 2019 Task Force III	Recommended adoption of Proposal 19-304 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-304.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-304.

NSSP Training Curriculum

BASIC TRAINING	Integrated Food Safety System	Jurisdiction	Laws, Regulations, Policies and Procedures	Communication Skills	Professionalism	Data and Information Systems	Public Health Principles	Biological Hazards	Environmental Hazards	Sampling	Traceability	Recalls	NSSP Program Overview
TRAINING BY ELEMENT (bold outline indicates required course)													
LEADERSHIP AND MANAGEMENT			**GROWING AREA CLASSIFICATION**			**LABORATORY**			**PATROL/ENFORCEMENT**		**SHELLFISH DEALER INSPECTION**		
Risk Analysis			Shellfish Growing Area			Laboratories			Basic Law Enforcement		Seafood HACCP		
Project Management			Sanitary Surveys of Shellfish Growing Areas; FD242			Shellfish Laboratory Methods and Evaluation; FD246			Shellfish Control Regulations		Shellfish Plant Standardization; FD245		
Program Evaluation									Shellfish Control Regulations Update		Shellfish Plant Program		
Policy Development									Inspections, Compliance and Enforcement		Inspections, Compliance and Enforcement		
Leadership Skills									Shellfish Patrol Program		Labeling		
Critical Thinking									Control of Harvest; FD243		Pest Control		
Traceback Investigation; ER220											Plumbing		
Imports											Basic Inspection; FD150		
Investigation Principles											Sanitation Practices		
Emergency Response; ER310											Transportation		
Foodborne Illness Investigations; FD215											Shellfish State Standardization Officer; FD241		
											Special Processes; FD152		
											Shellfish Tanks at Retail; FD212		

Proposal No. 19-305

Submitter	Kristin DeRosia-Banick, David Carey, Sue Ritchie Connecticut Department of Agriculture, NYS DEC – Division of Marine Resources Kristin.DeRosia-Banick@ct.gov
Proposal Subject	Evaluation of Shellfish Sanitation Program Elements
Specific NSSP Guide Reference	Section II Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority @.03 Evaluation of Shellfish Sanitation Program Elements
Text of Proposal/ Requested Action	A. The goal of shellfish program evaluation shall be to monitor program implementation and work with States to determine where problems may exist and how to address them. 1. Shellfish program evaluation methodologies shall: a. Monitor State Program implementation; b. Assess State program effectiveness; and c. Evaluate the validity of the elements of the NSSP Guide for the Control of Molluscan Shellfish. 2. The minimum components of shellfish program evaluation shall include: a. A description of the program activity; b. A comparison of FDA observations with State observations; and c. A measurement of conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish. 3. The focus of data collection shall be on measuring conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish. 4. The types of date collected shall include the following: a. Program records; b. Direct observation made by the evaluator; and c. Data and information from the Authority or other pertinent sources. 5. FDA shall not evaluate Shellfish Sanitation Program Elements while simultaneously training and/or standardizing newly hired FDA Shellfish Specialists or potential candidates being considered for a position as an FDA Shellfish Specialist. 6. FDA shall not evaluate Shellfish Sanitation Program Elements of any firm or a specific growing area that has been utilized to train and/or standardize newly hired FDA Shellfish Specialists or potential candidates being considered for a position as an FDA Shellfish Specialist for at least three (3) years from the date the candidate has been standardized as an FDA Shellfish Specialist with the following exceptions: a. When the State used for FDA training consists of less than the State's total inventory of certified shellfish dealers necessary to achieve a 95% probability of detecting a greater than or equal defect level of 20% for the State's Plant and Shipping Program Element; or b. When the State used for FDA training consists of less than the State's representative sampling plan designed to provide a 95% probability of detecting a 20% or greater defect level for the State's Growing Area Classification Program Element. Request that the NSSP Evaluation Committee consider changes to the Evaluation of Shellfish Sanitation Program Elements related to the use of a States' Shellfish Sanitation Program Element Evaluation for the purpose of training and standardizing

newly hired FDA Shellfish Specialists.

It is requested that the committee consider these or other additions to Section II. Chapter I. @.03 in order to more specifically define the purpose of an FDA PEER as intended to evaluate a States' compliance with the elements of the NSSP Guide for the Control of Molluscan Shellfish versus using a "PEER-modeled" evaluation of an SSCA to conduct training/standardization of a newly hired FDA Shellfish Specialist.

Public Health Significance

There are existing requirements in the NSSP for Standardizing FDA Shellfish Specialists and State Standardization Officers to conduct Shellfish Plant Inspections, whereby the inspections of certified dealers' facilities are used not to conduct regulatory inspections of the facilities, but are rather used as an opportunity to train and standardize the skills of the inspector.

Similarly, the concept presented here is that a "PEER-modeled" Shellfish Plant and Growing Area Evaluation used for the training and standardization of a newly hired FDA specialist would be defined and separated from the formal PEER evaluation process. The goals of these two types of evaluations should be clearly identified as distinct from one another.

The goals of the Evaluation of Shellfish Program Elements, as defined under Section II. Chapter I. @.03. A. is to "monitor program implementation and work with States to determine where problems may exist and how to address them." The purpose of conducting training/standardization of a newly hired FDA specialist is to ensure that newly hired FDA Specialists have the knowledge and ability to evaluate a State program effectively and objectively across the wide rang of State shellfish programs, while ensuring that Shellfish Specialists are standardized amongst themselves in the evaluation of State programs.

By separating these two types of evaluations, valuable discussions can occur which may lead to immediate corrective actions of critical deficiencies and ensure that, above all, public health is protected. This would also remove some of the stigma that has resulted from what is perceived as an increase in the number of deficiencies that have been identified in recent years in many States' PEERs in which multiple Specialists with differing levels of experience were evaluating a program.

During the period in which a new FDA Specialist is being trained in how to conduct a PEER evaluation of a shellfish program element for the State, information gathered during the training would not be used to determine a States' regulatory compliance with the requirements of the NSSP, but would rather provide an opportunity for an experienced Shellfish Specialist to impart his/her knowledge about how to evaluate a State's compliance, communicate his/her perception of the relative severity of compliance issues, and allows for open communication between a Specialist and the Authority. Issues discussed during the training process may or may not reflect significant compliance issues, however through open discussion, all parties would have the opportunity to communicate where disagreements of NSSP interpretation occur.

While the critical importance of training new hires in the role of FDA Shellfish Specialist is recognized, it should also be recognized that there are inherent differences between these two types of evaluations, and the existing application of

	the PEER Evaluation to the training and Standardization of new FDA hires may be creating unnecessary conflict between State Shellfish Authorities and the FDA Shellfish Specialists tasked with the difficult job of evaluating State programs.
Cost Information	No cost will be incurred by the industry or State regulatory agencies.
Action by 2019 Task Force III	Recommended referral of Proposal 19-305 to the Regulatory Relations Committee for resolution.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-305.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-305.

Proposal No. 19-307

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Add Audit, Research Management and Training to Standing Committees
Specific NSSP Guide Reference	Constitution of Bylaws and Procedures Article IV. Executive Board, Officers, Committees, Section 10.
Text of Proposal/ Requested Action	**Article IV. Executive Board, Officers, Committees**

Section 1. The Conference shall…

Section 2. The Board shall…

Section 3. The immediate past…

Section 4. The Treaty Tribes…

Section 5. The Board Chairperson…

Section 6. Each Board member…

Section 7. Elected Board members…

Section 8. The Board shall…

Section 9. The Executive Committee…

Section 10. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and will advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairperson. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference:

- Audit Committee
- Education Committee;
- Foreign Relations Committee;
- Laboratory Committee
- Model Ordinance Effectiveness Review Committee;
- Patrol Committee;
- Proposal Review Committee;
- Research Guidance Committee;
- Research Management Committee,
- Resolutions Committee;
- Shellfish Restoration Committee

- Study Design Guidance Committee
- Training Committee
- Vibrio Illness Review Committee; and
- *Vibrio* Management Committee.

The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Biennial Meeting.

Public Health Significance	The committees that are being proposed as standing committees provide ongoing support for conference activities.
Cost Information	
Action by 2019 Task Force III	Recommended adoption of Proposal 19-307 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-307.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-307.

Proposal No. 19-308

Submitter	ISSC Executive Office Interstate Shellfish Sanitation Conference issc@issc.org
Proposal Subject	Standardization Definitions
Specific NSSP Guide Reference	Section I. Purpose and Definitions, Definitions
Text of Proposal/ Requested Action	**(120)** ~~**State**~~ **Shellfish Standardization Inspector** means a person that has successfully completed the FDA Shellfish Plant ~~s~~Standardization training course (or one deemed acceptable by the FDA and the field evaluation phase of shellfish plant inspection with either an FDA Shellfish Specialist standardization officer or a ~~State~~ standardization officer). **(121)** ~~**State**~~ **Shellfish Standardization Officer** means a person that has successfully completed the FDA Shellfish Plant ~~s~~Standardization training course and the field evaluation phase of shellfish plant inspection with an FDA ~~standardization~~ standardized Shellfish Specialist or the National Shellfish Standard.~~officer.~~
Public Health Significance	States should be deleted from the titles because MOU countries as well as states are required to be standardized. The other changes are included to reflect actual practice.
Cost Information	
Action by 2019 Task Force III	Recommended adoption of Proposal 19-308 as submitted.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-308.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-308.

Submitter	Danielle Schools Virginia Department of Health, Division of Shellfish Safety Danielle.Schools@vdh.virginia.gov
Proposal Subject	Plant Element Evaluation Criteria
Specific NSSP Guide Reference	Section II Model Ordinance – Chapter I. Shellfish Sanitation Program for the Authority
Text of Proposal/ Requested Action	4. Plants Requirements for evaluation of the shellfish plant inspection program elements shall include at a minimum: a. Records audit of past shellfish processing facility inspections for a time frame not to exceed two certification periods. The number of files to be reviewed shall be based upon a representative sampling plan designed to provide a 95 percent probability of detecting a 20 percent or greater defect level. The ratio should be based upon the certification type of plants within that State's inventory (i.e. if 50% of plants are Shucker Packers, then 50% of the plants selected for evaluation should be Shucker Packers). b. ~~Direct observation of current shellfish processing facility conditions;~~ Evaluations of SSO(s), either via maintenance inspections or actual standardization depending on the expiration date of current SSO(s) during the plant element evaluation following the standardization protocol outlined in the NSSP MO Section IV Guidance Documents- Chapter III Harvesting, Handling, Processing and Distribution. No more than two SSOs will be evaluated per evaluation and no more than five maintenance inspections will be performed per SSO, not to exceed a total of ten inspections. For states having less than five plants during years when actual standardization is not required, the existing number of plants will be used for the SSO maintenance inspections. c. Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program. d. Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria evaluated during the file review: i. All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish. ii. ~~95~~ 90% of the certified dealers evaluated in the file review must have been inspected by the State at the frequency required by the current Guide for the Control of Molluscan Shellfish. iii. Where compliance schedules are required, no more than 10% of the certified dealers evaluated in the file review will be without such schedules. iv. States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated during the file review, and if the compliance schedules were not met, that proper administrative action

was taken by the State.

v. All critical deficiencies identified in the file review have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.

e. Plant Evaluation Criteria

i. Legal Authority – Chapter I @ .01 B.

The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer Certification requirements listed in Chapter I @ .01 and @ 02. [Critical]

ii. Initial Certification – Chapter I @ .02 B.

The Plant Sanitation Element will be deemed in compliance with this requirement when all plants reviewed in the file review are certified in accordance with criteria listed below:

(a) HACCP requirements:

(i) A HACCP plan accepted by the Authority

(ii) No critical deficiencies;

(iii) Not more than two (2) key deficiencies;

(iv) Not more than two (2) other deficiencies.

(b) Sanitation and additional Model Ordinance Requirements:

(i) No critical deficiencies;

(ii) Not more than two (2) key deficiencies;

(iii) Not more than three (3) other deficiencies.

iii. Inspection frequency– Chapter I @ .02 F. and G.

The Plant Sanitation Element will be deemed in compliance with this requirement when during the file review , ~~one (1) or~~ 10% or less ~~-~~ of plants ~~inspected~~ do~~esn't~~not meet the required inspection frequency ~~.~~

iv. Compliance schedules.

The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated during the file review are found to be without schedules.

v. Follow-Up.

The Plant Sanitation Element will be deemed in compliance with this requirement when the State demonstrates that they have performed proper follow-up for compliance schedules for 90% of dealers evaluated in the file review and if the compliance schedules were not met that administrative action was taken.

vi. Deficiency Follow-up.

The Plant Sanitation Element will be deemed in compliance with this requirement when the State demonstrates via the file review and/or other supporting documentation that all critical deficiencies have been addressed

vii. ~~In-Field Plant Criteria.~~SSO(s) Standardization Maintenance

~~Certified plants will be evaluated to determine compliance with the criteria~~

~~listed~~
~~below:~~
~~(a) Shucker/packers and repackers HACCP requirements:~~
~~(i) A HACCP plan accepted by the Authority;~~
~~(ii) No critical deficiencies; and~~
~~(iii) Not more than four (4) key deficiencies.~~
~~(b) Shucker/packers and repackers sanitation and additional Model Ordinance requirements:~~
~~(i) No critical deficiencies; and~~
~~(ii) Not more than four (4) key deficiencies.~~
~~(c) Shellstock shippers and reshippers HACCP requirements:~~
~~(i) A HACCP plan accepted by the authority;~~
~~(ii) No critical deficiencies; and~~
~~(iii)Not more than three (3) key deficiencies.~~
~~(d) Shellstock shippers and reshippers sanitation and additional Model Ordinance requirements~~
~~(i) No critical deficiencies; and~~
~~(ii) Not more than three (3) key deficiencies.~~

The Plant Sanitation Element will be deemed in compliance with this requirement when a SSO(s) achieves standardization and/or successfully meets the requirements for the Performance Criteria described in the NSSP MO Section IV Guidance Documents .02 Shellfish Plant Inspection Standardization Procedures

f. The overall Plant Sanitation Program element will be assigned one (1) of the following conformance designations based on compliance with the criteria listed in Chapter I. @03 B.4

i. Conformance: The program is in compliance with all of the criteria listed above and all plants evaluated are in compliance with Chapter I. @.03 B. 4. e. i-vii.

ii. Conformance with Deficiencies:
The program is in compliance with Chapter I. @ .03 B. 4. e. i ~~– vi. and has 25% or less of plants with deficiencies associated with Chapter I. @ .03 B. 4. e. vii.~~
but does not meet the criteria in one (1) of Chapter I. @.03 B. 4. e. iii. or iv. or v. or vi. and the SSO is given a "Needs Improvement" classification in the sections inspectional equipment and communication as described in the NSSP MO Section IV Guidance Documents.02 Shellfish Plant Inspection Standardization Procedures but is still standardized

iii.Nonconformance: The program is in compliance with Chapter I. @ .03 B. 4. e. i., but, does not meet the criteria in Chapter I. @.03 B. 4. e. ii. ~~or iii. or iv. or v. or vi. or has greater than 25% (but less than 51%) of plants with deficiencies~~

~~associated with Chapter I. @.03 B. 4. e. vii~~ or does not meet the criteria in two (2) of Chapter I. @.03 B. 4. e. iii. or iv. or v. or vi. and the SSO is unable to meet the Performance Criteria described in the NSSP MO Section IV Guidance Documents.02 Shellfish Plant Inspection Standardization Procedures

iv.Major Nonconformance:

~~C. The program has multiple deficiencies. It is non-compliant with Chapter I. @.03 B. 4. e. i., or two (2) or more of Chapter I. @.03 B. 4. e. ii., or iii., or iv., or v., or vi., or 51% or greater of plants with deficiencies associated with Chapter I. @.03 B. 4. e. vii.~~ The program is non-compliant with both Chapter I. @ .03 B. 4. e. i and Chapter 1. @03 B. 4. e. ii, or does not meet the criteria in three (3) of Chapter I. @.03 B. 4. e. iii. or iv. or v. or vi. and the SSO is unable to meet the Performance Criteria described in the NSSP MO Section IV Guidance Documents.02 Shellfish Plant Inspection Standardization Procedures FDA will follow the current compliance program for communication with the State agencies.

~~D. All deficiencies observed by FDA while conducting the in-plant inspection portion of the evaluation will be documented and included in the compliance determination outlined in Chapter I. @.03B.4.e.ii.~~

Public Health Significance

The Plant Element Evaluations conducted by FDA should be a comprehensive evaluation of the State Shellfish Control Authority's (SSCA) ability to promote the protection of public health as it relates to the handing of shellfish. State program audits should have a high level of uniformity and effectiveness in the actual audit criteria. The Plant Element Evaluation Criteria should focus on the actual SSCA's administration of the program with objective measurable items, which represent the SSCA work efforts along with a focus on the State Shellfish Standardization Officers (SSO). The SSCA SSO(s) are responsible for the standardization of the SSCA inspection staff and the NSSP MO already provides a methodology for the standardization and maintenance of the SSO staff which FDA can evaluate as part of the plant element evaluation criteria. The states participating in the ISSC do not all have the same amount or type of dealers. Geographic differences also exist in relation to producing states versus states consisting of mostly secondary processors. Because of this diversity in plant inventory amongst the States , the current in plant criteria element of the plant element evaluation in which FDA Specialist conduct actual inspections at a shellfish dealers facility cannot be uniform in implementation amongst States and does not uniformly assess a SSCA. The inclusion of actual plant inspections and the results of the individual dealer's compliance is not reflective of the SSCAs compliance with the NSSP as the in plant dealer evaluations are only assessments of the actual dealer, for which outside of a regulatory inspection or enforcement actions, the SSCA has no control. For example, a SSCA has no control over a refrigeration unit failing to maintain temperature on any particular day, a septic system failing due to age, a sewage back up, a roach infestation, and so on. Inspections of Shellfish dealer facilities are not true evaluations of the SSCA program's compliance with the NSSP.

	Focusing on the file review along with an evaluation of the State Shellfish Standardization Officer's (SSO) performance during actual standardization or standardization maintenance evaluations as a program element to be evaluated is key to assessing the uniform implementation of the NSSP MO.
Cost Information	None
Action by 2019 Task Force III	Recommended referral of 19-310 to the NSSP Evaluation committee. The NSSP Evaluation Committee is requested to immediately address concerns associated with the In-Field Plant Criteria and the development of recommendations for Executive Board interim action at the 2020 Spring Board meeting. Additionally, Task Force II recommends the suspension of In-Field Plant Criteria until the Executive Board provides modified criteria.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-310.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-310.

Proposal No. 19-311

Submitter	Kirk Wiles Department of State Health Services kirk.wiles@dshs.texas.gov
Proposal Subject	NSSP Plant and Shipping Evaluation Criteria
Specific NSSP Guide Reference	Section II. Chapter I Shellfish Sanitation Program for the Authority @.02 Dealer Certification Section II. Chapter I Shellfish Sanitation Program for the Authority @.03 Evaluation of Shellfish Sanitation Program Elements
Text of Proposal/ Requested Action	Request that the NSSP Evaluation Committee consider changes to the Evaluation of Shellfish Sanitation Program Elements related to plants. It is requested that the committee review the Cooperative Milk Program State Evaluation process and consider incorporating pertinent aspects into the Shellfish Plant Program element evaluation of state programs. The committee should specifically consider changes to include but are not limited to: • Developing a numerical score for plant inspections. • Using the numerical score to provide an average score for plants during the FDA In-Field Evaluation. This would be a better reflection of the true status of the plants that considers high performing plants as well as low performing plants. • Evaluating a state on model ordinance requirements of the authority to establish an authority performance rating. • Separating plant performance from authority and establish a plant performance rating based on a numerical average score of plants. The current plant element state evaluation is primarily dependent on In-Field Plant criteria. The current designations are in most cases dependent upon plant performance based upon a one-day evaluation by FDA. The criteria is based on plant failures with no credit toward plants that are high performing. The Authorities have model ordinance requirements in the plant element. State performance should be evaluated on those requirements. Authority performance and industry performance should be evaluated separately.
Public Health Significance	Changing the focus of the plant element evaluation away from plant performance would ensure that states are following model ordinance requirements that protect public health. Using the current In-Field evaluation process represents a one-day snap shot of industry performance. It is not reflective of whether the authority is meeting requirement of the model ordinance. Separating industry performance from the performance of the authority will encourage long term improvement in state implementation of model ordinance plant element requirements.
Cost Information	No cost increases.

Action by 2019 Task Force III	Recommended referral of Proposal 19-311 to the NSSP Evaluation Criteria Committee.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-311.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-311.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Plant and Shipping Element Evaluation Criteria
Specific NSSP Guide Reference	Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority @.03 B. 4.
Text of Proposal/ Requested Action	We have been using the plant and shipping evaluation criteria for approximately 10 years and have identified some areas that need review. FDA requests that the NSSP Evaluation Criteria Committee be charged with reviewing the criteria, especially with respect to these areas of concern: (1) In-field Plant Criteria (2) Compliance Schedules (3) Follow-Up for Compliance Schedules (4) Conformance Designations
Public Health Significance	Many states have expressed concerns to FDA and the ISSC Executive Office surrounding the Plant and Shipping evaluation criteria. In addition, FDA has identified its own concerns with the implementation of the criteria.
Cost Information	No additional cost
Action by 2019 Task Force III	Recommended referral of Proposal 19-312 to the NSSP Evaluation Criteria Committee
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-312.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-312.

Proposal No. 17-204

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Add in-field Compliance Criteria for Control of Harvest Element
Specific NSSP Guide Reference	Section II. Model Ordinance - Chapter I@03B.3
Text of Proposal/ Requested Action	3. ~~Patrol~~ Control of Harvest (Change "Patrol Element" to "Control of Harvest Element" in Chapter I@03B.3 Section.) a. Requirements for evaluation …. (new) i. In-field (Harvester) Compliance Criteria i. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities. **95% of harvesters have valid license Critical** ii. Each harvester shall obtain Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required harvest, handling, and transportation practices as determined by the Authority. A harvester shall be allowed ninety (90) days following initial licensing to obtain the required education. A harvester shall obtain proof of completion of the required training. Proof of training obtained by the harvester shall be presented to the Authority prior to certification, recertification, or licensing. At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training. The harvester shall maintain record of the completed training. **100% of licensed harvesters have required training within specified time.Critical** iii. Harvesters. Any harvester who engages in shellfish packing as defined in this Ordinance shall: Be a dealer; or Pack shellstock for a dealer. **95% of harvesters engaging in shellfish packing meet this requirementCritical** iv. Non-Vessel Harvesting. Harvesters shall assure shellstock are harvested, handled, and transported to prevent contamination, deterioration, and decomposition. **95% of the non-vessel harvesters meet this requirement Key** v. Vessels. The operator shall assure that all vessels used to harvest and transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the shellstock. **95% of the harvest vessels meet this requirement Key** Cats, dogs, and other animals shall not be allowed on vessels.

95% of the harvest vessels meet this requirement Key

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

100% of harvest vessels meet this requirement Critical

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

95% of the harvest vessels meet this requirement Critical

~~i.~~vi. Shellstock Washing. The harvester shall be primarily responsible for washing shellstock.

If shellstock washing is not feasible at the time of harvest, the dealer shall assume this responsibility. Water used for shellstock washing shall be obtained from: A potable water source; or a growing area in the: Approved classification; or in the open status of the conditionally approved classification.

If the harvester or dealer elects to use tanks or a recirculating water system to wash shellstock, the shellstock washing activity shall be constructed, operated, and maintained in accordance with Chapter XI. 02 A. (3) and Chapter XIII. 02 A. (3).

95% of the harvesters meet this requirement Critical

vii. Shellstock Identification. Each harvester shall affix a tag that meets Chapter VIII.02.F to each container of shellstock which shall be in place while the shellstock is being transported to a dealer.

95% of the harvesters meet this requirement Critical

viii. Bulk tagging of a lot of shellstock during transport from harvest area to the dealer facilities meets the requirements of Chapter VIII02.F(7).

95% of the harvesters utilizing bulk tagging meet this requirementCritical

ix. Shellstock Temperature Control. All harvesters shall comply with the applicable time to temperature requirements of a State *V.v.* and *V.p.* Control Plans outlined in Chapter II. @.06 and @.07; or Chapter VIII. @.02 Shellstock Time to Temperature Controls A. (3). All harvesters shall provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements.

95% of the harvesters meet these requirements Critical

j~~i~~. The following procedures will be implemented when an FDA evaluation identifies

deficiencies with the above ~~patrol~~ Control of Harvest evaluation criteria.

i. The overall ~~Patrol Program~~ Control of Harvest element will be assigned one of the following designations:
   (a) **Conformance:** The program is in compliance with all of the criteria listed above.
   (b) **Conformance with Deficiencies:** The program only has minor deficiencies associated with a key compliance item.
   (c) **Non-Conformance:** The program has:
      i. at least one (1) critical deficiency;
      ii. ~~two (2)~~ four (4) or more key deficiencies; or
      iii. a repeat **[Key]** deficiency from the previous evaluation.
   (d) **Major Non-Conformance:** The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest in harvest restricted waters.

ii. ….

Public Health Significance	Adds in-field compliance criteria to address Control of Harvest Element evaluation activities related to NSSP MO Chapter VIII Requirements for Harvesters. Proposal will bring in the in-field compliance criteria which is similar to plant compliance criteria which have administrative and in-field components.
Cost Information	NA
Action by 2017 Task Force II	Recommended referral of Proposal 17-204 to an appropriate committee as determined by the Conference Chair with instructions that this proposal be assigned to the appropriate multiple committees.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-204.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-204.
Action by 2019 NSSP Evaluation Criteria	Recommends the Conference Chairperson establish a workgroup including members from the NSSP Evaluation Criteria Committee and the Patrol Committee to review and make recommendations to the conference on proposal 17-204 working with FDA to consider consistency and uniformity of evaluation criteria for all program elements.
Action by 2019 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 17-204.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 17-204.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-204.