ISSC

Interstate Shellfish Sanitation Conference

SUMMARY OF ACTIONS

2023 Biennial Meeting

Baton Rouge, Louisiana
March 18-22, 2023

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.

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~~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.
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.

Recommended 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.
Action by 2023	

Aquaculture Committee Recommended:

1. Adoption of revised Chapter VI. Guidance language

Section IV Guidance Documents – Chapter VI. Shellfish Aquaculture or Section III Public Health Reasons and Explanations

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. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

Introduction

This chapter provides guidance on NSSP standards intended to address human health hazards specifically associated with molluscan shellfish aquaculture activities covered under Chapter VI. of the NSSP Model Ordinance requirements. Additional information concerning the disease-causing potential of molluscan shellfish can be found in the NSSP Model Ordinance Guidance Documents: G*uidance for Developing Marine Biotoxin Contingency Plan, Sanitary Survey and the Classification of Growing Waters*, and *Shellstock Relay*.

For the purposes of the NSSP Model Ordinance, Aquaculture is defined as the cultivation of bivalve shellfish in controlled conditions for human consumption. This includes cultivation of molluscan shellfish in natural water bodies or man-made systems. Aquaculture can also include the cultivation of molluscan shellfish with non-molluscan species in a common aquaculture system known as polyculture. Bivalve shellfish raised in open water aquaculture operations are generally subject to the same potential for contamination as naturally occurring bivalve shellfish populations. As a result, there is substantial overlap in the sanitary controls within the NSSP Model Ordinance for bivalve shellfish harvested from aquaculture operations and those harvested from naturally occurring populations. There are potential human health concerns specific to land-based or recirculating aquaculture that may require the implementation of operation specific management measures. Activities such as relaying, wet storage, depuration, growing area classification and tagging, are regulated under their respective NSSP Model Ordinance chapters. Aquaculture activities regulated underChapter VI. of the NSSP Model Ordinance are those unique to aquaculture operations and have the potential to pose a significant public health concern if not properly managed. As outlined in Chapter VI @.01A, these include, but are not limited to:

(1) Natural seed collection and/or the rearing of larvae and seed shellfish in growing

areas and/or hatcheries and nurseries in, or using, waters classified as Prohibited or Unclassified;

(2) Aquaculture activities that include off-bottom structures that may attract bird and/or mammal congregations to the extent that their waste may present a human health risk; and,

(3) Land-based aquaculture operations and/or Poly Culture.

Hatcheries and Nurseries- Exemptions and Exceptions to Chapter VI

Chapter VI. makes certain exemptions and exceptions for hatcheries and nurseries rearing larvae and/or seed that are located in, or draw water from, growing areas in the Approved or Conditionally Approved classifications. Hatcheries and nurseries rearing larvae and/or seed that are located in, or draw water from, growing areas in the the Restricted or Conditionally Restricted classification, are also exempt from these requirements if seed does not exceed the maximum seed size established by the Authority under Chapter VI @ .02 (A) or if they adhere to the relay requirements in Chapter V for seed that exceeds the maximum seed size established by the Authority per Chapter VI @ .02 (A).

Requirements for the Authority

To meet the requirements for shellfish aquaculture in Chapter VI, the Authority must have an adequate legal basis, and established procedures, to regulate aquaculture activities outlined in Chapter VI @.01A that occur within their jurisdiction. At a minimum, this includes oversight over the issuance of permits, the [1]review and approval of operational plans for any operations conducting activities in Chapter VI @.01A., and the ability to inspect such operations at least annually to verify that appropriate permits are up to date and operational plans are being implemented. It may also be necessary, based on the aquaculture operations practiced in a jurisdiction, for the Authority to impose additional control measures or recordkeeping requirements upon aquaculture practitioners in the form of regulation, policies, and/or enforceable permit conditions or operational plans Discussion of additional Authority imposed control measures and associated responsibilities are found under their respective subheading.

Requirements for the Harvester/Dealer (Aquaculture Operator)

It is the responsibility of the operator of an aquaculture facility to verify compliance with NSSP MO requirements, and associated local rules and regulations, and to obtain the permission of the Authority prior to conducting any of the aquaculture activities outlined in Chapter VI. The operator of an aquaculture facility may also be required to conduct record keeping and implement control measures as outlined in regulation, permit conditions, and/or their operational plan as necessary based on individual aquaculture practices and the requirements of the Authority. It is important to note that in many states the Authority does not require formal operational plans, rather the required elements of operational plans listed below are included in permit application materials and as regulations and/or enforceable permit conditions. Discussion of additional harvester control measures and responsibilities are found under their respective subheading.

Seed Production in Water Classified as Prohibited or Unclassified

When adequate controls are implemented, natural seed collection and/or the rearing

[1]

of larvae and seed shellstock in growing areas and/or hatcheries and nurseries located in, or using, waters classified as prohibited or unclassified, provides aquaculturists the opportunity to access shellstock resources or utilize areas or waters for seed production that would otherwise not be available for the production of shellstock intended for direct human consumption. Often areas that are unclassified or classified as prohibited due to real or potential pollution (such as marinas, boat yards, etc.) are ideal locations for hatchery or nursery operations due to their proximity to physical infrastructure (docks and piers, freshwater, electricity) and other factors (i.e. protection to wave action, ease of access, security, etc.) important to hatchery and nursery production.

The harvesting of shellstock from unclassified areas or areas in the prohibited classification is not allowed for any purpose, except depletion, gathering of seed or hatchery and nursery production. The use of prohibited or unclassified waters for the gathering of natural seed and/or hatchery and nursery production is acceptable because these operations do not produce shellstock for direct consumption; rather, the seed produced/gathered is moved to Restricted, Conditionally Restricted, or Approved areas in for grow-out prior to harvest for consumption. Research has shown that shellstock has the ability to purge itself of microbial pathogens and certain chemical contaminants over time when moved to clean saline water. In addition, limited exposure during early life stages to lipophilic or other contaminants that cannot be easily purged from shellstock does not constitute a public health hazard if the shellstock are moved to clean waters while these contaminants still represent a small constituent of the total shellstock tissue mass. As a result, seed from prohibited or unclassified areas does not pose a risk to public health provided the Authority ensures they are relocated to suitable waters and provided adequate time for the reduction of contaminants and growth prior to harvest for consumption. *For more information see Section IV Guidance Documents – Chapter II. Growing Areas*.

Maximum Seed Size

Section II Chapter VI @ .02 requires the Authority to sanction (permit) all sources of seed produced or collected in unclassified or prohibited waters, and to establish a maximum seed size for each species of shellfish that are produced in unclassified or prohibited waters. The Authority must set the maximum seed size to ensure a minimum of 120 days of growing to reach market size following movement from unclassified or prohibited waters to waters in other classifications. This period of growth is intended to ensure any potential contaminants accumulated in seed shellstock tissues while being reared in unclassified or prohibited waters will represent a small constituent of the total tissue mass at harvest. 120 days also provides sufficient time for the purging of any bacterial or viral pathogens.

A maximum seed size may be established via regulation, enforceable permit conditions, or within an individual aquaculture operations enforceable operational plan. To determine the appropriate maximum seed size for each species, the Authority may choose to rely on existing locally appropriate data or conduct species specific studies. Growth rates vary across and within regions and can be influenced by a number of environmental factors (i.e. temperature, food availability and quality), genetics (i.e. triploid vs. diploid), and culture practices (i.e. stocking density, on-bottom vs off-bottom). It is also common to see differential growth rates between individual shellfish within a single nursery system. Some hatchery and nursery activities are considered self-limiting with regards to the size of shellstock they can support (i.e. spat on shell, etc.). In such systems, shellstock are likely to be moved to clean waters and remain there for far longer than 120 days prior to harvest. For wild seed collection and other types of nursery activities (upwellers, floating nursery bags, etc.), operators may wait to move shellstock to clean waters until they are close to the

maximum seed size. In these cases operators must closely monitor growth rates to ensure shellstock does not exceed the maximum seed size and trigger the need for corrective actions.

The NSSP MO requires the Authority and operator to establish appropriate corrective actions, as required in Chapter VI .03 (B), for when seed that has been produced in waters classified as prohibited or unclassified exceeds the maximum size. With few exceptions, the seed will generally need to be destroyed or moved to a restoration site sanctioned by the Authority. It is critical that the Authority and aquaculture operators work together to ensure the establishment of a maximum seed size that is consistent with production practices and local environmental conditions, and ensures the minimum 120 days prior to harvest to prevent unnecessary loss of shellstock. Corrective actions may be established via regulation, enforceable permit conditions, or within an individual aquaculture operation's enforceable operational plan. If corrective actions are required, it is recommended that the operation and/or Authority adjust practices and/or reevaluate permit conditions and/or the operational plan to prevent further violation of maximum seed size requirements.

An important factor in determining the maximum seed size is if the Authority has established a market or legal harvest size for each species produced in waters classified as prohibited or unclassified. In states where a minimum enforceable market (AKA harvest) size is in place, it may be possible to establish a relatively larger maximum seed size and have sufficient confidence, and a legal basis, to ensure seed shellstock originating from waters classified as prohibited or unclassified will not be harvested prior to the required 120 days, without requiring additional record keeping, segregation, or other measures. In cases where a state does not have an established minimum market size, and are relying on long established market standards to base the determination of an appropriate maximum seed size, it is likely a conservative maximum seed size, and/or additional measures such as record keeping, segregation, or other measures will be required as an enforceable permit condition or enforceable element of an operational plan to provide verifiable compliance with the 120 day requirement. Alternatively, the Authority may allow an operator to adopt a minimum harvest size as an element of their enforceable operational plan and possibly forgo or reduce the need for record keeping, segregation, or other measures.

Operational Plan

The NSSP MO Section II Chapter VI .03 requires aquaculture operations that collect or culture seed in waters classified as prohibited or unclassified develop a written operational plan and receive approval by the Authority prior to its implementation; such a plan shall at a minimum 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; and,

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

If the information for items #1-4 is provided in permit application materials or as a condition on permits, these may be substituted for inclusion in a formal operational plan. Item #5 is often codified in state regulation, and adherence is agreed upon by the operator when signing their permit(s). In other cases, written operational plans containing elements, or the entirety, of the information required in #1-6 may be used to supplement other documentation provided by the permit holder or applicant to satisfy this requirement. In some instances additional information, such as an operator/Authority agreed upon minimum harvest size, segregation and record keeping protocols for shellstock relocated from prohibited areas, or other elements specific to managing human health risks associated with individual operations and as required by the Authority must be submitted. Any form of enforceable written record of the required information in #1-6, and agreed upon by the Authority, is sufficient to meet the intent of Chapter VI @ .03.

Facility Inspection

If an operation plan is determined to be required for an aquaculture site, the authority must inspect the operation at least annually. The inspection is intended to ensure the operation is adhering to the operational plan, and verify that appropriate permits and any reporting, if required, are up to date.

Aquaculture activities that include off-bottom structures that may attract bird and/or mammal congregations to the extent that their waste may present a human health risk

Microbial contamination from nonpoint pollution sources such as wildlife waste in growing areas represents a public health risk. Wildlife such as birds and/or mammals have been documented to host Campylobacter spp., Salmonella spp., Listeria, E. coli, Vibrio cholerae, Aeromonas spp., Enterococcus spp., and other zoonotic enteric viruses and bacteria within their digestive tract and feces. A number of these pathogens have a low infectious dose, and have the potential for survival and growth during harvest, processing, transportation and storage (Stelma et at. 1991). A detailed summary of zoonotic pathogens of concern to shellfish sanitation is provided in Stelma et at. 1991. While human enteric pathogens can be isolated in the intestinal tracts of a number of species of birds and/or mammals that inhabit coastal and marine waters, the level of risk to shellfish consumers from wildlife waste is not fully understood; however, it is believed to be less than that related to human sources (Stelma 1991). This largely because for pathogens introduced from wildlife waste to result in human infections they must be a strain that is pathogenic to humans and must be ingested at an infectious dose (Smith et al. 2021). The vast majority of enteric pathogen strains isolated from wildlife waste and growing area waters subject to nonpoint wildlife derived pollution have not been associated with reported human infections, and the majority likely do not have the ability to cause illness in humans (Smith et al. 2021; Stelma, 1991).

The use of floating and off-bottom gear, mainly for oyster culture, has increased in recent years due to the benefits these methods provide aquaculturists to avoid sensitive benthic habitats, and for ease of handling, maintenance, and improved

growth rates and survival. However, floating and exposed off-bottom aquaculture gear can provide a roosting platform for various types of birds and/or mammals and become a feeding and defecating site, when these congregations reach sufficient numbers they can present public health concerns.

Increased fecal coliform loading due to congregations of birds and mammals on or around aquaculture structures may result in degradation of water quality to the extent that growing areas no longer meet NSSP criteria outlined in Chapter IV, resulting in growing areas closures, a downgrade in water quality, or potentially a recall of harvested products. Waste associated with congregations of birds and/or mammals on floating and exposed off-bottom aquaculture gear has recently been associated with increased fecal coliform levels in shellfish growing areas and shellfish meats in New York, in some cases requiring growing area closures, and sampling of growing areas and oysters held in floating aquaculture gear prior to reopening of affected areas and farms (NYSDEC). Such actions have had significant adverse impacts on aquaculture operators and highlighted the need to identify potential water quality impacts associated with congregations of birds and mammals on or around aquaculture structures prior to them reaching the level of public health concern.

In addition to concerns associated with water quality degradation, shellstock held in or near structures that serve as a roosting platform for various types of birds and/or mammals may accumulate bird or mammal fecal matter that could serve as a vector for human infections when shellfish are consumed. In the U.S. reports of outbreaks and sporadic infections linked to wildlife contamination of molluscan shellfish are rare, but have been documented. In October, 2021, an investigation indicated that eight people became ill after consuming raw oysters harvested from a small coastal pond in Rhode Island. The illnesses were associated with *Campylobacter jejuni* bacterial contamination linked to the presence of flocks of birds congregating on floating aquaculture gear (RIDOH).

The recent incidence of shellfish derived human infections and water quality issues associated with bird congregations on floating and off bottom gear has prompted management measures focused on mitigating human health concerns related to wildlife congregations on aquaculture sites. Under the growing area classification responsibilities at Chapter VI. *Shellstock Growing Areas* the Authority is required to consider the presence of wild animals or resident and migrating bird populations for possible adverse effects on growing areas, and to identify and evaluate all actual or potential sources of pollution which may affect the growing area during routine water quality sampling, sanitary surveys, triennial, and annual evaluations. Under aquaculture specific provisions in Chapter VI.@04, the Authority is required to evaluate aquaculture sites to determine if the aquaculture operation and the associated culture gear may attract sufficient numbers of birds and/or mammals to the extent that their waste presents a human health risk. If the Authority determines a human health risk may exist or develop, the Authority must require the operator to submit a written operational plan, including mitigation or deterrent measures to minimize the potential pollution impact of birds and/or mammals, to the Authority for approval prior to its implementation. The two separate, yet interrelated, requirements provide a means for the Authority to evaluate risk associated with proposed aquaculture operations and, if necessary, institute deterrent or mitigation measure before they are approved, and a means to evaluate risk associated with existing aquaculture sites on a routine basis via observations and results from water quality sampling, sanitary surveys, triennial, and annual evaluations.

Risk Determination of Aquaculture Operations

Any aquaculture operation utilizing floating gear or other structures that may serve as

a roosting or resting platform for birds or mammals (e.g. work floats, pilings, etc.) has the potential to attract bird and mammal congregations. However, the presence of wildlife, or their waste, on aquaculture gear alone is generally not sufficient to determine if a human health risk may be present. Positioning sampling stations in proximity to aquaculture sites provides a means to evaluate risk associated with existing operations (*See Chapter VI. Shellstock Growing Areas for more information on pollution source sampling)*[1] . Shellstock sampling from existing sites may also provide an indication of potential risk; however, it is important to note fecal coliform counts do not differentiate between human pathogenic and non-pathogenic strains of bacteria, and we currently do not have an estimate of the correlation of human enteric pathogens with coliforms in wildlife waste; although, the risk is considered to be less than that from human derived sources (Stelma, 1991; Smith et al. 2021). Further, there are no bacteriological standards for shellstock meats within the Model Ordinance so an understanding of background levels would likely be necessary to support interpretation of shellfish sampling results.

When evaluating proposed sites the Authority can consider a number of site related factors that may influence whether bird and/or mammal congregations on aquaculture gear may present a risk to human health. These factors include evaluating existing information on the seasonal or year round abundance, type, and behavior of wildlife (e.g. feeding, nesting, migration, etc.), within the growing area where a site is being proposed. An evaluation of site specific hydrodynamic information for the growing area where a site is proposed to be located can also help inform the potential level of risk. Factors such as stratification, tidal magnitude, water depth, current velocity, and wave action can influence the extent to which wildlife waste may become an issue. Areas with minimal currents or flushing may be more susceptible to water quality impacts from smaller congregations of wildlife than those with high current velocities and flushing. Sites proposed within proximity to other facilities that may attract birds and mammals could also increase the risk of gear to serve as roosting platforms for existing populations of birds or mammals in the area. Operation design is also a major consideration for determining if a proposed aquaculture operation may present a risk to human health. The type, extent, and density of exposed gear on the site can impact flushing around gear arrays, and either reduce or increase fecal loading associated with bird and/or mammal waste. Other operation specific practices can be adapted to reduce the potential for a human health concern to develop. For example, floating gear is often used during the nursery and intermediate stages of culture. In areas where the potential risk of human health concerns are high, shellstock may be able to be moved from floating or exposed gear to submerged gear or planted on bottom for a period of time prior to harvest. In addition, the implementation of proactive deterrent measures may provide the Authority with confidence that issues can be avoided before they reach a level of human health concern.

The approach the Authority employs to meet the requirements of Chapter VI.04 will generally be based on the availability of resources to conduct required water quality sampling at existing aquaculture sites, the availability of resources and existing information needed to evaluate risks associated with proposed sites, and the Authority's confidence that bird and/or mammal congregations on aquaculture gear, and the resulting waste, may or may not present a human health risk based on their evaluation and observations. The information necessary to support an evaluation of risk for new and existing aquaculture operations may be derived from a number of sources such as growing area classification information, external sources, and/or information provided by the aquaculture operator within application materials or other reporting to the Authority. To the extent possible, aquaculture operators should detail to the Authority within their application materials, or other reporting, any site selection criteria or operational design specifics intended to minimize the potential

pollution impact of birds and/or mammals they are proposing to proactively employ. This will help the Authority determine which of the following approaches to meet the requirements of Chapter VI.04 they will employ.

1. **Monitoring approach**- If the Authority determines that sufficient evidence does not exist to preemptively require new or existing aquaculture operators to adopt mitigation or deterrent measures, they may choose to continue to monitor the growing area in compliance with growing area classification requirements in Chapter IV. The monitoring should be conducted in a manner that would allow the Authority to identify and address potential human health concerns associated with bird and/or mammal congregations on aquaculture gear, prior to them reaching a level of public health significance. This strategy may require adjusting water quality sampling stations and sampling frequency around aquaculture operations, shellstock meat sampling, microbial source tracking or other forms of directed pathogen sampling, and/or other monitoring or reporting measures as appropriate. In these cases, the Authority and operators should consider the development of procedures to rapidly institute operational plans including deterrent and/or mitigation measures should a concern be identified. The Authority should document any bird and/or mammal congregations on aquaculture sites during aquaculture site inspections, routine water quality monitoring, annual and triennial reviews, and sanitary surveys, and consider adjusting sampling/monitoring frequency around any observed seasonal, or other, trends in wildlife activity.

2. **Preemptive approach**- If the Authority determines that sufficient evidence of a public health concern associated with the use of floating gear exists, or that insufficient resources exist to increase monitoring around new aquaculture operations, they may choose to preemptively require aquaculture operators to provide an operational plan and institute bird and/or mammal mitigation and/or deterrent measures. Alternatively, the Authority may implement industry-wide or operation specific mitigation (e.g. submergence requirements) and/or deterrent measures to minimize impacts from birds and/or mammals via regulation, enforceable permit conditions and/or policies. The Authority should continue to document any bird and/or mammal congregations on aquaculture sites during aquaculture site inspections, routine water quality monitoring, annual and triennial reviews, and sanitary surveys, and monitor water quality within proximity to aquaculture facilities to evaluate efficacy of measure outlines within operation plans.

Operational Plan

Under Chapter VI.04, if the Authority determines that the aquaculture operation and the associated culture gear may attract sufficient numbers of birds and/or mammals to the extent that their waste presents a human health risk, the operator is required to enact mitigation measures as a component of an operational plan. The plan shall be approved by the Authority prior to its implementation and include:

1. A description of the design and activities of the culture facility;

2. The specific site(s) and boundaries in which the 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. A description of the mitigation or deterrent measures to minimize the potential pollution impact of birds and/or mammals; and

7. Maintenance of the required records.

If the information for items #1-4 & 6-7 is provided in permit application materials or on final permits, these may be substituted for inclusion in a formal operational plan. Likewise, #5 is often codified in state and/or federal regulation, and adherence is agreed upon by the operator when signing their permit(s) or by law. In other cases written operational plans containing elements, or the entirety, of the information required in #1-7 may be submitted. Any form of enforceable written record of these items is sufficient to meet the intent of Chapter VI @ .04. To meet the requirements of #6, if necessary, the written operational plan or application materials should clearly describe any operational, maintenance, handling and/or sanitary practices for the aquaculture gear and shellfish that will be conducted to prevent contamination of the growing area from waste attributed to congregations of birds and/or mammals on aquaculture structures. This may include a written description, sketches and/or photos of deterrents or mitigation measures to be used. Strategies may include a suite of deterrents (i.e. kites, cannons, sprinklers, spikes etc.) or mitigation measures (e.g. submerging gear and shellfish prior to harvest, relocating floating gear to areas with significant flow, seasonal harvest restrictions, configuring farm sites to maximize flushing, etc.) that will address human health concerns related to year-round or seasonal congregations of birds and/or mammals. In addition, plans should address evaluation of the efficacy of deterrent and/or mitigation measures, and potential triggers that would require changing or adapting deterrent or mitigation measures to address new bird or mammal species and/or behavioral changes, and amendments should be made to the plan, as needed, based on changes to the culture operation, gear, and/or reduced efficacy of the approved deterrents and/or mitigation measures employed by the aquaculture operator.

Facility Inspection

If an operation plan is determined to be required for an aquaculture site, the authority must inspect the operation at least annually. The inspection is intended to ensure the operation is adhering to the operational plan, verify that appropriate permits are up to date, and that control measures to prevent possible adverse public health effects from birds or mammals are effective. In addition, the Authority should continue to document any bird and/or mammal congregations on aquaculture sites during, routine water quality monitoring, sanitary surveys, triennial, and annual evaluations, and continue monitor water quality within proximity to aquaculture facilities to evaluate efficacy of mitigation and/or deterrent measure outlined within operation plans. The Authority should consider the development of written protocols associated with evaluating the effectiveness of the deterrents and/or mitigation strategies. If the Authority or Operator documents large congregations of birds and/or mammals on

aquaculture gear, and/or an accumulation of fecal matter, an evaluation of the efficacy of current control measures may be necessary to determine if additional control measures are needed.

Polyculture and Land-based Aquaculture Considerations

Polyculture and land-based monoculture operations must be under adequate control to assure the shellstock product harvested will be acceptable for human consumption. The Authority must establish detailed procedures for issuing permits for shellfish aquaculture, approving culturing facilities and boundaries, controlling of harvesting, sampling of shellstock, monitoring environmental parameters, keeping records, imposing quarantine measures, controlling the use of animal drugs to stimulate growth or treat diseases, and developing other control measures as may be necessary.

The Authority should work with FDA in its review of the plans for a land based aquaculture operation. Of particular concern in land-based systems is the use of a closed or recirculating water system. Potential exists for shellstock contamination through the failure of the water treatment system to sufficiently disinfect the water to control levels of human pathogens that might be introduced through the water supply or other means. There is also potential for the increased concentration of poisonous and deleterious substances such as animal drugs or antifouling agents in the water supply and subsequently the shellstock over time.

Prior to the harvest of shellstock from land-based systems for sale in interstate commerce, the aquaculturist must demonstrate that the water in the land-based system meets the NSSP Model Ordinance criteria for direct sale of shellstock to the consumer. If the water supply does not meet those criteria, the aquaculturist must subject the shellstock to relaying or depuration prior to sale. For more information related to Relay or Depuration, see Chapters V and XV, respectively.

The cultivation of shellfish with other species in a common aquaculture system is known as polyculture. There are some additional public health concerns related to polyculture. Greater potential may exist for contamination of oysters, clams, mussels and scallops with human pathogens and animal drugs in polyculture. However, the extent of that potential is not known. The extensive use of tanks, sea enclosures, floating rafts, ponds, etc. in polyculture makes the oysters, clams, mussels or scallops highly vulnerable to pollution from various sources, including their association with the other species present in the polyculture operation. The usage of anti-fouling agents (tributyltin, copper, etc.), hormones, and antibiotics in finfish aquaculture has evoked concern about its environmental effects and potential threat to human health through bioaccumulation in shellfish. Therefore, a conservative approach to polyculture is provided in the NSSP Model Ordinance requirements.

.05 Land Based Aquaculture

a. Need for polyculture and land-based monoculture operations to be under sanitary control. Potential increased consumer risk due to land-based operations.

b. Public health concerns of polyculture elaborated on

c. Conservative approach suggested

d. Authority must establish procedures for issuing permits, approving culturing sites and boundaries, controlling harvest, sampling of shellstock, monitoring environmental parameters, e. Authority encouraged to work with FDA for review of land-based aquaculture operation plans

.06 Polyculture Systems

A polyculture system shall: A. Meet all requirements in Section .05 Land Based Systems; B. Provide information concerning all sources and species of all organisms to be cultivated, cultured, and harvested; and 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.

Facility Inspections

If an operation plan is determined to be required for an aquaculture site, the authority must inspect the operation at least annually. The inspection is intended to ensure the operation is adhering to the operational plan, verify that appropriate permits and any reporting, if required, are up to date.

Citations

Stelma, G.N. and L.J. McCabe. 1990. Non-point pollution from animal sources and shellfish sanitation. J. of Food Protection. Vol. 55, No. 8, pp.649 -656.

Smith, O.M., Snyder, W.E. and Owen, J.P. (2020), Are we overestimating risk of enteric pathogen spillover from wild birds to humans?. Biol Rev, 95: 652-679. https://doi.org/10.1111/brv.12581

The Rhode Island Department of Health (RIDOH) Potters Pond Closed to Shellfish Harvesting. [(accessed on 1 July 2022)]; Available online: https://www.ri.gov/press/view/42081

2) Allow the Aquaculture Committee to continue to refine Chapter VI. Guidance on aspects related to managing human health concerns from bird and mammal congregations on aquaculture gear.

Action by 2023 Task Force I

Recommended adoption of the Aquaculture Committee recommendations on Proposal 13-107 with the word “cannon” struck.

If the information for items #1-4 & 6-7 is provided in permit application materials or on final permits, these may be substituted for inclusion in a formal operational plan. Likewise, #5 is often codified in state and/or federal regulation, and adherence is agreed upon by the operator when signing their permit(s) or by law. In other cases written operational plans containing elements, or the entirety, of the information

required in #1-7 may be submitted. Any form of enforceable written record of these items is sufficient to meet the intent of Chapter VI @ .04. To meet the requirements of #6, if necessary, the written operational plan or application materials should clearly describe any operational, maintenance, handling and/or sanitary practices for the aquaculture gear and shellfish that will be conducted to prevent contamination of the growing area from waste attributed to congregations of birds and/or mammals on aquaculture structures. This may include a written description, sketches and/or photos of deterrents or mitigation measures to be used. Strategies may include a suite of deterrents (i.e. kites, ~~cannons~~, sprinklers, spikes etc.) or mitigation measures (e.g. submerging gear and shellfish prior to harvest, relocating floating gear to areas with significant flow, seasonal harvest restrictions, configuring farm sites to maximize flushing, etc.) that will address human health concerns related to year-round or seasonal congregations of birds and/or mammals. In addition, plans should address evaluation of the efficacy of deterrent and/or mitigation measures, and potential triggers that would require changing or adapting deterrent or mitigation measures to address new bird or mammal species and/or behavioral changes, and amendments should be made to the plan, as needed, based on changes to the culture operation, gear, and/or reduced efficacy of the approved deterrents and/or mitigation measures employed by the aquaculture operator.

Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-107.
Action by FDA July 7, 2023	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 January 11, 2016	Concurred with Conference action on Proposal 13-111.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-111.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	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.
Action by 2023 Laboratory Committee	Recommended no action on Proposal 13-111. Rationale: ISSC Constitution, Bylaws, and Procedures – Procedure XV, Section 7, Subdivision A, states that "the method submitter has eighteen months from the date of the written request from the ISSC to provide the information/data necessary to complete the evaluation of the method. If there is no response from the submitter within this timeframe, the Laboratory Committee will recommend no action on the Proposal."
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 13-111.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-111.
Action by FDA July 7, 2023	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.
Action by 2023 Laboratory Committee	Recommended no action on Proposal 13-114. Rationale: Original submitter is no longer able to pursue this proposal and no other laboratory is available at this time.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 13-114.
Action by 2023 General Assembly	Adopted recommendation of Task Force I on Proposal 13-114.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 13-114.

Proposal No. 15-109

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 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.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 15-109 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 15-109.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 15-109.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 15-109.

Proposal No. 15-112

Submitter	Executive Board Interstate Shellfish Sanitation Conference (ISSC) 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)

	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.
Action by 2023 Laboratory Committee	Recommended no action on Proposal 15-112. Rationale: The DNA probe necessary for this method is no longer available.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 15-112.
Action by 2023 General Assembly	Adopted recommendation of Task Force I on Proposal 15-112.
Action by FDA July 7, 2023	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.
Action by 2023 Laboratory Committee	Recommended adoption of Proposal 15-114 as amended.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 15-114.
Action by 2023 General Assembly	Adopted recommendation of Task Force I on Proposal 15-114.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 15-114.

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.
Action by the 2023 Laboratory Committee	Recommended referral of Proposal 17-103 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 17-103.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-103.
Action by FDA July 7, 2023	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 Force I	Recommended adoption of the Laboratory Committee recommendation on 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.
Action by the 2023 Laboratory Committee	Recommended referral of Proposal 17-106 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 17-106.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-106.
Action by FDA July 7, 2023	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 recommendation of Task Force I on Proposal 17-108.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-108.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 17-108 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 17-108.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-108.
Action by FDA July 7, 2023	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.
Action by 2021 Laboratory Committee	Recommended adoption of Proposal 17-110 as amended with Interim Approval by the Executive Board
Action by 2021 ISSC Executive Board	Granted Interim Approval in effect until the Conference convenes at the 2023 ISSC Biennial Meeting.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 17-110.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-110.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 17-110.

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 frequencywith 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

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

(2)

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.
Action by 2021 Federal Waters Committee	Recommended deletion of the sunset date of November 1, 2021 from Proposal 17-116.
Action by 2021 Executive Board	Granted Interim Approval in effect until the Conference convenes at the 2023 ISSC Biennial Meeting.
Action by 2023 Task Force I	Recommended adoption of the Federal Waters Committee recommendation on Proposal 17-116.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-116.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 17-116.

Proposal No. 19-101

Submitter	Michael Hickey, Jeff Kennedy, Diane Regan Massachusetts Division of Marine Fisheries 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.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 19-101 to an appropriate committee as determined by the Conference Chairperson
Action by 2023 Task Force I	Recommended referral of Proposal 19-101 as amended to the Laboratory Committee with the provision that a recommendation for interim approval be provided at the 2023 Fall Executive Board Meeting.

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

vi. 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.~~

(c~~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;

Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-101.
Action by FDA July 7, 2023	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.
Action by 2023 Supplemental Lab Data	Recommended adoption of Proposal 19-105 as amended.

Chapter III. @.01

A. NSSP Conformance Required for all laboratories supporting the NSSP. For any toxin, pathogen, bacteria, virus, or other contaminant for which there is an action level specified in the NSSP and an Approved NSSP Method or Approved Limited Use Method of detection, ~~A~~all laboratory analyses ~~for compliance with classification requirements that require a specific method, actions level, and use defined in the Model Ordinance~~ generating data to support regulatory decisions 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~~ Chapter I @.03 B. 1.

(1) If there is a toxin, pathogen, bacteria, virus, or other contaminant for which the NSSP has no Approved NSSP Method or Approved Limited Use Method, the Authority may use a non-evaluated laboratory to generate data utilizing the best science available. In these circumstances, the Authority shall follow the procedures and guidelines defined in Chapter III @.02 Methods.

(2) Shellfish growing area closures may be made using data generated in non-evaluated laboratories.

Action by 2023Task Force I	Recommended adoption of the Supplemental Lab Data Committee recommendation on Proposal 19-105.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-105.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-105.

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.
Action by 2023 Aquaculture Committee	Recommended no action on Proposal 19-108. Rationale: There is not sufficient data or need for action.
Action by 2023 Task Force I	Recommended referral of Proposal 19-108 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-108.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-108.

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)I.
Text of Proposal/ Requested Action	I 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.
Action by 2023 Growing Area Classification Committee	Recommended no action on Proposal 19-110. Rationale: The proposed language is redundant with MO Section II, Chapter IV @.02 B, "Water Sample Stations. The Authority shall assure that the number and location of sampling stations is adequate to effectively evaluate all pollution sources."
Action by 2023 Task Force I	Recommended adoption of the Growing Area Classification Committee recommendation on Proposal 19-110.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-110.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-110.

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.
Action by Growing Area Classification Committee	Recommended no action on Proposal 19-112. Rationale: The proposal language is redundant with MO Section II, Chapter IV @.02 B, "Water Sample Stations. The Authority shall assure that the number and location of sampling stations is adequate to effectively evaluate all pollution sources."
Action by 2023 Task Force I	Recommended adoption of the Growing Area Classification Committee recommendation on Proposal 19-112.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-112.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-112.

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

c. 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.

I 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.
Action by 2023 Growing Area Classification Committee	Recommended adoption of Proposal 19-115 as amended.

@.03 Growing Area Classification

c. 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 data 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.~~

~~(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.

I 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:

Action by 2023 Task Force I	Recommended adoption of the Growing Area Classification Committee recommendation on Proposal 19-115.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-115.
Action by FDA July 7, 2023	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.
Action by 2023 Growing Area Classification Committee	Recommended adoption of Proposal 19-116 as amended: (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….
Action by 2023 Task Force I	Recommended adoption of the Growing Area Classification Committee recommendation on Proposal 19-116.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-116.

Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-116.

Proposal No. 19-123

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 t 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, Illness Course	Predominantly neurologic and include tingling of the lips, 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.ht
Diarrhetic Shellfish Poisoning	http://www.fao.org/3/y5486e/y5486e0e.ht
Neurotoxic Shellfish Poisoning	http://www.fao.org/3/y5486e/y5486e0o.ht
Amnesic Shellfish Poisoning	http://www.fao.org/3/y5486e/y5486e0n.ht
Azaspiracid Shellfish Poisoning	http://www.fao.org/3/y5486e/y5486e0p.ht
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_summa

ry.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.

References

Deeds, J.R., & Landsberg, J.H., Etheridge, S.M., Pitcher, G.C., Longan, S.W. (2008). Non-traditional vectors for paralytic shellfish poisoning. *Marine Drugs, 6(2)*, 308-348. Retrieved from https://doi.org/10.3390/md6020308.

Degrasse, S., & Rivera, V., Roach, J., White, K., Callahan, J., Couture, D., Simone K., Peredy, T., Poli, M. (2014). Paralytic shellfish toxins in clinical matric extension of AOAC official method 2005.06 to human urine and serum an application to a 2007 case study in Maine. *Deep Sea Research Part II: Topical Studies in Oceanography*, 103, 368-375. Retrieved from https://doi.org/10.1016/j.dsr2.2012.08.001.

Food and Agriculture Organization of the United Nations. (2015) Codex Alimentar Standard for Live and Raw Bivalve Molluscs Codex Stan 292-2008. Retrie from http://www.fao.org/fao-who-codexalimentarius/codex-texts/all-standards/en/

Food and Agriculture Organization of the United Nations. (2004). FAO Food and Nutrition Papers, 80 - Marine Biotoxins. Retrieved from http://www.fao.org/3/y5486e/y5486e00.htm

Joint Sanitation Seminar on North Pacific Clams Juneau, A., Felsing, W. A. (Willia August)., United States. Public Health Service., Alaska. Dept. of Health an Welfare. (1966). *Proceedings of Joint Sanitation Seminar on North Pacifi Clams.* Washington, D.C.: For sale by the Supt. of Docs., G.P.O.. Retrieve from https://babel.hathitrust.org/cgi/pt?id=pur1.32754081175147&view=1u eq=5

Klontz, K.C., & Abraham, A., Plakas, S., Dickey, R. (2009). Mussel-associated azaspiracid intoxication in the United States. *Annals of Internal Medicine,* 150(5), 361. Retrieved from https://www.researchgate.net/publication/24174858_Mussel-Associated_Azaspiracid_Intoxication_in_the_United_States

Liston, J. (1994). Association of *Vibrionaceae*, natural toxins, and parasites with f indicators, p. 215-216. In Hackney, C.R. and M.D. Pierson (eds.). *Environmental Indicators and Shellfish Safety*. Chapman and Hall, New Yo NY.

Lloyd, J.K., & Duchin, J., Borchert, J., Quintana, H.F., Robertson, A. (2013). Diarrh Shellfish Poisoning, Washington, USA, 2011. Emerging Infectious Diseases 19(8), 1314-1316. Retrieved from https://doi.org/10.3201/eid1908.121824.

Marsden I.D., & Contreras, A.M., MacKenzie, L., Munro, M.H.G. (2015). A comparison of the physiological responses, behaviour and biotransformatio of paralytic shellfish poisoning toxins in a surf-clam (*Paphies donacina*) a the green-lipped mussel (*Perna canaliculus*). *Marine and Freshwater Research,* 67, 1163-1174. Retrieved from http://www.publish.csiro.au/mf/MF14374

McCabe, R.M., & Hickey, B.M., Kudela, R.M., Lefebvre, K.A., Adams, N.G., Bill, B.D., Gulland, F.M.D., Thomson, R.E., Cochlan, W.P., Trainer, V.L. (2016). An unprecedented coastwide toxic algal bloom linked to anomalou ocean conditions. *Geophysical Research Letters,* 43(19), 10,366–10,376. Retrieved from https://DOI.org/10.1002/2016GL070023.

Morris, P.D., & Campbell, D.S., Taylor, T.J., Freeman, J.I. (1991). Clinical and epidemiological features of neurotoxic shellfish poisoning in North Carolin *American Journal of Public Health*, 81(4), 471-474. Retrieved from: https://DOI.org/10.2105/ajph.81.4.471.

National Shellfish Sanitation Workshop., United States. Shellfish Sanitation Branch. (1964). *Proceedings - National Shellfish Sanitation Workshop.* [Washington]: U.S. Dept. of Health, Education, and Welfare, Public Health Service, Food and Drug Administration, Shellfish Sanitation Branch. Retrieved from https://catalog.hathitrust.org/Record/006685147

Perl, T.M., & Bedard, L., Kosatsky, T., Hockin, J.C., Todd, E.C.D., NcNutt, L.A., Remis, R.S. (1990). Amnesic shellfish poisoning: a new clinical syndrome due to domoic acid. In: Hynie, I., Todd, E.C.D., editors. Proceedings of a symposium, domoic acid toxicity. Canada Disease Weekly Report; Ottawa, Ontario. Pp. 7-8.

Prakash, A., & Medcof, J.C., Tennant, A.D. (1971). Paralytic shellfish poisoning i eastern Canada. Bulletin 177, Fisheries Research Board of Canada. Ottawa, Canada. Retrieved from http://dfo-mpo.gc.ca/library/1498.pdf.

Pulido, O.M. (2008). Domoic acid toxicologic pathology: a review. *Marine Drugs, 6(2)*, 180-219. Retrieved from https://doi.org/10.3390/md20080010.

Quayle, D.B. (1969). Paralytic shellfish poisoning in British Columbia. Bulletin 168, Fisheries Research Board of Canada. Ottawa, Canada.

Schwalm, D.J. (1973). The 1972 PSP outbreak in New England. FDA Report, Boston, MA. U.S. Food and Drug Administration, Washington, D.C.

Tong, M., & Smith, J.L., Richlen, M.L., Steidinger, K., Kulis, D., Fux, E., Anderson, D.M. (2014) Characterization and comparison of toxin-producing isolates of *Dinophysis acuminata* from New England and Canada. *Journal of Phycology,* 51(1), 66-81. Retrieved from https://www.researchgate.net/publication/267340694_Characterization_and_comparison_of_toxin-producing_isolates_of_Dinophysis_acuminata_from_New_England_and_Canada .

Trainer, V.L., & Moore, L., Bill, B.D., Adams, N.G., Harrington, N., Borchert,

J., da Silva, D.A.M., Eberhard, B.T.L. (2013). Diarrhetic shellfish toxins and other lipophilic toxins of human health concern in Washington State. *Marine Drugs,* 11, 1815–1835. Retrieved from https://doi.org/10.3390/md11061815.

Twiner, M.J., & Bottein Dechraoui, M.Y., Wang, Z., Mikulski, C.M., Henry, M.S., Pierce, R.H., Doucette, G.J. (2007). Extraction and analysis of lipophilic brevetoxins from the red tide dinoflagellate *Karenia brevis*. *Analytical Biochemistry*, 369(1), 128-135. Retrieved from https://DOI.org/10.1016/j.ab.2007.06.031.

Twiner, M.J., & Rehmann, N., Hess, P., Doucette G.J. (2008). Azaspiracid shellfish poisoning: a review on the chemistry, ecology, and toxicology with an emphasis on human health impacts. *Marine Drugs, 6(2),* 39-72. Retrieved from https://doi.org/10.3390/md6020039.

Uchida, H., & Watanabe, R., Matsushima, R., Oikawa, H., Nagai, S., Kamiyama, T., Baba, K., Miyazono, A., Kosada, Y., Kaga, S., Matsuyama, Y., Suzuki, T. (2018). Toxin profiles of okadaic acid analogues and other lipophilic toxins in Dinophysis from Japanese Coastal Waters. Toxins (Basel). 10(11), 457. Retrieved from https://doi.org/10.3390/toxins10110457 .

US Center for Disease Control. (1973). Shellfish poisoning - Florida. *Morbidity Mortality Weekly Report,* 22(48), 397-398. Retrieved from https://stacks.cdc.gov/view/cdc/1843

US Food and Drug Administration. (1997). Poisonous or Deleterious Substances Food. *Federal Register,* 42(190), 52814-52819.

US Food and Drug Administration. (2000). Guidance for Industry: Action Levels fo Poisonous or Deleterious Substances in Human Food and Animal Feed. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterio substances-human-food-and-animal-feed.

US Food and Drug Administration. (2011). Fish and Fishery Products Hazards and Controls Guidance 4th Edition. Retrieved from https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls-guidance-4th-edition

US Public Health Service (PHS). (1958). Proceedings: 1957 Conference on Shellfis Poison. U.S. PHS, Washington, D.C. 125 pages. Retrieved from https://babel.hathitrust.org/cgi/pt?id=uc1.31822005678131&view=1up eq=7

Watkins, S.M., & Reich, A., Fleming, L.E., Hammond, R. (2008). Neurotoxic shellfish poisoning. *Marine Drugs, 6(3),* 431-455. Retrieved from: https://doi.org/10.3390/md6030431.

Wekell, J.C., & Hurst, J., Lefebvre, K.A. (2004). The origin of the regulatory limits f PSP and ASP toxins in shellfish. *Journal of Shellfish Research*, 23(3), 927- Retrieved from: https://www.researchgate.net/publication/285809374_The_origin_of_ _regulatory_limits_for_PSP_and_ASP_toxins_in_shellfish

Wiese, M., & D'Agostino, P.M., Mihali, T.K., Moffitt, M.C., Neilan, B.A. (2010). Neurotoxic alkaloids: saxitoxin and its analogs. *Marine Drugs*, *8(7),* 2185-2211. Retrieved from https://doi.org/10.3390/md8072185.

~~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 Recommended 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.
Action by 2023 Biotoxin Committee	Recommended adoption of Proposal 19-123 as substituted.

@.04 Marine Biotoxin Control

Marine Biotoxins Overview

Shellfish are filter feeders and, therefore, can 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 human exposure occurs when the shellfish are eaten (Gordan *et al.,* 1973). In most cases, the toxin has no effect on the shellfish itself, and toxin retention times vary by shellfish species. 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 toxin concentration ~~(dose)~~ in the shellfish and amount of shellfish consumed (dose). 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.

~~In most cases, the toxin has no effect on the shellfish itself, and toxin retention times vary by shellfish species. Additionally, there are non-traditional and emerging food~~

~~trends that can cause toxin poisoning. One example is that pufferfish, typically associated with tetrodotoxin, may also contain saxitoxin (e.g., puffers from coastal waters of Florida).~~

Toxic dinoflagellates and~~or~~ diatoms are single-cell marine ~~plants~~ algae 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~~ proliferate ("bloom") seasonally when water conditions are favorable. Blooms of these organisms can occur unexpectedly and accumulate rapidly; or may follow predictable patterns.

~~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, blue-green, red, and pink.~~ The relationship between red tides and biotoxin poisoning is widely misunderstood. Red tide refers to the discoloration of seawater caused by blooms of marine algae.~~, and many people mistakenly believe that shellfish are safe to eat if no red tide is visible.~~ While red tide ~~can~~ may be related to harmful algae, it is helpful to remember that:

- Harmful algal blooms (HABs) may be other colors (e.g. brown and green)~~, including amber, brown, purple, blue, green, and pink~~;
- Marine biotoxin poisoning can happen when there is no discoloration of the water; and
- Several marine algae species that pose no public health risk can cause water discoloration.

Diseases and Outbreaks Overview

Humans are susceptible to shellfish poisoning and although relatively few intoxications have been reported in the United States, fatalities have occurred (CDC 2022, Backer et al, 2015, Newell et al, 2022). Monitoring of water or shellfish for toxins to prevent commercial distribution of contaminated products is protective of public health, however, illnesses may also occur following self-harvest of shellfish (Watkins et al. 2008, Newell et al, 2022). Lack of awareness of closures or monitoring status, disregard for official quarantines, or failure to follow traditions associated with safe consumption might increase the risk of such illnesses.

Diagnosis of shellfish poisoning is generally based on observed symptoms and recent dietary history. Unconsumed shellfish might also be tested for algal toxins (Coleman et al, 2018). 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 (CDC Yellow Book, 2020).

~~All humans are susceptible to shellfish poisoning, although intoxication from commercially harvested product is extremely rare. Instead, a~~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, as well as fishers and recreational harvesters. This may be due to lack of awareness or disregard for either official quarantines or traditions of safe consumption.~~

~~Diagnosis of shellfish poisoning is generally 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.~~

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 or domoic acid poisoning (ASP), diarrhetic shellfish poisoning (DSP) and azaspiracid shellfish poisoning (AZP). ~~ASP (also known as domoic acid poisoning), DSP and 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 exposures. In addition, ASP can cause lasting neurological damage. DSP and AZP cause similar symptoms mostly related to diarrhea and abdominal pain.

Paralytic Shellfish Poisoning (PSP)

~~PSP is caused by saxitoxins produced~~ primarily ~~by the~~ certain ~~dinoflagellates of the genus *Alexandrium* (formerly *Gonyaulax*). The dinoflagellate *Pyrodinium bahamense* is also a producer of saxitoxins.~~ PSP is caused by saxitoxins produced by certain dinoflagellates of the genus *Alexandrium* (formerly *Gonyaulax*), ~~and~~ *Pyrodinium bahamense, and Gymnodinium catenatum*. Potential symptoms of PSP are numerous and can include tingling or numbness in the face, hands, and feet;~~,~~ weakness;~~,~~ slurred speech;~~,~~ difficulty swallowing;~~,~~ shortness of breath;~~,~~ nausea;~~,~~ vomiting;~~,~~ dizziness;~~,~~ headache and high blood pressure. Onset of symptoms is typically rapid (i.e. 30 minutes or less), and death from asphyxiation can occur in some cases (Etheridge 2010 and references therein).

Historically, *Alexandrium* blooms have occurred between April and ~~October~~ December along the Pacific coast~~s~~ 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~~evolving. The blooms generally last only a few weeks, and most shellfish (except for some species of clams and scallops which retain the toxin for longer periods) clear themselves rapidly of the toxin once the bloom dissipates. Toxic blooms can occur unexpectedly or follow predictable patterns.

For example, i~~I~~n 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.~~ In another case, ~~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. After further investigation, ~~It~~ it became~~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).

In 2002, the first saxitoxin event to occur in Florida waters was identified as a result of illnesses caused from consumption of pufferfish caught from the Indian River Lagoon in the Titusville area (Landsberg, 2006). This led to investigating *Pyrodinium bahamense* presence in the lagoon system as this species could cause shellfish toxicity. Shellfish meat samples collected in the Indian River Lagoon for *Pyrodinium bahemense* were found to test positive for saxitoxin. Initial shellfish samples collected showed only trace amounts of saxitoxin. As a result, the State of Florida integrated a monitoring program for PSP in the state's biotoxin management plan as it relates to molluscan shellfish. Over the years Florida has had growing area closures due to PSP but no illnesses due to shellfish consumption. Historically, *Pyrodinium bahamense* blooms have occurred between April and October along the east and west coasts of Florida.

Neurotoxic Shellfish Poisoning (NSP) – ~~TABLE DISCUSSION ON NSP UNTIL NEXT MEETING AS MORE INFROMATION IS NEEDED. NONE OF THE SUGGESTED CHANGES BELOW HAVE BEEN INCORPORATED.~~

From the Carolinas through the Gulf coast states~~In the United States~~, NSP is caused by brevetoxins that are primarily produced by the dinoflagellate *Karenia brevis*~~s of the genus *Karenia*~~ (formerly of the genus *Gymnodinium*). ~~From the Carolinas through the Gulf coast states, 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]). Onset of symptoms can occur within 18 hours of exposure, although an average onset time has been noted as three to four hours following consumption (Grattan et al 2016). Gastrointestinal symptoms are commonly reported, but neurological symptoms such as numbness and tingling in the face, hands, and feet;~~,~~ partial limb paralysis;~~,~~ slurred speech;~~,~~ loss of coordination; and even reversal of hot and cold sensations have also occurred (Watkins et al 2008).~~It regularly produces blooms along the coasts of Florida and Texas. Blooms may cause ocean~~ If seawater is colored, it may 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).~~

Karenia brevis ~~blooms show no indication of regular recurrence and shellfish generally take longer to eliminate the toxin. B~~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. They now regularly occur along the Gulf Coast between Florida and Texas, and a~~A~~lthough more ~~f~~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. If seawater is colored during a bloom, it may appear red, brown, or simply darkened, and blooms are usually accompanied by fish kills and mortalities in marine mammals and sea birds (Watkins, 2008).

Amnesic Shellfish Poisoni~~o~~ng (ASP) ~~– TABLE DISCUSSION ON ASP UNTIL NEXT MEETING AS MORE INFROMATION IS NEEDED about toxin producers and confirm not duplicating language from 19-124.~~

ASP is caused by domoic acid, which is produced by certain diatoms of the genus *Pseudo-nitzschia*. *Pseudo-nitzschia australis* and *Pseudo-nitzschia multiseries* are commo~~m~~n toxin producers on the west coast and in the Northeast, while members of the *Pseudo-nitzschia pseudodelicatissima*-complex are common toxin producers in the Gulf of Mexico. However, there are multiple potential toxic species in each region, and *Pseudo-nitzschia cuspidata~~e~~* has resulted in at least one (1) west coast and one (1) Bay of Fundy closure. ~~—~~

~~—~~

Acute exposure to domoic acid can cause nausea, diarrhea, headaches, confusion/disorientation, seizures, and most severely, permanent short-term memory loss, coma, or death (Lefebvre and Robertson 2010, Shumway et al 2018). Onset of these symptoms can occur within 24 to 48 hours of consumption (Perl et al 1990, Grattan et al 2016). The effects of chronic, low-level exposure to domoic acid through shellfish consumption are still being studied, but potential impacts include

impairment of fetal development, memory deficits, and kidney damage (Grattan et al. 2018 and Funk et al. 2014).

~~Paragraph to be drafted. (Bryant)~~

The factors which influence domoic acid production are not well understood but may include irradiance levels, photoperiod length, salinity, trace metals including iron and copper, the presence of marine bacteria, and decreased or halting cellular growth (Doucette et al. 2008, Lelong et al. 2014, Cusack et al. 2002). Nutrient limitations are suggested to influence species diversity which, at times, may favor toxin-producing species but studies are also underway to determine if nutrient limitations may influence domoic acid production (Thorel et al. 2017).

~~The effects of chronic, low-level consumption of domoic acid are being studied and may lead to the impairment of fetal development, memory deficits, and kidney damage (Grattan et al. 2018 and Funk et al. 2014).~~

Blooms of *Pseudo-nitzschia* are of varying intensity, duration and extent. 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~~ years (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 event~~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.~~

Diarrhetic Shellfish Poisoning (DSP)

~~DSP is caused by okadaic acid and related congeners (e.g., *dinophysis* toxins) produced primarily by dinoflagellates of the genus *Dinophysis*. Eight species of the genus *Dinophysis* are toxigenic (*D. acuminata, D. acuta, D. caudata, D. fortii, D, norvegica, D. ovum, D. sacculus, D. tripos*). All eight species are present on the U.S. east coast and Gulf of Mexico; five species (*D. acuminata, D. acuta, D. fortii, D. norvegica, D. tripos*) are present on the U.S. west coast. The dinoflagellate *Prorocentrum lima* and two species of *Phalacroma (P. rotundatum* and *P. mitra*) also produce DSP toxins. (Anderson, 2021) *Procentrum lima and Phalacroma rotundatum* are present on the U.S. east coast, west coast and Gulf of Mexico. *Phalacroma mitra* is present in the U.S. Gulf of Mexico.~~

~~A 2016 *Dinophysis norvegica* bloom in a Maine salt pond led to the identification of a toxin previously unknown to occur in shellfish, dihydrodinophysistoxin-1. Studies are occurring to determine the potency of the new toxin relative to regulated DSP toxins.~~

~~**Note: will be obtaining specific language**~~

Diarrhetic Shellfish Poisoning (DSP) is caused by okadaic acid and related congeners (e.g., dinophysis toxins) produced primarily by dinoflagellates of the genus *Dinophysis*. Typical symptoms of DSP include abdominal pain, nausea and vomiting, diarrhea, headache, fever, and chills, with a short onset time and symptoms lasting up to three days (Lloyd 2013, US National Office for HABs 2019). Eight *Dinophysis* species known to occur in U.S. waters, including *D. acuminata, D. acuta, D. caudata, D. fortii, D. norvegica, D. ovum, D. sacculus*, and *D. tripos*, as well as the dinoflagellate *Prorocentrum lima* and two species of *Phalacroma* (*P. rotundatum* and *P. mitra*) are all known to produce toxins (Reguera et al 2014). All eight *Dinophysis* species are present on the U.S. east coast and Gulf of Mexico, while five species (*D. acuminata, D. acuta, D. fortii, D. norvegica*, and *D. tripos*) are present on the U.S. west coast. *Prorocentrum~~.~~ lima* and *Phalacroma~~.~~ rotundatum* are present in U.S. east

coast, west coast, and Gulf of Mexico waters, while *Phalacroma~~-~~ mitra* has only been found in the Gulf of Mexico. DSP toxin profiles vary by species and strain (Anderson 2021).

A 2016 *Dinophysis norvegica* bloom in a Maine salt pond led to the identification of a toxin previously unknown to occur in shellfish, dihydrodinophysistoxin-1 (Deeds et al 2020). ~~As of 2021, studies are occurringbeing carried out to determine the potency of the new toxin relative to regulated DSP toxins.~~

Although there have been numerous outbreaks of DSP around the world, no confirmed cases of DSP in the U.S. that were due to domestically harvested shellfish occurred prior to 2011 (Trainer 2013). A cluster of DSP illnesses, with DSP toxins confirmed in blue mussels (Mytilus edulis), occurred in Washington state in July 2011 (3 persons; Lloyd 2013) and in British Columbia, Canada in July-August 2011 (62 persons; Taylor 2013). Subsequent harvesting closures and product recalls were issued. DSP toxins have been detected at levels exceeding the guidance level~~FDA regulatory limit~~ in the Eastern oyster (*Crassostrea virginica*; Texas; Campbell 2010; Deeds 2010)~~;~~, the Pacific oyster (*Crassostrea gigas*), varnish clam (*Nuttalia obscurata*), ~~and~~ manila clam (*Venerupis philippinarum*) (Washington; Trainer 2013),~~;~~ California mussels (*Mytilus californianus*) from Washington and Monterey Bay, CA (Trainer 2013; Schultz 2019)~~;~~, and various commercial and non-commercial shellfish species from New York, Massachusetts, and Maine~~, Delaware, and Maryland~~ waters (Hattenrath-Lehmann et al 2013, Deeds et al 2020, Trainer et al. 2013 ~~Wolny et al 2020,~~ Anderson 2021).~~.; and~~~~They~~DSP toxins have also been detected in non-commercial shellfish ~~in~~during research studies in Mid-Atlantic states. (Hattenrath-Lehmann et al 2013, Wolny et al 2020, Anderson 2021).

~~**Discussion tabled in 6/1/21 at this point**~~

~~Certain *Dinophysis* spp. and *Prorocentrum* spp. produce okadaic acid and dinophysis toxins that cause DSP. 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]). Dinoflagellates are known to thrive in stratified systems and *Dinophysis* has adaptive strategies to cope with freshwater plumes (Trainer, 2013).~~

~~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 three illnesses occurred in Washington State due to consumption of DSP-contaminated mussels. Subsequent harvesting closures and product recalls were issued (Lloyd, 2013).~~

Azaspiracid Shellfish Poisoning (AZP)

AZP is caused by azaspiracids produced by certain dinoflagellates of the genus *Azadinium and Amphidoma*. Compared to the other biotoxins discussed, AZP has been much less studied globally and within the United States, with only limited monitoring data available. Azaspiracids have been detected in seawater on both the w~~W~~est c~~C~~oast, in Washington (Puget Sound) (Trainer et al. 2013, Kim et al. 2017, Anderson et al. 2021) and the e~~E~~ast c~~C~~oast, in Virginia (Chesapeake Bay and VA coastal bays) (Onofrio et al. 2021). Harvesting closures in the United States have not been documented due to AZP toxins. Toxic blooms are known to occur in coastal regions of western Europe (James et al. 2002, Tillman et al. 2017) and northwestern

Africa (Taleb et al. 2006) .

~~*Azadinium* spp. is the producer of azaspiracids, which cause AZP. 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. Toxin blooms are known to occur in coastal regions of western Europe as well as northwestern Africa and eastern Canada.~~
Symptoms of AZP are similar to those noted with DSP, and include nausea, vomiting, cramps, and diarrhea, with symptoms typically persisting for two to three days from onset (Furey et al 2010, Shumway et al 2018).

The first case of AZP was detected in the Netherlands in 1995, where eight people became ill after consuming mussels harvested at Killary Harbour, Ireland (McMahon and Silke 1996). From 1997 ~~—~~through 2000, approximately 80 individuals reported illnesses from mussels and scallops harvested from Ireland, Italy, France, and the 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).

Marine Biotoxin Plans – Management & Contingency

The suitability of some growing areas for shellfish harvesting is periodically influenced by the presence of marine biotoxins. The occurrence of these toxins is often unpredictable, and the potential for them to occur exists along most coastlines of the United States and other countries ~~having~~ with shellfish sanitation ~~Memoranda of Understanding (MOU) agreements~~ arrangements with the United States. 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).

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 for those toxin groups.

Most authorities will have a combination of management and contingency plans~~-management plans~~. Management plans are used to address those growing areas with historic occurrence of certain toxin-producing phytoplankton~~,~~ and contingency plans are used 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 toxins.
~~those toxins.~~

Guidance for the development of contingency and management plans is found in Section IV Guidance Documents, Chapter II Growing Areas @.02.

Resources

U.S. National Office for Harmful Algal Blooms, https://Hab.whoi.edu

Food and Drug Administration, Marine Biotoxin Management for Molluscan Shellfish V1_2, https://collaboration.fda.gov/biotoxins/?elq=f3a546ff4e224fca89660b1cf26461f9&elqCampaignId=5608&elqTrackId=de384479b4e8416997f078b1277d4578&elqaid=6833&elqat=1&utm_campaign=Seafood+Safety+Update+-+Marine+Biotoxin+Video&utm_medium=email&utm_source=govdelivery

Woods Hole Oceanographic Institution, Anderson Lab, https://www2.whoi.edu/site/andersonlab/

U.S. Center for Disease Control, Harmful Algal Bloom Overview, https://www.cdc.gov/habs/illness-symptoms-marine.html
National Oceanic and Atmospheric Administration, Harmful Algal Bloom Overview, https://www.noaa.gov/what-is-harmful-algal-bloom

Centers for Disease Control and Prevention (CDC). National Outbreak Reporting System Dashboard. Atlanta, Georgia: U.S. Department of Health and Human Services, CDC. Last accessed. 05Aug2020. Available from URL: wwwn.cdc.gov/norsdashboard.

CDC Yellow Book https://wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/food-poisoning-from-marine-toxins

References

Anderson DM, Fensin E, Gobler CJ, Hoeglund AE, Hubbard KA, Kulis DM, Landsberg JH, Lefebvre KA, Provoost P, Richlen MR, Smith JL, Solow AR, Trainer VL. Marine harmful algal blooms (HABs) in the United States: History, current status and future trends. Harmful Algae. 2021;102: Article 101975.

Backer et al (2015). **Cyanobacteria and Algae Blooms: Review of Health and Environmental Data from the Harmful Algal Bloom-Related Illness Surveillance System (HABISS) 2007–2011. National Library of Medicine.**

Centers for Disease Control (a). 1973. Shellfish Poisoning - Florida. *Morbid. Mortal. Weekly Rep*. 22(48):397-398.

Centers for Disease Control (b). 1973. Neurotoxic Shellfish Poisoning - Florida. *Morbid. Mortal. Weekly Rep*. 22(48):397-398.

Coleman et al (2018). Saxitoxin Exposure Confirmed by Human Urine and Food Analysis. **National Library of Medicine**

Cusack, C., Bates, S., Quilliam, M., Patching, J., Raine, R. (2002). Confirmation of domoic acid production by Pseudo-nitzschia australis (Bacillariophyceae) isolated from Irish waters. Journal of Phycology, 38, 1106-1112.

Deeds, J.R., & Landsberg, J.H., Etheridge, S.M., Pitcher, G.C., Longan, S.W. (2008). Non-traditional vectors for paralytic shellfish poisoning. *Marine Drugs, 6(2)*, 308-348.

Deeds JR, Stutts WL, Celiz MD, MacLeod J, Hamilton AE, Lewis BJ, Miller DW, Kanwit K, Smith JL, Kulis DM, McCarron P, Rauschenberg CD, Burnell CA, Archer SD, Borchert J, Lankford SK. Dihydrodinophysistoxin-1 Produced by Dinophysis norvegica in the Gulf of Maine, USA and Its Accumulation in Shellfish. Toxins. 2020; 12(9):533.

Degrasse, S., & Rivera, V., Roach, J., White, K., Callahan, J., Couture, D., Simone K., Peredy, T., Poli, M. (2014). Paralytic shellfish toxins in clinical matrices extension of AOAC official method 2005.06 to human urine and serum and application to a 2007 case study in Maine. Deep Sea Research Part II: Topical

Studies in Oceanography, 103, 368-375.

Doucette, G., King, K., Thessen, A., Dortch, Q. (2008). The effect of salinity on domoic acid production by the diatom Pseudo-nitzschia multiseries.

Food and Drug Administration. 1977. Poisonous or Deleterious Substances in Food. *Federal Register* 42(190):52814-52819.

Food and Drug Administration. 1985. Action Levels For Poisonous or Deleterious Substances in Human Food and Animal Feed. U.S. Department of Health and Human Services, Public Health Service, Washington, D.C. 20204. 13 pages.

Funk, J., Janech, M., Dillon, J., Bissler, J., Siroky, B., Bell, P. (2014). Characterization of renal toxicity in mice administered the marine biotoxin domoic acid. Journal of the American Society of Nephrology, 25(6), 1187-1197.

Gordon, K., M.D., *et al*. 1973. Shellfish Poisoning. *Morbid. Mortal. Weekly Rep*. 22, (48):397- 398.

Grattan, L., Boushey, C., Liang, Y., Lefebvre, K., Castellon, L., Roberts, K., Toben, A. Morris, J. (2018). Repeated dietary exposure to low levels of domoic acid and problems with everyday memory: research to public health outreach. Toxins (Basel), 10(3), 103.

Hattenrath-Lehmann TK, Marcoval MA, Berry DL, Fire S, Wang Z, Morton SL, Gobler CJ. The emergence of Dinophysis acuminata blooms and DSP toxins in shellfish in New York waters. Harmful Algae. 2013; 26: 33-44.

James, K.J., Furey, A., Lehane, M., Ramstad, H., Aune, T., Hovgaard, P., Morris, S., Higman, W., Satake, M. and Yasumoto, T., 2002. First evidence of an extensive northern European distribution of azaspiracid poisoning (AZP) toxins in shellfish. *Toxicon*, *40*(7), pp.909-915.

Kim, J.H., Tillmann, U., Adams, N.G., Krock, B., Stutts, W.L., Deeds, J.R., Han, M.S.,Trainer, V.L., 2017. Identification of Azadinium species and a new azaspiracid from Azadinium poporum in Puget Sound, Washington State, USA. Harmful Algae 68, 152–167.

Klontz, K.C., & Abraham, A., Plakas, S., Dickey, R. (2009). Mussel-associated azaspiracid intoxication in the United States. Annals of Internal Medicine, 150(5), 361.

Landsberg, J.H., Hall, S., Johannessen, J.N., White, K., Conrad, S.M., Abbott, J.P., Flewelling, L.J., Richardson, R.W., Dickey, R.W., Jester, E.L.E., Etheridge, S.M., Deeds, J.R., Van Dolah, F.M., Leighfield, T.A., Zou, Y., Beaudry, C.G., Benner, R.A., Rogers, P.L., Scott, P.S., Kawabata, K., Wolny, J.L., Steidinger, K.A. 2006. Saxitoxin puffer fish poisoning in the United States, with the First Report of Pyrodinium bahamense as the putative toxin source. Environmental Health Perspectives, 114, 1502-1507.

Lelong, A., Hegaret, H., Soudant, P. (2014). Link between domoic acid production and cell physiology after exchange of bacterial communities between toxic Pseudo-nitzschia multiseries and non-toxic Pseudo-nitzschia delicatissima. Marine Drugs, 12(6), 3587-3607.

Liston, J. (1994). Association of Vibrionaceae, natural toxins, and parasites with fecal indicators, p. 215-216. In Hackney, C.R. and M.D. Pierson (eds.). Environmental Indicators and Shellfish Safety. Chapman and Hall, New York, NY.

Lloyd, J.K., & Duchin, J., Borchert, J., Quintana, H.F., Robertson, A. (2013). Diarrhetic Shellfish Poisoning, Washington, USA, 2011. Emerging Infectious Diseases 19(8), 1314-1316.

Lloyd JK, Duchin JS, Borchert J, Flores Quintana H, Robertson A. Diarrhetic shellfish poisoning, Washington, USA, 2011. Emerg Infect Dis [Internet]. 2013 Aug [date cited].

McCabe, R.M., & Hickey, B.M., Kudela, R.M., Lefebvre, K.A., Adams, N.G., Bill B. D., Gulland, F.M.D., Thomson, R.E., Cochlan, W.P., Trainer, V.L. (2016) An unprecedented coastwide toxic algal bloom linked to anomalous ocean conditions. Geophysical Research Letters, 43(19), 10,366–10,376.

Newell KG. Paralytic Shellfish Poisoning Update — Alaska, 1993–2021. State of Alaska. *Epidemiology Bulletin*. 5

Onofrio, M.D., Egerton, T.A., Reece, K.S., Pease, S.K., Sanderson, M.P., Jones III, W., Yeargan, E., Roach, A., DeMent, C., Wood, A. and Reay, W.G., 2021. Spatiotemporal distribution of phycotoxins and their co-occurrence within nearshore waters. Harmful Algae, 103, p.101993.

Perl, T.M., L. Bedard, T. Kosatsky, J.C. Hockin, E.C.D. Todd and R. Remis. 1990. Encephalopathy Caused by Contaminated Mussels. New England Medical Journal 322, 1775-80.

Reguera B, Riobo P, Rodriguez F, Diaz PA, Pizarro G, Paz B, Franco JM, Blanco J. Dinophysis toxins: causative organisms, distribution and fate in shellfish. Marine Drugs. 2014; 12: 394-461.

Schwalm, D.J. (1973). The 1972 PSP outbreak in New England. FDA Report, Boston, MA. U.S. Food and Drug Administration, Washington, D.C.

~~Tong, M., & Smith, J.L., Richlen, M.L., Steidinger, K., Kulis, D., Fux, E., Anderson, D.M. (2014) Characterization and comparison of toxin-producing isolates of Dinophysis acuminata from New England and Canada. Journal of Phycology, 51(1), 66-81. Retrieved from https://www.researchgate.net/publication/267340694_Characterization_and_comparison_of_toxin-producing_isolates_of_Dinophysis_acuminata_from_New_England_and_Canada.~~

Taleb, H., Vale, P., Amanhir, R., Benhadouch, A., Sagou, R. and Chafik, A., 2006. First detection of azaspiracids in mussels in north west Africa. *Journal of Shellfish Research*, *25*(3), pp.1067-1070.

Taylor M, McIntyre L, Ritson M, Stone J, Bronson R, Bitzikos O, et al. Outbreak of diarrhetic shellfish poisoning associated with mussels, British Columbia, Canada. Mar Drugs. 2013;11:1669–76.

Thorel, M., Claquin, P., Schapira, M., Le Gendre, R., Riou, P., Goux, D., Le Roy, B., Raimbault, V., Deton-Cabanillas, A., Bazin, P., Kientz-Bouchart, V., Fauchot, J. (2017). Nutrient ratios influence variability in Pseudo-nitzschia species diversity and particulate domoic acid production in the Bay of Seine (France). Harmful Algae, 68, 192-205.

Tillmann, U., Jaén, D., Fernández, L., Gottschling, M., Witt, M., Blanco, J. and Krock, B., 2017. Amphidoma languida (Amphidomatacea, Dinophyceae) with a novel azaspiracid toxin profile identified as the cause of molluscan contamination at the Atlantic coast of southern Spain. *Harmful Algae*, *62*, pp.113-126.

Trainer, V.L., & Moore, L., Bill, B.D., Adams, N.G., Harrington, N., Borchert, J., da Silva, D.A.M., Eberhard, B.T.L. (2013). Diarrhetic shellfish toxins and other lipophilic toxins of human health concern in Washington State. Marine Drugs, 11, 1815–1835.

Twiner, M.J., & Rehmann, N., Hess, P., Doucette G.J. (2008). Azaspiracid shellfish poisoning: a review on the chemistry, ecology, and toxicology with an emphasis on human health impacts. Marine Drugs, 6(2), 39-72.

United States National Office for Harmful Algal Blooms. Diarrhetic Shellfish Poisoning. 2019, https://hab.whoi.edu/impacts/impacts-human-health/human-health-diarrhetic-shellfish-poisoning/. Accessed 2 September 2021.

US Public Health Service (PHS). (1958). Proceedings: 1957 Conference on Shellfish Poison. U.S. PHS, Washington, D.C. 125 pages.

Watkins, S.M., & Reich, A., Fleming, L.E., Hammond, R. (2008). Neurotoxic

shellfish poisoning. Marine Drugs, 6(3), 431-455.

Wolny JL, Egerton TA, Handy SM, Stutts WL, Smith, JL, Whereat EB, Bachvaroff TR, Henrichs DW, Campbell L, Deeds JR. Characterization of Dinophysis spp. From the Mid-Atlantic region of the United States. Journal of Phycology. 2020; 56: 404-424.

Paralytic Shellfish Poisoning (PSP)[1,2,3]	
Toxin	Saxitoxins
Causative Organism(s)	*Alexandrium sp.* ; *Pyrodinium bahamense*; *Gymnoinium catenatum*
Historic Geographic Range (US)	Alexandrium sp.~~Northeast~~ Atlantic coast from New York to Maine; Pacific coast from Alaska to California; *Pyrodinium bahamense*- Gulf; and Atlantic coasts of Florida; *Gymnodinium catenatum* - Gulf coast
Onset/Duration	Onset within 30 minutes; Duration of a few hours to a few days
Major Symptoms	Tingling or numbness in face, hands, and feet; weakness; slurred speech; difficulty swallowing; shortness of breath; nausea; vomiting; dizziness; headache; high blood pressure. Death from asphyxiation can occur.

Neurotoxic Shellfish Poisoning (NSP)[1,4,5]	
Toxin	Brevetoxins
Causative Organism(s)	*Karenia brevis*
Historic Geographic Range (US)	Gulf ~~Coast~~ coast and ~~east~~ Atlantic coast of Florida; One instance ~~in~~ on the Atlantic coast of North Carolina
Onset/Duration	Onset within three~~3~~ to four~~4~~ hours or up to 18 hours; Duration of two to three days
Major Symptoms	Gastrointestinal symptoms; numbness and tingling in the face, hands, and feet; partial limb paralysis; slurred speech; loss of coordination; reversal of hot and cold sensations

Amnesic Shellfish Poisoning (ASP)[1,3,6]	
Toxin	Domoic Acid
Causative Organism(s)	*Pseudonitzschia sp.*
Historic Geographic Range (US)	~~Northeast~~ Atlantic coast from New York to Maine; Gulf ~~Coast~~coast; Pacific coast from Alaska to California
Onset/Duration	Onset within 24-48 hours; Duration of certain symptoms can be months to years or permanent
Major Symptoms	Nausea, diarrhea, headache, confusion/disorientation, seizures. Can cause short-term memory loss, coma, or death.

Diarrhetic Shellfish Poisoning (DSP)[1,3,7]	
Toxin	Okadaic Acid
Causative Organism(s)	*Dinophysis sp. ; Prorocentrum lima ; Phalacroma rotundatum* and *mitra*
Historic Geographic	~~East~~ Atlantic coast from Virginia to Maine; Gulf

Range (US)	~~Coast~~coast; Pacific ~~Coast~~ coast from Washington to California
Onset/Duration	Onset from 30 minutes to 15 hours; Duration up to three days
Major Symptoms	Abdominal pain; nausea; vomiting; diarrhea; headache; fever and chills

Azaspiracid Shellfish Poisoning (AZP)[1,3,8]	
Toxin	Azaspiracids
Causative Organism(s)	*Azadinium sp.*
Historic Geographic Range (US)	No known occurrences
Onset/Duration	Onset within hours; Duration up to three days
Major Symptoms	Abdominal pain; nausea; vomiting; diarrhea

[1]Anderson, D.M. et al (2021). Marine harmful algal blooms in the United States: History, current status and future trends. Harmful Algae, 102, Article 101975.
[2]Etheridge, S.M. (2010). Paralytic shellfish poisoning: Seafood safety and human health perspectives. Toxicon, 56, 108-122.
[3]Shumway, S.E., Burkholder, J.M., Morton, S.L. (2018). Harmful Algal Blooms: A Compendium Desk Reference. John Wiley & Sons Ltd.
[4]Grattan, L.M., Holobaugh, S., Morris, J.G. (2016). Harmful algal blooms and public health. Harmful Algae, 57(b), 2-8.
[5]Watkins, S.M. et al (2008). Neurotoxic shellfish poisoning. Marine Drugs, 6(3), 431-455.
[6]Lefebvre, K.A. and A. Robertson. (2010). Domoic acid and human exposure risks: A review. Toxicon, 56, 218-230.
[7]Trainer, V.L. et al (2013). Diarrhetic shellfish toxins and other lipophilic toxins of human health concern in Washington State. Marine Drugs, 11, 1815-1835.
[8]Twiner, M.J. et al (2008). Azaspiracid shellfish poisoning: A review on the chemistry, ecology, and toxicology with an emphasis on human health impacts. Marine Drugs, 6, 39-72

Action by 2023 Task Force I	Recommended adoption of the Biotoxin Committee recommendation on Proposal 19-123.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-123.
Action by FDA July 7, 2023	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 phytoplankto 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 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 th 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 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 shellfi 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, lik 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 pla 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 o 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 p of an effective biotoxin plan, whether contingency or management. As such, the authority should establish and formalize channels of communication with appropriat partner agencies (e.g., wildlife, epidemiology, local health, public safety, public heal and environmental), research or academic organizations (e.g., marine biologists), adjacent shellfish control authorities, industry, and other similar partners in advance any serious biotoxin event.

Information to be communicated includes that which is relevant to early warning as 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 defin how agencies will maintain contact lists. Model press releases, email notifications, a 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 clo status due to marine biotoxin contamination. The criteria should integrate pu 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 u 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 spec species).

   The biotoxin level governing the need to place the growing area in the close status may vary depending on the species of phytoplankton and the species o 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 dangerou biotoxin concentrations. In this situation, the authority may allow the harves of one species with no adverse public health consequences while prohibiting harvest of another species. In these situations, the authority must closely monitor the growing area and develop a sufficient database for use in makin 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 the 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 administrati 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 th authority's consideration of the public's health, and economic consequences.

A system of representative samples and other environmental indices are typically use 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 a sites where toxin is most likely to first appear, based either on past experienc or knowledge of site conditions. The geographic distribution for collection o samples should take into consideration the randomness of toxic algal blooms For these reasons, several years of baseline data are often necessary in order 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 wha commercially-harvested species are present in the growing area and samples should be collected of species which are most likely to reveal the early prese 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 authorit should establish the frequency and period for collection of samples in order t identify an event as early as possible. Historical occurrences and fluctuation coastal phytoplankton populations due to the influence of meteorological an 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 bloo 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, Cha I Shellfish Sanitation Program, @.03(B).

The Authority should consider where they can access sample processing for 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 o 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 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 a below the regulatory levels may trigger emergency or expanded testing, or precautionary closures. Growing areas should be closed at a level that provid an adequate margin of safety, since in many instances, toxicity levels will change rapidly and the time between sampling and results should be conside 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 station and/or increase the frequency of sampling for marine biotoxins. The procedu 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 definin 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, authorit plan should define records to be generated, reviewed, and maintained. Required reco 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 th 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 requirement ~~the program . NSSP *Model Ordinance* requirements apply only to interstate~~ commerce although most states apply the requirements intrastate. For the most up ~~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. T ~~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 taste. The presence of toxic phytoplankton in the water column or traces of their to in shellfish meat does not necessarily constitute a health risk, as toxicity is depende on concentration (dose) in the shellfish. To protect the consumer, the Authority m evaluate the concentration of toxin present in the shellfish or the toxic phytoplankto concentration in the water column against the levels established in the NSSP Mode

~~Ordinance to determine what action, if any, should be taken.~~

While there is a wide range of methodologies developed for screening and confirmat of toxic phytoplankton and their toxins, methods must be adopted into the NSSP if th 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 b the ISSC and found fit for purpose for the NSSP, thereby providing confidence in th methods for specific screening purposes. Toxin methods fall into two categories in t

~~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 to 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 th ~~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 mo ~~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*). Th dinoflagellate *Pyrodinium bahamense* is also a producer of saxitoxins. NSP is caus ~~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 o azaspiracids, which cause AZP.Both *Alexandrium* and *Karenia* can produce "red tide i.e. discolorations of seawater caused by blooms of the algae; however, they may als ~~reach concentrations that may result in toxic shellfish without imparting any water~~ discoloration. Toxic blooms of these dinoflagellates can occur unexpectedly or follo ~~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 (Schwal

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 th ~~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 tak ~~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) an Texas (Deeds et al. 2010) as well as off the coast in the northeast (e.g., Massachuset [Tong et al. 2015]).While AZP has occurred in the U.S., the contaminated shellfish w ~~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, ha 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 PSP toxin. Investigations indicate that lesser amounts of the toxin have no deleterio effects on humans. Shellfish growing areas should be closed at a PSP toxin level, w provides an adequate margin of safety, since in many instances PSP toxicity levels c ~~change rapidly.~~

The NSSP Model Ordinance requires that growing areas be placed in the closed statu ~~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, 198

~~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 ~~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 Mod Ordinance mandates that growing areas be placed in the closed status when any NS toxin is found in shellfish meat at or above 20 MU per 100 grams of shellfish, or w the cell counts for members of the genus *Karenia* in the water column equal or exc ~~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 w 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 var toxicity and species dominance within the bloom. The event started in late Septem in eastern Maine and ended in October; however, Rhode Island experienced anothe bloom in February of 2017.The NSSP Model Ordinance requires that growing area placed in the closed status when the domoic acid concentration is equal to or excee ~~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, a 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 shellf ~~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 a ~~evaluated by the Authority.~~
*Procedures should be instituted to return the Biotoxin contaminated areas to th ~~open status of their growing area classification.~~

Under the certification provisions of the NSSP, FDA and receiver states should hav the assurance that shellfish producing states or MOU countries are taking and can t adequate measures to prevent harvesting, shipping, and consumption of toxic shellf ~~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 ar ~~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 t ~~extent and intensity of the bloom~~
- ~~A sampling plan that considers species specific shellfish sampling~~
- Access to screening tests; both rapid and approved method
- ~~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 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 a history of toxin-producing phytoplankton, toxicity in shellfish and/or an illness ev 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 pl ~~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 gather ~~and evaluated by the~~
  - ~~Authority.~~
  - Procedures should be instituted to return the biotoxin contaminated area ~~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 an ~~toxin-like illnesses.~~
3. An early warning phytoplankton and/or shellfish-monitoring program shoul ~~be implemented.~~

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

   * Sampling stations should be located at sites where past experience ha ~~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 th highest toxin levels. For example, mussels have been found to be usefu

~~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 samplin ~~plans.~~

~~*~~ Frequency of sampling should be adequate to monitor for fluctuation ~~coastal phytoplankton populations.~~

4. Cha nnels of communication concerning shellfish toxicity should be establis with other states, countries (in the case of MOU countries), FDA, and other responsible officials. A marine Biotoxin control official should be designa

~~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 count ~~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.

~~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~~
3. ~~shellfish resource areas and species present in the state.~~ Criteria should be developed to define the circumstances under which grow ~~areas will be placed in the closed status because of marine Biotoxin~~ contamination. The criteria should integrate public health, conservation, a economic considerations. Principal items of concern include consideration

~~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 safe ~~zone), and the type of harvesting restrictions to be invoked (all species or~~ specific species). It may be appropriate to close harvesting areas adjacent t known toxic areas until increased sampling can establish which areas are to

~~free and that toxin levels have stabilized.~~

4. Procedures should be established to promptly identify which shellfish prod

~~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 (

~~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 close status, to withdraw interstate certification of dealers, and to embargo and recall shellfish should be delineated. The timeframe necessary to accompli ~~these actions should also be specified.~~
3. A plan should be developed which will define what type of patrol program necessary to properly control harvesting in toxin contaminated growing are The program should be tested to ensure prompt implementation in the even ~~is needed.~~
4. Procedures should be developed to promptly disseminate information on th ~~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 advan ~~of any serious biotoxin event.~~
5. Procedures should be established to coordinate control activities taken by st ~~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 Biotox ~~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. system of representative samples to establish detoxification curves should b ~~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 criter for PSP include a minimum of three (3) samples collected over a period of least fourteen (14) days. These samples should show the absence of PSP o ~~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~~

1. Center for Disease Control (a). 1973. Shellfish Poisoning - Florida. *Morbid. ~~Mortal. Weekly Rep.~~*22(48):~~397-398.~~
2. ~~Center For Disease Control (b). 1973. Neurotoxic Shellfish Poisoning - Florida. *Morbid. Mortal.Weekly Rep.* 22(48):397-398.~~
3. Felsing, W.A., Jr. 1966. Proceedings of Joint Seminar on North Pacific Cla

~~September 24-25,1965. U.S. Public Health Service, Washington, D.C.~~
4. Food and Drug Administration. 1977. Poisonous or Deleterious Substances ~~Food. *FederalRegister* 42(190):52814-52819.~~
5. ~~Food and Drug Administration. 1985. Action Levels For Poisonous or~~ Deleterious Substances in Human Food and Animal Feed. U.S. Department of Health and Human Services, Public Health Service, Washington, D.C. 20204. 1 ~~pages.~~
6. Gordon, K., M.D., *et al*. 1973. Shellfish Poisoning. *Morbid. Mortal. Weekly ~~Rep~~*. ~~22, (48):397-398.~~
7. Liston, J. 1994. Association of *Vibrionaceae*, natural toxins, and parasites w ~~fecal indicators, p.215-216. In Hackney, C.R. and M.D. Pierson (eds.),~~ *Environmental Indicators and Shellfish Safety*. Chapman and Hall, New York,
8. ~~Prakash, A., J.C. Medcof, and A. D. Tennant. 1971. Paralytic shellfish~~ poisoning in easternCanada. Bulletin 177, Fisheries Research Board of Canada ~~Ottawa, Canada.~~
9. Quayle, D.B. 1969. Paralytic shellfish poisoning in British Columbia. Bulle ~~168, FisheriesResearch Board of Canada. Ottawa, Canada.~~
10. Schwalm, D.J. 1973. The 1972 PSP outbreak in New England. FDA Report ~~Boston, MA. U.S.Food and Drug Administration, Washington, D.C.~~
11. U.S. Public Health Service (PHS). 1958. Proceedings: 1957 Conference on ~~Shellfish Poison. U.S.PHS, Washington, D.C. 125 pages.~~
12. Wilt, D.S. (ed). 1974. Proceedings of Eighth National Shellfish Sanitation Workshop. January 16-18. New Orleans, LA. National Technical Information Services (PB8 6 236916/AS), U.S. Dept. of Commerce, Springfield, VA. 158 p

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.
Action by 2023 Biotoxin Committee	Recommended adoption of 19-124 as substituted.

.02 ~~Guidance for Developing~~ Marine Biotoxin Control Guidance~~Plans~~

NSSP guidance documents provide Authorities with information and best practices on how to implement the components of the Model Ordinance ~~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. An overview of marine biotoxins including associated biological vectors, diseases, historic outbreaks, and emerging trends can be found in Section III Public Health Reasons and Explanations Chapter IV. @.04 Marine Biotoxin Control.

~~**Introduction**~~

~~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 human exposure occurs when the shellfish are eaten (Gordan *et al.,* 1973). These toxins are not normally destroyed by cooking or processing and cannot be detected by taste. 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.~~

~~There are a wide range of methodologies developed for screening and confirmation of toxic phytoplankton and their toxins. Only methods adopted into the NSSP can be implemented for the purpose of confirming toxin concentration levels and making decisions to reopen growing areas. Additionally, some screening methods have been evaluated by the ISSC and found fit for purpose for the NSSP, thereby providing confidence in their use for specific screening purposes. Toxin methods fall into two (2) categories in the NSSP: Approved Methods for Marine Biotoxin Testing (Section IV. Guidance Documents Chapter II Growing Areas .14 Table 2.) and Approved Limited Use Methods for Marine Biotoxin Testing (Section IV. Guidance Documents Chapter II Growing Areas .14 Table 4.). These methods range from mouse bioassays to immunochromatography and other antibody based platforms to chemical analytical methods such as high performance liquid chromatography (HPLC). Information available in the referenced Tables above provides references for the methods and, as applicable, what limitations are placed on the use of the method within the NSSP. For toxins that have no method adopted into the NSSP, best available science is employed.~~

~~There are five (5) types of shellfish poisonings which are specifically addressed in the NSSP Model Ordinance: PSP, NSP, ASP (also known as Domoic Acid poisoning), DSP and 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 exposures. 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 *Pseudo-nitzchia*. Certain *Dinophysis* spp. and *Prorocentrum* spp. produce okadaic acid and dinophysis toxins that cause DSP. *Azadinium* spp. is the producer of azaspiracids, which cause AZP.~~

~~Both *Alexandrium* and *Karenia* can produce "red tides", i.e. discolorations of seawater caused by blooms of the algae; however, they may also reach concentrations that cause toxic shellfish without imparting any water discoloration. Toxic blooms of these dinoflagellates can occur unexpectedly or follow predictable patterns. The unpredictability in occurrence of toxic blooms was demonstrated in New England in 1972 when shellfish suddenly became toxic in a previously unaffected portion of the coastline and resulted in many illnesses (Schwalm, 1973). Historically, *Alexandrium* blooms have occurred between April and October along the Pacific coasts from Alaska to California and in the Northeast from the Canadian Provinces to Long Island Sound (U.S. Public Health~~

~~Service, 1958); but these patterns may be changing. The blooms generally last only a few weeks and most shellfish (with the exception of some species of clams and scallops which retain the toxin for longer periods) clear themselves rapidly of the toxin once the bloom dissipates. Occurrence of *Karenia* blooms extends from the Carolinas south throughout the Gulf Coast States. 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 raw shellfish (FDA, 1977; FDA, 1985).~~

~~In shellfish growing areas where low levels of PSP toxin routinely occur, harvesting for thermal processing purposes may be an alternative to consider. Thermal processing as defined by applicable FDA regulations (21 CFR 113) will reduce 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.~~

~~ASP is caused by domoic acid, which is produced by diatoms of the genus *Pseudo-nitzschia*. Blooms of *Pseudo-nitzschia* are of varying intensity, duration and extent. 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. 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**~~

~~Under the certification provisions of~~In accordance with the NSSP, FDA and receiver States should have assurance that shellfish producing States or ~~MOU~~ countries ~~of~~with shellfish sanitation arrangements 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 either a marine biotoxin contingency plan and/or a marine biotoxin management plan for a specific list of biotoxins that covers each marine and estuarine shellfish growing area. Single plans can be developed for a whole state or can cover particular growing areas or toxins. An Authority may have an area with a contingency plan for some biotoxins and a management plan for others, a contingency plan for all biotoxins, or a management plan for all biotoxins.~~There are two (2) types of plans defined in the NSSP MO for the control of marine biotoxins.~~ A contingency plan is developed by an Authority that has no history or reason to expect toxin-producing phytoplankton in their growing areas. A marine biotoxin management plan is developed by an Authority that has historic occurrence of toxin-producing phytoplankton and toxicity in shellfish from their growing areas.

The Marine Biotoxin Contingency Plan
Section II. MO Ch IV. Shellstock Growing Areas @.04 Marine Biotoxin Control (A)

Purpose

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

The Model Ordinance requires that a contingency plan:

1. Address the toxins that cause each of the following illnesses (except those addressed in a biotoxin management plan): PSP, ASP, NSP, DSP, and AZP.

a. Even if the toxin has never been known to occur in the area or it is biologically unlikely to occur in the area, it still must be addressed.

2. Define the administrative procedures and resources necessary to: initiate an emergency shellfish sampling program; close growing areas and embargo shellfish; prevent harvesting of contaminated species; provide for product recall; disseminate information; coordinate control actions; and establish reopening criteria.
   a. It is important to note that the Model Ordinance does not require an Authority to take any actions following the development of a contingency plan, unless the Authority elects to include specific actions in their plan such as phytoplankton or biotoxin sampling protocols. Instead, this plan should define the procedures an Authority would follow in the event of a bloom or illness outbreak, as well as how the Authority would go about acquiring the resources needed to implement those procedures.

Contingency Plan Content Guidance

Element	**Recommended Plan Contents**
Emergency Sampling Program	• Identify area(s), phytoplankton, and/or shellfish for sampling • A procedure to promptly expand this sampling program, including increasing sampling stations and sampling frequency, in the event of increased toxicity/cell counts at any indicator monitoring stations identified within the plan • Identify partner sampling agencies available • Identify laboratory support, including capacity, method(s), contract(s) o In some circumstances, the Authority may have the laboratory support available in-house, but in other circumstances may have to identify alternate NSSP labs to conduct the necessary methods o If there is no approved method available, the Authority should identify an appropriate method for analysis following the procedures described in MO Chapter III @.02 Methods • Describe training for samplers • Identify financial resources available, request processes, and necessary approvals • Though not required by the Model Ordinance, it may be appropriate for the Authority to implement an early warning system within the contingency plan, as described in the *Marine Biotoxin Management Plan* section below

Close Growing Areas and Prevent Harvest of Contaminated Species	• Identify the legal authority to close areas and restrict harvesting • Protocols to initiate closures, taking into consideration public health, economic, and conservation concerns. The rapidity with which toxin levels can increase, 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) should all be considered ~~It may be appropriate to include adjacent harvesting areas in an initial closure until increased sampling can establish which areas are toxin free and that toxin levels have stabilized.~~ • Describe the mechanism to quickly notify growers, harvesters, and dealers of closures • Describe protocols to notify patrol entities of emergency closures, as well as patrol procedures necessary to prevent harvest from closed areas
Embargo Shellfish	• Identify the legal authority to embargo, detain, quarantine, or otherwise prevent the movement of shellfish in commerce and to withdraw interstate shipping permits • Describe procedures for embargoing shellfish, including the identification of affected lots and distribution networks, as well as any associated forms, tags, or other administrative tools used • Describe the mechanism for destruction of embargoed product if it is found to be adulterated, or the mechanism to release embargoed product if it is found to be free of contamination
Coordinate Control Actions	• Describe the mechanism to notify partner state, local, federal, and/or tribal agencies to avoid duplicative efforts and streamline response
Product Recall	• Identify the legal authority to recall product that may already be in commerce • Identify agency protocols for implementing a product recall • It may be helpful to develop templates and forms for recall, if they are not already in place
Disseminate Information to Partners	• Establish relationships and procedures to notify:

	○ ISSC and FDA Shellfish Specialist~~, if needed~~ ○ Adjacent states or states that may have received adulterated product ○ Local, tribal, and state public health and safety ~~-~~partners ○ Poison control partners • Describe efforts to inform and educate the public about risks associated with biotoxins • It may be useful to develop information sheets or fillable templates for notifications, press releases, partner agency communications, or other routinely used documents • Develop a model communications plan or agree in advance on lead communications points of contact
Reopening Criteria	• Establish how the authority will determine when an area can be reopened based on data ○ Reopening criteria should integrate public health, conservation, and economic considerations ○ To establish a detoxification curve or other environmental indices, such as phytoplankton concentration trends, more than one (1) sample collected at different times is needed.~~-~~ For example, some states collect two (2) samples over seven (7) days and others collect three (3) samples over fourteen (14) days. These samples should show the absence of biotoxins or levels below the closure guidance level ○ If species-specific sampling regimes are employed, then each species that exceeded the quarantine threshold must be tested independently to reopen • Identify laboratory support, including capacity, methods, and contracts ○ In some circumstances, the Authority may have the laboratory support available in-house, but in other circumstances, may have to identify alternate NSSP labs to conduct the lab methods approved for reopening ○ If there is no approved method available, the Authority should identify an appropriate method for analysis following the procedures described in MO Chapter III @.02 Methods

Additional Considerations:

a. If an Authority has a management plan and/or protocols such as patrol manuals or existing MOUs that are relevant and appropriate, the Authority may reference those documents within its contingency plan.

b. Relationships with academia, government, non-government, and industry partners can be extremely helpful in identifying the presence of previously unseen phytoplankton or biotoxins. It can be helpful to develop and maintain a general list of contact people or organizations that can collaborate on phytoplankton and biotoxin monitoring efforts.

c. The Model Ordinance also requires that certain records be maintained during and following an event. It is recommended that the contingency plan include details on record maintenance.

i. Appropriate records of illnesses should be compiled and maintained by the Authority. These records should include data on the incidence of illness and appropriate case history data. This information may be important in defining the severity of the problem, as well as for a retrospective evaluation of the adequacy of the entire control program.

ii. Records of shellfish sample results from toxin testing should include analysis of trends, detoxification curves, phytoplankton and water sample analyses, and pertinent environmental observations.

iii. Whenever possible, the Authority should archive shellfish or shellfish homogenates for additional analysis.

~~• A process for immediate precautionary closures;~~

~~• A sampling plan that considers water samples to evaluate the extent and intensity of the toxic phytoplankton distribution;~~

~~• A sampling plan that considers species-specific shellfish sampling;~~

~~• Access to biotoxin tests: both screening and approved methods;~~

~~• Trained staff to carry out sample collection and testing if necessary; and~~

~~Reopening criteria.~~

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

The Marine Biotoxin Management Plan

Section II. MO Ch IV. Shellstock Growing Areas @.04 Marine Biotoxin Control (B)

Purpose

The marine biotoxin management plan is ~~primarily~~ required for proactive management of marine biotoxins ~~for~~ in growing areas with a history of toxin-producing phytoplankton, toxins in shellfish at or above the guidance level in their

growing areas, ~~and toxicity in shellfish~~ and/or a previous illness ~~event or~~ outbreak. Similar to a contingency plan, the Model Ordinance requires that a~~The~~ management plan ~~must describe an early warning system,~~define the administrative procedures and resources necessary to: close growing areas and embargo shellfish; prevent harvesting of contaminated species; provide for product recall; disseminate information; coordinate control actions; and establish reopening criteria. Please refer to the Contingency Plan Content Guidance above for recommendations on how to develop these portions of the management plan

Additionally, the Model Ordinance requires that:

1. For any areas covered by a management plan, the Authority must maintain a toxin-producing phytoplankton and/or shellfish sampling program.
2. The management plan includes procedures to ensure that all shellfish harvested from growing areas or portion(s) of growing areas placed in the controlled access status will meet all conditions of harvest restrictions prior to being placed in distribution.

~~Strategies for meeting these requirements are described below.~~

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

- ~~An early warning system should be developed and implemented.~~
- ~~Procedures should be established to define the severity of occurrences.~~
- ~~The Authority should be able to respond effectively to minimize risk of illness.~~
- ~~Adequate intelligence and surveillance information should be gathered and evaluated by the Authority.~~

~~Procedures should be instituted to return the biotoxin contaminated areas to the open status of their growing area classification.~~

~~**Recommended Contingency Plan Guidelines**~~

~~**Implement an**~~ **Early Warning System**

~~** Provide an early warning system:*~~

It is recommended that any Authority with a management plan should have an early warning system in place (https://www.fao.org/3/cc4794en/cc4794en.pdf). Early warning systems may include additional phytoplankton and/or shellfish monitoring efforts conducted by the Authority and/or by use of a network of observers and partnerships as well as communications with other organizations to identify environmental or biological warning signs.

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

~~be implemented. These monitoring programs should use the "primary station" (for both phytoplankton and shellfish monitoring) and "critical species" concepts (for shellfish monitoring).~~

- Primary ~~Sampling~~ sampling stations ~~(primary stations)~~ should be located at sites where ~~past~~ experience has shown toxins or blooms are ~~is~~ most likely to appear first.
- ~~When~~ If monitoring shellfish, samples should be collected of species which are most likely to reveal the early presence of toxin and which are most likely to show the highest toxin levels ~~(critical species)~~. For example, in some circumstances, mussels have been found to be useful for early detection.
- Sampling design should always consider what species are present in the growing area and commercially harvested.

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

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

~~o 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 is also useful (Felsing, 1966; Quayle, 1969; Prakash *et al*., 1971).~~

~~*Define the severity of the problem:*~~

~~1. A procedure should be established to promptly expand the sampling program for marine biotoxins in the event of increased toxicity/cell counts at any indicator monitoring stations identified within the plan. Sampling stations and frequencies of sampling should be increased when monitoring data or other information suggests that toxin levels are increasing. The procedure should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program.~~

~~2. Information should be available concerning the location of commercial shellfish resource areas and species present in the State.~~

~~3. Criteria should be developed to define the circumstances under which growing areas will be placed in the closed status because of marine biotoxin contamination. The criteria should integrate public health, conservation, and economic considerations. Principal items of concern include consideration of the rapidity with which toxin levels can increase to excessive levels, the inherent delays in sample collection and results, the number of samples required to initiate action, the size of the area to be closed (including a safety zone), and the type of harvesting restrictions to be invoked (all species or specific species). It may be appropriate to close harvesting areas adjacent to known toxic areas until increased sampling can establish which areas are toxin free and that toxin levels have~~

stabilized.

4. Procedures should be established to promptly identify which shellfish products or lots might be potentially contaminated, and to determine the distribution of these products or lots.

Respond effectively to minimize illness:

1. A summary should be provided citing the laws and regulations in the State (or MOU country) that promptly and effectively allow the Authority to restrict harvesting, withdraw interstate shipping permits, and to embargo/recall any potentially toxic shellfish already on the market in the event of a marine 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.

** Gather follow-up data:*

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

Whenever possible the Authority should archive shellfish homogenates for additional analysis.

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

1. Once a growing area is placed in the closed status because of marine biotoxin contamination, a procedure should be instituted to gather data necessary to decide when the area can be returned to the open status of its classification. A system of representative samples to establish detoxification curves should be part of this procedure.
2. The Authority should develop a set of criteria that must be met before a growing area can be returned to the open status. These criteria should integrate public health, conservation, and economic considerations, and employ a sufficient number of samples and other environmental indices, if

~~used, to establish that the level of toxin or cell counts are below the closure level. For example, experience has shown that appropriate reopening criteria for PSP include a minimum of three (3) samples collected over a period of at least fourteen (14) days. These samples should show the absence of PSP or levels below 80 micrograms per 100 grams of shellfish tissue.~~

~~A program of consumer education should be continued as long as any area remains in the closed status because of marine biotoxin contamination.~~

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 (i.e. 36 phytoplankton samples for a phytoplankton strategy or 36 shellfish samples for a shellfish-related strategy). These samples should cover representative environmental conditions and a time span of at least three (3) years. Once this baseline dataset is developed and trends are established, the Authority may consider ~~modifying~~ reducing sample numbers, ~~and~~ frequency, and lot testing and/or increasing harvest days allowed in the marine biotoxin management plan in accordance with the strategies below.

All marine biotoxin management plans must establish, at a minimum, the below criteria:

- screening levels,
- methods,
- laboratory(s)/analyst(s),
- a representative sampling plan,
- representative sample locations (stations),
- representative sampling frequency; and
- a dataset that supports management decisions.

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 (3) 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 (1) 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 dataset; 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 sentinel 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 (3) 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 (1) 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

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 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 rates of specific toxins from all species of shellfish harvested from the growing areas (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. Additionally, 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 (3) years, the short duration of permitted harvest shall not exceed three (3) 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.

A~~The~~ marine biotoxin management plan that incorporates this strategy must also 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 (3) 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~~ A marine biotoxin management plan that incorporates this strategy must also 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 from 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 (3) 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 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~~ A marine biotoxin management plan that incorporates this strategy must also 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.~~

Heat Processing

In shellfish growing areas where low levels of biotoxins routinely occur, harvesting for thermal processing, referred to in the Model Oridinance as heat processing, purposes may be an alternative to consider. Thermal processing as defined by applicable FDA regulations (21 CFR 113) may reduce the biotoxin concentration of the shellfish via dilution, not destruction. While thermal processing has been demonstrated more for PSP toxins (Berenguer et al., 1993; Vieites et al. 1999; Dong et al., 2022), there are limited studies for the reduction of ASP and DSP toxins (McCarron et al 2008 and Vidal et al 2009). 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, as well as end product testing of processed shellfish.

Shellfish Meat Analyses and Toxin Profiles
Section II. Chapter III. @.02 C
Section IV. Guidance Documents Chapter II Growing Areas.14

There are a wide range of methodologies developed for screening and confirmation of toxic
phytoplankton and their toxins. Only methods adopted into the NSSP can be implemented for the purpose of confirming toxin concentration levels in shellfish and making decisions to reopen growing areas. Additionally, some screening methods have been evaluated by the ISSC and found fit for purpose for the NSSP, thereby providing confidence in their use for specific screening purposes.

Toxin analyses methods fall into two (2) categories in the NSSP:

1. Approved Methods for Marine Biotoxin Testing (Section IV. Guidance Documents Chapter II Growing Areas .14 Table 2.); and
2. Approved Limited Use Methods for Marine Biotoxin Testing (Section IV. Guidance Documents Chapter II Growing Areas .14 Table 4.).

The methods within these categories range from mouse bioassays to immunochromatography and other antibody-based platforms to chemical analytical methods such as high-performance liquid chromatography (HPLC). 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 applied to development of chemical analyses to replace or provide alternatives to in-vivo (live animal) bioassays. For toxins that have no method adopted into the NSSP, best available science is employed and emergency use adoption may be considered following the requirements described in Model Ordinance Chapter III. Laboratory @ .02 Methods.

The following table provides ~~a survey of the laboratory methods available~~ information for each toxin covered by the NSSP.

Paralytic Shellfish Poisoning (PSP) Toxins	
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 (Wiese et al., 2010). In addition to saxitoxin (the parent compound), monitoring laboratories typically analyze for approximately 12 other analogs that may contribute measurably to toxicity.
Guidance Level	0.8 ppm (80 µg saxitoxin equivalents /100 g tissue).
Origin	The regulatory limit was set in the 1930s (Wekell et al., 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 concentrations of less than 200 ug of the toxin have no deleterious effects on humans.
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 (RBA), a competition assay whereby radiolabeled saxitoxin competes with unlabeled saxitoxin for a finite number of available receptor sites, provides a measure of overall PSP toxicity in a sample (Van Dolah et al. 2009). The RBA was approved for mussels and approved limited use for clams and scallops in 2014.
General Molluscan ShellfishAssociations	Mussels, clams, cockles, oysters, and scallops (excluding the scallop adductor muscle).
Neurotoxic Shellfish Poisoning (NSP) Toxins	
Analogs	Comprised of more than 10 lipid-soluble cyclic polyethers. Several analogs and metabolites have been identified. NSP-causing toxins in shellfish include intact algal brevetoxins and their metabolites (collectively known as neurotoxic shellfish toxins or NSTs) (Plakas and Dickey, 2010).
Guidance Level	0.8 ppm (20 mouse units/100 g tissue or 80 µg brevetoxin-2 equivalents /100 g tissue)
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).
Shellfish Lab Methods	The approved NSSP method for NSP toxins is the mouse bioassay. The MARBIONC ELISA is approved for limited use. Efforts are underway to validate *in vitro* methods for detection of brevetoxins in shellfish. The methods that follow may be used for screening purposes. 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).
General Molluscan Shellfish Associations	Oysters and clams.
Amnesic Shellfish Poisoning (ASP) Toxin	
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.
Guidance Level	20 ppm (2mg domoic acid/100 g tissue)
Origin	In 1987 in eastern Canada, domoic acid poisonings sickened individuals, leading to Health Canada's establishment of the regulatory limit (Wekell, 2004).
Shellfish Lab Methods	The NSSP approved method for detecting domoic acid in seafood is a reversed-phase HPLC method with ultraviolet (UV) detection. The Reveal 2.0 ASP is an approved limited use method. There is an AOAC approved ELISA for the detection of domoic acid which may be used for screening purposes.
General Molluscan Shellfish Associations	Mussels, clams, cockles, oysters, and scallops (excluding the scallop adductor muscle).
Diarrhetic Shellfish Poisoning (DSP) Toxins	
Analogs	A group of lipid-soluble polyether toxins that includes okadaic acid (OA), the dinophysistoxins (DTXs), and a series of fatty acid esters of okadaic acid and the dinophysistoxins (collectively known as DSTs) (Uchida, 2018).
Guidance Level	0.16 ppm (0.16 mg total okadaic acid equivalents/kg tissue). Total okadaic acids equivalents equal combined free okadaic acid, dinophysistoxins, acyl-esters of okadaic acid and dinophysistoxins.
Origin	Established by FDA in 2011 for total (esterified plus nonesterified okadaic acid and the dinophysistoxins (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 dinophysistoxins in clams was approved in the NSSP. For other species, the best available science is recommended.
General Molluscan Shellfish Associations	Mussels, clams, cockles, oysters, and scallops (excluding the scallop adductor muscle).
Azaspiracid Shellfish Poisoning (AZP) Toxins	
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).
Guidance Level	0.16 ppm (160 µg azaspiracid-1 equivalents/kg tissue)
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.
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. Currently, there is no NSSP method for AZP toxins.
General Molluscan Shellfish Associations	Detected in mussels, oysters, scallops (excluding the scallop adductor muscle), clams, and cockles.

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.html
- **Diarrhetic Shellfish Poisoning** http://www.fao.org/3/y5486e/y5486e0e.html

- **Neurotoxic Shellfish Poisoning** http://www.fao.org/3/y5486e/y5486e0o.html
- **Amnesic Shellfish Poisoning** http://www.fao.org/3/y5486e/y5486e0n.html
- **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 whelks, snails, and, in some cases, even lobsters and octopi), may become toxic in areas where the source algae are present.

Model Ordinance, Public Health Reasons & Explanations, Guidance, and Appendices References

- Section I. Purposes & Definitions
- Section II. Model Ordinance –Chapter III. Laboratory @.02 Methods (C) and (D)
- Section III. Public Health Reasons and Explanations– Chapter IV. Shellstock Growing Areas @.04 Marine Biotoxin Control (A)
- Section IV. Guidance Documents– Chapter II. Growing Areas @.03 Determining the Size of a Closed Area as a Result of Illnesses
- Section IV. Guidance Documents– Chapter II. Growing Areas @.04 Determining the Harvesting Periods Associated with Implicated Product for Identifying Shellfish to Be Included in the Recall
- Section IV. Guidance Documents - Chapter II. Growing Areas @.05 Determining the Scope of Implicated Product for Conducting a Recall
- Section IV. Guidance Documents – Chapter II. Growing Areas @.08 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood
- Section IV. Guidance Documents – Chapter II. Growing Areas @.12 Growing Area Patrol and Enforcement
- Section IV. Guidance Documents – Chapter II. Growing Areas @.13 Control of Shellfish Harvesting
- Section IV. Guidance Documents – Chapter II. Growing Areas @.14 Approved NSSP Laboratory Tests
- Chapter XVI. Recalls, Closures, and Special Events Checklist & Appendices

~~References~~**Literature**

~~1. Centers for Disease Control (a). 1973. Shellfish Poisoning - Florida. *Morbid. Mortal. Weekly Rep*. 22(48):397-398.~~

~~2. Centers for Disease Control (b). 1973. Neurotoxic Shellfish Poisoning - Florida. *Morbid. Mortal. Weekly Rep*. 22(48):397-398.~~

1. Berenguer, J.A, et al (1993). The effect of commercial processing on the paralytic shellfish poison (PSP) content of naturally-contaminated *Acanthocardia tuberculatum* L, Food Additives and Contaminants 10(2), 217-230

2. Dong, C. et al (2022). Thermal processing induce release and degradation of paralytic shellfish toxin from mussels *Mytilus edulis*. Journal of Oceanology and Limnology 40(6), 2267-2276.

3. Felsing, W.A., Jr. 1966. Proceedings of Joint Seminar on North Pacific Clams, September 24-25, 1965. U.S. Public Health Service, Washington, D.C.

4. Food and Agriculture Organization of the United Nations. (2015) Codex Alimentar Standard for Live and Raw Bivalve Molluscs Codex Stan 292-2008.

~~3.~~5. Food and Agriculture Organization of the United Nations. (2004). FAO Food and Nutrition Papers, 80 - Marine Biotoxins.

~~4. Food and Drug Administration. 1977. Poisonous or Deleterious Substances in Food. *Federal Register* 42(190):52814-52819.~~

~~5. Food and Drug Administration. 1985. Action Levels For Poisonous or Deleterious Substances in Human Food and Animal Feed. U.S. Department of Health and Human Services, Public Health Service, Washington, D.C. 20204. 13 pages.~~

~~6.~~ Gordon, K., M.D., *et al*. 1973. Shellfish Poisoning. *Morbid. Mortal. Weekly Rep*. 22, (48):397- 398.

~~7.~~ Joint Sanitation Seminar on North Pacific Clams Juneau, A., Felsing, W. A. (William August)., United States. Public Health Service., Alaska. Dept. of Health and Welfare. (1966). Proceedings of Joint Sanitation Seminar on North Pacific Clams. Washington, D.C.: For sale by the Supt. of Docs., G.P.O..

~~8.~~ Marsden I.D., & Contreras, A.M., MacKenzie, L., Munro, M.H.G. (2015). A comparison of the physiological responses, behaviour and biotransformation of paralytic shellfish poisoning toxins in a surf-clam (Paphies donacina) and the green-lipped mussel (Perna canaliculus). Marine and Freshwater Research, 67, 1163-1174.

~~9.~~ McCarron, P., Kilcoyne, J., Hess, P. (2008). Effects of cooking and heat treatment on concentration and tissue distribution of okadaic acid and dinophysistoxin-2 in mussels (*Mytilus edulis*). Toxicon 51,1081-1089

~~10.~~ Morris, P.D., & Campbell, D.S., Taylor, T.J., Freeman, J.I. (1991). Clinical and epidemiological features of neurotoxic shellfish poisoning in North Carolina American Journal of Public Health, 81(4), 471-474.

~~11.~~ National Shellfish Sanitation Workshop., United States. Shellfish Sanitation Branch. (1964). Proceedings - National Shellfish Sanitation Workshop. [Washington]: U.S. Dept. of Health, Education, and Welfare, Public Health Service, Food and Drug Administration, Shellfish Sanitation Branch.

~~12.~~ Perl, T.M., & Bedard, L., Kosatsky, T., Hockin, J.C., Todd, E.C.D., NcNutt, L.A., Remis, R.S. (1990). Amnesic shellfish poisoning: a new clinical syndrome due to domoic acid. In: Hynie, I., Todd, E.C.D., editors. Proceedings of a symposium, domoic acid toxicity. Canada Disease Weekly Report; Ottawa, Ontario. Pp. 7-8.

~~6.~~13. Plakas, S.M., Dickey, R.W. (2010). Advances in monitoring and toxicity assessment of brevetoxins in molluscan shellfish. Toxicon 56, 137-149.

~~7. Liston, J. 1994. Association of *Vibrionaceae*, natural toxins, and parasites~~

~~with fecal indicators, p.215-216. In Hackney, C.R. and M.D. Pierson (eds.), *Environmental Indicators and Shellfish Safety*. Chapman and Hall, New York, NY.~~

14. Pulido, O.M. (2008). Domoic acid toxicologic pathology: a review. Marine Drugs, 6(2), 180-219.

~~8.~~15. Prakash, A., J.C. Medcof, and A. D. Tennant. 1971. Paralytic shellfish poisoning in eastern Canada. Bulletin 177, Fisheries Research Board of Canada. Ottawa, Canada.

~~9.~~16. Quayle, D.B. 1969. Paralytic shellfish poisoning in British Columbia. Bulletin 168, Fisheries Research Board of Canada. Ottawa, Canada.

~~10. Schwalm, D.J. 1973. The 1972 PSP outbreak in New England. FDA Report, Boston, MA. U.S. Food and Drug Administration, Washington, D.C.~~

~~11. U.S. Public Health Service (PHS). 1958. Proceedings: 1957 Conference on Shellfish Poison. U.S. PHS, Washington, D.C. 125 pages.~~

17. Trainer, V.L. et al (2013). Diarrhetic Shellfish Toxins and Other Lipophilic Toxins of Human Health Concern in Washington State. Marine Drugs 11, 1815-1835

18. Twiner, M.J., & Bottein Dechraoui, M.Y., Wang, Z., Mikulski, C.M., Henry, M.S., Pierce, R.H., Doucette, G.J. (2007). Extraction and analysis of lipophilic brevetoxins from the red tide dinoflagellate Karenia brevis. Analytical Biochemistry, 369(1), 128-135.

19. Uchida, H., & Watanabe, R., Matsushima, R., Oikawa, H., Nagai, S., Kamiyama, T., Baba, K., Miyazono, A., Kosada, Y., Kaga, S., Matsuyama, Y., Suzuki, T. (2018). Toxin profiles of okadaic acid analogues and other lipophilic toxins in Dinophysis from Japanese Coastal Waters. Toxins (Basel). 10(11), 457.

20. US Center for Disease Control. (1973). Shellfish poisoning - Florida. Morbidity Mortality Weekly Report, 22(48), 397-398.

21. US Food and Drug Administration. (1997). Poisonous or Deleterious Substances Food. Federal Register, 42(190), 52814-52819.

22. US Food and Drug Administration. (2000). Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed.

23. US Food and Drug Administration. (2011). Fish and Fishery Products Hazards and Controls Guidance 4th Edition.

24. Van Dolah et al (2009). Single-Laboratory Validation of the Microplate Receptor Binding Assay for Paralytic Shellfish Toxins in Shellfish 92(6), 1705-1714

25. Vidal, A., Correa, J., Blanco J.(2009). Effect of some habitual cooking process on the domaic acid concentration in the cockle (*Cerastoderma edule*) and Manila clam (*Ruditapes philippinarum*). Food Additives and Contaminants 26(7), 1089-1095

26. Vietas, J,M,, Botana, L.M., Vieytes, M.R., Leira, F.J. (1999). Canning Process that Diminishes Paralytic Shellfish Poison in Naturally Contaminated Mussels (*Mytilus galloprovincialis*). Journal of Food Protection, 62(5), 515-519

27. Watkins, S.M., & Reich, A., Fleming, L.E., Hammond, R. (2008). Neurotoxic shellfish poisoning. Marine Drugs, 6(3), 431-455.

28. Wekell, J.C., & Hurst, J., Lefebvre, K.A. (2004). The origin of the regulatory limits for PSP and ASP toxins in shellfish. Journal of Shellfish Research, 23(3), 927-9

29. Wiese, M., & D'Agostino, P.M., Mihali, T.K., Moffitt, M.C., Neilan, B.A. (2010). Neurotoxic alkaloids: saxitoxin and its analogs. Marine Drugs,

8(7), 2185- 2211.

~~12.~~30. Wilt, D.S. (ed). 1974. Proceedings of Eighth National Shellfish Sanitation Workshop. January 16-18. New Orleans, LA. National Technical Information Services (PB8 6 236916/AS), U.S. Dept. of Commerce, Springfield, VA. 158 p.

~~13. McCabe, Ryan M., *et al.* 2016. AGU100 *An unprecedented coastwide toxic algal bloom linked to anomalous ocean conditions*~~

Action by 2023 Task Force I	Recommended adoption of the Biotoxin Committee recommendation on Proposal 19-124.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-124.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-124.

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 21, 2020	Concurred with Conference action on Proposal 19-128.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 19-128 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 19-128.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-128.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-128.

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.
Action by 2023 Laboratory Committee	Recommended no action on Proposal 19-131. Rationale: There is no justification for changing the resistivity value in Line Item 1.7.6.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 19-131.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-131.
Axtion by FDA July 7, 2023	Concurred with Conference action on Proposal 19-131.

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.
Action by 2023 Laboratory Committee	Recommended adoption of Proposal 19-132 as submitted.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 19-132.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-132.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-132.

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 only 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 is not 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.
Action by 2023 Laboratory Committee	Recommended adoption of Proposal 19-133 as amended.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 19-133.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-133.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-133.

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.
Action by 2021 Laboratory Committee	Recommended adoption of Proposal 19-136 as amended with Interim Approval by the Executive Board
Action by 2021 ISSC Executive Board	Granted Interim Approval in effect until the Conference convenes at the 2023 ISSC Biennial Meeting.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 19-136.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-136.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-136.

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.
Action by 2023 Laboratory Committee	Recommended adoption of Proposal 19-138 as submitted.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 19-138.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-138.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-138.

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.
Action by 2022 Laboratory Committee	Recommended adoption of Proposal 19-140 as amended with Interim Approval by the Executive Board
Action by 2022 ISSC Executive Board	Granted Interim Approval in effect until the Conference convenes at the 2023 ISSC Biennial Meeting.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 19-140.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-140.
Action by FDA July 7, 2023	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.
Action by 2022 Laboratory Committee	Recommended adoption of Proposal 19-141 as amended with Interim Approval by the Executive Board
Action by 2022 ISSC Executive Board	Granted Interim Approval in effect until the Conference convenes at the 2023 ISSC Biennial Meeting.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 19-141.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-141.
Action by FDA Juy 7, 2023	Concurred with Conference action on Proposal 19-141.

Proposal No. 19-144

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.
Action by 2023 Male Specific Coliphage Committee	Recommended referral of Proposal 19-144 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force I	Recommended adoption of the Male Specific Coliphage Committee recommendation for Proposal 19-144.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-144.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-144.

Proposal No. 19-145

Submitter	US Food & Drug Administration (FDA) 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 This language will provide state shellfish Authorities with guidance regarding

Significance	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.
Action by 2023 Cleansing Study Committee	Recommended: 1) The committee recommended adoption of Proposal 19-145 as substituted.

Guidance on Studies Used in the Reopening of an Area Temporarily Placed in the Closed Status Due to an Emergency Condition, a Discharge of Raw Sewage, or when Conditional Area Management Plan (CAMP) Performance Standards are not Met

Note: Similar contaminant reduction studies associated with shellstock relaying and validation studies associated with the depuration process are not covered in this

guidance document. Instead, each has their own specific requirements which are covered in Chapter V. and Chapter XV., as well as Guidance Documents Chapter II .10 and .19, respectively.

A. When Are Studies Required?

Per Chapter IV. @.03 A.(5)(d) and C.(2)(c), studies are required for reopening a closed area to establish the environmental conditions and time required for pathogens (as measured by microbiological indicators) in shellstock and water to return to acceptable levels following the impact from an emergency condition, discharge of raw sewage, or when conditional area management plan (CAMP) performance standards are not met. Listed below is a summary of scenarios for reopening options:

1) Scenarios where studies are required to reopen once the emergency situation or condition has returned to normal, or CAMP performance standards are fully met, and sufficient time has elapsed to allow the shellstock to reduce pathogens and for the growing area water quality to return to acceptable levels:

(a) Chapter IV. @.03A.(5)(d):

- Reopening due to closures resulting from an emergency condition or situation when pathogens are of concern (other than raw untreated sewage discharged from a sewage collection system or WWSD), studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. Such coliform studies may establish criteria for reopening based on coliform levels in the water.

- Reopening due to emergency closures caused by the occurrence of raw untreated sewage discharged from a sewage collection system or WWSD, when the closure duration is less than 21 days or when analytical shellstock samples are utilized for comparison to the levels established in the Chapter IV. @.02 E. (4). The authority may use studies to establish pre-determined male-specific coliphage (MSC) levels in shellfish samples that are conducted no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted.

(b) Chapter IV. @.03 C.(2)(c)(iii):
For management plans based on WWSD function or pollution sources other than WWSD criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status.

- Reopening due to closures impacted by pathogens (other than raw untreated sewage discharged from a sewage collection system or WWSD) from a failure to comply with its conditional management plan, studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. These studies may establish criteria for reopening based on coliform levels in the water.

- Reopening due to temporary closures impacted by sewage from a failure to comply with the conditional management plan based on the WWSD performance standards, studies may be conducted to establish sufficient elapsed time and shall document the interval necessary for reduction of

viral levels in the shellstock. These studies may establish pre-determined levels based on regional species under regional conditions. These studies may establish criteria for reopening based on viral levels in shellfish meats.

2) Scenarios where sampling is required to reopen when a study is not conducted, include:

(a) Chapter IV. @.03A.(5)(d):

- Reopening due to emergency closures of harvest areas caused by the occurrence of raw untreated sewage discharged from a sewage collection system or WWSD, when the closure duration is intended to be less than 21 days, the analytical sample results shall not exceed the levels established in Chapter IV. @.02 E. (4).

- Reopening due to emergency closures of harvest areas when poisonous or deleterious substances are the concern, sampling shall establish that poisonous or deleterious substances in shellstock do not exceed FDA action levels, tolerances, guidance levels, and levels that are deemed unsafe through risk evaluation.

(b) Chapter IV. @.03C.(2)(c)(iii):

- Reopening due to temporary closures impacted by sewage from a failure to comply with the conditional management plan based on the WWSD performance standards, analytical sample results shall not exceed the MSC level established in Chapter IV. @.02 E. (4).

- Water quality sampling can be used to reopen an area following temporary closures resulting from a failure to comply with conditional management plan performance standards based on the effects of non-point sources of pollution such as rain events and/or stormwater runoff.

3) Scenarios where no studies or sampling are required to reopen, include:

(a) Chapter IV. @.03A.(5)(d)(ii) and C.(2)(c)(iii):

- Reopening due to the temporary closure from a discharge of raw untreated sewage or exceedance of management plan performance standards relating to WWTP function. If no studies or analytical samples are collected and compared to the levels established in Chapter IV. @.02 E. (4), the area must be in the closed status until the event is over and twenty-one (21) days have passed.

2) proposal be referred back to an appropriate committee as determined by the conference chair to allow for further development of additional sections of the Guidance Document.
3) expanding the charge of the committee to include reviewing Model Ordinance language relating to cleansing studies for reopening.

Action by 2023 Task Force I	Recommended adoption of the Cleansing Study Committee recommendation for Proposal 19-145.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-145.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-145.

Proposal No. 19-150

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.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 19-150 to an appropriate committee as determined by the Conference Chairperson
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 19-150.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-150.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-150.

Proposal No. 23-100

Submitter	Bryant Lewis[1], David Borkman[2], Jeff Kennedy[3] Maine Department of Marine Resources[1], Rhode Island Department of Environmental Management[2], Massachusetts Division of Marine Fisheries[3] Bryant.j.lewis@maine.gov[1], David.Borkman@dem.ri.gov[2], jeff.kennedy@state.ma.us[3]
Proposal Subject	Mooring Area Definition Change
Specific NSSP Guide Reference	Section I Purposes & Definitions, B. 79.
Text of Proposal/ Requested Action	**(79) Mooring Area** means any water area that is used to provide temporary or permanent anchorage for more than twenty (20) boats with marine sanitation devices. Mooring areas do not include any structures for docking boats.
Public Health Significance	The proposed Mooring Area definition change adds clarification that only vessels which have marine sanitation devices onboard are to be included in the count of boats in a mooring area. Inclusion of only vessels with marine sanitation devices is consistent with the risk evaluation of illicit discharge of human waste in shellfish growing area. It is logistically difficult for human waste to be discharged from a vessel that does not have a marine sanitation device onboard. The risk of fecal coliform contamination of a growing area from persons on vessels such as dinghies, daysailers, and small open boats that do not have marine sanitation devices onboard is no different than the risk presented by swimmers, shoreline walkers or any other person in or adjacent to the growing area. Shellfish Sanitation Control Authorities have engaged in numerous regulatory and educational programs to prevent illicit discharge of human waste into shellfish growing areas from vessels. Inclusion of the proposed clarifying language does not weaken those efforts.
Cost Information	No cost would be associated with this proposal. Clarifying the definition of a mooring area may also ease Authorites' administrative, patrol and fieldwork burdens with no impact on risk.
Action by 2023 Task Force I	Recommended adoption of Proposal 23-100 as submitted.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-100.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-100.

Proposal No. 23-101

Submitter	Kohl Kanwit Maine Department of Marine Resources Kohl.kanwit@maine.gov
Address Line 1	PO Box 8
Address Line 2	
City, State, Zip	West Boothbay Harbor, ME 04575
Phone	207-557-1318
Fax	
Email	
Proposal Subject	Definition of scallops
Specific NSSP Guide Reference	Section I. Definitions B. Definition of Terms. Section III. Intorduction
Text of Proposal/ Requested Action	Section I. Definitions B. Definition of Terms. (115) 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, attached or unattached to the shell. Section III. Introduction ….The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops in any form, except when the final product form is the adductor muscle only, attached or unattached to the shell) moving in interstate commerce through Federal/State cooperation and uniformity of State shellfish programs.
Public Health Significance	The current definition of scallops excludes the adductor muscle only. However, there is a value added market for scallop adductor muscles that remain attached to the ventral shell. This proposal seeks to allow scallop adductor muscles to be exempt from the NSSP attached or unattached from the ventral shell.
Cost Information	There is no cost associated with this change.
Action by 2023 Task Force I	Recommended adoption of Proposal 23-101 as submitted.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-101.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-101.

Proposal No. 23-102

Submitter	Kohl Kanwit
Affiliation	Maine Department of Marine Resources Kohl.kanwit@maine.gov
Proposal Subject	Seed sourced from Prohibited areas
Specific NSSP Guide Reference	Section I Purposes & Definitions Definitions B. Definition of Terms. Section II Model Ordinance, Chapter IV. Shellstock Growing Areas E. Prohibited Classification. Section IV Guidance Documents, Chapter II. Growing Areas Growing Area Classifications Section IV Guidance Documents, Chapter II. Growing Areas .19 Classification of Shellfish Growing Waters Adjacent to Waste Water Treatment Plants I. Introduction IV. Prohibited Classification A. Definition C. Allowable Uses of Shellfish from a Prohibited Growing Area D. Model Ordinance Requirements for Depletion and Gathering of Seed H. Public Health Significance
Text of Proposal/ Requested Action	Section I Purposes & Definitions Definitions B. Definition of Terms. (96) **Prohibited** means a classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion, gathering of seed or nursery culture for aquaculture or resource enhancement, is not permitted. (113) **Seed** means shellstock which is less than market size and complies with the criteria in NSSP Model Ordinance Chapter VI. Shellfish Aquaculture @.02 Seed Shellstock where necessary. Section II Model Ordinance, Chapter IV. Shellstock Growing Areas E. Prohibited Classification. (1) Exception. The prohibited classification is not required for harvest waters within or adjacent to marinas. The Authority, however, may use the prohibited classification for these waters. (2) General. The Authority shall: (a) Not permit the harvest of shellstock from any area classified as prohibited, except for the gathering of seed or nursery culture for aquaculture or resource enhancement or the depletion of the areas classified as prohibited; and (b) Ensure that shellstock removed from any growing area classified as prohibited is effectively excluded from human consumption unless it ~~is~~

~~seed to be cultured as outlined in the~~ complies with the criteria in NSSP Model Ordinance Chapter VI. Shellfish Aquaculture @.02 Seed Shellstock.

Section IV Guidance Documents, Chapter II. Growing Areas
Growing Area Classifications
A growing area is placed in the prohibited classification when the sanitary survey or marine biotoxin surveillance program indicates that fecal material, pathogenic microorganisms, poisonous or deleterious substances, marine biotoxin, or radionuclides may reach the harvest area in excessive concentrations. The NSSP Model Ordinance also requires that a growing area for which there is no sanitary survey be placed in the prohibited classification as a precautionary measure. Taking shellstock from a prohibited area for any human food purpose is not allowed except for the gathering of seed or nursery culture for aquaculture or resource enhancement or the depletion of the areas classified as prohibited.

Section IV Guidance Documents, Chapter II. Growing Areas
.19 Classification of Shellfish Growing Waters Adjacent to Waste Water Treatment Plants
I. Introduction
(1) Prohibited – A classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering of seed or nursery culture for aquaculture or resource enhancement, is not permitted.

IV. Prohibited Classification
A. Definition
A classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering of seed or nursery culture for aquaculture or resource enhancement, is not permitted.
C. Allowable Uses of Shellfish from a Prohibited Growing Area
(1) Depletion
Depletion means the removal, under the direct control of the Authority, of shellstock from a growing area classified as prohibited.
(2) Seed
Seed means shellstock which is less than market size and complies with the criteria in NSSP Model Ordinance Chapter VI. Shellfish Aquaculture @.02 Seed Shellstock where necessary.
D. Model Ordinance Requirements for Depletion and Gathering of Seed
(1) Chapter IV. Shellstock Growing Areas
@.03 Growing Area Classification
E. Prohibited Classification
(1) Exception…
(2) General. The Authority shall:
(a) Not permit the harvest of shellstock from any area classified as prohibited, except for the harvest of shellstock for the gathering of seed or nursery culture for aquaculture or resource enhancement or the depletion of the areas classified as prohibited; and
H. Public Health Significance
The positive relationship between disease and consuming contaminated shellfish has been clearly established. Prevention of consumption of contaminated shellfish is the primary objective of the NSSP. The prohibited area classification is the most restrictive growing area classification and is used for areas subject to gross pollution. The use of

this classification is also required for all growing areas immediately adjacent to a wastewater treatment plant and where the shellfish authority has not performed a sanitary survey. The harvesting of shellstock is not allowed for any human food use except for the gathering of seed or nursery culture for aquaculture or resource enhancement. For additional information concerning the classification of growing waters and the sanitary survey, see the NSSP Model Ordinance. Depletion and Gathering of Seed (Chapter IV @.03 E. Prohibited Classification (2) (a) & (b) and Chapter VI .03 Seed Shellstock A. & B.)

Public Health Significance	The NSSP MO prohibits any harvest from areas classified as Prohibited except for depletion and gathering of seed or nursery culture for aquaculture. The allowance for seed harvest from Prohibited areas for aquaculture purposes is coupled with a requirement for the Authority to define maximum seed sizes (Chapter VI. Shellfish Aquaculture @.02) that enable a minimum of 120 days of grow out before harvest and Control of Harvest requirements (Chapter VIII. Control of Shellfish Harvesting @.01). These requirements ensure safe harvest of seed coming from areas classified as Prohibited and should be extended to natural resource enhancement efforts. There are occasionally plentiful wild seed resources in Prohobited areas that can be safely transplanted to Approved areas for grow out and later harvest. Because of the existing maximum seed size regulation there is no risk of seed being harvested before 120 days. Allowing for the inclusion of harvest of seed from Prohibited areas for wild resource enhancement would not only increase resource utilization, but it would also deter illegal harvest by removing resources before they are market size.
Cost Information	There is no cost associated with this change.
Action by 2023 Task Force I	Recommended adoption of Proposal 23-102 as submitted.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-102.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-102.

Proposal No. 23-103

Submitter	Adam Wood Virginia Department of Health adam.wood@vdh.virginia.gov
Proposal Subject	Illness Outbreak – Growing Area Closure
Specific NSSP Guide Reference	Section II Model Ordinance, Ch. II. Risk Assessment and Risk Management @.01 .01 Outbreaks of Shellfish-Related Illness G(2)
Text of Proposal/ Requested Action	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 a previously unknown pollution source can be corrected, the closure period 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 until at least ~~for a minimum of~~ 21 days have passed from ~~after~~ the last date of harvest of~~on~~ the implicated shellstock if the illness is consistent with viral etiology; and (3) Develop a written report summarizing the findings of the investigation and actions taken.
Public Health Significance	This proposal alters the language relating to when the 21 day timeline starts for closures due to viral etiology. The new language means that if a growing area is closed due to a viral illness outbreak, the 21 day viral cleansing timeline starts on the last day of harvest of implicated shellstock and the area must remain closed until 21 days following the last harvest date. This is different from the previous language where the area remained closed for 21 days from the first day a viral outbreak was identified. The existing requirement has resulted in growing area closures months after the shellstock was harvested and the risk is no longer present, as viral outbreaks are often identified many months after consumption. There is usually a delay in illness reporting. Requiring a full 21 day closure later than the implicated harvest dates, sometimes weeks or even months later, does not offer additional protections to the consuming public specific to the related outbreak. Section G (1) addresses the need for a closure for investigation related to the outbreak and G (1)(b) addresses the source of contamination and time for natural depuration prior to reopening the growing area. If the source of contamination continues, the Authority has the ability to keep the area closed until the criteria of G(1)(b) is met.
Cost Information	N/A
Action by 2023 Task Force I	Recommended adoption of Proposal 23-103 as submitted.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-103.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-103.

Submitter	Danielle Schools, Division Director Virginia Department of Health, Division of Shellfish Safety Danielle.schools@vdh.virginia.gov
Proposal Subject	Vibrio illness reporting- time frame for action to close shellfish growing areas
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @02A@.02 Shellfish Related Illnesses Associated with Vibrio parahaemolyticus (V.p.)
Text of Proposal/ Requested Action	A. When the investigation outlined in Section @.01 A. (6) 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~~ thirty ~~(60)~~ (30) days 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.
Public Health Significance	According to the *Control of Communicable Diseases Manual 20th Edition*, the incubation period for Cholera and other vibrioses is a few hours to 5 days, usually 2-3 days. Section IV Guidance documents – Chapter II. Growing areas specifically states," The generally accepted minimum time period for elimination of microbial contaminants from shellstock is fourteen (14) days when environmental conditions are suitable for natural cleansing." Most states have requirements that communicable disease be reported to the state epidemiologist or health departments within set time frames- some as short as 24 hours. Closing a growing area beyond 30 days from the harvest date, due to inadequate reporting time frames, does not protect public health because after 30 days the molluscan shellfish will have had time to purge. In Section II Model Ordinance -Chapter II Risk Assessment and Risk Management @01 I(1) Molluscan shellfish that has been recalled because of an illness or outbreak is allowed to be reconditioned through placement into shellfish growing areas in the open status for a time frame not less than 14 days.
Cost Information	None
Action by 2023 Task Force I	Recommended adoption of Proposal 23-104 as submitted.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-104.

Action by FDA July 7, 2023

The FDA is concerned with the action taken by the Conference on Proposal 23-104. The language recommended by Task Force I and subsequently adopted by the General Assembly at Chapter II. @. 02A is "States will not be expected to close growing areas based on V.p. cases that are reported more than thirty (30) days when environmental parameters have changed, or monitoring indicates the V.p. risk is reduced."

The FDA believes this language will decrease the likelihood that the established number of reported *Vibrio parahaemolyticus* cases required for the Authority to take action as stated in Ch II @.02A will be met. This will lower the public health protection of the NSSP by essentially requiring the established number of cases to occur in a shorter time frame than the existing MO language allows prior to taking the necessary action to prevent product with illness-causing potential from entering into interstate commerce. Based on available data, changing the actionable reporting window from 60 days to 30 days will result in 25% fewer reported cases on which action could be taken. The timeline for public health action includes a series of events from the time a person is infected through the time an Authority may be notified of a shellfish-associated case. For example, a *Vibrio parahaemolyticus* case takes at least three days from time of the

victim seeking medical care to having a laboratory confirmed case reported to an Authority. As such, this proposal language essentially shortens the window for the number of cases and time frames to trigger an action by the Authority by those three days, at best. In instances where reporting takes longer (due to delay in seeking medical care, lab outsourcing, epidemiological investigations, and/or communication and reporting delays across multiple entities involved in the illness investigation), which is a more common scenario, this window to trigger action becomes even more narrow. The result of having to reach the reported cases threshold in a shorter time frame to trigger action goes against the intent of the existing language, which is to minimize these sporadic illnesses with a tiered, risk-based approach.

The Program, as a whole, has successfully implemented time-to-temperature controls and, as a result, *Vibrio parahaemolyticus* illness outbreaks are rare. However, sporadic cases of *Vibrio parahaemolyticus* illness do still occur and it weakens the shellfish safety provisions of the NSSP to require the same number of cases be reported in a shorter period of time to meet the trigger levels outlined in the MO for action by the Authority.

The FDA encourages the Executive Board to consider an alternate action and refer Proposal 23-104 back to the appropriate committee as determined by the Conference Chair for further discussion.

Proposal No. 23-105

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov US Food & Drug Administration (FDA)
Proposal Subject	Request to rescind the *Vibrio vulnificus* enzyme immunoassay (EIA) method
Specific NSSP Guide Reference	Section IV. Chapter II.14
Text of Proposal/Requested Action	**Approved Methods for Vibrio Enumeration**

	Vibrio 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 e for vvhA as described by Wright et al., or a method that a State can demonstrate is equivalent.

Public Health Significance	The method for detection of Vibrio vulnificus (Vv) by the enzyme immunoassay (EIA) method should no longer be included in the NSSP. There are no laboratories using this method in support of the Program. The antibody required for the test method is not produced and has not been for many years, indicating it is unlikely to be produced again in the future. There are multiple alternative methods in the Program for the detection and confirmation of Vv isolates. Additionally, the ISSC Constitution, Bylaws, and Procedures states in Procedure XV, 8. that a method is subject to recantation when reagents are no longer available. As such, there should be no impact to the Program and the protection of public health and the table indicating approved methods for vibrio enumeration, validated and approved under the NSSP, will reflect the available choices of analyses.
Cost Information	N/A
Action by 2023 Laboratory Committee	Recommended adoption of Proposal 23-105 as submitted.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 23-105.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-105.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-105.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Request to rescind the *Vibrio vulnificus* SYBR Green real-time PCR method
Specific NSSP Guide Reference	Section IV. Chapter II.14 Approved Methods for Vibrio Enumeration
Text of Proposal/ Requested Action	[Section IV. Chapter II.14]

Approved Methods for Vibrio Enumeration

	Vibrio 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	

[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.~~

[65]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.

[Modifications to the Microbiology PCR Checklist]
3.2.3 The PCR forward and reverse primers used target.
For Total and Pathogenic Vp Real-time PCR Method
tdh_269-20: 6FAM-5'-TGACATCCTACATGACTGTG-3'-MGBNFQ
trh_133-23: TET-5'-AGAAATACAACAATCAAAACTGA-3'-MGBNFQ
tlh_1043: TEXAS RED-5'- CGCTCGCGTTCACGAAACCGT -3'-BHQ2
IAC_109: CY5-5'- TCTCATGCGTCTCCCTGGTGAATGTG -3'- BHQ2
trh_20F: 5'-TTGCTTTCAGTTTGCTATTGGCT-3'
trh_292R: 5'-TGTTTACCGTCATATAGGCGCTT-3'
tdh_89F: 5'-TCCCTTTTCCTGCCCCC-3'
tdh_321R: 5'-CGCTGCCATTGTATAGTCTTTATC-3'
tlh_884F: 5'-ACTCAACACAAGAAGAGATCGACAA-3'
tlh_1091R: 5'-GATGAGCGGTTGATGTCCAAA-3'
IAC_46F: 5'-GACATCGATATGGGTGCCG-3'
IAC_186R: 5'-CGAGACGATGCAGCCATTC-3'

~~For Vv Real-time PCR Method~~
~~vvhF 5'-TGTTTATGGTGAGAACGGTGACA-3'~~
~~vvhR 5'-TTCTTTATCTAGGCCCCAAACTTG-3'~~

Public Health Significance	The specific instrumentation (Cepheid SmartCycler) required for the Vv Real-time PCR Method using SYBR Green for detection of Vibrio vulnificus (Vv) should no longer be included in the NSSP. There are no laboratories using this method in support of the Program. The instrumentation required for the test method is not produced and is no longer supported by the manufacturer, indicating a lack of ability to perform required maintenance and calibration to ensure integrity of results. There are multiple alternative methods in the Program for the detection and confirmation of Vv, including a Real-Time PCR Method. Additionally, the ISSC Constitution, Bylaws, and Procedures states in Procedure XV, 8. that a method is subject to recantation when equipment is no longer available. As such, there should be no impact to the Program and the protection of public health and the table indicating Approved Methods for Vibrio Enumeration will reflect the available choices of analyses.
Cost Information	N/A
Action by 2023 Laboratory Committee	Recommended adoption of Proposal 23-106 as submitted.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 23-106.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-106.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-106.

Proposal No. 23-107

Submitter	Robert Rheault East Coast Shellfish Growers Association bob@ecsga.org
Proposal Subject	Data evaluation when the nonpoint sources impacting a growing area are not from a human sewage source.
Specific NSSP Guide Reference	Section II. Model Ordinance; Chapter IV Growing Areas; Section @.02 Microbiological Standards F.1.
Text of Proposal/ Requested Action	F. Standard for the Approved Classification of Growing Areas when Evaluated for Nonpoint Sources. (1) Exception. (a) If the tidal stage increases the fecal coliform concentration, the authority shall use sample results collected during that tidal stage to classify the area. (b) If the Authority has documentation supporting that the nonpoint sources impacting the growing area are not from a human sewage origin they may exclude up to two outlier datapoints from the dataset being evaluated. (2) Pollution Sources. Growing areas shall be impacted only by randomly occurring, intermittent events. (3) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2) or Section F. (4). (4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median (or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed fourteen (14) per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of: (a) 43 MPN per 100 ml for a five-tube decimal dilution test; (b) 49 MPN per 100 ml for a three-tube decimal dilution test; or (c) 31 CFU per 100 ml for a MF (mTEC) test. (5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by: (a) Calculating the arithmetic mean and standard deviation of the sample result logarithms (base 10); (b) Multiplying the standard deviation in (a) by 1.28; (c) Adding the product from (b) to the arithmetic mean; (d) Taking the antilog (base 10) of the results in (c) to get the estimated 90th percentile; and (e) The MPN values that signify the upper or lower range of sensitivity of the MPN tests in the 90th percentile calculation shall be increased or decreased by one significant number. (6) Required Sample Collection.

(a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in Section E. (3) for application of the standard under Section E. (2).
(b) Systematic Random Sampling Standard. The requirement for systematic random sample collection shall be met when:
(i) Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution;
(ii) Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that, prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area, and if conditions at the time of scheduled sample collection are believed to be hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled at a later date as soon as practical;
(iii) A minimum of six (6) random samples shall be collected annually from each sample station in the growing area;
(iv) A minimum of two (2) random samples shall be collected annually from each sample station in the growing area while in the inactive status. The sample collection frequency of six (6) random samples per station per year specified under @.02 F. (6)(b) (iii) must resume at least six (6) months before an area is reactivated; and
(v) A minimum of the thirty (30) most recent randomly collected samples from each sample station shall be used to calculate the median or geometric mean and 90th percentile to determine compliance with this standard.
(c) Transition from Adverse Pollution Condition Standard to Systematic Random Sampling Standard. If the Authority:
(i) Does not have thirty (30) recent randomly collected sample results from each station, then the previous fifteen (15) samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum thirty (30) sample requirement for a transition period not to exceed three (3) years; and
(ii) Uses the transition period described in (i), as additional random samples are collected; the random samples shall replace chronologically the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1).

Public Health Significance

It is recognized that on occasion water quality may be impacted by non-human sources such as birds. Scientific literature also indicates that the presence of human enteric pathogens in wild birds is overestimated with the use of the coliform indicator (Smith et al. 2021) https://doi.org/10.1111%2Fbrv.12581
If a few aberrant samples can be reliably attributed to birds it is likely that the closure of the harvest area is an unwarranted response.

Cost Information

Research Needs Information (Optional)

a. Proposed specific

At this time we do not have an estimate of the correlation of human enteric pathogens with coliforms in wild bird waste. Our growing area classification has been entirely built on the correlation between pathogens and coliforms in

research need/ problem to be addressed	wastewater. Using the coliform standard to close harvest areas impacted by birds assumes the relationship is similar, when scientific literature indicates that the risk is being overestimated. Research is needed to describe the persistence of bird-sourced pathogens in the marine environment, and how long these pathogens persist in the shellfish if they are taken up by filter feeding bivalves
b. Explain the relationship between proposed research need and program change recommended in the proposal	Research to elucidate the relationship between human enteric pathogens and coliforms will help define the risk of illness associated with consumption of shellfish that may have been impacted by birds. Studies evaluating how these pathogens survive in the marine environment will further inform this relationship. Studies evaluating the purge rates of these pathogens will help growers devise management approaches to ensure potentially impacted product is held away for contaminated sites and is safe for consumption.
c. Estimated cost	Unknown
Action by 2023 Task Force I	Recommended referral of Proposal 23-107 as amended to an appropriate committee as determined by the Conference Chair.

F. Standard for the Approved Classification of Growing Areas when Evaluated for Nonpoint Sources.

(7) Exception.

(a) If the tidal stage increases the fecal coliform concentration, the authority shall use sample results collected during that tidal stage to classify the area.

(b) ~~If the Authority has documentation supporting that the nonpoint sources impacting the growing area are not from a human sewage origin they may exclude up to two outlier datapoints from the dataset being evaluated.~~

(8) Pollution Sources. Growing areas shall be impacted only by randomly occurring, intermittent events.

(9) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2) or Section F. (4).

(10) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median (or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed fourteen (14) per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of:

(a) 43 MPN per 100 ml for a five-tube decimal dilution test;

(b) 49 MPN per 100 ml for a three-tube decimal dilution test; or

(c) 31 CFU per 100 ml for a MF (mTEC) test.

(11) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by:

(a) Calculating the arithmetic mean and standard deviation of the sample result logarithms (base 10);

(b) Multiplying the standard deviation in (a) by 1.28;

(c) Adding the product from (b) to the arithmetic mean;

(d) Taking the antilog (base 10) of the results in (c) to get the estimated 90th percentile; and

(e) The MPN values that signify the upper or lower range of sensitivity of the MPN tests in the 90th percentile calculation shall be increased or decreased by one significant number.

Required Sample Collection.

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

(d) Systematic Random Sampling Standard. The requirement for

systematic random sample collection shall be met when:

(i) Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution;
(ii) Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that, prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area, and if conditions at the time of scheduled sample collection are believed to be hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled at a later date as soon as practical;
(iii) A minimum of six (6) random samples shall be collected annually from each sample station in the growing area;
(iv) A minimum of two (2) random samples shall be collected annually from each sample station in the growing area while in the inactive status. The sample collection frequency of six (6) random samples per station per year specified under @.02 F. (6)(b) (iii) must resume at least six (6) months before an area is reactivated; and
(v) A minimum of the thirty (30) most recent randomly collected samples from each sample station shall be used to calculate the median or geometric mean and 90th percentile to determine compliance with this standard.

(e) Transition from Adverse Pollution Condition Standard to Systematic Random Sampling Standard. If the Authority:
(i) Does not have thirty (30) recent randomly collected sample results from each station, then the previous fifteen (15) samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum thirty (30) sample requirement for a transition period not to exceed three (3) years; and
(ii) Uses the transition period described in (i), as additional random samples are collected; the random samples shall replace chronologically the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1).

Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-107.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-107.

Proposal No. 23-108

Submitter	Alex Manderson Oregon Department of Agriculture Alexis.manderson@oda.oregon.gov
Proposal Subject	Clarification of standards for reopening following WWTP sewage spill.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @. 03 A. (5) (d)(ii)
Text of Proposal/ Requested Action	(ii) For emergency closures of harvest areas caused by the occurrence of raw untreated sewage discharged from a large community sewage collection system or WWSD, the analytical sample results shall not exceed ~~the~~ MSC levels established in Chapter IV @.02 E (4) or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions from shellfish samples collected no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted or until the event is over and twenty-one (21) days have passed;
Public Health Significance	Chapt. IV @. 03 A. (5) (d)(ii) describes the how MSC can be utilized for reopening a growing area prior to 21 days in the case of a raw, untreated sewage spill closure. It is understood that MSC testing is the only acceptable method for reopening from raw sewage spills earlier than the mandated 21 day closure period. Including a reference to bacteriological data in this context is confusing and misleading since E. (4) is the regulation addressing the MSC standard., and utilizing MSC is the focus of (d) (ii).
Cost Information	None
Action by 2023 Task Force I	Recommended adoption of Proposal 23-108 as submitted.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-108.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-108.

Proposal No. 23-109

Submitter	U.S. Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Growing area reopening criteria
Specific NSSP Guide Reference	Chapter IV. @.03 A.(5)(d) Chapter IV. @.03 C.(2)(c)
Text of Proposal/ Requested Action	Chapter IV. @.03 A.(5)(d): (d) Reopened Status. A growing area temporarily placed in the closed status as provided in (b) above, shall be returned to the open status only when: (i) The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels. (ii) When pathogens are of concern, and the area is not impacted by human sewage, studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. Such coliform studies may establish criteria for reopening based on coliform levels in the water. (iii) When poisonous or deleterious substances are the concern, 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. (v) For emergency closures of harvest areas caused by the occurrence of raw untreated sewage or partially treated sewage discharged from a ~~large community~~ sewage collection system or WWSD: a. The male-specific coliphage (MSC) analytical sample results in shellfish shall not exceed the levels established in Chapter IV @.02 E.(4) or b. ~~p~~Pre-determined MSC levels in shellfish established by the Authority based on studies conducted on regional species under regional conditions from shellfish samples collected no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted or c. ~~until~~ Until the event is over, and twenty-one (21) days have passed. (vi) The requirements for biotoxins or conditional area management plans as established in Section @.04 and Section @.03, respectively, are met. (ivi) Supporting information is documented by a written record in the central file. Chapter IV. @.03 C.(2)(c): (c) For management plans based on WWSD function or pollution sources other than WWSD criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum reopening criteria for conditional management plans are: (i) Performance standards of the plan are fully met;

(ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;
(iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. ~~Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels.~~
(iv) Shellstock feeding activity is sufficient to achieve ~~microbial~~ pathogen reduction.
(v) If (i-iv) are met and if the conditional management plan closure performance standard(s) is(are) based on the effects of non-point sources of pollution such as rain events and/or storm water runoff, an area may be reopened when the water quality meets classification criteria without a shellstock cleansing study;~~.~~
(vi) For conditionally managed areas based on WWSD performance standards,the Authority may utilize MSC levels in shellstock to establish that sufficient time has elapsed to allow water quality and shellstock to return to acceptable levels in growing areas adjacent to WWSD:

a. Analytical shellstock tissue sample results shall not exceed the MSC levels established in Chapter IV @.02 E.(4) or
b. Pre-determined MSC shellstock tissue 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
c. The area shall be in the closed status until the event is over and twenty-one (21) days have passed.

Public Health Significance	The NSSP MO requires certain criteria are met in order to reopen a growing area closed due to an emergency closure or based on the performance standards of a conditional management plan. There has been some confusion regarding the present reopening criteria language. This proposed language is intended to clarify the requirements for reopening criteria.
Cost Information	Not applicable.
Action by 2023 Task Force I	Recommended adoption of Proposal 23-109 as submitted.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-109.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-109.

Proposal No. 23-110

Submitter	Adam Wood & Kathy Brohawn Virginia Department of Health, Maryland Department of the Environment adam.wood@vdh.virginia.gov
Proposal Subject	Marina classification
Specific NSSP Guide Reference	Section II Model Ordinance, Ch. IV Shellstock Growing Areas @.05 Marinas
Text of Proposal/ Requested Action	A. Marina Proper. The area within any marina which is in or adjacent to a shellstock growing area shall be classified as conditionally approved, restricted, conditionally restricted or prohibited. (1) Prior to the Authority establishing a classification of conditionally approved, restricted, 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 within the marina proper does not require a pollution assessment by the Authority.
Public Health Significance	Proper classification of shellfish havesting areas is critical to preventing shellfish related foodborne illnesses. The restricted classification is a key component of the proper classification of harvesting areas, this proposal is adding the restricted classification to the section governing the marina proper. The restricted classification should be an option in a marina proper with a pollution assessment justification by the Authority. A conditional classification management plan would only be needed if there is fluctuation in marina operation necessitating periodic and predictable closures of the growing area.
Cost Information	N/A
Action by 2023 Task Force I	Recommended no action on Proposal 23-110. Rationale: Restricted is not an appropriate classification for use in or adjacent to Marinas.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-110.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-110.

Proposal No. 23-111

Submitter	Adam Wood Virginia Department of Health adam.wood@vdh.virginia.gov
Proposal Subject	Relay timeframe
Specific NSSP Guide Reference	Section II Model Ordinance, Ch. V Shellshock Relaying @.02 Contaminant Reduction C(3)
Text of Proposal/ Requested Action	(1) The Authority may waive the requirements for a contaminant reduction study if: (1) Only microbial contaminants need to be reduced; and (2) The shellstock are relayed from a conditionally approved, restricted, or conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per Chapter IV. @.02 G. and Chapter IV. @.02 H.; and (3) The treatment period exceeds ~~sixty~~fourteen (~~60~~14) days. D. The time period shall be at least fourteen (14) consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequate
Public Health Significance	The change to 14 days is consistent with the literature available and already cited in the NSSP. The Guidance documents already have established 14 days as the ideal acceptable time for elimination of microbial contaminants. 60 days is not in any literature nor in any other already voted on sections of the NSSP for relaying. 21 days is the agreed upon value for harvesting waters adulterated with raw sewage, which is likely the worst-case scenario, relay from areas only impacted by microbial contamination should surely be less than those contaminated by raw sewage.
Cost Information	N/A
Action by 2023 Task Force I	Recommended referral of Proposal 23-111 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-111.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-111.

Proposal No. 23-112

Submitter	Kohl Kanwit and Vanessa Zubkousky-White Maine Department of Marine Resources and California Department of Public Health Kohl.kanwit@maine.gov; Vanessa.Zubkousky@cdph.ca.gov
Proposal Subject	Disposal of Human Sewage and Vomitus
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	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting Requirements for Harvesters

.02 Shellstock Harvesting and Handling.

(2) Disposal of Human Sewage and ~~Bodily Fluids~~ Vomitus.

(1) Human sewage and ~~bodily fluids~~ vomitus shall not be discharged overboard from any vehicle or vessel used in the harvesting of shellstock.

(2) As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel or available for the vehicle operator's use for the purpose of containing human sewage and ~~bodily fluids~~ vomitus.

Section II. Model Ordinance Chapter IX. Transportation Requirements for Harvesters

.01 Conveyances Used to Transport Shellstock to the Original Dealer

(3) Disposal of Human Sewage and ~~Bodily Fluids~~ Vomitus

(4) Human sewage and ~~bodily fluids~~vomitus shall not be discharged overboard from any vehicle or vessel which buys shellstock while the vehicles or vessels are in growing areas.

(5) As required by the Authority, in consultation with FDA, an approved MSD, portable toilet or other sewage disposal receptacle shall be provided on the vessel or available for the vehicle operator's use for the purpose of containing human sewage and ~~bodily fluids~~vomitus. Portable toilets shall meet the requirements of VIII. .02. D. (3).

Section II. Model Ordinance Chapter IX. Transportation Requirements for Harvesters

.02 Conveyances Used to Transport Shellstock from Dealer to Dealer

C. Disposal of Human Sewage and ~~Bodily Fluids~~Vomitus

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

(2) As required by the Authority, in consultation with FDA, an approved MSD, portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage and ~~bodily fluids~~vomitus. Portable toilets shall meet the requirements of VIII. .02. D. (3).

Public Health Significance	It is recognized that human digestive waste or vomit can put a shellfish growing area at risk of foodborne illness, e.g. norovirus, hepatitis A, etc. The current language references "bodily fluids" which is too broad a term for the recognized risks which include human digestive waste and vomitus. "Bodily fluids" can be interpreted to include liquids such as tears and sweat. This proposal attempts to limit the requirement to the recognized dangers of human digestive waste and vomitus.
Cost Information	There is no cost associated with this change.
Action by 2023 Task Force I	Recommended adoption of Proposal 23-112 as submitted.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-112.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-112.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Redesigned Section IV. Guidance Table of Contents
Specific NSSP Guide Reference	Section IV. Guidance
Text of Proposal/ Requested Action	**Section IV. Guidance Documents**

Chapter I. ~~General~~ Shellfish Sanitation Program

@.01 Administration

.01 Evaluation Standards

.02 Procedures for Initiating a New State Program Under the National Shellfish Sanitation Program

~~.02~~. 03 Shellfish Plant Inspection Standardization Procedures NSSP Standardized Shellfish Processing Plant Inspection Form

.04 Voluntary National Shellfish Regulatory Program Standards

~~.18~~.05 Decision Tree - Shellfish from Non-MOU Countries

@.02 Dealer Certification

~~03.01~~ Dealer Certification and the Interstate Certified Shellfish Shippers List (ICSSL)

@.03 Evaluation of State Shellfish Sanitation Program Elements

Chapter II. ~~Growing Areas~~ Risk Assessment and Risk Management

@.01 Outbreaks of Shellfish-Related Illness

.01 Guidance for Investigating an Illness Outbreak and Conducting Recall

~~03.02~~ Guidance for Harvest Area Closure and Recall Notification

~~.02~~.03 Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak

~~.03~~.04 Determining the Size of Closed Area as a Result of Illnesses

~~.04~~.05 Determining the Harvesting Periods Associated with Implicated Product for Identifying Shellfish to be Included in the Recall

~~.05~~. 06 Determining the Scope of Implicated Product for Conducting a Recall

@.03 Annual Assessment of *Vibrio vulnificus* and *Vibrio parahaemolyticus* Illnesses and Shellfish Production
.07.01 Production Reporting Guidance
@.04 Presence of Human Pathogens in Shellfish Meats
06.01 *Vibrio cholerae*
@.06 *Vibrio vulnificus* Control Plan
03.01 Guidance for Demonstrating the Effectiveness of Time to Temperature Reduction Criteria for *Vibrio vulnificus* and *Vibrio parahaemolyticus* (see below)
@.07 *Vibrio parahaemolyticus* Control Plan
06.01 *Vibrio parahaemolyticus* (*V.p.*) Control Plan Guidance
03.02 Guidance for Demonstrating the Effectiveness of Time to Temperature Reduction Criteria for *Vibrio vulnificus* and *Vibrio parahaemolyticus*

Chapter III. ~~Harvesting, Handling, Processing, and Distribution~~Laboratory
@.01 Quality Assurance
15.01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
@.02 Methods
14.01 Approved NSSP Laboratory Tests
.20.02 Quantitative Analytical Method Verification

Chapter IV. ~~Naturally Occurring Pathogens~~ Growing Areas
@.01 Sanitary Survey
.07.01 Sanitary Survey and the Classification of Growing Waters
@.02 Microbiological Standards
.01 Total Coliform Standards
.11.02 Systematic Random Sampling Monitoring Strategy
@.03 Growing Area Classification
.09.01 Management Plans for Growing Areas in the Conditional Classification
.16.02 Protocol for Reviewing Classification of Areas Implicated by Pathogens in Shellfish Meat Samples
.19 .03 Classification of Shellfish Growing Waters Adjacent to Waste Water Treatment Plants
.08. 04 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood
@.04 Marine Biotoxin Control
.02.01 Guidance for Developing Marine Biotoxin Plans
@.05 Marinas
.01 Guidance TBD
@.06 Mooring Areas
.01 Guidance TBD

Chapter V. ~~Illness Outbreaks and Recall Guidance~~ Shellstock Relaying
~~.10~~.01 Shellstock Relay

Chapter VI. Shellfish Aquaculture
.01 Guidance TBD

Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas
~~.05~~.01 Protocol for Addressing Positive Coliform Sample in an Artificial Wet Storage Water Body

Chapter VIII. Control of Shellfish Harvesting
@.01 Control of Shellstock Growing Areas
~~.12~~.01 Growing Area Patrol and Enforcement
~~.13~~.02 Control of Shellfish Harvesting
@.02 Shellstock Time to Temperature Controls
~~.08~~.01 Icing, Cold Water Dips and Ice Slurries for Cooling Shellstock
Shellstock Harvesting and Handling
See *Shellstock Tagging* (Chp. X. below)

Chapter IX. Transportation
See *Time and Temperature Controls* (Chp. XI-XIV below)

Chapters X. General Requirements for Dealers
.01-.03 Shellstock Identification, Shucked Shellfish Labeling, Shipping Documents and Records
.04 Shellstock Tagging

Chapter XI., XII., XIII., and XIV. – Shellfish Processing and Handling
.01 Shellfish Industry Equipment Construction Guide
~~06.02~~ Guidance for Reinstating a Previously Infected Employee
~~.07~~.03 Time and Temperature Controls

Chapter XV. Depuration
~~.17~~.01 Calculating the Ninetieth (90th) Percentile for End-Product Depurated Shellfish

Chapter XVI. Processes and Procedures for Pathogen Reduction
~~.02~~.01 Post- Harvest Processing (PHP) Validation/Verification Guidance for *Vibrio vulnificus (V.v.)* and *Vibrio parahaemolyticus (V.p.)*
~~.04~~.02 Method for Validation and Verification of a Two (2) or Three (3) Log Reduction of *Vibrio parahaemolyticus (V.p.)* in Oysters
~~.05~~.03 Template for Submission of Post-Harvest Process Validation Studies

.09.04 Irradiation Pre-labeling Guidance

Chapter XVII. Federal Waters
.06.01 Federal Waters Guidance (DRAFT)

Public Health Significance	The proposed organizational redesign of the NSSP Guide for the Control of Molluscan Shellfish, Section IV. Guidance and associated Table to Contents will allow the guide to be more in line with the MO and therefore, make it easier to reference. In addition, the FDA has conducted a review and suggested update of the growing area guidance section. The idea is to use this suggested updated Table of Contents to suggest the establishment of a growing area guidance review committee where FDA can provide what we have put together and then have the ISSC input.
Cost Information	N/A
Action by 2023 Task Force I	Recommended adoption of Proposal 23-113 as submitted.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-113.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-113.

Proposal No. 23-114

Submitter	Jackie Knue State of Alaska Environmental Health Laboratory Jacqueline.Knue@Alaska.gov
Proposal Subject	Domoic Acid (Amnesic Shellfish Poisoning) HPLC Method Laboratory Evaluation Checklist
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
Text of Proposal/ Requested Action	The requested action is to edit the text of the attached checklist for the HPLC method for detecting domoic acid and to append the checklist to the list of NSSP Laboratory Evaluation Checklists at the end of .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.
Public Health Significance	The attached checklist provides the quality assurance and method requirements that laboratory evaluation officers will use to evaluate laboratories implementing the HPLC method for domoic acid to support the NSSP. The checklist documents the number of critical, key or other nonconformities and how overall laboratory status for the method is determined.
Cost Information	None.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 23-114 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 23-114.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-114.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-114.

Proposal No. 23-115

Submitter	Jackie Knue State of Alaska Environmental Health Laboratory Jacqueline.Knue@Alaska.gov
Proposal Subject	Paralytic Shellfish Poisoning (PSP HPLC-PCOX) HPLC Method Laboratory Evaluation Checklist
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
Text of Proposal/ Requested Action	The requested action is to edit the text of the attached checklist for the HPLC method for detecting domoic acid and to append the checklist to the list of NSSP Laboratory Evaluation Checklists at the end of .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.
Public Health Significance	The attached checklist provides the quality assurance and method requirements that laboratory evaluation officers will use to evaluate laboratories implementing the HPLC method for domoic acid to support the NSSP. The checklist documents the number of critical, key or other nonconformities and how overall laboratory status for the method is determined.
Cost Information	None.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 23-115 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 23-115.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-115.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-115.

Proposal No. 23-116

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	NSSP Microbiology Laboratory Evaluation Checklist Sample Diluent
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 remove NSSP checklist item 3.2.13 - Specific edits in accompanying document. The current NSSP Microbiology Checklist has two duplicate items in 1.7.14 and 3.2.13 *Sterile phosphate buffered dilution water is used as the sample diluent.* This could result in a laboratory erroneously receiving two (2) Other cited nonconformities during an evaluation. By removing checklist item 3.2.13 it will ensure a laboratory is properly cited once in Microbiology Checklist Part I if they are not using an appropriate sample diluent for any method included in the Microbiology Checklist.
Public Health Significance	The proposed modifications are to improve consistency in the current NSSP Microbiology evaluation standard.
Cost Information	N/A
Action by 2023 Laboratory Committee	Recommended adoption of Proposal 23-116 as amended.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 23-116.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-116
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-116.

Proposal No. 23-117

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Modifications to NSSP Quality Systems 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 modified text in accompanying document.
Public Health Significance	The proposed modifications are to improve the current NSSP quality systems evaluation standard and remove redundant language.
Cost Information	N/A
Action by 2023 Laboratory Committee	Recommended adoption of Proposal 23-117 as submitted.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 23-117.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-117.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-117.

Proposal No. 23-118

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Part I Modifications to 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; References – NSSP Laboratory Evaluation Checklists 1. NSSP Laboratory Evaluation Checklist for Microbiology (link)
Text of Proposal/ Requested Action	The requested action is to adopt modified text of eleven (11) NSSP microbiology checklist items and remove one item in Part I; said NSSP checklist items are 1.4.8, 1.4.21, 1.4.22, 1.4.23, 1.6.4, 1.6.5, 1.6.6, 1.6.7, 1.6.21, 1.6.22, 1.7.2, 1.7.9. Specific text is in accompanying document.
Public Health Significance	The proposed modifications are to improve consistency in the current NSSP microbiology evaluation standard and account for technology improvements to laboratory equipment.
Cost Information	N/A
Action by 2023 Laboratory Committee	Recommended adoption of Proposal 23-118 as amended.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 23-118.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-118.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-118.

Proposal No. 23-119

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	NSSP Microbiology Laboratory Evaluation Checklist Productivity Controls
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 remove NSSP checklist items 2.2.2, 2.3.3, 2.5.4, 2.9.2, 2.12.8, 3.3.2, 3.4.2, 3.8.12 and modify checklist item 1.7.13 to include the intent of items removed. Specific edits are reflected in supporting documentation. The current NSSP Microbiology Checklist includes multiple items related to the culture media productivity testing requirement. This could result in several Critical nonconformities being cited during an evaluation and deem a laboratory nonconforming unnecessarily. By removing checklist items 2.2.2, 2.3.3, 2.5.4, 2.9.2, 2.12.8, 3.3.2, 3.4.2, 3.8.12, it will ensure a laboratory is appropriately cited once in Microbiology Checklist Part I if they are not adequately performing media productivity testing across all media types. Once checklist items are removed, editorial renumbering of the checklist will be required to maintain orderliness.
Public Health Significance	The proposed modifications are to improve consistency in the current NSSP Microbiology evaluation standard.
Cost Information	N/A
Action by 2023 Laboratory Committee	Recommended adoption of Proposal 23-119 as amended.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 23-119.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-119.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-119.

Submitter	Meredith Zahara Florida Fish and Wildlife Conservation Commission Meredith.Zahara@myfwc.com
Proposal Subject	Modification of 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 modify the current checklist to correct errors and make clarifications regarding specific quality assuarance parameters. (See attached.)
Public Health Significance	Brevetoxins produced by K. brevis are toxic to humans. Filter-feeding bivalves accumulate brevetoxins during blooms, and ingestion of contaminated shellfish can cause NSP in humans. The MARBIONC Brevetoxin ELISA method was approved for limited use at the 2017 ISSC meeting. The attached revised 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.
Cost Information	N/A
Action by 2023 Laboratory Committee	Recommended adoption of Proposal 23-120 as submitted.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 23-120.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-120.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-120.

Proposal No. **23-121**

Submitter	Bryant Lewis[1], David Borkman[2], Jeff Kennedy[3] Maine Department of Marine Resources[1], Rhode Island Department of Environmental Management[2], Massachusetts Division of Marine Fisheries[3] Bryant.j.lewis@maine.gov[1], David.Borkman@dem.ri.gov[2], jeff.kennedy@state.ma.us[3]
Proposal Subject	Mooring Area Guidance Document Request
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II Growing Areas
Text of Proposal/ Requested Action	The requested action is to have the ISSC refer to an appropriate committee a charge to develop a guidance document for mooring areas.

Public Health Significance	Mooring areas were incorporated into the 2019 Guide to for the Control of Molluscan Shellfish without a related guidance document. State shellfish authorities would benefit from guidance on how to complete mooring area assessments and classifications.
Cost Information	No cost would be associated with this proposal.
Action by 2023 Task Force I	Recommend adoption of Proposal 23-121 as submitted.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-121.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-121.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Addition of Vv MPN real-time PCR to Microbiology PCR 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; References – NSSP Laboratory Evaluation Checklists 6. Shellfish Laboratory Evaluation Checklist for PCR Microbiology (link)
Text of Proposal/ Requested Action	3.2.3 The PCR forward and reverse primers used target. For Total and Pathogenic Vp Real-time PCR Method tdh_269-20: 6FAM-5'-TGACATCCTACATGACTGTG-3'-MGBNFQ trh_133-23: TET-5'-AGAAATACAACAATCAAAACTGA-3'-MGBNFQ tlh_1043: TEXAS RED-5'- CGCTCGCGTTCACGAAACCGT -3'-BHQ2 IAC_109: CY5-5'- TCTCATGCGTCTCCCTGGTGAATGTG -3'- BHQ2 trh_20F: 5'-TTGCTTTCAGTTTGCTATTGGCT-3' trh_292R: 5'-TGTTTACCGTCATATAGGCGCTT-3' tdh_89F: 5'-TCCCTTTTCCTGCCCCC-3' tdh_321R: 5'-CGCTGCCATTGTATAGTCTTTATC-3' tlh_884F: 5'-ACTCAACACAAGAAGAGATCGACAA-3' tlh_1091R: 5'-GATGAGCGGTTGATGTCCAAA-3' IAC_46F: 5'-GACATCGATATGGGTGCCG-3' IAC_186R: 5'-CGAGACGATGCAGCCATTC-3' For Vv Real-time PCR Method (SYBR) vvhF 5'-TGTTTATGGTGAGAACGGTGACA-3' vvhR 5'-TTCTTTATCTAGGCCCCAAACTTG-3' For Vv Real-time PCR Method vvhF: 5'-TGTTTATGGTGAGAACGGTGACA -3' vvhR: 5'-TTCTTTATCTAGGCCCCAAACTTG-3' vvh_Probe: Cy5-5'-CCGTTAACCGAACCACCCGCAA-3'-IAbRQ IAC_46F: 5'-GACATCGATATGGGTGCCG-3' IAC_186R: 5'-CGAGACGATGCAGCCATTC-3' IAC_Probe: JOE-5'-TCTCATGCGTCTCCCTGGTGAATGTG-3'-IABkFQ
Public Health Significance	The current laboratory evaluation checklist for PCR methods does not include the details of the MPN-real-time PCR method for *V. vulnificus* adopted as an approved NSSP method at the 2019 Conference Biennial Meeting. The proposed modifications of this checklist will provide Laboratory Evaluation Officers an appropriate and standardized tool by which to evaluate laboratories implementing this method.
Cost Information	N/A
Action by 2023 Laboratory Committee	Recommended adoption of Proposal 23-122 as submitted.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 23-122.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-122.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-122.

Submitter	George Trevelyan Grassy Bar Oyster Company, Inc. gboysterco@gmail.com
Proposal Subject	Guidance for calculating the 90th percentile for end-product depurated shellfish
Specific NSSP Guide Reference	Section IV Guidance Documents; Chapter II Growing Areas; Section .17 Calculating the 90th percentile for end-product depurated shellfish
Text of Proposal/ Requested Action	Process verification in depuration is performed continuously to ensure that the microbial contaminant load is being effectively reduced. Two (2) indices of performance, the geometric mean and the ninetieth (90th) percentile have been developed to describe the effectiveness of the depuration process. Critical limits for these parameters have been established empirically by shellfish species. For soft clams (*Mya arenaria*), a geometric mean of fifty (50) and a ninetieth (90th) percentile of 130 have been set. For hard clams, oysters, manila clams and mussels, a geometric mean of twenty (20) and a ninetieth (90th) percentile of seventy (70) have been adopted. Geometric means and ninetieth (90th) percentiles are determined daily or as end-product results become available from the analysis of the most recent ten (10) consecutive harvest lots per species, per restricted harvest area used. If the critical limits for either the geometric mean and/or the ninetieth (90th) percentile are exceeded, the process is considered to be unverified; and, additional sampling requirements must be instituted to ensure effective process control. End-product depurated shellfish samples are analyzed using two (2) different methods of recovery, a pour plate procedure and a single dilution MPN test. Calculation of the ninetieth (90th) percentile for these samples is complicated by the fact that fecal coliforms recovered by the MPN and ETCP methods follow different statistical distributions. To accommodate these differences and maintain a high likelihood for detecting an unacceptable amount of process variability without having to change or alter the formula used requires the use of nonparametric or "distribution free statistics." Using "distribution free statistics," the position of the ninetieth (90th) percentile for end-product depurated shellfish samples is calculated by arraying the fecal coliform count data in ascending order and applying the formula (n + 1)P/100. As an example of the use of this formula, the Model Ordinance requires that the ninetieth (90th) percentile of the fecal coliform analytical data be calculated from the most recent ten (10) consecutive harvest lots for each shellfish species depurated from each restricted harvest area. Fecal coliform count data, whether from the ETCP or MPN procedure for these ten (10) lots must be arrayed from the smallest to the largest value using the arithmetic (not logarithmically transformed) count data. Applying the formula, n would be greater than or equal

to ten (10) for the ten (10) most recent consecutive harvest lots required by the Model Ordinance. P, the percentile of interest would be ninety (90). Using the minimum sample set of n=10, ~~Multiplying~~ multiplying the formula out gives the position of the ninetieth (90^{th}) percentile in the arrayed data. Performing these calculations, 10 + 1 = 11, 11 x 90 = 990/100 = 9.9. Thus, the ninetieth (90^{th}) percentile for end-product depurated shellfish data when n=10 is the value of the 9.9^{th} sample in the ten (10) sample array.

Using ~~the~~ ten (10) samples ~~as required by the Model Ordinance~~, the ninetieth (90^{th}) percentile for end- product depurated shellfish samples would always be the value of the 9.9^{th} sample in the ascending array of the arithmetic count data. To calculate this value from the arrayed data, interpolation between samples nine (9) and ten (10) is necessary. This is best illustrated using several samples.

Example 1…

Example 2…

Example 3…

In cases where more than ten samples have been analyzed in the most recent ten (10) consecutive harvest lots for each species depurated or for each harvest area used, the geometric mean and estimated 90^{th} percentiles may be calculated using the methodologies below in examples 4 and 5.

Example 4 (attached)

Example 5 (attached)

Public Health Significance	Incorrectly calculating the 90^{th} percentile can lead to erroneous decisions that could affect public health. For instance, both the California Dept of Public Health and the FDA mis-calculated the 90^{th} percentile for a data set in which n=36. They insisted, based on the examples given in the NSSP Guide, that the 90^{th} percentile was **always found between the 2 largest numbers** in the data set, even when n is large, which is incorrect.
Cost Information	This clarification to the NSSP Guide, with additional examples, will make it easier to correctly calculate this depuration performance index and should reduce confusion and disagreements, which could save time and money.
Action by 2023 Task Force I	Recommended referral of Proposal 23-123 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-123.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-123.

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Updated Marina and Mooring Area Guidance
Specific NSSP Guide Reference	Section IV. Guidance (Mooring Area)
Text of Proposal/ Requested Action	MARINA and MOORING AREA GUIDANCE - **DRAFT**

The following guidance is provided to ensure the uniform application of the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO) criteria, as adopted by the Interstate Shellfish Sanitation Conference (ISSC), for the evaluation and classification of shellfish growing waters in and around docks, marinas, and boat mooring areas.

BACKGROUND

A marina policy was developed at the ISSC conference held in August of 1986. It was recognized that a marina is a potential pollution source in a shellfish growing area, and that a closure zone is required to prevent the harvest of shellfish for human consumption in and around occupied marinas and mooring areas. The purpose of the policy was to establish a uniform national approach to marina and mooring area closures. At the July 1988 ISSC conference, approval was given to incorporate the marina policy into the definition and growing area classification sections of the NSSP MO. The 1989 "*Evaluation of Marinas by State Shellfish Sanitation Control Officials*", better known as the **1989 Marina Guideline,** was released in order to further clarify the new marina policy adopted into the 1990 NSSP Manual of Operations Part I Sanitation of Shellfish Growing Areas. The 1989 Marina Guideline was originally intended for the U.S. Food and Drug Administration (FDA) and State Shellfish Control Authorities (Authority) to use as guidance when classifying growing areas in and around marina facilities. The 1989 Marina Guideline has been used in all the FDA growing area training courses since inception as a reference on implementation of the NSSP MO marina criteria.

As a result of actions taken at the 2019 biennial conference, "marina" and "mooring area" were separated into two (2) definitions (NSSP MO Section I. B.). In addition, the NSSP MO Section II. Chapter IV. @.06 was created to allow for mooring areas to be classified as conditionally

approved and conditionally restricted in the open status if a detailed pollution assessment is conducted at the frequencies required by the NSSP MO Section II. Chapter IV. @.01 A. (2.), C., and D. indicating a significant reduced risk from pollution sources and if there is a Conditional Area Management Plan (CAMP) in place with sufficient controls to protect human health.

The justification for this change suggests that there may be a different level of human health risk associated with how a mooring area, as a pollution source, may be managed compared to a marina. Boats are considered a potential pollution source due to the capability to discharge human sewage into a growing area. As technology has improved and the management of mooring areas have evolved with the implementation of the Federal No Discharge Zone (NDZ) program and availability of boat waste pump out boats and facilities, there is the potential, with enough oversight and management controls in place, to limit the capacity for overnight occupancy and sewage discharge from boats in a mooring area compared to a marina.

This updated marina and mooring area guidance document is intended to serve as guidance for the FDA when evaluating state growing area classification programs and as guidance for authorities regarding the classification and management of marinas and mooring areas in accordance with the NSSP MO requirements.

GUIDANCE

This guidance will provide clarification for the pollution assessment, classification, dilution calculation, and conditional area classification management of marinas and mooring areas, in and adjacent to, shellfish growing areas.

Boats congregated into a marina or mooring area are operated and inherently occupied by people at some time and therefore, have the potential to discharge human sewage and graywater into associated shellfish growing areas. As a result, every public or private watercraft, barge, houseboat, or boat, that has the potential to produce an overboard discharge from a marine toilet or discharge graywater, should be considered a potential pollution source in the evaluation of shellfish growing areas.

Since marine toilets may provide only limited or no treatment, human sewage discharges from boats may contain bacteria and viruses attributed to human sewage and graywater. For this reason, discharges of graywater and marine toilets represent a greater public health risk than other discharges of sanitary waste, and since these discharges can be sporadic, it may represent a greater public health risk than the FC sources typically detected by routine bacteriological monitoring.

Since many marina facilities and mooring areas are in or adjacent to shellfish growing areas, and waste discharges are not uniformly distributed in the water column, detection of low levels of coliforms from waste discharges by current pollution monitoring methods may not provide sufficient information to properly classify the waters in or adjacent to a marina or mooring area. Therefore, each marina and mooring area pollution assessment, dilution analysis, classification, and closure zone should be considered on a site-by-site basis, given the potential significant public health risk combined with the unique characteristics of each site.

As a result, a classification other than approved or restricted is required for the area within a marina or mooring area. This requirement is based on the public health requisite that waters receiving sporadic waste discharges from marine toilets or discharge of graywater are not suitable for the direct harvest of shellfish destined for human consumption or for relay or depuration. A pollution assessment and dilution determination must be used for classifying and making status determinations for marinas and mooring areas and adjacent shellfish growing areas.

MARINAS

Per the 2019 Revision of the NSSP MO Section I. B.:

Definition: Marina - *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 (10) boats.*

MARINA PROPER

Per the NSSP MO Section II. Chapter IV. @.05 A, the marina proper shall be classified as: conditionally approved, conditionally restricted, or prohibited. A *pollution assessment* shall also be conducted in order to support the conditionally approved or conditionally restricted classification. The FDA's interpretation is that the marina pollution assessment is not intended to allow direct harvesting in the marina proper while more than 10 boats are present, but to document the seasonality and the presence of boats for the development of a Conditional Area Management Plan (CAMP) and to assess the marina proper as a pollution source, gather information for the dilution analysis, and provide documentation in the sanitary survey.

If more than 10 boats are not present during certain seasons (as in some geographical areas) the marina proper may be reclassified or changed to the open status if already classified as conditionally approved or conditionally restricted to permit harvest. During such periods the Authority must document that the area meets the specific NSSP MO criteria for the classification allowing harvest in the CAMP.

ADJACENT WATERS

Per the NSSP MO Section II. Chapter IV. @.05 B., waters adjacent to a marina proper may be impacted by pollution associated with the marina. Therefore, when more than 10 boats are present, a dilution analysis shall be used to determine if there is any impact to the adjacent growing area waters. The dilution analysis shall be based on the volume of water in the vicinity of the marina proper.

If the dilution analysis predicts a theoretical fecal coliform (FC) loading greater than (>) 14 FC/100 ml, the waters adjacent to the marina shall be classified as: conditionally approved, restricted, conditionally restricted, or prohibited. If the dilution analysis predicts a theoretical FC loading less than (<) 14 FC/100 ml, the waters adjacent to the marina may be classified as: approved or conditionally approved.

In reference to NSSP MO Section II. Chapter IV. @.05 B. (3), the dilution analysis around a marina proper shall incorporate the following factors. The recommendations provided represent guidance for how the authority may meet the intent of each requirement:

(a) **Slip occupancy rate for the marina**:

This is the quantity of waste potentially originating in a marina and depends on the number of people who are present in the marina. The fewer boats that are found to be occupied, the smaller the expected impact from the marina proper. The NSSP MO provides for establishing an occupancy rate for each marina. The slip occupancy rate of the marina should be documented by actual observation of marina operations during the time of highest usage such as weekends or holidays. Document the overall number of boats in a marina proper and the number of boats being occupied as well as the number of people on each boat. Document the number of slips in the marina proper.

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

Document the number of boats with a marine sanitation device (MSD) type used (i.e., MSD Type I, II, or III) in the marina. If the authority uses an assumed rate of discharge, that rate should be supported by data gathered during the pollution assessment of the marina.

(c) An occupancy per boat (number of persons per boat):

If the authority chooses not to determine a specific occupancy per boat rate by investigation, the authority shall assume a minimum occupancy rate of two (2) persons per boat (NSSP MO Section II. Chapter IV. @.05 B. (6)).

Document the number of boats with liveaboard capability as well as the number of people on liveaboard boats in the marina. This inventory should be taken during the expected high usage times such as weekends and holidays. The inventory should have continuity so that changes in population during high occupancy times will be documented. Regional differences in boat usage, and the percent of high usage, will vary.

(d) A fecal coliform discharge rate of 2×10^9 for the theoretical fecal coliform contribution per person per day.

(e) Assume 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**:

Provide documentation of the NDZ: enforcement records, vessel inspection records, marina use agreements, available educational material, and graywater regulations. Document in the management plan how vessels are inspected to ensure that boats equipped with an MSD that is not properly sealed to prevent discharge of sewage into the water is documented and enforced. Document Memorandums of Understanding or Agreements with local towns, municipalities, and patrol enforcement agencies defining each agency's responsibility in administering and enforcing the NDZ.

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

Document the availability and number of pump out facilities and boats available to the marina. Document use and maintenance records, operation procedures, ease of use, hours of operation, pump out log, previous spills, and the individual responsible for pump out operations. The pump out log should include: date, boat name and length, approximate number of gallons pumped, and initials of the operator.

Document enforcement records and boat inspection records. Document the procedures used if there is a waste spill. Document the frequency of when inspections are conducted to ensure pump-out stations are properly maintained and compliant with Clean Vessel Act (CVA) grant requirements. The records of inspections must be maintained and available for review.

MOORING AREAS

Per the 2019 Revision of the NSSP MO Section I. B.:

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

MOORING AREA PROPER

Per the NSSP MO Section II. Chapter IV. @.06, a designated mooring area, where there is anchoring or mooring of boats, which is in or adjacent to a shellstock growing area shall be classified as: conditionally approved, restricted, conditionally restricted, or prohibited.

Prior to the Authority establishing a classification of conditionally approved, conditionally restricted, or restricted in the mooring area proper, a *pollution assessment* supporting the classification will need to be conducted by the authority. The NSSP MO provides flexibility so that if the *pollution assessment* determines that the mooring area has controls in place and is not considered a pollution source and it is thoroughly documented in the CAMP, the area may be classified as conditionally approved or conditionally restricted and placed in the open status with boats present.

The following factors shall be considered and documented when conducting a *pollution assessment* to determine the classification of the mooring area and adjacent waters in accordance with the NSSP MO requirements.

POLLUTION ASSESSMENT

The NSSP MO Section II. Chapter IV. @.06 A. (1) requires that a *pollution assessment* supporting the classification of mooring areas be conducted by the authority. In accordance with the 1986 ISSC Marina Policy and the 1989 Marina Guidance, the basis for occupancy and discharge rates should reflect worst case conditions and the inventory should be taken during the expected high usage times such as weekends and holidays.

The *pollution assessment* shall include the following factors according to the NSSP MO Section II. Chapter IV. @.06 A. (1). The recommendations provided for each factor represents suggested guidance for how the authority may meet the intent of each required component of the *pollution assessment*:

(a) **Boat Type and Usage**:

- Documentation of the boat type and usage should be considered from a public health perspective and the risk of

the potential for overboard discharge from both treated and untreated sewage as well as graywater.

- Document the type and size of boats in the mooring or anchorage area such as cabin cruiser, houseboat, cuddy cabin, runabout, commercial fishing vessel, skiff, daysailer, etc.
- Document the number of boats in each type and size category.
- Document the usage of boats such as overnight, weekend, day use, as well as commercial, or recreational.
- The boat type and usage information may be used in a mooring area management strategy to separate out boats that might pose more of a human health risk into a different conditionally managed area using separate performance standards.

(b) **Density of Boats**:

- Document the geographic location of the mooring area and include a map defining the mooring area boundaries.
- If boats are geographically managed by type and use, document this management strategy using a map that defines the mooring area management areas.
- Document the density of boats as the number of boats per a unit of area (For example: 100 boats per 1 sq. mile).
- Each individual mooring or anchorage area in a growing area should be accounted for and evaluated and where multiple mooring areas are present in a growing area, the authority should evaluate the impact of those individual mooring areas on the growing area from a holistic or cumulative impact. As an example, using best human health protection management practices, it may not be appropriate to separate a single group of multiple mooring boats (greater than 20 boats) into numerous separate mooring areas of 20 or less boats.

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

- In reference to the term “parking lot” mooring area, such as a location where boats are temporarily moored for short periods of time, but not occupied overnight, document the factors which could reduce or increase the likelihood of overnight occupancy in the mooring area proper.
- Provide a detailed justification explaining how accessibility to boats in the mooring area increases or decreases the likelihood of overnight occupancy. This may include how

the access of the boats in the mooring area are managed and how accessible boats are to overnight occupancy.

- Document the municipal mooring area regulation(s), town charter(s), municipal regulation(s), and records documenting enforcement of said regulation(s) and charter(s) that limits or mandates no overnight occupancy.
- Document how boat owners access their vessels, such as through launch service (hours of operation), personal dinghy, etc.
- Provide and maintain records from the municipal or state enforcement agencies when overnight occupancy regulations are enforced or violated.

(d) **Occupancy Rates**:

- Document the number of mooring balls/buoys and the number of boats allowed on each.
- Document the overall number of boats in a mooring area and the number of boats being occupied as well as the number of people on each boat. If the mooring area is considered a "parking lot", such as a location where boats are temporarily moored for short periods of time but not occupied overnight, provide documentation to that effect, including justification for use.
- Document any transient mooring areas and their boat capacity.

(e) **Seasonal Use Pattern**:

- Document if there is a seasonal boat use pattern.
- Document what the seasonal boat use pattern is including the seasonal dates as to when more than 20 boats are present in the mooring area.

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

- Conduct and document an onsite assessment of the mooring area and document the type and number of boats that have the potential for discharging treated or untreated sewage including graywater.
- Document boats with marine heads and include the number and location of boats with each type of MSD (Type: I, II, or III).

(g) **Documentation, verification, and enforcement of Federal No Discharge Zones (NDZ), and locally well enforced no discharge and occupancy regulations or by-laws**:

- Provide documentation of the NDZ: enforcement records, boat inspection records, mooring area use agreements, available educational material, graywater discharge regulations, and occupancy records during high-use times.
- Document how boats equipped with a MSD, not properly sealed to prevent discharge of sewage into the water, are inspected.
- Provide any Memoranda of Understandings or Agreements with local towns, municipalities, and patrol enforcement agencies. Define each agency's responsibility in administering and enforcing the NDZ; including references to the statue, regulation, or charter that confers authority to enforce the NDZ.
- Document the CAMP communication requirements (contact tree) in case an emergency closure is warranted.

(h) **Availability and documented use of shore-based pump out facilities and pump out boats**:

- Document the availability and number of pump out facilities and pump out boats available to the boats in the mooring area proper.
- Document pump out practices, pump out procedures, educational information, and employee/operator training.
- Document the use and maintenance records, operation procedures, ease of use, hours of operation, pump out log, previous spills, and who is responsible for the pump out operations. The pump out log should include date, boat name and length, approximate number of gallons pumped, and initials of the operator.
- Document enforcement records and boat inspection records.
- Document the procedures if there is a waste spill.
- Document the frequency as to when inspections are conducted to ensure pump-out stations are properly maintained and compliant with Clean Vessel Act grant requirements; with records of past inspections maintained and available for review.

The NDZ is only one factor to consider when conducting a *pollution assessment* to classify a growing area with a mooring area(s) as conditionally approved or conditionally restricted in the open status with boats present. The FDA does not consider the NDZ designation to be a standalone *pollution assessment*, control mechanism, or justification for classifying a mooring area(s) as conditionally approved or conditionally

restricted in the open status. As stated in the NSSP MO language, documentation, verification, and enforcement of the NDZ and locally well enforced no discharge and occupancy regulations or by-laws will be necessary for the *pollution assessment* and for review during FDA growing area program 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, treated or untreated, is prohibited in an NDZ. The NSSP utilizes the CWA definition of sewage.

Definition: Sewage - human body wastes and the waste from toilets and other receptacles intended to receive or retain body wastes.

Graywater is not defined as "sewage" and is not prohibited under the NDZ requirements. Graywater may contain high levels of human bacteria and viruses and poses a significant human health risk when present and this should also be considered in the *pollution assessment*.

CONDITIONAL AREA MANAGEMENT PLAN (CAMP) FOR THE MOORING AREA PROPER CLASSIFIED AS CONDITIONALLY APPROVED OR CONDITIONALLY RESTRICTED IN THE OPEN STATUS

Per the NSSP MO Section II. Chapter IV. @.06 A. (1), a *pollution assessment* of the mooring area proper is required to determine if the mooring area can be classified as conditionally approved or conditionally restricted. Per the NSSP MO Section II. Chapter IV. @.06 A. (2), after the mooring area proper pollution assessment determines that the mooring area proper is not a pollution source and it is documented in the CAMP, the growing area may be placed in the open status.

The CAMP for each mooring area placed in a conditional classification is based on the information gathered during the *pollution assessment*. The CAMP will establish a strict set of criteria or performance standards, which must be met for the growing area to remain in the open status. Failure to meet the criteria or performance standards automatically places the growing area in the closed status, with immediate notice to the CAMP participants, affected industry, and the public.

Performance Standards for a Mooring Area CAMP should include:

- Establishment of a Memorandum of Understanding and/or an agreement to the conditions of the CAMP by the one (1) or more authorities involved including: mooring area management organizations, local municipalities, other local, State and Federal agencies, enforcement, harbor master, or other organizations which

may be involved in the management and enforcement of the mooring area proper, pump out operations, and NDZ management and enforcement.

- A written CAMP for the mooring area(s) and associated growing area being placed in the conditional classification, which includes a description of the mooring area(s) with a map showing the mooring area(s) boundaries.

- A sanitary survey that shows the growing area will be in the open status of its conditional classification and provide a description of the factors determining the growing area's suitability for being classified conditionally approved or conditionally restricted with supporting information and data.

- A description of the *pollution assessment* for the mooring area documenting how the reduction of an illicit human sewage (treated or untreated) and graywater discharge will be prevented and what management strategies are in place including, documenting boat types and uses, inspection of boat MSDs, documentation of pump out boats and facilities, NDZ regulations, education, management, and enforcement.

- A description of the plan for monitoring water quality including what will be sampled and the location of sample stations on a map, numbers of sample stations, and frequency monitored.

- A description of how the closed status for the conditional classification will be implemented which must include:
    - A clear statement indicating when the performance standards are not met, the growing area will immediately be placed in the closed status;
    - A requirement to notify the authority or authorities that management plan performance standards have not been met, including:
        - The name of the agency or other party responsible for notifying the authority;
        - The anticipated response time between the performance standards not being met and notification of the authority; and
        - The procedures for prompt notification including contingencies such as night, weekend, and absences of key personnel;
    - A description of implementation and enforcement, including:

- 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;
- The procedures and methods to be used to notify the shellfish industry; and
- 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 Aathority'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 of an area.

- A description of the criteria that must be met prior to reopening a mooring area or growing area in the closed status, including the need to determine that:
    - The performance standards established in the management plan are again compliant;
    - The flushing time for pollution dissipation is adequate;
    - A time interval has elapsed which is sufficient to permit reduction of human pathogens as measured by the coliform indicator group in the shellstock;
    - Where necessary, the bacteriological quality of the water must be verified; and
    - Shellstock feeding activity is sufficient to achieve reduction of pathogens to levels present prior to the pollution event.

- A commitment to a reevaluation of the management plan, at least annually, using the reevaluation requirements in the NSSP MO, or other regulations/rules required as necessary.
- A designation in the CAMP whether the shellstock may be harvested for relaying or depuration in a conditionally approved (closed status) or whether the harvested shellstock are to be relayed or depurated in a conditionally restricted area (open status).

ADJACENT WATERS

Per the NSSP MO Section II. Chapter IV. @.06 B., waters adjacent to a mooring area proper may be impacted by pollution associated as a result. Based on the pollution assessment conducted in NSSP MO Section II. Chapter IV. @.06 A., if the authority determines that the mooring area proper is a pollution source, a dilution analysis shall be used to determine if there is any impact to the adjacent waters. The dilution analysis shall be based on the volume of water in the vicinity of the mooring area proper.

If the dilution analysis predicts a theoretical FC loading greater than (>) 14 FC/100 ml, the waters adjacent to the mooring area shall be classified as: conditionally approved, restricted, conditionally restricted, or prohibited. It the dilution analysis predicts a theoretical FC loading less than (<) 14 FC/100 ml, the waters adjacent to the marina may be classified as: approved or conditionally approved.

The dilution analysis shall include the following factors according to the NSSP MO Section II. Chapter IV. @.06 B. The recommendations provided, represents guidance for how the authority may meet the intent of each requirement:

(a) **An occupancy rate for the mooring area**:

Consider that the quantity of waste potentially originating in a mooring area depends on the number of people who are present in the mooring area. The fewer boats that are found to be occupied, the smaller the expected impact from the mooring area. The occupancy rate of the mooring area should be documented by actual observation of mooring area operations during the time of highest usage such as weekends or holidays. Document the overall number of boats in a mooring area and the number of boats being occupied as well as the number of people on each boat. Document the number of mooring balls and buoys in the mooring area.

(b) **An actual of assumed rate of boats which will discharge untreated waste**:

Document the number of boats with installed toilets and document the MSD type used (MSD Type I, II, or III) in the mooring area having the capability to discharge to the environment. If the authority uses an assumed rate of discharge, that rate should be supported by data gathered during the pollution assessment of the mooring area.

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

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 (NSSP MO Section II. Chapter IV. @.06 B. (6)).

Document the number of people on liveaboard boats in the mooring area. This inventory should be taken during the expected high usage times such as weekends and holidays. The inventory should have continuity so that changes in population during high occupancy times can be documented. Regional differences exist regarding boat usage; therefore, the percent of high usage will vary.

(d) A fecal coliform discharge rate of 2 x 10^9 for the theoretical fecal coliform contribution per person per day.

(e) Assume that the wastes are completely mixed in the volume of water in and around the marina.
Document the average depth of the area based on bathymetry charts and the volume of dilution water needed if complete mixing is assumed.

DILUTION ANALYSIS

The NSSP MO Section II. Chapter IV. @.05 and @.06 states that a dilution analysis will be used for making classification and closure determinations for waters adjacent to each marina proper and mooring area proper (if a pollution assessment determines the mooring area may be a pollution source). The information collected from a pollution assessment will help in determining the potential pollution impact and classification and size of the classification area or closure zone.

This dilution analysis requirement is based on the public health requisite that waters receiving waste discharges from marine toilets from marinas and mooring areas are not suitable for the direct harvest of shellfish destined for human consumption.

The intentional or unintentional direct discharge of treated or untreated human sewage and graywater discharge from a boat into a marina or mooring area is considered a point source and a high human health risk and therefore, pursuant to the NSSP MO Section II. Chapter IV. @.03 E. (5) (a), "An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance."

The estimated per capita discharge of fecal coliforms, coupled with the estimated population in the marina or mooring area, can be used to determine the classification and estimate a closure zone. Closures for existing or proposed marinas and mooring areas should be developed assuming two (2) persons per boat, and a 2 x 10^9 fecal coliform (FC) contribution per person per day, unless actual persons per boat or occupancy and discharge rates are documented by surveys conducted for individual marinas or mooring areas on a case-by-case basis. The authority should assume 100% boat slip and mooring ball occupancy unless the actual occupancy rate is documented through observation or credibly estimated. This documentation shall be maintained as specified by the NSSP MO, Chapter I, for reevaluation of sanitary survey information.

Similarly, any expansion, modification, or change to the operation of a marina or mooring area will necessitate the reevaluation of the marina or mooring area occupancy rate.

In determining the above loading rates, a minimum factor should be considered to provide protection against intentional or unintentional waste discharges from boats in the marina or mooring area.

The theoretical waste discharge based on the occupancy and discharge rate, will be completely mixed in and around the marina or mooring area. The marina or mooring area closure zone shall be calculated to reduce the assumed bacterial load to 14 FC/100 ml, in the volume of water in the vicinity of the marina or mooring area. If the results of hydrographic studies are used, the estimated fecal coliform contribution can be distributed throughout the volume of water calculated to flow by the site in 24 hours.

Dilution hydrographic studies may be used to determine the water volume available for dilution and limits of travel of discharges from a marina. The area to be closed shall provide sufficient water volume for calculations to show that theoretical discharges from the marina or mooring area are diluted to 14 FC/100 ml of water. In situations where there are no hydrographic studies, the closed or prohibited area is to be established on a volumetric basis as though the wastes are completely mixed and uniformly distributed in and around the marina or mooring area. The closed area volume is typically based on average water depth and shall be sufficient to dilute the assumed waste load to a value of 14 FC/100 ml.

EXAMPLE CALCULATIONS

The following examples show how various factors are to be considered in closure area determinations around marinas or mooring areas:

CASE 1: No Documentation of Occupancy or Discharge Rates

Number of Boat Slips	50
Number of People	2 x 50 =100
Number of Fecal Coliforms (FC)	$100 \times 2 \times 10^9 = 200 \times 10^9$
Dilution Volume Required	200×10^9 FC (14 FC/100 mL) x (1000 mL/liter) Volume = 1.4×10^9 liters (5.0×10^7 cu ft)
Average Depth in Vicinity of Marina	3 meters (10ft)
Closed Area Required	1.4×10^9 liters (3 meters) x (1000 liters/cubic meter) A = 4.7×10^5 square meters (5.0×10^6 sq ft)

Radius of Half Circle Prohibited/Closed Area	$\sqrt{2/\pi\pi\ (4.7\ xx\ 10^5)}$ R = 550 meters (1800 ft)

CASE 2: Boat Slip Occupancy, Population, Holding Tanks and Pumpout Facilities Documented	
Number of Boat Slips	50
Slip Occupancy- Holiday Weekends	40 (80%)
Boats with No Holding Tanks*	16 (16/40 = 40%)
Average People per Boat	1.5
Number of People	1.5 x .40 x .80 x 50 =24
Number of Fecal Coliform (FC)	24 x 2 x 10^9 = 48 x 10^9
Dilution Volume Required	48 x 10^9 FC (14 FC/100 mL) x (1000 mL/liter) V = 3.4 x 10^8 liters (1.2 x 10^7 cu ft)
Average Depth in Vicinity of Marina	3 meters (10ft)
Closed Area Required	3.4 x 10^8 liters (3 meters) x (1000 liters/cubic meter) A = 1.1 x 10^5 square meters (1.2 x 10^6 sq ft)
Radius of Half Circle Closed Area	$\sqrt{2/\pi\pi\ (1.1\ xx\ 10^5)}$ R = 265 meters (870ft)

* Assumes pumpout facilities are consistently used, increase percentage if otherwise

REFERENCES

1. Interstate Shellfish Sanitation Conference Marina Policy. August 1986.
2. Evaluation of Marinas by State Shellfish Sanitation Control Officials. Guideline 1.0. June 1989.
3. National Shellfish Sanitation Program Manual of Operations, Part I. 1988 revision.
4. Department of Health and Human Services NE Technical Unit. 1986. Hydrographic Studies of the Great Salt Pond, Block Island, Rhode Island.
5. Geldreich, Edwin, et al. Bacteria in the Feces of 295 (March). 1962. The distribution of Coliform Bacteria in the Feces of Warm-Blooded Animals. JWPCF 34(3),
6. U.S. Environmental Protection Agency (EPA), Region IV. 1985. Coastal Marina Assessment Handbook.

7. U.S. Department of Health and Human Services, Northeast Technical Services Unit. 1983. Hydrographic Studies of the Kiawah River, South Carolina.
8. Title 33 Code of Federal Regulations, Section 159.7 https://www.govregs.com/regulations/expand/title33_chapterI_part159_subpartA_section159.7#title33_chapterI_part159_subpartA_section159.1
9. National Shellfish Sanitation Program (NSSP), Model Ordinance (MO). 2019 Revision
10. U.S. Environmental Protection Agency (EPA), Office of Waste Management. 2011. Graywater Discharges from Vessels.
U.S. Environmental Protection Agency (EPA), Federal No Discharge Zone (NDZ) Link: https://www.epa.gov/vessels-marinas-and-ports/vessel-sewage-no-discharge-zones

Public Health Significance	The 2019 NSSP MO included new language separating out marinas and mooring areas. The adopted language does not have descriptive details as to how the new mooring area language will be evaluated by the FDA. Given that marinas and mooring areas may be considered a potential pollution source and high risk if mooring areas are not assessed correctly, the proposed updated marina and mooring area guidance is presented to help provide the guidance on how to meet those new requirements.
Cost Information	N/A
Action by 2023 Task Force I	Recommended referral of Proposal 23-124 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-124.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-124.

Proposal No. 23-125

Submitter	ISSC Laboratory Committee issc@issc.org
Proposal Subject	Guidance for Laboratory Method Matrix Extensions
Specific NSSP Guide Reference	PROCEDURE XV. PROCEDURE FOR THE APPROVAL OF ANALYTICAL METHODS FOR THE NSSP and Section IV Guidance Documents – Chapter II. Growing Areas
Text of Proposal/ Requested Action	PROCEDURE XV. PROCEDURE FOR THE APPROVAL OF ANALYTICAL METHODS FOR THE NSSP

10. ~~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.~~

For methods already adopted into the NSSP, additional work must be done in order to expand the use of that method to a new molluscan shellfish matrix. To determine if a Matrix Extension is needed, please refer to the guidance provided in the NSSP Guide for the Control of Molluscan Shellfish, Section IV. Guidance Documents, Chapter II. Growing Areas .21 - Guidance for Laboratory Method Matrix Extensions. If a matrix extension is needed, the necessary information, studies, and data to be provided to the Laboratory Committee for consideration are summarized on the "ISSC Method Application Format for Biotoxin Methods Matrix Extension" and the "ISSC Method Application Format for Microbiology Methods Matrix Extension" documents available on the Laboratory tab of the ISSC website. This simplified, reduced approach to method validation for expanding an NSSP method to a new molluscan shellfish matrix is visually represented in the "Matrix Extension Guidelines" schematic, also available on the ISSC website.

Section IV Guidance Documents – Chapter II. Growing Areas

.20 Quantitative Analytical Method Verification

This guidance is provided to aid laboratories verifying the performance of an NSSP Approved Method or Approved Limited Use Method of analysis being transferred from the originating laboratory/submitter to the implementing

laboratory before being placed in service by the implementing laboratory. When a laboratory implements an NSSP method for the first time, the method performance must be verified in that laboratory. In addition, when a laboratory expands an existing method to a new shellfish matrix, method performance may need to be verified. Guidance outlined in .21 should be followed to determine if the new shellfish matrix is in the same matrix category as matrices previously implemented in the laboratory. If so, the method does not need to be verified. However, if the new shellfish matrix is in a different matrix category, then the method performance must be verified.The following performance criteria are to be verified: recovery, measurement uncertainty, precision (repeatability and intermediate precision), linear range, limit of detection (LOD), limit of quantitation (LOQ), and comparability.

Section IV Guidance Documents – Chapter II. Growing Areas (new section .21)

.21 Laboratory Method Matrix Extensions

Validating Use of an Analytical Method With A New Shellfish Matrix Analytical methods employed in the National Shellfish Sanitation Program (NSSP) are validated for their intended use before being adopted. Since differing characteristics of various molluscan shellfish matrices may impact the performance of certain methods, each validation is specific only to the shellfish species or matrices that were included in the validation studies.

In order to expand the use of any method already adopted into the NSSP for use with other molluscan shellfish matrices, additional validation studies need to be done. Based on proximate composition data (i.e. the amount of protein, fat, and carbohydrates in each species), as well as a review of existing empirical data where methods have been tested using multiple species, the Matrix Category Table below was developed to help determine if a Matrix Extension study is needed.

If a new shellfish species of interest is in the same matrix category (i.e. vertical column of the table) as an already validated species, then the method should not require further validation. For example, if a method has already been validated for use with the Eastern Oyster (*Crassostrea virginica*), and the new species of interest is the Pacific Oyster (*Crassostrea gigas*), then a matrix extension study is not necessary.

If a new species of interest is in a different matrix category from all previously validated species, then a Matrix Extension validation study should be conducted and data submitted to the ISSC for review following the process outlined in the ISSC Constitution, Bylaws, and Procedures, Procedure XV (10.). For example, if a method has already been validated for use with the Eastern Oyster (*Crassostrea virginica*) and the Soft Shell Clam (*Mya arenaria*), and the new species of interest is the Atlantic Surf Clam (*Spisula solidissima*), then a matrix extension study is needed.

If the new species of interest is not found in the Matrix Category Table, a request to add the new species should be submitted to the ISSC Executive Office.

The following information should be included in the request: common and scientific name of species, rationale for inclusion, and any available data for categorization (e.g, proximate composition, empirical data on use).

Regardless of the categorization of the species of interest, certain analytical methods require more species-specific data. The results of these studies will supersede the groupings described in the table below if significant matrix effects are identified.

1. For methods utilizing liquid chromatography, analyses shall be conducted to ensure sufficient separation of target analyte from sample matrix peaks through analysis of peak resolution utilizing retention times (e.g., AOAC[1]). Chromatograms supporting the analyses with labels noting peaks of interest as well as matrix peaks shall accompany the data package.

2. For methods utilizing mass spectrometry, comparison of neat and matrix-fortified standards shall be conducted to assess matrix effects on ionization.

1	2	3	4	5	6	7	8
Oysters	***Hard Clams***	***Non-US Hard Clams***	***Geoducks****	***Soft Clams***	***Mussels***	***Estuarine Mussels (non-***	***Scallops*** **
Eastern Oyster (*Crassostrea virginica*)	Atlantic Surfclam (*Spisula solidissima*)	Wedge Shell Clam (*Donax cuneatus*)	Pacific Geoduck Clam (*Panopea generosa*; formerly *P. abrupta*)	Softshell Clam (*Mya arenaria*)	Blue Mussel (*Mytilus edulis*)	Asian Green Mussel (*Perna viridis*)	Sea Scallop (*Placopecten magellanicus*)
Edible Oyster (*Ostrea edulis*)	Ocean Quahog (*Arctica islandica*)	Asiatic Hard Clam (*Meretrix meretrix*)	Atlantic Geoduck Clam (*Panopea bitruncata*)		Mediterranean Mussel (*Mytilus galloprovincialis*)		Rock Scallop (*Crassodoma gigantea*)
Olympia Oyster (*Ostrea lurida*)	Northern Quahog (*Mercenaria mercenaria*)				California Mussel (*Mytilus californianus*)		Bay Scallop (*Argopecten irradians*)
Pacific Oyster (*Crassostrea gigas*)	Southern Quahog (*Mercenaria campechiensis*)				Chilean Mussel (*Mytilus chelensis*)		Peruvian Scallop (*Argopecten purpuratus*)
	Northern Razor Clam (*Siliqua patula*)				Korean Mussel (*Mytilus coruscus*)		
	Pacific Littleneck Clam (*Protothaca staminea*)						
	Butter Clam (*Saxidomus gigantea*)						
	Sunray Venus Clam (*Macrocallista nimbosa*)						
	Japanese Littleneck Clam (*Venerupis philippinarum*)						

*Geoducks are generally analyzed as whole animals for microbiological methods and gutballs only for biotoxin methods. If a different form of the animal is to be processed (i.e., gutball for micro method or whole animal for biotoxin method), it should be considered a separate matrix.

**Scallops can be analyzed as whole animal or muscle excluded. These different forms of the animal should be considered a separate matrix. Methods for muscle only will not be considered as the product is not within the NSSP.

1 Association of Official Analytical Chemists. "AOAC Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals". Arlington, VA. 2002.

13. Public Health Significance

To ensure accurate reporting of analytical results within the NSSP, methods must be demonstrated to be fit-for-purpose. The program has recognized the potential interference from different shellfish types. This proposal is intended to provide additional detail on the conditions under which a matrix extension validation study is needed compared to when a method verification study is required.

14. Cost Information

Dependent upon the level of validation/verification needed.

Action by 2022 Executive Board

Granted Interim Approval in effect until the Conference convenes at the 2023 ISSC Biennial Meeting.

Action by 2023 Laboratory Committee

Recommended adoption of Proposal 23-125 as submitted.

Action by 2023 Task Force I

Recommended adoption of the Laboratory Committee recommendation on Proposal 23-125.

Action by 2023 General Assembly

Adopted the recommendation of Task Force I on Proposal 23-125.

Action by FDA July 7, 2023

Concurred with Conference action on Proposal 23-125.

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.
Action by *V.p.* Illness Response Committee, 2023	Recommended 15-226 be referred to the appropriate committee along with 17-206 as determined by the Conference Chair for continued development of guidance. The committee further recommended the Conference encourage the collection and characterization of environmental and clinical *V.p.* isolates.
Action by Task Force II, 2023	Recommended adoption of *V.p.* Illness Response Committee recommendation.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 15-226
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 15-226.

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.* illnesseswhen 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.

Cost Information

A reference to @ .01 J has been added for clarification.

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.
Action by *V.p.* Illness Response Committee, 2023	Recommended sending proposal 17-206 to the appropriate committee as determined by the conference chair, and the committee continue its work in the interim prior to the next conference.
Action by 2023 Task Force II	Recommended adoption of *V.p.* Illness Response Committee recommendation on Proposal 17-206.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 17-206.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 17-206.

Proposal No. 17-225

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 when "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.
Action by Time Temperature Committee, 2023	Recommended Proposal 17-225 be referred to an appropriate committee as determined by the conference chair.
Action by Task Force II, 2023	Recommended adoption of Time Temperature Committee recommendation on Proposal 17-225.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 17-225.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 17-225.

Proposal No. 19-200

Submitter	David Fyfe[1] & Tamara Gage[2]
Affiliation	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 Force II	Recommended adoption of Proposal 19-200 as submitted.

Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-200.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-200.
Action by Vibrio Management Committee, 2023	Committee recommended no action. Rationale: Proposal does not address specifics in Model Ordinance.
Action by Task Force II, 2023	Recommended adoption of Vibrio Management Committee recommendation on proposal 19-200.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 19-200.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-200.

Proposal No. 19-202

Submitter	ISSC Executive Office 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	**(18) 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: **(17) 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.

Action by Federal Waters Committee, 2022	Recommended No Action on Proposal 19-202. Rationale: This issue is resolved by action on Proposal 19-229.
Action by Task Force II 2023	Recommended adoption of Federal Waters Committee recommendation on Proposal 19-202.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 19-202.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-202.

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.
Action by Wet Storage Committee, 2023	Recommend no action on proposal 19-215. Rationale: Already covered under current food regulations. The committee further recommended that ISSC and FDA develop informational material related to food additives and labeling.
Action by Task Force II, 2023	Recommended adoption of the Wet Storage Committee recommendation on Proposal 19-215.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 19-215.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-215.

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.
Action by Time Temperature Committee, 2023	Recommended no action on Proposal 19-220. Rationale: This is adequately addressed in the Model Ordinance.

Action by Task Force II, 2023	Recommended adoption of the Time Temperature Committee recommendation on Proposal 19-220.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 19-220.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-220.

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.
Action by Shellstock Identification Committee, 2023	Recommended no action' on Proposal 19-222. Rationale: Adequately addressed in the NSSP Guide.
Action by Task Force II, 2023	Recommended adoption of the Shellstock Identification Committee recommendation on Proposal 19-222.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-222.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-222.

Proposal No. 19-223

Submitter	ISSC Executive Office 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.
Action by Federal Waters Committee, 2022	Recommended No Action on Proposal 19-202. Rationale: This issue is resolved by action on Proposal 19-229.
Action by Task Force II 2023	Recommended adoption of the Federal Waters Committee recommendation on Proposal 19-223.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 19-223.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-223.

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.
Action by Backflow Prevention Committee, 2023	Recommended adoption of the proposal as submitted with cost information updated below: Cost Information Hose bib vacuum breakers may continue to be used, provided the 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 $6-20 on average and up to $80 depending on the quality of the device where it is purchased. 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 backflow preventer, capable of protecting against backflow and back siphonage under continuous pressure in potable water systems, whether mounted vertically or horizontally, will cost approximately $4060-80. ~~Addition of an atmospheric vent to the dual check valve assembly will increase the cost.~~ A lead free ¾" dual check valve with atmospheric vent made by MATCO-NORCA is approximately $43. A Watts dual check valve backflow preventer with intermediate atmospheric vent costs $100-160. Additionally, the average rate for a licensed commercial plumber nationally is $100-150/hr. Consequently, the estimated cost to install a Watts lead-free dual check valve backflow preventer would be between $250 ($50 for the valve and two hours of labor at $100) to about $610 for a Watts lead-free dual check valve backflow preventer with intermediate atmospheric vent ($160 for the valve and three hours of labor at $150). Replacement costs could increase if a dealer opts to install a heavier duty valve or if there are existing plumbing issues that need to be corrected prior to installation of proper valve. Cost estimates for devices proved by Amazon.com, Google Shopping, Plumbing-deals.com, and Pexuniverse.com. Plumbing labor rates provided by Angi.com, Homeadviser.com, and Fixr.com. The costs cited in this section are accurate as of February 23. 2023.
Action by Task Force, II 2023	Recommended adoption of the Backflow Prevention Committee recommendation on Proposal 19-227.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 19-227.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-227.

Proposal No. 19-229

Submitter	ISSC Executive Office 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 XI. ~~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

FDA concurs with Conference Action on Proposal 19-229.

Action by 2022 Federal Waters Committee

Recommend adoption of the following language:

.06 FEDERAL WATERS GUIDANCE

I. INTRODUCTION

Requirements for Federal waters shellfish harvesters, dealers, the State of Landing Authority and FDA and NOAA are listed in multiple sections throughout the NSSP Model Ordinance. The following guidance provides additional information to assist in meeting these requirements.

II. HARVESTER REQUIREMENTS

A. HARVESTER LICENSING AND TRACEABILITY

The Food and Drug Administration (FDA) and the National Oceanographic Atmospheric Administration (NOAA) are the federal agencies responsible for shellfish growing areas and harvest control in Federal waters. The State of Landing Authority, through agreements and in coordination with the FDA and NOAA, may also take the lead and/or take on responsibilities in the management, control of

harvest, and/or marine biotoxin control associated with commercial shellfish harvested from Federal waters and landed in their state.

The NOAA Seafood Inspection Program (SIP) is the primary contact for all commercial shellfish harvesting activities in Federal waters. This does not supersede the harvester's responsibilities to contact other federal agencies related to federal fisheries permits and aquaculture siting permits.

To meet the requirement in the NSSP MO, Chapter VIII .03A. for Federal waters, the NOAA SIP utilizes the NOAA SIP contract that serves as the mechanism for the control of harvest and traceability for all commercial shellfish grown and harvested from Federal waters. It is the responsibility of shellfish harvesters to contact the NOAA SIP to obtain a NOAA SIP contract, which is the identified mechanism for authorizing harvesters to land shellfish harvested from Federal waters at a state certified dealer. The NOAA SIP contract also provides the unique identifier number that will be used on Federal waters shellfish harvester tags.

The NOAA SIP contract application process requires that the harvester provide their contact information as well as the intended Federal waters harvest and/or aquaculture site location information to the NOAA SIP. Harvester contact information will be used to contact each harvester in the event of an emergency closure (e.g., oil spill, hurricane, severe storm, chemical spill, WWTP spill, or ship discharge) and reopening, status change, classification change, and/or product recall.

The NOAA SIP will generate and maintain a NOAA SIP Contract Harvester List which can be accessed through the Interstate Shellfish Sanitation Conference (ISSC) website for reference. The NOAA SIP will coordinate with the FDA regarding meeting the requirements related to the growing area classification, control of harvest, and marine biotoxin control of the intended area of harvest as well as shellfish aquaculture operation and initial siting evaluation.

B. FEDERAL WATERS SHELLFISH CLASSIFICATION

The FDA is responsible for the classification of Federal waters shellfish growing areas (NSSP MO, Section II, Chapter IV @.03 F.). Federal waters are considered generally free from bacterial and chemical pollution and are therefore classified as approved for shellfish harvesting unless such areas are known to be polluted and involve commercial shellfish resources (Verber, 1977). Areas known to be polluted or are considered potential sources of pollution in Federal waters may include but are not limited to ocean dump sites designated for the disposal of contaminated wastes, areas where major estuarine complexes discharge large quantities of sewage effluents or other contaminants, wastewater treatment plant effluent pipes, commercial shipping channels and anchorages, and oil platforms.

When applying for the NOAA SIP contract, the harvester will provide the intended harvest location(s) to the NOAA SIP using either the 10-minute latitude and longitude grid number(s), the NOAA National Marine Fisheries Statistical grid, or the latitude(s) and longitude(s). The NOAA SIP will coordinate and provide the FDA with the intended harvest site location(s).

For shellfish harvest areas of concern, the FDA will conduct a site-specific sanitary survey in accordance with NSSP MO, Chapter IV. @.01. Once the sanitary survey is completed, the FDA will coordinate with the NOAA SIP to notify the harvester of

the sanitary survey findings, any growing area classification and/or status change, and if warranted, any microbiological and/or biotoxin monitoring requirements.

C. MARINE BIOTOXINS

To meet the NSSP MO, Chapter IV. @.04 requirements, once the harvester notifies the NOAA SIP of the intended harvest location(s) in Federal waters, through coordination with the NOAA SIP, the FDA will review available data and determine if marine biotoxins are of concern and which marine biotoxin requirements apply to the harvester for the intended harvest and/or aquaculture site locations. The harvester will then be notified by the NOAA SIP of any marine biotoxin requirements.

If the harvester is harvesting from a location in Federal waters where the associated State of Landing Authority has agreed to be responsible for marine biotoxin control, the harvester must abide by the State of Landing Authority marine biotoxin contingency plan and if applicable, marine biotoxin management plan.

i. MARINE BIOTOXIN CONTINGENCY PLAN

To meet the NSSP MO, Chapter IV. @.04 A. requirements, as a default, each harvester will abide by the FDA/NOAA SIP Marine Biotoxin Contingency Plan that addresses the management of paralytic shellfish poisoning (PSP), amnesic shellfish poisoning (ASP), neurotoxic shellfish poisoning (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.

If applicable, in the case where the State of Landing Authority chooses to be responsible for the control of marine biotoxins in Federal waters, the harvester will follow the State of Landing marine biotoxin contingency plan. The FDA will review the Federal waters component in the State of Landing Authority's marine biotoxin contingency plan during the state program growing area evaluation process.

ii. MARINE BIOTOXIN MANAGEMENT PLAN

To meet the NSSP MO, Chapter IV. @.04 B. requirements (and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans), the FDA and NOAA SIP will work with other federal and associated state agencies as well as the shellfish industry to collect and review all available data to assist in identifying and delineating shellfish growing areas in Federal waters that meet(s) the criteria and requirement for a marine biotoxin management plan. If harvesting in these designated areas, each harvester must utilize the FDA/NOAA SIP Marine Biotoxin Management Plan template and specify and abide by the marine biotoxin management strategy(ies) of choice, intended state of landing, and the laboratory to be used for marine biotoxin sample analysis.

In the case where the State of Landing Authority has agreed to be responsible for the management of biotoxins and/or has an established a biotoxin management strategy(ies) for shellfish landed in their state from Federal waters, each harvester must coordinate with the State of Landing Authority to meet the marine biotoxin management plan requirements.

In coordination with the NOAA SIP, the FDA will review all harvester marine biotoxin management plans for compliance with NSSP MO, Chapter IV. @.04 B. For marine biotoxin management plans associated with Federal waters managed by the State of Landing Authority, the FDA will evaluate these management plans during the State of Landing growing area program evaluation.

In addition, to meet the requirements for marine biotoxin management strategies that include shellfish lot testing or pre-harvest shellfish toxicity screening coupled with lot testing [NSSP MO, Chapter IV. @.04 B.(4)(d) & (e) and (5)] and allow the landing of shellfish harvested in a growing area that is placed in the controlled access status, the harvester will be required to enter into an agreement or memoranda of understanding (MOU) between the State of Landing Authority, individual growers, individual shellfish dealers, and NOAA SIP. At a minimum, the agreement or MOU should reference the marine biotoxin management plan and include language indicating that all signatories agree with and will abide by the marine biotoxin management plan. The FDA and NOAA SIP will review the agreement or MOU for NSSP compliance.

To meet the restricted tag requirement of the NSSP MO, Chapter IV. @.04 C. (7), all shellstock harvested from growing areas in the controlled access status shall be tagged with restricted shellstock tags. Information included on the restricted shellstock tag should include specific details defining the restriction.

iii. LABORATORY REQUIREMENTS FOR SAMPLE ANALYSES

To meet the laboratory requirements for the analysis of regulatory samples from Federal waters, the harvester will be responsible for identifying and using a laboratory with an operational status of conforming or provisionally conforming to the requirements set forth by the NSSP and implement NSSP approved and/or approved limited use method for fecal coliform and marine biotoxin analysis. For guidance on available laboratories, the harvester may refer to the Interstate Shellfish Sanitation Conference (ISSC) website for the Domestic NSSP Laboratory List (https://www.issc.org/laboratory-1).

D. VIBRIO RISK ASSESSMENT & TIME/TEMPERATURE CONTROL

The harvester is responsible for meeting the requirements in the NSSP MO, Chapter VIII. @.02 & Chapter II. @.06 & @.07. To meet this requirement, the harvester must meet the time to temperature matrix found in the NSSP MO, Chapter VIII. @.02 A. (3) or if the risk of Vibrio Parahaemolyticus or Vibrio Vulnificus illness has been determined to be reasonably likely to occur, then they must meet the defined Vibrio Control Plan for the area.

E. HARVESTER TRAINING

To meet the NSSP MO, Chapter VIII. .01 B. harvester training requirement, each harvester will be provided an electronic harvester training document during the application process for the NOAA SIP contract.

F. SHELLFISH AQUACULTURE OPERATIONAL PLAN

Per the NSSP MO, Chapter VI .07 B., each Federal waters shellfish aquaculture site is required to develop and maintain a site-specific Operational Plan. During the NOAA SIP contract application process, each Operational Plan will be provided to

the NOAA SIP by the harvester for review by the FDA and NOAA SIP to ensure that it meets the NSSP requirements. The Operational Plan must at a minimum, include all items from the NSSP MO, Chapter VI. .05 A. and Chapter VI. .07 B.

G. FINALIZE NOAA SIP CONTRACT

Once all the harvester requirements have been reviewed and found to conform with the NSSP MO by the FDA and NOAA SIP, the NOAA SIP contract may be finalized with signatures, an effective date, and the contract number assigned by NOAA SIP to be used as the shellfish harvester's tag number. The finalized NOAA SIP contract will be added to the NOAA SIP Contract Harvester List located on the ISSC website.

III. DEALER REQUIREMENTS

To meet the requirement for state shellfish dealers listed on the Interstate Certified Shellfish Shippers List (ICSSL) List to only accept shellfish harvested from Federal waters from a harvester with a NOAA SIP contract, the dealer may go to the ISSC website and review the NOAA SIP Contract Harvester List to verify that a Federal waters harvester has a valid NOAA SIP contract.

When receiving shellstock harvested from Federal waters in the controlled access status, the dealer must agree to be a signatory to an agreement or MOU to abide by the marine biotoxin management plan. In addition, the biotoxin management plan will include specific language detailing the use of the restricted shellstock tag(s) as well as restrictions that require further processing and testing prior to the distribution of the shellstock into commerce.

IV. REFERENCES/SOURCES/LINKS

- Verber, 1977, Classification of Offshore Waters, James L. Verber
- NOAA SIP CONTRACT:
  - NOAA SIP Contract information:
    TBD Website: https://www.fisheries.noaa.gov/resource/document/us-department-commerce-approved-establishments
    HARVESTER CONTRACT LIST: Discuss about adding this list to the ICSSL as well. It can just be a one-stop shop, as opposed to dealers and harvesters going to multiple sites for different things.
- Link to state of landing shellfish contacts:
  https://www.cfsanappsexternal.fda.gov/scripts/shellfish/sh/shellfish.cfm#state
- FDA/NOAA SIP MARINE BIOTOXIN CONTINGENCY and MANAGEMENT PLAN
  - Link: TBD
  - NSSP Conforming Laboratories, ISSC Website: https://www.issc.org/laboratory-1

Action by Task Force II, 2023	Recommended adoption of the Federal Water Committee recommendation on Proposal 19-229.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 19-229.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-229.

Proposal No. 19-231

Submitter	Blake Millett / Jon Strauss
Affiliation	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.
Action by Time Temperature Committee, 2023	Recommended no action on Proposal 19-231. Rationale: This adequately addressed in the Model Ordinance.
Action by Task Force II, 2023	Recommended adoption of the Time Temperature Committee recommendation on Proposal 19-231.
Action By 2023 General Assembly	Adopted recommendation of Task Force II on 19-231.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-231.

Proposal No. 19-240

Submitter	Bill Dewey
Affiliation	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.

Chart source – Enrico Buenaventura, Health Canada

Chart source – Erika Atherly, Washington DOH

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.
Action by *V.p.* Illness Response Committee, 2023	Recommended referral of Proposal 19-240 to the appropriate committee as determined by the Conference Chair. The committee further recommended the Conference consider the development of additional language related to the design of appropriate scientific studies and control measures allow the harvest of shellstock from areas closed as a result of *V.p.* illness.
Action by Task Force II, 2023	Recommended adoption of the *V.p.* Illness Response Committee recommendation on Proposal 19-240.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 19-240.
Action by FDA July 7, 2023	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 e~~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 other than a State laboratory."

Subdivision b. Was the illness epidemiologically linked to shellfish? Epidemiologically linked will mean "associated with" the consumption of oysters. Consumption means ingested; eaten within 7 days of onset of symptoms. Date of onset may be before hospitalization. Further information may be warranted; discretion may be exercised.

Subdivision c. Were the shellfish consumed?

Subdivision de. 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

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

ISSC *Vibrio vulnificus* Illness Review Criteria Table

Review Date: _____

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	Harvest	Harvest	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	N/A
Action by 2019 Task Force II	Recommended to referral of Proposal 19-241 to the appropriate committee as directed 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.
Action by Vibrio Management Committee, 2023	Recommended adoption of Proposal 19-241 as amended with effective implementation date of March 24, 2023.

Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.06 *Vibrio vulnificus* Control Plan

D. All States not currently implementing a *V.v.* Control Plan shall develop and implement a *V.v.* Control Plan if the risk evaluation indicates two (2) or more etiologically confirmed, and epidemiologically linked severe *V.v.* illnesses from consumption of commercially harvested 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

B. 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 nonO1 *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 wound infections, invasive disease usually characterized by bacteremia, and less commonly diarrheal illness associated with the consumption of seafood. Evidence shows that individuals with ~~such~~ chronic diseases such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy are susceptible to severe illness and death from raw seafood, ~~especially~~ including raw oysters and hard-shell clams. 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~~ likely 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

On at least an annual basis FDA and the Centers for Disease Control and Prevention (CC) shall compile and reconcile all reported *V.v.* cases involving the consumption of shellfish. The *V.v.* Illness Review Committee will ~~annually~~ review all *V.v.* cases submitted by FDA and CDC.~~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 electronic 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~~ISSC Executive Office.

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 apply the criteria and guidelines in Section 3. 2016 is the first full year to which these criteria will be applied. ~~and~~ The Committee will 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 other than a State laboratory."

Subdivision b. Was the illness epidemiologically linked to shellfish? Epidemiologically linked will mean "associated with" the consumption of oysters. Consumption means ingested; eaten within 7 days of onset of symptoms. Date of onset may be before hospitalization. Further information may be warranted; discretion may be exercised.

~~Subdivision c. Were the shellfish consumed?~~

Subdivision ~~d~~c. Were the shellfish commercially harvested? Commercially harvested shall mean the shellfish were intended for sale or distribution in

commerce. Commercial harvest will include those cases involving a foreign state.

Subdivision ~~e~~d. From what State was the shellfish harvested?

Subdivision ~~f~~e. 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).

Subdivision ii. For patients with no report on the COVIS case form of wound exposure to a body of water or drippings from raw or live seafood during the 7 days before illness began, ~~Any~~ any of the following were indicated on the ~~COVIS case report~~ form:

~~1. Fever~~

~~2.~~ 4. Septic Shock

5. Death

~~3.~~6. Any of the following sequelae: necrosis; or invasive procedure, such as surgery, amputation, skin graft, wound debridement, fasciotomy, or incision and drainage.

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~~ISSC Executive Office.

Subdivision g. The appellant will receive a final decision from the ~~Committee~~ ISSC Executive Office 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

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

ISSC *Vibrio vulnificus* Illness Review Criteria Table

Review Date: _____

Case Identifier/Number:	Criteria Status		
Criteria	Yes	No	Unknown
1. Etiologically Confirmed?			
2. Epidemiologically Linked?			

3. 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	Harvest	Harvest	Species	Comment

Action by Task Force II, 2023 Recommended adoption of the Vibrio Management Committee recommendation on Proposal 19-241 with amended implementation date to concur with the date of Summary of Action concurrence by the FDA.

Action by 2023 General Assembly Adopted recommendation of Task Force II on Proposal 19-241.

Action by FDA July 7, 2023 Concurred with Conference action on Proposal 19-241.

Proposal No. 23-200

Submitter	David Fyfe
Affiliation	Northwest Indian Fisheries Commission dfyfe@nwifc.org
Proposal Subject	Definition of Harvest
Specific NSSP Guide Reference	Section I Definitions (52) Harvest
Text of Proposal/ Requested Action	(52) Harvest means the act of ~~harvest means the act of removing shellstock from growing areas and its placement on or in a man made conveyance or other means of transport~~ (1) placing shellstock on or in a container which remains at the harvest site for sale to a dealer or (2) removing shellstock from a harvest site for sale or wet storage .~~.~~
Public Health Significance	Currently, some operations gather **shellstock** and place it in bags, totes or cages and that **shellstock** is then sold, on-site, to a **dealer** who is either better equipped to move large quantities of **shellstock**, or who simply prefers to conduct business this way. Whatever the reason, since the current definition of **harvest** requires both placement on or in a **conveyance** AND removal from a **growing area**, technically, in the example above, **harvest** has not occurred. Other terms such as **growing area**, have intentionally not been used here because they are problematic. A **growing area**, for example, can be huge. If **shellstock** is merely moved up or down the beach to a stand, for sale to the public, it has never left the **growing area**, and thus technically, has never been **harveste**d. And if removal from the water is the criterion for removal from a **growing area**, **shellstock** is often gathered after or as the tide recedes, and thus the **shellstock** has already left the **growing area** at a low tide. This proposed definition change solves the problem outlined in the example above, removes some ambiguity and should not impose new regulations on approved, existing operations.
Cost Information	There should be no increased costs associated with this change as it is intended to merely clarify what is already occurring.
Action by Task Force II, 2023	Recommended referral of Proposal 23-200 to appropriate committee as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-200.
Action by FDA Juy 7, 2023	Concurred with Conference action on Proposal 23-200.

Proposal No. 23-201

Submitter	Kim Coulbourne Maryland Department of Health Kim.coulbourne@maryland.gov
Proposal Subject	Inspection Frequency/Inspection Report
Specific NSSP Guide Reference	Section II Model Ordinance – Chapter I. Shellfish Sanitation Program for the Authority @.02 Dealer Certification (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~~ triannually for dealer's activities certified as shucker-packer or repacker; and (iv) At least semiannually for other dealer activities or annually for seasonal other dealer activities that are only certified for 6 months or less. (2) The Authority shall provide a copy of the completed inspection form to the person in-charge at the dealer's operation ~~at the~~ within a reasonable time of completing ~~time of~~ the 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. (3) The plant inspection shall be conducted by the SSO or SSI using the appropriate inspection form.
Public Health Significance	Many shucker-packer or repacker operations operate on a seasonal basis. In most instances, the third and fourth inspections at these facilities are when the firm is not operating at all or is only operating as a shipper and not a shucker-packer or repacker. By reducing the minimum inspection frequency to once every 4 months from once every 3 months, this will allow state Authorities to focus limited resources where they are most valuable without jeopardizing public health. Currently the FDA inspects high priority food manufacturing plants once every three years. This proposal still has a shucker-packer or repacker being minimally inspected at a rate 9 times that frequency. This proposal also clarifies that a firm that is only certified for 6 months or less will minimally be inspected once per year. Without this clarification, state Authorities are expected to inspect these firms twice during the 6 month period that they are certified each year. This proposal also would allow for the inspection report to be provided to the dealer by email once the report is completed because many states now use electronic inspection reports and are no longer hand writing the inspections.
Cost Information	No cost

Action by Task Force II, 2023

Recommended adoption of Proposal 23-201 as amended.

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 triannually for dealer's activities certified as shucker-packer or repacker; and

(iv) At least semiannually for other dealer activities or annually for seasonal other dealer activities that are only certified for six (6) months or less.

(2) The Authority shall provide a copy of the completed inspection form to the person in-charge at the dealer's operation withing a reasonable time of completing the 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.

(3) ~~The plant inspection shall be conducted by the SSO or SSI using the appropriate inspection form.~~

Action by 2023 General Assembly

Adopted recommendation of Task Force III on Proposal 23-201.

Action by FDA July 7, 2023

Concurred with Conference action on Proposal 23-201.

Proposal No. 23-202

Submitter	U.S. Food and Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Sampling for reopening following *Vp* illness closure
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 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) Shall follow the procedure outlined in Chapter II @ .02 (10)(a) or (b) for closures resulting from V.p. illnesses. (45) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific. G. When the growing area is… @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)* A… (10) Prior to reopening an area closed as a result of @.02 A. (9)(a) or (b) ~~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. (i) Samples shall be collected to be representative of the growing area, harvest/culture practices, and shellfish types. (ii) Multiple sample collection events shall span the closure time period in @.02 A. (9)(a) or (b) and be collected at intervals necessary to determine trends in the implicated harvest area. (b) Ensure that environmental conditions have returned to levels not associated with V.p. cases. (11) Shellfish harvesting may…
Public Health Significance	Following growing area closures due to *Vibrio parahaemolyticus* illnesses, it is essential to ensuring public health that the Program has confidence that the risk of illness from product has subsided. A representative and robust reopening sampling approach is critical to providing that confidence. The proposed language is intended to provide general recommendations for these sampling approaches.
Cost Information	Dependent on the number of samples collected.
Action by Task Force II, 2023	Recommended adoption of Proposal 23-202 as amended. @.01 Outbreaks of Shellfish-Related Illness 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) Shall follow the procedure outlined in Chapter II @ .02 (10)(a) or (b) for

closures resulting from V.p. illnesses.

(5) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.

G. When the growing area is…

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

A…

(10) Prior to reopening an area closed as a result of @.02 A. (9)(a) or (b), 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.

(i) Samples shall be collected to be representative of the ~~growing~~ area~~,~~ ~~harvest/culture practices,~~ and shellfish types; and~~.~~

(ii) Multiple sample collection events shall span the closure time period in @.02A. (9)(a) or (b) and be collected at intervals necessary to determine trends in the implicated ~~harvest~~ area;~~.~~

Or

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

(11) Shellfish harvesting may…

Action by 2023 General Assembly — Adopted recommendation of Task Force II on Proposal 23-202.

Action by FDA July 7, 2023 — Concurred with Conference action on Proposal 23-202.

Proposal No. 23-203

Submitter	Adam Wood & Kim Coulbourne Virginia Department of Health, Maryland Department of Health adam.wood@vdh.virginia.gov
Proposal Subject	Commingling in Wet Storage
Specific NSSP Guide Reference	Section II Model Ordinance, Ch. VII. Wet Storage in Approved and Conditionally Approved Growing Areas: @.03 Wet Storage Sites in Natural Bodies of Water (Offshore) C. @.04 Wet Storage in Artificial Bodies of Water (Land-Based) D.(2)
Text of Proposal/ Requested Action	@.03 Wet Storage Sites in Natural Bodies of Water (Offshore) C.: C. ~~Different lots of shellstock shall not be commingled in wet storage. If more than one (1) lot of shellstock is held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.~~ @.04 Wet Storage in Artificial Bodies of Water (Land-Based) D.(2): ~~(2) Unless the dealer is in the Authority's commingling plan under Chapter I. @.01 G., different lots of shellstock shall not be commingled during wet storage in tanks. If more than one (1) lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.~~
Public Health Significance	Deletion of the commingling sections in .03 and .04 will not impact in any way the ability for a state to allow commingling under their Commingling Plan. This simply clarifies what is already allowed under the .02 General section H. The proposed strikethrough language was an omission when the original language for Wet Storage in Artificial Bodies of Water was added, or when Commingling became permissible. This proposal is simply correcting and mirroring language already used in the Chapter under @.04 Wet Storage in Artificial Bodies of Water (Land-Based) D. Shellstock Handling (2) "Unless the dealer is in the Authority's commingling plan under Chapter I. @.01 G., different lots of shellstock shall not be commingled during wet storage in tanks. If more than one (1) lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained." This is redundant language and already provided in @.02 General allowing for commingling under the Authority's commingling plan.
Cost Information	N/A
Action by Task Force II, 2023	Recommended adoption of Proposal 23-203 as submitted.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-203.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-203.

Proposal No. 23-204

Submitter	Maxwell Rintoul Hog Island Oyster Co. max.rintoul@hogislandoysters.com
Proposal Subject	Proposal for Clarifying Wet Storage Holding Temperatures for Shipped Shellstock
Specific NSSP Guide Reference	Chapter XIII. Shellstock Shipping .01 Critical Control Points (A) (2)(d) and (B)(2)(b)
Text of Proposal/ Requested Action	Under the current language in the Model Ordinance, shellstock shipped to another approved dealer, must be held under 45F. Per Chapter XIII. .01 B. (2) (b); "…be placed in a storage area or conveyance maintained at 45 F or less. Additionally, per Chapter XIII. .01 A (2) (d) "Shipped the shellstock in a conveyance at or below 45 F ambient air temperature; and (e) Cooled the shellstock to an internal temperature of 50F". It seems the primary concern in holding pre-chilled shellstock is an internal temperature of less than 50F. However, these rules are written under the language of Cold Storage, or chilled conveyances, this language does not consider validated artificial wet storage systems. To maintain an internal temperature of less than 50 F in Cold Storage, the temperature of the cold storage system must be set to less than 45 as the difference between the chiller and the internal temperature will vary by a few degrees. In an artificial wet storage system, the temperature of the chiller and the internal temperature of the animal will vary by ~1 degree. So, in theory you are not permanently raising the holding temperature of pre-chilled shellstock by putting them in wet storage of 50 F or less. Local authority has been clear to our company that holding temperatures of shipped shellstock must be held at 45 F or less, as to match the temperature of the conveyance it was shipped on. We are requesting guidance documents or language changes to Chapter XIII. .01 B that would allow pre chilled shipped shellstock to be held in a validated Wet Storage system at 50 F or less.
Public Health Significance	Maintaining the internal temperature of shipped shellstock within a wet storage system.
Cost Information	No cost to authorities, potentially significant cost savings to shippers with energy savings.

Proposal No. 23-204

Action by Task Force II, 2023

Recommended adoption of Proposal 23-204 as substituted.

Chapter XI. Shucking and Packing

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

(1) If wet storage or depuration ~~in artificial bodies of water~~ is practiced, water quality meets the requirements outlined in Chapter VII for wet storage for chapter XV for depuration..~~04; and~~ [C]

(2) Once placed under temperature control and until shucked the shellstock shall; :

(a) Be placed in wet storage or depuration; or [C]

(~~a~~b) Be iced; or [C]

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

(~~c~~d) Except while in wet storage or a depuration process, not be permitted to remain without ice or mechanical refrigeration for more than two (2) hours at points of processing or transfer, such as loading docks. [C]

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

Chapter XIII. Shellstock Shipping

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

(1) If wet storage or depuration ~~in artificial bodies of water~~ is practiced, water quality meets the requirements outlined in Chapter VII for wet storage for chapter XV for depuration..~~04; and~~ [C]

(2) Once placed under temperature control and until shucked the shellstock shall; :

(a) Be placed in wet storage or depuration; or [C]

(~~a~~b) Be iced; or [C]

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

(~~c~~d) Except while in wet storage or a depuration process, not be permitted to remain without ice or mechanical refrigeration for more than two (2) hours at points of processing or transfer, such as loading docks. [C]

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

Action by 2023 General Assembly

Adopted recommendation of Task Force II on Proposal 23-204.

Action by FDA July 7, 2023

The FDA does not concur with Conference action to adopt proposal 23-204 as amended by Task Force II. The initial proposal requested guidance on maintaining wet storage water temperatures at ≤50°F instead of ≤45°F since the NSSP allows internal temp of shellstock to be ≤50°F. The rationale provided was that wet storage water temps are more representative of internal temps than in dry storage.

Task Force II discussed the request for guidance, drafted edits to language in Chapters XI and XIII, and recommended adoption by the General Assembly. The language that was recommended and subsequently adopted by the General Assembly is as follows where it occurs in Chapter XI .01 B. (2) and Chapter XIII .01 B. (2):

"B. (2) Once placed under temperature control and until shucked the shellstock shall:

a) Be placed in wet storage or depuration; or [C]

b) Be iced; or [C]

c) Be placed or stored in a storage area or conveyance maintained at 45°F (7.2°C) or less; and [C]

d) Except while in wet storage or a depuration process, not be permitted to remain without ice or mechanical refrigeration for more than 2 hours at points of processing or transfer, such as loading docks. [C]"

It is FDA's position that the adopted language is in direct conflict with the principles of 21 CFR 123, *Seafood HACCP Regulation* and the policy outlined in the Fish and Fishery Products Hazards and Controls Guidance, 4th edition (2022 version) (Hazards Guide). CFR 123 and NSSP Guide Chapter X. .01 A. stipulate dealers conduct a hazard analysis which identifies critical control points (CCP) in their process where they can control identified species and process related hazards. Original dealers are responsible for demonstrating the control of pathogen growth from the growing area via critical limits (CL) that demonstrate the hazard has been controlled. At the Receiving CCP, dealers show controls from the harvest area via approved source labeling (tags, harvest controls) and the documentation of time of harvest to time in temperature control during Vibrio control months. The harvest/process related hazard of pathogen growth is controlled at the Storage CCP via the CL of temperature (≤50°F prior to shipping, with a <10-hour clock attached during Vibrio control months).

Since the original dealer is responsible for demonstrating control of the hazard, secondary dealers need only demonstrate how they are maintaining control of the hazard through temperature control until it reaches the final destination (point of sale - where food code takes over). Those controls are demonstrated via documentation of adequate ice/internal temperature of shellstock/temperature of cooler and that shellstock shall not remain out of that temperature control for more than 2 hours at points of processing or transfer.

In other words, once the hazard has been controlled by the original dealer, everyone down the chain documents how it stays in control through their Receiving CCP (receiving temperature), and Storage CCP (temperature of cooler/ presence of ice) showing it can keep that hazard controlled. The reason for having "not to remain out of temp control for more than 2 hrs" is to maintain the control established by the original dealer. All tags/labels are required to say "KEEP REFRIGERATED" for the same reason.

Temperature is our only barrier to control pathogen growth in shellstock (outside of post-harvest processing). Once the original dealer has demonstrated product has been cooled to ≤50°F and controlled the hazard, secondary dealers taking it out of temp control for wet storage or depuration goes against the established principles of CFR 123 and basically re-introduces the hazard. Please see Chapter 12 of the Hazards Guide for Control Strategy 2-Refrigerated Storage and Refrigerated Processing Control as well as Control Strategy 4-Unrefrigerated Processing Control, and Table 12-5 which shows no more than 2 hours >50°F to ensure control of pathogen growth for ready to eat product. The original dealer controls the potential hazards from the growing area (Chapter 2) and then they and everyone else who touches the product maintains the control via temperature ≤50°F (Chapter 12).

In summary, the adopted language allows for potential re-introduction of a hazard that original dealers have controlled if temperature control is not maintained down the chain of custody. FDA recommends that Proposal 23-204 be sent to Committee for further discussion.

Proposal No. 23-205

Submitter	James R. Becker Maine Department of Marine Resources James.becker@maine.gov
Proposal Subject	Recirculating Wet Storage Water Quality Threshold
Specific NSSP Guide Reference	Section II Model Ordinance – Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas Section .04 Wet Storage in Artificial Bodies of Water (Land-Based) C. Wet Storage Source Water (1) General. (3) Recirculating Water System. Section IV Guidance Documents – Chapter III. Harvesting, Handling, Processing, and Distribution .05 Protocol for Addressing Positive Coliform Sample in an Artificial Wet Storage Water Body
Text of Proposal/ Requested Action	Section II Model Ordinance – Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas Section .04 Wet Storage in Artificial Bodies of Water (Land-Based) C.Wet Storage Source Water (1) General. (f) Disinfected process water entering the wet storage tanks shall have ~~no detectable levels~~ less than or equal to 2 cfu/100ml of the coliform group as measured by an approved NSSP method appropriate for UV process water and follow the protocol of the Decision Tree (Section IV. Guidance Documents Chapter III. .05) (g) When the laboratory analysis of a single sample of disinfected process water entering the wet storage tanks shows ~~any~~ a ~~positive~~ result above 2 cfu/100ml for the coliform group daily sampling shall be immediately instituted until the problem is identified and eliminated. (h) When the problem that is causing disinfected process water to show positive results above 2 cfu/100ml for the coliform group is eliminated, the effectiveness of the correction shall be verified on the first operating day following correction through the collection, over a twenty-four (24) hour period, of a set of three (3) samples of disinfected process water. (3) Recirculating Water System. (b) Once sanctioned for use, the recirculating process water system shall be sampled weekly to demonstrate that the disinfected water is ~~negative~~ less than or equal to 2 cfu/100ml for the coliform group. (c) The dealer shall inspect and/or clean the system if a weekly sample tests positive for the coliform group, but is less than or equal to 2 cfu/100ml. ~~(c)~~ (d)When make-up water of more than ten (10) percent of the process water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three (3) samples of disinfected water and one (1) sample of the source water prior to disinfection shall be collected over a twenty-four (24) hour period to reaffirm the ability of the system to produce process water with less than or equal to 2 cfu/100ml for the coliform group ~~free from the coliform group or viable bacteria~~. ~~(d)~~ (e)When ultra-violet treatment is used as the water disinfectant, each time a bulb change is required either to replace a burned out bulb or for servicing, new ultraviolet bulbs shall be installed and old bulbs discarded, and the weekly disinfected process water sample shall be

collected and analyzed.

Section IV Guidance Documents – Chapter III. Harvesting, Handling, Processing, and Distribution

.05 Protocol for Addressing Positive Coliform Sample in an Artificial Wet Storage Water Body

If the water sample is ~~positive~~ above 2 cfu/100ml for coliforms in the recirculating system, institute daily sampling.

Public Health Significance	The NSSP regulations for wet storage allow for flow through systems in approved waters without disinfection. However, recirculating wet storage systems in the US currently need to meet a zero coliform threshold for weekly process water tests to meet NSSP regulations. When the laboratory analysis of a single sample of disinfected process water entering the wet storage tanks shows any positive result for the coliform group, daily sampling must be immediately instituted until the problem is identified and eliminated. This is a significant burden on the industry and the shellfish laboratories. This proposal would change the trigger for daily testing to samples that exceed 2 cfu/100ml. This does not reduce public health protections and requires the dealer to inspect and/or clean the system if a sample comes back positive but less than or equal to 2 cfu/100ml. This proposal does not eliminate~~eleiminte~~ the need for the system to be initially verified by testing negative for the coliform group under normal operating conditions. Justification for this proposal is partly based on the Canadian recirculating~~recirulating~~ wet storage process water quality threshold of ≤ 2cfu/100ml which is found in the Canadian Shellfish Sanitation Program manual.
Cost Information	This proposal will result in significant cost savings for the dealers in collecting and shipping daily samples as well as the laboratory in processing unnecessary samples when 2 or less cfu/100ml is observed in process waters.
Action by Task Force II, 2023	Recommended referral of Proposal 23-205 to appropriate committee as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-205.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-205.

Proposal No. 23-206

Submitter	Nicole Martin Florida Department of Agriculture, Division of Aquaculture Nicole.Martin@FDACS.gov
Proposal Subject	Wet Storage Sampling Requirements
Specific NSSP Guide Reference	Section II Model Ordinance. Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas. .04 (C)(3) Recirculating Water System

Text of Proposal/ Requested Action

(3) Recirculating Water System.

(a) A study shall be required to demonstrate that disinfection for the recirculating system can consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall meet the requirements in Section C. (2) (b) above.

(b) Once sanctioned for use, the recirculating process water system shall be sampled weekly to demonstrate that the disinfected water is negative for the coliform group

(c) If the recirculating process water system passes (20) consecutive weekly samples, monthly sampling can be initiated. If a monthly sample fails, weekly sampling will resume until twenty (20) consecutive weekly samples demonstrate that the disinfected water is negative for the coliform group.

(d) If the recirculating process water system passes twelve (12) consecutive monthly samples. Quarterly sampling can be initiated. If a quarterly sample fails, weekly sampling will resume until twenty (20) consecutive weekly samples demonstrate that the disinfected water is negative for the coliform group.

(e) When make-up water of more than ten (10) percent of the process water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three (3) samples of disinfected water and one (1) sample of the source water prior to disinfection shall be collected over a twenty-four (24) hour period to reaffirm the ability of the system to produce process water free from the coliform group or viable bacteria.

(c)(f) When ultraviolet treatment is used as the water disinfectant, each time a bulb change is required either to replace a burned out bulb or for servicing, new ultraviolet bulbs shall be installed and old bulbs discarded, and the weekly disinfected process water sample shall be collected and analyzed.

Public Health Significance	Many wet storage facilities only operate a few days a week and may only have shellfish products in the wet storage system for a few hours, with potentially different products in the system on a daily basis. Weekly sampling for these recirculating systems is excessive and does not provide an accurate accounting as to whether a facility is going to have a sample failure. We propose a tiered sampling system for facilities that have a history of passing water samples and accounts for what to do when a sample does fail for Total Coliform.
Cost Information	There is significant cost to the shellfish wet storage facilities to overnight samples to a certified lab, in addition to the cost for the sampling and shipping supplies. Additionally, extra costs are incurred by the certified laboratories that have to run more samples.
Action by Task Force II, 2023	Recommended referral of Proposal 23-206 to the appropriate committee as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-206.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-206.

Proposal No. 23-207

Submitter	Andrew Bell State of Delaware, Department of Natural Resources & Environmental Control, Shellfish & Recreational Water Program andrew.bell@delaware.gov
Proposal Subject	Repacking Shellstock without a Dealer Facility
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XIII. Shellstock Shipping
Text of Proposal/ Requested Action	F. Shellfish Storage and Handling. (1)… (2)… (3) A dealer whose activity consists of trucks or docking facilities only shall: (a) Have a permanent business address at which records are maintained and inspections can be performed.~~; and~~ [K] (b) ~~Not repack shellstock. [K]~~ (4) A dealer who stores ~~or repacks~~ shellstock shall have: (a) His own facility for proper storage ~~or repacking~~ of shellstock; or [K] (b) Arrangements with a facility approved by the Authority of the storage ~~or repacking~~ of shellstock. [K] (5) Repacking of shellstock shall be conducted under overhead cover on a clean surface meeting the requirements of Chapter XIII. .03 E. (~~5~~6)…
Public Health Significance	There is no public health significance of a Shellstock Shipper repacking shellstock without a facility, as long as proper sanitation controls are put into place. Currently, the exception at the beginning of Chapter XIII states that "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 a building." However, .03 F. requires that a dealer who repacks shellstock have a facility. This makes it appear that the exception does not apply to dealers who repack shellstock. Many states certify dealers without facilities, who may transport shellstock in refrigerated trucks or in coolers with ice. Many dealers without facilities have need to repack minimal amounts of shellstock (for example, if shellstock are harvested in bushel containers but a customer wants only a half bushel). Therefore, it is probable that many states could be out of compliance with this requirement as it is currently written. There is no public health reason why dealers without a facility should not be able to quickly transfer shellstock into different containers, if it is done under overhead cover and on an appropriate surface. Other requirements in Chapter XIII ensure that shellstock will be protected from contamination and temperature abuse during this action.
Cost Information	None.
Action by Task Force II, 2023	Recommended no action on proposal 23-207. Rationale: Already addressed by Model Ordinance.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-207.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-207.

Proposal No. 23-208

Submitter	Mitch Jurisich Louisiana Oyster Task Force mitchjurisich@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 (10 °C)	36 hours
Level 2	65 °F - 74 °F (18 °C - 23 °C)	18 hours
Level 3	> 74 °F - 84 °F (> 23 °C - 28 °C)	16 hours
Level 4	> 84 °F (≥ 28 °C)	14 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

Proposal No. 23-208

Action by Task Force II, 2023

Recommended adoption of proposal 23-208 as amended:

@.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 (1) of the following:
(1) The Stat *V.v* Control Plan as outline in Chapter II. @.06; or
(2) The State *V.p.* Plan as Outline 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 °F - 60 °F (10 °C - 15 °C)	24 hours
Level 3	> 60 °F - 80 °F (15 °C - 27 °C)	18 hours
Level 4	> 80 °F (≥ 27 °C)	12 hours

B. If the Authority's Vibrio Control Plan time to temperature requirements allow for more time from exposure than the @.02 A(3) temperature matrix then the time requirements of the Vibrio Control Plan may be applied in place of @.02 A(3) temperature matrix.

B. C. 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. D. The Authority shall establish the water 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 for each growing area by averaging the previous five (5) years maximum monthly temperatures.

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

E. F. The Authority shall ensure that harvesters document and provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements. For States that establish and limit harvest times that assure compliance with the times outlined in the matrix of Chapter VIII. @.02 A. (3) recording the time harvest begins is not required.

F. G. Shellstock intended for Wet Storage, Depuration, PHP or "For Shucking Only by a Certified Dealer" must either be shucked, introduced into PHP, Wet Storage, or Depuration within times outlined in the matrix in Chapter VIII. @.02 A. (3) or meet the applicable time to temperature controls of Chapter VIII. @.02 A. (3). Shellstock

harvested under a State Vibrio Plan intended for Wet Storage or Depuration, must be placed in Wet Storage, Depuration or refrigeration to comply with time to temperature controls outlined in the State Authority *V.v* or *V.p.* Control Plan

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

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

I. J. Shellstock intended for a validated pathogen reduction process hwere refrigeration would reduce efficacy of the process (and appropriately labeled with name of the receiving dealer) is exempt from the requirements in Chapter VIII. @.02 A. (1) and (2).

Action by 2023 General Assembly

Adopted recommendation of Task Force II on Proposal 23-208.

Action by FDA July 7, 2023

Concurred with Conference action on Proposal 23-208.

Proposal No. 23-209

Submitter	Bill Dewey Taylor Shellfish Farms billd@taylorshellfish.com
Proposal Subject	Waivers from Vp & Vp control plans for Authority approved pathogen reduction processes
Specific NSSP Guide Reference	Chapter VIII Control of Shellfish Harvesting @.02 Shellstock Time to Temperature Controls I. (page 80)
Text of Proposal/ Requested Action	I. Shellstock intended for a validated pathogen reduction process or other pathogen reduction process approved by the Authority where refrigeration or wet storage temperatures exceeding those required in the V.p. or V.v. Contol Plan would reduce efficacy of the process (and appropriately labeled with name of the receiving dealer) ~~is exempt~~ can be granted waivers from the requirements in Chapter VIII. @.02 A. (1) and (2) Chapter IX .04 and Chapter XIII. 01.B. (2) and (3).
Public Health Significance	Temperature controlled wet storage is emerging as a promising means of reducing vibrio in oysters and achieving a significant illness risk reduction. Unfortunately it appears it may not be practical to achieve a 3.0 or 3.52 log reduction to validate the process as prescribed by the Model Ordinance in a reasonable period of time. Taylor Shellfish and their Canadian subsidiary, Fanny Bay Oyster Company have successfully been achieving a 90-95% reduction in vibrio holding oysters in recirculating, refrigerated wet storage at 52°F for 3 – 5 days depending on initial levels. This is above the temperature allowed for holding oysters per Vp control plans. This temperature has been demonstrated through research to be the most effective at reducing vibrio in the shortest period of time. A waiver provision would allow Taylor and other companies interested in deploying this technology the ability to most effectively reduce vibrio in oysters and the associated illness risk.
Cost Information	There would be an unknown cost for Authorities to evaluate pathogen reduction processes for approval. Pursuing waivers for approved pathogen reduction processes is voluntary therefore there is no cost to companies unless they chose to pursue a process. Companies using refrigerated wet storage would have a reduced electrical cost if they are able to operate the system at warmer temperatures to achieve maximum vibrio reduction. Beyond producing oysters with substantially lower vibrio levels, Taylor has experienced significant benefits with refrigerated wet storage, including product quality, inventory control and handling efficiencies.
Action by Task Force II, 2023	Recommended no action on Proposal 23-209. Rational: The requested action was resolved by Proposal 23-204.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-209.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-209.

Proposal No. 23-210

Submitter	Federal Waters Committee ISSC issc@issc.org
Proposal Subject	Addition of NOAA SIP contract language to allow for the harvest of molluscan shellfish from Federal Waters
Specific NSSP Guide Reference	Section II, Model Ordinance Chapter VIII. Control of Shellfish Harvesting, Requirements for Harvesters, .03 Shellstock Harvesting in Federal Waters, A. (1) and (2) and Section II., Model Ordinance Chapter X. General Requirements for Dealers, .09 Restricted Shellfish from Federal Waters A. (1) and (2)
Text of Proposal/ Requested Action	**.03 Shellstock Harvesting in Federal Waters** A. The harvester shall obtain a NOAA contract to land commercial shellfish harvested from Federal waters at a state certified dealer. In addition, if applicable, obtain the required NOAA NMFS managed fisheries harvester license(s) and/or permit(s). ~~A~~B. Prior to harvesting shellfish in Federal waters from an area in the controlled access status~~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)~~ (1) Enter into~~Be a party to~~ agreements or memoranda of understanding between the landing stateAuthority, ~~the landing state,~~ NOAA, and the shellfish dealers receiving the shellfish as necessary to comply with the requirements outlined in the NSSP MO, Chapter IV.@.04 B. and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. **Chapter X. General Requirements for Dealers** .09 ~~Restricted~~ Shellfish Harvested from Federal Waters A. The dealer shall: (1) ~~Obtain permission from the Authority to receive restricted shellstock prior to receipt.~~~~Only receive product from harvesters in Federal waters that have a NOAA contract.~~ (2) ~~Develop~~ If receiving shellstock harvested from Federal waters in the controlled access status, be a party to agreement~~to~~agreements or memoranda of understanding between the Authority, ~~National Oceanic Atmospheric Administration (~~NOAA), and the individual harvesters as necessary to comply with the biotoxin controls outlined in the NSSP MO, Chapter IV.@.04 B. and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.
Public Health Significance	This proposal allows for contracts to be set up between the Authority, NOAA, and individual harvesters to allow for the safe harvest of molluscan shellfish from Federal Waters. These agreements will assure safe harvest from controlled access status areas.
Cost Information	None known
Action by Task Force II, 2023	Recommended adoption of Proposal 23-210 as submitted.

Adopted recommendation of Task Force II on Proposal 23-210.

Action by 2023 General Assembly

Action by FDA July 7, 2023

Concurred with Conference action on Proposal 23-210.

Proposal No. 23-211

Submitter	Wyllys Chip Terry BlueTrace chip@blue-trace.com
Proposal Subject	Digital Recalls
Specific NSSP Guide Reference	Model Ordinance Chapter X. ,05 Shellstock Identification B. Tags, .06 Shucked Shellfish Labeling A. Shellfish Labeling
Text of Proposal/ Requested Action	.05 B. Tags. (1) The dealers' tags shall: (a) Be durable… (b) Be at least… (2) The dealer's tag shall contain the following indelible, legible information in the order specified below: (a) The dealer's … (b) The dealer's … (c) The original … (d) The harvest … (e) If wet … (f) The most … (g) The type … (h) The following … (i) A link to a digital record where the consumer can check whether the product has been recalled. Link can be a web address, QR code, UPC, or other digital link approved by the Authority. The link destination must be maintained by the harvester, dealer, Authority, or their designee. .06 A. Shellfish Labeling. (1) The dealer … (2) If the … (3) If the dealer … (4) At a minimum … (5) The dealer … (6) The dealer … (7) The dealer … (8) If the dealer … (9) If the dealer … (10) If the dealer … (11) The dealer … (12) A link to a digital record where the consumer can check whether the product has been recalled. Link can be a web address, QR code or other digital link approved by the Authority. The link destination must be maintained by the harvester, dealer, Authority, or their designee.
Public Health Significance	This will save lives by getting contaminated product off the shelves more quickly. Currently recalls rely on all participants in the supply chain communicating effectively and efficiently. Often communications are dropped as product moves and consumers/restaurants/retailers do not know a product has been recalled. Since every product has a tag/label there is a built in mechanism for communicating recalls (or most often the lack of) easily.
Cost Information	Most companies already have a website. Adding a page for recalls and linking to it from a shellfish tag is a minimal cost.

Action by Task Force II, 2023	Recommended no action on Proposal 23-211. Rationale: Already addressed by the Model Ordinance.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-211.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-211.

Proposal No. 23-212

Submitter	U.S. Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Shipping documents and records
Specific NSSP Guide Reference	Chapter X. .08 A. (1-2)
Text of Proposal/ Requested Action	Chapter X. .08 A. Shipping Documents (1) Each shellfish shipment shall be accompanied by a shipping document that contains accurate and legible information to permit a container of shellfish to be traced back to the specific incoming lot of shellfish from which it was taken. (2) The shipping document shall contain: (a) The name, address, and certification number of the shipping dealer.; (b) The name and address of the ~~major~~ consignee~~.; and~~ (c) The kind and quantity of the shellfish product(s)~~.; and~~ (d) The lot code(s) (if applicable). (e) The growing area(s), date(s) of harvest, and (if possible) the harvester(s) or group of harvester(s) for (i) a lot (or commingled lots as per Section I B. (72) and Chapter I. @.01 G.) of shucked shellfish, (ii) a lot of shellstock (as per Section I B. (70) and Chapter I. @.01 G.), and (iii) a lot of in-shell product (as per Section I B. (69)); and (f) The wet storage history of the shellstock including, original harvest site(s), original harvest date(s), wet storage site(s), and date(s) (if applicable), and wet storage lot number(s); and (g) The depuration history of the shellstock including the date(s) of depuration processing and the depuration cycle or lot number(s); and (h) The federal sequential tag number(s) for federally allocated shellfish (surf clams and ocean quahogs) caught in federal waters using the National Marine Fisheries Service tagging protocol.
Public Health Significance	The NSSP requires certified dealers keep shipping documents and records to trace a shellfish shipment, through all the various dealers who have handled it, back to its point of origin. In the event of a shellfish related illness, tags are a tool, which, used in concert with records must provide for traceability of shellfish from the final consumer back through every middleman, (retailer, wholesaler, carrier, and dealer) who handled the product, to a specific growing area, harvest date, and if possible, the individual person who harvested the shellstock. Shipping documents are often used by certified dealers as part of the traceability record keeping but there must be details on the shipping document that specify the growing area(s), harvest date(s), wet storage details, depuration details, lot code(s), and for federally allocated shellfish (surf clams and ocean quahogs) caught in federally regulated waters, the federal sequential tag number(s). Certified dealers often have "records" in the most general sense, but these records are not in the form that meets the intent of the NSSP requirement to provide traceability on a lot-by-lot basis. As a result, follow-up investigations of illnesses and illness outbreaks have been stymied, identification of the cause of the outbreak has been delayed, and outbreaks have continued. In case of an illness or illness outbreak attributable to shellfish, it is necessary that health departments and other appropriate state and federal agencies be able to determine the source of contamination, and thereby to prevent any further outbreaks from this source. This can be done most effectively by following the course of a shipment, through all the various dealers who have handled it, back to the point of origin by means of shipping documents and transaction records kept by the shellfish dealers and retailers.

Cost Information	Not applicable.
Action by Task Force II, 2023	Recommended no action on Proposal 23-212. Rationale: Adequately addressed by the Model Ordinance.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-212.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-212.

Proposal No. 23-213

Submitter	Maxwell Rintoul Hog Island Oyster Co. max.rintoul@hogislandoysters.com
Proposal Subject	Proposal For Clarifying Product Loading Rules During Validation Study of Artificial Wet Storage Systems
Specific NSSP Guide Reference	Chapter 7 .04 C Wet Storage Source Water
Text of Proposal/ Requested Action	The purpose of the Validation study for a Wet Storage system is to demonstrate the ability of the System to properly disinfect the water from all coliforms. The Model ordinance states that this Study should be done under "Normal operating conditions" per Chapter 7 .04 C 3a. For our Artificial Wet Storage System, normal operating conditions means product being taken out, and new product going into the system on a daily basis. To fully test the ability of the system to disinfect from coliforms during a validation study new product would have to be cycled in and out. However, there is no guidance in the model ordinance on the loading of product in the tanks, only the sampling procedure. It seems that Normal Operating Conditions have been interpreted differently by state authorities. Some authorities have the thought that tanks should be fully loaded, and no product should be removed for the duration of the study. The reason for not removing product being the system should always be at max load and removing product for any period would reduce the potential load the system would have to disinfect. It is our belief that removing products and adding new products increases the potential coliform group load by introducing animals that are harboring more potential coliforms. Allowing for removal and adding of new products during the Validation Study is more representative of the maximum number of animals a Wet Storage system would experience. This is what 'Normal Operating Conditions' would mean for us; we are asking for clarification and guidance on Normal Operating Conditions for Land-Based Recirculating Wet Storage Systems.
Public Health Significance	Ensuring artificial wet storage systems are validated under their maximum load as they would during 'Normal Operating Conditions'.
Cost Information	Potential cost increases for Authorities and Shippers. More product used in the validation study would lead to increases in traceability documents on the authorities side. More product needed for the validation study on the Shipper's side.
Action by Task Force II, 2023	Recommended referral of Proposal 23-213 to the appropriate committee as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-213.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-213.

Proposal No. 23-214

Submitter	Andrew Bell State of Delaware, Department of Natural Resources & Environmental Control, Shellfish & Recreational Water Program andrew.bell@delaware.gov
Proposal Subject	Shellfish Dealer Receiving Critical Limits for Shellstock Received from a Dealer
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter XI. Shucking and Packing .01 A. (2)&(3) Chapter XIII. Shellstock Shipping .01 A (2)&(3) Chapter XIV. Reshipping .01 A. (1)&(2) Chapter XV. Depuration .01 A (2)&(3)
Text of Proposal/ Requested Action	Chapter XI. Shucking and Packing .01 Critical Control Points A. 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 at or below 45 °F (7.2 °C) ambient air temperature; and [C]~~ ~~(e)~~(d) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less. [C] (3) A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter ~~XIII~~XI. .01 A. (2) (c)~~, (d)~~ or (~~e~~d). 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 device or comply with Chapter ~~XIII~~XI. .01 A. (2) (c)~~, (d)~~ or (~~e~~d). Shipments of four (4) hours or less must have documentation as required in Chapter IX..05 A. [C] Chapter XIII. Shellstock Shipping .01 Critical Control Points A. 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 at or below 45 °F (7.2 °C) ambient air temperature; and [C]~~ ~~(e)~~(d) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less. [C] (3) A dealer may receive shellstock from a dealer who has elected to

ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c) or (~~e~~d). 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 device or comply with Chapter XIII. .01 A. (2) (c), or (d) ~~or (e)~~. Shipments of four (4) hours or less must have documentation as required in Chapter IX. .05 A. [C]

Chapter XIV. Reshipping

.01 Critical Control Points

A. Receiving Critical Control Point – Critical Limits.

(1) The dealer shall reship only shellfish obtained and transported from a dealer who has:

(a) Identified the shellstock with a tag as outlined in Chapter X. .05, identified the in-shell product with a tag as outlined in Chapter X. .07, and/or identified the shucked shellfish with a label as outlined in Chapter X. .06; and [C]

(b) Provided documentation as required in Chapter IX. .05; and [C]

(c) Adequately iced the shellstock; or [C]

(d) ~~Shipped the shellstock in a conveyance at or below 45 °F (7.2 °C) ambient air temperature; and [C]~~

~~(e)~~(d) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less; [C] or

~~(f)~~(e) 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]

(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.~~XIV.

(2) .01 A. (2) (c), or (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 device or comply with Chapter XIII. 01 A. (2) (c), or (d) ~~or (e)~~. Shipments of four (4) hours or less must have documentation as required in Chapter IX. .05 A. [C]

Chapter XV. Depuration

(1) The dealer shall…

(2) The dealer shall receive and depurate only shellstock obtained and transported from a dealer who has:

(a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05 or transaction record with each bulk shipment as outlined in Chapter VIII. .02 F. (8); [C] and

(b) Provided documentation as required in Chapter IX. .05; and [C]

(c) Adequately iced the shellstock, or [C]

(d) ~~Shipped the shellstock in a conveyance at or below 45 °F (7.2 °C) ambient air temperature; and [C]~~

~~(e)~~(d) Cooled the shellstock to an internal temperature of 50 °F (10 °C) or less. [C]

(3) Should a dealer receive shellstock from a dealer who is shipping shellstock harvested in accordance with Chapter VIII. @.02 A. (3) or restricted use shellstock that has not been cooled to an internal temperature of 50 °F (10 °C), the shellstock must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. This product can be received without meeting the receiving requirements of Chapter XIII. .01 A. (2) (c), or (d) ~~or (e)~~. Shipments of four (4) hours or less will not be required to have a time/temperature device. [C]

Public Health Significance	None. This proposal merely corrects a significant problem resulting from Proposal 19-237, which was adopted at the 2019 ISSC. Before this proposal's adoption, the receiving critical limits for shellstock received from a dealer were that, unless adequately iced, the shellstock were shipped in a conveyance at or below 45ºF ambient air temperature OR the shellstock were cooled to an internal temperature of 50ºF or less. Proposal 19-237 changed the "or" to an "and", so that the receiving critical limits for un-iced shellstock are now that they are shipped in a conveyance at or below 45ºF ambient air temperature AND cooled to an internal temperature of 50ºF or less. This has caused significant problems for receiving dealers, with no public health significance. Though un-iced shellstock are required to be shipped in a conveyance with 45ºF ambient air temperature (which remains a requirement in Section II. Chapter IX. Transportation), it is unnecessary as a Receiving critical limit, and also unpracticable due to limitations on accurately measuring the conveyance ambient air temperature upon receipt. The ambient air temperature of a conveyance increases as soon as the door is opened, making it difficult if not impossible to measure accurately by the receiving dealer, especially because this measurement (as a HACCP critical limit) must be conducted with a calibrated thermometer. The shellstock temperature is the receiving critical limit with public health significance, which is why other seafood products under HACCP regulation require only the product temperature at receipt. The current Model Ordinance requires the receiving dealer to perform and document a corrective action if the conveyance ambient air temperature exceeds 45ºF, which is unnecessary if the product temperature is within the critical limit. This requirement puts dealers in such a difficult position that it may lead to falsified records across NSSP-participating jurisdictions when the product was received at a temperature that meets the critical limit but conveyance air temperature may have exceeded the limit due to inability to measure accurately. Pre-chilling and maintaining conveyances remains a requirement for the shipping dealer under Chapter IX. The intent of this proposal is only to remove the ambient air temperature of the conveyance as a requirement for the receiving dealer, because it is unnecessary, redundant, and unpractible. There are also what appear to be some minor typos (such as Chapter XI. .01 A. (3) referring to receiving requirements in Chapter XIII.) in the Model Ordinance text that this proposal corrects.
Cost Information	None
Action by Task Force II, 2023	Recommended adoption of proposal 23-214 as submitted.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-214.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-214.

Proposal No. 23-215

Submitter	Blake Millett Utah Department of Agriculture and Food Bmillett@utah.gov
Proposal Subject	Addition of Criticalities to Shellstock Shipping Shellfish Storage and Handling
Specific NSSP Guide Reference	Chapter XIII Shellstock Shipping .03 Other Model Ordinance Requirements F. Shellstock Storage and Handling
Text of Proposal/ Requested Action	(6) All shellstock obtained from a licensed harvester shall be: (a) Adequately iced within two (2) hours of receipt; [C]or (b) Placed in a storage area maintained at 45 °F (7.2 °C) within two (2) hours of receipt; [C] (c) Product intended for relay, wet storage or depuration, or either geoduck clams (Panopea generosa), or Mercenaria spp. which are being cooled utilizing an Authority approved tempering plan are exempt from the requirements listed above in .03 F. (6).
Public Health Significance	Addition of criticalities to maintain consistency with the rest of Chapter XIII.
Cost Information	N/A
Action by Task Force II, 2023	Recommended referral of Proposal 23-215 to the appropriate committee as determined by the Conference Chair with instructions to consider the appropriate criticality code.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-215.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-215.

Proposal No. 23-216

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Removal of language in "Shellfish Storage and Handling" section of Chapter XIV. (Reshipping) that does not belong in that section
Specific NSSP Guide Reference	NSSP MO Chapter XIV .03.F. Shellfish Storage and Handling
Text of Proposal/ Requested Action	NSSP MO Chapter XIV .03.F. ~~(1) The dealer shall buy shellfish only from sources certified by the Authority or listed in the ICSSL. **[K]**~~ (21) The dealer shall not: (a) Commingle, sort, or repack shellfish; or **[K]** (b) Remove or alter any existing tag or label. **[K]** (~~3~~2) A dealer whose activity consists of trucks only shall… (43) During storage frozen shellfish shall be maintained frozen. **[$S^{K/O}$]**
Public Health Significance	Failure to obtain shellfish from a certified dealer is a Critical **[C]** deficiency; however, Chapter XIV erroneously lists this as a Key **[K]** deficiency in the current text of the NSSP Model Ordinance. Furthermore, the statement in question is incorrectly located under ".03 F. Shellfish Storage and Handling". This proposal seeks to correct both errors. Receiving shellfish from a certified dealer is a HACCP CCP in Chapter XIV .01 A.(1)(a), which states that shellfish shall only be obtained and transported by 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]**". All these sections require the tag or label to have a dealer certification number, and a "dealer" is required to be certified by definition (NSSP MO Chapter I (32)). This deficiency has a Critical **[C]** criticality code if not met. While it is true that Reshippers can ship to each other without adding their certification number to the tag or label, the certification number of the shipping dealer must be included in shipping documents under NSSP MO Chapter X. .08.A.(2)(a). Therefore, a shipping dealer would need to be certified in order to meet that requirement. Removing the language in Chapter XIV .03.F. will reduce confusion, since the requirement is covered elsewhere in the NSSP MO as described above.
Cost Information	No Cost
Action by Task Force II, 2023	Recommended no action on proposal 23-216. Rationale: Addressed by proposal 23-217.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-216.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-216.

Proposal No. 23-217

Submitter	Blake Millet Utah Department of Agriculture and Food bmillett@utah.gov
Proposal Subject	Removal of Contradictory Information in Reshipping Shellfish Storage and Handling.
Specific NSSP Guide Reference	Chapter XIV Reshipping .03 Other Model Ordinance Requirements F. Shellfish Storage and Handling
Text of Proposal/ Requested Action	F. Shellfish Storage and Handling. ~~(1) The dealer shall buy shellfish only from sources certified by the Authority or listed in the ICSSL. [K]~~ (21) The dealer shall not: (a) Commingle, sort, or repack shellfish; or [K] (b) Remove or alter any existing tag or label. [K] (~~3~~2) A dealer whose activity consists of trucks only shall: (a) Have his own facility for the storage of shellfish; or [K] (b) Have arrangements with a facility approved by the Authority for the storage of shellfish; and [K] (c) Have a permanent business address at which records are maintained and inspections can be performed. [K] (43) During storage frozen shellfish shall be maintained frozen. [SK/O]
Public Health Significance	The strikethrough line above is in direct conflict with XIV .01 A, which already describes the requirements of the dealer to receive shellstock from an approved and licensed dealer and lists the criticality as a Critical deficiency.
Cost Information	N/A
Action by Task Force II, 2023	Recommended adoption of Proposal 23-217 as submitted.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 23-217.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-217.

Proposal No. 23-218

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Depuration tanks and trays are food contact surfaces
Specific NSSP Guide Reference	Chapter XV .02 B. (2) (a)
Text of Proposal/Requested Action	Chapter XV .02 B. ~~(2)~~ Cleaning and sanitizing of food contact surfaces. (a) Food contact surfaces of the depuration units, equipment, and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces. ~~Depuration tanks and trays are not considered to be food contact surfaces.~~ The dealer shall: (i) Provide applicable adequate cleaning supplies and equipment, brushes, detergents, and sanitizers, hot water and pressure hoses; [K] (ii) Sanitize equipment prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; and [K] (iii) Wash and rinse equipment at the end of each day. [K]
Public Health Significance	The need to effectively clean and sanitize processing tanks, containers, and pipes carrying process water is well established. The inadequate cleaning and sanitizing of process equipment can result in microorganisms being resuspended in the process water and increasing the bacterial loading to such a level that adequate depuration will not occur. Processing tanks and containers used to hold shellfish that have cracked, rough or inaccessible surfaces, or made of improper material, are apt to harbor accumulations of organic material in which bacteria, including pathogens, may reside and grow. Such organisms can be regularly introduced into the system and these potentially may contaminate the shellfish. Surfaces, therefore, must be smooth and easily cleanable if bacteria are to be flushed out in the cleaning and sanitizing process. Surfaces that cannot be cleaned can result in inconsistent depuration effectiveness, and, possibly, the reintroduction of pathogens into the shellfish. Additionally, there are several references in Chapter XV that clearly state depuration tanks and trays are food contact surfaces, specifically: Chapter XV .01 B. (2) (b) states that containers which may have become contaminated during storage shall be properly washed, rinsed, and sanitized prior to use or are discarded. (c) states, shellstock depuration tanks shall be cleaned and sanitized on a regular schedule as part of a plant sanitation standard operating procedure. Chapter XV .02 A. (6) states that the depuration unit, including depuration tanks, reservoir tanks, and related piping…(c) Meets the requirements for food contact surfaces. Chapter XV .03 E. (3) Cleaning activities for the depuration unit and equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellstock and food contact surfaces.
Cost Information	No additional cost to depuration processors.

Action by Task Force II, 2023

Recommendation: Adopt substitute language.

Chapter XV. 02 B.

(1) Cleaning and sanitizing of food contact surfaces.

(a) Food contact surfaces of the depuration units, equipment and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces. Depuration tanks and trays are not considered to be food contact surfaces for the purposes of cleaning and sanitizing. Cleaning and sanitizing schedules shall be addressed in the dealer's Depuration Plant Operations Manual. The dealer shall:

(i) Provide applicable adequate cleaning supplies and equipment, Brushes, detergents, and sanitizers, hot water and pressure Hoses; [K]

(ii) Sanitize equipment prior to the start-up of each day's activities And following any interruption during which food contact Surfaces may have been contaminated; and [K]

(iii) Wash and rinse equipment at the end of each day. [K]

Action by 2023 General Assembly

Adopted recommendation of Task Force II on Proposal 23-218.

Action by FDA July 7, 2023

Concurred with Conference action on Proposal 23-218.

Proposal No. 23-219

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Depuration unit and equipment are food contact surfaces
Specific NSSP Guide Reference	Chapter XV .03 E. (3)
Text of Proposal/Requested Action	Chapter XV .03 E. Equipment Condition, Cleaning, Maintenance and Construction of Non-food Contact Surfaces. ~~(3) Cleaning activities for the depuration unit and equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellstock and food contact surfaces. [K]~~ ~~(4)~~(3) All conveyances and equipment which come into contact with the stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. [O]
Public Health Significance	The need to effectively clean and sanitize the interior of processing tanks, containers, and the interior of pipes carrying process water is well established. The inadequate cleaning and sanitizing of process equipment can result in microorganisms being resuspended in the process water and increasing the bacterial loading to such a level that adequate depuration will not occur. Processing tanks and containers used to hold shellfish that have cracked, rough or inaccessible surfaces, or made of improper material, are apt to harbor accumulations of organic material in which bacteria, including pathogens, may reside and grow. Such organisms can be regularly introduced into the system and these potentially may contaminate the shellfish. Surfaces, therefore, must be smooth and easily cleanable if bacteria are to be flushed out in the cleaning and sanitizing process. Surfaces that cannot be cleaned can result in inconsistent depuration effectiveness, and, possibly, the reintroduction of pathogens into the shellfish. Additionally, there are several references in Chapter XV that clearly state the interior surfaces of depuration tanks and trays are food contact surfaces, specifically: Chapter XV .02 B. Condition and Cleanliness of Food Contact Surfaces. (2) (b) states that containers which may have become contaminated during storage shall be properly washed, rinsed, and sanitized prior to use or are discarded. (c) states, shellstock depuration tanks shall be cleaned and sanitized on a regular schedule as part of a plant sanitation standard operating procedure. Chapter XV .02 A. Plumbing and Related Facilities. (5) (b) (2) Cleaning and sanitizing of food contact surfaces. (a) Food contact surfaces of the depuration units, equipment, and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces. Chapter XV .02 A. (6) Depuration Unit. states that the depuration unit, including depuration tanks, reservoir tanks, and related piping…(c) Meets the requirements for food contact surfaces.
Cost Information	No additional cost to depuration processors.

Action by Task Force II, 2023	Recommended no action on Proposal 23-219. Rationale: Addressed by proposal 23-218. Adopted recommendation of Task Force II on Proposal 23-219.
Action by 2023 General Assembly	Concurred with Conference action on Proposal 23-219.
Action by FDA July 7, 2023	

Proposal No. 11-310

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 Bienninal Meeting. 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.
Action by 2023 Standards Committee	Recommended continued development of the voluntary program standards.
Action by 2023 Task Force III	Recommended adoption of the Standards Committee recommendation on Proposal 11-310.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 11-310.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 11-310.

Proposal No. 13-301

Submitter	ISSC Executive Office 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 Committee

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 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.
Action by Growing Area Evaluation Criteria Committee	Recommended referral of Proposal 13-301 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force III	Recommended adoption of the Growing Area Evaluation Criteria Committee recommendation on Proposal 13-301.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 13-301.

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

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

ji. 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.
Action by 2023 Control of Harvest Evaluation Criteria	Recommended referral of Proposal 17-204 to an appropriate committee as determined by the Conference Chairperson.

Action by 2023 Task Force III	Recommended adoption of the Control of Harvest Evaluation Criteria Committee recommendation on Proposal 17-204.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 17-204.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 17-204.

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.
Action by 2023 Plant Evaluation Criteria Committee	Recommended no action on Proposal 19-305. Rationale: It is not appropriate Model Ordinance language and FDA Specialists are already instructed to work with each state concerning evaluations.
Action by 2023 Task Force III	Recommended adoption of the Plant Evaluation Criteria Committee recommendation on proposal 19-305.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 19-305.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-305.

Proposal No. 19-310

Submitter	Danielle Schools, Plant Program Manager, SSO 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.

iii. 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~~ iv. ~~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.
Action by 2022 Plant Evaluation Criteria Committee	Recommended adoption of Proposal 19-310 as amended with interim approval by the Executive Board. Replace language in proposed language 4. f with following. There are no other changes to suggested language.

f. Conformance Designations
i. 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.:
a) Conformance:
The program is in compliance with all of the criteria listed in Chapter I. @.03 B. 4. e. i.-vi. and has 25% or fewer of plants with deficiencies as outlined in Chapter I. @.03 B. 4. e. vii.
b) Provisional Conformance:
The program is in compliance with Chapter I. @ .03 B. 4. e. i - vi. and has 26% to 42% of plants with deficiencies as outlined in Chapter I. @ .03 B. 4. e. vii. For plant sanitation programs that have 26-42% deficiencies, the Authority can achieve a designation of conformance by successful completion of the actions listed in Chapter I. @.03 B. 4. f. ii. b).
c) 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 42%of plants with deficiencies as outlined in Chapter I. @.03 B. 4. e. vii.. Two consecutive FDA audits of Provisional Conformance will result in a conformance designation of Non-Conformance. This conformance

designation requires an action plan as outlined in Chapter I. @.03 B, 4. f. ii. c). the program has been deemed in Provisional Conformance on two consecutive FDA audits.

d) Major Nonconformance:
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., The failure of a state to develop and implement an acceptable and effective action plan.

ii. Each conformance designation will require the actions listed below:

a) Conformance: The Authority will work cooperatively with the individual firms to correct deficiencies or develop deficiency-specific compliance schedules in plants audited by FDA.

b) Provisional Conformance: For plant sanitation programs that have 26-42% deficiencies, the Authority can achieve a designation of Conformance by successful completion of the actions listed below:

1. Correct deficiencies or develop deficiency-specific compliance schedules in plants audited by FDA within 30 days of the in-field closeout meeting. If there are any disagreements between the Authority and FDA an additional 15 days will be allowed to resolve differences.
2. The State must take one of the following actions.
   - Within 30 days, the SSO will conduct an audit of the same number of plants as the original FDA evaluation to determine compliance with Chapter I @.03 B. 4. e. vii., (The Authority will work with FDA to select the plants.); or
   - Conduct inspections of all certified dealers with 120 days to identify and correct deficiencies. Within 30 days of completion of the inspections, the SSO will conduct an audit of the same number of plants to determine compliance with Chapter I @.03 B. 4. e. vii. (The Authority will work with FDA to select the plants.)
3. Conduct a file review for the purpose of comparing FDA and SSO findings to previous inspections
4. Determine if inspector re-standardization or additional training is needed.
5. Re-standardize and provide additional training for inspectors as needed.

Should the SSO audit outlined in Chapter I.@.03 B. 4. f. ii. b).2. above determine that compliance with Chapter I.@.03 B. 4. f. i. a) the program will be reassigned a conformance designation of Conformance. This reassignment will be acknowledged in FDA correspondence to the Authority.

Should the SSO audit outlined in Chapter I.@.03 B. 4. f. ii. b).2. determine that the program is not in compliance with Chapter I.@.03 B. 4. f. i. a), the program will be reassigned a designation of nonconformance. This reassignment will be acknowledged in FDA correspondence to the Authority.

c) Nonconformance: The Authority must develop and complete an action plan that includes a plan to specifically address any deficiencies associated with Chapter I @03 B.4.e. ii-vi. Should the designation of Nonconformance be the result of deficiencies associated with Chapter I @03 B.4.e.vii the action plan shall include the following:

1. Correct deficiencies or develop deficiency-specific compliance schedules in plants audited by FDA within 30 days of the in-field closeout meeting. Should the state disagree with FDA regarding an

identified deficiency(s), an additional 15 days will be allowed for resolution and/or correction of those specific deficiencies.

2. Within 10 days of correcting the deficiencies identified in the FDA audit, the Authority shall request re-standardization of state SSO(s) by FDA.
3. Within 60 days of SSO re-standardization by FDA, the SSO will conduct an abbreviated re-standardization of all inspectors using a minimum of 3 plants for the purpose of evaluating staff competency.
4. Provide additional inspector training as determined by the Authority.
5. Following re-standardization, the state will conduct a state-wide compliance inspection of all plants (excluding plants audited by FDA). This activity must be completed within 120 days or another timeframe mutually agreed upon by the Authority and FDA..
6. Within 30 days of completion of the state-wide compliance effort, the SSO will conduct an audit of the same number of plants to determine compliance with Chapter I @.03 B. 4. E. (The Authority will work with FDA to select the plants)
7. The state SSO will conduct a file review for the purpose of comparing FDA and SSO findings to previous inspections

Failure to complete an effective action plan will result in a Conformance designation of major Non-Conformance
If Non-Conformance is the result of Provisional Conformance failure, an action plan would be required consistent with a conformance designation of Non-Conformance.

d) Major Non-Conformance: All determinations of Major Non-Conformance and the identification of deficiencies that pose imminent health concerns will be immediately reported to the ISSC Executive Board for consideration for appropriate action.

g. FDA will follow the current compliance program for communication with the State agencies.

h. 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.

Action by 2022 ISSC Executive Board	Granted Interim Approval in effect until the Conference convenes at the 2023 ISSC Biennial Meeting.
Action by 2023 Task Force III	Recommended adoption of the Executive Board interim action on Proposal 19-310
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 19-310.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-310.

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.
Action by 2023 Plant Evaluation Criteria Committee	Recommended no action on Proposal 19-311. Rationale: This issue is resolved by action on Proposal 19-310.
Action by 2023 Task Force III	Recommended adoption of the Plant Evaluation Criteria Committee recommendation on Proposal 19-311.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 19-311.
Action by FDA July 7, 2023	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.
Action by Plant Evaluation Criteria Committee	Recommended referral of Proposal 19-312 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force III	Recommended adoption of the Plant Evaluation Criteria Committee recommendation on proposal 19-312
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 19-312.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-312.

Proposal No. 23-300

Submitter	US Food & Drug Administration (FDA) Melissa.Abbott@fda.hhs.gov
Proposal Subject	Definition of Shellfish
Specific NSSP Guide Reference	Section I. Purpose & Definitions Definitions B. (115) Shellfish
Text of Proposal/Requested Action	Modify the definition of "Shellfish" as follows: **(115) Shellfish** means all species of: (a) Bivalve mollusks (e.g. ~~O~~oysters, clams, ~~or~~ mussels, cockles) 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.
Public Health Significance	As currently written in the Model Ordinance, the definition of "Shellfish" is exclusive to oysters, clams, mussels, and scallops and is not inclusive of all types of bivalve molluscan shellfish that may be encountered and that the Guide for the Control of Molluscan Shellfish must cover. This change will expand the definition to include all bivalve molluscan shellfish (such as cockles, penshells, etc) so that consumers are afforded the same protections from the risks that all raw bivalve molluscan shellfish can present. Whether these additional types of bivalve molluscan shellfish are aquacultured or imported from other countries, this change is needed to ensure the products are all covered by NSSP requirements.
Cost Information	N/A
Action by 2023 Task Force III	Recommended adoption of Proposal 23-300 as submitted.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-300.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-300.

Proposal No. 23-301

Submitter	Eric Hickey, MA Department of Public Health Kathy Brohawn, MD Department of the Environment Jeff Kennedy, MA Division of Marine Fisheries Michael Bott, DE Department of Natural Resources and Environmental Control Bryant Lewis, ME Department of Marine Resources Chris Nash, NH Department of Environmental Services Danielle Schools, VA Department of Health, Division of Shellfish Safety eric.hickey@mass.gov
Proposal Subject	Guidance Documents
Specific NSSP Guide Reference	ISSC Constitution and Bylaws ☐ Section I. Purpose & Definitions ☐ Section II Model Ordinance, Chapter I. Shellfish Sanitation Program Requirements for the Authority @03 A. (1) (c) and (3) ☒ Section IV. Guidance Documents
Text of Proposal/Requested Action	**Section I. Purpose & Definitions** (50) **Guidance Document** means a document that provides ISSC current thinking and/or general applicability suggestions on a NSSP provision. Guidance documents do not create or confer any rights or requirements for or on any person that are beyond those outlined in the NSSP Model Ordinance and do not operate to bind FDA, the Authority, or the public. Guidance documents do not preclude the use of alternative approaches for the implementation of NSSP Model Ordinance requirements. ~~(50)~~(51) **HACCP** is an acronym that stands for Hazard Analysis Critical Control Point, a systematic, science-based approach used in food production as a means to assure food safety. The concept is built upon the seven principles identified by the National Advisory Committee on Microbiological Criteria for Foods (1992). ~~(51)~~(52) **HACCP Plan** means a written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in 21 Code of Federal Regulations (CFR) 123.6 as adopted by the Interstate Shellfish Sanitation Conference. **Section II. Model Ordinance** **Ch. I @.03 Evaluation of Shellfish Sanitation Program Elements** A. The goal of shellfish program evaluation shall be to monitor program implementation and work with States to determine where problems may exist and how to address them. 1. Shellfish program evaluation methodologies shall: a. Monitor State program implementation; b. Assess State program effectiveness; c. Evaluate the validity of the elements of the NSSP ~~Guide to the Control of Molluscan Shellfish~~ Model Ordinance. **Ch. I @.03 Evaluation of Shellfish Sanitation Program Elements** A. 3. The focus of data collection shall be on measuring conformity of shellfish program activities with elements of the NSSP ~~Guide to the Control of Molluscan Shellfish~~ Model Ordinance.

ISSC Constitution Bylaws and Procedures Procedure IV Responsibilities of the FDA

~~3.~~ The FDA should prepare an annual evaluation of the shellfish program of each state in accordance with the Procedures of the NSSP Model Ordinance. This evaluation should consider the program as a whole and should also specifically address the legal authority, the classification of shellfish growing waters, the shellfish sanitation control and certification, personnel training, patrol, relaying, depuration and laboratory phases of the program, and the status of state authorities Memorandums of Understanding. The state evaluation prepared by the Regional Shellfish Specialist should be reviewed and discussed with the appropriate state shellfish officials prior to submission to FDA headquarters. A PEER deficiency item can only be found based on the Model Ordinance requirements (not guidance).

INTRODUCTORY STATEMENT TO BE PLACED AT THE BEGINNING OF SECTION IV:

Guidance documents are intended to provide supporting information on how to implement the criteria set forth in the Model Ordinance or the current thinking on topics referenced in the Model Ordinance. Alternative approaches that satisfy requirements of the Model Ordinance may be used. Guidance documents are not intended to be solely used by FDA as a reference to cite NSSP deficiencies in a PEER or determine program conformance with the requirements of the NSSP Model Ordinance.

Public Health Significance

The purpose of this proposal is to address concerns of state control authorities and to clarify areas of confusion which include, but are not limited to, guidance concerning marinas and moorings, biotoxin management strategies, and shellfish program element evaluations. Under 21 CFR Part 123 FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidance describes ISSC current thinking on relevant topics and should be viewed only as supporting information, recommendations, and NSSP implementation aids unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidance means that something is suggested or recommended, but not required. Guidance documents represent FDA's current thinking on a topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. The Authority can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. The same definition of guidance and how it is applied should be adopted in the NSSP MO to be consistent with FDA policy and definitions.

Cost Information

N/A

Action by 2023 Task Force III

Recommended referral of Proposal 23-301 to an appropriate Committee or Committees as determined by the Conference Chair.

Further recommends that the committee(s) review NSSP Guidance to identify requirements that need to be moved from guidance into the Model Ordinance with completion of the review by the next ISSC Biennial meeting.

Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-301.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-301.

Proposal No. 23-302

Submitter	ISSC Executive Office issc@issc.org
Proposal Subject	Removal of Office Manager and Program Chair Posistions
Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures, Article IV 3. & 9., Article V. 4., Article VI. 5, Article IX
Text of Proposal/Requested Action	ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES 1. The Conference shall… 2. The Board shall… 3. The immediate past Chairperson, ~~the Program Chairperson,~~ the three (3) Task Force Chairpersons, the Executive Director, and the Biennial Meeting Office Manager, except as otherwise provided, shall serve as non-voting members of the Board. 4. The Treaty Tribes… 5. The Board Chairperson… 6. Each Board member… 7. Elected Board members…. 8. The Board shall… 9. The Executive Committee, at a minimum, shall consist of the Board Chairperson, Vice Chairperson, Executive Director, ~~Office Manager, Program Chairperson,~~ one Industry Executive Board member, and the immediate past Board Chairperson. The function of the Executive Committee is to provide administrative guidance to the Executive Office of the ISSC for management of daily activities. Industry representation on the Executive Committee shall be appointed by the Chairperson of the Executive Board, at each Biennial Meeting, with recommendation from the industry members of the Board. 10. The Board may… 11. A quorum for… 12. The nine-member… 13. The Executive Board… 14. The Executive Board… 15. The Executive Board… 16. The Executive Board… 17. The Executive Board… ARTICLE V. DUTIES OF THE BOARD 1. The Board shall… 2. The Board shall… 3. The Board may… 4. The Board shall direct the Executive Director ~~and the Program Chairperson~~ in the preparation of programs for each General Assembly of the Biennial Conference meeting. 5. The Board shall…

6. In the event…
7. If a member…
8. A Board member…
9. The Board shall…
10. The Board shall…
11. The Board shall…

ARTICLE VI. DUTIES OF THE BOARD CHAIRPERSON

1. The Board Chairperson…
2. The Board Chairperson…
3. The Board Chairperson…
4. The Board Chairperson…
5. ~~The Board Chairperson, with the approval of the Board, shall appoint a Program Chairperson and a Biennial Meeting Office Manager.~~
6. 5. The Board Chairperson…
7. 6. The Board Chairperson…

~~ARTICLE IX. DUTIES OF THE PROGRAM CHAIRPERSON~~

~~1. The Program Chairperson shall assist the Executive Director in planning and arranging for all Conference meetings.~~
~~2. The Program Chairperson shall serve as a non-voting member of the Executive Board.~~

Public Health Significance	None. The positions of Office Manager and Program Chairperson have been vacant for numerous years and are unnecessary to the operations of the ISSC.
Cost Information	None
Action by 2023 Task Force III	Recommended adoption of Proposal 23-302 as submitted.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-302.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-302.

Submitter	ISSC Executive Office issc@issc.org
Proposal Subject	Revision of Standing Committee List
Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures, Article IV 10
Text of Proposal/Requested Action	ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES 18. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairperson. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference: ~~Audit Committee;~~ Credentials Committee; ~~Education Committee;~~ ~~Foreign Relations Committee;~~ Laboratory Committee Model Ordinance Effectiveness Review Committee; Pathogen Review Committee; ~~Patrol Committee;~~ Proposal Review Committee; ~~Research Guidance Committee;~~ ~~Research Management Committee;~~ Resolutions Committee; ~~Shellfish Restoration Committee;~~ Study Design Guidance Committee; ~~Training Committee;~~ Unresolved Issues Committee; ~~Vibrio~~Vibrio vulnificus 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	Standing committees are committees that have been assigned charges by the ISSC Constitution, By-laws & Procedures. These committees are appointed either every Biennial Meeting cycle for ongoing charges or as needed as defined in the ISSC Constitution By-laws & Procedures. Committees should not be included in the standing committee list unless a purpose for the committee has been defined by the ISSC Constitution, By-laws & Procedures. The revisions to the standing committee list will remove committees that have

	not been defined by the ISSC Constitution, By-laws & Procedures and will add committees that are defined in the ISSC Constitution, By-laws & Procedures.
Cost Information	None
Action by 2023 Task Force III	Recommended referral of proposal 23-303 to an appropriate committee as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-303.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-303.

Proposal No. 23-304

Submitter	ISSC Executive Office issc@issc.org
Proposal Subject	Remove Proposal Review Committee
Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures, Article IV 10. & 13., Article XIII. 3.

Text of Proposal/Requested Action

ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES

19. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairperson. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference:
    - 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.
20. A quorum for…
21. The Nine-member…
22. ~~The Executive Board Chairperson shall appoint a 12-member Proposal Review Committee. The Committee will be comprised of a Chairperson, four (4) regulatory members, four (4) industry members, and a representative from the FDA, NOAA, and EPA. The Committee will review and link proposals for Conference consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.~~

ARTICLE XIII. PROCEDURE FOR THE SUBMISSION OF PROPOSALS

~~3.~~ Proposals submitted by any Conference participants requiring Conference action are to be referred to the Executive Director for assignment to the appropriate Task Force. Proposals that lack required information will be deemed incomplete and returned to the submitter for completion. ~~The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid.~~

Public Health Significance	None. The Proposal Review Committee is not necessary as the charge of linking proposals has not proved to be effective. There has also been no need to ask the committee for consultation with Task Force Assignment or invalidating a proposal during the last decade of Biennial Meeting cycles.
Cost Information	None
Action by 2023 Task Force III	Recommended referral of Proposal 23-304 to an appropriate committee as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-304.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-304.

Proposal No. 23-305

Submitter	ISSC Executive Office issc@issc.org
Proposal Subject	Biotoxin Management Plan Criteria
Specific NSSP Guide Reference	Section II Model Ordinance; Chapter IV. Shellstock Growing Areas @.04.B
Text of Proposal/Requested Action	**Section II Model Ordinance; Chapter IV. Shellstock Growing Areas @.04.B.** 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 (1) 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~~Section 4 Marine Biotoxin Management Strategies. (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.~~

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 (1) 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 dataset; 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.

(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.~~

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 (3) 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.

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.

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

(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.~~

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 (3) years, the short duration of permitted harvest shall not exceed three (3) 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. ~~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.
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 (3) years shall be developed before the biotoxin monitoring plan may be modified.
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 dealer. ~~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).

This strategy shall permit harvest from 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 (3) 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 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.

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 .02

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 (3) 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 (3) 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 (1) 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 dataset; 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 sentinel 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 (3) 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 (1) 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 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 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 rates of specific toxins from all species of shellfish harvested from the growing areas (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. Additionally, 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 (3) years, the short duration of permitted harvest shall not exceed three (3) 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 (3) 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 from 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 (3) 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 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.~~

Public Health Significance	Several sections of Chapter IV of the Model Ordinance refer to language in Section IV Guidance Documents that indicate that the guidance is mandatory. This proposal moves these criteria and strategies for Biotoxin Management from Guidance to Chapter IV of the Model Ordinance to clarify what are minimum requirements for NSSP compliance versus suggested options.
Cost Information	No cost
Action by 2023 Task Force III	Recommended referral of Proposal 23-305 to an appropriate committee as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-305.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-305.

Proposal No. 23-306

Submitter	ISSC Executive Office issc@issc.org
Proposal Subject	Unresolved Issue process clarification
Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures, Procedure IX
Text of Proposal/Requested Action	**PROCEDURE IX. PROCEDURES FOR HANDLING COMPLAINTS AND CHALLENGES REGARDING THE ADEQUACY OF CERTIFICATION CONTROLS**

1. Complaints from any state or non-state party regarding possible non-conformities in a producing and/or shipping state shall be handled as follows:
   a. Only complaints regarding the sanitary quality and effectiveness of public health controls shall be covered under this procedure.
   b. Complaints shall be made in writing to the Authority as listed in the ICSSL, with a copy to the appropriate FDA Regional Office.
   c. The complaint shall provide specific and complete factual information concerning all items not in conformity and shall specifically verify that all sampling and testing has been conducted in accordance with the NSSP.
   d. The Authority shall make an investigation of the complaint within twenty (20) working days of receipt, promptly notify the complainant in writing of the findings and any actions being taken, and provide a copy to the appropriate FDA Regional Office.
   e. Upon receipt of the response or upon the failure to receive a response within thirty (30) days, the complainant may request in writing to the ISSC Board Chairperson that further investigation by FDA be conducted. FDA may also undertake further investigation at their own initiative.
   f. FDA shall provide a written report of its findings or the status of the complainant within thirty (30) days to the parties involved and the ISSC Board Chairperson.
   g. If FDA's investigation does not lead to a satisfactory resolution of the problem, the problem shall be handled as an unresolved issue according to Procedure IX. Section 3.

2. When an FDA field inspection or an overall program evaluation indicates a state program is not meeting the minimum requirements of the NSSP Model Ordinance, the following actions shall be taken:
   a. FDA shall provide written notification to the Authority of the item(s) requiring action with supporting documentation and recommendations as appropriate.
   b. The state shall investigate the item(s) and provide a written response within thirty (30) days that it has been corrected, that a corrective action plan has been developed and will be implemented within a specific time frame, or that it disagrees with FDA's finding. The state shall provide supporting documentation regarding any

disagreements. FDA shall review the materials submitted by the state and respond to the state within thirty (30) days.

c. When a state does not disagree with FDA ~~findings~~observations, but ~~does disagree~~disagrees with an FDA report or FDA's findings in the report regarding the state's NSSP compliance status, the state shall provide written notification to FDA of the areas of disagreement with supporting documentation and recommendations as appropriate. FDA shall review the information submitted and provide a written response within thirty (30) days that it agrees and the report has been corrected, that it agrees but the report cannot be corrected, or that it disagrees with the state. FDA shall provide supporting documentation regarding any inability to correct a report or any disagreement. The state shall review the materials submitted by FDA and respond to FDA within thirty (30) days.

d. If corrective action is taken by the state or by the FDA or a mutually agreed upon action plan is developed and implemented, no action by the Conference will be necessary.

e. If the state and FDA are unable to find a mutually agreeable resolution to the disagreement, or FDA considers the action (or lack of action) taken by the state to be inadequate to resolve the item(s), FDA shall notify the state and the ISSC Executive Director of an unresolved issue. ~~If the State disagrees with FDA's findings or response,~~In response to the FDA notice, the State may pursue one of the following actions:

   i. The State may request consultation from the Consultation Subcommittee of the ISSC Unresolved Issues Committee. The purpose of this consultation will allow the State the opportunity to seek guidance from the Consultation Subcommittee regarding program requirements and FDA findings; or

   ii. The State shall notify the ISSC Executive Director of an unresolved issued.

f. Upon notification from both FDA and the state of an unresolved issue, the ISSC Executive Director shall consult with both the state and FDA and prepare recommendations, which will be submitted to the Board with the unresolved issue. The referred unresolved issue shall be handled according to Procedure IX., Section 3. FDA may also take any actions it considers appropriate to deal with any adulterated product.

3. After receipt of an unresolved issue, the Executive Director shall immediately send the unresolved issue to the Executive Board. Within thirty (30) days of receipt of the unresolved issue by the Executive Director, the Executive Board shall take one (1) of the following actions:

   a. Resolve the issue on their own initiative.

   b. Refer the matter to the Unresolved Issues Committee.

4. When an issue has been referred, the Unresolved Issues Committee shall convene a meeting, giving all involved parties an opportunity to participate.

The Committee shall review the issue, and considering input from involved parties, submit its recommendations to the Executive Board.

5. The following list of deficiencies and sanctions shall serve as a guide for actions should the Executive Board confirm the findings of the FDA evaluation.
   a. State program deficiencies, which may result in ISSC sanctions, are as follows:
      i. Administrative - Inadequate State Laws/ Regulations to Enforce the Program
      ii. Growing Areas
         a. Failure to properly classify.
         b. Failure to close in an emergency situation.
         c. Repeated failure to comply with conditional management plans.
         d. Lack of sanitary survey and supporting documentation justifying classifications.
         e. Lack of Biotoxin contingency plan.
         f. Failure to comply with contingency plans.
      iii. Plant Sanitation
         a. Failure to have a standardization officer.
         b. Certification of plants by non-standardized inspector.
         c. Failure to take action on critical deficiencies.
         d. Significant differences between state vs. state/FDA inspections.
         e. Repeated Critical and Key items at significant number of firms.
         f. Inadequate state laws/ regulations to enforce program.
      iv. Other Program Areas
         a. Inadequate tagging and records by shellfish dealers.
         b. Refusal to participate/provide cooperation in FDA program evaluations.
         c. Failure to control relaying.
   b. The following actions shall be taken by the Executive Board as appropriate:
      i. Meeting(s) with responsible state officials to express ISSC concern about the unresolved issue and to develop an acceptable action plan.
      ii. A letter to top state program administrators, including the governor, expressing ISSC concern regarding state program deficiencies.
      iii. Notification to ISSC members of the unresolved issue for their information.
      iv. Recommendation to FDA to include a notice in the ICSSL regarding the unresolved issue.
      v. Recommendation to the Authority to remove affected dealers from the ICSSL.

vi. Recommendation to FDA to remove all certified dealers from future ICSSL publications.

vii. Notification to all states and other appropriate authorities describing the unresolved issue and that action against products from a state with significant control problems may be appropriate for their consideration.

A letter to FDA expressing ISSC concern regarding the position of FDA.

Public Health

Significance	The proposal is intended to clarify some of the steps involved in FDA/state disagreements and the unresolved issue process.
Cost Information	No cost
Action by 2023 Task Force III	Recommended adoption of proposal 23-306 as submitted.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-306.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-306.

Proposal No. 23-307

Submitter	ISSC Executive Office issc@issc.org
Proposal Subject	Emergency Procedures
Specific NSSP Guide Reference	Section II. Model Ordinance; Chapter I Shellfish Sanitation program Requirements for the Authority; Section @.01 Administration
Text of Proposal/Requested Action	**Administration** A. Scope… B. State Laws and Regulations… C. Records… D. Shared Responsibilities… E. Administrative Procedures… F. Epidemiolotically Implicated Outbreaks of Shellfish-Related Illness… G. Commingling… H. Personnel training requirements… I. Request for Emergency Consideration In the event of a declared public health emergency or natural or man-made disaster, including the activation of the State Emergency Response Plan, if the Authority is not in a position to operate the program in full compliance with NSSP program requirements, the Authority shall immediately notify the ISSC and the FDA. The FDA shall immediately conduct discussions with the authority to reach a mutually acceptable resolution.
Public Health Significance	The COVID-19 pandemic had significant impacts on state and federal shellfish programs. Recognizing that special considerations regarding NSSP program compliance were necessary, the ISSC Executive Board responded with a plan to address the issue that was specific to the COVID-19 pandemic. This language recognizes that similar situations may arise in the future and provides guidance for initiating the process for emergency consideration.
Cost Information	No cost.
Action by 2023 Task Force III	Recommended adoption of proposal 23-307 as amended: I. Request for Emergency Consideration In the event of a an official declared ~~public health~~ emergency ~~or~~, natural or man-made disaster, including the activation of the State Emergency Response Plan, if the Authority is not in a position to operate the program in full compliance with NSSP program requirements, the Authority shall immediately notify the ISSC and the FDA. The FDA shall immediately conduct discussions with the ~~a~~Authority to reach a mutually acceptable resolution.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-307
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-307.

Submitter
l

U.S. Food and Drug Administration (FDA)
Melissa.Abbott@fda.hhs.gov

Proposal Subject

Removed the words “hand sanitizing” from item 11 and add Model Ordinance references to items 2, 4, 5, 6 and 7

Specific NSSP Guide Reference

NSSP Standardized Shellfish Processing Plant Inspection Form

Agency Name:						Date	
Type of Inspection	☐ Certification ☐ Pre-operational ☐ Routine ☐ Follow-up ☐ Standardization						
Dealer Name:					Certification Number		
Dealer Address:							
	Hazard Analysis Critical Control Point (HACCP)						
1.	**HACCP Plan** Yes ☐ No ☐ Required for Certification						
2.	Plan Elements Identified and Adequate	Citation	✓/✗ NA	Code	Citation	✓/✗ NA	Code
	(a) Hazards	X.01.C.(1)		O	(e) Critical Control Points X.01.C.(2)		K
	(b) Records	X.01.C.(6)		O	(f) Monitoring X.01.C.(4)		K
	(c) Critical Limits	X.01.C.(3)		K	(g) Verification Procedures X.01.C.(7)		O
	(d) Name, Address, Signed and Dated	X.01.H.(1) X.01.D.		O	(h) Corrective Action if identified X.01.C.(5)		K
3.	**HACCP Training** Yes ☐ No ☐			Code O	Activities	Records	
4.	**Plan Implementation**				**Corrective Actions Recorded (K)** X.01.F.(1) X.01.F.(4) **Verification Procedures (K) (Signature)** X.01.G.(1) X.01.G.(1)(c) **Monitoring Procedures (K)** X.01.C.(4) X.01.C.(6) **Records: Accurate/ Maintained (K) Format (O)** X.01.H **Initialed/Dated (O)** X.01.H **Firm's Name on record (O)** X.01.H	✓/✗ NA	Code
	(a) Receiving						
	(b) Shellstock Storage						
	(c) Processing						
	(d) Shucked Meat Storage						
	(e) Other Critical Limits						
5.	Approved Source Control Failure				.01 A		C
6.	Time/Temperature Control Failure				.01 A,B,C,D		C
7.	Other Critical Control Failure				.01 A,B,C,D,E,F		C
	Sanitation Items				**Citation**	✓/✗	**Code**
8.	Safety of water for processing and ice production				.02A		
9.	Condition and cleanliness of food contact surfaces				.02B		
10.	Prevention of cross-contamination				.02C		
11.	Maintenance of hand-washing, ~~hand-sanitizing~~ and toilet facilities				.02D		
12.	Protection from adulterants				.02E		
13.	Proper labeling, storage, and use of toxic compounds				.02F		
14.	Control of employees with adverse health conditions				.02G		
15.	Exclusion of pests				.02H		
16.	Sanitation Monitoring and Records						S(K/O)
	Additional Model Ordinance Requirements				**Citation**	✓/✗	**Code**
17.	Plants and Grounds				.03A		
18.	Plumbing and related facilities				.03B		
19.	Utilities				.03C		
20.	Disposal of other waste				.03D		
21.	Equipment condition and cleaning, maintenance, and construction of non-food contact surfaces				.03E		
22.	Shellfish storage and handling				.03F		
23.	Heat shock				.03G		
24.	Supervision				.03H		
25.	Transportation (To include only the person shipping)				IX.05		K
26.	Labeling and Tagging				X.05,.06,.07		S (K/O)
27.	Shipping Documents and Records / Written Recall Procedures				X.08, .03		K
Dealer's Signature					**Inspector's Signature**		

[Code: Critical -C; Key-K; Swing-S; Other-O] ISSC Form 93-01(A) revised ISSC 2020 Page 1 of ___
Effective Date: 11/2020

Text of Proposal/ Requested Action

16. Sanitation Monitoring and Records X. 02 A, B S(K/O)

Public Health Significance

The Model Ordinance requires that deficiencies are marked with the proper citation from the MO. Currently, Line 16 is missing its citation. This proposal would correct this oversight.

Cost Information	N/A
Action by 2020 Executive Board	Granted Interim Approval in effect until the Conference convenes at the 2023 ISSC Biennial Meeting.
Action by 2023 Task Force III	Recommended adoption of proposal 23-308 as submitted.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-308.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-308.

Proposal No. 23-309

Submitter	Blake Millett Utah Department of Agriculture and Food Bmillett@utah.gov
Proposal Subject	Addition of Citation to ISSC Form 93-01(A)
Specific NSSP Guide Reference	ISSC Form 93-01(A) revised ISSC 2020 NSSP Standardized Shellfish~~Shelfish~~ Processing Plant Inspection Form Line 16 Citation
Text of Proposal/ Requested Action	16. Sanitation Monitoring and Records X. 02 A, B S(K/O)
Public Health Significance	The Model Ordinance requires that deficiencies are marked with the proper citation from the MO. Currently, Line 16 is missing its citation. This proposal would correct this oversight.
Cost Information	N/A
Action by 2023 Task Fore III	Recommended no action on proposal 23-309. Rationale: The issue is addressed by proposal 23-308.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-309.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-309.