

**ISSC 2023
Committee Report**

Committee Name : Federal Waters
Chairperson: Joel Hansel
Date of Meeting: 2020-2022
Recorder:

Approved By: Joel Hansel
Printed Name: Joel Hansel

Committee Members Present:

<input checked="" type="checkbox"/> Joel Hansel (Chairperson)	<input checked="" type="checkbox"/> Eric Hickey	<input checked="" type="checkbox"/> Quentin Forrest (FDA Delegate)	<input checked="" type="checkbox"/> Stephen Wilson (NOAA Delegate)
<input checked="" type="checkbox"/> Kohl Kanwit	<input checked="" type="checkbox"/> Ian Jefferds	<input checked="" type="checkbox"/> Stacey Wiggins	<input checked="" type="checkbox"/> Jon Bell
<input checked="" type="checkbox"/> Andrew Bell	<input checked="" type="checkbox"/> Bob Schuster	<input checked="" type="checkbox"/> (FDA Advisor)	<input checked="" type="checkbox"/> (NOAA Advisor)
<input checked="" type="checkbox"/> Kirk Wiles	<input checked="" type="checkbox"/> Portia Sapp	<input checked="" type="checkbox"/> David Wiggins	<input checked="" type="checkbox"/> Laurice Churchill
<input checked="" type="checkbox"/> Vanessa Zubkousky- White	<input checked="" type="checkbox"/> Virginia Roberts (CDC Delegate)	<input checked="" type="checkbox"/> Raymond Burditt (FDA Advisor)	<input checked="" type="checkbox"/> Chris Schillaci (NOAA Advisor)

Charges

Charge 1: Proposal 17-116: Sanitary Control of Molluscan Shellfish Harvested from Federal Waters

Proposal 17-116 has a sunset date of November 1, 2021. The committee is requested to develop recommendations regarding the appropriateness of maintaining the language adopted in Proposal 17-116.

Findings/Conclusions: The Committee has determined that the sunset date adopted by Task Force I in 2017 and associated with this proposal is no longer necessary. Because this date would have come into effect prior to the biennial conference, the Committee sought and received interim approval from the Executive Board to remove this sunset date.

Recommendations: Consistent with the actions of the Executive Board, the Committee recommends Task Force II delete the sunset date of November 1, 2021 from Proposal 17-116.

Charge 2: Develop guidance for the incorporation of shellfish from Federal waters into the NSSP. In developing this guidance, the committee should consider the requirements adopted in 2019 associated with the following proposals:

19-120	19-214	19-229
19-202	19-223	
19-203	19-228	

Findings/Conclusions: The Committee has developed the requested guidance based on the 7 proposals. The Guidance document is attached and would be added to Section IV, Chapter II, .06 in the NSSP Guide.

Additionally, it was determined that certain revisions to the NSSP Guide are necessary to fully implement the Federal Waters program and associated requirements of the 7 proposals above. The Committee has submitted Proposal 23-210 to allow for effective implementation of the Guidance document as the associated proposals above.

Recommendations: 1) The Committee recommends Task Force II approve the attached guidance as submitted.
2) The Committee recommends Task Force II approve Proposal 23-210 as submitted by the Committee.

Charge 3: • Continue to address action items included in the Federal Waters Committee Report.

Findings/Conclusions: The Committee continues to monitor implementation of this program and will make changes as needed.

Recommendations: No recommendations at this time

Section IV. Guidance Documents, Chapter II Growing Areas
.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: [ISSC Website TBD](#)
- 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>