



National Shellfish Sanitation Program (NSSP) Federal Waters Molluscan Shellfish Overview and Update

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Federal Waters Molluscan Shellfish PROPOSALS

NSSP MO and Guidance Changes:

- 2017 NSSP MO - Federal Waters Proposal
17-116
- 2019 NSSP MO - Federal Waters Proposals
19-120, 19-202, 19-203, 19-214, 19-223, 19-228,
19-229, and 19-149 (biotoxins)

Federal Waters Delineation Map

(Proposal **17-116**)

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 (EEZ).





Federal Waters Molluscan Shellfish *ADMINISTRATION (Who is responsible for what?)* (Proposal **19-203**)

NSSP MO,
Section II,
Chapter I @.01
A, B, D, & E.

- ☐ FDA/NOAA are the responsible federal regulatory agencies for shellfish growing areas & harvest control in FWs
- ☐ If more than one agency is involved need MOU/A
- ☐ FDA/NOAA shall have laws, regulations, and administrative procedures sufficient to regulate growing areas and harvest control in FW
- ☐ The State “Authority” may take on responsibilities in FW (i.e., MA & ME).



Federal Waters Molluscan Shellfish *GROWING AREA CLASSIFICATION* (Proposal **17-116** & **19-120**)

NSSP MO,
Section II,
Chapter IV
@.01 E.
@.03 F.
&
Chapter VI
@.03A.(2)

The FDA is responsible for the sanitary survey and classification of growing areas in Federal waters.



Federal Waters Molluscan Shellfish

MARINE BIOTOXIN - CONTINGENCY PLAN

(Proposal **19-149**)

NSSP MO, Section
II, Chapter
IV@.04A.
&
Chapter VI.07B.

Develop and adopt a
MARINE BIOTOXIN
CONTINGENCY PLAN



Federal Waters Molluscan Shellfish

MARINE BIOTOXIN – MANAGEMENT PLAN

(Proposal **19-149**)

NSSP MO, Section II,
Chapter IV@.04B.

&

Chapter VI.07B.

&

Guidance, Section IV,
Chapter II .02

Develop and adopt a
MARINE BIOTOXIN
MANAGEMENT PLAN...



Federal Waters Molluscan Shellfish

MARINE BIOTOXIN – MANAGEMENT STRATEGIES

(Proposal **19-149**)

NSSP MO, Section II,
Chapter IV @.04 B.

(4)

&

Guidance, Section IV,
Chapter II .02

(4) Marine biotoxin management strategies are as follows:

- (a) Phytoplankton monitoring
- (b) Routine shellfish toxicity monitoring
- (c) Pre-harvest shellfish toxicity testing
- (d) Shellfish lot testing
- (e) Pre-harvest shellfish toxicity screening and lot testing

MARINE BIOTOXIN CONTROL 2019 NSSP GUIDE (FDA Stacey Wiggins, Ph.D.):
https://www.issc.org/Data/Sites/1/media/--2020-issc-fda-meeting/stacey_wiggins_biotoxins_fda_mtg.pdf



Federal Waters Molluscan Shellfish

MARINE BIOTOXIN – MANAGEMENT STRATEGIES

(Proposal **19-149**)

NSSP MO,
Section II,
Chapter IV
@.04 B. (4)
& Guidance,
Section IV,
Chapter II .02

- (4) Marine biotoxin management strategies are as follows:
- (a) Phytoplankton monitoring
 - (b) Routine shellfish toxicity monitoring
 - (c) Pre-harvest shellfish toxicity testing
 - (d) Shellfish lot testing
 - (e) Pre-harvest shellfish toxicity screening and lot testing



Federal Waters Molluscan Shellfish *VIBRIO RISK ASSESSMENT & TIME/TEMPERATURE CONTROL*

**NSSP MO,
Section II,
Chapter VIII
@.02 A. &
Chapter II @.06
& @.07**

@.02 A. Each shellfish producing State shall establish time to temperature requirements for the harvesting of all shellstock to ensure that harvesters shall comply with one (1) of the following:

- (1) The State V.v. Control Plan as outlined in Chapter II. @.06; or
- (2) The State V.p. Plan as outlined in Chapter II. @.07; or
- (3) All other shellstock shall comply with the time/temperature matrix



Federal Waters Molluscan Shellfish *Harvester Training*

NSSP MO,
Section II,
Chapter VIII
.01 B.

Each harvester shall obtain Authority approved training.

(1) A harvester shall obtain proof of completion of the required training....

(2) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training.



Federal Waters Molluscan Shellfish - AQUACULTURE

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Federal Waters Molluscan Shellfish - **AQUACULTURE**

OBTAIN PERMISSION FROM FEDERAL AGENCIES

(Proposal **17-116**)

NSSP MO,
Section II,
Chapter VI .07
A.

A. Prior to beginning any aquaculture activities,... shall obtain the appropriate permission(s) from Federal agencies.



Federal Waters Molluscan Shellfish - **AQUACULTURE**

OPERATIONAL PLAN

(Proposal **17-116**)



NSSP MO, Section
II, Chapter VI .07
B. and C.

&

Chapter VI .05 A.

&

@.03 A. (2)

B. Operational Plan. Each aquaculture facility shall have a written operational plan.

Each aquaculture facility shall obtain a review of the Operational Plan from the FDA.



Federal Waters Molluscan Shellfish - **AQUACULTURE**

NOAA SIP Contract
(Proposal 17-116)

NSSP MO,
Section II,
Chapter VI
@.03 A. (1)
&
Chapter VIII
@.01 C. & .03
A. (1)

The NOAA SIP is responsible for establishing a CONTRACT, in consultation with FDA...



Federal Waters Molluscan Shellfish

SHELLFISH IN FEDERAL WATERS - PRESENT PROCESS KEY POINTS

- Harvester/Aquaculturist contact NOAA SIP and State of Landing Authority
- Aquaculture: Contact NOAA SIP as early as possible for FDA and NOAA site review and other requirements
- Biotoxins:
 - All harvesters (+Aquaculture) will need a Marine Biotoxin Contingency and Management Plan (as applicable)
 - Marine Biotoxin Management Plan: Lot testing and Pre-harvest Shellfish Toxicity Screening and Lot Testing management strategies will require an agreement or MOU with NOAA, Authority, Harvester, and Dealer
- Harvester Training: Contact NOAA SIP



Federal Waters Molluscan Shellfish

SHELLFISH IN FEDERAL WATERS in DEVELOPMENT

- FDA has established the Federal Waters Shellfish Biotoxin Advisory Board (FWSBAB)
- FDA Geodatabase Visualization Tool (FDA internal):
 - Biotoxin data from the FWSBAB and other sources as applicable
 - Data of known potential and actual pollution sources for sanitary survey and classification review
- ISSC Federal Waters Subcommittee is developing draft Guidance for Federal Waters to replace .06
- FDA/NOAA SIP Federal Waters NSSP Requirements Lists:
 - Aquaculture – COMPLETED
 - Wild Harvest - Forthcoming
- NOAA SIP CONTRACT for ALL shellfish harvesters in Federal Waters



Federal Waters Molluscan Shellfish

NSSP REQUIREMENTS REFERENCE LISTS



NATIONAL SHELLFISH SANITATION PROGRAM (NSSP) REQUIREMENTS FOR HARVESTING BIVALVE MOLLUSCAN SHELLFISH FROM FEDERAL WATERS: AQUACULTURE

NSSP - MODEL ORDINANCE (MO) REFERENCE SITE:

This document is a list of the requirements outlined in the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO) for the harvesting of aquacultured bivalve molluscan shellfish in Federal waters. The Food and Drug Administration (FDA) and the National Atmospheric and Oceanographic Administration (NOAA) Seafood Inspection Program (SIP) are the primary federal agencies responsible for implementing the NSSP MO requirements in Federal waters. This list does not include the requirements of other federal agencies and regulatory organizations.

☐ SITE SELECTION/CLASSIFICATION:

The Food and Drug Administration (FDA) is responsible for the classification of molluscan shellfish 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. It is highly suggested to contact the FDA and the National Oceanographic and Atmospheric Administration (NOAA) Seafood Inspection Program (SIP) regarding the growing area classification of the specific area of consideration before developing a bivalve molluscan shellfish aquaculture site in Federal waters. (NSSP MO Reference: Section II, Chapter IV. @.03 F. & Chapter VI. @.03)

☐ OBTAIN PERMISSION FROM FEDERAL AGENCIES:

Once the appropriate permits and clearances for siting and the construction of the aquaculture facility/farm have been obtained and 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 (FDA and NOAA) as described in the NSSP MO, Section II, Chapter VI @.03. (NSSP MO Reference: Section II, Chapter I, @.01 and Chapter VI. @.03 and .07)

☐ SANITARY SURVEY:

A Sanitary Survey to identify and evaluate any potential pollution sources that may have an impact on each aquaculture site in Federal waters is required. Sanitary surveys for Federal waters will be the responsibility of the FDA. If microbiological (fecal coliform and/or Male Specific Coliform [MSC]) samples are required, the aquaculture company will be responsible for the cost of the sample collection and laboratory analyses. Sanitary surveys will be conducted in accordance with Chapter IV @.01, as applicable. (NSSP MO Reference: Section II, Chapter IV. @.01 E.)

☐ OPERATIONAL PLAN:

The aquaculture company shall develop an Operational Plan. The 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. (NSSP MO Reference: Section II, Chapter VI. @.03 A. (2), .03 B., .04 A., .05 A., .06 C., and .07 B. and C.). In addition, the requirements for operation and harvest vessels used for Federal waters aquaculture must adhere to the requirements in the NSSP MO, Section II, Chapter VIII .02.

☐ SOURCE OF SEED:

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 (FDA in Federal waters); and B. Operational Plan: Each aquaculture site that cultures seed in waters classified as



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Questions?

FDA



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