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## FDA GUIDE FOR MOLLUSCAN SHELLFISH AQUACULTURE HARVESTING FROM FEDERAL WATERS:

NATIONAL SHELLFISH SANITATION PROGRAM (NSSP) - MODEL ORDINANCE (MO) REFERENCE SITE:  
<https://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006754.htm>

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- SITE SELECTION**: The 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 and involve commercial shellfish resources. It would be prudent to contact the Food and Drug Administration (FDA) regarding the classification of the specific area of consideration before developing a molluscan shellfish aquaculture site in Federal waters. (NSSP MO Reference: Chapter IV.@.03F.)
- SANITARY SURVEY**: The FDA is responsible for conducting a Sanitary Survey to evaluate any potential pollution sources that may impact the proposed shellfish aquaculture site in Federal waters. (NSSP MO Reference: Chapter IV.@.01E.)
- OPERATIONAL PLAN**: The aquaculture company/harvester must develop an Operational Plan. The FDA will need to review and approve the Operational Plan for each proposed shellfish aquaculture site. (NSSP MO Reference: Chapter VI.@.03A.(2), & .07B. [*which lists what is required in the Operational Plan*])
- MARINE BIOTOXIN CONTINGENCY PLAN**: The aquaculture company/harvester must develop a Marine Biotoxin Contingency Plan. The FDA will need to review and approve the Marine Biotoxin Contingency Plan. (NSSP MO Reference: Chapter IV.@.04A. & Chapter VI.07B.)
- MARINE BIOTOXIN MANAGEMENT PLAN**: The aquaculture company/harvester must develop a Marine Biotoxin Management Plan. The FDA will need to review and approve the Marine Biotoxin Management Plan. (NSSP MO Reference: Chapter IV.@.04B. & Chapter VI.07B.)
- NATIONAL OCEANOGRAPHIC & ATMOSPHERIC ADMINISTRATION (NOAA) SEAFOOD INSPECTION PROGRAM (SI) CONTRACT/HARVEST PERMIT**: A NOAA SI contract is required between the shellfish aquaculture company/harvester and the NOAA SI Program to provide the tag number and traceability component (NSSP MO Reference: Chapter VI.@.03A.(1) & .07 & Chapter VIII.@.01C.)  
  
NOAA SI: <https://www.fisheries.noaa.gov/insight/oaas-seafood-inspection-program>
- MOU OR AGREEMENT WITH STATE OF LANDING**: The company/harvester and the FDA/NOAA SI will enter into an MOU or Agreement with the State of Landing indicating that the State of Landing agrees that FDA/NOAA SI will provide assurance that the aquacultured shellfish product is from an approved source and that the requirements of the NSSP MO have been met. (NSSP MO Reference: Chapter IV.@.04B.(6))
- VIBRIO RISK ASSESSMENT & TEMPERATURE CONTROL**: The FDA will conduct a Vibrio Risk Assessment (NSSP MO Reference: Chapter VIII.@.02 & Chapter II.@.06 & @.07)
- HARVESTER TRAINING**: The FDA will provide the required Harvester Training (NSSP MO Reference: Chapter VIII.01B.)
- SAMPLE SHUCKING EVALUATION**: The FDA Laboratory Evaluation Officer (LEO) will evaluate harvester staff if marine biotoxin samples will be processed (i.e., shucking, homogenizing, or initiating extraction) prior to sending the samples to a laboratory that has been evaluated and conforms to the NSSP.
- MARINE BIOTOXIN SCREENING KIT TRAINING**: The FDA LEO, FDA marine biotoxins expert, or their designee will provide training in the use of the marine biotoxin screening methods.
- LABORATORY**: All post-harvest (i.e., dockside/confirmatory) samples must be analyzed by a laboratory evaluated and found to conform to the NSSP; only NSSP Approved Methods can be used.
- VESSEL AND SITE INSPECTION** (Details provided through the NOAA SI Contract)

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