

	<p>Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting</p>	<p>a. <input checked="" type="checkbox"/> Growing Area b. <input type="checkbox"/> Harvesting/Handling/Distribution c. <input type="checkbox"/> Administrative</p>
Submitter	U.S. Food and Drug Administration (FDA)	
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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	<p>Insert the following definition for Federal Waters in Section I Purposes & Definitions as follows:</p> <p><u>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.</u></p> <p>Insert the language below for Section II Model Ordinance Chapter IV Shellstock Growing Areas</p> <p>@.01 Sanitary Survey. <u>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.</u></p> <p>@.03 Growing Area Classification. <u>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 .</u></p> <p>Insert the language below for Section II Model Ordinance Chapter VI Shellfish Aquaculture just after the text in @.03and prior to Shellfish Gardening</p> <p><u>@.04 Aquaculture in Federal Waters</u> <u>A. Federal Agency Responsibilities. Once the appropriate permits for the construction of the aquaculture facility have been obtained,</u> <u>(1) NOAA is responsible for establishing a contract, in consultation with FDA, with the aquaculture facility describing requirements of the NSSP including (a) the frequency with which NOAA will audit the aquaculture facility and vessels, (b) testing requirements of the aquaculture facility, and (c) the generation of product identification for traceability (i.e., tag numbers); and</u> <u>(2) FDA is responsible for reviewing the aquaculture facility operational</u></p>	

	<p style="color: red;"><u>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.</u></p> <p>@.0405_Shellfish Gardening</p> <p>Insert the language below for Section II Model Ordinance Chapter VI Shellfish Aquaculture just after .07</p> <p style="color: red;"><u>.08 Requirements for the Harvester in Aquaculture in Federal Waters</u></p> <p style="color: red;"><u>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.</u></p> <p style="color: red;"><u>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:</u></p> <ul style="list-style-type: none"> <li style="color: red;"><u>(1) Description of harvest, tagging, handling, storage, transportation, and landing procedures;</u> <li style="color: red;"><u>(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.;</u> <li style="color: red;"><u>(3) Description of a contingency in the event of an emergency situation or condition (e.g., sewage or oil spills); and</u> <li style="color: red;"><u>(4) Procedures for implementing product recalls.</u> <p style="color: red;"><u>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.</u></p>
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.