NSSP Strategies for Addressing COVID-19

I. FDA Responsibilities

A. Program Element Evaluations:

FDA evaluations are suspended and will resume once the COVID-19 National Emergency has ended. When FDA resumes evaluations, states with previous deficiencies/action plans will be considered as a priority.

Additional Information:
FDA has suspended all surveillance work as a result of COVID – 19 National Emergency through at least May 1, 2020. Suspended activities may be extended to match restriction guidelines. As a result, OSCP Shellfish Specialists are not able to conduct program element evaluations. Once surveillance activities are reinstituted by FDA, Shellfish Specialists will resume activities on an incremental basis, recognizing that the state's and FDA's work will take time to resume to normal rhythm.

FDA suspended all routine surveillance work as a result of COVID-19 National Emergency in March 2020. FDA's efforts to return to conducting routine work is now evaluated weekly based on the COVID status reported by each state. Once the COVID 19 status of states improves and routine activities are reinstated by FDA, Shellfish Specialists will resume activities on an incremental basis, recognizing that the state's and FDA's work will take time to resume to normal rhythm.

Shellfish Specialists will work closely with the state Authority to determine what evaluation work can be accomplished based on staff availability, potential continuing issues with travel and industry activity. Shellfish Specialists will work cooperatively with states and may utilize alternate methods to evaluate state programs, such as record review and desk audit. OSCP will prioritize work based on state need, state compliance or conformance status, state and OSCP staff availability and industry activity.

B. Laboratory Evaluations:

FDA Laboratory Evaluation Officers (LEO's) will contact laboratories with a pending evaluation to discuss evaluation options. Evaluations will be prioritized based on laboratory and state needs, conformance status, laboratory and LEO staff availability and industry activity. Every effort will be made to complete scheduled laboratory evaluations in an expeditious manner.

C. Standardizations

All Shellfish Standardization Officer (SSO) and State Shellfish Laboratory Evaluation Officer (LEO) standardizations that expire in calendar year 2021 will be extended until December 31, 2021. Should it be necessary to extend additional standardizations expiring after December 31, 2021, the FDA will advise the ISSC Executive Board.

D. Interstate Certified Shellfish Shippers List (ICSSL)

All firms listed on the ICSSL whose certifications are set to expire on or before June 30, 2021, will be extended until September 30, 2021 unless requested otherwise by state shellfish control authorities. Should it be necessary to extend additional certifications, the FDA will advise the ISSC Executive Board.

**This strategy was adopted by the ISSC Executive Board on April 15, 2021 and will be updated as deemed necessary by the US FDA and ISSC Executive Board.

II. State Responsibilities

A. Harvest Area Patrol

If a state patrol authority is unable to conduct any patrols of harvest areas, all harvest from the state must cease and the state should not ship shellfish in interstate commerce. Should a state be unable to meet the established minimum patrol frequencies, the patrol authority should submit a modified patrol plan for FDA review. Should FDA and the state patrol agency not agree on an acceptable plan, FDA will advise the ISSC Executive Board prior to any further action.

B. Biotoxin Monitoring and Sample Analysis

Should a state be unable to conduct required marine biotoxin monitoring, the affected growing area(s) must be closed.

Additional Information:
States should make every effort to adhere to their present marine biotoxin management plan. The ISSC Executive Board should consider allowing states to start implementing proposed NSSP Model Ordinance language of Proposal 19-149 that was adopted at the ISSC 2019 Biennial Meeting and concurred with by the FDA. Proposal 19-149 provides additional strategies for marine biotoxin control as well as a means for potential reductions in marine biotoxin sampling. Such reductions should be based on at least 36 samples over 3 years and should scientifically support the proposed sampling modifications. Marine Biotoxin Management Plans should be updated accordingly in writing. The FDA is available to provide technical assistance in reviewing sampling data for proposed changes in monitoring and/or updating the Marine Biotoxin Management Plan. Due to the inherent risk of biotoxins in molluscan shellfish to consumers, states should ensure that science-based marine biotoxin monitoring continues in accordance with NSSP requirements if growing areas are to remain open.

C. Water Sampling and Analysis of Depuration Processors and Wet Storage Facilities

All wet storage and depuration processor facilities must meet the current minimum NSSP requirement for sampling. These samples must be analyzed in an approved laboratory utilizing approved methods. Facilities unable to meet these requirements should cease all sale of any wet stored or depurated product.

D. Certification/Recertification Inspections of Dealers

All state issued certifications listed on the ICSSL that expire on or before June 30, 2021 will be extended until September 30, 2021. States have the discretion to add or delete firms during this period. Should it be necessary to extend these or additional certifications past this date, the state will notify FDA.

E. Routine inspections of Certified Dealers and Aquaculture Operations

States will be considered in compliance with the NSSP minimum inspection frequencies if the following conditions are met:

Certified Dealer Inspections

1. The certified dealer is closed for operation and the closure is documented by the state authority; or
2. The state performs all required inspections with the exception of those due during the

time period affected by COVID-19 outbreak.

Aquaculture Operations Inspections

1. States will be allowed one year from the time of availability of staff for inspections to comply with Chapter VI @.01 B. 2.

Additional Information:
States may not be able to accomplish compliance inspections for certification due to travel restrictions and staff and firm availability. In many cases, states will not have the manpower to meet the minimum inspection frequencies during the remainder of the year. States should make every effort to continue to conduct routine inspections of Shucker-Packer (SP), Repacker (RP), Wet Storage (WS) and Depuration Processor (DP) facilities at the required NSSP frequency. If a firm is voluntarily closed as a result of the COVID-19 pandemic, there would not be a need to inspect that facility during the period it is not in operation. There will be no need to re-inspect the facility prior to reopening. It may be necessary to waive strict quarterly inspection requirements for SP and RP and monthly inspection requirements for DP for the duration of this event taking into consideration local or state mandates.

Due to the on-going COVID-19 pandemic and increasing case counts requiring routine work and travel restrictions, it is understood that state Authorities are not able to conduct certification inspections or meet NSSP inspection frequencies. While ISSC and FDA have approved flexibilities extending firm certifications, the duration and severity of the pandemic is requiring a new approach to firm inspection to ensure public health protection. The health and safety of state inspection staff must also be a top priority and means of reducing staff in-person interaction with firm employees should be considered. Therefore, ISSC and FDA will temporarily, until further notice, accept virtual inspections conducted by standardized state inspectors for certification inspections and routine firm inspections as an optional alternative to in-person inspections.

Should the Authority deem necessary, it is the responsibility of the Authority to develop and implement a virtual inspection protocol. Virtual inspections must meet the requirements of Chapter I @.02 to the fullest extent possible and be conducted through means acceptable to the firm and the Authority. ISSC and FDA recommend that a virtual inspection include, but not be limited to the following:

- Record review (HACCP plan and appropriate HACCP records, PHP records, wet storage/depuration records, sales/distribution records, etc.)
- Review of labeling and/or tagging of finished products
- Visual inspection of the facility (utilizing a phone, tablet or other device with video and audio capability and agreed-upon application) to include coolers, processing areas, dry storage and grounds.

Additionally, ISSC and FDA recommend that the authority develop a disclaimer to be added to the inspection report stating that the inspection was conducted through a remote/virtual format and that not everything may have been seen by the inspector. Deficiencies identified during the inspection, as well as any other objectionable conditions must be corrected by the firm.

F. Growing area water sampling and analysis

States will be considered in compliance with the NSSP minimum growing area bacteriological monitoring requirements when the state conducts all monitoring with the exception of the time period affected by COVID-19 outbreak. The minimum number of annual samples would be adjusted to meet the time periods associated with the COVID-19 outbreak. The statistical analysis requirements for growing area classification allow adequate flexibility for choosing an

adequate number of representative samples for analysis. If the state is unable to sample conditionally approved growing areas monthly as required, the authority should consider placing the areas in the closed status until sampling can resume to assure acceptable water quality.

Bacteriological water samples must continue to be analyzed by an approved laboratory using NSSP approved methods.

Also note that the language adopted into the 2019 NSSP Guide for the Control of Molluscan Shellfish Model Ordinance regarding Proposals 19-111 and 19-119 l reduced sampling requirements in certain circumstances.

Additional Information:
The COVID-19 outbreak is impacting states' abilities to conduct routine monitoring of growing areas and the ability to complete shoreline survey requirements. In many cases, states will not have the manpower to meet the minimum sampling frequencies during the remainder of the year. States should make every effort to prioritize growing areas in terms of risk to focus resources. Risk factors not limited to, but may include, production volumes (higher production volume areas may be considered greater risk than lower volume production areas), classification (conditionally approved areas with intermittent pollution insults would be considered at a higher risk than approved areas), and frequency of pollution events. States should document their decision-making process related to leaving conditionally approved areas open in absence of monthly required sampling.

G. Response to shellfish-borne illnesses

States should continue to respond to complaints, illness investigations/traceback and emergency issues. If illness investigations are not able to be completed in the timeframes outlined in applicable sections of Chapter II, growing areas must be placed in a precautionary closure until the investigation is completed. Depending on the results of the investigation, it may be possible to reopen areas immediately.

H. Emergency conditions such as spills, WWTP bypass/overflow, etc.

If an emergency condition occurs, states must follow the NSSP MO requirements for addressing the emergency condition or the growing area must be closed and remain closed until the NSSP Model Ordinance requirements are met.

I. State Contingency Plans

States will submit documentation to FDA outlining the effects of the COVID-19 National Emergency on their ability to meet the requirements of the NSSP. The documentation should include a plan for addressing NSSP requirements. A template will be provided assist states in submitting this information. The information should be submitted within 14 days of Executive Board adoption.

III. Required NSSP Training

All NSSP training courses offered by the FDA Office of Training, Education and Development (OTED) scheduled for FY 2021 will be presented in a virtual format. Two (2) sessions of FD245 Shellfish Plant Sanitation and one (1) session of FD242 Sanitary Surveys of Shellfish Growing Areas are scheduled for this year. Although offered virtually, class size will still be limited to aid in

learning.

IV. COVID-19 Impact Period

The interim action taken by the ISSC Executive Board Actions outlined in this document only address the time periods associated with impacts from the COVID-19 outbreak. It is expected that the impact of the outbreak may vary with each federal or state agency with NSSP implementation responsibilities. As a result, the time frames may vary by agency. In establishing the affected time frames, each agency should consider emergency orders and directives issued by both the President of the United States and state governors.