CHAPTER 18: TECHNICAL ASSISTANCE

SUBJECT:	IMPLEMENTATION DATE:
MOLLUSCAN SHELLFISH *ORA Concurrence # FF21072701*	UPON RECEIPT

DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
52B--04 (Water Related to Shellfish Growing Areas) 16E [] [] [] (Shellfish)	18004 Molluscan Shellfish Evaluation Prog 18004A Vibrio Management/Risk Assessment Evaluation 18004B Growing Area Evaluation 18004C Control of Harvest Evaluation 18004D Plant Processing and Shipping Evaluation 18004E ISSC Activities 18004F RRA Vibrio Management/Risk Assessment Evaluation 18004G RRA Growing Area Evaluation 18004H RRA Control of Harvest Evaluation 18004I RRA Plant Processing and Shipping Evaluation 18004S Shellfish Remote Assessment

Pursuant to the National Shellfish Sanitation Program (NSSP) "Guide for the Control of Molluscan Shellfish Model Ordinance" (MO), molluscan shellfish under this compliance program means all species of:

(a) Oysters, clams or mussels, whether:

(i) Shucked or in the shell;

(ii) Raw, including post-harvest processed;

(iii) Frozen or unfrozen;

(iv) Whole or in part; and

(b) Scallops in any form, except when the final product form is the adductor muscle only.

This compliance program covers bivalve molluscan shellfish that are raw (live, fresh, or fresh

frozen) and molluscan shellfish subjected to post-harvest processing (PHP) as defined in the NSSP MO. Cooked shellfish, shellfish subject to 21 Code of Federal Regulations (CFR) part 113 or 114, or raw shellfish packaged with the explicit intent that they will be cooked by the end consumer (such as breaded or marinated), are generally recognized as products that are beyond the scope of the NSSP and are subject to the Fish and Fishery Products regulation (21 CFR part 123). However, such shellfish products intended for interstate commerce are still subject to the appropriate harvest and/or approved source controls outlined in the NSSP MO when they are necessary to control a food safety hazard.

This compliance program covers evaluation of state, tribal, and foreign shellfish programs and related technical assistance only and is primarily intended for use by shellfish specialists, CFSAN shellfish SMEs and those involved in making admissibility decisions of products covered by this compliance program. All participating states and certified shellfish firms, aare listed in the Interstate Certified Shellfish Shippers List (ICSSL). http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006753.htm

In non-NSSP participating states, the FDA Human and Animal Food (HAF) division cover these products using Seafood Processor Inspection Program – Domestic and Foreign Facilities Compliance Program (7303.842). Any questions about this compliance program are to be referred to the shellfish specialist(s) or Office of State Cooperative Programs (OSCP) branch director(s). Instructions covering inspection of domestic firms and the sampling of domestic shellfish are in the Seafood Processor Inspection Program – Domestic and Foreign Facilities Compliance Program (7303.842). Instructions for the sampling of imported shellfish are covered in the Import Seafood Products Compliance Program (7303.844). Follow-up conducted under the authority of the Food, Drug, and Cosmetic Act (FD&C Act) should be reported under the Seafood Processor Inspection Program – Domestic and Foreign Facilities Compliance Program (7303.842) or the Import Seafood Products Compliance Program (7303.844). **NOTE**: **FDA regulatory inspections and sample collections should not be conducted under this compliance program.**

FIELD REPORTING REQUIREMENTS:

1. The ORA/OSCP/DSS Shellfish Specialist(s) will write the report and send the final Program Element Evaluation Report (PEER) and a cover letter to the branch director who will send, via e-mail, the PEER and cover letter to the authority and those listed in the electronic carbon copy section. Branch directors must provide an electronic copy of final reports to CFSAN according to the following schedule:

Table 1. Reporting Requirements

REPORT	DUE DATE	SUBMIT FINAL REPORT TO:
Program Element Evaluation Report (PEER)	60 calendar days after completion of	Division of Seafood Safety (DSS)/Shellfish and Aquaculture Policy Branch (SAPB),

	evaluation but no later than January 31	National Shellfish Standard, and appropriate subject matter expert
Annual Program Evaluation Report (APER)	30 calendar days upon completion of all PEERs but no later than March 1	DSS/SAPB and National Shellfish Standard
International Program Element Evaluation Report (IPER)	120 calendar days after completion of evaluation	DSS/SAPB and National Shellfish Standard
Annual Domestic Evaluation Schedule	January 1	DSS/SAPB and National Shellfish Standard

2. Data Reporting

All program operations are to be reported in the Field Accomplishment Compliance Tracking System (FACTS) as follows: with Industry 16, Product Class E in Product Code Field. Refer to the "National Shellfish Specialist Team FACTS Reporting Guidance" for details. Below are the primary operating codes used in the shellfish program.

OPERATION CODE	OPERATION DESCRIPTION
83	Training Given by FDA Personnel
84	Training Received by FDA Personnel
92	Coordination/Technical Assistance
95	Program Evaluation (Domestic)
96	Standardization of Non-FDA Personnel

Molluscan Shellfish facilities participating in the NSSP are distinguished in the Official Establishment Inventory by District Use Code (DUC): @S - "@16 ONLY establishments, NSSP States ONLY".

@16 = Establishment covered under the NSSP including depuration plants. Designated as a Workload Obligation NO for Districts.

@16 = Not covered under the NSSP, including depuration plants.
Designated as a Workload Obligation "YES" for Districts.
This is an FDA obligation.

@= establishment type of shellfish shipper
If they are certified, they will fall under the NSSP and workload obligation "NO" for

Districts

If they are NOT certified, they will NOT fall under the NSSP and they will be workload obligation “YES” for Districts

@S is the district use code- is added for additional information.

Contents

Change History

Item	Change	Date
Report timeframes - Revised timeframes for completing PEERs, receiving state response, and issuing reports	• Previous timeframe to complete PEERs was 30 days after completing evaluation but no limit on evaluation period; updated to 30 days to complete evaluation and 30 days to complete PEER. • Previous timeframe for states to respond to draft PEER prior to finalization, 30 calendar days; updated to 15 business days to review and comment before it is finalized. If the state does not respond within 15 business days, the OSCP will issue the final report.	12/1/2021
Coordination - Added language emphasizing coordination and cooperation with the state authority throughout the evaluation process	• Language for coordination and cooperation not just in the Planning section. • Planning section emphasizes coordination and cooperation. • Added 'must coordinate' in Plant Processing and Shipping section for standardization activities.	12/1/2021
Reports - Updated issuance of all reports and letters to specify electronic format and electronic signature	Previous CP required hard copies of PEER and APER letters with wet signature. Updated all reports, PEER, and APER letters to electronic format and electronic signatures.	12/1/2021
Templates - Updated language to specify using the PEER, APER and IPER templates for writing reports	Previous CP had attachments with rudimentary PEER, IPER, and APER outlines. The update requires the shellfish specialists to use the PEER templates specific to each program element, IPER template, APER template, and PEER and APER cover letter templates.	12/1/2021
Authority - Updated use of SSCA (State Shellfish Control Authority) to 'Authority' throughout the CP	Previous CP used outdated State Shellfish Control Authority (SSCA); updated CP to use current language 'Authority'.	12/1/2021

Fieldwork timeframes - Established timeframe for specialists to complete field portion of evaluations	Previous timeframe to complete PEERs was 30 days after completing evaluation but no limit on evaluation period; updated to 30 days to complete evaluation once initiated.	12/1/2021
Consultation - Included language requiring Specialists to consult with state authority prior to scheduling Plant Processing and Shipping evaluations and SSO standardizations at the same time.	Previous CP stated that "shellfish specialist will develop and coordinate activities with state program officials"; updated CP language "Shellfish specialists must coordinate with the authority regarding standardization activities and whether the standardization activity is conducted during a plant processing and shipping evaluation."	12/1/2021
Control of Harvest evaluation - Changed frequency of Control of Harvest evaluation from annual to biennial and defined follow-up activities for Control of Harvest evaluations	Previous CP required a risk assessment determination and high risk evaluated annually with no change in frequency allowed; low risk determination evaluated every other year. Updated CP defines risk based on states risk assessment and the number of high and medium risk areas; evaluation every 2 years unless on an action plan. Additionally, states that have at least one (1) High Risk patrol area, or states where >20% of their patrol areas are in the Medium Risk category, shall receive a follow-up review in non-evaluation years to ensure those patrol areas are being patrolled at minimum required frequencies.	12/1/2021
Plant and Shipping evaluation - Clarified follow-up activities for Plant Processing and Shipping evaluations	Updated CP states "States that are on an action plan or that have outstanding nonconformities associated with administrative criteria (Chapter I @.03 B. (4) (e) (i – vi) shall have a follow-up review conducted during the non-evaluation year using the "Guidance to the Field: Conducting Follow-Up Evaluations of the Plant Processing and Shipping Evaluation". For states that are on an action plan for in-field criteria non-compliance (Chapter I @.03 B. (4) (e) (vii), shellfish specialists will continue to work with the state throughout the non-evaluation year."	12/1/2021
References – updated references and added links to references	Added links to support documents and references instead of including information in the CP	12/1/2021

PART I – BACKGROUND

1. National Shellfish Sanitation Program (NSSP)

The NSSP is based on public health principles and controls formulated at the Conference on Shellfish Sanitation called by the Surgeon General of the United States (U.S.) Public Health Service in 1925. It was designed to prevent illness associated with the consumption of raw fresh and fresh-frozen shellfish. Sanitary controls cover all phases of the growing, harvesting, shucking, packing, and distribution of fresh and fresh-frozen shellfish.

The NSSP is a cooperative tripartite program, administered by the U.S. Food and Drug Administration (FDA), implemented by cooperating states, and followed by the shellfish industry.

2. Interstate Shellfish Sanitation Conference (ISSC)

The ISSC was formed in 1982 to foster and promote shellfish sanitation through the cooperation of state and federal control agencies, the shellfish industry, and the academic community. On March 14, 1984 the FDA entered into a Memorandum of Understanding (MOU) (see https://www.fda.gov/about-fda/non-profit-and-other-mous/mou-225-84-2003) with the ISSC to accept assistance from state and local health authorities in the enforcement of laws to prevent and suppress communicable disease.

The FDA recognizes the ISSC as the primary organization of shellfish officials that provides guidance and counsel on matters relating to the sanitary control of shellfish.

3. National Marine Fisheries Service (NMFS)

In 2009, the FDA and the NMFS entered into a MOU (see https://www.fda.gov/about-fda/domestic-mous/mou-225-09-0008) to increase and improve cooperation on the enforcement of the Lacey Act against the illegal harvest, transport, export, import, sale, and purchase of molluscan shellfish in violation of any U.S., state, or tribal law or regulation.

4. FDA Responsibility

The FDA evaluates the programs of participating state and foreign government authorities and provides capacity building of states to include technical assistance, model ordinance interpretations, standardization and training. Hereafter, all references to "state" in the document include countries with which the FDA has an active shellfish MOU or other official FDA agreement. The FDA also provides technical assistance to states and advises them on matters pertaining to public health. The FDA enters into MOUs or other official FDA agreements with sovereign nations meeting NSSP MO criteria and conducts periodic

program evaluations, in addition to determining the admissibility of affected articles when offered for import into the United States.

PART II - IMPLEMENTATION

1. **Objectives**

A. Overall Objectives

(1) Fulfill the responsibilities of the FDA under the U.S. Public Health Service Act, and the Federal Food, Drug, and Cosmetic Act to prevent shellfish-related foodborne illness;
(2) Fulfill the responsibilities of the FDA under the FDA/ISSC MOU and the FDA MOUs or other official FDA agreements with foreign countries by:
  (a) Promoting the uniform adoption and implementation of public health criteria, regulations, and procedures;
  (b) Provide capacity building to state programs including training, standardization, research, and technical assistance; and
  (c) Evaluating public health control programs of shellfish-producing and/or shipping states.

B. Program Objective

The objective of this compliance program is to evaluate the activities of the participating states using a risk-based approach and to provide capacity building for the state program. The compliance program will focus on five (5) specific state program elements: growing area classification, plant processing and shipping, control of harvest, *Vibrio spp*. control, and laboratory evaluation. The compliance program includes a focused evaluation of state and industry efforts to control *Vibrio spp.* in accordance with state *Vibrio vulnificus* and *Vibrio parahaemolyticus* management and control plans.

Activities in these areas of focus shall include the following:

(1) Give priority to shellfish-associated illness outbreaks;
(2) Conduct file reviews and field evaluations of growing areas, patrol areas, and certified shellfish firms;
(3) Determine the compliance status of the state program elements with all NSSP MO criteria.
(4) Determine the compliance status of the state plant processing and shipping element using the evaluation criteria in the "Guide for the Control of Molluscan Shellfish Model Ordinance" found here: NSSP Guide 2019 link" Chapter I @.03 B. (4.);
(5) Determine the compliance status of the control of harvest element using the evaluation criteria in the "Guide for the Control of Molluscan Shellfish Model Ordinance" Chapter I @.03 B. (3.);
(6) Determine: a) the compliance status of state *Vibrio vulnificus* Control Plans and *Vibrio parahaemolyticus* Control Plans with NSSP Vibrio requirements, b) industry compliance with state Vibrio Control Plans, and c) state enforcement of Vibrio Control Plan requirements;
(7) Conduct training, standardization and maintenance of Shellfish Standardization

Officers (SSO).

(8) Provide technical assistance including, making recommendations on implementing the public health goals to reduce foodborne illness and;

(9) Work cooperatively with the authority to plan, schedule and conduct the program element evaluations.

Shellfish specialists shall give top priority to shellfish-associated illnesses and outbreaks as soon as they are reported. In the event of such outbreaks, shellfish specialists shall inform the Center Shellfish Illness Coordinator (CSIC) from the SAPB in CFSAN via electronic mail at ShellFishEpi@fda.hhs.gov. Illness outbreaks shall be coordinated between states with assistance from the FDA (Office of Regulatory Affairs (ORA) and CFSAN) where needed to ensure adherence to all NSSP requirements.

2. Program Management Instructions

A. General

The FDA's OSCP Shellfish Sanitation Division management has primary responsibility for the implementation and effectiveness of program operations performed under this compliance program. ORA management has the flexibility to change priorities from one program element to another to follow-up on illness and outbreak investigations, assist with recalls, and provide technical assistance and training. The work format and schedule are at the discretion of ORA management and should be reviewed by the FDA OSCP Shellfish Division branch director(s).

B. Planning Activities

OSCP Shellfish specialists will develop and coordinate activities with state program officials to include planning a schedule for conducting evaluations, standardization activities, and technical assistance based upon the FY workplan.

C. International Program Evaluations

International shellfish program evaluations shall be scheduled by the CFSAN SAPB to ensure that internationally recognized shellfish producing countries that ship to the United States under an existing agreement, or countries that wish to enter into an agreement, are producing shellfish that are safe for human consumption. The SAPB will coordinate with OSCP Shellfish Division branch directors and shellfish specialists to assign shellfish specialists to carry out international shellfish program evaluations.

D. Cooperative Agreement Funding

The ORA Office of Partnerships (OP) is responsible for managing cooperative agreement funding to support state program capacity building. A Joint Advisory Group comprised of subject matter experts is utilized to ensure supporting goals are achieved. For questions, the shellfish specialists may contact the OP shellfish sanitation program specialist or direct the authorities to the awarding organization.

PART III - INSPECTIONAL

1. **Operations**

Specific program activities appear below in this section. Activities are subject to modification based on changing program needs. Should modifications occur, OSCP management, shellfish specialists, CFSAN/Office of Compliance, and ORA HAF Programs will receive notification via memorandum from the SAPB.

A. **General**

All operations are to be conducted in cooperation with the participating state.

B. **Operation Descriptions**

(1) Program Evaluation

The evaluation of the state program elements will be conducted by shellfish specialists and will be reported by utilizing the OSCP DSS PEER and IPER templates. The shellfish specialist shall document the time period under review in the PEER. The shellfish specialist will use Table 2 to determine the number of growing areas selected for growing area classification and control of harvest, and the number of certified dealers selected for evaluation.

Table 2. Number of Units to Select for Evaluation

TOTAL INVENTORY	NUMBER OF UNITS TO BE SELECTED
1-5	ALL
6-7	5
8	6
9	7
10-13	8
14-18	9
19-24	10
25-34	11
35-64	12
64-297	13
>297	14

Specifics related to each program element can be found in subsequent sections; please refer to Part III Operations, A. (1.- 4.) for additional details.

The shellfish specialist will complete the in-field portion of the evaluation within 30 calendar days of initiation. In the event the shellfish specialist cannot meet the in-field evaluation or report deadline, the evaluator shall discuss it as soon as possible with their OSCP Shellfish Division branch director and notify the CFSAN national shellfish standard of the newly agreed upon deadline. The shellfish specialist shall complete a

draft PEER for OSCP management and CFSAN SME review within 30 calendar days of completing the evaluation. OSCP management and CFSAN SMEs have 10 business days to provide feedback on draft reports. OSCP management will work with CFSAN if there are questions about the feedback. After the OSCP management review, the draft PEER will be provided to the authority for review, comment, and to provide the summary of the state's response. The authority will be given 15 business days to review, comment, and provide the summary of the state's response to the PEER before it is finalized. If the state does not respond within 15 business days the OSCP will issue the final report and document in the PEER that the state did not review, comment, or provide a summary of the state's response.

Program activities will focus on the evaluation of the following elements of the state's program:

(a) Growing Area Classification Element

The growing area classification element will be evaluated by the shellfish specialist at a frequency determined by a risk assessment and/or whether the state is on an action plan. Risk factors have been identified for the growing area classification element. Each factor is assigned a specific level of risk based upon a defined point rating system in Table 3. Totaling the points assigned for each risk factor will determine the frequency of evaluation for the growing area classification element.

Shellfish specialists will work with the authority, where appropriate, to either assign a point value or review a prior point value for each risk factor and complete the Growing Area Risk Assessment Form table in each PEER.

Three (3) risk factors have been identified for shellfish growing area classification. They are production, classification complexity, and illness outbreaks.

i. Production:

Assign the following point value based upon the commercial harvest (in pounds) of the following shellstock as appropriate for the state; oysters (all species totaled), clams (all species totaled), mussels (all species totaled), and scallops (all species totaled when the final product is whole or roe-on). Production will only be based upon shellfish harvested within state classified waters. Work with the authority to determine the state's production data as required by the NSSP MO, Chapter II.@.03. B.

Production data shall be based on the average of the most recent three (3) years of final data. Landings data will only be based on state's reporting as required by the NSSP. If the data are not available, the shellfish specialist will assign the high-risk factor.

Risk Factor	**Production in pounds**

High (4)	≥4,700,000
Medium High (3)	≥2,000,000 to < 4,700,000
Medium Low (2)	≥1,000,000 to < 2,000,000
Low (1)	<1,000,000

ii. Classification Complexity:
Assign the following point value based upon the growing area classification complexity within the state:

Risk Factor	Description
High (4)	>20% of the state's total number of growing areas have a conditionally approved or conditionally restricted classification
Medium-High (3)	<20% of the state's total number of growing areas have a conditionally approved or conditionally restricted classification
Medium-Low (2)	approved, restricted, and prohibited only
Low (1)	approved and prohibited only

iii. Illness Outbreaks (excluding outbreaks attributed to naturally occurring pathogens):

Assign the following point value based upon the occurrence of an illness outbreak(s) associated with a growing area in the state being assessed.

Risk Factor	In the past 5 years
High (3)	Two (2) or more outbreaks
Medium (2)	One (1) outbreak
Low (1)	No outbreaks

iv. Overall Risk Determination for Growing Area Classification Element:

Total the above risk factor point values to determine the risk category for the growing area classification program element.

High Risk = Range 7-11
Low Risk = Range 2-6

Table 3. Growing Area Classification Risk Assessment Form

RISK FACTORS	SCORE(0-4)	RATING (H/MH/M/ML/L)	EXPLANATION
PRODUCTION			
CLASSIFICATION			

COMPLEXITY			
ILLNESS OUTBREAKS			
	TOTAL	OVERALL RISK (H OR L)	

Growing area classification elements with totaled points that indicate an overall high risk will be evaluated every year. Growing area classification elements with totaled points that indicate an overall low risk will be evaluated once every two (2) years.

States that have a high risk for the illness outbreak factor will have the area(s) impacted by the illness outbreak(s) evaluated by the shellfish specialist(s) annually until the risk has been addressed regardless of the state's overall risk rating.

Growing area classification elements that do not meet overall NSSP requirements will be placed in the high-risk category and will be evaluated annually until the state has demonstrated that the element is again in full compliance with the NSSP. Once the element is again in full compliance with the NSSP, the frequency of evaluation will be based on the element's risk category (high or low).

States having a high-risk growing area classification element that is found to be compliant for two (2) consecutive years may request in writing to the FDA OSCP Shellfish Division branch director that the FDA reduce the evaluation frequency to that of the low risk category. Any future finding of non- compliance in the growing area element restores the high-risk classification and increases the evaluation frequency to annual.

The shellfish specialist will use Table 2 to determine the number of growing areas selected for evaluation. The shellfish specialist and the authority will collaborate to select growing areas for evaluation. The selection of growing areas should be risk-based, represent the state's overall inventory, and to the extent possible, consider the efficient use of time and resources to conduct the evaluation.

The shellfish specialist will consult with the CFSAN Shellfish Laboratory Evaluation Officers (LEOs) to ensure the laboratory method(s) used by the state for regulatory purposes related to shellfish growing area management and classification is approved under the NSSP, and that the data values reported by the state are within the limits of the testing method(s) used. The shellfish specialist, after using the shellfish specialist laboratory job aid, can consult with the CFSAN LEOs regarding test method(s) and utilization of data. The shellfish specialist laboratory job aid is available at: Shellfish Specialist Lab

Methods Job Aid (fda.gov).

(b) Plant Processing and Shipping Element

All states shall have the shellfish plant processing and shipping element evaluated every two (2) years to determine conformance with the NSSP MO and evaluation criteria. The frequency of the plant processing and shipping element evaluation shall not be reduced for any reason.

States that are on an action plan or that have outstanding nonconformities associated with administrative criteria (Chapter I @.03 B. (4.) (e.) (i. – vi.) shall have a follow-up review conducted during the non-evaluation year using the "Guidance to the Field: Conducting Follow-Up Evaluations of the Plant Processing and Shipping Evaluation". Evaluation For states that are on an action plan for in-field criteria non-compliance (Chapter I @.03 B. (4.) (e.) (vii.), shellfish specialists will continue to work with the state throughout the non-evaluation year.

The shellfish specialist will use Table 2 to determine the number of certified dealers selected for evaluation. The shellfish specialist and the authority will collaborate to select firms for evaluation. The firm selection should be risk-based, represent the state's overall firm inventory, and to the extent possible, consider the efficient use of time and resources to conduct the evaluation. The ratio should be based upon the certification type of plants within the state's inventory (i.e. if 50% of plants are shucker packers, then 50% of the plants selected for evaluation should be shucker packers).

After each plant processing and shipping evaluation, the shellfish specialist shall complete the OSCP Deficiencies by Dealer Type spreadsheet to provide an overview of the individual deficiencies documented during the evaluation. The spreadsheet shall be sent to the OSCP Shellfish Division branch directors and the SAPB national shellfish standard for review and reporting of metrics.

Determine the conformance status of the state plant processing and shipping element using the NSSP evaluation criteria in the NSSP MO Chapter I @.03 B. (4.) and complete a PEER using the plant processing and shipping element PEER template.

Shellfish specialists must coordinate with the authority regarding standardization activities and whether the standardization activity is conducted during a plant processing and shipping evaluation.

(c) Control of Harvest Element

All shellfish producing states shall have the shellfish control of harvest element evaluated every two (2) years to determine conformance with the NSSP MO and Chapter I @.03 B. (3.) evaluation criteria. The frequency of the control of harvest element evaluation shall not be reduced for any reason.

States that are on an action plan or that have outstanding nonconformities shall receive a follow-up review during the non-evaluation year. States that have at least one (1) High Risk patrol area, or states where >20% of their patrol areas are in the Medium Risk category, shall receive a follow-up review in non-evaluation years to ensure those patrol areas are being patrolled at minimum required frequencies. Shellfish specialists should prioritize states and patrol areas that have recently been the source of shellfish associated illness(es) or outbreaks resulting from illegal commercial harvest in closed areas, and those reviews shall be documented either during full biennial evaluations or in a follow-up review if it is a non-evaluation year.

The shellfish specialist will use Table 2 to determine the number of areas selected for evaluation. The shellfish specialist and the authority will collaborate to select growing areas for evaluation. The selection of areas should be risk-based, represent the state's overall inventory, and to the extent possible, consider the efficient use of time and resources to conduct the evaluation.

(d) *Vibrio vulnificus* and *Vibrio parahaemolyticus*

States that are required to have a *Vibrio vulnificus* Control Plan and/or a *Vibrio parahaemolyticus* Control Plan will be evaluated annually by shellfish specialists to determine compliance. States that have implemented a voluntary Vibrio Control Plan will be evaluated every 2nd or 3rd year as determined to be adequate by the shellfish specialist in consultation with the OSCP Shellfish Division branch director. The CFSAN vibrio SME and the SAPB branch chief will be notified of the newly agreed upon deadline and frequency.

At a minimum, the evaluation of *Vibrio vulnificus* Control Plans and *Vibrio parahaemolyticus* Control Plans shall include an assessment of the items outlined in the OSCP Vibrio PEER template.

(e) Laboratory Evaluation

The shellfish specialist is responsible for informing the FDA CFSAN Shellfish LEOs of laboratories requesting an initial evaluation in order to be able to support the NSSP and laboratories no longer actively supporting the NSSP. Laboratory evaluations are conducted by CFSAN Shellfish LEOs triennially either onsite or, under certain circumstances, by comprehensive desk audit. The CFSAN Shellfish LEOs will provide the shellfish specialists with a tentative list of domestic laboratories to be evaluated early in the year for planning purposes. The CFSAN Shellfish LEOs will coordinate the scheduling of onsite evaluations with the shellfish specialist and appropriate laboratory officials. Every effort will be made to accommodate the shellfish specialist; however, priority will be given to the laboratory and LEOs' schedule.

If budget and schedules permit, the shellfish specialist should accompany the

CFSAN Shellfish LEO during onsite evaluations to become familiar with laboratory personnel, laboratory procedures, and overall laboratory operation. If the shellfish specialist is not able to attend in person, the shellfish specialist should make every effort to be available virtually for the close-out meeting of onsite evaluations.

Laboratory conformance is based on the criteria established in the NSSP MO Chapter I @.03 B. (1.). Evaluation findings and recommendations are discussed with state laboratory officials at the close-out meeting. In the event a laboratory is found to be out of conformance, the shellfish specialist will be notified immediately by telephone or email at the conclusion of the close-out meeting if they are not in attendance.

A report of the findings, written in indelible ink, is provided to the laboratory at the conclusion of the close-out meeting and serves as the formal record of the evaluation. This report covers any nonconformities cited, the corrections required, the timeframe for corrections, and any recommendations. A narrative report, including the checklist and recommendations presented to the laboratory at the close-out meeting, will be completed and forwarded to the shellfish specialist, the OSCP Shellfish Division branch director, and the SAPB branch chief within 45 calendar days of completion of the laboratory evaluation. In the event the CFSAN Shellfish LEO cannot meet report deadlines, the LEO shall discuss this as soon as possible with their team lead. The shellfish specialist and the OSCP Shellfish Division branch director will be notified of the newly agreed upon deadline. If nonconformities are cited in the evaluation, the CFSAN Shellfish LEO is responsible for monitoring the progress of corrective actions and keeping the shellfish specialist informed on the overall program impact of non-conformities and progress of corrective actions. The CFSAN Shellfish LEO may request shellfish specialist assistance when corrective actions are not made or are incomplete. After completion of all corrective actions, a Completed Corrective Action Memo will be issued to the laboratory within 30 calendar days with a copy to the shellfish specialist, the OSCP Shellfish Division branch director, and the SAPB branch chief. The narrative report can be summarized and/or excerpted by the shellfish specialist for inclusion in the PEER(s)/APER as appropriate.

Laboratory evaluations are generally onsite evaluations but can, under certain circumstances, be conducted by desk audit or remote evaluation. A desk audit follows the same procedure as an onsite evaluation, e.g. the CFSAN Shellfish LEO completes a NSSP checklist, nonconformities are cited, and a narrative report is prepared. The shellfish specialist will be provided with a copy of the completed NSSP checklist and associated narrative report.

Domestic evaluations may also be performed by certified State Shellfish Laboratory Evaluation Officers (State Shellfish LEOs). State Shellfish LEOs are encouraged to coordinate their evaluations with the shellfish specialist.

When budgets and schedules permit, the shellfish specialist should make a concerted effort to attend these evaluations. If the shellfish specialist is not able to attend in person, the shellfish specialist should make every effort to be available virtually for the close-out meeting of onsite evaluations.

(2) Guidelines for Writing Program Element Evaluation Report (PEERs), Annual Program Evaluation Reports (APERs), and International Program Evaluation Reports (IPERs)

(a) Program Element Evaluation Report (PEER)

The PEER is intended to provide information on a program element to the applicable state program element manager, ORA management, and CFSAN personnel. The PEER should accurately reflect each program element that is evaluated and the current findings using the PEER templates. The PEER shall be written as a stand-alone document for all elements.

(b) PEER Cover Letter

The shellfish specialist must use the PEER cover letter template. The PEER cover letter requires the electronic signature of the OSCP Shellfish Division branch director and must be addressed to the shellfish program manager of the department(s) in which the shellfish program element(s) is located.

(c) Annual Program Evaluation Report (APER)

The purpose of the APER is to provide an executive summary annual status of the entire state program to the state agency, ORA management, and CFSAN personnel. The shellfish specialist must use the APER template. An APER must be issued if an evaluation was conducted in the state during a calendar year.

After the OSCP management review, the draft APER will be provided to the authority(ies) for review and comment. The authority(ies) shall be given five (5) business days to review and comment on the APER before it is finalized. If the state does not respond within five (5) business days, the OSCP will issue the final report.

(d) APER Cover Letter

The shellfish specialist must use the APER cover letter template. The APER cover letter requires the electronic signature of the OSCP office director and must be addressed to the commissioner(s) or equivalent of the department(s) in which the shellfish program element(s) is located. If the office director has not signed within 10 business days, the branch director will sign the letter and issue the final APER.

(e) International Program Evaluation Report (IPER)

The lead evaluator must use the IPER template and work with all who participated in the international program evaluation. The IPER is intended to provide information on international program elements. The IPER should accurately reflect each program element that is evaluated and the current findings using the template.

The IPER shall be submitted to the CFSAN SAPB within 120 calendar days of completion of the trip. Upon receipt of the draft IPER, SAPB/DSS/OFS management will review within 45 calendar days and then CFSAN SAPB shall send a draft to the country for review with copy to the International Affairs Staff and FDA foreign office (if applicable). The country will have 30 calendar days to respond with comments.

The laboratory activities of international programs shall be evaluated by the SAPB LEOs who will prepare a laboratory evaluation report. When performed as part of a foreign evaluation team and in conjunction with a program evaluation, the laboratory section of the IPER shall be submitted to the country's shellfish control authority within 120 calendar days of completion. If the SAPB LEO performs an international evaluation independent of an international program evaluation team, and only the laboratory is evaluated, the LEO will prepare a laboratory evaluation report within 90 days of the completion.

(f) IPER Cover Letter

The lead evaluator must use the IPER cover letter template. The IPER cover letter shall have a summary paragraph describing the overall status of the country’s program including major findings, recommendations, and a request for the correction of deficiencies. The letter should acknowledge participation by the country’s officials during the evaluation.

The CFSAN SAPB will provide the cover letter, prepared by the evaluation team, with a final report to the country’s shellfish control authority within 45 calendar days of receipt of the country’s response to the draft IPER.

(3) Standardization and Certification

(a) Plant Standardization

The purpose of standardization of shellfish plant inspectors is to ensure that plants are uniformly inspected for compliance with sanitation and Hazard Analysis Critical Control Point (HACCP) requirements.

Shellfish specialists shall perform standardization of state personnel in

accordance with the NSSP MO, maintain a record showing the dates of standardization, standardization expiration, and standardization maintenance (renewal classes or plant inspection), and provide this record annually to the FDA national shellfish standard.

Shellfish specialists shall conduct standardization and maintenance inspections as needed.

(b) LEOs Standardization and Certification

The purpose of standardization of shellfish LEOs is to ensure that laboratories are uniformly evaluated for conformance to the NSSP requirements for quality systems, operations, and technical proficiency. FDA LEOs certify state LEOs every six (6) years as per the procedures listed in the current NSSP Guide for the Control of Molluscan Shellfish, to ensure they are free from any commercial, financial, or other pressures or conflicts of interest, verify experience with the method types that will be evaluated, ensure they are able to lead evaluations against the NSSP standard efficiently and effectively, and are able to accurately and effectively document results in a transparent and traceable manner for defensibility of results. All LEOs, whether state or federal, will be standardized by the FDA National Laboratory Standard and will attend the FD 246 laboratory training when offered for their cohort groups.

(4) Training and Meetings

(a) Training

The ORA Office of Training Education and Development (OTED) is responsible for developing, delivering, and maintaining FDA shellfish training courses, in conjunction with the shellfish specialists and the CFSAN SAPB. The CFSAN SME's role during course development, maintenance, and delivery is to check and approve content for agency policy. The shellfish specialist should assist the authority annually in determining training needs and priorities. These training needs should be discussed with their OSCP Shellfish Division branch director or designee. Upon approval, the training needs should be forwarded to the OTED training officer, who will plan the necessary courses to meet the determined needs.

The OTED meets annually to plan courses for a rolling two-year period. The dates, times, and course locations will be included in course announcements found in the OTED Pathlore Learning Management System (LMS) Course Catalogue. Course announcements will also be sent to the shellfish specialists and the CFSAN for further distribution.

Authority staff members, with their management's approval, will be able to self-nominate for planned courses in the LMS system (upon availability). If they are

unable to utilize this option, then nominations, in the form of an Attachment "A" from OTED, can be forwarded to the training officer, through the shellfish specialist and CFSAN.

Shellfish specialists may provide training other than that provided through OTED courses to FDA and non-FDA personnel such as industry, state, or other governmental personnel (including foreign officials) in inspection or analytical techniques or other technical areas related to shellfish program implementation. Any training provided by shellfish specialists must receive prior approval from OSCP Shellfish Division branch director(s) and clearance from CFSAN SME(s) for agency policy.

(b) Regional Seminars or Meetings

Seminars, meetings, workshops, training courses (not OTED), and conferences provide an opportunity for the FDA, state shellfish program officials, federal agencies, industry and academia to participate in discussions of the latest science related to shellfish sanitation, food safety, interpretations of the model ordinance, information exchange, and problem solving. Shellfish specialists are required to attend these mission critical training seminars and meetings to support FDA stakeholders and to obtain and maintain level II cooperative programs professional development and certification unless an exception has been approved by the OSCP Shellfish Division branch director.

(c) Interstate Sanitation Shellfish Conference (ISSC)

In accordance with the FDA/ISSC MOU, participation at the ISSC is critical to success of the implementation of the NSSP. CFSAN and ORA staff on the National Shellfish Team are required to attend and actively participate at the meeting of the ISSC. The ISSC meeting is held to:

i. Discuss administrative and technical problems and solutions;
ii. Deliberate proposed NSSP model ordinance changes with stakeholders; and
iii. Provide scientific and technical expertise

The shellfish specialist's role is to actively participate in the ISSC meeting. When assigned present the FDA's position in alignment with the Agency positions at committee and task force deliberations. CFSAN is responsible for program policy development. Activities include: planning for attendance, drafting proposals, research of proposals, writing and reviewing backgrounder information. Participation as voting members or support staff on conference committees, task forces, and work groups charged with the responsibility for developing consensus recommendations on significant program related public health safety issues/controls. Refer to the "Work Instructions for Development, Review, Management Clearance, and Submission of FDA Proposals to the Interstate Shellfish

Sanitation Conference" located on the National Shellfish Team SharePoint site for procedures on developing proposals for submission to the ISSC.

(5) Technical Assistance

The shellfish specialist provides technical assistance to shellfish programs and other stakeholders as requested.

Technical assistance may be provided by responding to direct inquiries and requests from shellfish control authorities, participating in workgroups and committees, and interaction with other FDA operational divisions. Shellfish specialists account for time spent providing technical assistance in FACTS. Specific examples of technical assistance provided by shellfish specialists include but are not limited to the following:

(a) Interpreting and advising on NSSP requirements
(b) Consultation and assistance on complex implementation requirements of the NSSP
(c) Assisting in the development/interpretation of state regulations to include the NSSP
(d) Providing technical consultation and assistance at meetings with industry, public interest groups, consumers and trade organizations on the requirements of the NSSP
(e) Coordinate and advise during illness outbreaks
(f) Participating in CFSAN SAPB requested initiatives including but not limited to dye studies and laboratory evaluations
(g) Participating in ISSC Committees and workgroups to include proposal development and deliberation
(h) Participating in regional seminars including preparation activities
(i) Participating in the Shellfish Steering Committee (SSC) or established workgroups to include shellfish specialist team representatives
(j) Participating in national team workgroups
(k) Assistance to OHAFO and Import Divisions regarding NSSP requirements
(l) Representing the Agency on interagency committees and taskforces
(m) Assistance with state coordination of partnership activities, agreements and funds

Requests for unique technical assistance (i.e. engineering calculations, field dye studies, GARB or VARB support) that require collaboration and assistance from CFSAN SAPB shall be submitted by the shellfish specialist on behalf of the authority. The "National Shellfish Specialist Team FACTS Reporting Guidance" provides specific instruction for how to account for the above listed items when entering hours into the FACTS database.

(6) Uniformity and Collaboration

(a) National Shellfish Team

The National Shellfish Team (NST) includes the OSCP, CFSAN SAPB and Division of Seafood Safety and Technology (DSST), OTED, OP, CFSAN and other ORA and CFSAN personnel who address molluscan shellfish sanitation. There are times when all FDA shellfish components collaborate and work on a variety of projects.

(b) Shellfish Steering Committee (SSC)

The SSC is a forum for discussion and consensus building amongst the National Shellfish Team (NST) representatives, regarding public health concerns related to molluscan shellfish safety. This group directs the priorities of the NST by assisting management with recommendations of project prioritization, organizational development and guidance on shellfish safety and guidance. The members of the SSC act as a mechanism for directional unification within the NST. The SSC serves as the primary liaison between ORA and CFSAN personnel and provides for coordination and guidance among all the FDA components involved with ensuring shellfish safety. The SSC's mission also includes ensuring uniform application and evaluation of NSSP MO guidelines, consistent policy, making recommendations to agency leadership, and assessing the value and feasibility of new national initiatives for reducing the incidence of injury and disease transmitted through the consumption of raw molluscan shellfish products.

The SSC meets monthly. The vision statement, mission, organizational structure, operational procedures, and roles and responsibilities of the SSC are described in the "Food and Drug Administration Molluscan Shellfish Steering Committee Charter".

Two (2) shellfish specialists are nominated to serve as team representatives on the SSC for a two (2)-year term. The team representatives serve as a liaison between the SST and the SSC.

(c) Shellfish Specialist Team (SST)

The SST is comprised of all the shellfish specialists in the OSCP, Division of Shellfish Sanitation, Branches I and II. The SST is a part of the NST and meets at least quarterly. The SST maintains bylaws, standard operating procedures (SOPs), and other documents.

The SST is responsible for evaluating the field implementation of the requirements of the NSSP and members serve as liaisons to state and tribal regulatory personnel, as well as multiple offices within the FDA. The roles and responsibilities of the SST include, but are not limited to:

- Facilitating the understanding and uniform implementation of the NSSP

within state and tribal jurisdictions;

- Assisting in the development/review of new/revised state shellfish laws and regulations to ensure uniformity with NSSP requirements;
- Developing, conducting, and participating in program training for regulatory officials, industry, and other interested parties;
- Developing and implementing program policies and objectives, including those related to shellfish HACCP;
- Providing technical assistance, such as NSSP MO interpretations, program consultation, and recommendations as necessary to regulatory officials, academia, and industry;
- Administering field standardization to the State Standardization Officers (SSO) as well as other regulatory staff as needed;
- Coordinating information exchange between the FDA Import Program and state regulatory agencies regarding the importation of raw molluscan shellfish in violation of the NSSP;
- Participating in special projects such as Regional, SSO, and LEO meetings, as well as, CFSAN initiatives, international/federal/state shellfish conferences and other events as needed.

PART IV - ANALYTICAL

If samples of domestic or imported shellfish are collected and analyzed, follow the information provided in the Seafood Processor Inspection Program – Domestic and Foreign Facilities Compliance Program (7303.842) or the Import Seafood Products Compliance Program (7303.844), respectively.

1. Emergency Situations

Samples may arrive at FDA laboratories for investigatory analysis in emergency situations. Refer any emergency questions to supervisors.

2. Routine Technical Assistance

Internal FDA requests e.g., ORA requests to the CFSAN, for routine technical assistance provided by the FDA shellfish specialists, or external requests which require only minimal FDA resources are processed as needed.

3. Growing Area Review Board (GARB)/ Vibrio Assistance Review Board (VARB)

The CFSAN has two (2) groups called the GARB and the VARB. These groups exist to facilitate research needs and technical assistance. The FDA receives requests from ORA shellfish specialists through the PEER, state or foreign authorities, and laboratory evaluation officers to provide training, technical assistance, and research in support of the NSSP. Requests for assistance from these groups must be received via shellfish specialists, and the FDA will review requests and make recommendations to management regarding the prioritization and acceptance of submissions.

There are laboratories within CFSAN under the DSST and the Office of Regulatory Science (ORS) in which laboratory support is offered either for emergencies or through GARB, VARB requests. Requests for emergency assistance or technical support from these groups do not have to be received via shellfish specialists; however, if assistance is offered by either ORS labs or DSST labs, the CFSAN SAPB branch chief must be notified by the laboratory.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

1. Imminent Health Hazard

In the event an authority fails to take appropriate action and there appears to be an imminent hazard to health, the shellfish specialist, in consultation with the OSCP and the SAPB, shall notify the senior emergency response coordinator (SERC) of the hazard and of the state's position.

The notification should include information on the violation.

An imminent hazard to public health is defined in 21 Code of Federal Regulations 2.5.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 2--GENERAL ADMINISTRATIVE RULINGS AND DECISIONS
Subpart A--
General Provisions

Sec. 2.5 Imminent hazard to the public health

i. Within the meaning of the Federal Food, Drug, and Cosmetic Act an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held. The imminent hazard may be declared at any point in the chain of events which may ultimately result in harm to the public health. The occurrence of the final anticipated injury is not essential to establish that an imminent hazard of such occurrence exists.

ii. In exercising his judgment on whether an imminent hazard exists, the Commissioner will consider the number of injuries anticipated and the nature, severity, and duration of the anticipated injury.

2. The National Shellfish Sanitation Program (NSSP)

The ISSC "Constitution, By-Laws, and Procedures" and this compliance program contain procedures for achieving compliance when an FDA evaluation identifies program deficiencies with requirements and evaluation criteria contained in the NSSP MO. http://www.issc.org/constitution-bylaws-procedures

A. General Instructions and Administrative Criteria for Non-Conforming State Program Elements

Shellfish specialists should make every reasonable effort to discuss all observations with the authority as they are observed, and/or daily unless otherwise requested. The shellfish specialist shall explain any program deficiencies found during the evaluation.

Shellfish specialists that identify program deficiencies during an evaluation or find any element of an authority's program with deficiencies with NSSP requirements and/or in non-conformance with the NSSP evaluation criteria shall notify the OSCP Shellfish Division branch director of the situation prior to close out with the authority. The OSCP Shellfish Division branch director will consult with SAPB to determine appropriate action.

If corrective action is taken (during the evaluation or prior to finalizing the PEER), the shellfish specialist follows the PEER template and document the correction in the appropriate section of the PEER and follows up on the corrective actions during the next evaluation.

For deficiencies that cannot be corrected during growing area classification, control of harvest, and vibrio evaluations, or prior to finalizing the PEER, the authority must provide a written action plan, including detailed explanations of corrections to be made for the program element deficiency(ies) related to growing area classification, control of harvest, or vibrio evaluations, to the shellfish specialist within 30 calendar days of receipt of the final PEER indicating:

- How the items were corrected or a detailed description of how the authority proposes to correct the deficiency(ies);
- A completion date or a timeline for completion of corrections; or
- If the state does not concur with the FDA's findings, the reasons for non-concurrence.

For deficiencies that cannot be corrected during the plant processing and shipping evaluation, or prior to finalizing the PEER, the authority must develop and complete an action plan that includes a plan to specifically address any deficiencies associated with Chapter I @.03 B. (4.) (e.) (ii. – vi.). For deficiencies associated with Chapter I @.03 B. (4.) (e.) (vii.) the action plan shall include the correction of deficiencies or develop deficiency-specific compliance schedules in accordance with Chapter I @.03 B. (4.) (f.) (ii.) (a. – d.).

The deficiency (ies) and conformance status, though corrected, remains documented in the PEER and the deficiency is reported as corrected. If the authority develops and submits an action plan prior to issuance of the final PEER, the shellfish specialist incorporates the action plan into the summary of states response following concurrence

from OSCP BDs and CFSAN.

All corrective action plans shall be scheduled for completion within 180 calendar days (growing area classification, control of harvest, and vibrio elements) of receipt of the final PEER. Where appropriate, exceptions to the 180 calendar days may be granted on a case by case basis by the OSCP Shellfish Division branch director in consultation with the CFSAN SAPB. The shellfish specialist shall meet with the authority and confer with the OSCP Shellfish Division branch director and CFSAN during the development of the action plan to ensure that it provides enough detail and is acceptable to the FDA. The shellfish specialist shall send a letter to the authority that the action plan is acceptable to the FDA and has concurrence from CFSAN using the action plan response letter template. If elements of the action plan are not acceptable to the FDA, the letter will explain in detail the reason for the disagreement within the action plan response letter with concurrence from CFSAN. If the authority submits an action plan before the PEER is finalized, the shellfish specialist will use action plan response template letter language within the conclusions section of the PEER with concurrence from CFSAN for those items that have been accepted and/or a detailed explanation of the areas of disagreement and a separate letter is not necessary. The shellfish specialist shall be responsible for monitoring the progress of the action plan in consultation with their OSCP Shellfish Division branch director and CFSAN.

The shellfish specialist shall review the documents submitted by the authority and respond within 15 business days in consultation with their OSCP Shellfish Division branch director and CFSAN.

If the authority fails to submit or implement an action plan to correct all deficiencies or if consensus with the FDA's findings is not reached, the shellfish specialist, in consultation with the OSCP Shellfish Division branch director, the OSCP Director and CFSAN SAPB, shall consider appropriate actions in accordance with the ISSC "Constitution, By-Laws, and Procedures" including:

- Referral of the matter to the ISSC Executive Board as an unresolved issue (The ISSC "Unresolved Issue Process" is a peer review process for states not meeting the requirements of the NSSP MO), and/or
- De-listing shippers from the ICSSL (de-listing can only be initiated by the Office of Food Safety in consultation with the Office of Chief Counsel).

3. Federal Statutes Covering Shellfish in Interstate Commerce

A. FD&C Act

The FDA depends upon the participating states and tribes to carry out shellfish program responsibilities on a voluntary basis; however, the FDA is responsible for shellfish products shipped in interstate commerce. Therefore, when potentially

violative conditions are encountered and the state authority has been contacted, but is unable or unwilling to take corrective measures, the shellfish specialist in consultation with their OSCP Shellfish Division branch director, will advise the appropriate ORA Human and Animal Food program division director to initiate an appropriate investigational and regulatory follow-up. This may include FDA inspection, sampling, analysis, seizure, injunction, and/or prosecution. The FDA would also coordinate any voluntary recall actions by responsible firms. For those violative situations in which recall actions are handled exclusively by the states, the shellfish specialist will serve as liaison between the states and the FDA division office.

B. The Lacey Act

The Lacey Act prohibits the illegal transport, export, import, sale, and purchase of shellfish violating U.S. laws and regulations and prescribes civil and criminal penalties for such actions. It also provides for federal enforcement of state laws and regulations for shellfish shipped in interstate commerce.

The FDA Office of Compliance will decide the appropriate regulatory action regarding tagging violations, e.g., the PHS Act, the FD&C Act, the Lacey Act, or a combination thereof.

Assistance regarding the Lacey Act can be obtained by contacting the National Marine Fisheries Service (NMFS), Office of Law Enforcement, 1315 East- West Highway, 3rd Floor, Silver Spring, MD 20910, (301) 427-2300, https://www.fisheries.noaa.gov/about/office-law-enforcement.

4. Action regarding Imported Shellfish

A. Certified Shippers

For the purposes of determining admissibility, raw molluscan shellfish offered for import into the United States may only originate from certified shippers from a country with whom FDA has an active MOU or other official FDA agreement **and** who are listed on the FDA Interstate Certified Shellfish Shippers List (ICSSL): http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm20 06753.htm

Raw molluscan shellfish from certified shippers must be packed in containers bearing a certification number issued by the exporting country. If, based upon examination or other regulatory follow-up activity, it is determined that the containers of imported, raw shellfish do not bear this certification number, the import division should contact the indicated shellfish specialist. The shellfish specialist should then report this discrepancy/violation to the authority for additional regulatory follow-up at the state level. Furthermore, any violations of the NSSP MO (https://www.fda.gov/food/federalstate-food-programs/national-

shellfish-sanitation-program-nssp) should be reported to the compliance branch director and shellfish specialist.

If a shipment of imported, raw shellfish packaged in containers without this certification number is offered for import into the United States, the shellfish specialist, the local FDA import division and the authority where the shipment was offered for entry should coordinate throughout the regulatory process. Also see Section B below.

NOTE: Raw Molluscan shellfish originating from certified shippers in European Union Member States may only be harvested from Class A production areas; listed in the accompanying document to the ICSSL. See also "DIO Notice – Addition of European Union (EU) Countries to the Interstate Certified Shellfish Shippers List (ICSSL)."

B. Uncertified Shippers

Molluscan shellfish offered for import into the United States from uncertified shippers requires special attention. Uncertified shippers are either from a country without an active MOU or other official FDA agreement or they are shippers that are not certified by the authority in a country with a MOU or other official FDA agreement. Raw molluscan shellfish offered for import originating from an entity in a country without a MOU or other official FDA agreement is not in and of itself sufficient to support detention of the articles under section 801(a).

When raw, fresh, or frozen molluscan shellfish is offered for import, the entry review application will inform the entry reviewer to check the ICSSL to verify the origin of the molluscan shellfish.

When possible, an examination may be conducted by the division to determine whether the molluscan shellfish presented for import from an uncertified shipper is misbranded or adulterated providing evidence for the FDA to act under Section 801(a) of the Act.

1. FDA staff members will take the following steps when molluscan shellfish is offered for import from an uncertified shipper and there is enough evidence to support an 801(a) violation: The division will hold the indicated molluscan shellfish entry line(s), notify the shellfish specialist, and submit a detention request (DTR) to the compliance branch (CB) following the normal detention and hearing process for violative articles under 801(a).

2. FDA staff members will take the following steps when molluscan shellfish is offered for import from an uncertified shipper and there is insufficient evidence to support an 801(a) violation: The division will refer the indicated molluscan shellfish entry line(s) directly to the appropriate other government

agency (OGA), without issuing a release and submit all documentation/information to the compliance branch director and the shellfish specialist. The shellfish specialist will confirm the receipt of the OGA referral regarding the shipment with the state shellfish authority for regulatory follow-up at the state level. If a state chooses not to destroy shellfish from uncertified shippers, the shellfish specialist or the division should contact CFSAN, OFS/DSS/SAPB and CFSAN, Office of Compliance, Division of Enforcement contacts (see Part VI). *Note: while the state is the authority, they do not have the capability of knowing shipments from uncertified dealers have been released into interstate commerce without notification from the FDA.

Refer to the Import Seafood Products Compliance Program (7303.844) or any local or national procedures for additional information regarding examination, sample collection, analyses and regulatory follow-up of raw molluscan shellfish.

PART VI REFERENCES AND PROGRAM CONTACTS

1. **References**

National Shellfish Sanitation Program "Guide for the Control of Molluscan Shellfish". The "Guide for the Control of Molluscan Shellfish Model Ordinance" is available at https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp.

"Recommended Procedures for the Examination of Sea Water and Shellfish", 4th Edition, 1970, American Public Health Association, New York, NY. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1530666/

"Constitution, By-Laws, and Procedures of the Interstate Shellfish Sanitation Conference". Available online at the Interstate Shellfish Sanitation Conference web site: www.issc.org

"Memorandum of Understanding between FDA and the Interstate Shellfish Sanitation Conference (ISSC)", MOU 225-84-2003: https://www.fda.gov/about-fda/non-profit-and-other-mous/mou-225-84-2003

"Bilateral Agreements Between FDA and Sovereign Nations Certifying Imports Under the NSSP Model Ordinance". Complete copies of the individual MOUs or other official FDA agreements on shellfish sanitation can be obtained from the Office of Food Safety, Division of Seafood Safety, Shellfish and Aquaculture Policy Branch, (240) 402-2300

The "Interstate Certified Shellfish Shippers List" (ICSSL) is published by FDA for the information and use by state control officials, the seafood industry and other interested persons. The ICSSL is available on CFSAN's website at https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list

"Memorandum of Understanding between FDA and the National Marine Fisheries Service", MOU 225-09-0008; see https://www.fda.gov/about-fda/domestic-mous/mou-225-09-0008

"Investigations Operations Manual", Chapter 3 Federal and State Cooperation, Chapter 4 Sampling, Chapter 6 Imports, and Chapter 8 Investigations
http://www.fda.gov/ICECI/Inspections/IOM/default.htm

2. **Program Contacts**

Compliance Program General Information: Markeesa (Keesa) Scales, Markeesa.Scales@fda.hhs.gov 615-366-7991, Office of Compliance, Division of Field Programs and Guidance, Program Assignment Monitoring Branch

Regulatory Guidance: Brandon Bridgman, Brandon.Bridgman@fda.hhs.gov, 510-337-6794, Office of Compliance, Division of Enforcement, Food Adulteration Assessment Branch

Technical Assistance and Training: Floyd (Raymond) Burditt, Floyd.Burditt@fda.hhs.gov, (240) 402-1562, Office of Food Safety, Division of Seafood Safety, Shellfish and Aquaculture Policy Branch,, Main # (240) 402-2300
http://inside.fda.gov:9003/CFSAN/OfficeofFoodSafety/ucm013415.htm

ISSC Liaison: Melissa Abbott, Melissa.Abbott@fda.hhs.gov, (240) 402-1401, Office of Food Safety, Division of Seafood Safety, Shellfish and Aquaculture Policy Branch, Main # (240) 402-2300. http://inside.fda.gov:9003/CFSAN/OfficeofFoodSafety/ucm013415.htm

Shellfish Aquaculture Policy Branch Chief: Melissa (Lizzie) Farrell, Melissa.Farrell@fda.hhs.gov, (240) 402-2055, Office of Food Safety, Division of Seafood Safety, Shellfish and Aquaculture Policy Branch, Main # (240) 402-2300.
http://inside.fda.gov:9003/CFSAN/OfficeofFoodSafety/ucm013415.htm

Shellfish Sanitation Program Specialist: Michael Antee, Michael.Antee@fda.hhs.gov, Point Pleasant, New Jersey Mobile (206) 715-3481, Office of Partnerships, Standards Implementation Staff http://inside.fda.gov:9003/ORA/Federal-StateRelations/default.htm

3. **Imports Contacts**

Patrick Bowen, Branch Chief, Import Operations Branch, Office of Enforcement and Import Operations, ORA HQ, (T) 240-402-8047.

Melissa Gonzalez, Branch Chief, Import Compliance Branch, Office of Enforcement and Import Operations, ORA HQ, (T) 240-402-4288.

4. **Training for FDA/State Personnel**

Brent W. Higgs, (881) 321-5694 Ext. 1109, FAX (801) 524- 3188, 2090 N. Redwood Rd., Salt Lake City, UT 84116, Office of Training, Education and Development HFR-SW2520

http://inside.fda.gov:9003/EmployeeResources/Training/OTED/default.htm

5. **ORA Office of State Cooperative Programs Branch Directors and List of Shellfish Specialists**

   http://inside.fda.gov:9003/ORA/Offices/OHAFO/StateCoopProgram/ucm523045.htm

   Shellfish Sanitation Branch I
   Dr. Bess Ormond, Director, Shellfish Sanitation Branch I Office of State Cooperative Programs
   DHHS/PHS/FDA
   3550 Buschwood Dr., Suite 230
   Tampa, FL 33618
   (407) 415-9630
   Elizabeth.Ormond@fda.hhs.gov

   Shellfish Sanitation Branch II

   TBD

PART VII - CENTER RESPONSIBILITIES

1. Liaison with the Interstate Shellfish Sanitation Conference (ISSC)

The FDA's Office of Food Safety (OFS) is the designated agency liaison with the ISSC. All communications with the executive director and chairman of the ISSC will be directed through CFSAN, OFS, including any status reports on state programs and other pertinent reports and letters. The Office of Food Safety, Division of Seafood Safety, Shellfish and Aquaculture Policy Branch, in consultation with ORA OSCP and the SSC, will identify FDA shellfish specialists to serve as members and/or advisors on various ISSC task forces and committees.

2. International Programs

The SAPB will be responsible for initiating foreign program element evaluation activities and providing copies of previous evaluation reports, action plans, and copies of any correspondence between FDA and the country's shellfish control authorities to the program evaluation team.

The SAPB representative will contact the country's shellfish control authorities to discuss dates for the evaluation and develop an itinerary for the evaluation. SAPB will request feedback from the shellfish specialist(s) and program evaluation team and then forward the itinerary to the country's shellfish control authorities. SAPB shall arrange a conference call with the program evaluation team at least one month prior to the start of the trip to address the elements to be evaluated and coordinate trip logistics.

SAPB coordinates any international visits/audits of US Shellfish programs within OIP, CFSAN, and ORA.

3. Technical Assistance

CFSAN provides technical assistance and training on program elements to shellfish authorities upon request in collaboration with ORA. CFSAN may request ORA shellfish specialist's assistance after consultation and approval from the OSCP Shellfish Division branch director (s) to assist in their specific areas of technical expertise and may be detailed to other geographic areas. CFSAN also provides technical assistance to the ORA.

4. State Program Element Evaluation Review and Follow Up on Action Plans

The SAPB is responsible for compiling inspectional information from the state program evaluations to be presented to the ISSC Executive Board annually.

The SAPB, through communication with the shellfish specialist, shall monitor state follow-up activities in coordination with ORA in order to address state program deficiencies.

5. Work Planning

CFSAN works in collaboration with OSCP to identify program priorities and provides input in the OSCP work planning process.

6. NSSP "Guide for the Control of Molluscan Shellfish Model Ordinance"

OFS, in conjunction with the ISSC, is responsible for updating and making the *"*Guide for the Control of Molluscan Shellfish Model Ordinance*"* available on the FDA website. Copies may be downloaded via FDA's website at http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.

7. The Interstate Certified Shellfish Shippers List (ICSSL)

State and international regulatory officials shall submit the names and other pertinent information of certified shippers electronically to CFSAN using FDA 3038 Forms. The ICSSL will be compiled and maintained by the CFSAN retail food protection staff and posted on CFSAN's website: http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006752.htm

Shellfish specialists and authorities will receive confirmation via email when a shipper in their state has been certified and added to the ICSSL.

8. Laboratory Evaluation

The CFSAN shellfish LEOs are responsible for conducting laboratory evaluations, training, certification/ recertification/ decertification, standardization, and monitoring of the activities of state shellfish LEOs. Laboratory evaluations are scheduled triennially for both domestic and international laboratories providing laboratory support to the NSSP. Evaluation findings and recommendations are provided to laboratory officials in a written report at the conclusion of the closeout meeting. For domestic evaluations, a separate comprehensive report of the operation of the laboratory including findings and recommendations is prepared by the LEO for the shellfish specialist and the laboratory(ies). This report is provided to the shellfish specialist, the OCSP branch director, and the laboratory(ies) and will be summarized and/or excerpted for inclusion in the PEER and APER by the shellfish specialist as appropriate. The shellfish specialist is informed of the status of the laboratory(ies) when not present for the evaluation or evaluation closeout. FDA CFSAN shellfish LEOs are responsible for monitoring the progress of corrective actions and may request assistance from the shellfish specialist when corrective actions are not implemented or are incomplete.

9. Vibrio Assistance Review Board (VARB)

The FDA receives requests throughout the year from states, industry, and other stakeholders to provide training, technical assistance, and research on *Vibrio spp.* In the past, requests were made via official and unofficial channels, and the FDA has made every attempt possible to accommodate all requests for assistance. The VARB was developed to standardize the process by which external requests for vibrio-related technical assistance and research are submitted, reviewed, prioritized, and granted. This process does not apply to internal FDA requests (e.g. ORA requests to CFSAN), routine technical assistance provided by shellfish specialists, or external requests which require only minimal CFSAN resources. This process is not intended

to supersede the FDA's ability and willingness to respond to emergency situations or requests that arise due to such emergencies.

Request forms will be provided during VARB Quarterly Call for Requests and must be submitted to the FDA VARB via the shellfish specialist. The shellfish specialist will submit the request to the VARB chair, and it is the chair's responsibility to assign the request an official tracking number and a VARB liaison, upon receipt. The chair will notify the request submitters of the tracking number and liaison, with a copy to the shellfish specialist and VARB liaison. Requests will be received on an ongoing basis. However, any requests that require technical assistance or research during the *Vibrio spp.* season (May - October) must be submitted no later than March 31 of that year.

The VARB chair and vice-chair will prepare a summary of the number and types of requests received and distribute to the FDA National Shellfish Team, approximately two weeks prior to each VARB meeting. If questions arise about a request, the shellfish specialist, in coordination with the VARB liaison, will work with the request submitter(s) to obtain clarification prior to the VARB meeting. The VARB will meet quarterly (typically the first week of February, May, August, and November), or ad hoc as needed, to review and prioritize requests. At least five (5) VARB members must be present for the review and prioritization to proceed. Shellfish specialists with a request(s) will serve on the VARB for that review panel. Requests will be evaluated and ranked during the VARB meeting and must receive a score that is at least half of the possible total points to be considered for support.
Upon CFSAN/OFS management concurrence with the VARB recommendations, the VARB chair will notify request submitters, with a copy to the shellfish specialist, OSCP Shellfish Division branch director and VARB liaison, of the outcome (generally within four (4) weeks of VARB meeting). The VARB will prepare a summary of the supported requests and share, via the VARB chair, with the ISSC within one (1) week of notifying the request submitters of final decisions. An internal FDA summary of all decisions will be distributed via the VARB chair to the FDA National Shellfish Team within one week of notifying the request submitters of final decisions.

The shellfish specialist will remain involved throughout the duration of the project, serving to facilitate communication between the requestor and the VARB liaison regarding project progress.

10. Growing Area Review Board (GARB)

The FDA receives requests from authorities and other stakeholders to provide technical assistance, training, and research on issues related to growing area classification, such as hydrographic modelling and dye studies, the use of geographic information systems (GIS), and microbiological analyses of pollution sources. In the past, requests were made via official and unofficial channels, and the FDA has made every attempt possible to accommodate all requests for assistance. The GARB was developed to standardize the process by which external requests for growing area-related technical assistance, training, and research are submitted, reviewed, prioritized, and granted. This process does not apply to internal FDA requests (e.g. ORA requests to CFSAN), routine technical assistance provided by shellfish specialists, or external

requests which require only minimal CFSAN resources. This process is not intended to supersede the FDA's ability and willingness to respond to emergency situations or requests that arise due to such emergencies.

Growing Area Technical Assistance and Research Request forms will be provided to the authority by the shellfish specialist during the GARB Annual Call for Requests. The forms must be submitted to the FDA GARB via the shellfish specialist during the time period specified in the Call for Requests. The shellfish specialist will submit the request to the GARB chair, and it is the chair's responsibility to assign the request an official tracking number.

The GARB Chair will prepare a summary of the number and type of requests received and distribute to the GARB members prior to the GARB meeting for the review of requests. If questions arise about a request, the shellfish specialist will work with the request submitter(s) to obtain clarification. The GARB will meet annually or more often as needed. At least five (5) GARB members must be present in order for the review and prioritization to proceed. Shellfish specialists with a request(s) will serve on the GARB for that review panel. Requests will be evaluated and ranked during the GARB meeting. Refer to the GARB SOP for additional details.

Upon CFSAN/OFS management concurrence with the GARB recommendations, the GARB chair will notify the shellfish specialist of the outcome who will then notify the submitter(s).

The shellfish specialist will be the liaison and will be involved throughout the duration of the project, serving to facilitate communication between the requestor and the GARB regarding project progress.