

## CHAPTER 18 – TECHNICAL ASSISTANCE

SUBJECT:  The Molluscan Shellfish Compliance Program	IMPLEMENTATION DATE: 09/20/2017
	COMPLETION DATE Continuing
DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
For Evaluation 52B--04 16E[] [] []	18004 - Evaluations

**NOTE: FDA regulatory inspections and sample collections should not be conducted under this compliance program.** Instructions covering inspection of domestic firms and the sampling of domestic shellfish are in the Domestic Fish and Fishery Products Inspection 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 FD&C Act should be reported under the Domestic Fish and Fishery Products Inspection Program (7303.842), or the Import Seafood Products Compliance Program (7303.844).

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 and those involved in making admissibility decisions of products covered by this compliance program.

**FIELD REPORTING REQUIREMENTS:****A. ELECTRONIC COPY REPORTS TO THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN) BY SHELLFISH SPECIALISTS**

REPORTS	ATTACHMENT	DUE DATE <sup>1</sup>	SUBMIT REPORT TO:
Program Element Evaluation Report (PEER)	A	30 calendar days after completion of evaluation, but no later than January 31	Division of Seafood Safety(DSS)/Shellfish and Aquaculture Policy Branch(SAPB),HFS-325, National Shellfish Standard
International Program Evaluation Report (IPER)	B	45 calendar days after completion of evaluation	DSS/SAPB (HFS-325), National Shellfish Standard
Annual Program Evaluation Report (APER)	C	30 calendar days upon completion of all PEERs but no later than March 1	DSS/SAPB (HFS-325), National Shellfish Standard
Annual Evaluation Schedule	L	Calendar Year Evaluation January 1	DSS/SAPB (HFS-325), National Shellfish Standard

In the event the Shellfish Specialist cannot meet report deadlines, the Specialist shall discuss this as soon as possible with their Branch Director, Office of State Cooperative Programs (OSCP). The CFSAN National Shellfish Standard Officer (HFS-325) will be notified of the newly agreed upon deadline.

**B. HARD COPY REPORTS TO STATES BY SHELLFISH SPECIALISTS**

1. State/International Program Evaluation Report (ATTACHMENTS A & B)
2. Annual Program Evaluation Report (ATTACHMENT C)

**C. 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. Below are the primary reporting codes used in the Shellfish Program.

Operation CodeOperation Description

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

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Molluscan Shellfish facilities participating in National Shellfish Sanitation Program (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  
Therefore, 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.

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## 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 U.S. Public Health Service in 1925. It was designed to prevent illness associated with the consumption of raw fresh and fresh-frozen shellfish (oysters, clams, mussels, and scallops - scallops are excluded when the final product is the shucked adductor muscle only). 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 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 FDA entered into a Memorandum of Understanding (MOU) (see <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/OtherMOUs/ucm118388.htm>) with the ISSC to accept assistance from state and local health authorities in the enforcement of laws to prevent and suppress communicable disease.

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)

On July 7, 1986, FDA and NMFS entered into an MOU (see <http://www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmous/domesticmous/ucm116369.htm>)

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 law or regulation of any state or any Indian tribal law.

### 4. FDA Responsibility

The FDA evaluates the programs of the participating state and foreign government (hereafter all references to "State" shall include countries with which FDA has an active shellfish MOU or other official FDA agreement) State Shellfish Control Authorities (SSCA). FDA also provides technical assistance to states and advises them on matters pertaining to the preservation and improvement of public health. FDA enters into MOUs or other official FDA agreements with sovereign nations meeting NSSP Model Ordinance (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

- Fulfill FDA responsibilities under the U.S. Public Health Service Act, and the Federal Food, Drug, and Cosmetic Act to prevent shellfish-related foodborne illness;
- Fulfill FDA responsibilities under the FDA/Interstate Shellfish Sanitation Conference (ISSC) MOU and FDA MOUs or other official FDA agreements with foreign countries by:
  - Promoting the uniform adoption and implementation of public health criteria, regulations, and procedures;
  - Providing training, research, and technical assistance; and
  - 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 SSCAs using a risk-based approach. This compliance program will focus on five specific state program elements: *Vibrio* control and management, growing area classification, plant processing and shipping, control of harvest, and laboratory evaluation. The compliance program includes a focused evaluation of state and industry efforts to control *Vibrios* in accordance with state *Vibrio vulnificus* and *Vibrio parahaemolyticus* management and control plans.

Activities in these areas of focus shall include the following:

- Give priority to shellfish-associated illness outbreaks;
- Conduct file reviews and field evaluations of growing areas, patrol areas, and processing and shipping firms selected randomly from the Interstate Certified Shellfish Shippers List (ICSSL);
- Determine the compliance status of the state Plant Processing and Shipping Element using the evaluation criteria in ATTACHMENT G;
- Determine the compliance status of the Control of Harvest Element using the evaluation criteria in the *Guide for Preparing Control of Harvest Program Element Evaluation Reports* (ATTACHMENT I);
- 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* Plans, and c) state enforcement of *Vibrio* Plan requirements; and
- Conduct standardization and maintenance of State Shellfish Standardization Officers (SSO).

The evaluation of these state program elements will be achieved by utilizing procedures described within this compliance program.

Shellfish Specialists shall give top priority to shellfish-borne illnesses and outbreaks as soon as they are reported. In the event of such outbreaks, Shellfish Specialists shall inform the Senior Emergency Response Coordinator (SERC) and the Shellfish and Aquaculture Policy Branch (SAPB) in CFSAN. Illness outbreaks shall be coordinated among FDA personnel and offices as set forth in the Coordinated Outbreak Response and Evaluation Network Standard Operating Procedure.

<http://inside.fda.gov:9003/downloads/CFSAN/CORE/UCM396111.doc>

### 2. Program Management Instructions

#### A. General

FDA's Office of Regulatory Affairs (ORA) management has primary responsibility for the implementation and effectiveness of program operations performed under this compliance program.

## B. Planning Activities

(1) It is imperative that FDA program evaluations and technical assistance be planned in cooperation with state program officials. FDA personnel should meet frequently with state program officials to mutually:

- Plan a schedule for evaluating program elements; and
- Plan any FDA assistance needed to help avoid program deficiencies and correct those deficiencies identified.

The evaluation of individual program elements is the mechanism FDA uses to determine and document program compliance. These evaluations identify program elements, or portions of program elements, that do not meet NSSP Model Ordinance requirements, and they provide the information necessary to determine overall compliance with the NSSP.

(2) Shellfish Specialists will develop and coordinate activities with state program officials to include: joint work schedules to complement the state work plan to conduct FDA - state field evaluations and standardization activities, and technical assistance. The choice of format for the joint work schedule is at the discretion of ORA management and should be reviewed by the FDA OSCP Branch Director

To address state program needs and to accomplish the NSSP goals and objectives, ORA management will have the flexibility to change priorities listed on the joint work schedules from one program element to another to: follow-up on illness outbreak investigations, assist with recalls, and provide technical assistance and training.

## C. FDA District Activities

The Shellfish Specialist is the principal individual who will accomplish the work in this compliance program. Any questions about this program are to be referred to the Shellfish Specialist or OSCP Branch Director. In non-ISSC participating states, Districts cover these products using Compliance Program 7303.842. Shellfish Specialists shall give top priority to shellfish-borne illnesses and outbreaks. All participating states are listed on the Interstate Certified Shellfish Shippers List (ICSSL).

<http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006753.htm>

## D. Scheduling International Program Evaluations

International Shellfish Program Evaluations, see ATTACHMENT D, shall be scheduled on an "as needed" basis by SAPB to ensure that internationally recognized shellfish producing countries that ship to the US under an existing agreement, or countries that wish to enter into an agreement, are producing shellfish that is safe for human consumption. As outlined in ATTACHMENT D, SAPB will coordinate with OSCP Branch Director and Shellfish Specialists to assign Shellfish Specialists to carry out international shellfish program evaluations.



## PART III - OPERATIONS

Specific program activities appear below in this section. Activities are subject to modification based on changing program needs. Should modifications occur, Shellfish Specialists and the Office of Compliance, Field Programs Branch, HFS-615 will receive notification via memorandum from the SAPB, HFS-325.

### 1. General

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

### 2. Operation Descriptions

- A. Program Evaluations
- B. Standardization
- C. Training and Conferences
- D. Technical Assistance
- E. FDA Shellfish Steering Committee

#### A. Program Evaluation

The purpose of the FDA program evaluation process is to assess compliance with all NSSP Model Ordinance criteria for each program element.

The Shellfish Specialist shall develop a two-year evaluation schedule for the Growing Area Classification Element and a two-year evaluation schedule for the Control of Harvest Element to meet the frequency requirements determined using the risk assessment described in Part III of this compliance program. The schedule, along with a copy of

ATTACHMENT H, shall be sent to the SAPB (HFS-325) for review. While it is anticipated that the risk category will not change from year-to-year, the Shellfish Specialist shall annually review the state's risk category assignments.

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

#### (1) Growing Area Classification Element

The Growing Area Classification Element will be evaluated by the Shellfish Specialist at a frequency determined by a risk assessment. 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. Totaling the points assigned for each risk factor will determine the frequency of evaluation for the Growing Area Classification Element. 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 years. States that have a high risk for the illness outbreak factor will be evaluated by the Shellfish Specialists annually regardless of the state's overall risk rating.

Shellfish Specialists will work with the SSCA, where appropriate, to either assign a point value or review a prior point value for each risk factor within the growing area classification element for their states and determine the overall program element risk level and, thereby, the frequency of evaluation of this element. Complete ATTACHMENT H, the Risk Assessment Form (RAF) for each NSSP participating state and submit to SAPB (HFS-325) for concurrence.

Three risk factors have been identified for shellfish growing area classification. They are:

- (a) Production
- (b) Classification Complexity
- (c) Illness Outbreaks

(a) Production:

Assign the following point value based upon the commercial harvest (in pounds) of the following shell stock 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 SSCA to determine the state's production data as required by the NSSP Model Ordinance Chapter II.@.03.B.

<http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.htm>

Production data shall be based on the average of the most recent three years. Annual production may be based on NMFS Commercial Fisheries Landings Data site <http://www.st.nmfs.noaa.gov/commercial-fisheries/index> or state's landing data. After 2019, landing data will only be based on state's reporting as required by the NSSP.

High Risk Factor (4)	>4,700,000 lbs
Medium High Risk Factor (3)	>2,000,000 - 4,700,000 lbs
Medium Low Risk Factor (2)	≥1,000,000 – 2,000,000 lbs
Low Risk Factor (1)	< 1,000,000 lbs

(b) Classification Complexity:

Assign the following point value based upon the growing area classification complexity within the state:

High Risk Factor (4) =	Approved, Restricted, Prohibited, and > 20% of the state's total number of growing areas have a Conditionally Approved or Conditionally Restricted classification.
Medium High Risk Factor (3) =	Approved, Restricted, Prohibited, and < 20% of the state's total number of growing areas have a Conditionally Approved or Conditionally Restricted classification.
Medium Low Risk Factor (2) =	Approved, Restricted, and Prohibited only
Low Risk Factor (1) =	Approved and Prohibited only

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

Assign the following point value based upon the occurrence of illness outbreaks associated with shellfish from a growing area in the state being assessed.

High Risk Factor (3) =	2 or more outbreaks in past 5 years
Medium Risk Factor (2) =	1 outbreak in past 5 years
Low Risk Factor (0) =	No outbreaks in past 5 years

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

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 consecutive years may request in writing to the FDA OSCP Branch Director that 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.

Conduct file reviews and field evaluations of growing areas selected randomly from a list of all growing areas in the state. The number of growing areas to be evaluated shall be based upon a representative sampling plan (ATTACHMENT E) designed to provide a 95 percent probability of detecting a 20 percent or greater defect level. The Shellfish Specialist will consult with Laboratory Evaluation Officer (LEO) to ensure the laboratory method used by the state for shellfish growing water classification is appropriate, and that the data values reported by the state are within the limits of the testing method used. The Shellfish Specialist will consult with the LEO regarding test method, utilization of data, and classification method.

(2) Plant Processing and Shipping Element

All states shall have the shellfish Plant Processing and Shipping Element evaluated every two years. States that are on an action plan or that have outstanding nonconformities shall have a follow-up review conducted during the non-evaluation year. The frequency of the Plant and Shipping Element evaluation shall not be reduced for any reason.

The Shellfish Specialist conducts file reviews and field evaluations of shellfish processors selected randomly from those listed in the Interstate Certified Shellfish Shippers List (ICCSL) to ensure that the requirements of the NSSP are fulfilled. The number of processors to be evaluated shall be based upon a representative sampling plan (ATTACHMENT E) designed to provide a 95 percent probability of detecting a 20 percent or greater defect level. The ratio should be based upon the certification type of plants within that State's inventory (i.e. if 50% of plants are Shucker Packers, then 50% of the plants selected for evaluation should be Shucker Packers).

Complete ATTACHMENT F – Objectionable Conditions Cited by Plant and include the attachment in the Program Element Evaluation Report (PEER). ATTACHMENT F should provide an overview of the individual plant deficiencies found during the evaluation. The column identified as "code" contains the critical, key, and other (swing) code deficiency indicators. Where an "other" or "swing" deficiency is noted, the final result should be included in the "code result" column.

Determine the compliance status of the state Plant Processing and Shipping Element using the ISSC evaluation criteria (ATTACHMENT G, State Inspection Program Evaluation Criteria).

(3) Control of Harvest (Patrol)

The Shellfish Specialist will work with the SSCA to assign a risk category (high or low) for the Control of Harvest Element for their states based upon MO chapter VIII risk assessment criteria and thereby, the frequency of evaluation of this element.

Ranking of the state Control of Harvest Element will be as follows:

- High Risk = one or more of the state's total patrol areas has a NSSP risk category ranking of high and/or greater than or equal to 20% of the state's total number of patrol areas have a NSSP risk category ranking of medium;
- Low Risk = none of the state's patrol areas have a NSSP risk category ranking of high and < 20% of the state's patrol areas have a NSSP risk category ranking of medium).

The Shellfish Specialist will work with the SSCA to assign a risk category (high or low) for the Control of Harvest Element for their states based upon MO chapter VIII risk assessment criteria and thereby, the frequency of evaluation of this element.

States in the high risk category for this program element must be evaluated yearly. States in the low risk category must have this program element evaluated at least every second year. The frequency of the Control of Harvest Element evaluation shall not be reduced for any reason.

Control of Harvest 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).

Conduct file reviews and field evaluations of patrol areas selected randomly from a list of all patrol areas in the state to ensure that the requirements of the NSSP are fulfilled. The number of patrol areas shall be based upon a representative sampling plan (ATTACHMENT E) designed to provide a 95 percent probability of detecting a 20 percent or greater defect level. Control of Harvest evaluations is to be conducted in accordance with the Guide for Preparing Control of Harvest PEERs (see ATTACHMENT I.)

(4) *Vibrio vulnificus* and *Vibrio parahaemolyticus*:

Shellfish Specialists shall evaluate and report annually the compliance of states required to have a *Vibrio vulnificus* Control Plan and/or a *Vibrio parahaemolyticus* Control Plan. States who have implemented a voluntary Vibrio Control Plan will be evaluated every 2<sup>nd</sup> or 3<sup>rd</sup> year as determined to be adequate by the Shellfish Specialist in consultation with the OSCP Branch Director. The CFSAN Vibrio Policy Subject Matter Expert (SME) and SAPB Branch Chief (HFS-325) will be notified of the newly agreed upon deadline.

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 "State Vibrio Control Plan/Implementation Evaluation Worksheet" (see ATTACHMENT J.)

The Worksheet, which is intended to serve only as a guide for consideration during an evaluation, and not as a stand-alone report, should be used in combination with the report reference outline "Points of Consideration When Writing the Vibrio Program Element Evaluation Reports"(see ATTACHMENT K) to develop a comprehensive state Vibrio PEER.

The Vibrio Element Evaluation report (PEER) shall be a stand-alone report, independent of other program element reports.

(5) Laboratory Evaluation:

Laboratory evaluations are conducted by FDA Shellfish Laboratory Evaluation Officers (FDA Shellfish LEOs) triennially either onsite or under certain circumstances by comprehensive desk audit. FDA 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 FDA Shellfish LEOs will coordinate the scheduling of onsite evaluations with the Shellfish Specialist and appropriate laboratory officials.

If budget and schedules permit, the Shellfish Specialist should accompany the FDA Shellfish LEO during onsite evaluations to become familiar with laboratory personnel, laboratory procedures, and overall laboratory operation. While it is preferable for the Shellfish Specialist to be present for the entire onsite evaluation, it may not always be possible.

The Shellfish Specialist should make every effort to be available if not in person then telephonically for the closeout meeting of onsite evaluations. Finding of conformance is based on the criteria established in the NSSP Guide. Evaluation findings and recommendations are discussed with laboratory officials at the closeout meeting. In the event a laboratory is found out of conformance, the Shellfish Specialist will be notified immediately by telephone or email at the conclusion of the close out meeting if he/she is not in attendance. A report of the findings, written in indelible ink, is provided to the laboratory at the conclusion of the closeout meeting and serves as the formal record of the evaluation. This report covers any nonconformities noted, the corrections required and the timeframe for corrections and any recommendations made. A narrative report, including the checklist and recommendations presented to the laboratory at the closeout meeting, should be completed and forwarded to the Shellfish Specialist, the OSCP Branch Director and the Shellfish and Aquaculture Policy Branch Chief within 30 days of completion of the laboratory evaluation. In the event the FDA Shellfish LEO cannot meet report deadlines, the LEO shall discuss this as soon as possible with their Team Lead and Branch Chief. The Shellfish Specialist and the OSCP Branch Director will be notified of the newly agreed upon deadline. After completion of all corrective actions, a notification letter of upgraded status will be issued to the laboratory within 14 days with a copy to the Shellfish Specialist, the OSCP Branch Director, and the Shellfish and Aquaculture Policy Branch Chief. The narrative report can be summarized and/or excerpted by the Shellfish Specialist for inclusion in the APER as appropriate.

The Shellfish Specialist will be informed of the status of the laboratory when not present at the evaluation or the evaluation closeout. If nonconformities are noted in the evaluation, the FDA Shellfish LEO is responsible for monitoring the progress of these corrections and keeping the Shellfish Specialist informed on progress of corrective actions. The Shellfish LEO may call upon the Shellfish Specialist for assistance when corrections are not made or are incomplete. The Shellfish Specialist is responsible for informing the FDA 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. For domestic evaluations conducted by desk audit, the Shellfish Specialist will be provided with a copy of the findings in a short narrative with summary of nonconformities found during the desk audit. These findings can be included in the APER as appropriate. The Shellfish Specialist will be informed of the laboratory's status based on the results of the desk audit. If problems are noted in the desk audit, the FDA Shellfish LEO is responsible for monitoring the progress of corrections and may call upon the Shellfish Specialist for assistance when corrections are not implemented or are incomplete.

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. While it is preferable for the Shellfish Specialist to be present for the entire evaluation it may not always be possible. However, the Shellfish Specialist is encouraged to be available if not in person then telephonically for the closeout meeting of the evaluation.

A separate report of the evaluation findings is prepared by the FDA Shellfish LEO and a copy provided to the Shellfish Specialist. This report can be summarized and/or excerpted for inclusion in the APER as appropriate. The FDA Shellfish LEO and Shellfish Specialist will be informed of the status of the laboratory when not present for the evaluation. If nonconformities are noted in the evaluations, the State Shellfish LEO is responsible for monitoring the progress of these corrections and may seek assistance from the Shellfish Specialist through the FDA Shellfish LEO when corrections are not implemented or are incomplete.

NSSP Laboratories will participate in appropriate Proficiency Testing and if applicable, laboratory corrective action plans will be reviewed during triennial evaluation for any poor, questionable, or unsatisfactory performance identified.

(6) 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. A well-documented description of the objectionable conditions found and corrective actions taken by the state should be provided. The PEER should describe all evaluation activities undertaken to determine compliance and how these activities were conducted. The PEER shall be written as a stand-alone document in accordance with ATTACHMENT A for all elements except Control of Harvest and ATTACHMENT I for the Control of Harvest Element.

The PEER shall be prepared within 30 calendar days after completion of the program element evaluation. It is not necessary to cite or discuss the statutory authority for conducting state evaluations. The state shall be given 30 calendar days to respond to the PEER before it is finalized. The Shellfish Specialist shall respond to the state's response within 15 calendar days after receipt. The final report is to be submitted to DSS/SAPB, National Shellfish Standard by no later than January 31.

Transmittal Cover Letter

The cover letter accompanying the PEER shall have a summary paragraph describing the overall status of the state program including major findings, recommendations, accomplishments, and a request for the correction of deficiencies. The letter should acknowledge participation by state officials during the evaluation.

Note: The cover letter for PEERs requires the signature of the OSCP Branch Director and must be addressed to the shellfish program manager of the department(s) in which the shellfish program element(s) is located.

Content of Report:

Prepare the body of the report following the outline in ATTACHMENT A for all elements except Control of Harvest and ATTACHMENT I for the Control of Harvest Element.

Each PEER shall have the following major sections:

i. Status of Previous Program Evaluation.

Provide a summary of each deficiency identified in the FDA's previous evaluation report. Include a short description of how previous deficiencies were corrected and when.

ii. Total Number of Growing Areas, Plants, and Patrol Areas Evaluated.

Provide the total number of growing areas, plants, and patrol areas that exist in each state's program and the number of these as well as other segments of the program that were evaluated. Also report the total number of file reviews conducted.

Shellfish Specialists shall provide a detailed description of what was covered during the evaluation of each program element.

iii. Current Findings

Provide a description of findings with respect to each applicable NSSP Model Ordinance requirement. Provide recognition of compliance, discussion of how compliance was verified, statements recognizing sound management practices, and examples of program effectiveness as warranted.

When deficiencies are noted, the specific NSSP Model Ordinance reference for each deficiency should be included in the narrative. It is recommended that supporting documentation or evidence (e.g., photographs) specific to the deficiencies be submitted with the report.

iv. Corrective Action Taken by the State

The Shellfish Specialist shall discuss any corrective action (not requiring a formal action plan) taken by the state during the evaluation. Action taken by the state to correct deficiencies during the evaluation or immediately thereafter shall be recognized as evidence of compliance with NSSP requirements and no additional follow-up will be required.

v. Formal Action Plan

The Shellfish Specialist shall request an Action Plan for correcting program deficiencies not corrected during the evaluation. The Plan shall consist of a written response from the state to the Shellfish Specialist acknowledging the evaluation finding(s) and describing the measures to be taken to correct the deficiencies with completion date(s). The Shellfish Specialist is responsible for monitoring all Action Plans and reporting the progress and/or outcomes to ORA and SAPB management.

vi. State Program Accomplishments

The state should be acknowledged for maintaining program components at an acceptable level of compliance.

vii. New or Emerging Problems

Provide information on any new or emerging program practice(s) or deficiency(ies) that may impact public health and require additional program resources or specific action by state officials.

viii. Technical Assistance and/or Training Requested by the State

If the state needs special technical assistance or training from FDA, it should be reported here.

ix. Summary of the State's Response to FDA Evaluation (If applicable)

If the state responds to an FDA evaluation before a PEER is completed, the Shellfish Specialist shall summarize the state's response in this section.

x. Conclusions

Formulating conclusions about the adequacy of the state's shellfish sanitation program and its compliance with the NSSP from the information gathered during an evaluation is an important aspect of the Shellfish Specialist's responsibilities. At the conclusion of the evaluation the Shellfish Specialist shall identify any deficiencies to senior state officials.

xi. Recommendations

At the conclusion of each evaluation, the Shellfish Specialist shall discuss recommendations to improve the state's shellfish sanitation program in a close-out session with senior state officials. Those recommendations should be documented in this section. Recommendations related to NSSP deficiencies should be clearly identified so that they are addressed by the state.

CFSAN Review of the PEER

The PEER is to be reviewed by SAPB within 30 calendar days after SAPB receives the final copy that has been issued to the State. PEERs shall be reviewed to ensure consistency in its content, completeness of reporting and level of conformance determination. It is important that program element evaluations reported in PEERs be objective, deficiencies and recommendations are well documented, and the report is consistent with the format in ATTACHMENT A or ATTACHMENT I depending on the element being reported.

Any discrepancies, questions or concerns regarding a PEER shall be transmitted to the OSCP Branch Director and the Shellfish Specialist responsible for the report. The Shellfish Specialist shall submit a response to the SAPB within 15 calendar days after receipt. All PEERs go through ORA management review prior to final submission to CFSAN.

(b) Annual Program Evaluation Report (APER):

The purpose of the APER is intended to provide an executive summary annual status of the entire state program to the state agency, ORA management and CFSAN personnel. This report should include information on progress made by the state to correct any deficiencies found during the state program element evaluation. It should be concise and



to the point with reference to the PEERs. The APER should clearly indicate the state's compliance at the end of the evaluation year (December 31).

The Shellfish Specialist shall send the APER to the state for review no later than January 1. Provide the state 15 calendar days to respond and finalize the report and submit it to DSS/SAPB, National Shellfish Standard by no later than March 1. All APERs go through ORA management review prior to final submission to CFSAN.

Content of Report:

Prepare the body of the report following the outline in ATTACHMENT C. The Shellfish Specialist has the flexibility to include additional subheadings when necessary.

Each APER shall have the following major sections:

- i. Overall Program Status (by program element)  
Describe the overall status of the state's program, including laboratories.
- ii. Status of Deficiencies Currently Identified While Conducting Program Element Evaluation  
Include information on progress made by the state to correct any deficiencies found during the state program element evaluation.
- iii. Specific Information on Illnesses, Outbreaks, and/or Recalls  
Provide detailed information on any illnesses, outbreaks, or recalls that involved shellfish products in interstate commerce.
- iv. State Program Accomplishments  
Include information on improvements in the state's program and acknowledge the state for maintaining program components in compliance.
- v. New or Emerging Findings  
Provide information on any new or emerging program deficiency(ies) that may impact on public health and require additional program resources or specific action by state officials.
- vi. Unresolved Issues  
Provide a detailed description of any circumstances that may result in an NSSP unresolved issue.

Please Note: The APER should be reviewed by the OSCP Branch Director. The cover letter for APERs requires the signature of the Director, Office of State Cooperative Programs. and must be addressed to the commissioner(s) or the equivalent of the department(s) in which the shellfish program element(s) is located.

(c) International Program Evaluation Report (IPER):

Shellfish Specialists participating in International program evaluations shall work directly with the CFSAN representative who participated in the international program evaluation. When a CFSAN representative is not part to the international program evaluation team the Shellfish Specialist shall work through their OSCP Branch Director in submitting reports to CFSAN.

Any concerns from CFSAN on work products shall be communicated to the OSCP Branch Director.

Transmittal Cover Letter

The cover letter accompanying the IPER shall have a summary paragraph describing the overall status of the country's program including major findings, recommendations, accomplishments, and a request for the correction of deficiencies. The letter should acknowledge participation by the country's officials during the evaluation.

The IPER shall follow the outline in ATTACHMENT B and be submitted to SAPB (HFS-324) within 45 calendar days of completion of the trip. SAPB shall send a draft to the country for review within 30 calendar days. The country will have 21 calendar days to respond with comments. 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.

B. Standardization

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

Shellfish Specialists shall perform standardization of state personnel in accordance with the NSSP Model Ordinance, 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 Shellfish Plant Standardization Officers.

Shellfish Specialists shall conduct standardization and maintenance inspections as needed.

C. Training and Meetings

(1) Training Courses

The Office of Regulatory Affairs (ORA), Office of Training Education and Development (OTED) will send its Annual Training Needs Survey to the State Shellfish Control Authorities and the OSCP Branch Director in the second quarter. The Shellfish Specialist should assist the states annually in determining training needs and priorities. During the second quarter, state program officials shall be advised by the Shellfish Specialist of the opportunity to request FDA training courses. Training requests are submitted to their OSCP Branch Director or designee for prioritization of all training needs in the State Cooperative Programs (Shellfish, Milk & Retail Food) and forwarded to OTED.

Near the end of the 3rd Quarter, OTED conducts its annual planning meeting for all training courses for the next fiscal year. The draft OTED training schedule is submitted to the OSCP Branch Director, Field Food Committee and Steering Committees for final review and comment.

OTED courses are developed and delivered in conjunction with the Shellfish Specialists and the Center for Food Safety and Applied Nutrition's (CFSAN), Office of Food Safety, Division of

Seafood Safety, Shellfish and Aquaculture Policy Branch (HFS-325). Once scheduled, the Shellfish Specialists, in cooperation with OTED, shall finalize the course agenda (based on participants' qualifications), training location, dates, and participants.

(2) Shellfish Sanitation Training Seminars or Meetings

Shellfish Sanitation Training Seminars or Meetings provide an opportunity for FDA and state shellfish program officials including State Standardization Officials to participate in discussions of the latest science in food safety, interpretations of the model ordinance, information exchange and problem solving. Shellfish Specialists are required to attend this annual training unless an exemption has been approved by the OSCP Branch Director. This includes Shellfish Sanitation Training Seminars or meetings as well as Program Manager Meetings. These training meetings are required for Level II State Cooperative Programs Investigator's Certification.

(3) National Conferences

Participation at the ISSC is critical to success of the implementation of the NSSP. The Shellfish Specialist and OSCP Branch Directors are required to attend and actively participate at the meeting of the ISSC. The ISSC meeting is held to:

- (a) Discuss administrative and technical problems and solutions;
- (b) Recommend NSSP program changes; and
- (c) Review scientific and technical developments.

The Shellfish Specialist's role is to actively participate in the ISSC meeting and present FDA's position at committee and Task Force deliberations. The Center for Food Safety and Applied Nutrition (CFSAN) is responsible for program policy development. Proposals for submission to the ISSC, prepared by the Shellfish Specialists, shall be submitted to SAPB, HFS-325.

D. Technical Assistance

The Shellfish Specialist may provide technical assistance to the states as requested. Requests for technical assistance that exceed the capabilities of the geographic staff shall be submitted to SAPB by the Shellfish Specialist on behalf of the State.

E. Uniformity and Collaboration

(1) National Shellfish Team

The National Shellfish Team (NST) includes all the shellfish specialists, OSCP, SAPB staff, OTED, OP, SSC, and Gulf Coast Seafood Lab personnel who address molluscan shellfish sanitation. There are times when all FDA shellfish components collaborate and work on a variety of projects.

(2) Shellfish Steering Committee

The Shellfish Steering Committee (SSC) is the forum for discussion and resolution of shellfish program criteria, policy and implementation issues and serves as the primary liaison vehicle with the Shellfish Specialists Team and CFSAN personnel. The Steering Committee provides for coordination and guidance among the various FDA components having employees involved with ensuring shellfish safety (e.g. CFSAN/OFS, ORA Shellfish Specialists, ORA Office of State Cooperative Programs Office Director and Branch Directors, ORA/OP, and ORA/OTED).

Two Shellfish Specialists serve as representatives on the National Shellfish Steering Committee and function as ORA Shellfish Specialist team leaders.

(3) Shellfish Specialist Team

The Shellfish Specialist Team (SST) is the forum for discussion and resolution of shellfish program criteria and implementation issues and serves as the primary liaison vehicle with all of the Shellfish Specialists and OSCP Representative(s). The SST provides for coordination and guidance among the various FDA Shellfish Specialists with a OSCP representative(s) involved with ensuring shellfish safety (e.g. CFSAN/OFS, ORA Shellfish Specialists, ORA OSCP Branch Directors, ORA/OP, and ORA/OTED).

Two Shellfish Specialists are nominated to serve as representatives on the Shellfish Steering Committee for two-year terms.

**PART IV – ANALYTICAL**

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

## PART V - REGULATORY/ADMINISTRATIVE STRATEGY

### 1. Imminent Health Hazard

In the event a state fails to take appropriate action and there appears to be an imminent hazard to health, the Shellfish Specialist in consultation with the OSCP and SAPB, shall notify the 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

(a) 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.

(b) 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 NSSP contains procedures for achieving compliance when an FDA evaluation identifies program deficiencies with criteria contained in the NSSP Model Ordinance,  
<http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.htm>.

#### GENERAL INSTRUCTIONS AND ADMINISTRATIVE CRITERIA FOR NON-CONFORMING STATE PROGRAM ELEMENTS

If, in an evaluation, the Shellfish Specialist finds any element of a state program in non-conformance with the NSSP, the Shellfish Specialist shall promptly apprise the OSCP Branch Director of the situation. The OSCP Branch Director will consult with SAPB (HFS-325) to determine appropriate action.

During the close-out meeting with the state program officials, the Shellfish Specialist shall explain any program deficiencies found during the evaluation. Within 30 calendar days of completion of the evaluation, the Shellfish Specialist shall provide to the state and the SAPB a copy of the PEER.

The state should investigate the program element deficiencies and provide a written response to the Shellfish Specialist within 30 calendar days of receipt of the PEER indicating:

- How the items were corrected;
- An action plan with a completion date; or
- If the state does not concur with FDA's findings, the reasons for non-concurrence; and
- If corrective action is taken (during the evaluation) or an Action Plan is developed and implemented (pursuant to the PEER); the item shall be considered corrected or adequately addressed.

The elements of an acceptable Action Plan are as follows:

- The program deficiency(ies) is/are described in detail;
- Specific measures to be taken to correct the program deficiency(ies); and
- The program deficiency(ies) is/are assigned a date for correction.

The development period for the state Action Plan SHALL NOT EXCEED 30 CALENDAR DAYS after receipt of the PEER.

All corrective Action Plans shall be scheduled for completion within 180 calendar days of receipt of the PEER. Where deemed appropriate, exceptions to the 180 calendar days may be granted. Failure to develop an Action Plan shall result in initiation of the procedures for an unresolved issue as set forth in the ISSC Constitution, By-Laws and Procedures at [www.issc.org](http://www.issc.org). The Shellfish Specialist shall meet with state program officials and confer with CFSAN during the development of the Action Plan to ensure that it provides sufficient detail and is acceptable to FDA. The Shellfish Specialist shall be responsible for monitoring the progress of the state action plan in consultation with their OSCP Branch Director.

The Shellfish Specialist shall review the documents submitted by the SSCA and respond to the state within 15 calendar days in conjunction with their OSCP Branch Director.

If the state fails to implement the Action Plan to correct all deficiencies or if consensus with FDA's findings is not reached, the Shellfish Specialist, in consultation with the OSCP Branch Director and SAPB, shall consider appropriate actions 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 Model Ordinance.) and/or
- De-listing shippers from the ICSSL in accordance with the ISSC Constitution, By-Laws, and Procedures (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. Violation of the FD&C Act

FDA depends upon the participating states to carry out shellfish program responsibilities on a voluntary basis; however, FDA is responsible for shellfish products shipped in interstate commerce. Therefore, when potentially violative conditions are encountered and the state control agency has been contacted, but is unable or unwilling to take corrective measures, the Shellfish Specialist after consultation with their OSCP Branch Director, will advise the appropriate Division Director to initiate an appropriate investigational and regulatory follow-up. This may include FDA inspection, sampling, analysis, seizure, injunction and or prosecution. 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. Shellfish Specialists should follow the recall instructions provided in Part II of this compliance program.

#### B. The Lacey Act

The Lacey Act prohibits the illegal transport, export, import, sale, and purchase of shellfish violating United States 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 division office compliance branch will decide the appropriate regulatory action with regard to tagging violations, e.g., the PHS Act, the FD&C Act, the Lacey Act, or a combination thereof. With regard to the Lacey Act, the FDA division office compliance branch can obtain assistance by contacting the National Marine Fisheries Service (NMFS), Office of Law Enforcement, 1315 East-West Highway, Ste 3301, Silver Spring, MD 20910, (301) 427-2300,

[http://www.nmfs.noaa.gov/ole/compliance\\_assistance/who\\_to\\_call.html](http://www.nmfs.noaa.gov/ole/compliance_assistance/who_to_call.html).

#### 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/ucm2006753.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 state shellfish control authority for additional regulatory follow-up at the State level. Furthermore, any violations of the National Shellfish Sanitation Program (NSSP) Model Ordinance

<http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.htm>

should be reported to the Compliance Branch Director and Shellfish Specialist. The Shellfish Specialist should report any discrepancy/violation to the State shellfish control authority for additional regulatory follow-up at the State level.

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 State Shellfish Control Authority where the shipment was offered for entry should coordinate throughout the regulatory process. Also see Section B below.

##### 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 shellfish control 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 FDA to act under Section 801 (a) of the Act.

1. FDA staff will take the following steps when molluscan shellfish is offered for import from an uncertified shipper and there is sufficient 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



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Request (DTR) to the Compliance Branch (CB) following the normal detention and hearing process for violative articles under 801(a).

2. FDA staff 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 (HFS-325) and CFSAN, Office of Compliance, Division of Enforcement contacts (see Part VI). \*Note: while the State is the Shellfish Control Authority, they do not have the capability of knowing shipments from uncertified dealers have been released into interstate commerce without notification from 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, ATTACHMENTS, AND PROGRAM CONTACTS

### 1. References

National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

Recommended Procedures for the Examination of Sea Water and Shellfish, 4th Edition, 1970, American Public Health Association, New York, NY.

Constitution, By-Laws, and Procedures of the Interstate Shellfish Sanitation Conference. Available online at the Interstate Shellfish Sanitation Conference web site: [www.issc.org](http://www.issc.org)

Memorandum of Understanding between FDA and the Interstate Shellfish Sanitation Conference (ISSC): <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/OtherMOUs/ucm118388.htm>

Bilateral agreements between FDA and Sovereign Nations Certifying Imports under the NSSP MO. 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, HFS-325 (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 <http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006753>

Memorandum of Understanding between FDA and the National Marine Fisheries Service (NMFS); see <http://www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmous/domesticmous/ucm116369.htm>

Investigations Operations Manual (IOM), 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

#### A. Center for Food Safety and Applied Nutrition Contacts:

Compliance Program General Information: Teja Patel, (240) 402-2339, Office of Compliance, Division of Field Programs and Guidance, Program Assignment Monitoring Branch, (HFS-615)

Regulatory Guidance: Millie Benjamin, Office of Compliance, Division of Enforcement, Food Adulteration Assessment Branch, HFS-607 (240) 402-1424

Technical Assistance and Training: Floyd "Raymond" Burditt, (240) 402-1562, FAX (301) 436-2601, Office of Food Safety, Division of Seafood Safety, Shellfish and Aquaculture Policy Branch, (HFS-325), Main # (240) 402-2300, HFS-325  
<http://inside.fda.gov:9003/CFSAN/OfficeofFoodSafety/ucm013415.htm>

Policy: Melissa Abbott, (240) 402-1401, FAX (301) 436-2601, Office of Food Safety, Division of Seafood Safety, Shellfish and Aquaculture Policy Branch, Main # (240) 402-2300, HFS-325  
<http://inside.fda.gov:9003/CFSAN/OfficeofFoodSafety/ucm013415.htm>

#### B. Office of Regulatory Affairs (ORA) Contacts

Shellfish Sanitation Program Specialist: Michael Antee, FDA Puget Sound resident Post, 1000 Second Ave, Ste 2400, Seattle WA 98104, (206) 340-8215, Cell (W) (206) 715-3481, FAX: (206)

553-7020, [michael.antee@fda.hhs.gov](mailto:michael.antee@fda.hhs.gov), HFR-PA36 Office of Partnerships, Standards Implementation Staff <http://inside.fda.gov:9003/ORA/Federal-StateRelations/default.htm>

Investigational Contact: Eric S. Pittman, Acting Director, Division of Food and Feed Program Operations and Inspections, Office of Food and Feed Operations, ORA HQ, 550 W. Jackson, 15<sup>th</sup> Floor, Rm 1651, Chicago, IL 60661, (T) 312.596.4259 HFR-CE650

Imports Contacts:

Lisa Elrand, Import Operations and Maintenance Branch, Division of Import Operations, Office of Enforcement and Import Operations, ORA HQ, (T) 425.302.0415 HFR-PA340.

John Sakowski, Import Operations and Maintenance Branch, Division of Import Operations, Office of Enforcement and Import Operations, ORA HQ, (T) 301.796.8969

Training for FDA/State Personnel: Brent W. Higgs, (881) 321-5694 Ext. 1109, FAX (801) 524-3188, Midland Commerce Center, 2090 N. Redwood Rd., Salt Lake City, UT 84116, Division of Human Resource Development HFR-SW2520  
<http://inside.fda.gov:9003/ORA/OfficeofResourceManagement/DivisionofHumanResourceDevelopment/default.htm>

ORA Office of State Cooperative Programs Branch Directors and list of Shellfish Specialists:  
<https://www.accessdata.fda.gov/scripts/shellfish/sh/shellfish.cfm>

**Shellfish Sanitation Branch I**

Ms. Laurie Farmer, Director, Shellfish Sanitation Branch I  
Office of State Cooperative Programs  
DHHS/PHS/FDA  
60 Eighth St., NE  
Atlanta, GA 30309  
(404) 253-1175  
(FAX) (404) 253-2257  
[laurie.farmer@fda.hhs.gov](mailto:laurie.farmer@fda.hhs.gov)

**Shellfish Sanitation Branch II**

Mr. Luis A. Solorzano, Director, Shellfish Sanitation Branch II  
Office of State Cooperative Programs  
DHHS/PHS/FDA  
1431 Harbor Bay Parkway  
Alameda, CA 94502  
(510) 337-6832  
Cell: (510) 455-1431  
[luis.solorzano@fda.hhs.gov](mailto:luis.solorzano@fda.hhs.gov)

3. **Attachments**

- A. PROGRAM ELEMENT EVALUATION REPORT (PEER)
- B. INTERNATIONAL PROGRAM EVALUATION REPORT (IPER)
- C. ANNUAL PROGRAM EVALUATION REPORT (APER)

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- D. INTERNATIONAL SHELLFISH PROGRAM EVALUATION PROTOCOL
  - E. NUMBER OF UNITS NECESSARY TO ACHIEVE A 95% PROBABILITY OF DETECTING A GREATER THAN OR EQUAL DEFECT LEVEL OF 20%
  - F. OBJECTIONABLE CONDITIONS CITED BY PLANT
  - G. STATE INSPECTION PROGRAM EVALUATION CRITERIA
  - H. RISK ASSESSMENT FORM (RAF)
  - I. GUIDE FOR PREPARING CONTROL OF HARVEST PEER
  - J. STATE VIBRIO CONTROL PLAN/IMPLEMENTATION EVALUATION WORKSHEET
  - K. POINTS FOR CONSIDERATION WHEN WRITING VIBRIO EVALUATION REPORTS
  - L. ANNUAL EVALUATION SCHEDULE

## PART VII - CENTER RESPONSIBILITIES

### 1. **Liaison with the Interstition Shellfish Sanitation Conference (ISSC)**

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 will identify FDA Shellfish Specialists to serve as advisors on various ISSC task forces and committees.

### 2. **International Programs**

SAPB will be responsible for providing copies of previous evaluation reports, action plans, and copies of any correspondence between FDA and the country's shellfish control authorities to the Shellfish Specialist.

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 forward the itinerary to the Shellfish Specialist and the country's shellfish control authorities. SAPB shall arrange a conference call with the Shellfish Specialist a month prior to the start of the trip to address the elements to be evaluated.

The laboratory activities of international programs shall be audited by the SAPB LEO who will prepare a laboratory evaluation report. The report shall be submitted to the country's shellfish control authority within 90 calendar days of completion of the laboratory audit.

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

### 3. **Technical Assistance**

FDA provides technical assistance and training on program elements. Technical assistance to the field and states will be provided upon request in collaboration with ORA. CFSAN may request ORA Shellfish Specialists to assist in their specific areas of technical expertise. This may require Shellfish Specialists to be detailed to other geographic areas.

### 4. **State Program Evaluation Review**

SAPB is responsible for compiling inspectional information from the state program evaluations conducted by the Shellfish Specialists.

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. **Compliance Program Evaluation**

During the course of this compliance program, but no later than 60 calendar days after final data receipt, SAPB will identify any deficiencies in the conduct of the field operations or program evaluation quality so that any necessary corrective action may be initiated and will provide feedback to ORA management.

### 6. **Publication of the NSSP Guide for the Control of Molluscan Shellfish**

OFS, in conjunction with the ISSC, is responsible for updating and making the Guide 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 SSCAs will receive confirmation via email when a shipper in their state has been certified and added to the ICSSL.

#### 8. **Laboratory Evaluation**

SAPB is responsible for conducting laboratory evaluations, training, certification/ recertification/ decertification 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. This report is provided to the Shellfish Specialist and OSCP Branch Director and will be summarized and/or excerpted for inclusion in the APER by the Shellfish Specialist as appropriate. The Shellfish Specialist is informed of the status of the laboratory when not present for the evaluation or evaluation closeout. FDA (SAPB) 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. **FDA Shellfish Steering Committee**

The Shellfish Steering Committee is the forum for discussion and resolution of shellfish program criteria, policy and implementation issues and serves as the primary liaison vehicle with the Shellfish Specialists Team, OSCO Director and Branch Directors and CFSAN personnel. The Steering Committee provides for coordination and guidance among the various FDA components in shellfish safety (e.g. CFSAN/OFS, ORA Shellfish Specialists, ORA OSCP Director and Branch Directors, ORA/OP, and ORA/DHRD).

#### 10. **Vibrio Assistance Review Board**

FDA receives numerous requests throughout the year from states, industry, and other stakeholders to provide training, technical assistance, and research on Vibrios. In the past, requests were made via official and unofficial channels, and FDA has made every attempt possible to accommodate all requests for assistance. The Vibrio Assistance Review Board (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 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 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 VARB members must be present in order 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 Branch Director and VARB liaison, of the outcome (generally within four 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 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.

**ATTACHMENT A – Program Element Evaluation Report (PEER)**

## PROGRAM ELEMENT EVALUATION REPORT (PEER)

STATE: \_\_\_\_\_

DATE OF EVALUATION: \_\_\_\_\_ SHELLFISH SPECIALIST: \_\_\_\_\_

PROGRAM ELEMENT EVALUATED: \_\_\_\_\_  
(Submit within 30 calendar days of completion of the program element evaluation)**A. Status of Previous Program Evaluation**

- Summary of deficiencies
- State action(s) to correct deficiencies
- Present status
- Status of any official Action Plan(s)
- FDA follow-up (if any) regarding deficiencies and/or Action Plan(s)

**B. Status of Current Evaluation****1. Total Number of Growing Areas, Plants, and Patrol Areas Evaluated****2. Current Findings**

- Include discussion of all NSSP administrative requirements for the element evaluated
- Provide a detailed description of deficiencies found during evaluation (deficiencies must be documented)

 Document any FDA follow-up needed to address deficiencies**3. Corrective Actions Taken by the State (document any Non-Action Plan corrections taken by the state)****4. Action Plan If an official (developed by state and FDA) Action Plan is needed, document the Action Plan here, include milestone activities and completion dates)****5. State Program Accomplishments (program accomplishments noted by states and/or observed by the Shellfish Specialist)****6. New or Emerging Problems.****7. Technical Assistance and/or Training Requested by the State****8. Summary of the State's Response to FDA Evaluation. (if applicable)****9. Conclusion (discuss State's program compliance with NSSP guidelines)****10. FDA Recommendations (if applicable)**



**ATTACHMENT B – International Program Evaluation Report (IPER)**

INTERNATIONAL PROGRAM EVALUATION REPORT (IPER)  
SHELLFISH SPECIALIST: \_\_\_\_\_

COUNTRY: \_\_\_\_\_ DATE OF EVALUATION: \_\_\_\_\_

PROGRAM ELEMENT(S) EVALUATED: \_\_\_\_\_  
(Submit within 45 calendar days upon return to the United States).

**A. Summary of Previous Program Evaluation by Element**

- Summary of deficiencies
- Summarize Country's action(s) to correct deficiencies cited
- Present status of deficiencies
- Status of any official Action Plan(s)
- FDA follow-up conducted regarding deficiencies and/or Action Plan(s)

**B. Status of current evaluation**

1. Program Elements and/or Areas Evaluated Including Total Number of Growing Areas, Plants, and Patrol Areas Evaluated
2. Current Evaluation Findings
  - Summarize NSSP Model Ordinance administrative requirements in compliance
  - Provide detail description of deficiencies found during evaluation (deficiencies must be documented)
  - Document Non-Action Plan activities undertaken by the country to correct deficiencies.
  - Document any official Action Plan(s) developed by the Country and approved by FDA (include milestone activities and completion dates).
  - Present status of each program element (level of compliance and official Action Plan progress/completion)
  - Document any FDA follow-up needed to address deficiencies/Action Plan(s)
3. Summarize all joint meetings with Country officials concerning the evaluation and action plan
4. Country's accomplishments
5. Special projects, training programs, and technical assistance requested by the Country
6. New emerging issues
7. Summary of the Country's response to the FDA evaluation and exit interview
8. Conclusions
9. Recommendations

**ATTACHMENT C – Annual Program Evaluation Report (APER)**

## ANNUAL PROGRAM EVALUATION REPORT (APER)

SHELLFISH SPECIALIST: \_\_\_\_\_  
STATE \_\_\_\_\_

- A. Overall program status (by program element).
- B. Status of deficiencies identified during current year program element evaluations:
- Present status of deficiencies
  - Status of any Action Plan(s)
  - Discuss any FDA follow-up on deficiencies conducted after completion of the element evaluation and the PEER.
- C. Provide **detailed** information concerning illness, outbreaks and/or recalls.
- D. State program accomplishments (summarize any other state accomplishment not cited in the PEER).
- E. New or emerging problems (summarize any new/emerging problems that arose after completion of the element evaluation)
- F. Unresolved issues (document fully – NSSP Model Ordinance citations, issues in dispute, FDA expectations for resolution, etc.)

## **ATTACHMENT D – International Shellfish Program Evaluation Protocol**

### **INTERNATIONAL SHELLFISH PROGRAM EVALUATION PROTOCOL**

#### **International requests for FDA evaluation:**

1. The planning process for international evaluations should begin at least one year prior to the planned evaluation. As soon as evaluation plans begin, notification should be sent to OIP, IAS, OP, and OSCP Branch Directors.
2. Office of Food Safety, Division of Seafood Safety (DSS), Shellfish and Aquaculture Policy Branch (SAPB) submits letter to MOU or other official FDA agreement country requesting "letter of invitation" for FDA to conduct a program evaluation. SAPB will instruct country to send "letter of invitation" to OFS/DSS.
3. MOU or other official FDA agreement country forwards "letter of invitation" to DSS.
4. SAPB coordinates with OIP, IAS, and OSCP Branch Director regarding travel arrangements and funding for selected specialists (see section below).
5. Assessments of non-MOU countries and urgently needed assessments of MOU countries, which are not planned in advance, may require scheduling with little advance notice. In these cases, the planning and selection process may be expedited or revised.

#### **Personnel Selection/Assignment for International Travel:**

1. SAPB issues a "Call for Nomination for International Evaluation" with suggestions regarding appropriate Shellfish Specialists to OSCP Branch Directors.
2. OSCP Branch Directors will submit Shellfish Specialist nominations to SAPB.
3. OSCP Branch Directors in consultation with SAPB will select Shellfish Specialists from nominees to conduct international evaluations. Consideration will be given to:
  - a. Completion of domestic work,
  - b. International evaluation consistency, and
  - c. Introduction of Specialist into the international program evaluation process.
4. OSCP Branch Directors confirm with SAPB the selection of Specialists for each assignment. At this time, SAPB provides the assigned Specialists and their OSCP Branch Directors with the planned time frame for the evaluation and any special circumstances for which the Specialist may be required to prepare.

#### **Pre-trip briefing with Shellfish Specialist:**

1. Prior to each international trip, a pre-trip briefing will be conducted with the Specialist.
  - a. SAPB will coordinate the briefing.
  - b. SAPB and the Specialist must participate. OSCP Branch Directors will be informed.
  - c. SAPB will provide a copy of the country's previous evaluation to the Specialist.
  - d. Briefings will be conducted no later than one month prior to the scheduled trip.
2. Briefings will address:
  - a. Evaluation coverage.
  - b. Identification of evaluation team leader (if multiple FDA participates).
  - c. Previous evaluation findings/follow-up.
  - d. Close out meeting with foreign officials, including list of nonconformities.

**Draft Evaluation report:**

1. The Specialist will write and submit draft evaluation report to SAPB no later than 45 days following completion of the trip.

**CFSAN-SAPB review of draft evaluation report:**

1. SAPB will review the Specialist's draft evaluation report.
2. SAPB will compile and forward written comments to the Specialist no later than 3 weeks after receiving the Specialist's draft report.

**Final evaluation report:**

1. The Specialist will finalize the report based on comments received, from SAPB, if any.
2. The Specialist will draft the evaluation report transmittal letter for SAPB signature. The transmittal letter shall:
  - a. List significant program deficiencies.
  - b. Request a corrective action plan outlining specific goals and milestone dates for correcting each program deficiency.
  - c. Establish the date by which the country must respond in writing to the evaluation report.
  - d. The Specialist will forward the final draft report and draft transmittal letter to SAPB no later than 3 weeks following receipt of comments from SAPB.
3. SAPB shall send a final draft evaluation report to the country for review within 30 calendar days.
4. The country will have 21 calendar days to respond with comments.

**Transmittal of evaluation report:**

1. Within 45 calendar days of receiving comments on the final draft evaluation report from the country, SAPB will:
  - a. Address any comments on the final draft evaluation with the Specialist.
  - b. Send the final evaluation report and transmittal letter to the foreign country.
  - c. Send a copy of the transmittal letter and the final evaluation report) to the Specialist.

**Review of foreign country's written response to final evaluation report:**

1. Within 1 week of receipt by SAPB, SAPB shall provide the Specialist with a copy of the country's written response to the evaluation report.
2. Within 3 weeks of receipt by the Specialist, the Specialist shall:
  - a. Review and evaluate the country's written response.
  - b. Draft a letter of response back to the country for SAPB signature.
3. SAPB shall finalize and send the written response to the country within 2 weeks of receiving the draft response from the Specialist.

- 
4. If the country does not respond within the specified time or the response is inadequate, SAFB/OFS/ORAs Shellfish Specialist shall conference to determine a course of action. SAPB will coordinate the conference.

**Laboratory Evaluation:**

1. SAPB submits letter to MOU or other official FDA agreement country requesting "letter of invitation" for FDA to conduct a laboratory program evaluation. SAPB will instruct country to send "letter of invitation" to OFS/DSS.
2. MOU or other official FDA agreement country sends "letter of invitation" to DSS.
3. SAPB and the FDA LEO will be responsible for coordinating and conducting laboratory evaluations.
5. Laboratory evaluations will be conducted on an as needed basis.
6. Following a laboratory evaluation the FDA LEO shall:
  - Write the laboratory evaluation report and transmittal letter.
7. SAPB will transmit final report within 90 calendar days of completion of the laboratory audit.

**Review of foreign country's written response to laboratory evaluation report:**

1. Within 3 weeks of receipt of the country's written response to the laboratory evaluation SAPB shall:
  - a. Review and evaluate the response.
  - b. Write a letter of response back to the country.
2. If the country does not respond within the specified time or the response is inadequate, SAPB shall determine an appropriate course of action.

**ATTACHMENT E – Number of Units Necessary to Achieve 95% Probability****Number of Units Necessary to Achieve a 95% Probability  
of Detecting a Greater than or  
Equal Defect Level of 20%**

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

## ATTACHMENT F – Objectionable Conditions Cited by Plant

### Objectionable Conditions Cited by Plant (Number of Inspection Checklist Violations by Firm Type)

Item	Model Ordinance Reference	Description	Code	#	Violative Firms			
					SP _ firms	SS _ firms	RS _ firms	RP _ firms
<b>1. HACCP Plan</b>								
HACCP Plan	X.01.B	Presence of a HACCP Plan	C					
<b>2. Plan Elements</b>								
2(a).	X.01.C(1)	Hazards Identified and Adequate	O					
2(b).	X.01.C(6)	Records Identified and Adequate	O					
2(c).	X.01.C(3)	Critical Limits Identified and Adequate	K					
2(d).	X.01.D(2)(c)	Name, Address, Signed and Dated	O					
2(e).	X.01.C(2)	Critical Control Points Identified	K					
2(f).	X.01.C(4)	Monitoring identified and Adequate	K					
2(g).	X.01.C(7)	Verification Procedures and Adequate	O					
2(h).	X.01.C(5)	Corrective Actions (if identified)	K					
<b>3. HACCP Training (Yes/No) X.01.I</b>			O					
<b>4. Plan Implementation</b>								
4(a).	X.01.B	Receiving	K/O					
4(b).	X.01.B	Shellstock Storage	K/O					
4(c).	X.01.B	Processing	K/O					
4(d).	X.01.B	Shucked Meat Storage	K/O					
4(e).	X.01.B	Other Critical Limits	K/O					
5.	XI - XIV.01.A	Approved Source Control Failure	C					
6.	XI-XVI.01.B &C	Time/Temperature Control Failure	C					
7.	NA	Other Critical Control Failure	C					
<b>Sanitation Items</b>								
8.	.02.A	Safety of water for processing and ice production	K/O					
9.	.02.B	Condition and cleanliness of food contact surfaces	K/O					
10.	.02.C	Prevention of cross-contamination	C/K/O					
11.	.02.D	Maintenance of hand-washing, hand sanitizing, and toilet facilities	C/K/O					
12.	.02.E	Protection from adulterants	C/K/O					
13.	.02.F	Proper labeling, storage, and use of toxic compounds	K					
14.	.02.G	Control of employees with adverse health conditions	K					
15.	.02.H	Exclusion of pests	K					
16.	.02.A.B	Sanitation Monitoring and Records	K					
<b>Additional Model Ordinance Requirements</b>								
17.	.03.A	Plants and Grounds	C/K/O					
18.	.03.B	Plumbing and related facilities	C/K					
19.	.03.C	Utilities	C/K					
20.	.03.D	Disposal of other waste	O					
21.	.03.E	Equipment condition and cleaning, maintenance, and construction of non-food contact surfaces	O					
22.	.03.F	Shellfish storage and handling	K/O					

23.	.03.G	Heat shock	K					
24.	.03.H.K	Supervision	K					
25.	IX.	Transportation (To include only the person shipping)	K					
26.	X.05, 06, and 07	Labeling and Tagging	K/O					
27.	X. and 03	Shipping Documents and Records/Written Recall	K					

C=Critical; K=Key;

O=Other

RP=Repacker; SP=Shucker Packer; RS=Reshipper; SS=Shellstock Shipper; DP=Depuration Processor



**ATTACHMENT G – State Inspection Program Evaluation Criteria****STATE INSPECTION PROGRAM EVALUATION CRITERIA****I. Plant Evaluation Criteria****1. Legal Authority**

The Plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the requirements listed in Chapter I @ .01 and @ 02. [Critical]

**2. Initial Certification-Chapter I @ 02 B**

The Plant Sanitation Element will be deemed in compliance with this requirement when all plants are certified in accordance with criteria listed below:

**a. HACCP requirements:**

- (i) A HACCP plan accepted by the Authority;
- (ii) No critical deficiencies;
- (iii) Not more than 2 key deficiencies;
- (iv) Not more than 2 other deficiencies

**b. Sanitation and additional Model Ordinance Requirements:**

- (i) No critical deficiencies;
- (ii) Not more than 2 key deficiencies;
- (iii) Not more than 3 other deficiencies.

**3. Inspection frequency - Chapter I @ 02 F and G**

The Plant Sanitation Element will be deemed in compliance with this requirement when no more than one plant inspected doesn't meet the required inspection frequency.

**4. Compliance schedules**

If a plant has deficiencies the SSCA places them on a compliance or re-inspection schedule. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated are found to be without schedules.

**5. Follow-up**

The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that they have performed proper follow-up for compliance schedules for 90% of dealers evaluated and if the compliance schedules were not met that administrative action was taken.

**6. Deficiency Follow-up**

The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that all critical deficiencies have been addressed.

**7. In-Field Plant Criteria**

The in-field Plant Sanitation Element will be deemed in compliance with this requirement when the plant meets the following criteria:

- a. Shucker/packers and repackers
  - (i) HACCP requirements:
    - (a) A HACCP plan accepted by the Authority;
    - (b) No critical deficiencies;
    - (c) Not more than 4 key deficiencies;
  - (ii) Sanitation and additional Model Ordinance Requirements:
    - (a) No critical deficiencies;
    - (b) Not more than 4 key deficiencies;
- b. Shellstock shippers and reshippers
  - (i) HACCP requirements:
    - (a) A HACCP plan accepted by the Authority;
    - (b) No critical deficiencies;
    - (c) Not more than 3 key deficiencies;
  - (ii) Sanitation and additional Model Ordinance Requirements:
    - (a) No critical deficiencies;
    - (b) Not more than 3 key deficiencies;

II. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria:

- a. Conformance: The program is in compliance with all of the criteria listed above.
- b. Conformance with Deficiencies: The program is in compliance with I.1., I.2., I.3., I.4., I.5., I.6 and has 25% or less of plants with deficiencies associated with I.7.
- c. Non-Conformance: The program is in compliance with I.1., but, does not meet the criteria in I.2., or I.3 or I.4 or I.5 or I.6 has greater than 25% (but less than 51%) of plants with deficiencies associated with I.7.
- d. Major Non-Conformance: The program has multiple deficiencies. It is non-compliant with I.1, or 2 or more of I.2 or I.3 or I.4 or I.5 or I.6 or 51% or greater of plants with deficiencies associated with I.7.



**ATTACHMENT H – Risk Assessment Form****RISK ASSESSMENT FORM**

STATE: \_\_\_\_\_ DATE OF RATING: \_\_\_\_\_

SHELLFISH SPECIALIST: \_\_\_\_\_ STATE OFFICIAL: \_\_\_\_\_

**A. GROWING AREA CLASSIFICATION ELEMENT**

RISK FACTORS	SCORE (0-4)	RATING (H,MH,M,ML,L)	EXPLAIN RATING
PRODUCTION			
CLASSIFICATION COMPLEXITY			
ILLNESS OUTBREAKS			
	TOTAL	OVERALL RISK (H OR L)	

COMMENTS:

**B. CONTROL OF HARVEST**

RISK FACTORS	NUMBER		
PATROL AREAS IN MO HIGH RISK CATEGORY	≥ 1	0	
	-and/or-	-and-	
PATROL AREAS IN MO MEDIUM RISK CATEGORY	≥ 20 %	< 20 %	
	OVERALL RISK (check one)		EXPLAIN RATING
	HIGH	LOW	

COMMENTS:

**ATTACHMENT I – Guide for Control of Harvest (Patrol) PEERs***Guide for Preparing Control of Harvest (Patrol) PEERs*

CY [year]  
PROGRAM ELEMENT  
EVALUATION REPORT

OF  
THE

CONTROL OF HARVEST  
ELEMENT [CONTROL  
AUTHORITY NAME(S)]  
[PATROL AGENCY NAME]  
STATE OF  
[STATE]

PREPARED  
BY

[SPECIALIST NAME]  
SHELLFISH SPECIALIST  
[FIELD OFFICE]  
FOOD AND DRUG  
ADMINISTRATION

ON

[report completion date]

**PROGRAM ELEMENT EVALUATION REPORT**

STATE:

DATES OF EVALUATION:

PROGRAM ELEMENT EVALUATED: Control of Harvest

**A. Status of Previous Program Evaluation (General information to include, but not limited to)**

1. Provide a summary of the findings from the previous PEER. Summarize any deficiencies cited during previous evaluation. List them.
2. Provide a summary of any actions(s) taken by the program as a result of deficiencies reported in the PEER.
3. Status of Action Plan(s) specifically requested in the PEER to correct program deficiencies, and FDA follow-up (if any) regarding deficiencies and/or Action Plan(s).
4. Status of Program Element prior to current evaluation.

**B. Status of Current Evaluation**

1. Description of Responsibilities

(NOTE: The Control of Harvest Element includes requirements for patrol, harvester licensing, legal penalties, and harvesters)

- a. Identify each of the agencies involved in control of harvest and briefly describe their responsibilities. Include a description of any significant changes to the organization or responsibilities of the Program since the last evaluation.
- b. Describe if and how agency responsibilities are divided up by region/district/county/etc. and the relevant delegation of authorities.
- c. Describe how the program conducts its patrols including the types of vehicles used (boat, land vehicle, aircraft, etc.).
- d. Describe responsibilities of harvesters as required by State Program.

## 2. Total Number of Patrol/Harvest Areas Evaluated

- a. The number of areas evaluated shall be consistent with CP ATTACHMENT E requirements
- b. Table 1: Patrol/Harvest areas evaluated

Patrol Area Evaluated	Classification(s)	Risk Category

## 3. Program Areas in Compliance

a. Provide an overview of how the program evaluation was conducted to determine the Program's level of compliance with NSSP requirements. Describe those activities that were part of the evaluation (e.g., review of NSSP MO requirements; review of regulations; accompanied marine patrol officer on a shellfish patrol; review the Patrol Policy Document; review patrol records to determine if patrol frequency was met; review educational materials given to harvesters; inspect harvest vessels)

b. Describe compliance with the following NSSP requirements for Patrol:

- (1) Legal penalties – Are the laws and penalties sufficient to deter illegal harvest?  
Provide brief discussion of the penalties [Critical]

**Compliance Criteria:** The patrol element will be deemed in compliance if laws and regulations exist that provide penalties for controlling harvest from areas of restricted harvest.

- (2) Notification of areas of restricted harvest - Is the industry notified of the boundaries of areas of restricted harvest? [Critical]

**Compliance Criteria:** The patrol element will be deemed in compliance with this requirement when the appropriate State Authority demonstrates that the industry has been notified of the boundaries.

- (3) Comprehensive listing of all areas of restricted harvest – Does the Patrol Agency have

a comprehensive listing of areas of restricted harvest? [Critical]

**Compliance Criteria:** The patrol element will be deemed in compliance with this requirement when it is determined that the State Authority has a comprehensive listing of all areas of restricted harvest.

(4) Patrol Policy Document –Does the patrol agency have a Patrol Policy Document?  
[Key]

**Compliance Criteria:** The patrol element will be deemed in compliance with this requirement when the State Authority provides a patrol policy document.

(5) Patrol Policy Document updated – Is the Patrol Policy Document current and updated annually? [Key]

**Compliance Criteria:** The patrol element will be deemed in compliance with this requirement when it is determined that the patrol policy document includes all items in Chapter VIII. @.01 B. (Part I of the Patrol Document Specification table below) and the patrol policy document is updated every calendar year.

(6) NSSP patrol training requirements – Has the marine patrol agency met the NSSP patrol training requirements [Key]? Briefly describe the training provided

**Compliance Criteria:** The patrol element will be deemed in compliance with this requirement when the Patrol Agency can demonstrate that all officers have met or are scheduled for the training requirements of Chapter VIII. @.01 B.(6) before assuming their patrol duties.

(7) Growing area patrol – Has the agency determined risk categories for all areas of restricted harvest? [Critical]

**Compliance Criteria:** The patrol element will be deemed in compliance with this requirement when the State Authority assigns risk categories for each harvest restricted area and provides a listing of those categories.

(8) NSSP patrol frequency – Has the patrol frequency requirement been met in all areas evaluated? Describe how this requirement was evaluated [Critical/Key]

**Compliance Criteria:** The patrol element will be deemed in compliance as follows:

- (i) When the State Authority achieved 95-100 percent of required patrols in all harvest restricted areas the program is considered to be in conformance with NSSP patrol frequency requirements.
- (ii) When the State Authority achieved 80 – 94 percent of required patrols in all harvest restricted areas the program is considered to be in non-conformance with NSSP patrol frequency requirements. **[Key]**
- (iii) When the State Authority achieved <80 percent of required patrols in all harvest restricted areas the program is considered to be in major non-conformance with NSSP patrol frequency requirements. **[Critical]**

(9) Formalized MOA/MOU – If enforcement of shellfish regulations is shared with another agency(s), is there a formalized MOA/MOU with the other agency(s)?  
[Key]

**Compliance Criteria:** The patrol element will be deemed in compliance when the authority has developed a Memorandum of Understanding/Agreement with all Authorities which have delegated patrol responsibilities.





(i) Patrol unit name, address & phone number;	
(ii) The roster and chain of command;	
(iii) Area assignments that support the frequencies of patrol delineated in B.(2)[of MO]; and	
(iv) A listing of specific vessels, vehicles & equipment that support the frequencies of patrol delineated in B. (2).	
(d) Summaries of training in shellfish patrol techniques;	
(e) The methods used to inform officers of growing area classifications and status, and of any special activities licensed in the area;	
(f) A listing of growing areas where patrol is required;	
(g) An identification of any patrol problems;	
(h) The type & frequency of reporting by patrol personnel;	
(i) Copy of agreements with other agencies responsible for shellfish patrol activities;	
(j) Citations/summonses for the past year. If available, this information may include:	
(i) The number of convictions or dismissals;	
(ii) Fines in dollar amount;	
(iii) Equipment or property confiscations and forfeitures;	
(iv) License suspensions or revocations;	
(v) Jail sentences; and	
(vi) Written warnings.	
Part II: The remaining items in B.3.d. represent ancillary information (AI) that although not specifically required, could provide important information for evaluating B.3.d. (a) – (j).	
Resources Used to Meet Required Patrol Frequencies:	
(a) Vessels: Number & type suitable and adequate to support the minimum patrol frequency for each area:	
(i) shallow draft needs	
(ii) open water/adverse weather	

(iii) rocky bottom	
(iv) wetland/marsh area	
(v) ocean	
(vi) barrier island	
(b) Aircraft: Number & type suitable and adequate to support the minimum patrol frequency for each area:	
(i) wheeled	
(ii) seaplanes	
(iii) helicopters	
(iv) access to plane & pilot (i.e. affiliated with another patrol unit or another agency)	
(v) need for coordination with vessels for apprehension, especially with wheeled planes	
(c) Vehicles: Number & type suitable and adequate to support the minimum patrol frequency for each area:	
(i) vessel towing capabilities	
(ii) number of vehicles (size and type)	
(iii) number of vehicles out of service	
<b>Other Types of Transportation Used to Conduct Patrols:</b>	
- all terrain vehicle (ATV)	
- motorcycles	
- jet skis (Personal water craft)	
<b>Vision Enhancement Equipment: Number &amp; Type Used to Support the Minimum Patrol Frequency for Each Area:</b>	
- binoculars	
- spotting scopes	
- night vision	
- infrared vision equipment	
- radar	
- additional support equipment used (i.e. electronic devices that can be used to detect motion and alert the patrol officer of possible illegal activities)	
<b>Communication Equipment: Number &amp; type Used to Support the Minimum Patrol Frequency for Each Area:</b>	
- access to 24-hour dispatching	

- poor reception areas	
- number of portable radio units	
- number of cellular phones & area of coverage	
Classification of Radio Frequencies:	
- public access	
- undercover operations	
- scrambled frequencies	
Special Operations Equipment & Personnel: Number & Type Used to Support the Minimum Patrol Frequency for Each Area:	
(a) How used	
(b) Patrol officers: Number adequate to support the minimum patrol frequency:	
(i) Total unit active staff roster (Responsible for growing area patrols only)	
(ii) Total number of active field officers conducting patrols	
(iii) Other patrol responsibilities: fin fishing, lobstering & crabbing, waterfowl hunting, upland hunting, boating safety, search & rescue, etc.	
(iv) Other activities: administrative, court appearances, training courses, etc.	
Assistance from Other Enforcement Units:	
- Federal, i.e. USCG, NMFS	
- state, i.e. sister agencies or units in same state or agencies in other states	
- local, i.e. county or town marine police, shellfish wardens, bay constables	
- signed MOUs or interagency agreements:	

**e. Requirements for Harvesters**

- (1)** Evaluate harvester licensing; describe how harvesters are licensed (include agencies involved, how licenses are renewed, how often licenses have to be renewed, etc.) and

review the information provided which explains the public health risk associated with illegally harvesting shellstock in areas of restricted harvest; describe how this requirement was evaluated. [ @.01.A(3) & @.01.C]

- (2) Evaluate harvest vessels (proper construction, protection of shellstock, protection of shellstock culling and holding areas); describe how this requirement was evaluated. [.02.B]
- (3) Determine if human waste containers are present and properly used, and if education materials are provided; describe how this requirement was evaluated. [.02.C]
- (4) Determine if shellstock is properly washed; describe how this requirement was evaluated. [.02.D]
- (5) Determine if shellstock is properly identified with harvest tags and if harvest tags are being properly completed; describe how this requirement was evaluated. What was the disposition of any untagged or improperly tagged shellfish? [.02.E]
- (6) Determine if the harvesters are meeting the appropriate harvest time/temperature matrix; indicate which matrix is being used; describe how this requirement was evaluated. [.03]

#### 4. Current Findings of the Element Evaluation

- a. Describe the patrol period under review (calendar or fiscal year, etc.).
- b. Fully describe any deficiencies cited in sections 3.a., 3.b., 3.c., 3.d., and 3.e. (include NSSP MO references); if no deficiencies, then so state.
- c. Describe any required FDA follow-up (if required).

#### 5. Corrective actions taken by state in response to FDA findings

#### 6. FDA recommendations (if no recommendations, state that fact).

#### 7. Technical Comments (if applicable) (Describe informational items which have no direct impact on the program's compliance with NSSP requirements).

#### 8. Formal Action Plans

[Example] No formal corrective action plans have been requested. or  
[Example] A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) calendar days to demonstrate how the state will comply with the requirement to patrol closed shellfish growing areas. Per Chapter VIII@.01.B.2, closed shellfish growing waters shall be patrolled at the established frequency so as to deter illegal harvesting which would place the unsuspecting public at a greater risk of contracting a foodborne illness.

#### 9. State Program Accomplishments

#### 10. New or Emerging Problems

[Example] There were no new or emerging trends identified as a result of this evaluation.  
or

[Example] The review of the patrol effort [suggests that during unforeseen events such as extended training, illness or injury and state or national emergencies the minimum level of patrols

needed to adequately protect public health may not be performed. The [State] patrol efforts will be greatly enhanced by the hiring of additional officers to fill the current vacancies.

#### 11. Technical Assistance and/or Training Requested by the State

[Example] The [State] Patrol Program has not requested any additional assistance or training at this time.

*or*

[Example] The [State] has requested that the Specialist participate in the New Hire Training Course scheduled for the early part of 2016.

#### 12. Summary of the State's Response to the FDA Evaluation

#### 13. Conclusions (Describe program element's level of compliance)

The overall Patrol Program element will be assigned one of the following designations based on the compliance criteria listed above in B.3.b (1)

– (10):

- a. **Conformance:** The program is in compliance when all of the compliance criteria have been met.
- b. **Conformance with Deficiencies:** The program only has minor deficiencies associated with one key item.
- c. **Non-Conformance:** The program has:
  - (1) at least one (1) critical deficiency; or
  - (2) two (2) or more key deficiencies; or
  - (3) a repeat key deficiency from the previous evaluation.
- d. **Major Non-Conformance:** The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest in harvest restricted waters.

#### 14. Acknowledgements

## ATTACHMENT J – State Vibrio Control Plan/Implementation Evaluation Worksheet

STATE *VIBRIO* CONTROL PLAN/IMPLEMENTATION EVALUATION  
WORKSHEET

NSSP MO Requirement	NSSP MO Reference	Yes/ No	Comments (If Applicable)
<i>Vibrio vulnificus</i> Control Plan/Implementation:			
A. Annual assessment of <i>V. vulnificus</i> (Vv) illnesses, including a record of Vv shellfish related illnesses reported within and from receiving states, number of illnesses per event, actions taken in response to illnesses	II.@.03  and  II.@.06.E.(2)(a)		
B. Clearly defined written <i>V. vulnificus</i> (Vv) Control Plan	II.@.06.E II.@.06.B and C.		
C. Process for collecting standardized information for each Vv illness  Is state using COVIS form?			<i>Use of COVIS form or equivalent</i>
D. Control Plan identifies which of the following controls or equivalent controls are being implemented with the intent of achieving the MO risk per serving standards:	II.@.06.E.(1)(b)		

<p>1. Labeling all oysters “For Shucking by a Certified Dealer” when average monthly maximum water temp exceeds 70°F</p> <p>2. Subjecting all oysters intended for raw half shell market to a State approved PHP (with FDA concurrence) that reduces Vv levels to &lt;30 MPN/g when average monthly maximum water temp exceeds 70°F</p> <p>3. Reducing time of exposure to ambient air temperature prior to delivery to the initial dealer. State Vv plans will include time/temperature controls intended to minimize risk to NSSP MO levels</p> <p>4. Other equivalent controls that will reduce the risk to levels comparable to those in II.@.05.E(1)(b)(iii)</p>	<p>II.@.06.E.(1)(b)(i)</p> <p>II.@.06.E.(1)(b)(ii)</p> <p>II.@.06.E(1)(b)(iii)</p> <p>II.@.06.E.(1)(b)(iv)</p>		<p>MEETING RISK PER SERVING STANDARDS IS NOT A NSSP COMPLIANCE REQUIREMENT WHEN THE STATE MPLEMENTS CONTROLS BASED ON THE RISK CALCULATOR II.@.05.E.(2)(c).</p> <p>HOWEVER, THE STATE IS REQUIRED TO ESTABLISH TIME AND TEMPERATURE CONTROLS INTENDED TO REDUCE RISK TO NSSP LEVELS USING THE RISK CALCULATOR II.@.05.E.(1)(B)(iii)</p>
<p>E. State conducts annual risk per serving calculations</p>	<p>II.06.E(2)(a)(i)</p>		
<p>F. State risk per serving calculations indicate State control plan minimizes risk to NSSP intended levels for each of the three NSSP water temperature periods</p>	<p>II.06.E.(1)(b)(iii)</p>		<p>THIS IS INTENDED FOR INFORMATIONAL PURPOSES ONLY.</p> <p>MEETING RISK PER SERVING STANDARDS IS NOT A NSSP COMPLIANCE REQUIREMENT WHEN THE STATE MPLEMENTS CONTROLS BASED ON THE RISK CALCULATOR II.@.05.E.(2)(c).</p>

G. Risk per serving calculations shared with the ISSC	II.06.E(2)(d)		
H. Harvester compliance with state Vv Control Plan time and temperature requirements	VIII.02.G		<i>Checks can be made during harvester landing site visits and boat checks at landing and in growing areas at time of harvest.</i>
I. Harvesters maintain and provide records to initial dealer to document compliance with time to refrigeration requirements	VIII.02.G		<i>When possible conduct harvester/dealer records comparison.</i>
J. Dealer HACCP plans comply with state Vv control plan requirements	X.01.A, B, C		
K. Dealers maintain records to demonstrate compliance	X.01.H		
L. State laws and regulations provide adequate legal basis and authority to implement and manage Vv Control Plan and industry compliance	I.@.01.B.  and  I.@.02.H.(1)		
M. State takes action in accordance with NSSP MO requirements to address issues of Noncompliance	I.@.02.H.(2)  [Pertains to processors]		<i>Describe actions taken</i>
<b><i>Vibrio parahaemolyticus Control Plan/Implementation:</i></b>			
A. Annual assessment of V. parahaemolyticus (Vp) illnesses, including a record of Vp shellfish related illnesses reported within and from receiving states, number of illnesses per event, actions taken in response to illnesses	II.@.03		



B. Annual <i>Vp</i> risk evaluation (oysters/clams)	II.@.07.A.		
C. Risk evaluation considers the seven NSSP risk factors	II.@.07.A.(1)-(7)		<i>Describe which of the seven factors were used and how they were used to determine risk. Indicate reason why any of the seven factors were not used.</i>
D. State implemented <i>Vp</i> Control Plan when risk evaluation determines reasonably likely risk  OR:	II.@.07.B.(1)		
<p>State implemented <i>Vp</i> Control Plan when average monthly daytime water temperatures exceed those listed below:</p> <p>1. Waters bordering Pacific Ocean = 60°F</p> <p>2. Waters bordering Gulf of Mexico &amp; Atlantic Ocean (NJ &amp; south) = 81°F</p> <p>3. Waters bordering Atlantic Ocean (NY &amp; north) = 60°F</p>	<p>II.@.07.B.(2)</p> <p>II.@.07.B.(2)(a)</p> <p>II.@.07.B.(2)(b)</p> <p>II.@.07.B.(2)(c)</p>		

<p><b>E. Plan not necessary if State conducts a risk evaluation that determines it is not reasonably likely that Vp illnesses will occur from the area's oysters and/or clams</b></p> <p><b>If so: State evaluated area factors listed in II.A during times when temperatures exceed those in II.B.(2)</b></p> <p><b>State considered how factors listed in II.A differ from those in areas known as source of shellfish linked to Vp cases</b></p>	<p><b>II.@.07.B.(2)(d)</b></p> <p><b>II.@.07.B.(2)(c)(i)</b></p> <p><b>II.@.07.B.(2)(c)(ii)</b></p>		
<p><b>F. State developed and implemented Control Plan for areas linked to an outbreak within last 5 years</b></p>	<p><b>II.@.07.B.(3)</b></p>		

<p><b>G. Vp Control Plan includes the following:</b></p> <p><b>1. Triggers [temps in II.B.(2) or other triggers] for when control measures begin</b></p> <p><b>2. State implemented one or more of the following control measures when risk is reasonably likely to occur:</b></p> <p><b>i. PHP process validated to achieve a 2 log Vp reduction for the Gulf and Atlantic and a 3 log reduction for the Pacific</b></p> <p><b>ii. Close harvest area to oyster and/or clam harvest</b></p> <p><b>iii. Restrict oyster and/or clam harvest to product labeled “For Shucking Only” or other measure to address hazard</b></p> <p><b>iv. Limit time from harvest to refrigeration to ≤ 5 hrs (or other times based on modeling or sampling in consultation with FDA)</b></p> <p><b>v. Limit time from harvest to refrigeration such that levels after cooling to 60°F are no greater than 0.75 logs higher than average levels at harvest</b></p> <p><b>vi. Other control measures based on appropriate scientific studies designed to ensure that risk of Vp illness is not likely to occur</b></p>	<p><b>II.@.07.B.(4)</b></p> <p><b>II.@.07.B.(4)(a)</b></p> <p><b>II.@.07.B.(4)(b)</b></p> <p><b>II.@.07.B.(4)(b)(i)</b></p> <p><b>II.@.07.B.(4)(b)(ii)</b></p> <p><b>II.@.07.B.(4)(b)(iii)</b></p> <p><b>II.@.07.B.(4)(b)(iv)</b></p> <p><b>II.@.07.B.(4)(b)(v)</b></p> <p><b>II.@.07.B.(4)(b)(vi)</b></p>		<p><i>The intended purpose is to reduce Vp levels to those found at times of the year when Vp illness is not reasonably likely.</i></p>
<p><b>H. Dealers cool oysters to 50°F in 10 hours or less and HACCP plan includes controls to ensure, document, verify that internal temperature reaches 50°F</b></p>	<p><b>II.@.07.B.(4)(c)</b></p>		<p><i>Describe how State made this determination.</i></p>

I. State evaluated the effectiveness of the Control Plan	II.@.07.B.(4)(d)		<i>Describe how the State made this determination.</i>
J. State modifies Control Plan when evaluation shows Plan is ineffective or new information/technology is available that indicates Plan needs modification	II.@.07.B.(4)(e)		
K. Harvesters/processors maintain adequate records relative to time/temp requirements	VIII.@.02.E		<i>When possible conduct harvester/dealer records comparison.</i>
L. Harvesters maintain and provide records to initial dealer to document compliance with time to refrigeration requirements	VIII.02.G		<i>When possible conduct harvester/dealer records comparison.</i>
M. Dealer HACCP plans comply with state Vp control plan requirements	X.01.A, B, C		
N. Dealers maintain records to demonstrate compliance	X.01.H		
O. Strict implementation of NSSP mandatory control measures in response to sporadic illnesses (tiered response) including:  1. Information exchange, closure of area(s), recall, consumer advisories  2. Area closure for NSSP required period  3. Compliance with NSSP reopening criteria	II.@.02.A  II.@.02.A.(1)(2)(3)  II.@.02.A.(4)  II.@.02.A(5)		
P. State laws and regulations to provide adequate legal basis and authority to implement and manage Vp Control Plan	I.@.01.B.  and  I.@.02.H.(1)		

<p><b>Q. State takes action in accordance with NSSP MO requirements to address issues of non-compliance as determined by State or Fed</b></p>	<p><b>I.@.02.H.(2) [Pertains to processors]</b></p>		<p><i>Describe actions taken.</i></p>
<p><b>PHP Validation/Verification</b></p>			
<p><b>A. PHP processors are validated and approved by State with FDA concurrence to reduce pathogens in shellfish intended for the raw half shell market</b></p>	<p><b>XVI.A.(2)</b></p>		<p><i>Provide firm names and certification numbers and describe what PHP treatment is used (IQF, High Pressure, Cool Pasteurization, irradiation)</i></p>
<p><b>B. State maintains PHP validation studies in a central file available for review</b></p>	<p><b>I.@.01.C.</b></p>		
<p><b>C. Validated PHP firms have adequate HACCP plans that include:</b></p> <ol style="list-style-type: none"> <li><b>1. Process controls to ensure end product criteria are met for every lot</b></li> <li><b>2. A sampling program to periodically verify compliance with end point criteria</b></li> <li><b>3. Where verification sampling demonstrates failure of the validated process, reevaluation and revalidation conducted</b></li> </ol>	<p><b>XVI.A.(1)</b></p> <p><b>XVI.A.(1)(a)</b></p> <p><b>XVI.A.(1)(b)</b></p> <p><b>NSSP Guidance Documents, IV.02 Validation/ Verification Interim Guidance</b></p> <p><b>NSSP Guidance Documents, IV.02 Validation/ Verification Interim Guidance</b></p>		
<p><b>D. Of the validated PHP processors in the State, how many label finished product with approved safety added language?</b></p>	<p><b>N/A</b></p>		<p><i>Provide name and certification number.</i></p>

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<b>E. Of the validated PHP processors in the State, how many employ the PHP process but do not label with safety added language?</b>	<b>N/A</b>		<b>Provide number and explain why if possible.</b>
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## ATTACHMENT K – Points for Consideration when Writing The Vibrio Evaluation Reports

### Points for Consideration When Writing *Vibrio* Evaluation Reports

In addition to using the *State Vibrio Control Plan/Implementation Evaluation Worksheet* when conducting State *Vibrio* (*Vv* and *Vp*) evaluations, this outline is intended to provide a reference for developing the report details necessary for FDA to understand and report on implementation, enforcement and compliance of *Vibrio* control efforts by individual states and at the national level. All items may not be applicable to a given state. A detailed description of the objectionable conditions found and the corrective actions taken by the state should be well documented.

- 1) Status of Previous *Vibrio* Evaluation including but not limited to:
  - A. Summary of deficiencies
  - B. Actions taken to correct deficiencies
  - C. Status of Action plan if required
  
- 2) Status of Current *Vibrio* Evaluation
  - A. Names and roles of state agencies involved in *Vibrio* management.
  
  - B. Are laws, regulations and penalties in place to provide adequate legal basis, management and enforcement? Are penalties effectively applied to deter repeat violations by industry?
  
  - C. Has state conducted an annual assessment of *Vibrio* illnesses in strict accordance with NSSP-MO Chapter II@.03 requirements? What is the assessment result? Submit copy of state assessment with *Vibrio* PEER.
  
  - D. Does State *Vibrio* Control Plan meet NSSP-MO requirements? If not, explain. For states not implementing Control Plan has a risk evaluation been conducted in accordance with NSSP-MO Chapter II. @.06 and .07 requirements?
  
  - E. Briefly describe the mechanics of the State's *Vibrio* Control Plan. Submit a copy of the State Control Plan as an attachment to the *Vibrio* PEER.
  
  - F. Have changes/modifications been made to the State *Vibrio* Control Plan since the previous PEER? What precipitated the changes? Cite appropriate changes to state law or health code if applicable.
  
  - G. In field industry compliance review:
    - i. Were points of landing visited to verify compliance with required harvester records and time-temperature requirements? How many? Where applicable, were internal oyster and/or clam temperatures measured? Provide compliance results of landing site visits.
  
    - ii. Were processing plants, including PHP plants, visited? How many? Were records and labeling reviewed for verification and compliance with HACCP plans and NSSP-MO? Results of internal product temperature checks for compliance with HACCP/NSSP-MO? Provide compliance results of plant visits, including state actions where issues of non-compliance are encountered.
  
    - iii. What were the State activities for verifying industry compliance? What were the State's actions regarding industry noncompliance?
  
  - H. Is State basing time and temperature controls on FDA risk calculator? Is calculator being properly used?

I. For Gulf states, has the State conducted risk per serving calculations in accordance with Chapter II@.06E.(2)(b)(iii)(c) and (d)? Did the State inform ISSC of the results for purposes of evaluating trends? What control or combination of controls are in place to achieve the risk per serving standards (e.g. time-temperature, harvest closures, PHP, labeling for shucking, etc.)?

J. *Vibrio* illnesses/outbreaks

i. What are the numbers of illnesses and outbreaks for the most recent calendar year?

ii. Are illnesses increasing or decreasing relative to previous years? Explain. If increasing, is the State planning modification of *Vibrio* Control Plan?

iii. If outbreak was recall initiated? Performance of recall in accordance with NSSP-MO?

iv. Is CDC notified of illnesses and outbreaks as they occur? Is the State providing COVIS form to CDC for each illness? Is COVIS form complete? Does the State use a different reporting form? If yes, provide alternative form as an attachment to the *Vibrio* PEER.

v. Is product trace-back associated with illnesses/outbreaks effectively conducted? What are the impediments to effective trace-back?

vi. Is the State complying with *Vp* tiered controls as required in NSSP-MO Chapter II.@.02A?

vii. How does the occurrence of continuing sporadic illnesses effect changes to the State *Vibrio* Control Plan?

K. Does the State conduct additional follow-up inspection/investigation of firms linked to multiple illnesses to assess potential cause or determine persistent problem of noncompliance with State Control Plan.

L. Are there exemptions to State *Vibrio* Control Plan? Explain. Compliance with exemption requirements?

M. State program accomplishments and future goals.

N. New or emerging issues associated with *Vibrio* (e.g. *Vp* illnesses associated with clams).

O. Technical Assistance or Training Requested by the State.

P. Summary of the State responses to FDA Evaluation including corrective actions taken.

Q. Conclusions.

R. Recommendations and/or Request for Action Plan.

Provide details.

S. Attachments



