CHAPTER 18 – TECHNICAL ASSISTANCE

SUBJECT:	**IMPLEMENTATION DATE**
THE MOLLUSCAN SHELLFISH COMPLIANCE PROGRAM (FY 06/07) *This program has completed a Good Guidance Practices clearance by CFSAN's ORP and OC/DFP/CPB in July 0f 2006.*	9/5/06
	COMPLETION DATE 9/30/07

DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
For Evaluation 52B--04 16E[] [] []	18004 - Evaluations

Note: Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted; (&) denotes one or more paragraphs were deleted; and (%) denotes an entire attachment was deleted.

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). This compliance program covers evaluation of state and foreign shellfish programs and related technical assistance only * and is primarily intended for use by Regional Shellfish Specialist and those involved in making admissibility decisions of products covered by this compliance program.* 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).

FIELD REPORTING REQUIREMENTS

A. HARD COPY REPORTS TO HEADQUARTERS BY SHELLFISH SPECIALISTS

REPORTS	ATTACHMENT	DUE DATE [1]	SUBMIT REPORT TO:
Program Element Evaluation Report (PEER)	A	30 days after completion of evaluation	Shellfish Safety Team (SST), (HFS-628);
International Program Evaluation Report (IPER)	A-1	45 days after return to U.S.	SST (HFS-628); Office of Seafood(OS) (HFS-417)
Annual Program Evaluation Report (APER)	B	November 15	SST (HFS-628);
Risk Assessment Form (RAF)	G	* January 1 *	SST (HFS-628);

B. HARD COPY REPORTS TO STATES BY SHELLFISH SPECIALISTS

1. State/International Program Evaluation Report (Attachments A & A-1)

2. Annual Program Evaluation Report (Attachment B)

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.

Operation Code	Operation Description
83	Training Given by FDA Personnel
92	Coordination/Technical Assistance
95	Program Evaluation
96	Standardization of Non-FDA Personnel
95	Foreign Evaluation
13	Domestic Investigation

[1]In the event the Shellfish Specialist cannot meet report deadlines, the Specialist shall notify *the SST Shellfish Plant Standardization Officer (HFS-628)* to request additional time.

PART I – BACKGROUND

A. 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.

B. 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 FDA Federal Cooperative Agreements Manual, 1996 edition, pg. 4-17) 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.

C. National Marine Fisheries Service (NMFS)

On July 7, 1986, FDA and NMFS entered into an MOU (see FDA Federal Cooperative Agreements Manual, 1996 edition, pg. 4-4) 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.

D. 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) shellfish control authorities. 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 with sovereign nations meeting NSSP Model Ordinance (MO) criteria and conducts periodic program evaluations using the same criteria as those applied to State Shellfish Control Authorities (SSCA).

PART II - IMPLEMENTATION

A. OBJECTIVES

1. 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; and
- Fulfill FDA responsibilities under the FDA/Interstate Shellfish Sanitation Conference (ISSC) MOU and FDA MOUs 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.

2. 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 three specific state program elements: growing area classification,* plants * and shipping, and control of harvest. Activities in these program elements shall include, but not be limited to the following:

- 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 and shipping element using the evaluation criteria in Attachment F;
- Conduct standardization and maintenance of State Shellfish Standardization Officers (SSSO); and
- Give priority to shellfish-associated illness outbreaks.

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 Office of Seafood, the Division of Cooperative Programs, SST, and ORO, Emergency Operations Staff as new information becomes available. The Shellfish Specialists will serve as the focal point between FDA district offices and state authorities for coordination of state initiated recalls. The Shellfish Specialists will monitor the adequacy of the recall and will obtain information from the state authority consistent with FDA's Regulatory Procedures Manual, Chapter 7, Recalls, Attachment B (*Recommendation for Recall Classification*). Where the recall is determined to be inadequate, the Shellfish Specialist will work with the state authority, where practical, and with the FDA district office to ensure additional necessary actions occur.

B. PROGRAM MANAGEMENT INSTRUCTIONS

1. General

FDA regional management has primary responsibility for the implementation and effectiveness of program operations performed under this compliance program.

2. Planning Activities

a. 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 correct identified program deficiencies.

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 compliance with NSSP requirements.

b. 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 each Region and should be reviewed by the FDA Regional State Program Manager.

To address state program needs and to accomplish the NSSP program goals and objectives, the RFDD or the FDA Regional State Program Manager 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.

3. FDA District Activities

The Shellfish Specialist is the principal individual who will accomplish the work in this compliance program. District investigators who are trained by Shellfish Specialists may provide assistance.

* 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 Office of Seafood, the Division of Cooperative Programs, SST, ORO and Emergency Operations Staff as new information becomes available.

The Shellfish Specialists will serve as the focal point between FDA District Offices and state authorities for coordination of state initiated recalls. The Shellfish Specialists will monitor the adequacy of the recall and will obtain information from the state authority consistent with FDA's Regulatory Procedures Manual, Chapter 7, Recalls, Attachment B (Recommendation for Recall Classification). Where the recall is determined to be

inadequate, The Shellfish Specialist will work with the state authority, where practical, and with the FDA District Office to ensure additional necessary actions occur. *

4. Scheduling International Program Evaluations

Follow the instructions provided in the International Shellfish Program Evaluation Protocol, see Attachment C.

PART III – INSPECTIONS

Specific program activities appear below in this section. Activities are subject to modification based on changing program needs. Should modifications occur, Shellfish Specialists will receive notification via memorandum from the Compliance Programs Branch, HFS-636.

A. GENERAL

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

B. OPERATION DESCRIPTIONS

1. Program Evaluations
2. Standardization
3. Training and Conferences
4. Technical Assistance
5. * FDA Shellfish Steering Committee *

1. 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 plant and shipping element will be evaluated once every two years. The growing area classification and control of harvest elements will be evaluated 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 whose totaled points indicate an overall high risk will be evaluated every year. Growing area classification elements whose totaled points indicate an overall low risk will be evaluated once every two years.*

* For the control of harvest element the risk category (high or low) will be based on the MO Chapter VIII risk assessment of patrol areas (see attachment G). Control of harvest elements that fall into the high category will be evaluated annually. Control of harvest elements that fall into the low category will be evaluated once every two years. *

* For the growing area classification element, states that have a high risk for the illness outbreak factor will be evaluated annually regardless of the state's overall risk rating.*

* States having a high risk growing area classification element that are found to be compliant for two consecutive years may request in writing to the FDA Regional State Program Manager 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. The frequency of the plants and shipping element and control of harvest element evaluation shall not be reduced for any reason.*

* Growing area classification and 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).*

During the first quarter the Regional Shellfish Specialist will work with the SSCA to, where appropriate, 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 G, the Risk Assessment Form (RAF) for each NSSP participating state. * The Regional 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. 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.* The schedule along with a copy of Attachment G shall be sent to the Shellfish Safety Team (HFS-628) for review. While it is anticipated that the risk category will not change from year-to-year, the 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:

A. GROWING AREA CLASSIFICATION ELEMENT

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

(1) Production
(2) Classification Complexity
(3) Illness Outbreaks

(1) Production:

Assign the following point value based upon the 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.

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 *

(2) 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

(3) Illness Outbreaks (excluding V.p. illness outbreaks):

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*

States for which the scores for the Growing Area Classification Element result in a high risk must have this program element evaluated yearly. Scores resulting in a low risk category must have this program element evaluated every second year.

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 D) designed to provide a 95 percent probability of detecting a 20 percent or greater defect level.

B. *PLANT* AND SHIPPING ELEMENT

* All states shall have the shellfish plant 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.*

Conduct file reviews and field evaluations of shellfish processors selected randomly from those listed in the Interstate Certified Shellfish Shippers List (ICCSL). The number of processors to be evaluated shall be based upon a representative sampling plan (Attachment D) designed to provide a 95 percent probability of detecting a 20 percent or greater defect level.

Complete Attachment E – Objectionable Conditions Cited by Plant and include the Attachment in the Program Element Evaluation Report (PEER). Attachment E 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 another or swing deficiency is noted, the final result should be included in the "code result" column.

Determine the compliance status of the state plant and shipping element using the ISSC evaluation criteria (Attachment F, State Inspection Program Evaluation Criteria).

C. CONTROL OF HARVEST

Frequencies for conducting the control of harvest element evaluation will be based upon the state's risk assessment of patrol areas in accordance with NSSP Model Ordinance Chapter VIII. 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).*

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 every second year.

Conduct file reviews and field evaluations of patrol areas selected randomly from a list of all patrol areas in the state. The number of patrol areas shall be based upon a representative sampling plan (Attachment D) designed to provide a 95 percent probability of detecting a 20 percent or greater defect level.

D. *VIBRIO VULNIFICUS AND VIBRIO PARAHAEMOLYTICUS:*

Shellfish Specialists shall evaluate* and report annually* the compliance of states required to have a *Vibrio vulnificus* Risk Management Plan. At a minimum, annual evaluations *and reports* of the Vibrio vulnificus Risk Management Plans shall include the status of management plan components. These include: (1) whether the state has a written plan and (2) whether the management plan consists of the requisite components, those being (a) consumer education program, (b) a process to collect standardized information on each illness and communicate with state epidemiologists, (c) a standardized process for tracking products implicated in each illness, (d) identification of preparations and implementations for achieving post-harvest treatment goals, and (e) identification of and preparations for implementation of controls should the goal for 60% illness reduction not be reached.* Shellfish specialists shall report on each of these requirements and provide detail specific to actions the state has taken to comply with each requirement.*

Using NSSP Model Ordinance Chapter II. @.01.J criteria, Shellfish Specialists shall evaluate and report annually the compliance of states to annually assess *Vibrio parahaemolyticus* illnesses associated with the consumption of molluscan shellfish. In addition, Shellfish Specialists

should annually evaluate and report *V. parahaemolyticus* Contingency Plan efforts in those states whose waters have been confirmed as the source of shellfish associated with two or more *V. parahaemolyticus* illnesses annually in the most recent three years or with an outbreak in the last three years. In addition, annual evaluations and reports of the *V. parahaemolyticus* Risk Management Plans shall include the number of cases and outbreaks in each state, the number of cases and outbreaks outside the state related to shellfish from that state, communications with state epidemiologists, and the process to collect standardized information on each illness and outbreak that each participating NSSP state is required to perform each year.

E. LABORATORY EVALUATION:

The FDA Shellfish Laboratory Evaluation Officer (LEO) will schedule laboratory evaluations with the appropriate state officials. The Shellfish Specialist should accompany the LEO during the evaluation to become familiar with laboratory personnel, laboratory procedures and overall laboratory operation. The Shellfish Specialist should be available for the laboratory close out meeting with the state officials. Where needed, the LEO may call upon the Shellfish Specialist to assist in monitoring the progress of completion of an action plan.

F. GUIDELINES FOR WRITING PROGRAM ELEMENT EVALUATION REPORTS (PEERs), ANNUAL PROGRAM EVALUATION Reports (APERs), AND INTERNATIONAL PROGRAM EVALUATION REPORTS (IPERs).

(1) Program Element Evaluation Report (PEER)

The PEER is intended to provide general information on a program element to the applicable state program element manager and FDA Headquarters personnel. The PEER should accurately reflect each program element that is evaluated and current findings. The written report must be factual, objective, free of unsupported conclusions, and concise while covering the necessary aspects of the evaluation. 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.

The PEER shall be prepared within 30 days after completion of the program element evaluation. It is not necessary to cite or discuss the statutory authority for conducting state evaluations.

a) 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.

b) Content of Report:

Prepare the body of the report following the outline in ATTACHMENT A. Each PEER shall have the following major sections:

A. 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.

B.1. 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.

B.2. Program Areas in Compliance

This section may contain subheadings for each program component to be recognized as in compliance, how compliance was verified, a statement recognizing sound management practices, and examples of program effectiveness.

B.3. Current Findings

Provide a description of the deficiencies found during the evaluation. 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.

B.4. 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, no additional follow-up will be required.

B.5. Action Plan

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

B.6. State Program Accomplishments

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

B.7. 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.

B.8. Technical Assistance and/or Training Requested by the State

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

B.9. 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.

B.10. Conclusions

Formulating conclusions from the information gathered during an evaluation is an important aspect of the Shellfish Specialist's responsibilities.

B.11. Recommendations

At the conclusion of each evaluation, the Shellfish Specialist shall discuss recommendations in a close-out session with senior state officials. Those recommendations should be documented in this section.

c) FDA Headquarters Review of the PEER

The PEER is to be reviewed and summarized by SST * after receipt of the final copy that has been issued to the State. * It is important that evaluations reported in PEERs be objective, deficiencies and recommendations are well documented, and the report is consistent with the format in Attachment A.

(2) Annual Program Evaluation Report (APER):

The purpose of the APER is to provide an annual status of the entire state program to the state agency and FDA Headquarters. This report should include information on progress made by the state to correct any deficiencies found during the state program element evaluation. The APER should describe all evaluation activities undertaken to determine compliance and how these activities were conducted. The APER should clearly indicate the state's compliance at the end of the evaluation year (September 30).

The Shellfish Specialist shall send the APER to the state for review no later than October 15. Provide the state 15 days to respond and finalize the report and submit it to SST by November 15.

a) Content of Report:

Prepare the body of the report following the outline in Attachment B. The Shellfish Specialist has the flexibility to include additional subheadings when necessary. Each APER shall have the following major sections:

A. Overall Program Status (by program element)

Describe the overall status of the state's program, including laboratories.

B. 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.

C. Specific Information on Illnesses, Outbreaks, and/or Recalls

Provide detailed information on any illnesses, outbreaks, or recalls that involved shellfish products in interstate commerce.

D. State Program Accomplishments

Include information on improvements in the state's program and acknowledge the state for maintaining program components in compliance.

E. New or Emerging Findings

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

F. Unresolved Issues

Provide a detailed description of any circumstances that may result in an NSSP unresolved issue.

Please Note: The cover letter for APERs requires the signature of the RFDD and must be addressed to the commissioner(s) or the equivalent of the department(s) in which the shellfish program elements are located.

3) International Program Evaluation Report (IPER):

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 A-1 and be submitted to OS (HFS-417) and SST (HFS-618) within 45 days of completion of the trip. OS shall send a cover letter with a final report to the country's shellfish control authority within 45 days of receipt of the IPER.

Please Note: IPER transmittal letters require OS signature.

2. STANDARDIZATION

The purpose of standardization of shellfish plant inspectors is to ensure that plants are uniformly evaluated for sanitation and 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.

3. TRAINING AND CONFERENCES

- Training Courses

  * The Office of Regulatory Affairs (ORA), Division of Human Resource Development (DHRD), and State Training Team (STT) (HFC-60) will send its Annual Training Needs Survey to the State Shellfish Control Authorities in the second quarter. DFSR maintains the master mailing list. 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 Regional State Program Director or designee for prioritization of all training needs in Cooperative Programs (Shellfish, Milk & Retail Food) and forwarded to STT. STT provides training requests to the Steering Committee for review and comment.*

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

  * STT courses are developed and delivered in conjunction with the Shellfish Specialists and the Center for Food Safety and Applied Nutrition's (CFSAN), Office of Compliance, Shellfish Safety Team (HFS-628).* Once scheduled, the Shellfish Specialist, in cooperation with the State Training Team, shall finalize the course agenda (based on participants' qualifications), training location, dates, and participants.

- Regional Meetings

  Regional meetings provide an opportunity for FDA and state shellfish program officials to participate in information exchange and problem solving. Shellfish Specialists are encouraged to participate in these meetings.

- National Conferences

  The Shellfish Specialist shall, with RFDD approval, attend the biennial meeting of the Interstate Shellfish Sanitation Conference (ISSC). The ISSC biennial meeting is held to:

  - Discuss administrative and technical problems and solutions;
  - Recommend NSSP program changes; and
  - 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. Issues for submission to the ISSC, prepared by the Shellfish Specialists, shall be submitted to OS, HFS-417.

4. TECHNICAL ASSISTANCE

The Shellfish Specialist may provide technical assistance to the states as requested. Requests for technical assistance shall be submitted to SST. The Shellfish Specialist has overall responsibility for joint state/regional technical assistance projects. This may include:

- Coordinating resources;
- Participating in field project activities; and
- Providing study results to the state

***5. FDA SHELLFISH STEERING COMMITTEE**

Two Shellfish Specialists serve as representatives on the National Shellfish Steering Committee. The Steering Committee is the forum for discussion and resolution of shellfish program criteria and implementation issues and serves as the primary liaison vehicle with the National Shellfish Specialists Team and headquarters personnel. *

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

A. 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 SST and OS shall immediately notify ORO, Emergency Operations Staff, the Office of Compliance, Division of Enforcement, and Division of Federal-State Relations of the hazard and of the state's position.

The notification should include information on the violation. CFSAN will promptly evaluate the hazard and take an appropriate course of action.

* 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. *

B. 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.

GENERAL INSTRUCTIONS AND ADMINISTRATIVE CRITERIA FOR OUT-OF-COMPLIANCE STATE PROGRAM ELEMENTS

If, in an evaluation, the Shellfish Specialist finds any element of a state program out of compliance with the NSSP, the Shellfish Specialist shall promptly apprise the RFDD or the Regional State Program Manager of the situation. The RFDD or the Regional State Program Manager will consult OS (HFS-417),and SST (HFS-628) 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 days, the Shellfish Specialist shall provide to the state and the SST a copy of the PEER.

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

- How the items were corrected;
- an action plan has been developed 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(s) is described in detail;
- Specific measures to be taken to correct the program deficiency(s); and,
- The program deficiency(s) is assigned a date for correction.

The development period for the state Action Plan SHALL NOT EXCEED 30 DAYS after receipt of the PEER. All corrective Action Plans shall be scheduled for completion within 180 days of receipt of the PEER. Failure to develop an Action Plan shall result in initiation of the procedures for an unresolved issue. 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.

The Shellfish Specialist shall review the documents submitted by the SSCA and respond to the state within 15 days.

If the state fails to implement an appropriate Action Plan to correct deficiencies or consensus with FDA's findings is not reached, the Shellfish Specialist in consultation with the RFDD or the Regional State Program Manager, OS, and OC shall consider appropriate actions including:

- Referral of the matter to the ISSC Executive Board as an unresolved issue (The ISSC has adopted in its Constitution, Bylaws, and Procedures an "Unresolved Issue Process," which is a peer review process for states not meeting the requirements of the NSSP Model Ordinance requirements.) 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 Seafood in consultation with the Director, Division of Cooperative Programs, the Director, Division of Federal-State Relations, and the Office of Chief Counsel.)

C. FEDERAL STATUTES COVERING SHELLFISH IN INTERSTATE COMMERCE

1. 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 to take corrective measures, the Shellfish Specialist will advise the appropriate District 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 district office. Shellfish Specialists should follow the recall instructions provided in Part II, Pages 1 and 2 of this compliance program.

The district should submit recommendations for appropriate regulatory action to the Office of Compliance, Division of Enforcement (HFS-605)* as outlined in Part V of the Domestic Fish and Fishery Products Compliance Program (7303.842). *

2. 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 district office compliance branch will decide the appropriate regulatory action (that which would normally be taken in the case of a labeling violation) 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 compliance branch can obtain assistance by contacting the National Marine Fisheries Service (NMFS), Office of Enforcement, 8484 Georgia Ave., Silver Spring, MD 20910, (301) 427-2300.

D. ACTION REGARDING IMPORTED SHELLFISH

1. Certified Shippers

Shellfish acceptable for interstate shipment originate only from certified shippers from a country with whom FDA has an active MOU and who are listed on the FDA Interstate Certified Shellfish Shippers List (ICSSL). Only Canada, the Republic of Korea, Chile, New Zealand, and *Mexico* participate in the NSSP through formal Memoranda of Understanding with the U.S.

Shellfish from certified shippers should be packed in containers bearing a certification number issued by the MOU country. Shipment of imported shellfish without this certification number should be reported to the state shellfish control authority by the Shellfish Specialist for follow-up.

* Whenever such a scenario occurs, there should be coordination between the Shellfish Specialist and the local FDA Import Branch

where the shipment was offered for entry. See 2. below also. *

2. Uncertified Shippers

Molluscan shellfish * offered for entry into the United States * from uncertified shippers require**s** special attention. Uncertified shippers are either from a non-MOU country or they are shippers that are not certified by the shellfish control authority in a MOU country.

Upon entry of raw molluscan shellfish from a dealer not listed on FDA's ICSSL the Shellfish Specialist should work with local district import branches to determine whether or not evidence exists for FDA to act under Section 801(a) of the FD&C Act. The origin of shellfish from a dealer in a non-MOU country may not be in and of itself be sufficient to support an 801(a)(1) violation. When possible, product sampling, conducted in accordance with the Import Seafood Products Compliance Program, 7303.844, can be used to determine whether or not shellfish is adulterated under 801(a)(1). Product labels should also be examined to determine if shellfish is misbranded (i.e. raw product labeled as cooked) and that product labels comply with the Federal Seafood HACCP Rule, 21 CFR, Part 123.28.

When efforts described above do not result in FDA action, the Shellfish Specialist should work with the local district import branch **to** contact the state shellfish control authority in the state where the shipment was offered for entry * to request a state embargo of the product (a state embargo is the most expeditious course of action to remedy the problem). * The importer should be advised that FDA will request the state to embargo the product if FDA releases it into U.S. commerce. If a state chooses not to take an embargo action or seize shellfish from uncertified shippers, the Shellfish Specialist or the district should contact CFSAN, OC/DCP/SST, HFS-628, Team Leader, (301) 436-2147 and the Office of Compliance, Import Branch Compliance Officer (see Part VI., Item B., 1. Import). *

Refer to the Import Seafood Products Compliance Program (7303.844) for additional information.

PART VI – REFERENCES, CONTACTS, AND ATTACHMENTS

A. REFERENCES

National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish,* 2002*.

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. Copies are available from the Interstate Shellfish Sanitation Conference, Executive Office, (803) 788-7559.

Memorandum of Understanding between FDA and the Interstate Shellfish Sanitation Conference (ISSC); see FDA Compliance Policy Guide 7158.04. A copy can be obtained from the Office of Enforcement, Division of Compliance Policy, HFC-230, * (240) 632-6860 *.

Bilateral agreements between FDA and Sovereign Nations Certifying Imports under the NSSP MO. Complete copies of the individual MOUs on shellfish sanitation can be obtained from the Office of Enforcement, Division of Compliance Policy, HFC-230, * (240) 632-6860 *.

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, http://www.CFSAN.FDA.GOV/~ear/shellfish.html.

Memorandum of Understanding between FDA and the National Marine Fisheries Service (NMFS); see the FDA Federal Cooperative Agreements Manual or contact the Division of Compliance Policy, Office of Enforcement, HFC-230, * (240) 632-6860 * for a complete copy of the MOU.

Investigations Operations Manual (IOM), Chapter 4 Sampling, Chapter 3 Federal and State Cooperation, Chapter 6 Imports, and Chapter 9 Investigations.

B. PROGRAM CONTACTS

1. Center for Food Safety and Applied Nutrition Contacts

Compliance Program General Information: Office of Compliance, Division of Field Programs, Compliance Programs Branch (HFS-636), William Baczynskyj, (301) 436-1612; FAX Number (301) 436-2657

Regulatory Guidance:

Domestic: Office of Compliance, Division of Enforcement, Domestic Branch, (HFS-607),* Frank Sikorsky, (301) 436-1623* or Priya Joy (301) 436-2078; Fax Number (301) 436-2716

Import: Office of Compliance, Division of Enforcement, Import Branch, (HFS-606),* Mildred Benjamin, (301) 436-1424*; FAX Number (301) 436-2716

Technical Assistance and Training: Office of Compliance, Division of Cooperative Programs, Shellfish Safety Team (HFS-628), William

Watkins, (301) 436-2147; Fax Number (301) 436-2672

Policy: Office of Seafood, Program and Enforcement Branch (HFS-417), Paul DiStefano, (301) 436-1410, FAX number (301) 436-2601

2. Office of Regulatory Affairs (ORA) Contacts

State Liaison: Division of Federal-State Relations, State Information Staff, (HFC-150),* (301) 827-2905 *

Training: Division of Human Resource Development (HFC-60)

Training for FDA/State Personnel: Clint Chamberlin, (301) 594-3844

C. ATTACHMENTS

A. PROGRAM ELEMENT EVALUATION REPORT (PEER)

A-1. INTERNATIONAL PROGRAM EVALUATION REPORT (IPER)

B. ANNUAL PROGRAM EVALUATION REPORT (APER)

C. INTERNATIONAL SHELLFISH PROGRAM EVALUATION PROTOCOL

D. NUMBER OF UNITS NECESSARY TO ACHIEVE A 95% PROBABILITY OF DETECTING A GREATER THAN OR EQUAL DEFECT LEVEL OF 20%

E. OBJECTIONABLE CONDITIONS CITED BY PLANT

F. * INTERIM* STATE INSPECTION PROGRAM EVALUATION CRITERIA

G. RISK ASSESSMENT FORM (RAF)

PART VII - CENTER RESPONSIBILITY

A. LIAISON WITH THE INTERSTATE SHELLFISH SANITATION CONFERENCE (ISSC)

FDA's Office of Seafood is the designated Agency liaison with the ISSC. All communications with the Executive Director and Chairman of the ISSC will be directed through CFSAN, OS, including any status reports on state programs and other pertinent reports and letters. The Office of Seafood, the Shellfish Safety Team, and the Division of Federal State Relations will jointly identify FDA Shellfish Specialists to serve as advisors on various ISSC task forces and committees.

B. INTERNATIONAL PROGRAMS

SST 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 SST representative will contact the country's shellfish control authorities to discuss dates for the evaluation and develop an itinerary for the evaluation. SST will forward the itinerary to OS, the Shellfish Specialist and the country's shellfish control authorities. SST shall arrange a conference call with OS and the Shellfish Specialist a month prior to the start of the trip to brief Headquarters of the elements to be evaluated.

The laboratory activities of international programs shall be audited by the SST LEO who will prepare a laboratory evaluation report. The report shall be submitted to OS within 30 days of completing the audit. OS shall forward the report to the country's shellfish control authority.

C. TECHNICAL ASSISTANCE

FDA provides technical assistance and training on program elements. Technical assistance to the field and states will be provided upon request. Headquarters may call upon the national pool of Shellfish Specialists to assist in their specific areas of technical expertise. This may require Shellfish Specialists to be detailed to other regions.

D. STATE PROGRAM EVALUATION REVIEW

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

SST shall monitor state follow-up activities in order to address state program deficiencies.

E. COMPLIANCE PROGRAM EVALUATION

During the course of this compliance program, but no later than 60 days after final data receipt, SST will identify any deficiencies in the

conduct of the field operations or program quality to OS and the Division of Field Programs (DFP), so that any necessary corrective action may be initiated.

The DCP/SST, in conjunction with OS will * prepare periodic, formal evaluations of this compliance program. When completed and cleared, the evaluation will be available for agency personnel on CFSAN's OC intranet site **#**. *

F. PUBLICATION OF THE NSSP GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH

OS, in conjunction with the ISSC, is responsible for updating and making the Guide available on the CFSAN website. Copies may be downloaded via CFSAN's website at WWW.CFSAN.FDA.GOV/~ear/NSSPOTOC.html.

G. THE INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST (ICSSL)

State and international regulatory officials shall submit the names and other pertinent information of certified shippers directly to SST using FDA 3038 Forms. The Shellfish Specialists should request that state certifying officials provide the regional office with copies of these forms. The ICSSL will be compiled by the SST and posted on CFSAN's website at, WWW.CFSAN.FDA.GOV/~ear/shellfish.html.

H. LABORATORY EVALUATION

SST is scheduled on a triennial basis to evaluate each domestic and foreign laboratory providing analytical data to the SSCA. Following close out discussions with the person in charge of the individual laboratory, the SST LEO shall prepare a written report and provide a copy to the Shellfish Specialist so that the laboratory information can be included in the APER. Non-conforming laboratories shall be immediately reported to the SSCA through the Shellfish Specialist. The SST LEO shall monitor corrective actions and shall forward appropriate information to the Shellfish Specialist for inclusion in the APER. OS shall be notified whenever uncorrected deficiencies occur which could potentially require notification of the ISSC.

*I. FDA SHELLFISH STEERING COMMITTEE

OS and SST will participate as active members of the FDA Shellfish Steering Committee. The Steering Committee is the forum for discussion and resolution of shellfish program criteria and implementation issues and serves as the primary liaison vehicle with the National Shellfish Specialists Team and headquarters personnel. The Steering Committee provides for coordination and guidance among the various FDA components having employees involved with ensuring shellfish safety (e.g. DPEP, DCP, DFP, DFSR, and DHRD).*

PROGRAM ELEMENT EVALUATION REPORT (PEER)

STATE: _____

DATE OF EVALUATION:_____SHELLFISH SPECIALIST:_____

PROGRAM ELEMENT EVALUATED: _____

(Submit within 30 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. Program Areas in Compliance (include discussion of all NSSP administrative requirements for the element evaluated)

3. Current Findings

   - Provide a detailed description of deficiencies found during evaluation (deficiencies must be documented)

   - Document any FDA follow-up needed to address deficiencies

4. Corrective Actions Taken by the State (document any Non-Action Plan corrections taken by the state)

5. 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)

6. State Program Accomplishments (program accomplishments noted by states and/or observed by the Regional Shellfish Specialist)

7. New or Emerging Problems.

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

9. Summary of the State's Response to FDA Evaluation. (if applicable)

10. Conclusion (discuss state’s program compliance with NSSP guidelines)

11. FDA Recommendations (if applicable)

INTERNATIONAL PROGRAM EVALUATION REPORT (IPER)

SHELLFISH SPECIALIST: _____

COUNTRY: _____ DATE OF EVALUATION: _____

PROGRAM ELEMENT(s) EVALUATED: _____

(Submit within 45 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

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.)

INTERNATIONAL SHELLFISH PROGRAM EVALUATION PROTOCOL

Foreign program evaluations are planned to be conducted according to the following schedule:
*

&

*

International requests for FDA evaluation:

1. Office of Compliance, Division of Cooperative Programs (DCP) submits letter to MOU country requesting "letter of invitation" for FDA to conduct a program evaluation. DCP will instruct country to send "letter of invitation" to OS, and DCP shall copy the Office of Seafood (OS).

2. MOU country forwards "letter of invitation" to OS.

3. OS submits copy of "letter of invitation" to DCP.

4. DCP notifies ORO/DFSR to coordinate travel arrangements and funding for selected specialists (see section below).

Personnel Selection/Assignment for International Travel:

1. DCP issues a "Call for Nomination for International Evaluation" with suggestions regarding appropriate Shellfish Specialists to ORO/DFSR during the 3rd quarter of the FY.

2. ORO will coordinate with regional managers who will submit Shellfish Specialist nominations to ORO by the end of the 3rd quarter of the FY.

3. DFSR in consultation with DCP will select Shellfish Specialists from regional nominees to conduct international evaluations during the upcoming FY. 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. ORO/DFSR confirms with the regional program managers the selection of Specialists for each assignment. At this time we provide the region with the planned time frame for the evaluation and any special circumstances for which the Specialist may be required to prepare for.

Pre-trip briefing with Shellfish Specialist:

1. Prior to each international trip, a pre-trip briefing will be conducted with the Specialist.

   a. DCP will coordinate the briefing.
   b. DCP, OS and the Specialist must participate. ORA/DFSR will be invited.
   c. DCP 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 non-conformities.

Draft Evaluation report:

1. The Specialist will write and submit draft evaluation report to DCP no later than 3 weeks following completion of the trip.

2. DCP will forward a copy of draft report to OS.

Headquarters review of draft evaluation report:

1. DCP and OS will jointly review the Specialist's draft evaluation report.

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

3. DCP will forward a copy of the written comments to OS.

Final evaluation report:

1. The Specialist will finalize the report based on DCP/OS comments received from DCP, if any.

2. The Specialist will draft the evaluation report transmittal letter for OS 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 report and draft transmittal letter to OS no later than 3 weeks following receipt of DCP/OS comments from DCP.

Transmittal of evaluation report:

1. Within 3 weeks of receiving the final evaluation report and draft transmittal letter OS will:

   a. Send the final evaluation report and transmittal letter to the foreign country.
   b. Send a copy of the final report and transmittal letter to DCP.
   c. Send a copy of the transmittal letter (without the evaluation report) to the Specialist and ORA DFSR.

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

1. Within 1 week of receipt by OS, OS shall provide DCP and 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 OS signature.

3. OS 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, OS/DCP/ORA DFSR/ Shellfish Specialist shall conference to determine a course of action. DCP will coordinate the conference.

Laboratory Evaluation:

1. DCP submits letter to MOU country requesting "letter of invitation" for FDA to conduct a laboratory program evaluation. DCP will instruct country to send "letter of invitation" to OS. DCP shall copy OS.

2. MOU country sends "letter of invitation" to OS.

3. OS submits copy of "letter of invitation" to DCP.

4. DCP will be responsible for coordinating and conducting laboratory evaluations.

5. Laboratory evaluations will be conducted according to schedule above.

6. Following a laboratory evaluation DCP shall:

   - Write the laboratory evaluation report.
   - Forward to OS the evaluation report and draft transmittal letter for OS signature within 3 weeks of returning from the trip.

7. OS will not be directly involved the laboratory evaluation or report writing.

8. OS will review laboratory report and discuss any concerns/suggestions with DCP within 2 weeks of receiving the report from DCP.

9. DCP will determine the need to adjust the report in accordance with OS comments.

10. OS will transmit final report within 3 weeks of receiving the initial report from DCP.

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

1. Within 1 week of receipt, OS shall provide DCP with a copy of the country's written response to the laboratory evaluation.

2. Within 3 weeks of receipt DCP shall:

a. Review and evaluate the response.
b. Draft a letter of response back to the country for OS signature.

3. OS and DCP shall coordinate the final letter.

4. OS shall transmit the final letter to the country within 3 weeks of OS receiving the draft from DCP.

5. If the country does not respond within the specified time or the response is inadequate, OS and DCP shall conference to determine an appropriate course of action. DCP shall coordinate the conference.

NUMBER OF UNITS NECESSARY TO ACHIEVE A 95% PROBABLITY

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

Objectionable Conditions Cited by Plant

(Total Number of Violative Firms by Type)

Item	Model Ordinance Reference	Description	Code	Code Result	Violative Firms					
					SP	SS	RS	RP	DP	
1. HACCP Plan										
HACCP Plan	X.01.B	Presence of a HACCP Plan	C							
2. Plan Elements										
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)	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							
3. HACCP Training (Yes/No) X.01.I			O							
4. Plan Implementation										
4(a).	X.01.F	Receiving -Corrective Actions (C)	C							
4(a).	X.01.G	Receiving -Verification (K)	K							
4(a).	X.01.C	Receiving -Monitoring (K)	K							
4(a).	X.01.H	Receiving - Records Accurate/Maintained (K); Format (O)	K/ O							
4(b).	X.01.F	Shellstock Storage -Corrective Actions (C)	C							
4(b).	X.01.G	Shellstock Storage –Verification (K)	K							
4(b).	X.01.C	Shellstock Storage –Monitoring (K)	K							
4(b)	X.01.H	Shellstock Storage–Records Accurate/Maintained (K); Format (O)	K/ O							
4(c).	X.01.F	Processing - Corrective Actions (C)	C							
4(c).	X.01.G	Processing - Verification (K)	K							
4(c).	X.01.C	Processing - Monitoring (K)	K							
4(c)	X.01.H	Processing - Records Accurate/Maintained (K);Format (O)	K/ O							
4(d).	X.01.F	Shucked Meat Storage - Corrective Actions (C)	C							
4(d).	X.01.G	Shucked Meat Storage - Verification (K)	K							
4(d).	X.01.C	Shucked Meat Storage - Monitoring (K)	K							
4(d)	X.01.H	Shucked Meat Storage – Records Accurate/Maintained (K); Format (O)	K/ O							
4(e).	X.01.F	Other Critical Limits - Corrective Actions (C)	C							
4(e).	X.01.G	Other Critical Limits - Verification (K)	K							
4(e).	X.01.C	Other Critical Limits - Monitoring (K)	K							
4(e)	X.01.H	Other Critical Limits - Records Accurate/Maintained (K); Format (O)	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							
Sanitation Items										
8.	.02.A	Safety of water for processing and ice production	C/K							

Objectionable Conditions Cited by Plant

(Total Number of Violative Firms by Type)

Item	Model Ordinance Reference	Description	Code	Code Result	Violative Firms					
					SP	SS	RS	RP	DP	WS
9.	.02.B	Condition and cleanliness of food contact surfaces	K							
10.	.02.C	Prevention of cross-contamination	C/K							
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/O							
Additional Model Ordinance Requirements										
17.	.03.A	Plants and Grounds	C/K/O							
18.	.03.B	Plumbing and related facilities	C/K/O							
19.	.03.C	Utilities	C/K							
20.	.03.D	Insects and vermin control	K							
21.	.03.E	Disposal of other waste	O							
22.	.03.F	Equipment construction (non-food contact surfaces)	O							
23.	.03.G	Cleaning non-food contact surfaces	O							
24.	.03.H	Shellfish storage and handling	K/O							
25.	.03.I	Heat shock	K							
26.	.03.J	Personnel	K/O							
27.	.03.K	Supervision	K							
28.	IX.05	Transportation (To include only the person shipping)	K/O							
29.	X.05, X.06	Labeling and Tagging (Other than receiving)	K/O							
30.	X.07	Shipping Documents and Records	K							

C=Critical; K=Key; O=Other

***INTERIM*STATE INSPECTION PROGRAM EVALUATION CRITERIA**

FDA should at a minimum include the following* interim *criteria in evaluating the plant and shipping element of a state shellfish sanitation program. *Pending adoption at the 2005 ISSC meeting, the requirements will be retroactive to include evaluations beginning October 1, 2004. The criteria should be used to evaluate subsequent full evaluations (not including follow up). If the same criteria are again found to be non-compliant, the program element is considered to be out of compliance.*

a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.

b) 95% of certified dealers must be evaluated with an inspection frequency, which is compliant with the current Guide for the Control of Molluscan Shellfish.

c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.

d) States must demonstrate 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.

e) All critical deficiencies have been addressed in accordance with the Guide for the Control of Molluscan Shellfish.

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

COMMENTS: