

APPENDIX C: Seafood HACCP Partnership Agreement

INTRODUCTION

The attached model is to serve as the basis for the negotiation of partnership agreements between Food and Drug Administration (FDA) district or regional offices and state or local regulatory agencies for the inspection of fish and fishery product processors. It is a model and, as such, deviation from the prescribed language may be necessary in some cases. However, its contents reflect the principles essential to any such agreement.

This model was developed by a work group comprised of representatives of the FDA Center for Food Safety and Applied Nutrition, the FDA Office of Regulatory Affairs, the Alaska Department of Environmental Conservation, the Florida Department of Agriculture and Consumer Services, the Maine Department of Agriculture, and the Virginia Department of Agriculture and Consumer Services. It is consistent with the guidance provided in the ORA-21 "Partnership Agreement" Guidance Document (1/23/96).

The central goal of seafood HACCP partnerships is the development of a network of equivalent federal and state inspection efforts that collectively make up a cohesive national program. Such a program makes possible: enhanced consumer protection through the enforcement of the HACCP system of preventive controls; improved efficiencies through the minimization of duplication of inspectional effort; national uniformity in the application of food safety standards; and, a national data base of inspectional results. Moreover, the program should enhance both the domestic and international credibility of U.S. seafood products through proper recognition of all relevant regulatory inspections, i.e., the combined federal-state inspections as recorded in the national data base.

In order for a national inspection program that is based on partnerships to be truly cohesive, all of the parties to the partnerships must perform equivalent inspections. Equivalency can only be achieved through consistency in: training; standards; inspection procedures; and, reporting. In order for the program to be meaningful, combined inspection frequencies must be adequate to provide public confidence in the product. There must also be some level of joint inspections for the purpose of confirming equivalency. In order for the effectiveness of the program to be determined and communicated to its stake holders, a national data base of the inspection results must be established. These principles are the basis of the following model partnership agreement.

The attached model contains required language, which should, with few exceptions, be a part of all federal/state, seafood HACCP partnership agreements. It also contains optional additional language, which can be used to tailor the agreement to local circumstances. In particular, the optional additional language will be relevant if the parties wish to include inspection of bivalve, molluscan shellfish processors in the partnership agreement, an arrangement which may be desirable in some localities. Other issues may be included in the agreement, or additional detail may be provided for the existing issues, if desired.

SEAFOOD HACCP PARTNERSHIP AGREEMENT

(Required Language)

1. Agreement to Establish Partnership

The **(district or region name)** of the Food and Drug Administration and the **(state agency name)** agree to establish a partnership for the regulation of the fish and fishery products processing industry in **(state)**.

This agreement applies to fresh and saltwater fin fish, crustaceans, other forms of aquatic life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin, and the roe of such animals) other than birds and mammals, and to other mollusks (other than bivalve), where such animal life is intended for human consumption. Such animal life is referred to in this agreement as "seafood" or "fish and fishery products."

This agreement does not apply to the regulation of bivalve, molluscan shellfish, which are covered under the National Shellfish Sanitation Program, a cooperative, federal/state/industry program.

(See also "Optional Additional Language")

2. Partnership Purpose and Goals

- a. This agreement covers the period *(insert period of agreement)* and may be extended as agreed upon by the parties.
- b. The anticipated outcomes of the partnership are:
 - To promote the widespread inspection of processors of fish and fishery products based on Hazard Analysis Critical Control Point (HACCP) principles.
 - To provide enhanced protection to consumers of fish and fishery products by securing industry compliance with the Seafood HACCP Regulation, the Current Good Manufacturing Practices Regulation, and other applicable regulations and standards;
 - To secure this compliance through adequate and credible inspectional coverage of the fish and fishery products processing industry in the State of **(name of state)** through a combined Federal/State inspection frequency of HACCP-based inspections of at least once per year (i.e. a minimum frequency of once per year, with the actual inspection frequency being risk-based);
 - To foster uniform, consistent Federal/State application of the Seafood HACCP Regulation, the Current Good Manufacturing Practices Regulation, and other applicable regulations and standards to the benefit of consumers and the fish and fishery products processing industry;
 - To enable the development of a national data base of inspectional data from both Federal and State inspections. The combined total number of consistent, state-of-the-art inspections in the national data base will, among other things, foster domestic and international confidence in U.S. fish and fishery products, including products from the State of **(name of**

state), and provide both Federal and State public health authorities with a better understanding of the state of the industry;

Note: Presently, it is expected that the national data base will be developed by FDA and state partners completing data collection forms and faxing them to a central computer at CFSAN/Office of Seafood. The forms will be received on a fax modem, enabling the data to be merged with existing FDA data sets. The data will be accessible on-line by FDA district offices and through periodic reports by state partners. FDA is in the process of identifying data needs for the potential users of the data base (i.e., FDA headquarters and field and state partners). In particular, there is a desire to minimize duplication of and maximize integration with existing reporting and data handling.

- To improve the efficiency of both the Federal inspection program for fish and fishery products and that of the State of **(name of state)** through complementary activities that conserve resources and minimize duplication of effort;
- To improve the proficiency of Federal and State fish and fishery products inspection personnel (inspectional personnel may include analysts involved in team inspections) through joint training and inspection;

Note: FDA is in the process of developing a certification process for FDA investigators and analysts performing seafood inspections, and an equivalent process for state inspectors. When such a system is developed, it would be appropriate to refer to it at this point in the agreement.

- To foster the development and retention of both Federal and State expertise in the inspection and regulation of fish and fishery product processors, and, through training, sharing of information, and other cooperative activities, to help both Federal and State regulators keep pace with new developments and technologies in fish and fishery product processing and the regulation of fish and fishery product processing; and,
- To facilitate timely, accurate regulatory decisions through improved communications between the **(district or region name)** and **(state agency name)** and through the prompt sharing of policy and other regulatory information;

(See also "Optional Additional Language")

3. Program Areas and Activities for Partnership

a. Program areas for partnership include:

- Inspections of fish and fishery product processors to ensure conformance with the requirements of the Seafood HACCP Regulation, the Current Good Manufacturing Practices Regulation, and other applicable regulations and standards;
- Exchange of inspectional and analytical data relating to processors of fish and fishery products;
- Sharing of policy and other regulatory information between the **(district or region name)** and **(state agency name)**;
- Regulatory follow-up to noncompliance with the requirements of the Seafood HACCP Regulation, the Current Good Manufacturing Practices Regulation, and other applicable regulations; and,

- Training and joint inspection activities for seafood processor inspection personnel (inspection personnel may include analysts involved in team inspection).

Note: FDA is in the process of developing a certification process for FDA investigators and analysts performing seafood inspections, and an equivalent process for state inspectors. When such a system is developed, it would be appropriate to refer to it at this point in the agreement.

b. Cooperating Agency Contacts:

FDA

(name and title of FDA contact)

Date _____

(name of state)

(name and title of state contact)

Date _____

c. Statutory Basis for Partnership Agreement:

FDA

Federal Food, Drug, and Cosmetic Act: Section 301 *****

Public Health Service Act: *****

21 Code of Federal Regulations: Parts 110, 113, 114, 123

(name of state)

(state statutes, regulations, ordinances)

(See also "Optional Additional Language")

4. Responsibilities

a. Joint:

- Each party will provide to the other its establishment inventories of fish and fishery product processors in the State of ***(name of state)***, on an annual basis, to produce a combined list.
- The parties will conduct annual joint planning meetings to develop annual inspection work plans, discuss joint and independent projects, and evaluate the effectiveness of the agreement.
- The parties will conduct joint emergency meetings when requested by either party.

- Each party will ensure that its inspection personnel (inspection personnel may include analysts involved in team inspections) that are involved in work under this agreement are adequately trained (i.e. the principles of HACCP and the requirements of the Seafood HACCP Regulation [e.g. the Alliance HACCP course, or equivalent], and the performance of a HACCP inspection [e.g. the Regulator HACCP course]). In addition, each party will strive to provide training in food science and microbiology (i.e. the FDA Food Microbiological Control course, or equivalent) and in evidence development and interviewing technique, to its inspection personnel (inspection personnel may include analysts involved in team inspections) that are involved in work under this agreement.

Note: FDA is in the process of developing a certification process for FDA investigators and analysts performing seafood inspections, and an equivalent process for state inspectors. When such a system is developed, it would be appropriate to include it as a requirement at this point in the agreement.

Note: Explanation of "strive for": It is likely that the FDA food microbiology course, or its equivalent, will be a requirement for FDA certification of inspection personnel. At such time, attendance at a food microbiology course should be a requirement for performance of those seafood HACCP inspections that are counted in the national data base. FDA will work to provide the FDA Food Microbiology Control course and training in interviewing technique and evidence development in a manner that is accessible to States in time to meet the likely certification requirement. States should be encouraged to seek such training through available sources in the interim.

- The combined efforts of FDA and **(name of state agency)** will result in the inspection of all fish and fishery product processors in the state of **(name of state)** at least annually in a manner consistent with the terms of this agreement.

Note: This is a general statement of intent. More specific inspectional commitments are contained in the FDA and state responsibilities sections. Federal/State work planning may result in a dividing of the inventory between the agencies or, simply, inclusion of some or all state inspections in the national data base. Some States are obligated to inspect all registered establishments as a condition of registration.

There are various options available to the parties. For example, where a State inspects several times a year, one of those inspections could become a full HACCP-based inspection under the partnership and would therefore count in the national database, while the other inspections could remain relatively abbreviated in nature. The State could decide to reduce the number of abbreviated inspections it conducts a year on the grounds that one full HACCP-based inspection reduces the need.

- FDA and **(name of state agency)** will jointly perform a minimum of 5% of the inspections covered by this agreement. The joint inspections will serve training, technology and information exchange, and verification functions.
- For each inspection that is covered by this agreement, the inspector will complete, at a minimum:
 - the Seafood HACCP Inspection Report;
 - the Computer Generated Cover Sheet or similar document that contains, at a minimum: the voluntary corrections taken by the processor; and, the final classification of the inspection by the agency for each of the products inspected and for both compliance with the Seafood HACCP Regulation and other applicable regulations (i.e. separate classification for each); and,

- an FDA-483 or similar document that lists the specific violations noted during the inspection.

Note: FDA is developing a HACCP-based inspection reporting form that States could fax to FDA for consolidation into the national data base. The form will include data on the status of the processor's HACCP program and administrative information relevant to the inspection. The State version of the reporting form will contain all the critical data from the Computer Generated Cover Sheet so that State inspectors will not have to complete both.

- Each party will provide to the other a copy (*i.e.*, electronic or hard copy) of each of the above described documents.
- Voluntary or compulsory enforcement actions taken as a result of inspections conducted by one agency (e.g. voluntary destructions, recalls, embargoes, seizures, prosecutions) will be reported in a timely manner to the other agency
- Either party may elect to perform inspections or take enforcement actions as follow-up to inspections or actions taken by the other party when deemed necessary, after consultation with the other agency.

Note: This provision may be especially relevant where a State does not adopt as its own the FDA Seafood HACCP Regulation but is willing to conduct HACCP-based inspections as long as FDA takes any enforcement actions as a result of those inspections.

- FDA and **(name of State agency)** will evaluate the effectiveness of the agreement annually.

b. FDA:

- FDA will develop, on an annual basis, a combined establishment inventory of fish and fishery product processors, including their central file numbers, and provide it to **(name of state agency)**.
- FDA will provide training for FDA and **(name of state)** fish and fishery product inspection personnel (inspection personnel may include analysts involved in team inspections) in the performance of a HACCP inspection (*i.e.* the Regulator HACCP Course), as needed.

Note: FDA is working toward the development of CD-ROM-based, video-based, or satellite-transmitted versions of the FDA Food Microbiology Control and introductory regulatory training (e.g. evidence development, and interviewing technique) courses. When completed they can be made available to state partners as part of this agreement.

- FDA will conduct at least **(enter the appropriate number of inspections that are to be performed by FDA under the terms of the agreement, but in no case less than 10% of the fish and fishery products processors in the state)** inspections of fish and fishery product processors consistent with the terms of this agreement (exclusive of joint inspections).

Note: Reasons for requiring that FDA inspect at least 10% of the processors include: maintaining FDA inspectional capacity in case the State's capacity is reduced, or problems arise with the partnership; maintaining domestic and international credibility through some FDA inspectional presence in each State; and maintaining intelligence about the industry throughout the country.

- FDA will develop and provide to **(name of state agency)** quarterly data summary reports on

the number of inspections conducted under the terms of this agreement, the voluntary actions taken by the processors, the final agency classifications, and a summary of the Seafood HACCP Inspection Report findings.

- FDA will include State inspections conducted under this agreement in a national inspection data base, which is reported to the public, the Congress, and to international trading partners for trade purposes.

c. **(name of state agency):**

- **(name of state agency)** will develop and implement inspection procedures that are equivalent to those delineated in the Regulator HACCP course, the Domestic Fish and Fishery Products Inspection Program, and the Investigations Operations Manual.
- **(name of state agency)** will conduct at least **(enter the appropriate number of inspections that are to be performed by the state under the terms of the agreement, but in no case may the sum of the FDA and state inspections be less than the total number of the fish and fishery products processors in the state)** inspections of fish and fishery product processors, consistent with the terms of this agreement.

(See also "Optional Additional Language")

5. Planned Resources

a. Funding:

- Training - costs of attendance for FDA and **(name of state agency)** fish and fishery product inspection personnel (inspection personnel may include analysts involved in team inspections) at introductory regulatory training (e.g. evidence development, interviewing technique), food science and microbiology (e.g. the FDA Food Microbiological Control course, or equivalent, the principles of HACCP and the requirements of the Seafood HACCP Regulation (e.g. the Alliance HACCP course, or equivalent), and the performance of a HACCP inspection (e.g. the Regulator HACCP course) will be the responsibility of:

(indicate which agency will be responsible for funding training, as agreed to by FDA and the state)

- Inspection - costs associated with inspections (e.g. travel, per diem) will be funded by the agency performing the inspections.
- Compliance - costs associated with compliance activities (e.g. travel, per diem) will be funded by the agency performing the compliance activities.

b. Personnel:

- Development and maintenance of combined establishment inventory - FDA will provide personnel necessary to accomplish this task.
- Generation of quarterly data summary reports - FDA will provide personnel necessary to accomplish this task.
- Planning and assessment meetings - FDA and **(name of state agency)** will provide personnel necessary to accomplish this task.

- Training -
- FDA and **(name of state agency)** will provide inspection personnel (inspection personnel may include analysts involved in team inspections) to receive training as follows:

(list the number of FDA and state inspection personnel that will receive training in introductory regulatory issues [e.g. evidence development, interviewing technique], food science and microbiology [e.g. the FDA Food Microbiological Control course, or equivalent], the principles of HACCP and the requirements of the Seafood HACCP Regulation [e.g. the Alliance HACCP course, or equivalent], and the performance of a HACCP inspection [e.g. the Regulator HACCP course].)

- FDA will provide facilitator(s) for the Regulator HACCP course.
- Inspections -
- FDA and **(name of state agency)** will provide investigators to perform inspections, including joint inspections.
- Compliance -

(describe the agency that will be responsible for regulatory follow-up performed under this agreement)

(See also "Optional Additional Language")

6. Assessment Mechanisms

- Annually, FDA and **(name of state agency)** will review the quarterly data summary reports to determine:
 - The number of inspections conducted and the frequency of inspection;
 - The types and frequency of HACCP violations noted;
 - The percentage of inspections in the various classifications; and,
 - The number and kind of voluntary and regulatory actions taken.
- Annually, FDA and **(name of state agency)** will review the results of the joint inspections.
- Annually, FDA and **(name of state agency)** will review the results of violative samples collected from processors covered by this agreement.
- Annually, FDA and **(name of state agency)** will determine the number and percentage of FDA and **(name of state agency)** inspection personnel (inspection personnel may include analysts involved in team inspections) that are adequately trained

Note: FDA is in the process of developing a certification process for FDA investigators and analysts performing seafood inspections, and an equivalent process for state inspectors. When such a system is developed, it would be appropriate to refer to it at this point in the agreement.

- FDA and **(name of state agency)** will prepare a written annual evaluation at least annually.

7. Conclusions and Recommendations.

Signing of this agreement formalizes the partnership between **(name of district or region)** and **(name of**

state agency) for the regulation of the fish and fishery products processing industry. It becomes effective on the date of the last signature.

Based on the annual evaluations performed, the project coordinators will jointly prepare options for follow-up agency actions, as appropriate, for approval by the signatories to this agreement.

8. Signatures of Responsible Parties

For FDA

(signature, name, and title of FDA representative)

Date _____

For (name of State agency)

(signature, name, and title of State representative)

Date _____

(Optional Additional Language)

1. Agreement to Establish Partnership

This agreement applies to molluscan shellfish, which are also covered under the National Shellfish Sanitation Program, a cooperative, Federal/State/industry program, as well as to fresh and saltwater fin fish, crustaceans, other forms of aquatic life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin, and the roe of such animals) other than birds and mammals, and to other mollusks, where such animal life is intended for human consumption.
(optional replacement for required language paragraph)

2. Partnership Purpose and Goals

b. The anticipated outcomes of the partnership are:

- To provide enhanced protection to consumers of fish and fishery products by securing industry compliance with the Seafood HACCP Regulation, the Current Good Manufacturing Practices Regulation, other applicable regulations and standards, and the provisions of the National Shellfish Sanitation Program; *(optional replacement for required language bullet)*
- To secure this compliance through adequate and credible inspectional coverage of the fish and fishery products processing industry in the State of *(name of State)* through a combined Federal/State inspection frequency of HACCP-based inspections of at least once per year for non-molluscan shellfish processors (i.e. a minimum frequency of once per year, with the actual inspection frequency being risk-based) and combined Federal/State inspection frequencies consistent with the inspection frequencies specified by the National Shellfish Sanitation Program for the various classes of molluscan shellfish processors; *(optional replacement for required language bullet)*
- To foster uniform, consistent Federal/State application of the Seafood HACCP Regulation, the Current Good Manufacturing Practices Regulation, other applicable regulations and standards, and the provisions of the National Shellfish Sanitation Program to the benefit of consumers and the fish and fishery products processing industry; *(optional replacement for required language bullet)*

3. Program Areas and Activities for Partnership

a. Program areas for partnership include:

- Inspections of fish and fishery product processors to ensure conformance with the requirements of the Seafood HACCP Regulation, the Current Good Manufacturing Practices Regulation, other applicable regulations, and the provisions of the National Shellfish Sanitation Program; *(optional replacement for first required language bullet)*

4. Responsibilities

a. Joint:

- Each party will include their establishment inventories of fish and fishery product processors in an on-line data base (either inclusive or exclusive of bivalve molluscan shellfish processors) to produce a combined list. *(optional replacement for required language bullet)*
- Each party will ensure that its inspection personnel (inspection personnel may include

analysts involved in team inspections) that are involved in work under this agreement are adequately trained (i.e. introductory regulatory training [e.g. evidence development, interviewing technique], the principles of HACCP and the requirements of the Seafood HACCP Regulation [e.g. the Alliance HACCP course, or equivalent], the performance of a HACCP inspection [e.g. the Regulator HACCP course], and bivalve, molluscan shellfish plant inspection standardization). In addition, each party will strive to provide training in food science and microbiology (e.g. the FDA Food Microbiological Control course, or equivalent) to their inspection personnel (inspection personnel may include analysts involved in team inspections) that are involved in work under this agreement. *(optional replacement for required language bullet)*

Note: FDA is in the process of developing a certification process for FDA investigators and analysts performing seafood inspections, and an equivalent process for state inspectors. When such a system is developed, it would be appropriate to include it as a requirement at this point in the agreement.

- The combined efforts of FDA and *(name of State agency)* will result in the inspection of all non-molluscan shellfish fish and fishery product processors in the state of *(name of State)* at least annually and all classes of molluscan shellfish processors at frequencies specified by the National Shellfish Sanitation Program, in a manner consistent with the terms of this agreement. *(optional replacement for required language bullet)*

Note: this is a general statement of intent. More specific inspectional commitments are contained in the FDA and State responsibilities sections. Federal/State work planning may result in a dividing of the inventory between the agencies or, simply, inclusion of some or all State inspections in the national data base. Some States are obligated to inspect all registered establishments as a condition of registration.

- FDA and *(name of State agency)* will jointly perform a minimum of 5% of the non-molluscan shellfish inspections covered by this agreement. FDA and *(name of State agency)* will jointly perform all of the molluscan shellfish inspections specified in the appropriate FDA Compliance Program. The joint inspections will serve training, technology and information exchange, and verification functions. *(optional replacement for required language bullet)*
- For each inspection that is covered by this agreement, the inspector will complete, at a minimum:
- the Seafood HACCP Inspection Report;
- the Computer Generated Cover Sheet or similar document that contains, at a minimum: the voluntary corrections taken by the processor; and, the final classification of the inspection by the agency for each of the products inspected and for both compliance with the Seafood HACCP Regulation and other applicable regulations (i.e. separate classification for each);
- an FDA-483 or similar document that lists the specific violations noted during the inspection; and,
- for molluscan shellfish inspections, the National Shellfish Sanitation Program Standardized Shellfish Processing Plant Inspection Form.

(optional replacement for required language bullet)

- FDA and *(name of State agency)* will coordinate anticipated publicity relative to regulatory actions taken against fish and fishery products. *(optional additional bullet)*

Note: In order to reduce the possibility for inconsistent publicity between FDA and the states, it is advisable to include this bullet in the agreement.

b. FDA:

- FDA will maintain a combined establishment inventory of fish and fishery product processors, including their central file numbers, and provide on-line access to it to *(name of State agency)*. *(optional replacement for required language bullet)*
- FDA will provide standardization training for FDA and *(name of State)* bivalve, molluscan shellfish inspection personnel (inspection personnel may include analysts involved in team inspections), as needed. *(optional additional bullet)*
- FDA will provide training for FDA and *(name of State agency)* personnel on product coding, classification of inspections, and completion of the relevant documents, as needed. *(optional additional bullet)*
- FDA will commission State inspection personnel under section 702(a) of the FD&C Act as necessary to facilitate their carrying out of functions under this agreement. *(optional additional bullet)*

Note: this will be germane at least where a State has not adopted as its own the FDA Seafood HACCP Regulation. Commissioning under these circumstances would be necessary to ensure access to HACCP plan and records that are required under the FDA regulation.

- FDA will conduct at least *(enter the appropriate number of non-molluscan shellfish inspections that are to be performed by FDA under the terms of the agreement, but in no case less than 10% of the fish and fishery products processors in the state)* inspections of non-molluscan shellfish fish and fishery product processors consistent with the terms of this agreement (exclusive of joint inspections). Additionally, FDA will cover molluscan shellfish processing during inspections of multiple product processors. *(optional replacement for required language bullet)*
- FDA will provide analytical and regulatory follow-up support to *(name of state agency)*, as requested. *(optional additional bullet)*
- FDA will initiate all enforcement actions relating to deficiencies in processors' HACCP systems, as revealed through inspections conducted pursuant to this agreement.

Note: this is germane where a State has not adopted the FDA Seafood HACCP Regulation as its own but is conducting HACCP-based inspections under partnership with FDA and reporting the results to FDA.

c. *(name of State agency)*:

- *(name of State agency)* will develop and implement inspection procedures that are equivalent to those delineated in the Regulator HACCP course, the Domestic Fish and Fishery Products Inspection Program (for non-molluscan shellfish inspections), the Investigations Operations Manual (for non-molluscan shellfish inspections), and the National Shellfish Sanitation Program (for molluscan shellfish inspections).

5. Planned Resources

a. Funding:

- Training - costs of attendance for FDA and *(name of State agency)* fish and fishery product inspection personnel (inspection personnel may include analysts involved in team inspections) at introductory regulatory training (e.g. evidence development, interviewing technique), food science and microbiology (e.g. the FDA Food Microbiological Control course, or equivalent), the principles of HACCP and the requirements of the Seafood HACCP Regulation (e.g. the Alliance HACCP course, or equivalent), the performance of a HACCP inspection (e.g. the Regulator HACCP course), molluscan shellfish plant inspection standardization, product coding, classification of inspections, and completion of the relevant documents will be funded as follows:

(describe funding as agreed to by FDA and the State) (replacement for required language bullet)

Note: include only the relevant training programs.

b. Personnel:

- Training -
- FDA and *(name of State agency)* will provide inspection personnel (inspection personnel may include analysts involved in team inspections) to receive training as follows:

(list the number of FDA and State inspection personnel that will receive training in introductory regulatory issues [e.g. evidence development, interviewing technique], food science and microbiology [e.g. the FDA Food Microbiological Control course, or equivalent], the principles of HACCP and the requirements of the Seafood HACCP Regulation [e.g. the Alliance HACCP course, or equivalent], the performance of a HACCP inspection [e.g. the Regulator HACCP course], molluscan shellfish plant inspection standardization, product coding, classification of inspections, and completion of the relevant documents.)

- FDA will provide *(appropriate number of facilitators)* facilitator(s) for the Regulator HACCP course, as needed.

- *(list the number of FDA and State trainers for the standardization course)*

- FDA will provide *(appropriate number of trainers)* trainer(s) for training in product coding, classification of inspections, and completion of the relevant documents.

(replacement for required language bullet)

- Sample Analysis - FDA will provide *(describe the location and number of analysts or FTEs that will be responsible for analyzing the samples collected under this agreement)* analysts *(or FTEs)* for analyzing regulatory follow-up samples collected as needed under this agreement. *(optional additional bullet)*