Note: Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted. Deletions are marked as follows:
(#) denotes one or more words were deleted
(&) denotes one or more paragraph were deleted
(@) denotes one more web sites not accessible by non FDA users were deleted

CHAPTER 03 - FOODBORNE BIOLOGICAL HAZARDS

SUBJECT:	**IMPLEMENTATION DATE**
DOMESTIC FISH AND FISHERY PRODUCTS INSPECTION PROGRAM - FY 08, 09, 10	12/18/07
	COMPLETION DATE 9/30/10

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
INDUSTRY CODE 16, USE APPROPRIATE PRODUCT CODES **Note:** Most seafood inspections will consist of both HACCP and non-HACCP components. HACCP and non-HACCP activities, whether performed by FDA or by states under contract or partnership, should be reported separately using the individual PACs provided; however, for reporting of general investigational operations the non-HACCP portion of the inspection should be reported under 03842 and the HACCP portion under 03842H. It is not necessary to attribute time specifically to PPS areas other than 03, unless a substantial amount of time is spent in other PPS areas. For example, if problems are noted in the area of chemical contamination requiring investigational follow-up, then report that time under 04842H. (Report both FDA and State Partnership work under PACs 03842 and 03842H. The Position Class will be used to distinguish between the State Partnership and FDA accomplishments.)	1. LABS REPORT SAMPLE ANALYSIS UNDER THE FOLLOWING PACS: 03842B Filth 03842C Decomposition 03842D Microbiological (includes % water phase salt) 03842H HACCP Microbiological and HACCP Decomposition Verification 04842A Chemical Contamination 07842 ASP and PSP 07842H HACCP ASP and PSP Verification 09842E Color Additives 09842F Food Additives 09842H HACCP Color and Food Additives Verification 2. REPORT ALL OTHER OPERATIONS FOR PMS 03, 04, AND 09, ONLY UNDER THE FOLLOWING PACS: 03S001 - Foodborne Biological Hazards (Non-HACCP) – State Contract 03S002 - Seafood HACCP: State Contract 03842 - Foodborne Biological Hazards [non-HACCP] and all Documentary samples 03842H - Seafood HACCP 04842H - Chemical Contamination 09842 - Food and Color Additives 03R233 Inspections of Foreign Processors 03803E Targeted Allergen Inspection

Note: See note regarding Food Economics under **Laboratory Reporting** on the next page prior to using PAC 21842	3. REPORT ALL OPERATIONS FOR THE FOLLOWING AREAS UNDER THE DESIGNATED PACS: 21005 NLEA/FPLA/FALCPA (Food Allergen Labeling Consumer Protection Act) /and other general labeling 21R829 All activities involving nutritional health fraud issues 21842 Food Economics- Please see note in the section on LABORATORY REPORTING before doing any activity using this PAC

SPECIAL HACCP REPORTING

This Compliance Program will utilize a special HACCP reporting form: **FDA DOMESTIC SEAFOOD HACCP revised Form FDA 3501.**

FDA investigators are now to use the electronic version.
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States are to continue to use the hard copy of the 3501 which is to be faxed to a dedicated phone line (301) 436-2313 on an as completed basis. Only in the event that an office is unable to FAX the report in, and only after contacting Rochelle King at (301) 436-1416, should the original copy be sent to:

Food and Drug Administration
CFSAN/Office of Food Safety, Division of Seafood Safety, HFS-325
Attention: Rochelle King
5100 Paint Branch Parkway
College Park, MD 20740

LABORATORY REPORTING

Report the following analytical results into the FACTS Data System:

1.	Biotoxins (Natural Toxins)	Use PAF:	BIO
2.	Color Additives	Use PAF:	COL
3.	Decomposition	Use PAF:	DEC
4.	Filth	Use PAF:	FIL
5.	Food Additives	Use PAF:	FAD
6.	Microbiology	Use PAF:	MIC

	Salmonella Speciation	use sub-PAF	SAL
	Antibiotic Resistance	use sub-PAF	ABR
	Percent (%) Water Phase Salt and Nitrate		
		Use sub-PAF	WPS-NTR
	pH	Use sub-PAF	NAR
7.	Parasites	Use PAF:	PAR
8.	Pesticides	Use PAF	PES
9.	Salmonella Speciation	Use PAF	SAL

10. Note: **(&)**

If economic work is conducted under this program, use the appropriate PAF:

FDL- labeling
FDE- economic deception
FDQ- standard of quality
FDI- standard of identity

PART I – BACKGROUND

This compliance program provides coverage of firms that process fish and fishery products to ensure a safe and wholesome domestic seafood supply. This program provides direction to the field for developing inspectional priorities and instructions specific to the inspection of seafood processing facilities and products.

Under FDA's HACCP system of controls, a foreign processor of seafood intended for importation into the U.S must also operate in conformance with the seafood HACCP Regulation. FDA currently conducts inspections of both domestic and foreign seafood processors to determine compliance with 21 CFR, Part 123, the "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products" Final Rule (the Seafood Hazard Analysis and Critical Control Point (HACCP) Regulation (http://www.cfsan.fda.gov/~lrd/searule3.html). This compliance program contains instructions for both domestic and foreign processor inspections.

The Office of Food Safety, Division of Seafood Safety has associated certain seafood products with specific safety hazards either by association with a specific fish species or through subsequent processing activities (http://www.cfsan.fda.gov/~comm/haccp4c.html). The current regulatory strategy outlined in this program emphasizes areas of concern. It prioritizes processing activities and products based on a risk assessment that considers both the severity of consequences associated with a hazard and program data accumulated since the implementation of the Seafood HACCP Regulation. This compliance program reflects the most current evaluation of the Seafood HACCP Program which is posted at http://www.cfsan.fda.gov/~comm/haccpsea.html.

Based upon the most recent evaluation, the program will continue to list (#) high risk potential products. Aquaculture drugs have been moved from a low risk potential to high risk potential and its priority for inspection increased. Processors of these products are designated as a high priority for inspection and should be inspected annually.

Based on GAO findings, CFSAN continues to integrate investigational activities between the Import Compliance Program and the Domestic Compliance Program. The Office of Food Safety, Division of Seafood Safety has determined that data gathered during domestic investigations of importers provides a valuable targeting mechanism to assure that foreign inspection resources are directed towards foreign processors that have failed to comply with the seafood HACCP regulation. Conversely, data gathered during foreign investigations of processors can, in turn, help CFSAN determine importers that are accepting product from foreign processors that are not in compliance with the seafood HACCP regulation, and provide insight into the reliability of third party inspections and foreign certification programs.

The Domestic Seafood Compliance Program, CP 7303.842, continues to provide coverage to processors and products that are not covered under the Molluscan Shellfish Evaluation Program CP 7318.004 and additional coverage to processors and products covered under the Acidified and Low Acid Canned Food Compliance Program CP 7303.003A, i.e., hermetically sealed low-acid seafood and acidified shelf stable seafood for hazards that are not addressed by those programs.

PART II - IMPLEMENTATION

OBJECTIVE

This program is implemented to ensure a safe and wholesome fish and fishery products supply in the U.S. This is done by gathering information during inspections of domestic establishments involved in the production, storage and distribution of fish and fishery products, and by foreign fish and fishery processors that export their products to the U. S.

This will be accomplished by:

- Conducting inspections at both domestic and foreign production facilities.
- Determining during domestic inspections, that imported products used by a domestic facility are safe and wholesome.

APPROACH

The Domestic Fish and Fishery Products Inspection Compliance Program will have a two-pronged approach. It incorporates HACCP review for food safety by investigators specially trained in Seafood HACCP, and inspection for those areas such as filth, decomposition, etc., that may be considered adulteration under The Act rather than health hazards. In the former, investigators trained in seafood HACCP will review seafood processors' HACCP plans, HACCP records, and HACCP controls as they relate to safety hazards. In the latter, investigators will perform traditional compliance inspections for the non-HACCP attributes noted above. Thus both food safety (HACCP) and non-HACCP concerns will be covered during each inspection. For either type of inspection, it is important that the investigator be present at the firm to evaluate the entire operation from start-up to finish, including any sanitation procedures at the beginning and end of the operation.

When an investigator encounters a facility with no HACCP plan or an inadequate HACCP plan, a full HACCP inspection must still be performed following the guidelines established in the **Seafood HACCP Regulator Training Program Manual.** This is in addition to completing the non-HACCP portion of the inspection. The investigator must: [1] construct a flow chart for the product(s) being evaluated during his walk through; [2] independently identify the appropriate, hazards that are reasonably likely to occur and their Critical Control Points (CCPs); and [3] determine if the CCPs are being adequately monitored. On the FDA Form 483 it must be noted that there is no written HACCP plan and any deviations from acceptable GMPs must be noted. While the investigator must do a full HACCP inspection, this should not be interpreted to mean that either the flow chart or the HACCP plan should be prepared **for the firm** by the investigator.

PROGRAM MANAGEMENT INSTRUCTIONS

A. PROGRAM PRIORITIES AND RESOURCE UTILIZATION

1. Resources shown in the ORA workplan can be used to cover PMS 03, 04, 07, 09 and 21 using instructions provided in this program. It is not necessary to attribute time specifically to any one PAC other than 03, unless a substantial amount of time is spent in other specific areas. For example, if problems are noted in the area of chemical contamination requiring investigational follow-up, then report that time under 04842H.

2. Please note that re-inspections of out of compliance firms should not be conducted until good faith efforts between the firm and FDA at correcting and addressing significant problems have been

concluded.

Office of Food Safety, Division of Seafood Safety evaluations of prior years' seafood HACCP programs indicate that the percentage of firms that do not have a HACCP plan when one is required remains steady. They have not yet identified causes for this trend; however, this program element was prioritized for regulatory follow-up in compliance programs in previous years. This remains one of the top two priorities in this program. Each district seafood coordinator has been sent a list of firms that fit this category.

Compliance Program Inspectional priorities are listed (#) below:

a. Reinspection of manufacturers, repackers, primary processors of aquacultured fish, and refrigerated warehouses that receive/store any of the following "high risk potential" product types a, b, c, d, e, and f (as listed in A., 3 below) whose most recent inspection was classified as OAI for HACCP violations

b. Manufacturers, repackers, relabelers and refrigerated warehouses of any product that required the presence of a HACCP plan, but for which the firm had not developed one as of the most recent previous inspection

c. Reinspection of manufacturers, repackers, primary processors of aquacultured fish, and refrigerated warehouses that receive/store any of the following "high risk potential" product types a, b, c, d, e, and f (as listed in A., 3 below) whose most recent inspection and was classified as VAI for HACCP violations

d. Processors of "high risk potential" product types as specified in "A., 3." below that have never had an FDA or equivalent State HACCP inspection

e. Manufacturers and repackers of the "high risk potential" product types a, b, c, d, e, and f (as specified in "A., 3." below) which were classified as NAI during the most recent previous inspection

f. Processors producing only "low risk potential" products that have yet to have a FDA or equivalent State HACCP inspection

g. Manufacturers, repackers, relabelers and warehouses of high and low risk potential products such as breaded entrees, fish for sushi, etc. for which a HACCP plan is required, but which are not covered by one of the above bullets

h. Manufacturers, repackers, relabelers and warehouses of products for which a HACCP plan is not required. Note these firms should be inspected as resources permit, after the above-mentioned inspectional obligations have been met

3. For the purposes of this program "high risk potential" products include the following:

a. Refrigerated seafood products packed in Reduced Oxygen Packaging (ROP) (e.g., vacuum packaging, modified atmospheric packaging, hermetically sealed containers) including cooked seafood, smoked fish, fresh fish, seafood

soups or chowders, seafood salads, and sandwiches in such packaging

Seafood in such packages is subject to growth of anaerobic bacteria, such as *C. botulinum*.

ROP is oxygen impermeable or oxygen limiting packaging that reduces the transmission of oxygen to unsafe levels (less than 10,000 cc/m^2/24 hours) or prevents the transmission of oxygen In addition to hermetically sealed or canned goods requiring refrigeration, packaging where oxygen has been manually or mechanically expressed (vacuum), Modified Atmosphere Packs (MAP), lidded goods with heat sealed inner films, or deep containers that provide sufficient volume to prevent the exchange of oxygen throughout the package are included in this category.

b. Ready-To-Eat fish or fishery products either in ROP or non-ROP packaging, using any of the following processes:

(1) cooking or pasteurization process (e.g., cooked shrimp, crabmeat, cooked lobster, cooked crayfish, pasteurized crab meat, surimi-based analogs, etc.)

(2) hot or cold smoking process

The major concerns for these products are safe handling to prevent toxin formation by *Staphylococcus aureus* either before or after the cook process, cook processes that are inadequate to insure control pathogen survival, and subsequent mishandling after cooking that may allow the re-introduction of pathogens and/or pathogen growth and toxin formation.

c. Seafood mixes - Combination of seafood products including all raw, all cooked, or a mixture of raw and cooked product

Because of problems previously encountered with imported product, major concerns are the inclusion of raw molluscan shellfish from non-MOU sources, and cooked products that have not received an adequate cook.

d. Scombrotoxin-forming (histamine-forming) species (#) :

mahi mahi (dolphin fish), tuna, escolar, amberjack, yellow tail, anchovies, bluefish, bonito, jack (e.g., bluerunner, crevalle, rainbow runner, rooster fish (trevally), mackerel, marlin or saury and others listed in the Fish & Fisheries Products Hazards & Controls Guidance book

Preformed scombrotoxin prior to the canning process is not eliminated or reduced by the canning process and is to be covered in this program since it is not covered in the Domestic Acidified and Low Acid Canned Food Program, CP 7303,803A.

e. Aquacultured seafood

The major concern is the use of unapproved chemotherapeutics in aquacultured fisheries products. Note samples are to be collected only under the Chemotherapeutics in Seafood

Compliance Program, CP 7304.018.

e. Stuffed seafood products

The concern is that processing/handling may allow *Staphylococcus aureus* toxin development. Compliance data indicates that stuffed seafood processors have an increased likelihood of non-compliance with the seafood HACCP regulation.

f. Ready-To-Eat fish or fishery products that have not undergone a cook process (such as, cold smoked fish, caviar, urchin roe, pickled fish, or raw fish intended for sashimi/sushi) that are meant to be consumed raw (meat uncoagulated)

The concerns are that these products are subject to contamination and the growth of pathogens and the presence of viable parasites.

g. Salt-cured, and/or air-dried, un-eviscerated fish, such as Kapchunka, or bloaters

The concern is growth of *C. botulinum*, which is present in fish viscera, and subsequent toxin formation. CFSAN is to be contacted if this type of product is encountered.

Note: The following products (#) is provided under other compliance programs:

h. Acidified and low acid canned foods

The Domestic Acidified and Low Acid Canned Foods Program, CP 7303.803A covers the safety hazards associated with the formation of *Clostridium botulinum* toxin. However, this domestic seafood program covers other potential hazards in these products such as scombrotoxin in canned tuna that is not eliminated or reduced by the canning process.

i. Raw (fresh and fresh frozen) molluscan shellfish

Inspected under a cooperative agreement with the Interstate Shellfish Sanitation Conference (ISSC) are primarily covered by the Molluscan Shellfish Evaluation Program CP 7318.004. Coverage is provided for these products under this program only when the appropriate state authority cannot or will not provide appropriate coverage under the terms of the National Shellfish Sanitation Program NSSP or the shellfish is processed in a state that is not a member of the NSSP.

4. For the purposes of this program, CP 7303.842, "Low-Risk Potential Products" include all other fish and fishery products (#).

B. IDENTIFICATION OF A DISTRICT SEAFOOD COORDINATOR

Each District MUST designate a "District Seafood Coordinator" to be listed in the IOM.

C. REPORTING HACCP REVIEWS

A separate seafood HACCP inspection report **(FDA DOMESTIC SEAFOOD HACCP, FORM FDA 3501**) is to be completed for the HACCP portion of the inspection for each product evaluated during a domestic inspection. See Part III, Section A, 3 for complete instructions.

Note: A FDA Form 3501 is also to be prepared for inspections of foreign seafood processors. The form is to be prepared after returning from the foreign inspection trip and is to be emailed as instructed.

D. SAMPLE COLLECTION

HACCP Verification Samples are not to be routinely collected. They should be collected only when a specific request is made to a district by CFSAN.

See Part III C "Sampling" for complete sampling instructions.

The current ORA Field Workplan provides resources primarily for "for cause" sample collection and analysis.

E. INTERACTION WITH OTHER PROGRAMS/ASSIGNMENTS

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1. Domestic Acidified and Low Acid Canned Foods, CP 7303.803A

   Resources expended in inspections of firms for compliance with the low acid canned foods regulation (21 CFR 113) or the acidified foods regulation (21 CFR 114) must be reported under CP 7303.803A. Inspectional coverage of acidified or canned seafood related to other safety hazards, (e.g., histamine, food/color additives, or decomposition) is to be reported under this program CP 7303.842.

2. Molluscan Shellfish Evaluation Compliance Program, CP 7318.004

   FDA evaluates State inspectional coverage of shellfish growing areas and shellfish shippers under The Molluscan Shellfish Evaluation Program, CP 7318.004. After reviewing the states' accomplishments FDA refers any problem to the appropriate State for follow-up. Inadequate State follow-up or unresolved issues are referred to the Interstate Shellfish Conference (ISSC) for resolution. Coverage under this program, CP 7303.842, is provided only if appropriate action cannot be achieved within the structure of the National Shellfish Sanitation Program (NSSP).

3. NLEA, Nutrition Sampling and Analysis, and General Labeling Requirements – Domestic and Import, CP 7321.005

   NLEA coverage will be conducted during routine inspections conducted under the Domestic Fish and Fishery Products Inspection Program of firms that are labeling or relabeling fish and fishery products. Coverage will be reported under the compliance program CP 7321.005.

   This program covers allergen labeling issues and other labeling requirements of FALCPA

4. Pesticides and Industrial Chemicals in Domestic and Imported Foods CP 7304.004

Coverage will be conducted to determine compliance with the pesticide residue regulation and directed to firms and products for which there is little or no information from previous years' sampling, or for firms that have a violative history for pesticide or chemical contamination of seafood.

5. Toxic Elements in Foods, Foodware, and Radionuclides in Foods, Domestic and Imported, CP 7304.019

Coverage will be conducted to develop broader background level data for certain toxic elements in foods, including seafood. Primary interest is in lead and cadmium.

6. Chemotherapeutics in Seafood Compliance Program, CP 7304.018

Coverage consisting of sample collections will be conducted to evaluate compliance with regulations governing the use of chemotherapeutic agents in seafood. Only inspections of seafood farms will be done under program CP 7303.842.

F. FEDERAL/STATE CONTRACTS AND PARTNERSHIPS

Contracts exist with a number of states to inspect seafood establishments. This program will be incorporated by reference in these contracts as guidance in conducting fish and fishery product sanitation inspections.

All seafood inspections conducted either under state contract or partnership must be HACCP based and consistent with the methods included in the Seafood HACCP Regulator 2-day course. The inspections must be based on the Seafood HACCP regulation and FDA recommendations as opposed to local state requirements. Districts must ensure that state investigators assigned to do HACCP inspections are HACCP trained, i.e., they have successfully completed a Seafood HACCP Alliance 3-day course or its equivalent and successful completion of the Seafood HACCP Regulator 2-day course including passing the course examination, and the Food Microbiology Control Course.

In anticipation of moving towards HACCP-based partnerships for the inspection of seafood processors, the Agency has developed a model FDA-state partnership agreement. Partnership agreements with state regulatory agencies for the inspection of seafood processors should be consistent with this model which can be found at. http://www.fda.gov/ora/Partnership_Agreements/PA_standard_model_3.htm

PART III - INSPECTIONAL

Domestic and foreign seafood HACCP inspections are to be performed according to the instructions that follow, including the completion of a Form FDA 3501. The one exception is that no samples are to be collected at foreign processors.

For scientific and technical HACCP questions during and following inspections, contact the Seafood Technical and Policy Branch at (301) 436-2300.

For inspectional instructions and procedures, investigators are advised to refer to the following references:

Seafood HACCP Regulator Training Program Manual (RTM) - HACCP inspection procedures/activities;

Fish and Fishery Products Hazards and Controls Guidance (FFPH&CG) - Recommended hazards and controls in seafood processing, most recent edition;

Food Microbiological Control Manual, most recent edition;

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Additional references listed in Part VI.

All seafood inspections must include at least a non-HACCP Seafood component (see section **D** below). Most seafood inspections will include a HACCP Inspection component although sometimes that will be limited to determining that the facility does not require a HACCP plan.

A. **Training Requirements:**

Investigators performing seafood inspections (state and federal) must have successfully completed the following courses:

- Seafood HACCP Alliance 3-day course or its equivalent such as The Seafood Alliance Internet 2 day on-line course plus a third day of live instruction by a certified seafood HACCP instructor
- FDA's Seafood HACCP Regulator's Course – 2 day video

Investigators performing seafood inspections (state and federal) should have successfully completed the following courses. If they have not, they should obtain the training as soon as possible.

- FDA's Food Microbiology Control course (video or internet) and
- Seafood HACCP Alliance Sanitation Control Procedures Course

B. **HACCP (Safety) Inspection Component**

Inspection: The investigator's role includes evaluating the adequacy of the firm's HACCP plan, the adequacy of the implementation of the plan, the presence or absence of adequate controls when there is no written plan, and sanitation monitoring. If a question arises about the adequacy of the plan or its implementation, the investigator is encouraged to seek advice from the district, region, or CFSAN. If the issue cannot be resolved, collect as much information as possible for later review by

the district/region/CFSAN/National Expert.

To accomplish this, it is important that as per the Seafood HACCP Regulators Course, the following steps be completed and included in the EIR:

1. Conduct an initial interview

2. Develop an independent hazard analysis including a flow diagram with descriptions of each step

3. Evaluate the processor's hazard analysis, if available

4. Evaluate the processor's HACCP plan

5. Determine if the HACCP plan is properly implemented and describe the implementation of the HACCP controls

6. Determine and describe the firm's implementation of sanitation monitoring

7. Review records and make copies as necessary

8. Document objectionable conditions

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a "Supplemental Inspection Instructions" that contains more detailed information regarding what is required for each of the points listed above. This document is not a replacement for any of the required training but serves as a refresher for the points covered in the more detailed Seafood Regulators Training Course.

There are a number of points that were not covered in the regulator's training course:

1. The seafood HACCP inspection should be performed in a manner consistent with the Seafood HACCP Regulator Training Manual. Additionally, in circumstances outlined below, special, **LIMITED PLAN REVIEWS** of high risk products not covered by the inspection are to be conducted.

   (#). For firms producing both high and low risk potential products, the inspection should be conducted when high risk product(s) are produced. In the event an investigator arrives at a firm prepared to do a HACCP inspection and the firm is not in operation, the inspection should be rescheduled if possible. If it is not feasible to reschedule (e.g., the firm is at a distant location), an inspection that includes a **complete HACCP Records Review** should then be conducted.

   Note: For logistical reasons, it is recognized that it will be impractical to inspect most processing vessels when they are in operation. Inspections of these vessels will normally be performed when the vessel is in port and not in operation.

2. If the firm IS NOT OPERATING on the day of the inspection, the investigator should attempt to answer HACCP questions as completely as possible. HACCP records (HACCP plans, Critical Control Point (CCP) monitoring and corrective action records) and sanitation monitoring records covering previous production days should be reviewed. Any sanitation defects observed should still

be noted on the FDA Form 483.

Note: Reasonable effort should be made to perform the inspection while the firm is producing the product previously selected for coverage (e.g., the product for which the last inspection received a classification of VAI/OAI.) Also acceptable would be an inspection while the firm was producing a product with identical CCPs that is covered under the same HACCP plan. This is particularly true if past inspections have been conducted when the firm was not producing the product. In some cases it may be necessary to contact the firm and determine their production schedule for the product of interest. The district should then inspect when that product will be in production. Districts should use their discretion in employing this approach. If the re-inspection is not accomplished and instead an inspection is performed on a product covered by a HACCP plan other than one that was the subject of OAI/VAI classification, the district, at its earliest opportunity, is still obligated to perform a re-inspection for the product of the OAI/VAI classification or a product with identical CCPs covered under the same HACCP plan. (#).

3. Investigators are to conduct a **limited revie**w of HACCP plans for all products listed in Part II, A, 3. in addition to the standard review of the product being processed. This limited review should consist only of a review of the written HACCP plan to determine if appropriate/reasonable hazards, CCPs, critical limits etc. are identified. The investigator need not review production records, processing conditions, etc. Any significant problems with the HACCP plan(s) should be documented and reported on the EIR and the FDA 483. A FDA Form 3501 should be completed for one product covered by each HACCP plan that has only had this limited review. However, ensure that the Question # 10 (Actively Processing) is answered **NO**.

4. In the event that an investigator encounters a facility with no HACCP plan, or an inadequate HACCP plan, a full HACCP inspection must be performed following the guidelines established in the HACCP Regulator's Manual, to determine what controls are in place in the absence of such plan. The investigator will [1] independently construct a flow chart for the product(s) being evaluated, [2] independently identify the appropriate, significant hazards and the CCP and [3] determine if the CCPs are being adequately monitored. This information will be noted on the Form FDA 483. This is in addition to completing the non-HACCP portion of the inspection.

5. Document **all** deficiencies to the seafood HACCP regulation and GMPs on the Form FDA 483 in a manner consistent with the Seafood HACCP Regulator Training Course. Narrative EIRs should be completed as directed by existing instructions. Consistent with such instructions, these narrative reports should describe the firm’s HACCP control program, investigator observations, and the HACCP-related deficiencies noted during the inspection.

6. During HACCP inspections coverage of allergens should be conducted consistent with the HACCP Guide. Additionally, allergen labels issues should be as per the instructions in NLEA, Nutrition Sampling and Analysis, and General Labeling Requirements – Domestic and Import, CP 7321.005.

C. Reporting - FDA DOMESTIC SEAFOOD HACCP REPORT, Form FDA 3501

Investigators are instructed to complete an **FDA DOMESTIC SEAFOOD HACCP REPORT, Form FDA 3501** for each product covered during a seafood processor inspection, domestic or foreign. Follow the line-by-line instructions provided for completing the FDA Form 3501. These instructions are posted on the Internet under the Seafood HACCP program area. Access via the sequence: http//www.fda.gov, then click the foods icon (CFSAN home page), then click Seafood, then HACCP, then to Seafood HACCP web page or go to http://www.cfsan.fda.gov/~comm/haccpsea.html.

Please notice this special definition of **actively processing** that is only for the purposes of the FDA Form 3501, Question 10: "Was the firm actively processing the finished product you listed in Block 9?" - Whether a firm is to be considered as actively processing at the time of inspection depends upon the nature of the firm. If it is a warehouse and has the product listed in Block 9 in storage, it is to be considered as actively processing that product. If a firm is a manufacturer, repacker, or relabeler, it is to be considered as actively processing on the FDA Form 3501 only if it is actually manufacturing, repacking or relabeling that product during the inspection. If a manufacturer, repacker or relabeler only has the product in inventory, it is not to be considered to be actively processing even though it is considered to be processing under 123.3(k)

Only data elements from properly completed forms can be entered into the National Seafood HACCP Inspection Database. All information requested in Section I and questions, A, D, and E in the "For Official Use Only" Section must be completed. The following are required to enter inspection findings in the Database and conduct various analyses: FEI [1], date of inspection [3], firm identifier information [5], inspection basis [6], type of establishment [7], complete product code/description [8 & 9], intrastate commerce only [11], and the FDA District/Agency Code [A], Employee Phone Number [F] and, lastly, whether a HACCP plan was needed and was there a written plan? [13 & 14] Please be very specific and accurate in describing the finished product and entering its product code. Accurate product codes are essential in determining the significance of hazards and sanitation deficiencies. For assistance, consult the line-by-line instructions or the FDA Product Code Builder.

FDA investigators are now to use the electronic version of the **FDA DOMESTIC SEAFOOD HACCP, revised FDA Form 3501...** (@)

Until further notice, states will continue to use the hard copy of the 3501 which is to be faxed to a dedicated phone line (301) 436-2313 on an as completed basis. Only in the event that an office is unable to FAX the report in, and only after contacting Rochelle King at (301) 436-1416, should the original copy be sent to:

Food and Drug Administration
CFSAN/Office of Food Safety, Division of Seafood Safety, HFS-325
Attention: Rochelle King
5100 Paint Branch Parkway
College Park, MD 20740

D. **Inspection Component(s) for Reasons Other than Seafood-HACCP**

It is important to remember that HACCP is only one element of a seafood processor inspection, not the entire agenda. The investigators need to continue to apply existing skills to look for deficiencies of other regulations and statutes, such as those relating to filth, decomposition, and good manufacturing practice. As in the past, such

deficiencies will be noted on FDA Form 483 in addition to seafood HACCP deficiencies.

Perform LACF/AF inspections at firms producing such products and report the LACF/AF portion under CP 7303.803A.

E. **Sampling**

For specific instructions on sample collection and shipment to analyzing labs see

- Attachment A contains both general guidance (page 1 -4) and specific guidance (other pages).
- Consult the current ORA Field WorkPlan to determine appropriate analyzing labs.
- Prior to collecting samples for microbiological examination, please carefully review IOM sections 5.4.7.2 and 4.3.7.7 for inspectional guidance and sampling instructions, respectively, for products susceptible to contamination with pathogenic organisms.

1. **"For Cause" Safety Sample Collection**

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Collect "for cause" safety samples:

a. To determine if an imminent public health hazard exists, or,

b. To make a determination about the product controls that cannot be determined by observation (e.g., whether the salting process has resulted in an appropriate water-phase salt concentration in the finished product).

Most deficiencies found from the Seafood HACCP Regulation do not require a physical sample to confirm or document them.

Note that the number of samples identified in the ORA workplan is for planning purposes. Samples should be collected only if conditions warrant.

2. **Non-HACCP (Non-Safety) Sample Collection (For Cause only)**

Official Samples for non-safety defects (such as non-scrombrotoxic decomposition/filth (for example rodent defiled raw material)/sanitation/misbranding, etc) are to be collected for cause only (e.g., if inspectional conditions warrant). Please note that the number of samples identified in the ORA workplan is for planning purposes. Samples should be collected only if conditions warrant.

3. **Documentary Samples**

All documentary samples (e.g., to support interstate commerce) are to be reported **only** under PAC 03842. Documentary samples are NOT to use the PACs (those ending in 842H) reserved for verification samples nor are they to count towards district Workplan obligations.

4. **HACCP Verification Samples**

(#). They should be collected only when a specific request is

made to a district from CFSAN. If requested, CFSAN will also supply instructions regarding what is to be sampled.

F. **Special Instructions for Foreign Establishment Inspections**

An inspection of a foreign processor who exports seafood to the United States provides a limited opportunity for FDA to evaluate a processor's compliance with the seafood HACCP regulation. (#). The Division of Seafood Safety will notify investigators of the products that are of concern at each firm and will provide a list of products, with entry numbers, that each processor imports into the United States.

Investigators should focus their attention on the implementation of the HACCP program for those targeted products and conduct a full seafood HACCP inspection. If the targeted product or a product with identical hazards, processing steps, and controls is not being processed during the investigation, the investigator should conduct a full records review of the targeted product, and a seafood sanitation inspection, and put all observations, flow charts, records reviews, etc. in the EIR and complete an FDA Form 3501 for each product. The investigator should also conduct a seafood HACCP inspection of current processing activities, if time permits and if the product has been imported into the U. S.

Sanitation evaluations should determine if the eight key areas of sanitation listed in 21 CFR 123.11 are adequately controlled and monitored. General GMP deficiencies should also be addressed, if time permits, but investigators should devote their attention primarily to safety issues.

Investigators must obtain copies of the HACCP plans and examples of the monitoring records, corrective action records, and key sanitation monitoring records, such as daily sanitation monitoring and water quality tests, which show how the plan(s) for the targeted product and sanitation monitoring procedures are implemented by the firm. The investigator's observation and those records should be included in the EIR.

Foreign processors are not required to maintain their records in English. Since most of the firms inspected do not use English as their primary language, investigators should either request that the firm translate key areas of the records or plans for the investigator, or provide the investigator with translated examples. Translations should be noted on a copy of the record, if necessary, and included in the EIR. The translations obtained from the processor will help assure accuracy.

PART IV - ANALYTICAL

When sample analyses are required for cause or for HACCP Verification, use the methods referenced in the appropriate section of this Part.

The sections of this part are:

A Project 03: **Filth, Mold, and Foreign Objects: Microscopic/Macroscopic**

B Project 03: **Parasite**

C Project 03: **Decomposition**

D Project 03: **Microbiological**

E Project 04: **Chemical Contaminants**

F Project 07: **Natural Toxins**

G Project 09: **Food and Color Additives**

H Project 21: **Food Composition, Standards, Labeling and Economics**

- Servicing laboratories are not identified in this compliance program. Please consult the current workplan to determine the appropriate laboratory.
- As BAM and AOAC methods are updated, the most recent method should be used unless this compliance program specifically states not to use updated methods.

A. **Project 03: FILTH, MOLD AND FOREIGN OBJECTS: MICROSCOPIC/MACROSCOPIC**

FIELD LABORATORIES: Refer to the current ORA Field Workplan for the correct servicing laboratory.

METHODOLOGY:

AOAC, 18th Ed., Chapter 16, Extraneous Materials: Isolation

JAOAC (Interim Official First Action Methods)

FDA Laboratory Bulletin (LIB) # 3172 - Filth in Shrimp

Macroanalytical Procedures Manual (MPM)

Note: No specific analytical method exists to determine filth in Shucked Shellfish; however, depending on the type of filth suspected, adaptations of methods described in the Macroanalytical Procedures Manual (MPM) and in the AOAC, 18th Ed., are appropriate.

COMMENTS: Each subsample should be examined individually and not composited.

CONTACTS: CFSAN, Office of Regulatory Science, /Division of Analytical Chemistry, Microanalytical Branch, HFS-315, George Ziobro, (301) 436-1932

REPORTING: Report all results of analytical results in FACTS using Problem Area Flag: FIL and PAC 03842B.

B. **PARASITE ANALYSIS**

FIELD LABORATORIES: Refer to the current ORA Field Workplan for the correct servicing laboratory.

METHODOLOGY: Bacteriological Analytical Manual (BAM) on line at http://www.cfsan.fda.gov/~ebam/bam-toc.html, Chapter 19, Parasitic Animals in Foods, II. Candling to Detect Parasites in Finfish, page 19.04 - 19.05.

1. **Parasite Identification**

   Fix parasites as described in BAM and contact Clarke Beaudry at (301) 436-2503 to determine where to send them.

   Send a minimum of 3 whole parasites of each species found and all head/tail fragments found. Label vials with sample and subsample numbers and include a report form copy in the shipping container.

2. **Report**

   All results are to be recorded in FACTS using Problem Area Flag PAR and PAC 03844B.

3. **Parasite Fixation** See reference in BAM, Chapter 19.

C. DECOMPOSITION ANALYSIS

FIELD LABORATORIES: Refer to the current ORA Field Workplan for the correct servicing laboratory.

METHODOLOGY: Indole: AOAC, 18th Ed., 981.07, Section 35.1.35, liquid chromatographic fluorometric method.

Histamine: AOAC, 18th Ed., 977.13, Section 35.1.32, fluorometric method

Organoleptic: Original and confirmatory organoleptic analyses may only be performed by analysts qualified in the particular seafood product category as found in ORA's "Seafood Sensory Analyst Product Category Ratings List" This list is maintained by ORA's Division of Field Science.

Products that have been treated with chemicals or additives, that have no obvious odors of decomposition or where odors may have been masked, should be chemically analyzed for decomposition where chemical indicators of decomposition are applicable. CFSAN's Office of Regulatory Science, Division of Analytical Chemistry, Spectroscopy Mass Spectrometry Branch (HFS-707) can be consulted for appropriate testing methods and applications. The Branch chief is John Callahan at 301-436-2039.

REPORTING: Enter all analytical results including organoleptic results into FACTS using PAF DEC and PAC 03842C.

When samples are involved in an illness, in addition to notifying the Office of Emergency Operations (OEO) at 301-443-1240 and ORA/DIOP, contact CFSAN/Office of Food Defense, Communication and Emergency Response, Division of Public Health and Biostatistics, /Emergency Coordination and Response Staff at (301) 436-1608.

ANALYSIS REQUIREMENTS ARE SPECIFIC FOR PRODUCTS AS FOLLOWS:

1. **POTENTIALLY SCOMBROTOXIC SPECIES Raw Fresh/Frozen and Processed Fish Products** (To identify scombrotoxin (histamine-forming)species, consult the Fish and Fisheries Products Hazards and Controls Guidance, Table 3-1)

   a. **ORGANOLEPTIC EXAMINATION**

   Follow the Organoleptic Method and Reporting Requirements as specified in the beginning of this section. The minimum number of subsamples to be organoleptically examined should be:

Product Type	Number of Subs to Examine
Raw Fresh or Fresh/Frozen	18
Canned/pouched tuna greater than or equal to 900 grams (2 lbs)	18
Processed other than canned/pouched tuna greater than or equal to 900 grams	24

Note: Processed products include cooked, canned, and/or treated with chemicals or additives, including such things as salt, chlorine, smoke, and carbon monoxide. Dried products and sauce/paste products are not included; CFSAN's Office of Regulatory Science, Division of Analytical Chemistry, Spectroscopy Mass Spectrometry Branch (HFS-707) should be consulted if decomposition analysis is indicated for dried or sauce/paste articles. The Branch chief is John Callahan at 301-436-2039.

(1) Positive Findings:

When an original organoleptic analysis is performed and odors of decomposition are detected, original results should be confirmed by:

- An analyst qualified for confirmat1on analysis, i.e. Level II (B) or III analysts, in the appropriated product category as found in ORA's "Seafood Sensory Analyst Product Category Ratings List"

  Or

- Examination of an additional sample (same number of subsamples from the same production code mix as the original sample) by another servicing laboratory.

  A second analyst is not needed when a National Expert performs the confirmatory organoleptic analysis on a sample delivered from another lab following original findings of decomposition.

  Or

- Histamine analysis

  When confirming positive organoleptic results by histamine analysis, analyze a minimum of six subsamples for histamine including the subs exhibiting odors of decomposition. In addition, the remaining subsamples should be analyzed if histamine greater than or equal to 35 ppm is detected in any of the initial six subsamples.

(2) Negative Findings:

- If the sample does not exhibit odors of decomposition, or if only one subsample is determined to have odors of decomposition, a histamine analysis of at least six subsamples is recommended. The remaining subsamples should be analyzed if histamine greater than or equal to 35 ppm is detected in any of the initial.

- If the sample does not exhibit odors of decomposition, and the product is processed with additives or chemical treatments (e.g. chlorine dip) that could mask odors of decomposition, all

subsamples in the sample should be analyzed additionally for histamine.

b. **HISTAMINE ANALYSIS**

Follow histamine method as specified in the beginning of this section. Preparation for histamine analysis should begin immediately after completion of the organoleptic examination.

Organoleptic analysis is recommended in addition to histamine analysis on all samples. Follow the instructions above for selection of subsamples when conducting histamine analysis as confirmation of organoleptic findings (positive or negative). If histamine analysis is conducted in the absence of an organoleptic examination, all subsamples in the sample should be analyzed unless sufficient decomposition to support regulatory action is found.

SAMPLE PREPARATION [NOTE: THERE ARE NO "A" OR "B" PORTIONS.]

Whole Fish, Fillets, and Loins: Cut a transverse section (approximately 250 to 500 grams) from the anterior end (if it can be determined) of the fish and grind each subsample. For larger fish, the lower anterior portion provides the best sample. For very small fish (e.g. anchovies), more than one fish may need to be used to prepare a representative sample of edible portion that may include the entire length of the fish. (Preferentially use pieces from the sub that "failed" the sensory analysis if so segregated.)

Steaks, Strips, Cubes, etc.: Grind 250 to 500 grams of the edible portion of each subsample (i.e. excluding bone). For packages (subsamples) containing multiple pieces, include portions of each piece to make up the sample. For very small pieces, grind a representative number (preferentially use pieces from the sub that "failed" the sensory analysis if so segregated).

Cans and Pouches: Grind 250 to 500 grams of each subsample or the entire can/pouch for smaller container sizes. For large containers, break up and rough mix the flesh before collecting the test portion including a representative amount of the aqueous portion in the package.

Analysis: Homogenize the specified fish portion in a food grinder or a food processor and remove a 10 gram aliquot from each subsample.

Histamine Check Analysis: When two or more subsamples contain histamine at or above 50 ppm, or any subsample contains histamine at or above 500 ppm, a check histamine analysis should be performed on a minimum of two subs showing the highest histamine levels. Use an addition 10 g aliquot from the same ground portions to perform the check analysis. (Check analysis of histamine findings is also warranted if a case is being developed on the basis of one subsample failed for odors of decomposition and one subsample failed for histamine at or above 50 ppm.)

c. **Criteria for Regulatory Action:**

Based on analytical data, refer to CPG 540.525.

2. **SHRIMP**
Raw Fresh/Frozen and Processed Products

a. **ORGANOLEPTIC EXAMINATION:**

Follow the Organoleptic Method and Reporting Requirements as specified in the beginning of this section. A minimum of 12 subsamples (18 subs for processed product) should be organoleptically examined.

Note: Processed products include cooked (including pasteurized), canned, and/or treated with chemicals or additives. Product treated with sulfites or phosphates may be considered raw unless the compounds are used in excessive levels in efforts to mask decomposition. Dried products and sauce/paste products are not included; CFSAN's Office of Regulatory Science, Division of Analytical Chemistry, Spectroscopy Mass Spectrometry Branch (HFS-707) should be consulted if decomposition analysis is indicated for dried or sauce/paste articles. The Branch chief is John Callahan at 301-436-2039.

(1) Positive Findings:

When an original organoleptic analysis is performed and odors of decomposition are detected, original results should be confirmed by:

- An analyst qualified for confirmatory examinations in the appropriate product category as found in ORA's "Seafood Sensory Analyst Product Category Ratings List" (maintained by the Office of Field Science, HFC-140)

Or

- Examination of an additional sample (same number of subsamples from the same production code mix as the original sample) by another servicing laboratory

  A second analyst is not needed when a National Expert performs the confirmatory organoleptic analysis on a sample delivered from another lab following original findings of decomposition.)

Or

- Indole analysis.

  When confirming positive organoleptic results by indole analysis, analyze a minimum of six subsamples for indole including the subs exhibiting odors of decomposition. The remaining subsamples should be analyzed if indole is detected at 15-24 micrograms /100 grams for shrimp in any of the

initial six subsamples. Additional subs need not be analyzed if two or more subsamples are found to contain 25 micrograms indole/100g or more in shrimp.

(2) **Negative Findings:**

- If the sample does not exhibit odors of decomposition, or if only one subsample is determined to have odors of decomposition, an indole analysis of at least six subsamples is recommended. The remaining subsamples should be analyzed if indole is detected at 15-24 micrograms /100 grams for shrimp in any of the initial six subsamples Additional subs need not be analyzed if two or more subsamples are found to contain 25 micrograms indole/100 grams or more in shrimp.

- If the sample does not exhibit odors of decomposition and the product is processed with additives or chemical treatments (e.g. chlorine dip) that could mask decomposition, all subsamples in the sample should be analyzed for indole.

b. **INDOLE ANALYSIS**

Follow Indole Method as specified in the beginning of this section.

Organoleptic analysis is recommended in addition to indole analysis on all samples. Follow the instructions above for selection of subsamples when conducting indole analysis as confirmation of organoleptic findings (positive or negative). If indole analysis is conducted in the absence of an organoleptic examination, all subsamples in the sample should be analyzed.

For canned shrimp or cooked frozen shrimp, when the sub size is equal to or less than 454 grams, composite the entire sub. Discard any liquid before compositing unless the liquid is intended to be eaten, e.g., canned soup product. If the sub is larger than 454 grams, remove 454 grams of the sub and composite this for indole analysis.

Check Analysis: When two or more subsamples contain indole at or above 25 micrograms/100 grams in shrimp, a check indole analysis should be performed on a minimum of two subs showing the highest indole levels using the composites utilized for the original indole analysis. Check analysis of indole findings is also warranted if a case is being developed on the basis of one subsample failed for odors of decomposition and one subsample failed for indole levels.

c. **CRITERIA FOR REGULATORY ACTION**

When decomposition is detected and confirmed, all positive analytical results should be referred to CFSAN, Division of Enforcement, for review.

3. **OTHER SEAFOOD PRODUCTS -** Except Scombrotoxin-forming Fish (see item 1 above), or Shrimp (see item 2 above)

a. **ORGANOLEPTIC EXAMINATION:**

Follow the organoleptic Method and Reporting Requirements as specified in the beginning of Part IV, C. **DECOMPOSITION ANALYSIS**. A minimum of 12 subsamples (18 subs for processed product) should be organoleptically examined.

Note: Processed products include cooked, canned, and/or treated with chemicals or additives, including such things as salt, chlorine, and carbon monoxide. Product treated with sulfites or phosphates may be considered raw unless the compounds are used in excessive levels in efforts to mask decomposition. Dried products and sauce/paste products are not included; CFSAN's Office of Regulatory Science, Division of Analytical Chemistry, Spectroscopy Mass Spectrometry Branch (HFS-707) should be consulted if decomposition analysis is indicated for dried or sauce/paste articles. The Branch chief is John Callahan at 301-436-2039.

Positive Findings:

When an original organoleptic analysis is performed and odors of decomposition are detected in two or more subsamples, original results should be confirmed by:

- An analyst qualified for confirmatory examinations in the appropriate product category as found in ORA's "Seafood Sensory Analyst Product Category Ratings List" (maintained by Office of Field Science, HFC-140)

Or

- Examination of an additional sample (same number of subsamples from the same production code mix as the original sample) by another servicing laboratory.

  A second analyst is not needed when a National Expert performs the confirmatory organoleptic analysis on a sample delivered from another lab following original findings of decomposition.

b. **Criteria for Regulatory Action:**

Based on analytical data, refer to CPG 540.575.

D. Project 03: MICROBIOLOGICAL ANALYSIS

FIELD LABORATORIES: Refer to the current ORA Field Workplan for the correct servicing laboratory.

NOTE: Confirmation tests for *Clostridium botulinum*, which require animals, will be performed at ARL.

If there is direct evidence of botulism toxin and it is implicated by clinical evidence, samples should be sent directly to the designated servicing laboratory.

GENERAL METHODOLOGY:

1. Bacteriological Analytical Manual (BAM) on line at http://www.cfsan.fda.gov/~ebam/bam-toc.html

2. AOAC, 18th Ed., (or as updated) Chapter 17, Microbiological Methods

3. **THE LABORATORY BRANCH WILL PERFORM ADDITIONAL ANALYSES IN CONJUNCTION WITH THOSE SPECIFIED BY THE INVESTIGATOR ON THE SAMPLES PROVIDED, IF DEEMED APPROPRIATE FOR REGULATORY PURPOSES.**

4. **COMPOSITE FOR ANALYSIS IF SPECIFIED BY BAM METHODOLOGY OR BY THE FOLLOWING "SPECIAL METHODS INSTRUCTIONS" SECTION, IF INDICATED. OTHERWISE, EACH INDIVIDUAL SUBSAMPLE IS TO BE ANALYZED.**

SPECIAL METHODS INSTRUCTIONS

1. ***Escherichia coli***

LST-MUG for Detection of *E. coli* and Coliforms in Chilled or Frozen Foods Exclusive of Bivalve Molluscan Shellfish BAM, Chapter 4, Section I. For determining *E. coli* in Shellfish Meats, see BAM, Chapter 4, Section IV

LST-MUG may be used when both *E. coli* and coliform analyses are required in **chilled and frozen foods, ONLY**. The presumptive test for coliforms can be performed in conjunction with the test for *E. coli* by preparing LST-MUG with gas tubes (i.e., using the same medium, LST-MUG, for the detection of *E. coli* and coliforms).

2. ***Listeria*** Do not analyze products with PIC codes of B, C, or D for *Listeria* unless there is a comment on the collection report that the district feels that there is reason to believe the product will be consumed raw.

a. **General Method**: Use BAM, Chapter 10 *Listeria monocytogenes*, and Chapter 11, Serodiagnosis of *Listeria monocytogenes*. Additionally, Rapid Test Kits as identified in the memo, "Guidance for the use of *Listeria* Rapid Methods for Food Microbiology" dated July 9, 1998 may be used as per the instructions and restrictions contained therein. If a laboratory does not have this memo on hand, they should request a copy of it from the Division of Field Science, HFC-140.

SAFETY PRECAUTIONS: Media preparation for *L. monocytogenes* directs the use of cycloheximide which is an **extremely toxic** chemical and acriflavine which is a powerful mutagen (**use caution**).

Since the *L. monocytogenes* method gives the option of using α -naphthol, **DO NOT** use α - Naphthylamine. All analysts should take **extreme safety precautions** when handling these chemicals; e.g., weigh in a containment hood free of drafts; wear gloves and face mask. Those laboratories with pesticide capabilities should take additional precautions against possible contamination as cycloheximide is a fungicide.

b. **Compositing/Sample Preparation Instructions**

Listeria analysis will be performed on Ready-To-Eat food products that require minimal or no further processing by the consumer.

The analysis will be conducted on a composite basis ONLY (i.e., analyze two (2) composites per samples).

This includes all follow up samples collected based on an initial positive finding (if appropriate).

Use the following procedure for preparing each composite:

6 subs/sample - Remove 80 g from each of three (3) subsamples. Each composite size is 240 g.

10 subs/sample - Remove 50 g from each of five (5) subsamples. Each composite size is 250 g.

Once the two composites have been prepared, remove 25 g or mL from each composite for analysis. Mix the 25 mL or g with 225 mL *Listeria* enrichment broth without the selective agents...

Note: If the sample is to be analyzed for both *Listeria* and *Salmonella* then composite subsamples for *Salmonella* as outlined in BAM, Chapter 1, page 1.03, Then randomly select ten (10) subsamples from the original sample to prepare the two composites for *Listeria* analysis as outlined above.

c. Incubate BLEB (buffered Listeria enrichment broth) mixture for a total of 48 hours at 30° C. adding the selective agents after the first 4 hours of incubation. Proceed with BAM, Chapter 10, page 10.04, D. Isolation Procedure. Use of one of the new differential agars in addition to an esculin agar is strongly recommended.

3. ***Salmonella***

a. **General Method**: Use BAM, Chapter 5, *Salmonella* Additionally, Rapid Test Kits as identified in the memo, "Guidance for the use of Rapid Methods for Food Microbiology" dated April 24, 1998 may be used as per the instructions and restrictions contained therein. If a laboratory does not have this memo on hand, they should request a copy of it from the Division of Field Science, HFC-140.

b. **Speciation**

If positive for *Salmonella*, prepare BHI slants and provide hardcopy information requested under BAM, E. 11 and send **under seal** for speciation:

Isolates from NRL, WEAC, SRL and ARL should be sent to:

Arkansas Regional Laboratory
3900 NCTR Rd., Bldg. 14, Room 14C-126
Jefferson, Arkansas 72079-9502
Attention: Gwendolyn Anderson

Tel# 870-543-4624

Isolates from SAN, PRL-NW, PRL-SW and DEN should be sent to:

Denver District Laboratory
6th Avenue & Kipling Street
DFC Building 20
Denver Colorado 80225-0087
Attention: Doris Farmer

Tel# 303-236-9604
Fax# 303-236-9675

4. ***Staphylococcus aureus and* other *staphylococcal* species**

a. Examine individual subsamples

b. Direct microscope examination, BAM, Chapter 2, Microscopic Examination of Foods. **NOTE: Do not quantitate.** Do smear to get general idea of number of cocci present, only.

c. Enumeration

1. Direct Plate Count (DPC), BAM, Chapter 12, *Staphylococcus aureus.*
2. Most Probable Number (MPN), BAM, Chapter 12, *Staphylococcus aureus*.

NOTE: CFSAN recommends that both the DPC and the MPN methods of enumeration be started at the same time since it is impossible to ascertain whether any results might be obtained from the DPC method which is designed to recover organisms greater than 1000 organisms per gram. If the population is less than 100 organisms per gram, it would readily be detected by the MPN method if present in the analyzed product.

d. Identification, coagulase, ancillary tests, and viable count (MPN) BAM, Chapter 12, *Staphylococcus aureus*.

5 *Staphylococcal* enterotoxin Determination

a. Entertoxigenicity of isolates. BAM, Chapter 13, Section D, 1, 2, 3, Staphylococcal Enteratoxins.

b. Preformed enterotoxin in product. BAM, Chapter 13, Staphylococcal Enterotoxins, Extractions of enteratoxins from foods for ELISA (TECRA) testing.

NOTE: Perform enterotoxin testing if product abuse is suspected, the product is incriminated in a food poisoning outbreak, or if the product contains $1x10^4$ organisms per gram by DPC, or if 11,000 organisms by MPN are recovered.

Follow methodology outlined in the memo **Revised Guidance for *Staphylococcal* enterotoxin Testing in Foods** dated August 1, 1997. If a laboratory does not have this memo on hand, they should request a copy of it from the Division of Field Science, HFC-140.

6. ***V. cholerae, V. parahaemolyticus, V. vulnificus***

a. **General Instructions**

Each sample will be examined on an individual subsample basis except for the analysis using the Polymerase Chain Reaction (PCR) for *V. cholerae* enterotoxigenic strains method (see *V. cholerae* section below).

When the PCR method is used, the sample will be analyzed on a composite basis (see below for instructions).

b. **Methods**

General Method: BAM, Chapter 9, *V. cholerae, V. parahaemolyticus, V. vulnificus*, and Other *Vibrio* spp...

PCR for *Vibrio cholerae*: BAM, Chapter 28, Detection of Enterotoxigenic *Vibrio cholerae* in Foods by the Polymerase Chain Reaction

Vibrio parahaemolyticus: Isolation, identification, and enumeration.

Vibrio vulnificus: Isolation, identification, and enumeration.

(1) Each sample will be analyzed using the BAM, Chapter 9 **and** Chapter 28.

(2) If the sample was found to be positive for *Vibrio cholerae*, notify Mahendra Kothary at (301) 210-7873 or (301) 240-876-9015 and send one set of ALL isolates of *Vibrio cholerae* O1 or non-O1 to the following address for confirmation:

FDA/CFSAN/Office of Applied Research and Safety Assessment/Division of Virulence Assessment/Virulence Mechanisms Branch, HFS-025
ATTN: Mahendra Kothary
MOD-1 Facility
8301 Muirkirk Road
Laurel, MD 20708

(3) Alkaline Peptone Water (APW) Lysate Preparation for PCR analysis

NOTE: THE FOLLOWING INSTRUCTIONS ARE TO BE USED IN LIEU OF CHAPTER 28, PAGE 28.04, APW ENRICHMENT LYSATE PREPARATION.

(a) Once the appropriate dilutions have been prepared for each of the individual ten (10) subsamples using the BAM method, the laboratory will **prepare two (2) APW Lysate composites from the original 1:10 APW dilutions** (e.g., the

blended solution) **PRIOR** to incubation.

NOTE: For products with potential inhibitory effect of the PCR reaction (e.g., oyster, raw shrimp, products with possible high concentration of microflora) APW Lysate composites will be prepared from the original 1:100 APW dilutions.

(b) One APW Lysate composite will be prepared by removing 1.0 mL from each of the 1:10 (or 1:100, as appropriate) dilutions for subsamples 1 through 5 (e.g., composite #1A) and the second APW Lysate composite will be prepared by removing 1.0 mL from each of the 1:10 (or 1:100, as appropriate) dilutions for subsamples 5 through 10 (e.g., composite #1B).

(c) These APW Lysate composites will be **designated as zero (0) time Lysate, (e.g., composites 1A and 1B)**. Boil for 5 min, and then freeze.

NOTE: THIS 0 TIME ALIQUOT WILL BE USED FOR PCR TESTING ONLY IF THE 6 - 8 HOUR OR 16 - 24 HOURS INCUBATED LYSATE SHOWS A POSITIVE REACTION ON THE PCR TEST.

(d) A second set of APW Lysate composites will be prepared using step (b) above from the original 1:10 or 1:100 dilutions **AFTER** the 6 - 8 hour incubation period at 37° C.
If the sample is a **frozen food product**, then the APW Lysate composites will be prepared using step (2) above from the original 1:10 or 1:100 dilutions **AFTER** the 16 - 24 hour incubation.

NOTE: THIS LYSATE WILL BE TESTED FIRST USING THE PCR TEST. IF THIS LYSATE CANNOT BE TESTED IMMEDIATELY, THEN FREEZE UNTIL THE PCR TEST CAN BE PERFORMED.

(e) See BAM, Chapter 28 for clarification and further instructions for PCR analysis.

7. *Clostridium botulinum* Do not test for the presence of spores or toxin unless implicated in a food poisoning case. If there is direct evidence of botulism toxin and it is implicated by clinical evidence, samples should be sent directly to a servicing laboratory with animal capabilities.

a. Examine 10 individual subsamples.

b. Use BAM, *Clostridium botulinum*.

8. **ADDITIONAL ANALYSES, if applicable for Smoked Fish/Pickled Seafood**

a. **WATER PHASE SALT**

(1) Moisture Content **(Total Solids)**

AOAC, 18th Ed., 952.08, Sec. 35.1.13.

Note: The above method uses asbestos fibers. In

lieu of asbestos fibers, use 10 g of sand.

(2) Water Phase Salt

AOAC, 18th Ed., 937.09, Sec. 35.1.18

NOTE: Formula for calculating water phase salt, i.e., salt concentration expressed as percent of salt in aqueous of loin muscle by the formula:

$$\%\ \text{salt aqueous phase} = \frac{\%\ \text{salt} \times 100}{\%\ \text{water} + \%\ \text{of salt}}$$

b. **NITRITE**

Analyze for nitrite only if declared on label as being used or if no labeling accompanied the sample to determine nitrite use.

(1) Examine individual subsamples (10).

Note: CPGs 540.200 and 540.500 relate to levels (excessive) of the food additive sodium nitrite that would render the product adulterated. That analysis is done on a composite basis as directed in the 2 CPGs cited. However, for microbiological safety, the concern is to ensure sufficient levels of nitrite are present in individual subsamples to prevent botulism. Therefore for the microbiological safety analysis, 10 subsamples are to be each analyzed individually.

(2) AOAC, 18th Ed., 973.31, Sec. 39.1.21

c. Special test for **pickled seafood labeled keep refrigerated**: Check pH. If the pH is greater than or equal to 4.6, check for water phase salt and for nitrite concentration in ppm as above. If pH is less than 4.6, the analysis is finished.

9. Molluscan Shellfish Sample Preparation/Methods

NOTE: FRESH MOLLUSCAN SHELLFISH SAMPLES MUST BE ANALYZED WITHIN 24 HOURS FROM TIME OF COLLECTION.

Sample Preparation/Method for Microbiological Analysis

Cleaning shellfish in the shell (Part III, B, 2.1) and preparing shucked shellfish (Part III, B, 2.2), Recommended Procedures for the Examination of Sea Water and Shellfish, APHA, Inc. 4th. Ed., 1970.

For each subsample:

a. Weigh 200 g of shell liquor and meats (approximately 10 - 12 medium/large shellfish; approximately 25 small shellfish or ½ lb. shucked shellfish).

b. Grind for 30 seconds. If not possible, blend in sterile blender for 30 sec. It may be necessary to cut meats with sterile scissors or knives prior to grinding/ blending.

c. Remove 25 g of the meat homogenate for *V. parahaemolyticus* and *V. vulnificus* analysis.

d. Remove two (2) - 25 g meat homogenate portions for *V. cholerae* analysis.

e. The remaining approximate 100 g meat homogenate will be blended with 100 mL sterile buffered phosphate water or 0.5% sterile peptone water for 60 sec. This homogenate will be used for APC, coliforms, fecal coliforms and *E. coli* (ETEC as appropriate).

NOTE: If the shellfish product is cooked, smoked, pasteurized or thermally processed then remove an additional 25 g meat homogenate for *Listeria* analysis. The remaining meat homogenate will be approximately 75 g and this should be blended with 75 mL sterile buffered phosphate water or 0.5% sterile peptone water for step "e." above.

E. Project 04: **CHEMICAL CONTAMINANTS**

For all analytical guidance, including Field Laboratories, Methodology, and Reporting, refer to Part IV of Compliance Programs Pesticides and Industrial Chemicals in Domestic and Imported Foods 7304.004 and Toxic Elements in Foods and Foodware, and Radionuclides in Foods, Domestic and Import, CP 7304.019

For WATER PHASE SALT and NITRATE, see Part IV, section D, 9a and 9b of this program.

F. Project 07: **NATURAL TOXINS**

1. **Analyzing Laboratories** for Paralytic Shellfish Poison and Amnesic Shellfish Poison (ASP)/Domoic Acid and SE regions should be sent to SRL. All other regions should ship samples to PRL-NW. Because this can change from FY to FY, George Salem or ORA/DFS should be contacted before sample shipment to ensure that these are still the correct analyzing laboratories.

General Sample Preparation

a. Molluscan Shellfish:

Each subsample will be homogenized and analyzed separately (e.g., total of three (3) analyses per sample).

b. **Scallops:**

For **each** subsample, separate the adductor muscle from the viscera. The viscera portions will be homogenized and analyzed separately, e.g., total of three (3) analyses for the viscera per sample.

c. **Crustaceans:**

For **each** subsample, separate the edible portion from the viscera (hepatopancreas/mustard to be included with the viscera) in the case of lobsters and crabs or separate the edible portion from the heads in the case of shrimp.

NOTE: Crab samples must be cooked for fifteen (15) minutes in boiling water before being separated and homogenized.

The viscera/head portions will be homogenized and analyzed separately (, e.g., total of three (3) analyses for the viscera/head per sample.

d. **Fin Fish (Planktivorous and Uneviscerated; Consumed Whole):**

For **each** subsample, the whole sub-sample will be homogenized and analyzed separately, total of three (3) analyses per sample.

2. **PSP Sample Preparation/Method**

See AOAC, 18th Ed. (or as updated), 959.08, Sec. 49.9.01.

Each subsample will be homogenized and analyzed separately (e.g., 3 analyses per sample).

Laboratories can obtain a PSP standard through Sherwood Hall, HFS-716 ((301) 436-1653).

If you do not have 100 grams of sample, please call Sherwood Hall at (301) 436-1653 at CFSAN to discuss how to use a smaller sample amount.

3. **ASP (Domoic Acid) Sample Preparation/Method**

a. ASP Methodology:

Sample Prep:
(1) Weigh out homogenized sample (10g or more)
(2) Add equal weight of water.
(3) Blend thoroughly
(4) Boil 5 Min
(5) Reweigh to obtain final weight to calculate dilution factor.(final weight/initial weight sample=dilution factor)
(6) Centrifuge
(7) Filter (0.22 micron or 0.45 micron)
(8) Inject in HPLC

The analysis for domoic acid is simple but not without an occasional problem. The most common problem is the coelution of Tryptophan with domoic acid. The addition of 0.1ml/L Trimethylamine to the mobile phase results in a separation of the compounds with the Tryptophan eluting earlier by approximately 1 min.

HPLC conditions:

1 L mobile phase:	873mL water 94g acetonitrile adjust to pH of 2.5 with 8.5% phosphoric acid (should take 2 to 4 mL) 0.1ml Trimethylamine
Column:	C-18 (CFSAN uses Rainin microsorb axial compression 5µ 4.6 x 150mm)
Flow	1.0mL/min
Detection:	UV absorbance at 242nm

If there any questions about the method, contact Sherwood Hall or Stacey Etheridge at (301) 436-1653 or 210-2162

b. Each subsample will be homogenized and analyzed separately. For bivalve mollusks, and Fin Fish (Planktivorous and Uneviscerated; Consumed Whole) the entire animal should be homogenized. For other animals, homogenize only the viscera.

4. **REPORTING**

Results should be entered into FACTS using the PAF of "BIO" and PAC 07842.

If the following levels are found, notify collecting District's Compliance Branch immediately so that the appropriate follow up action can be initiated:

Greater than 80 micrograms/100 g paralytic shellfish poison in molluscan shellfish

Greater than 80 micrograms/100 g paralytic shellfish poison in the edible portion for seafood products other than molluscan shellfish

Greater than 20 ppm domoic acid, except in the cases of dungeness

crab viscera, where the level is greater than 30 ppm.

G. Project 09: **FOOD AND COLOR ADDITIVES**

ANALYZING LABORATORIES

1. for Food and Color Additives: Refer to the current ORA Field Workplan for the correct servicing laboratory.

2. for Astaxanthin: Districts should contact ORO/Division of Field Science for placement of samples for astaxanthin analysis. This analysis will require a HPLC chiral column.

Analytical Methodology

Use methodology appropriate to the product as well as the additive for which the product is being tested. Various analytical methodology sources (e.g., LMS Code Manual; Appendix N for colors and Appendix S for food additives) are available for food additives or food additive combinations in addition to those listed below. Consult with the ORA Scientific Contact prior to analysis if there are questions about the appropriate methodology.

1. Color Additives

Refer to color guidance in the Import Food and Color Additives Compliance Program 7309.006 for all color additives except Astaxanthin.

For Astaxanthin: HPLC chiral columns are needed to analyze for astaxanthin. Methodology for the determination of astaxanthin in salmonids is available at JAOAC Int. 80, 622 (1997), S Turujman, et. al. in the article titled "Rapid Liquid Chromatographic Method to Distinguish Wild Salmon from Aquacultured Salmon Fed Synthetic Astaxanthin." This determination is for the relative amounts of the conformational isomers of astaxanthin (using chiral column) to determine wild from aquacultured salmon. Since this is an economic concern rather than a health concern, testing for astaxanthin should not be done without prior approval from CFSAN.

2. Sample Preparation for Food Additives

a. The analytical sample should consist of a composite of the three subsamples.

FROZEN Shrimp/Prawns - Thaw shrimp at room temperature or in the refrigerator. Do not thaw by immersing in water. Allow the liquid to drain. Remove and discard shells.

FRESH Shrimp/Prawns - Remove and discard shells.

b. Compositing:

Grind (comminute) sample in a consistent manner to obtain a uniform composite. Excessive grinding or incorporation of air may reduce sulfite levels.

Select "original" and "check" portions from the homogenate. Maintain these in a frozen state unless analyzed immediately.

3. Methods for Food Additives

a. AOAC, Official Methods of Analysis, 18th Edition, Chapters 47 and 48

b. Food Additives Analytical Manual, Vol. I and II, 1983 and 1987

c. Food Chemicals Codex, 3rd Edition

d. Nitrites Examine individual subsamples (e.g., 10). Use AOAC, 18thEdition, 973.31, Sec. 39.1.21

e. Sulfites in Shrimp

Appropriate screening techniques may be used to determine residual sulfites. However, since all screening techniques may not give results equivalent to the Modified Monier-Williams method, contact the ORA Scientific contact for approval before use.

f. Sulfites In tuna

Appropriate screening techniques may be used to determine residual sulfites. However, since all screening techniques may not give results equivalent to the Optimized Monier-Williams method, contact the ORA Scientific contact for approval before use.

If sulfites are declared, it is not necessary to analyze for sulfite.

Each sample should consist of 1 can of tuna from each of 6 cartons (6 cans total), when cans are smaller than 66.5 ounces, for a total of 6 cans. When cans are 66.5 ounces, each sample should consist of 1 can of tuna from each of 3 cartons for a total of 3 cans. Samples should be composited following the instructions listed in "2. Sample Preparation for Food Additives, b. Compositing". The entire solid and liquid contents of each can should be included in the composite.

NOTE: When compositing a sample of 66.5 oz cans of tuna for sulfite analysis, the entire contents of each can is poured into a pan and mixed by hand so that large pieces are broken up and the liquid is mixed in. An equal portion is removed from each sub and those 3 portions are composited in a food chopper according to instructions in #2. Sample Preparation". They are placed in a food chopper for blending (just to a consistent mix). This will permit the drawing of a representative sample without subjecting the product to excessive grinding that might lead to loss of sulfite. Analytical and reserve portions are removed from the composite at this point.

Each laboratory may choose to use the Optimized Monier-Williams Method (Method #990.28. AOAC Official Methods of Analysis, 18th Ed.) for the original and check analysis. If the results are <10 ppm, no further analysis is needed.

Whenever the original analytical results of an Optimized Monier-Williams test (titration) are greater than 10 ppm sulfite, a check analysis using titrimetric results with gravimetric confirmation must be performed. Alternatively,

the Ion-Pairing HPLC Method (JAOAC (2003) 86, 544-550 Perfetti and Diachenko) may be performed...

Results from a Monier-Williams Method of more than 100 ppm may be due to the presence of thiosulfate, from dithonate, an unapproved food additive. Therefore, whenever the original analytical results of an Optimized Monier-Williams Method (titration) are greater than 100 ppm sulfite, a check analysis using the Ion-Pairing HPLC Method (JAOAC (1989) 72(6), 903-906) must be performed. Use of the ion-pairing method will determine if the sulfite is from approved or unapproved additives. When the Optimized Monier-Williams Method and the ion pairing method yield significantly different values, the analyst should contact Gregory Diachenko [(301) 436-1898] to determine what additional steps need to be taken.

4. Reporting

Report all analytical results (food and color additives) into the FACTS Data System.

The following PACs are to be used for reporting all operations:

09842E	Color Additives
09842F	Food Additives

Use PAF: FAD - Food Additives
COL - Color Additives
FDF - Food Economics, Standards, Labeling (if applicable)

H. Project 21: **FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS**

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Districts should hold resource expenditures in this area to a minimum. The Program Assignment Code (PAC) for seafood economics, 21842, will remain in effect and the field should continue to report these activities when performed.

If a district plans any economic work, they must first obtain Center concurrence by contacting the Domestic Seafood Monitor at (301) 436-2079.

FACTS REPORTING REQUIREMENTS:

A. Report resources utilized for all operations except for Fair Packaging Labeling Act (FPLA) against PAC 21842.

B. Report resources utilized for NLEA and FPLA against PAC 21005. Do not report inspections under NLEA. See current NLEA Compliance Program for reporting instructions.

C. Report resources utilized for nutritional health fraud issues against 21R829.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

This program addresses both seafood HACCP and non-HACCP deficiencies. In instances where a district believes that a fish or fishery product poses an imminent public health hazard, the district should contact CFSAN/Office of Compliance/Division of Enforcement to discuss an appropriate response.

A. Seafood HACCP violations including Sanitation Monitoring

Regulatory action can be recommended under 402(a) (4) based on violation of the seafood HACCP regulation. It is not required to couple other adulteration charges, such as 402(a) (1) or 402(a) (3) violations in order to recommend action.

The following information may assist you in prioritizing Seafood HACCP cases for potential regulatory action:

1. Assign higher priority to cases (#) with the deficiencies listed below:

   a. The absence of a HACCP plan when one is needed, failure to identify a hazard associated with a, or failure to list a critical control point

   b. Deficiencies associated with monitoring procedures, including inadequate monitoring programs, failure to maintain monitoring records, or failure to implement monitoring procedures

   c. Deficiencies associated with critical limits, such as, failure to list a critical limit, inadequate critical limits and critical limits not validated

      Note: Inadequate and un-validated critical limit charges must be supported by inspectional observations, such as internal temperatures, or analytical results that demonstrate that the critical limits are inadequate to control the identified hazard.

   d. Failure to have an appropriate corrective action plan (when included in the HACCP plan), take a corrective action when a critical limit is exceeded, or document the corrective action

   e. Failure to perform sanitation monitoring in facilities that process Ready-To-Eat products. (Note: always cite sanitation deficiencies associated with the seafood HACCP regulation as per 21 CFR Part 123.11.)

2. Assign lower priority to cases involving:

   a. Hazards or products other than those listed under 1 above

   b. Failure to perform sanitation monitoring in facilities that do not process Ready-To-Eat products

3. Do not normally recommend follow-up regulatory action under seafood HACCP involving the following, unless conditions are

judged to be egregious:

- Metal fragments
- Pesticides and environmental contaminants from the harvest water.

B. Violations other than seafood HACCP

These following instructions apply to the non-HACCP deviations for fish and fishery products of adulteration, misbranding, economic deception, non-scombrotoxin decomposition, etc. If significant deficiencies are encountered at a firm or for a particular product in interstate commerce, districts should consider appropriate follow-up action. If the deficiency is not addressed in this program, then follow the instructions in the compliance program that addresses the deficiency; for instance, for food labeling, follow the 7321.005 Compliance Program - Domestic and Import NLEA, Nutrient Sample Analysis, and General Food Labeling consider action to remove the food from commerce. However, if circumstances do not permit seizure of the product, the district may consider recommending a Warning Letter to address the deficiency. If a Warning Letter is recommended, the district should send its recommendation with supporting evidence to the Division of Enforcement, (HFS-606) in CFSAN using the Center's Compliance Management System. The proposed Warning Letter should include the non-HACCP and any serious HACCP deficiencies documented during the inspection. Districts should consult the Compliance Policy Guides (CPG) for direct reference legal actions. Legal actions not covered under CPG direct reference guidance must receive evaluation and concurrence of the Center prior to issuance.

C. Advisory Actions - Center-Concurrence Warning Letters:

Warning Letters should be considered for significant deficiencies of the seafood HACCP regulation to communicate the Agency's position on these deviations and to notify the firm that the agency may initiate enforcement action if the deviations are not corrected

Model Warning Letter and Untitled Letter templates and standard language can be found and downloaded from ORA, Office of Enforcement's intranet site at (@)

All Warning Letters must receive Center evaluation and concurrence. The recommendation, proposed Warning Letter, and supporting evidence should be sent to the Center via (@). Warning Letter cases should also be forwarded to the Center in FACTS (with the assigned FACTS/Compliance number). The Center requests that the district upload a copy of the final, signed letter that the district issues into the CMS file for that particular case. This electronic copy supersedes any additional hardcopy cc to the Center compliance unit.

D. JUDICIAL ACTIONS

Recommendations for legal actions must be submitted to CFSAN for

evaluation and concurrence. These actions should be entered and forwarded to the Center's compliance unit in FACTS and the case should be submitted electronically to the Center via its Compliance Management System (@). Early conversation and collaboration with CFSAN's Division of Enforcement (see list of enforcement contacts below) is recommended in all potential seizure or injunction situations. The Center and ORA have a robust enforcement program in seafood HACCP. (#)

Prosecution: Suspected criminal violations, such as falsification of HACCP or sanitation monitoring records must be discussed with CFSAN, Division of Enforcement, Domestic Compliance Branch and with the Office of Criminal Investigations.

E. Center's Regulatory Contacts:

Districts should contact the Division of Enforcement, for early discussion concerning possible recommendations for seizures, injunctions, or prosecutions under this program.

Millie Benjamin	(301) 436-1424
Giselle Jordan	(301) 436-1576
Crystal A. McKenna	(301) 436-1620
Ronald Pace	(301) 436-1742
Priya Joy Rathnam	(301) 436-2078
Frank Sikorsky	(301) 436-1623

The Center's Compliance Officer assigned to the case will coordinate discussions with appropriate scientific and technical experts within the Office of Food Safety, Division of Seafood Safety.

F. Regulatory Guidance - Sources

Use follow-up activities and legal actions that are consistent with guidance in Compliance Policy Guides. References are listed below for a number of products, involving both HACCP and non-HACCP issues.

1. APPROPRIATE REGULATORY ACTION

This is not intended to be an all-inclusive list of available guidance. Please consult the CPG manual for other topics.

To determine if the appropriate initial action of choice is direct reference seizure, voluntary recall, or referral to CFSAN, consult the appropriate Compliance Policy Guides listed below:

DECOMPOSITION	Sec. 540.375	Canned Salmon - Adulteration Involving Decomposition (7108.10)
	Sec. 540.525	Decomposition and Histamine - Raw, Frozen Tuna and Mahi Mahi; Canned Tuna; and Related Species (7108.240)
	Sec. 540.575	Fish - Fresh and Frozen - Adulteration Involving Decomposition (7108.05)
FILTH	Sec. 540.590	Fish - Fresh and Frozen, as

		Listed - Adulteration by Parasites (7108.06)
FOOD ADDITIVES	Sec. 500.200	Food Additives - "GRAS" (7117.12)
	Sec. 540.200	Chubs, Hot Process Smoked with Added Nitrite- Adulteration involving Food Additives, Sodium Nitrite (7108.15)
	Sec. 540.500	Tuna, Sable, Salmon, Shad, - Smoked Cured, Adulteration Involving Food Additives, Sodium Nitrite (7108.18)
FOOD LABELING:	For labeling inquiries consult the *Domestic and Import NLEA, Nutrient Sample Analysis, and General Food Labeling Program (7321.005).*	
FOOD ECONOMICS	Consult with the Division of Enforcement, Domestic Branch, HFS-607 before preparing any enforcement action involving an economic issue.	
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MICROBIOLOGY	Sec. 555.300	Food Products, except dairy products-Adulteration with – this CPG includes direct reference enforcement action criteria for *Salmonella* in Ready-To-Eat products. **The direct reference does not apply to *Salmonella* in seafood products that are not Ready-To-Eat.**—Cases involving *Salmonella* in raw food should be referred to CFSAN for case-by-case consideration. (7120.20)
	Sec. 540.275	Crabmeat-Fresh and Frozen-Adulteration with Filth, Involving Presence of E. coli (7108.02)
	Sec. 540.420	Raw Breaded Shrimp - Microbiological Criteria for Evaluating Compliance with Current Good Manufacturing Practice Regulations (7108.25)
	Sec. 540.650	Salt-cured, Air-dried, Uneviscerated Fish (e.g., "Kapchunka") (7108.17)
NATURAL TOXINS	Sec. 540.250	Clams, Mussels, Oysters,

Fresh, Frozen or Canned-
Paralytic Shellfish Poison
(7108.02)

Sec. 540.600 Fish, Shellfish, Crustaceans, and Other Aquatic Animals – Fresh, Frozen or Processed – Methyl Mercury (7108.07)

PARASITES: Sec. 540.590 prescribes action levels that will be used only for those fresh water fish species listed in that CPG.

In the absence of a DAL for unlisted species, CFSAN/OC/DE/Domestic Branch, HFS-607 will consider enforcement action for parasites on a case by case basis.

For any sample of fish referred to CFSAN/OC/DE/Product Adulteration Branch, HFS-606, Districts must first send the whole parasites and fragments to the parasite expert for confirmation.

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PART VI - ATTACHMENT, REFERENCES AND PROGRAM CONTACTS

ATTACHMENT

A. Sampling Guide Matrix

REFERENCES

Seafood HACCP Regulator Training Program Manual (RTM) - HACCP inspection procedures, First Edition, March 1997

FDA Inspectional Methods, October 1996 (Interim Guidance) (IMI) - Inspection methods, sampling guidance and reporting

Fish and Fishery Products Hazards & Controls Guidance (HCG) - Recommended hazards and controls in seafood processing; Third Edition, June 2001

Memo: Revised Guidance for *Staphylococcal enterotoxin* testing in Foods dated August 1, 1997

Seafood HACCP Encore Course Manual (Seafood HACCP Alliance)
HACCP Regulation for Fish and Fishery Products Questions and Answers/Issue Three/January 1999

AFDO Sanitation Course Manual

21 CFR 123 and its Preamble

Seafood HACCP Alliance Course, Sanitation Control Procedures Manual

PROGRAM CONTACTS

General Program Questions:	Andrea L. Wade, CFSAN, Office of Compliance, Division of Field Programs and Guidance, Field Programs Branch, HFS-615, (301) 436-2079, FAX (301) 436-2657.
General Investigational Questions:	Norman Fogg, ORA, ORO Division of Field Investigations, HFC-130, (301) 827-5645.
Scientific, Technical and Seafood HACCP Policy Questions:	CFSAN, Office of Food Safety, Division of Seafood Safety, Seafood Processing Technical Policy Branch, (301) 436-2300

General Analytical Questions: ORA, ORO, Division of Field Sciences, HFC-141, 301/ 827-7605, 7606

Decomposition, organoleptic & chemical	Donald Lech
Filth/Decomposition	Larry D'Hoostelaere
Food/Color Additives	Donald Lech
Food Economics, standards, Labeling	Darlene Saudarg
Microbiological - Including tests for preservation	Lydia I. Rosas-Marty
Micro analytical (filth, Mold, foreign objects	Larry D'Hoostelaere
Seafood toxins (Natural Toxins)	Donald Lech
Nutrient Analysis	Darlene Saudarg

CFSAN Analytical Questions

Color Additives Analysis	Office of Cosmetics and Colors, Division of Cosmetics and Color, Division of Cosmetics and Compliance, Richard Jewell, HFS-125, (301) 436-1345
Decomposition Analysis	CFSAN, Office of Regulatory Science, Division of Analytical Chemistry, Spectroscopy Mass Spectrometry Branch (HFS-707), John Callahan at 301-436-2039 or Walter Staruszkiewicz, 301-436-1495
Filth Analysis:	Office of Regulatory Science, /Division of Analytical Chemistry, Microanalytical Branch, HFS-315, George Ziobro, (301) 436-1932
Food Additives Analysis	Office of Regulatory Science, /Division of Analytical Chemistry, Gregory Diachenko, HFS-705, (301) 436-1898
Microbiological analysis	CFSAN, Office of Regulatory Science/ Division of Microbiology, Direct general questions to the Division Director - Keith Lampel HFS-706, (301) 436-2007, specialized questions go to the following at HFS-516

General	Keith Lampel	(301) 436-2007
E. coli	Peter Feng	(301) 436-1650
Listeria	Anthony D. Hitchins	(301) 436-1649
Salmonella	Wallace H. Andrews	(301) 436-2008
Staphylococcus	Reginald W. Bennett	(301) 436-2009
Clostridium	Mary Losikoff	(301) 436-1412

Vibrios: parahaemolyticus, vulnificus, and cholerae Angelo DePaola, CFSAN, Office of Food Safety, Division of Seafood Science & Technology (DSST), Microbiological Hazards Science Branch (251) 690-3367 or Barbara McCardell, Office of Applied Research Safety (OARS) Assessment at (301) 210-7871

V. Cholerae PCR Methodology: Barbara McCardell, (OARS) at (301) 210-7871

PSP/ASP	Office of Regulatory Science, Division of Bioanalytical Chemistry, Chemical Contaminates Branch, Sherwood Hall, HFS-716, (301) 436-1653
Parasite Analysis	Office of Food Safety, Division of Seafood Safety, Clarke Beaudry, HFS-325, (301) 436-2503
Species Substitution	Office of Food Safety, Division of Seafood Safety, Seafood Processing and Technology Policy Branch, Clarke Beaudry, HFS-325, (301) 436-2503

Scallops – with added water or hydroscopic chemicals - Office of Food Safety, Division of Seafood Safety, William Jones, HFS-325, (301) 436-1422

Compliance Matters:	CFSAN/Office of Compliance/Division of Enforcement, HFS-607, Mildred Benjamin at (301) 436-1424, Priya Joy at (301) 436-2078, Crystal McKenna at (703) 719-5718, Frank Sikorsky at (301) 436-1623

PART VII - CENTER RESPONSIBILITIES

Program Evaluation

During the course of this program the Office of Food Safety, Division of Seafood Safety, HFS-325 will identify any deficiencies in program operations or program quality. The Division of Seafood Safety will submit an evaluation of this program every other year.

The most current version of the evaluation can be found in the section titled **Overview** at:http://www.cfsan.fda.gov/~comm/haccpsea.html

Table: Sampling Schedules Domestic Fish and Fishery Products Inspection Program

General Information for Sampling:

1.	See the current ORA workplan for a list of the District servicing laboratories. Because of laboratory specialization, the analyses for some samples may be performed in different FDA laboratories. This will require either dividing the sample by the laboratory personnel, or collecting a duplicate sample by the investigator. This procedure should be worked out between the two branches prior to sample collection. See IOM shipping instructions for frozen samples and 452.6 for shipping instructions for refrigerated samples.
2.	Please note that the number of samples identified in the ORA workplan is for planning purposes. There is no target number of samples that need to be collected per district. Prior to collecting samples, please review the sampling section in PART III-INSPECTIONAL. It is particularly important that samples for safety defects (HACCP) are to be collected for cause only where it is necessary to determine the extent of the problem in order to facilitate a decision about the appropriate regulatory response.
3.	It may be necessary for the collecting District to collect additional (duplicate) subsamples for another servicing lab or for the national expert in seafood sensory testing for confirmation analysis. Contact the servicing laboratory to determine whether these additional subsamples are necessary.
4.	The sample sizes listed include both the analytical sample portions and the duplicate sample portions called for in Section 702(b) of the Act. The duplicate sample portions are required UNLESS exempted by CFR 21 Part 2.10 (high cost, sample collected from person named on label who is also the owner, etc.).
5.	It is important that all collections for Microbiological Analysis be made aseptically. It is necessary that analysis begin quickly after collection; therefore, please contact the servicing laboratory prior to collecting the sample. Additionally, frozen samples should be kept frozen prior to delivery to the lab and all other samples should be kept at refrigerated temperatures.
6.	For Filth/Decomposition samples: Collect raw material, in-line and finished product samples, if contaminated raw materials are believed to be used; however, **do not** sample finished products to support 402(a)(3) charge of adulteration **if** inspectional evidence indicates little likelihood of detecting this contamination in the finished product. **Instead**, collect physical samples of contaminated raw materials and filth exhibits as a basis for 402 (a)(4) charges with documentation of the use of these contaminated raw materials in the manufacture of a specific lot or lots of finished product.

Table: Sampling Schedules Domestic Fish and Fishery Products Inspection Program

General Information for Sampling:

7. For decomposition: In those cases where extremely large fish are encountered and the sample cost incurred would be prohibitive, each subsample may consist of a minimum of 450 grams (1 lb.) transverse portion cut from the backbone to belly (do not include the belly flap)from the anterior end of one side of the fish. In the case of very large fish:

- If a properly trained seafood sensory field investigator or a qualified seafood sensory analyst accompanies the investigator during sampling, the fish may be examined by using the drill method and the proportion of decomposed fish in the lot estimated. Collect 1 or 2 passable & a minimum of 3 decomposed fish for laboratory examination; or
- Use a core or plug method to obtain a minimum of 454 grams of flesh per subsample from the anterior portion of the fish as described for the transverse section. (Sometimes the owner of the goods can cut out the desired samples using a band saw or other tool if aseptic technique is not required for the sample.)

Very small seafood items may require multiple items to total ≥ 454 grams of edible portion per subsample.

8. Prior to collecting samples for Project Area 04 - CHEMICAL CONTAMINANTS, please refer to the Compliance Program Pesticides and Industrial Chemicals in Domestic Foods 7304.004. Also refer to the IOM, Sample Schedule, Chart 3 "Pesticide Sampling Guidance" and check with the Servicing laboratory to determine the proper type of collection container.

9. Although this attachment contains sampling requirements for economics, no resources have been allocated for this work in the field workplan. With a shrinking resource base, all economics work is viewed as low priority by CFSAN. Districts should hold resource expenditures in this area to minimum and should conduct field activities only after consultation with CFSAN.

For species substitution – collect 12 fillets or steaks

For overglazing: 48 subs, if available, from lot

Breading Standards: Random, 1 sub from each case, if possible same lot.
If package size is 10 to 20 ounces, 2 packages per sub and 10 to 30 subs.

If package size is 454 grams to 2265 grams (1 lb. To 5 lb.) 1 package per sub, 10 – 30 subs

If package size is 2265 (5 lb) or more, one package per sub and 3 – 15 subs.

10.

Table: Sampling Schedules Domestic Fish and Fishery Products Inspection Program

General Information for Sampling:

11. Sample handling for Molluscan Shellfish - Clams, Mussels, Oysters, Scallops for Natural Toxin Analysis

- Samples need not be collected aseptically.
- In-shell Molluscan Shellfish - Samples of shellfish should be collected in clean containers. The container should be waterproof, and be durable enough to withstand the cutting action of the shellfish and abrasion during transportation. Waterproof paper bags, paraffined cardboard cups or plastic bags are suitable types of containers. A tin can with a tight lid is also suitable. Shell-stock samples should be kept in dry storage at refrigerated temperature. Shell stock should not be allowed to come in contact with ice.
- Shucked Molluscan Shellfish - A sterile wide mouth jar of a suitable capacity with a watertight closure is an acceptable container for subsamples. Consumer size packages are acceptable provided that they contain an adequate number of animals for analysis (10 or more, 20 gm or more each). Samples of shucked shellfish shall be refrigerated immediately after collection by packing in crushed ice and be kept so until examined.
- Frozen Shucked Molluscan Shellfish - If the package contains an adequate number of animals, (see a) Sample Size above) one or two packages may be taken as a subsample. Subsamples from larger blocks may be taken by coring with a suitable instrument or by quartering, using sterile techniques. Cores or quartered sample should be transferred to sterile wide mouth jars for transportation to the laboratory. Keep samples of frozen shucked molluscan shellfish in the frozen state at temperatures close to those at which the stock was maintained. When this is not possible, samples should be packed in crushed ice and kept so until examined.

12. Special instructions for sampling scombrotoxin forming fish: If the product is chilled (e. g. with ice, gel ice, or refrigeration) but inadequate chilling is suspected, the temperature of the fish (deep flesh and near surface at the exposed portions) should be measured. Especially if any fish shows temperature over 40 F, sample the lot for organoleptic and histamine analysis.

13. Do not request analysis for Listeria on products with PIC of B, C, or D unless there is reason to believe that the product ***will*** be consumed raw and in that case, it is necessary to explain that the product probably ***will*** be consumed raw in the remarks section of the collection report

14. For decomposition: Processed products include cooked, canned, and/or treated with chemicals or additives, including such things as salt, chlorine, smoke, and carbon monoxide. Product treated with sulfites or phosphates may be considered raw unless the compounds are used in excessive levels in efforts to mask decomposition. Dried products and sauce/paste products should not routinely be sampled for decomposition.

Table: Sampling Schedules Domestic Fish and Fishery Products Inspection Program General Information for Sampling:
15. For decomposition: Import shipments often contain more than one line item based on attributes such as species, market form, size of pieces(count), package size (net weight), etc. Within a line item there may be multiple production codes. Generally, for surveillance purposes, it is recommended to collect a sample from a multi-code lot randomly as a commingled lot without isolation on a particular production code. However, the production code of each subsample should be documented if possible. If the shipment consists of numerous line items, more than one sample can be considered for collection.
16. Subsamples should generally be collected randomly to give the broadest representation of the lot (i.e. one subsample per carton/tote/container randomly selected from the lot). More selective sampling, i.e., less randomized representation, may be acceptable only when the collector has specifically identified that potentially violative product appears more likely to be isolated in a particular portion of the lot and the sample is collected for analysis of that violation. In these situations, the collection record should indicate the collector's observations, in addition to the sampling method.

Table: Sampling Schedules Domestic Fish and Fishery Products Inspection Program

General Information for Sampling:

17. General Information **PROJECT 09 - FOOD AND COLOR ADDITIVES**

A. The Center is prepared to move quickly against products containing banned, illegal, or improperly used food or color additives.

Past food additive problem areas include the following:

- Undeclared Sulfites in shrimp
- Undeclared nitrates and nitrites in fishery products

Collect samples of imported seafood products having a known or suspected potential for food and color additive violations. Substances specifically prohibited from use in human food are listed in 21 CFR 189. The functions of common categories of food chemicals are given in 21 CFR 170.3(o). Refer to IOM for food additive and color additive status lists.

B. Cooked Salad Shrimp

Cooked salad shrimp may be colored if the shrimp is labeled in accordance with CPG 7127.01 (new Section 587.100) and if the principal display panel of the label bears the product name as Artificially Colored Cooked Shrimp. When FD&C Red No. 40 is used as the color, the common or usual name of the certified color must be stated in the ingredient list, i.e. FD&C Red No. 40, Red No. 40, or Red 40, as per Section 101.22(k). Examine the labels of cooked shrimp collected to ascertain the shrimp are accurately labeled if color is added.

C. Sample Collection

1. Food Additives

In most cases, the size of a sample collected for filth analysis will be sufficient for the food additive analysis as well. However, it is best to consult with the analyzing laboratory on the amount of sample required for analysis of specific food additives.

Canned Tuna for Sulfite Testing

Each sample should consist of 1 can of tuna from each of 6 cartons (6 cans total). Each sample should represent only one lot code. Collect only three (3) cans of tuna when packaged in 66.5 ounce cans.

2. Color Additives

When sampling, collect at a minimum four (4) subs, each consisting of 127 g (4 oz), of the sampled product.

TABLE: Sampling Schedules Domestic Fish and Fishery Products Inspection Program FY 00/01/02

Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842 .
FINFISH:					
Non-scombrotoxic species: Fresh raw or Frozen Raw Fish		Fillets, steaks, loins, chunks, breaded portions 15 subs; 200g (7 oz.) per sub, excluding breading, glaze, etc. If ea. piece. < 200g (7 oz). collect enough so 1 sub=200 g (7 oz).	12 sub-samples. Minimum of 454 grams (1 lb) per sub	Note: only do micro on raw fish that is intended to be consumed raw. General Micro.-10 individual fish, duplicate, same lot. Min 227g (8oz.) ea. (for all micro but *Salmonella*). *Salmonell*a: 15 – 114g (4oz.) subs from same lot	Refer to Table #3-1, Chapter 6 in FFPHCG. Only collect samples of fish for which natural toxin is listed as a hazard.; or puffer fish for PSP 3 subs per sample; 227 grams (8 oz) meat per sub
Non-scombrotoxic Species: Fish Blocks/Minced Fish Blocks, Frozen		Minced, to be processed further; not consumer size. Collect 2 blocks. 18 subs. /lot.	12 sub samples. Minimum of 454 grams (1 lb) per sub	General Micro: 10 - 227g (8 oz) subs from same lot. *Salmonella:* 15 – 114g (4oz.) subs from same lot	
Non-scombrotoxic species: Bulk Fish:		Do not collect fish in round for parasite analysis	12 sub samples. Minimum of 454grams (1 lb) per sub	Same as fresh frozen.	
Non- scombrotoxin species other than salmon: Cans or Retorted Pouches If analyses to include decomposition, filth, standards and industrial chemicals, collect 120 cans.	Filth only: If cans <=900 g (2 lb) > 50 cases – 24 cans 50 cases or more – 48 cans If cans> 900 g: > 600 cases – 24 cans 600 cases or more – 48 cans		18 sub-samples, minimum of 6 ounces per sub; collect multiple cans or pouches per sub if less than 6 ounce size containers.		
Canned Salmon	Filth only: If cans <=900 g (2 lb) > 50 cases – 24 cans 50 cases or more – 48 cans If cans> 900 g: > 600 cases – 24 cans 600 cases or more – 48 cans		Do not sample for decomposition – canned salmon is examined under an arrangement with the Food Products Association. If unordinary circumstances dictate the need to collect canned salmon for decomposition, collect 18 subsamples as per canned fish instructions		

TABLE: Sampling Schedules Domestic Fish and Fishery Products Inspection Program FY 00/01/02

Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842 .
Canned or retorted tuna or other canned/retorted scombrotoxin-forming fish	Filth only: If cans <=900 g (2 lb) > 50 cases – 24 cans 50 cases or more – 48 cans If cans> 900 g: > 600 cases – 24 cans 600 cases or more – 48 cans		24 sub-samples, minimum of 170 grams (6 ounces) per sub; if the units are less than 6 ounces each, collect multiple cans/pouches per sub. 18 sub-samples when containers weigh more than 907 grams (2 lbs)		
Scombrotoxin-forming fish processed products other than canned/retorted pouches	Filth only: If cans <=900 g (2 lb) > 50 cases – 24 cans 50 cases or more – 48 cans If cans> 900 g: > 600 cases – 24 cans 600 cases or more – 48 cans		24 sub-samples, minimum of 454 grams (1 lb) per sub;	General Micro.-10 individual fish, duplicate, same lot. Min 227g (8oz.) ea. (for all micro but *Salmonella*). *Salmonell*a: 15 – 114g (4oz.) subs from same lot	
Fresh raw or Frozen raw Scombrotoxic spec: (Tuna, mahi-mahi, amberjack, blue, mackerel, herring, sardines, etc.) Fillet or steak.			18 sub-samples, Minimum of 454 grams (1 lb) per sub		Refer to Table #3-1, Chapter 6 in FFPHCG. Only collect samples of fish for which PSP is listed as a hazard. 3 subs per sample, each sub must be 227 g (8 oz.) **plus** 25 g viscera in duplicate.

TABLE: Sampling Schedules Domestic Fish and Fishery Products Inspection Program FY 00/01/02

Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842 .
Smoked or Salted Fish: Seafood products packed in reduced oxygen packaging (e.g., vacuum packaging, modified atmosphere packaging, hermetically sealed containers,) including **smoked fish** and fresh fish in such packaging				General Micro: Collect 10 subs from 1 lot. , 454g (1 lb.) each If hermet/vac. sealed, take 10 additional. 454 g (1 lb) subs for *C. Botulinum*, unless original sub is greater than 900 g (2 lb) *Salmonella*: 30 - 114g (4oz). subs from same lot. (Use only as follow-up to suspected poisoning. For water phase salt determination & nitrites collect 10 subs, each 454 g (1 lb)	
CRUSTACEANS					
Crabmeat Frozen Crab, cooked or pasteurized Crab, whole raw Crabmeat, canned	Frozen, cooked or raw: Collect 10 - 227g (8 oz) subs in duplicate. canned: Collect 6 cans, randomly, min.		18 subs, 227g (8 oz) ea, in duplicate from same lot.	*E. coli*, 6 -227g (8oz.) subs in duplicate from same lot. [General Micro: 10 - 227 g (8oz.) subs from same lot. If smallest size container > than 5 lbs, collect 3 containers *Salmonella* for cooked, parboiled: 30 – 114g (4oz.) subs from same lot. *Salmonella* for Fresh, Froz-en: 15 – 114g (4oz.) subs from same lot.	If possible, collect whole raw crabs' viscera intact. If not available, collect cooked with viscera intact crab. Collect 3 subs, min. 227g (8oz.) edible portion and 25 g viscera If collected for ASP and PSP, double subsample size

TABLE: Sampling Schedules Domestic Fish and Fishery Products Inspection Program FY 00/01/02

Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842 .
Lobster Fresh, Frozen Cooked, Parboiled Whole, raw	6 subs min. 900 g - 1.36 kg (2-3 lb.)		Fresh or Frozen Raw: 12 sub-samples. Minimum of 454 grams (1 lb) per sub. Processed: 18 sub-samples. Minimum of 454 grams (1 lb) per sub.	General Micro: 10-227g (8oz.) subs from same lot. *Salmonella* for cooked, parboiled: 30 – 114g (4oz.) subs from same lot. *Salmonella* for Fresh, Frozen: 15 – 114g (4oz.) subs from same lot.	If possible, collect whole raw lobsters with head on and viscera intact. If not available, collect cooked with head on and viscera intact lobster. Collect 3 subs, min. 227g (8oz.) edible portion and 25 g viscera in duplicate.
Shrimp Cooked Cooked, frozen Fresh, peeled, raw Fresh, raw Frozen, peeled, raw Frozen, raw Whole, raw, fresh	6 subs, min.900 g - 1.36 kg (2-3 lb.) per sub. [] in duplicate		Fresh or Frozen Raw: 12 sub-samples. Minimum of 454 grams (1 lb.) per sub Processed: 18 sub-samples. MINIMUM OF 454 GRAMS (1 LB.) PER SUB	General Micro: 10 -227g (8oz.) subs in duplicate from same lot. For *Salmonella*, if Cooked Cooked, frozen Then: 30 subs @ 114g (4oz) from same lot. [IOM, op cit, Category II food] For *Salmonella* if Fresh, peeled, raw Fresh, raw Frozen, peeled, raw Frozen, raw Whole, raw, fresh Then: 15 subs @ 114g (4oz) from same lot. [IOM, op cit, Category III food]	Whole Raw (Preferred): Head and viscera, if possible. If not, collect whole, cooked with viscera and head intact. Collect 3 subs/sample. Min 227g (8oz.)/sub edible portion and 25 g viscera in duplicate.

TABLE: Sampling Schedules Domestic Fish and Fishery Products Inspection Program FY 00/01/02

Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842 .
Shrimp Canned	48 cans/case: ▸200 cs,48 cans >200 cs,96 cans Collect (If several codes in lot, rep. ea code by min. 16 cans, sample enough codes to give # above.		18 sub-samples, minimum of 170 grams (6 ounces) per sub; collect multiple cans or pouches per sub if less than 6 ounce size containers May need 24 additional cans for organoleptic expert check analyses at another lab.		
Shrimp, Raw Breaded.	**Min. Of 6 subs, each** 900 g -1.36kg (2-3 lbs.) in duplicate		18 sub-samples. Minimum of 454 grams (1 lb) per sub.	Whether bulk or consumer size. Headless: Collect stock, finished product & raw material samples: 142g (5 oz) duplicate subs of stock 4 times/day, 2 days of production (16 subs); 170g (6oz.) (or 1 retail package) duplicate subs of finished product 4 times/day, total 16 subs; and min.170g (6oz.) subs of raw materials, other than shrimp, from each lot of breading used over 2 days. [CPG 540.420]	
Shrimp, Freeze dried Shrimp, Sun dried	Freeze dried: 6 subs, 250g (10 oz.) Sun dried: 6 subs. 680 g (24 oz.) in duplicate from same lot.		Freeze dried: 6 subs, 10 oz (250g) Sun dried: 6 subs, 680 g (24 oz.) in duplicate, from same lot. It may be necessary to collect additional subsamples for the National Expert. Check with servicing lab prior to sample collection.	General Micro: 10 subs, 227g (8 oz) each in duplicate from same lot. *Salmonella*: 30 -114g (4 oz.) subs from same lot.	
Other Crustacean Products	6 subs, 900 g - 1.36 kg (2-3 lbs)/sub.		Fresh or Frozen Raw: 12 sub-samples. Minimum of 454 grams (1 lb) per sub. Processed: 18 sub-samples. Minimum of 454 grams (1 lb) per sub.	10 - 227 g (8oz.) subs	

TABLE: Sampling Schedules Domestic Fish and Fishery Products Inspection Program FY 00/01/02

Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842 .
SHELLFISH:					
Abalone, Canned			18 cans in duplicate from same lot.		
Molluscan Certified: Oysters, clams, mussels, Whole, roe-on-scallops	6 - 114g (4 oz) subs shucked product only, in duplicate.		Raw Fresh or Raw Frozen: 12 sub-samples. Minimum of 454 grams (1 lb) per sub. Processed: 18 sub-samples. Minimum of 454 grams (1 lb) per sub. (If canned/retorted, Minimum 170 grams (6 ounces) per sub.)	Collect aseptically: [See note 2 in first column. Med. Large in-shell (pacific oysters, surf and hard clams: 5 subs, 12 each, or enough to = 300 g meat and liquid... Small (olympias, ostrea lurdia, little neck clams, mussels): Min. of 20. To give at least 300g (11 oz). meat & liquid. Shucked: 5 subs - enough to give 300 g meat and liquid. Shucked product should be kept in same state as it is collected, i.e., either refrigerated or frozen. Blocks: Core or quarter.	Collect 3 subs/sample Med. Large (in-shell) – Pacific oysters, surf and hard clams) 12 individual/sub. Sm. (in shell) - min. 12 individual - enough to provide. 20 g meat and liquid. (Double if doing both ASP and PSP) Collect subs in duplicate
Scallops: Canned Fresh Frozen Shucked	Scallops, shucked: 6 subs 227g (8 oz) min, in duplicate.		Raw Fresh or Raw Frozen: 12 sub-samples. Minimum of 454 grams (1 lb) per sub. Processed: 18 sub-samples. Minimum of 454 grams (1 lb) per sub. (If canned/retorted, Minimum 170 grams (6 ounces) per sub.)	General Micro: 10 - 227g (8oz.) subs in duplicate from same lot. *Salmonella*: 30 - 114g (4oz) subs from same lot. 15 – 114 g (4 oz) subs from the same lot for fresh, frozen and/or shucked.	This work can only be done on whole scallops, collect 3 subs. Minimum 227 g (8 oz.)/sub edible portion plus 25 g viscera in duplicate

Note:

1. Record certification number of sampled shipment and final destination of shipment in "remarks" section of collection report. This information may be needed to trace back.

2. Micro samples must be analyzed within 24 hrs of collections. Contact servicing lab prior to sample collection.

TABLE: Sampling Schedules Domestic Fish and Fishery Products Inspection Program FY 00/01/02

Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842 .
OTHER SEAFOOD:					
Anchovies, Sardines, Etc. and uneviscerated fin fish to be consumed whole.)	6 subs, 900 g - 1.36 kg (2-3 lbs)/sub.		For scombrotoxin-forming species 24 subsamples For non-scombrotoxin-forming species, 18 subs If canned/retorted pouches: – 170 grams (6 ounces) per sub, collect multiple cans/pouches per sub if less than 6 ounce per container For all other products: 450 gram (1 pound.) sub-samples	10 - 227 g (8oz.) subs	3 subs/sample. Min. 227g (8 oz)/sub edible and min. 25 g viscera in duplicate.
Crayfish, langostinos, cooked, parboiled.	6 subs, 900 g - 1.36 kg (2-3 lbs)/sub.		Same as anchovies	Same as anchovies	
Squid Processed Surimi analogs. Seafood Salads Stuffed, RTE Stuffed, not RTE Other Seafood Products that do not fit a specific category	6 subs, 900 g - 1.36 kg (2-3 lbs)/sub.		Raw Fresh or Raw Frozen: 12 sub-samples. Minimum of 454 grams (1 lb) per sub. Processed: 18 sub-samples. Minimum of 454 grams (1 lb) per sub. (If canned/retorted, Minimum 170 grams (6 ounces) per sub.)	General Micro: 10 - 227 g (8oz.) subs Salmonella for cooked, parboiled: 30 subs – 114 gram (4 ounce) subs Salmonella for Fresh, Frozen : 15 subs - – 114 gram (4 ounce) subs	

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