CHAPTER 03 - FOODBORNE BIOLOGICAL HAZARDS

SUBJECT:	**IMPLEMENTATION DATE**
Seafood Processor Inspection Program – Domestic and Foreign Facilities	Upon Receipt
	COMPLETION DATE
	Continuous

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
INDUSTRY CODE 16, USE APPROPRIATE PRODUCT CODES **Note**: 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, DSP, NSP, AZP, CFP, TTX, 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-safety) – State Contract 03S002 - Seafood HACCP: State Contract 03842 - Foodborne Biological Hazards [non-safety] 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 Domestic Fish and Fishery Products (Econ/Label)- Please see note in the section on LABORATORY REPORTING before doing any activity using this PAC

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
	PFGE - *Salmonella*	use sub PAF	GSA
	PFGE – *L. monocytogenes*	use sub PAF	GLI
	PFGE – *V. cholerae*	use sub PAF	GVC
	PFGE – *V. parahaemolyticus*	use sub PAF	GVP
	PFGE – *C. botulinum*	use sub PAF	GCB
	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

10. Note: **Limited resources are available for Food Economics issues. CFSAN's current priorities focus on food safety. Districts should follow-up on consumer or industry reports of economic fraud; however, general surveillance activities should receive CFSAN concurrence prior to expending District resources.** CFSAN may periodically issue special assignments to address food economics issues.

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 regulatory 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 skills and focus and instructions specific to the inspection of seafood processing facilities and products.

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.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm2006751.htm). 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 (http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/UCM252383.pdf). The current regulatory strategy outlined in this program prioritizes areas of concern based on a risk assessment that considers, at a minimum, the severity of health consequences associated with the hazard and industry compliance history.

CFSAN continues to integrate investigational activities between the Import Compliance Program and the Seafood Processor Inspection Program – Domestic and foreign and Foreign Facilities. 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. Additionally, 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 Seafood Processor Inspection Program – Domestic and Foreign Facilities, 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

The primary objective of this program is to ensure a safe and wholesome fish and fishery products supply in the U.S. This is done through inspections of both domestic and foreign establishments that process seafood products intended for consumption in the U.S. to determine if they have met the requirements of 21 CFR 123 and other applicable U.S. regulations.

APPROACH

The Seafood Processor Inspection Program – Domestic and Foreign Facilities covers all seafood processing activities. It incorporates an evaluation of the processors' seafood HACCP controls required by 21 CFR 123 and an inspection of conditions against the requirements of 21 CFR 110. Selection and prioritization of processors and products for inspection will be risk based. Investigators who meet the training requirements for conducting seafood HACCP inspections will approach inspections by doing their own hazard analysis, evaluating HACCP plans or the controls in the absence of a plan; evaluating sanitary conditions; determining if the HACCP plan and sanitation monitoring are being implemented, that corrective actions are being taken when necessary, reviewing records and citing deficiencies. 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, and observe the firm's implemented sanitation monitoring procedures.

Inspections should be conducted in accordance with the inspection components outlined in the Conducting Seafood Inspections Training Course and the Investigations Operations Manual. Additional information can be obtained through Supplemental Inspection Instructions at http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/Seafood/UCM045647.pdf.

PROGRAM MANAGEMENT INSTRUCTIONS

A. PROGRAM PRIORITIES AND RESOURCE UTILIZATION

1. Resources shown in the ORA workplan can be used to cover PPS 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 OAI firms should not be conducted until good faith efforts by the firm to correct and address the significant problems have been completed.

   Priorities for foreign processor inspections may vary from domestic and foreign priorities based on country specific problems, emerging issues, and controls through other means such as import alerts.

3. Products and processors in Risk Areas A, B, and C are considered high regulatory priorities. Products and processors in Risk Area E is a low regulatory priority. The Compliance Program Priorities are listed in descending order below:

Risk Classification of Processor	Facility Type
A. Processors of "High risk potential" product types A, B, C, D, E, and F (as listed in A., 3 below)	1.Domestic and foreign processors whose last inspection was classified OAI
	2. Domestic and foreign processors whose last inspection was classified VAI for HACCP violations
	3. Processors that have never had an FDA or equivalent FDA-contracted State inspection
B. Processors of "High risk potential" product types G, H, and I (as listed in A., 3 below)	1.Domestic and foreign processors whose last inspection was classified OAI
	2. Domestic and foreign processors whose last inspection was classified VAI for HACCP violations
	3. Processors that have never had an FDA or equivalent FDA-contracted State inspection
C. Processors of "High risk potential" product types A, B, C, D, E, F, G, H , and I (as listed in A., 3 below)	1.Domestic and foreign processors whose last inspection was classified NAI
D. Processors of products that are not classified as "high risk potential" or "low risk potential" and are associated with hazards that are considered of regulatory significance.	1.Domestic and foreign processors whose last inspection was classified OAI
	2. Domestic and foreign processors whose last inspection was classified VAI for HACCP violations
	3. Processors that have never had an FDA or equivalent FDA-contracted State inspection

E. Processors of products that are associated with “Low risk potential” (as listed in A., 4 and 5 below) hazards and products that have no associated food safety hazards.	1.Domestic and foreign processors whose last inspection was classified OAI
	2. Domestic and foreign processors whose last inspection was classified VAI.
	2. Domestic and foreign processors who have never had an FDA or equivalent FDA-contracted State inspection
	3. Domestic and foreign processors whose last inspection was classified NAI
Frozen storage warehouses that request inspections to obtain an FEI number in order to be added to the European Union Approved List must be inspected. Although they are not a high priority, these inspections should be accomplished in a timely manner.	

4. “High risk potential” products and processes are listed below. Some seafood products may fall into more than one category. For the purposes of this program "high risk potential" products and processes include the following

Product or Process Type	**Description**	**Risk**
A. Refrigerated seafood products packed in Reduced Oxygen Packaging (ROP)	ROP is oxygen impermeable or oxygen limiting packaging that reduces the transmission rate of oxygen to levels that can result in potentially unsafe conditions if refrigeration or secondary barriers are inadequate. Examples include cans, jars, lidded plastic containers with a heat sealed inner liner, vacuum packaging, heat sealed plastic bags, packaging where air has been manually expressed and the bag sealed, seafood packed in oil, and pasteurized seafood.	The hazard of concern is *C. botulinum* growth and toxin formation. The severity of health consequences associated with this hazard elevates the risk associated with the products. ROP seafood products usually require either strict temperature control and/or processes that are usually complex and require multiple HACCP controls to ensure a safe product.

	See Chapter 13 of the Seafood HACCP Guide* for additional information	
B. Processed uneviscerated finfish(e.g. cooked, acidified, salted, dried, or partially dried)	Such as Kapchunka, alewives, or bloaters	The hazard of concern is *C. botulinum* growth and toxin formation. (*C. botulinum* is present in the environment and consequently present in the fish viscera.) Immediate regulatory action may be necessary when these product or processes are encountered. CFSAN should be contacted when these products or processes are encountered.
C. Raw molluscan shellfish and products that include raw molluscan shellfish that will not be cooked prior to consumption	Such as clams, mussels, whole scallops, oysters, and seafood mixes that contain molluscan shellfish	Hazards include *Vibrio* spp., *Salmonella*, *Hepatitis* A, *Cholera* spp. Norovirus and marine toxins. A significant number of illnesses are directly attributed to consumption of raw molluscan shellfish. **See Item H in this section for additional inspectional coverage information**
D. Cooking, smoking, fermentation, acidification processes, or drying process for RTE dried seafood	Products include heat treated seafood products (e.g., cooked shrimp, crabmeat, cooked lobster, cooked crayfish, hot smoked, etc.) OR Cold smoked seafood OR Refrigerated pickled seafood	The primary food safety hazards of concern include *C. botulinum* for products in ROP packaging, *L. monocytogenes*, and *S. aureus* growth and toxin formation. These processes are normally complex and require multiple HACCP and strict sanitation controls to ensure a safe product.

* Fish and Fisheries Products Hazards and Controls Guidance

	OR Seafood pastes	
E. Scombrotoxin-forming (histamine-forming) species	Table 3-A in the Seafood HACCP Guidance will provide the species of concern.	Scombrotoxin (histamine) is a heat stable toxin that is not eliminated through thermal processing or acidification. A significant number of illnesses are associated with scombrotoxin forming species.
F. Ready-to-Eat (RTE) seafood processors who do NOT operate cooking, smoking, fermentation, or acidification operations, but receive, store, manufacture, or otherwise process RTE seafood.	RTE seafood Examples include: Caviar, fish roe, urchin roe, pickled fish, or raw fish intended for sashimi or sushi, cold smoked fish, ceviche, pickled fish OR Products prepared from RTE fisheries products including seafood salads, seafood sandwiches, seafood spreads, seafood dips, seafood mixes OR Refrigerated products listed in Item D. OR RTE dried seafood	The primary pathogen of concern is usually *L. monocytogenes,* however other pathogens may also be of concern. Parasites may be a hazard in products intended for raw or undercooked consumption, such as sashimi, pickled fish, ceviche, cold smoked fish, and sushi. Refer to Chapter 5 and Tables 3-2 and 3-3 in the Fish and Fishery Products Hazards and Controls Guidance for further information on the parasite hazard.

G. Formulated seafood products containing multiple ingredients AND Products where sodium metabisulfites or FDA Yellow No.5 are likely to be used.	Examples include seafood mixes, soups, chowders, salads, pastas, meals, battered or breaded seafood, spreads, surimi analogs, dips, sandwiches, sushi OR Chapter 19 of the Seafood HACCP Guidance can provide additional information with regards to species associated with undeclared food intolerance substances	The food safety hazard of concern is undeclared allergens and food intolerance substances.
H. Aquacultured seafood	Table 3-A in the Seafood HACCP Guidance will provide the species of concern.	The food safety hazards of concern are the use of unapproved aquaculture drugs and the improper use of aquaculture drugs. Chemotherapeutics in Seafood Compliance Program, CP 7304.018. An increased incidence of unapproved drug residues is associated with imported aquacultured species. Foreign processors should have an increased priority for inspection.

5. The following food safety hazards are considered a “low risk potential”, - metal inclusion, glass inclusion, environmental chemicals, and methyl mercury. Deficiencies with regards to these hazards should be noted as FDA 483 Observations but Districts should not routinely pursue regulatory discretion for deficiencies associated with these hazards. It is recommended that the districts contact CFSAN for concurrence of charges associated with these hazards

6. Food safety hazards that are not listed as a “low risk potential” are considered significant and regulatory action should be considered when deficiencies associated with these hazards occur.

B. IDENTIFICATION OF A DISTRICT SEAFOOD COORDINATOR

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

C. SAMPLE COLLECTION

Samples of seafood products should not be collected to support seafood HACCP charges. Samples may be collected if an investigator is unsure if critical limits are adequate based on the Seafood HACCP Guidance or consultation with CFSAN, but not when controls are clearly inadequate. Samples can be collected in response to illness outbreaks or as follow-up on consumer or industry complaints. CFSAN may periodically issue special assignments to address food economics issues or as targeted assignments for emerging issues.

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

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

D. SPECIAL HACCP REPORTING

This Compliance Program will utilize a special HACCP reporting form **FDA 3501.**

FDA investigators are now to use the electronic version. To access the form, go to https://cfsanappsinternal.fda.gov/scripts/seahaccp/default.cfm. Instructions for use of the forms are located at the top of the page.
There are different links for creating forms for domestic and foreign and foreign inspections.

E. INTERACTION WITH OTHER PROGRAMS/ASSIGNMENTS

Note: All CFSAN Compliance Programs can be found at http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm013763.htm

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

The Domestic Acidified and Low Acid Canned Foods Program, CP 7303.803A covers the safety hazards associated with the control of *Clostridium botulinum* toxin through the sterilization or acidification. This program covers HACCP controls addressing hazards that are not eliminated through thermal process or acidification.

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 inspections of raw (fresh and fresh frozen) molluscan shellfish under this program should only be conducted when the shellfish are processed in a state that does not participate in

the NSSP. Processors who do not participate in the NSSP but operate within a participating state should be reported to the local shellfish authority. To determine if an operator or state participates in the ISSC, refer to the Interstate Certified Shellfish Shippers List (ICSSL) at http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006753.htm
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 Sanitation 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 Seafood Processor Inspection Program – Domestic and foreign and Foreign Facilities 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 the HACCP controls that assure that accurate product labeling occurs.

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. This program covers inspection of primary processors of aquacultured seafood products.

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 conducted in accordance with the inspection components in the Conducting Seafood Inspections Training 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 inspectors 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 Conducting Seafood Inspections Training 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/ForFederalStateandLocalOfficials/PartnershipsContracts/CurrentPartnershipAgreements/ucm116013.htm

Inspectors conducting contract or partnership seafood HACCP inspections must also complete the form FDA 3501. They can access their link for FDA 3501 through ESAF.

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.

For scientific and technical HACCP questions that are not address in the Guide during and following inspection, contact the either a National Expert or the Seafood Technical and Policy Branch at (240)402-2300.

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

Conducting Seafood Inspections Training Manual - HACCP inspection procedures/activities;

Fish and Fishery Products Hazards and Controls Guidance (FFPH&CG) - Hazards and recommended controls for seafood processors, most recent edition;

Food Microbiological Control Manual, most recent edition;

Office of Food Safety (Division of Seafood Safety) Website "Supplemental Inspection Instructions" at http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/Seafood/UCM045647.pdf

Sanitation Control Procedures for Processing Fish and Fishery Products

Additional references listed in Part VI.

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 Segment 2 (a third day of live instruction by a certified seafood HACCP instructor)
- "Conducting Seafood Inspections" Training Course

It is suggested that investigators performing seafood inspections (state and federal) also completed the following courses.

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

B. Inspection Component

Investigators who meet the training requirements for conducting seafood HACCP inspections will approach inspections by doing their own hazard analysis, evaluating HACCP plans or the controls in the absence of a plan; evaluating sanitary conditions; determining if the HACCP plan and

sanitation monitoring are being implemented, that corrective actions are being taken when necessary, reviewing records and citing deficiencies. 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, or National Expert.

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

   HACCP inspections should be planned for times when the firm is known to be in production. For firms producing both high and low risk potential products, the inspection should be conducted when high risk product(s) are produced. Product selections should be risk-based and target a particular higher risk product/process.

   During a HACCP inspection, it is important to observe the implementation of monitoring, verification, corrective action and sanitation procedures during production. In some cases it may be necessary to contact the firm and determine their production schedule for the product of interest. Districts should use their discretion in employing this approach. If an evaluation of a previously classified OAI/VAI HACCP inspection of a particular product cannot be accomplished during a re-inspection, , the district is still obligated , at its earliest opportunity, to perform a re-inspection of that product or a product with identical CCPs covered under the same HACCP plan. The OAI/VAI classification for this product will remain open until a satisfactory inspection is 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. 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., foreign inspections, limited harvest season), an inspection that includes a **complete HACCP Records Review** should then be conducted and include all of the inspection components, however, information will need to be gathered by asking questions and having the firm show you what they do. Although it isn't the best situation, but it will still provide valuable information on the compliance of the firm. All deficiencies should still be listed on a FDA 483.During a complete HACCP records review, an investigator should have the processor walk them through the process and describe the operation. HACCP plans, monitoring records, verification documents, corrective action records, and sanitation monitoring records covering previous production days should be reviewed. Any sanitation deficiencies or deficiencies with the HACCP plan or HACCP records observed should still be noted on the FDA Form 483.

3. Investigators should conduct, if time allows, a **technical revie**w of HACCP plans for all products listed as "high risk potential" in Part II. 4. , in addition to the standard review of the product being processed. The technical review is one that consists only of a review of the written HACCP plan to determine if appropriate/reasonable hazards and controls are identified. It is not necessary to review monitoring records or corrective action records. 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 technical review. However, ensure that the Question # 10 (Actively Processing) is answered **NO**.

4. Document **all** seafood HACCP regulation and GMPs deficiencies on the Form FDA 483 in a manner consistent with the Conducting Seafood Inspections 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.

C. Reporting HACCP Findings – FDA 3501 (Seafood HACCP Report)

A separate seafood HACCP inspection report **(FDA 3501**) is to be completed electronically for the HACCP portion of the inspection for each product evaluated during a domestic or foreign inspection, including both observed processing evaluations and technical reviews.

FDA investigators are now to use the electronic version. To access the form, go to https://cfsanappsinternal.fda.gov/scripts/seahaccp/default.cfm. Instructions for use of the forms are located at the top of the page. There are different links for creating forms for domestic and foreign and foreign inspections.

Contracted state inspectors are also to use the electronic version. They can access their link for FDA 3501 through ESAF.

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 being stored, the warehouse is considered to be actively processing that product. A firm that is a manufacturer, repacker, or relabeler, must be actually manufacturing, repacking or relabeling the product listed in Block 9 during the inspection it is to be classified as actively processing on the FDA Form 3501. If a manufacturer, repacker or relabeler only has the product in inventory, it is not to be considered to be actively processing even though those activities are listed as " processing" under 123.3(k)

It is important to fill the reports out completely and accurately. The information is entered in the National Seafood HACCP Inspection Database and used to track overall industry compliance and to develop

risk rankings for products and processes. Please be very specific and accurate in describing the finished product and entering its product code. Accurate product codes and product descriptions are essential. Inaccurate information can result in a misidentification of problem areas. For assistance, consult the line-by-line instructions or the FDA Product Code Builder.

D. Inspection Component(s) for Regulations other than 21 CFR 123.

It is important to remember that compliance with 21 CFR 123 is only one element of a seafood processor inspection. 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, economic fraud and other non-seafood HACCP related deficiencies. As in the past, such deficiencies will be noted on FDA Form 483 in addition to seafood HACCP deficiencies.

Economic fraud in the form of species substitution and misbranding can present additional safety concerns. Hazards such as ciguatera, histamine, tetrodotoxin, environmental chemicals, and parasites are associated with specific species of fish and the safety controls for these hazards are specific to the type of hazard. In addition, scientific research has determined that some allergic reactions to finfish are specific to the species of fish. Incidents of illness have been linked to seafood products where a fish species was not accurately identified by their “common or usual” name. During seafood HACCP or GMP inspections of seafood processors, receiving records such as purchase orders and raw materials labeling should be compared against the finished product labeling. Purchase orders should be compared against raw materials labeling when possible. Evidence of misbranding should be included in the FDA 483 investigation observations and information documented in the Species Substitution Questionnaire at https://cfsanappsinternal.fda.gov/scripts/seahaccp/default.cfm.

If an inspection is intended to cover a processor who is covered under more than one compliance program, for example a canned tuna processor, investigators should conduct the inspection in accordance with the applicable programs. It may be necessary to address each program separately during the inspection to provide adequate coverage of all the processing activities and allocation of time. The EIR should reflect this separation

For example, if part of the inspection is covered under the LACF or Acidified Foods regulations, that portion of the inspection under CP 7303.803A and the seafood processing activities not covered under those regulations would be reported under CP 7303.842.

E. Sampling

1. Seafood HACCP

The Seafood HACCP regulation was promulgated under 402(a)(4) of the Food, Drug, and Cosmetic Act. Because of that it is not necessary to routinely collect samples to support regulatory action. Work plan allocations for domestic sampling have been reduced to reflect this policy. If the firm clearly does not

have controls in place, there is no need to collect a sample. The lack of controls should be clearly stated on the FDA 483 and in the EIR. If a district thinks a sample is necessary, they should contact CFSAN prior to collecting the samples, to discuss the collection.

2. ”For Cause” Sampling

Official Samples are to be collected “for cause” only (e.g., if inspectional conditions warrant or as part of investigations of illness outbreaks or consumer complaints. Investigators should not normally collect samples for pathogen testing if HACCP controls are clearly inadequate.

In accordance with IOM 8.3.4.6.1: where vector animals or evidence thereof is present, collect samples and submit to laboratory as filth exhibits. **Collection of these samples is not necessary for support of violations of 21 CFR 123.11(b), failure to monitor sanitation conditions with sufficient frequency.**

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 Work Plan 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.

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

4. **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.

F. National Marine Fisheries Service (NMFS)

FDA currently has a Memorandum of Understanding (MOU) with NMFS (Dept. of Commerce, NOAA). The MOU sets forth the working arrangements between the two agencies to facilitate each agency's efforts to carry out its responsibilities related to the inspection of fish and fishery products. Investigators should review and follow procedures outlined in FMD#-029 (http://www.fda.gov/downloads/ICECI/Inspections/FieldManagementDirectives/UCM278188.pdf)when conducting both domestic and foreign

establishment inspections.

G. 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 compliance with the seafood HACCP regulation. These processors are chosen by CFSAN for several reasons including the products they process, their history of compliance and even the countries compliance history for certain products. A listing of products that are targeted for inspection should be provided to investigator for each firm that is to be inspected along with any refusals that FDA has had as part of the support materials prior to each inspection trip.

Investigators should follow normal investigation protocols and should focus their attention on the implementation of the HACCP program for those targeted products. If the targeted product or a product with identical hazards and controls is not being processed during the inspection, the investigator should conduct a full records review of the targeted product which includes a walk-through of the facility following the steps of production, and a sanitation inspection of the facility, and put all observations, flow charts, records reviews, etc. in the EIR. 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. Investigators should not focus attention on products that are not shipped to the U.S.

It is crucial that investigators obtain documentary or photographic evidence to accompany their EIR during inspections of foreign processors. Due to the shortened time for inspection, a comprehensive review of records may need to take place at CFSAN. Investigators should obtain copies of the HACCP plans, monitoring records, corrective action records, and sanitation monitoring records.

Since most of the foreign 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 each record, if necessary, and included in the EIR. The translations obtained from the processor will help assure accuracy. A plan or records without at least partial translation are usually useless. CFSAN obtaining routine translations of the documents is cost prohibitive.

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.

- 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.
- Where available, NSSP methods are provided for detection of natural toxins in shellfish and are considered the preferred methods.

CHEMICAL CONTAMINANTS Project 04

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 http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm014792.htm and
and Toxic Elements in Foods and Foodware, and Radionuclides in Foods, Domestic and Import, CP 7304.019 http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm073204.pdf.

CHEMOTHERAPEUTICS

For all analytical guidance, including Field Laboratories, Methodology, and Reporting, refer to Part IV Compliance Program Chemotherapeutics in Seafood Compliance Program, CP 7304.018. http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm073192.pdf

The sections of this part are:

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

B Project 03: **Parasites**

C Project 03: **Decomposition**

D Project 03: **Microbiological**

F Project 07: **Natural Toxins**

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

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

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 Food Safety, HFS-316, George Ziobro, (240-402-1965)

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

a. CRITERIA FOR REGULATORY ACTION:

Regulatory action may be recommended for fresh or frozen raw shrimp as a consequence of the above surveillance sampling and testing when six 2 – 3 pound subs indicates filth at or above the following levels:

- FLIES AND OTHER INSECTS (WHOLE OR EQUIVALENT)

  Disease-carrying insects* - 2 in a sample;

  or

  Other insects - 3 of the same species in a sample.

- INSECT FRAGMENTS

  Fragments from disease-carrying insects* - 5 fragments (excluding setae) present in at least 2 of 6 subs. These fragments are clearly identified as parts of a disease-carrying insect;

  or

Large body parts of disease-carrying insects* (i.e., head, thorax, abdomen) - 1 in at least 2 of 6 subs.

- HAIRS

  Rat or Mouse - Average of 1 per sub, any size;

  or

  Striated but not rat or mouse - Average of 4 per sub, any size.

The above guidance does not include all types of filth or the different combinations of filth that may be found in shrimp. Samples containing filth elements not discussed above should be submitted to CFSAN/Office of Field Programs, Division of Enforcement & Programs, Import Branch (HFS-606).

*DISEASE-CARRYING INSECTS

A disease-carrying species of insect has all of the following attributes:

1. Wild populations known to carry E. coli, Salmonella, and Shigella.
2. Synanthropy (a preference to live in human settlements).
3. Endophily (tendency to enter buildings).
4. Communicative behavior (oscillating between filth and human food).
5. Attraction to both human food and excrement or other pathogen reservoirs.
6. Recognition by medical entomological authorities as a disease-carrying species.

Examples include:
Flies:

Little house fly (*Fannia canicularis* (L.))
Latrine fly (*Fannia scalaris* (F.))
House fly (*Musca domestica* (L.))
Stable fly (*Stomoxys calcitrans* (L.))
Cosmopolitan blue bottle fly (*Calliphora vicina* (Robineau-Desvoidy))
Holarctic blue bottle fly (*Calliphora vomitoria* (L.))
Oriental latrine fly (*Chrysomya megacephala* (F.))
Blue bottle fly (*Cynomyopsis cadaverina* (R.-D.))
Secondary screwworm (*Cochliomyia macellaria* (F.))
Green bottle fly (*Phaenicia sericata* (Meigen))
Black blow fly (*Phormia regina* (Meigen))
Redtailed flesh fly (*Sarcophaga haemorrhoidalis* (Fallen))

Ants:

Pharaoh ant (*Monomorium pharaonis* (L.))
Thief ant (*Solenopsis molesta* (Say))

This is not necessarily a complete list of disease-carrying insects that might be found in shrimp.

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.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm 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 240-402-2503 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. **Parasite Fixation** See reference in BAM, Chapter 19.

CONTACTS: CFSAN, Office of Food Safety, HFS-325, Clarke Beaudry, (240-402-2503)

REPORTING: Report all results of analytical results in **FACTS using** PAC 03844B and PAF "PAR".

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 confirmation organoleptic analyses may only be performed by analysts qualified in the particular seafood product category as found in the agency's "Seafood Sensory Analyst Product Category Ratings List." This list is maintained by ORA's Division of Field Science (HFC-140).

Products that have been treated with chemicals or additives, that have no obvious sensory indicators of decomposition or where sensory indicators may have been masked, should be chemically analyzed for decomposition where chemical indicators of decomposition are applicable. Steve Plakas or Ron Benner, CFSAN, Office of Food Safety, Division of Seafood Science and Technology, Gulf Coast Seafood Laboratory, Dauphin Island (HFS-400), 251-690-3403 or 251-690-2319, respectively, can be consulted for appropriate testing methods and applications.

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, contact CFSAN/Coordinated Outbreak Response and Evaluation Network (CORE), Roberta Hammond at 240-402-3035.

ANALYSIS REQUIREMENTS ARE SPECIFIC FOR PRODUCTS AS FOLLOWS:

1. **SCOMBROTOXIN-FORMING 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 3-2.)

   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
Processed (e.g., cooked, canned/pouched (retorted), and/or treated with chemicals or additives, including such things as salt, acid, chlorine, smoke, and carbon monoxide)	24
Canned/pouched tuna greater than or equal to 907 grams (2 lbs)	18

Note: Dried products and sauce/paste products are not included; Steve Plakas or Ron Benner, CFSAN, Office of Food Safety, Division of Seafood Science and Technology, Gulf Coast Seafood Laboratory, Dauphin Island (HFS-400), 251-690-3403 or 251-690-2319, respectively, should be consulted if decomposition analysis is indicated for dried or sauce/paste articles.

(1) Positive Findings:

When an original organoleptic analysis is performed and sensory indicators 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 the agency's "Seafood Sensory Analyst Product Category Ratings List" maintained by ORA's Division 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 having analysts qualified in the particular seafood product category as found in the agency's "Seafood Sensory Analyst Product Category Ratings List";

  or

- Histamine analysis - When using histamine analysis to confirm a positive original organoleptic result, analyze a minimum of six subsamples for histamine including the subs exhibiting sensory indicators of decomposition. Analyze the remaining subsamples if histamine greater than or equal to 35 ppm is detected in any of the initial six subsamples. Additional subs need not be analyzed if two or more subsamples are found to contain 50

ppm or more histamine, or if one subsample is found to contain 500 ppm or more histamine.

A check histamine analysis should be performed on a minimum of two subs showing the highest histamine levels. Use an additional 10 g aliquot from the same ground subsample portions to perform the check analysis.

(2) Negative Findings:

If only one subsample is determined (by original and confirmation analysis) to have sensory indicators of decomposition, or if all subsamples pass the sensory examination but with one or more subsamples in the mid-pass or borderline-pass region consistent with the analysts' sensory training, conduct histamine analysis on a minimum of six subsamples including the subsample that failed or those subsamples in the mid-pass or borderline-pass region. Analyze the remaining subsamples if histamine greater than or equal to 35 ppm is detected in any of the initial six subsamples.

Additional subs need not be analyzed if:

- histamine greater than or equal to 50 ppm is detected in two or more of the initial six subsamples;

or

- one subsample failed for sensory indicators of decomposition and histamine greater than or equal to 50 ppm is detected in a separate subsample of the initial six subsamples;

or

- histamine greater than or equal to 500 ppm is detected in one or more of the initial six subsamples.

A check histamine analysis should be performed on a minimum of two subs showing the highest histamine levels when the histamine results are to be used to support a regulatory action (i.e. one sub ≥ 500 ppm, two subs ≥ 50 ppm, or one sub with sensory indicators of decomposition and another sub ≥ 50 ppm). Use an additional 10 g aliquot from the same ground subsample portions to perform the check analysis.

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

b. **HISTAMINE ANALYSIS**

Follow the analytical method for histamine testing 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.

Whole Fish, Fillets, and Loins: Cut a section (approximately 250 to 500 grams) from the anterior end (if it can be determined) of the fish (or fish portion) and grind each subsample. For larger fish, the lower anterior loin 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 that "failed" the sensory analysis within the subs to be tested if so segregated.)

Steaks, Strips, Cubes, etc.: Grind 250 to 500 grams of the edible portion of each subsample (i.e. excluding bone and skin). 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 that "failed" the sensory analysis within the subs to be tested 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 fish meat before collecting the test portion (include 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 from the original analysis 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 additional 10 g aliquot from the same original ground portions to perform the check analysis.

c. **CRITERIA FOR REGULATORY ACTION:**

Based on analytical data, refer to CPG Sec. 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, canned/pouched (retorted), and/or treated with chemicals or additives. Product treated with only sulfites or phosphates may be considered raw unless there is a suspicion or evidence that the compounds are used at excessive levels such that decomposition could be masked in the article. Dried products and sauce/paste products are not included; Steve Plakas or Ron Benner, CFSAN, Office of Food Safety, Division of Seafood Science and Technology, Gulf Coast Seafood Laboratory, Dauphin Island (HFS-400), 251-690-3403 or 251-690-2319, respectively, should be consulted if decomposition analysis is indicated for dried or sauce/paste articles.

(1) Positive Findings:

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

- An analyst qualified for confirmation analysis, i.e., Level II(B) or III analysts, in the appropriate product category as found in the agency's "Seafood Sensory Analyst Product Category Ratings List" (maintained by ORA's Division 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 having analysts qualified in the particular seafood product category as found in the agency's "Seafood Sensory Analyst Product Category Ratings List";

or

- Indole analysis.

  When using indole analysis to confirm a positive original organoleptic result, analyze a minimum of six subsamples for indole including the subs exhibiting sensory indicators of decomposition. The remaining subsamples should be analyzed if indole is detected at 15-24 micrograms /100 grams

of shrimp in any of the initial six subsamples. Additional subs need not be analyzed if indole greater than or equal to 25 micrograms/100g of shrimp is detected in two or more subsamples.

When two or more subsamples contain indole at or above 25 micorgrams/100 grams, a check indole analysis should be performed on a minimum of two subs showing the highest indole levels. Use an additional aliquot from the same ground subsample portions to perform the check analysis.

(2) **Negative Findings:**

- If only one subsample is determined (by original and confirmation analysis) to have sensory indicators of decomposition, or if all subsamples pass the sensory examination but with one or more subsamples in the borderline-pass region consistent with the analysts' sensory training, an indole analysis on a minimum of six subsamples (including the subsample that failed or those subsamples in the borderline-pass region) is recommended.

- The remaining subsamples should be analyzed if indole is detected at 15-24 micrograms /100 grams of shrimp in any of the initial six subsamples. Additional subs need not be analyzed if:

  o indole greater than or equal to 25 micrograms /100 grams of shrimp is detected in two or more of the initial six subsamples;

  or

  o one subsample failed for sensory indicators of decomposition and indole greater than or equal to 25 micorgrams/100 grams is detected in a separate subsample of the initial six subsamples.

  A check indole analysis should be performed on a minimum of two subs showing the highest indole levels when the indole results are to be used to support a regulatory action (i.e. two subs ≥ 25 micorgrams/100 grams, or one sub with sensory indicators of decomposition and another sub ≥ 25 micorgrams/100 grams). Use an additional aliquot from the same ground subsample portions to perform the check analysis.

- If the sample does not exhibit sensory indicators 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 the analytical method for indole testing 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.

When the size of the individual subsamples is equal to or less than 454 grams, grind the entire sub. For canned shrimp, discard any liquid before compositing. If the sub is larger than 454 grams, remove 454 grams representative of the sub and grind this for indole analysis.

Check Analysis: When two or more subsamples from the original analysis contain indole at or above 25 micrograms/100 grams of shrimp, a check indole analysis should be performed on a minimum of two subs showing the highest indole levels. Use an additional aliquot from the same original ground subsample portions to perform the check analysis.

c. **CRITERIA FOR REGULATORY ACTION**

Based on analytical data, refer to CPG Sec. 540.370.

3. **OTHER SEAFOOD PRODUCTS -** Except Scombrotoxin-forming species (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 (including pasteurized), canned/pouched (retorted), and/or treated with chemicals or additives, including such things as salt, acid, chlorine, smoke, and carbon monoxide. Product treated with only sulfites or phosphates may be considered raw unless there is a suspicion or evidence that the compounds are used at excessive levels such that decomposition could be masked in the article. Dried products and sauce/paste products are not included; Steve Plakas or Ron Benner, CFSAN, Office of Food Safety, Division of Seafood Science and Technology, Gulf Coast Seafood Laboratory, Dauphin Island (HFS-400), 251-690-3403 or 251-690-2319, respectively, should be consulted if decomposition analysis is indicated for dried or sauce/paste articles.

Positive Findings:

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

- An analyst qualified for confirmation analyses, i.e., Level II (B) or III analysts, in the appropriate product category as found in the agency's "Seafood Sensory Analyst Product Category Ratings List" (maintained by the Division 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 having analysts qualified in the particular seafood product category as found in the agency's "Seafood Sensory Analyst Products Category Ratings List".

b. **CRITERIA FOR REGULATORY ACTION**:

Based on analytical data, refer to CPG Sec. 540.370. http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm123201.htm .

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.fda.gov/food/foodscienceresearch/laboratorymethods/ucm2006949.htm

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***- Based on existing CPGs, cooked ready-to-eat crabmeat and raw breaded shrimp are products that should be analyzed for *E. coli.*

   LST-MUG for Detection of *E. coli* and Coliforms in Chilled or Frozen Foods Exclusive of Bivalve Molluscan Shellfish BAM, Chapter 4, Section II.

   For determining *E. coli* in Shellfish Meats, see BAM, Chapter 4, Section IV.

   Alternatively, LST MUG method (Ch. 4, eBAM Section II) may be used to examine for coliforms when both *E. coli* and coliform analysis are required in **chilled and frozen foods ONLY and exclusive of bivalve molluscan shellfish**. The presumptive test for coliforms can be performed in conjunction with the test for *E. coli* by preparing LST-MUG (M77) with gas tubes (i.e., using the same medium, LST-MUG, for the detection of *E. coli* and coliforms).

   Do not perform ETEC analysis unless *E. coli* is greater than or equal to 10,000 CFU/gram. See BAM, Ch. 24, "Identification of Foodborne Bacterial Pathogens by Gene Probe", "Enterotoxigenic E. coli".

   PRL-SW will provide radioactive probes for ETEC. The laboratory contact is Michael Kawalek at 949-608-3505.

2. ***Listeria monocytogenes*** - Only analyze products processed ready-to-eat for *Listeria monocytogenes* (e.g. cooked, smoked, etc.) or if the district has indicated on the collection report that the there is reason to believe the product will be consumed raw.

   a. **General Method**:

Rapid Test Kits as identified in ORA-LAB.1 attachment 3 (*The attachment does currently exist, the screening kits currently used in the field lab will be added to an attachment 3 of ORA-LAB.1)* may be used as screening method.

http://inside.fda.gov:9003/downloads/ORA/OfficeofRegionalOperations/DivisionofFieldScience/UCM240894.pdf

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 □ -naphthol, **DO NOT** use □ - 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 83.3 g from each of three (3) subsamples. Each composite size is 250 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 buffered *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, 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, D. Isolation Procedure. Use of one of the new differential agars in addition to an esculin agar is strongly recommended.

3. ***Salmonella*** **–** Do not routinely analyze non-ready-to-eat products for *Salmonella.* Ready-to-eat products should receive a higher priority when allocating resources.

a. **General Method**: Use BAM, Chapter 5, *Salmonella* Additionally, Rapid Test Kits as identified in Rapid Test Kits as identified in ORA-LAB.1 attachment 2 may be used as screening method. http://inside.fda.gov:9003/downloads/ORA/OfficeofRegionalOperations/DivisionofFieldScience/UCM240894.pdf

b. **Speciation**

If positive for *Salmonella*, prepare BHI slants and provide hardcopy information requested under BAM Chapter 5, Section E. and send **under seal** for speciation:

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

Arkansas Regional Laboratory
3900 NCTR Rd., Bldg. 26, 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 –** Raw, unprocessed seafood should not be tested for *Staphylococcus aureus or Staphylococcal* enterotoxin.

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*.

there is no need to perform MPN and DPC simultaneously since MPN is designed to detect organism less than 100, which neither trigger a regulatory action, nor an indication for further toxin analysis. DPC alone will serve the purposes.

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. This BAM chapter no longer exists. Chapter 13A only provides instruction on food not isolates.)

b. Preformed enterotoxin in product. BAM, Chapter 13A, Staphylococcal Enterotoxins, section D, Extractions and chromatographic separation of enterotoxin from food.

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.

the decade old guidance should no longer be cited in the program anymore, it should have already been updated in the BAM.

6. ***V. cholerae, V. parahaemolyticus, V. vulnificus*** **–** Do not analyze non-ready-to-eat products for *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 Or for V. cholerae sample, use either Chapter 9 or Chapter 28.(or means sample can be tested by culture or PCR, not both)

(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, Section C. Procedure for amplification of cholera toxin gene sequences from V. cholerae using APW enrichment broth.

(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 6 through 10 (e.g., composite #1B).

(c) These APW lysate composites will be **designated as zero (0) time lysates, (e.g., composites 1A and 1B)**. Boil for 5 min, then freeze.
The strategy is not clear on the purpose of performing PCR analysis on lysate at 0 hr, 6-8 hr or 16-24 hr, since the isolate will be needed for serotyping and PCR is not used for confirmation. (this is different from Shigella testing where PCR is intended to be used as confirmation, where 0hr, 6hr and 24hr are tested to show the growth.)

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 confirmatory lab ARL, which has mouse bioassay capability.

a. Examine 10 individual subsamples.

b. Use BAM, *Clostridium botulinum*.

7. ADDITIONAL ANALYSES

For Smoked, Brined, Salted, Cured, Dried, or Pickled Seafood Methodology for Water Activity can be found in the analytical section of the Domestic AF & LACF Program: http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/FieldPrograms/ucm018814.pdf#analyt

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 pH is less than 4.6, the analysis is finished. If the pH is greater than or equal to 4.6, check for water phase salt and, if appropriate, for nitrite concentration in ppm as above.

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.

F. Project 07: NATURAL TOXINS

1. **Analyzing Laboratories** for Paralytic Shellfish Poison and Amnesic Shellfish Poison (ASP)/Domoic Acid are SRL and PRL-NW. Samples from the SE region 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:**

For each subsample (see Attachment A), whole animals (exception: scallops) will be homogenized, extracted, and analyzed separately (e.g., total of three (3) analyses per sample). In the case of scallops, gonads are to be homogenized, extracted, and analyzed for roe-on scallop products; gonads and viscera are to be homogenized, extracted, and analyzed for whole scallop products.

b. **Crustaceans:**

For **each** subsample, separate the edible portion from the viscera. For crab and lobster, viscera portions will comprise hepatopancreas (e.g., mustard/tomalley). Muscle and viscera portions will be homogenized and analyzed separately (e.g., total of three (3) analyses for the muscle/viscera/head per sample).

NOTE: Crab samples must be cooked for fifteen (15) minutes in boiling water before tissues are collected.

d. **Finfish:**

For fish consumed whole (uneviscerated), each subsample will be homogenized in entirety and analyzed (total of three (3) analyses per sample). For all other fish, edible portions will be homogenized and analyzed (total of three (3) analyses per sample).

Note: For CTX and TTX analyses in finfish, subsamples are not composited.

2. **PSP (saxitoxins) Sample Preparation/Method**

AOAC, 18th Ed. (or as updated), 959.08, Sec. 49.9.01. This method is also accepted by NSSP.

AOAC, 18th Ed. (or as updated), 2011.02. This method is accepted by NSSP.

AOAC, 18th Ed. (or as updated), 2005.06.

Laboratories can obtain a PSP (saxitoxin) standard from NIST http://www.nist.gov/ts/msd/srm/.

For any questions related to the analysis of PSP toxins, please call Stacey DeGrasse at (240) 402-1470 at CFSAN/Office of Regulatory Science, College Park, MD.

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

AOAC, 18th Ed. (or as updated), 991.26, Sec. 49.10.02. This method is also accepted by NSSP; however, the extraction to be used is that found in AOAC 2006.02 (see below).

AOAC, 18th Ed. (or as updated), 2006.02, Sec. 49.10.04. This extraction procedure is approved by NSSP; however, the assay itself is not.

The extraction procedure for domoic acid should follow that found in AOAC 2006.02 regardless of the method employed. The original publication of this recommended extraction procedure is Quilliam and Hardstaff (1995).

An LIB of an improved domoic acid method with the appropriate extraction procedure is currently being prepared.

If there any questions about domoic acid analysis, contact Stacey DeGrasse (240-402-1470) at CFSAN/Office of Regulatory Science, College Park, MD or Steven Plakas (251-690-3403)/Alison Robertson (251-690-3224) at CFSAN Gulf Coast Seafood Laboratory, Dauphin Island, AL.

4. **DSP (Okadaic Acid, Dinophysistoxins, and their derivatives)**

European Union Reference Laboratory for Marine Biotoxins. EU-Harmonized Standard Operating Procedure for Determination of Lipophilic Marine Biotoxins in Molluscs by LC/MS/MS Version 2, July 2010.

An LIB based on the EU Harmonized SOP is currently being prepared.

There are currently no methods for the determination of DSP toxins that are approved by the NSSP.

Certified reference Okadaic Acid (OA) can be purchased from the National Research Council Canada (NRC), Institute for Marine Biosciences, Halifax (http://www.nrc-

cnrc.gc.ca/eng/programs/imb/crmp.html).

If there are questions about DSP analysis, contact Jonathan Deeds (240-402-1474) at CFSAN/Office of Regulatory Science, College Park, MD or Steven Plakas (251-690-3403)/Alison Robertson (251-690-3224) at CFSAN's Gulf Coast Seafood Laboratory, Dauphin Island, AL.

5. **NSP (Brevetoxins)**

APHA Mouse Bioassay (NSSP approved). LC-MS/MS method validation and commercial ELISA kit evaluation are in progress. If there are questions about NSP amalysis, contact Steven Plakas (251-690-3403)/Ann Abraham (251-690-3083) at CFSAN's Gulf Coast Seafood Laboratory, Dauphin Island, AL. Certified reference brevetoxin is not currently available.

6. **AZP (Azaspiracids)**

European Union Reference Laboratory for Marine Biotoxins. EU-Harmonized Standard Operating Procedure for Determination of Lipophilic Marine Biotoxins in Molluscs by LC-MS/MS Version 2, July 2010.

An LIB based on the EU Harmonized SOP is currently being prepared.

There are currently no methods for the determination of AZP toxins that are approved by the NSSP.

Certified reference Azaspiracid-1, -2, and -3 (AZA1, AZA2, and AZA3) can be purchased from the National Research Council Canada (NRC), Institute for Marine Biosciences, Halifax http://www.nrc-cnrc.gc.ca/eng/programs/imb/crmp.html

If there are questions about AZP analysis, contact Steven Plakas (251-690-3403)/Alison Robertson (251-690-3224) at CFSAN's Gulf Coast Seafood Laboratory, Dauphin Island, AL.

7. **CFP (Ciguatoxin)**

Tiered method for toxicity assessment (in vitro cytotoxicity assay) and confirmatory analysis (LC-MS/MS) are in the process of being validated. If there are questions about CFP analysis, contact Steven Plakas (251-690-3403)/Alison Robertson (251-690-3224) at CFSAN's Gulf Coast Seafood Laboratory, Dauphin Island, AL. Certified reference ciguatoxin is not currently available.

8. **TTX (Tetrodotoxin)**

Note: FDA makes no recommendations in HACCP for controls of tetrodotoxin but both domestic pufferfish and imported pufferfish (a.k.a. fugu), intentionally mislabeled to avoid import restrictions (see Import Alert 16-20) have been associated with illness and analyses for this toxin are occasionally required.

Domestic pufferfish from the east coast of Florida have also been found to contain significant concentrations of saxitoxins in their muscle and have been associated with illnesses.

AOAC, 18th Ed. (or as updated), 959.08, Sec. 49.9.01. (This mouse bioassay method for STX can also be used for TTX – STX can also be used as a standard for this assay).

An LIB based on LC-MS/MS is currently being prepared.

Certified Reference TTX is not currently available but a standard can be purchased from Sigma-Aldrich (product # T8024). (TTX standard lyophilized in citrate buffer should not be used for LC-MS/MS analysis).

If there are questions about TTX analysis, contact Jonathan Deeds (240-402-1474) at CFSAN/Office of Regulatory Science, College Park, MD.

9. REPORTING

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

If levels are found above the regulatory action level, notify collecting District's Compliance Branch immediately so that the appropriate follow up action can be initiated. FDA established action levels for natural toxins can be found in Chapter 6 of the FFPH&CG.

G. Project 09: FOOD AND COLOR ADDITIVES

ANALYZING LABORATORIES

1.	Food and Color Additives:	Refer to the current ORA Field Workplan for the correct servicing laboratory.
2.	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 Timothy Begley [(240) 402-1893] to determine what additional steps need to be taken.

4. Reporting

Report <u>all</u> analytical results (food and color additives) into the

FACTS Data System.

Use the following PACs 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**

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 CFSAN concurrence by contacting the CFSAN OFP Seafood Monitor at (240)402-3036 prior to allocating resources.

Some cases of economic fraud, specifically species substitutions, have the additional potential to present a safety hazard (e.g., puffer fish labeled as monk fish, escolar is labeled as grouper or bass, etc.). When a district learns of such conditions, the information should be forwarded to CFSAN for possible follow-up. Chapter 3 (Potential Species-Related and Process-Related Hazards) of the 4th edition of the Fish and Fisheries Hazards and Controls Guidance should be consulted if misbranding that results in exposure to additional hazards is suspected.

SPECIES SUBSTITUTION

1. Methods for Analysis

   a. AOAC Official Method 980.16 Identification of fish species thin-layer polyacrylamide gel isoelectric focusing method.

   b. A single laboratory validated method for the generation of DNA barcodes for the identification of fish for regulatory compliance. J. AOAC. 94(1) 201-210. If there are any questions concerning this method or species substitution analytical issues contact Jonathan Deeds at CFSAN (240-402-1474).

2. Sampling

   Due to the possibility of species mixtures, species identification analysis does not utilize composite sampling. One sample should be collected per lot. One sample should be comprised of 8 subsamples, preferably 2 subsamples each from 4 randomly selected containers. A subsample is defined as one fillet, steak, or retail package. In the event that the subsample is >1 lb, a 1 lb portion should be taken, where possible. If subsamples are fillets, steaks, or a portion of a retail package, each subsample should be bagged and labeled individually. Label subsamples from each container as 1-4, etc. Label individual fillets from each container as A and B, etc. An ideal sample will be comprised of a 1A, 1B, 2A, 2B, 3A, 3B, 4A, 4B subsample – each bagged and labeled individually. For domestic sampling, the B subsamples can be used as the reserve (702b) samples with only the A portions being analyzed. For import sampling, both the A and the B subsamples can be analyzed. Subsamples should be packaged and labeled for shipment following normal procedures per IOM 4.5

3. Criteria for Regulatory Action

   For servicing lab information, please contact coordinator for

Food Composition, Standards, Labeling and Economics at Division of Field Science at 301-796-5992

Class	Finding	Laboratory Criteria	Description
1	In Compliance	Qualified consensus sequence matches Reference Standard Sequence Library (RSSL) no less than 98% (≥98%) for all 4 individual subs	The analysis determined that the specific genetic identity of the product tested matched the specific product labeling.
2	Regulatory action not indicated	n/a	The analysis determined the specific genetic identity of the product tested however sufficient product labeling was not provided or available to determine non-compliance, or, a specific genetic identification of the product could not be made due to lack of a proper standard
3	Adverse findings	Qualified consensus sequence from any single sub has matches with RSSL less than 98% (<98%)	The analysis determined the specific genetic identity of the product tested and it did not match the specific product labeling.
4	No classification Required	n/a	Such as consumer complaint samples
5	Sample not analyzed or reviewed	n/a	The analysis of the sample could not be completed or was otherwise canceled.

NET WEIGHT – OVERGLAZING

This methodology applies to frozen seafood products whose surface is protected with a frozen water glaze.

1. Methods for Analysis – AOAC, Official Method 963.18, Net Contents of Frozen Seafoods, Drained Weight Procedure

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.

D. Report resources utilized for species substitution against PAC 21842. Use PAF “FDF”, Food Economics and Standard, followed by Sub-PAF “FDE”, Economic Deception.

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 associated with products or processes defined as “high risk potential” in Part II.

2. Cases involving products not defined as “high risk potential” or “low risk potential” should precede the cases listed below in 3.

3. Cases associated with hazards defined as a “low regulatory priority” in Part II or when hazards are not associated with the product should be assigned a lower priority for review, follow-up, or regulatory action unless conditions are considered egregious.

B. Violations of regulations other than 21 CFR 123

This following instructions apply to deficiencies associated with seafood products or encountered at seafood processors that may not be violations of 21 CFR 123 (i.e., seafood HACCP regulation). These include of misbranding, economic deception, non-scombrotoxin decomposition, etc. If significant deviations are exist with products or processes subject to FDA’s regulation, districts should consider appropriate follow-up action. When deficiencies are not addressed in this program, instructions may be found in other compliance programs that address the deficiency category; for example, follow the 7321.005 Compliance Program - Domestic and foreign and Import NLEA, Nutrient Sample Analysis, and General Food Labeling when considering seizure of a product with regards to labeling deficiencies covered under that program. Warning letters to seafood processors do not have to be solely limited to violations of the seafood HACCP regulation. Violations to other regulations should also be included when appropriate. Districts should consult the Compliance Policy Guides (CPG) for direct reference legal actions.

C. National Marine Fisheries Service (NMFS)

FDA currently has a Memorandum of Understanding (MOU) with NMFS. The MOU sets forth the working arrangements between the two agencies to facilitate each agency's efforts to discharge its responsibilities related to the inspection of fish and fishery products. District compliance officers and management should review and follow procedures outlined in FMD#-029 (http://www.fda.gov/downloads/ICECI/Inspections/FieldManagementDirectiv

es/UCM278188.pdf) following inspections and subsequent regulatory actions involving NMFS contracted processors

D. Advisory Actions - Warning Letters

Warning Letters should be considered for significant deviations 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 (See CFSAN section): http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/Enforcement/ucm023598.htm

E. Detention without Physical Examination

Foreign processors may be subject to detention without physical examination if deviations noted during foreign inspections or records reviews by CFSAN are not corrected. Requests for release of detained shipments or removal from the import alert should be forwarded to CFSAN for concurrence. Applicants should provide evidence, in English, showing that the deficiencies noted have been corrected and monitoring records demonstrating that the changes to the plan have been implemented.

F. 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 at: http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176710.htm.

Be advised that as of May 20, 2011, changes in the procedures for the streamlined seizure and injunction process have been incorporated into Chapters 6 and 10 of the RPM. While we are working on updating the HTML versions of these Chapters, please refer to the current PDF versions available in the list of the site above.

The revisions in the RPM include early conversation (Preliminary Assessment Calls, i.e., PAC) and collaboration with CFSAN's Division of Enforcement, Division of Seafood Safety, DCMO and OCC is now included as part of the case development on all potential seizure and/or injunction situations. The Center and ORA have a robust enforcement program in seafood HACCP. Examples of filed Complaints for seizures under this compliance program have been posted by CFSAN's Office of Compliance at http://intranet.cfsan.fda.gov/OC/pages/seaseize.htm. This site includes examples of the filed Complaint for Injunction and their resulting, corresponding Consent Decrees or Order and in the case of litigation, includes the posted federal court opinions.

Prosecution: Suspected criminal violations, such as falsification of HACCP or sanitation monitoring records must be discussed with CFSAN,

Division of Enforcement, Domestic and foreign Compliance Branch and with the Office of Criminal Investigations.

H. Species Misbranding

Species misbranding is in violation of the Act [21 U.S.C. 343(b)]. Regulatory recommendations regarding a firm with the above deviation must be submitted to the Division of Enforcement/ via electronic copy (e.g., doc, pdf, etc.) via the "Mission Accomplishment and Regulatory Compliance Services-Compliance Management Services" (MARCS-CMS) link located on Inside FDA's IT Application Page under ORA Applications as a warning label with the misbranding charge. The District should also contact Latasha Robinson of the Labeling Compliance Team/Division of Enforcement at Latasha.Robinson@fda.hhs.gov, (240) 402-1890.

Specimen charge:

The article is misbranded within the meaning of Section 403(b) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 343(b)] in that it is offered for sale under the name of another food.

For violations discovered as Domestic-Import samples:

Species misbranding that is linked to products of foreign origin may warrant detention without physical examination of future shipments from the implicated foreign supplier. The collecting District should submit a case via CMS to DIOP (HFC-172) for DWPE consideration. DIOP and CFSAN will confer on DWPE recommendations.

F. 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	240-402-1424
Denise Beuttenmuller	240-402-2439

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.

G. 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 and located on-line at http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119201.htm.

DECOMPOSITION	Sec. 540.525	Decomposition and Histamine - Raw, Frozen Tuna and Mahi Mahi; Canned Tuna; and Related Species (7108.240)
	Sec. 540.370	Fish and Fishery Products – Decomposition
FILTH	Sec. 540.590	Fish - Fresh and Frozen, as Listed - Adulteration by Parasites (7108.06)
	Sec. 555.425	Foods – Adulteration Involving Hard or Sharp Foreign Objects
	Sec. 555.450	Foods – Adulteration Involving Infestation and 1080 Rodenticide (7120.02)
	Sec 555.500	All Food Sanitation (Including Bacteriological) Inspections – Classification of Establishments (7120.24)
	Sec. 555.600	Filth from Insects, Rodents, and Other Pests in Foods
	Sec. 555.650	Interpretation of Insect Filth in Foods (7120.18)
	Sec. 580.100	Food Storage & Warehousing – Adulteration – Filth (Domestic and Import) (7103.01
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 foreign and Import NLEA, Nutrient Sample Analysis, and General Food Labeling Program (7321.005).*	

	Sec. 540.150	Caviar, Use of Term – Labeling (7108.01)
	Sec. 540.475	Snapper – Labeling (7108.21)
	Sec. 540.700	Processed and/or Blended Seafood Products (7108.16)
	Sec. 540.750	Common or Usual Names for Seafood in Interstate Commerce (7108.26)
FOOD ECONOMICS	Sec. 540.285	Crabmeat Products – Labeling; Crabmeat Products with Added Fish or Other Seafood Ingredients – Labeling (7108.03)
	Sec. 540.390	Canned Shrimp – Labeling, Size Designations and Corresponding Counts (7108.13)
	Sec. 540.410	Shrimp – Frozen, Raw, Breaded or Lightly Breaded, Misbranding Involving Non-Compliance with Standards (7108.12)
	Sec. 540.450	Imitation Breaded Shrimp (7108.14)

Seek CFSAN concurrence prior to devoting resources to food economics issues.

MICROBIOLOGY	Sec. 555.300	Food Products, Except Dairy Products -Adulteration with Salmonella (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)

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/Product Adulteration Branch, HFS-606 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. Contact Clarke Beaudry, CFSAN/OFS/DSS, at 240-402-2503 to determine where to send them.

NOTE: REGULATORY ACTION WILL NOT BE CONSIDERED FOR PARASITES FOUND IN "FISH IN THE ROUND" OR FOR "DRIED FISH".

NOTE: THERE IS NO TOLERANCE FOR LIVE (ACTIVELY MOVING) WORMS IN RTE PRODUCTS WITH A PARASITE HAZARD

PART VI - ATTACHMENTS, REFERENCES AND PROGRAM CONTACTS

1. ATTACHMENTS – Tables A-1 and A-2, Sampling Guide

2. REFERENCES

Conducting Seafood Inspections Training Manual

Fish and Fishery Products Hazards & Controls Guidance (HCG) - Recommended hazards and controls in seafood processing; Fourth Edition, April 2011 http://www.fda.gov/food/guidanceregulation/ucm2018426.htm

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

21 CFR Parts 123 and 1240, Federal Register/Vol. 60, No. 242/Monday, December 18, 1995
http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm2006751.htm

21 CFR Part 110, Good Manufacturing Practices
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=110

Seafood HACCP Alliance Course, Sanitation Control Procedures Manual
http://nsgl.gso.uri.edu/flsgp/flsgpe00001/flsgpe00001index.html

Investigations Operations Manual
http://www.fda.gov/ICECI/Inspections/IOM/default.htm

Regulatory Procedures Manual
http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/RPMMasterList/default.htm

Compliance Policy Guidance for FDA Staff

HACCP Regulation for Fish and Fishery Products – Questions and Answers
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm176892.htm

Environmental Sampling for the Detection of *Listeria monocytogenes*
http://inside.fda.gov:9003/downloads/ProgramsInitiatives/FieldOperations/FieldGuidance/ucm022967.pdf

Environmental Sampling for the Detection of Salmonella
http://inside.fda.gov:9003/downloads/ProgramsInitiatives/FieldOperations/FieldGuidance/ucm022966.pdf

Supplemental Inspection Instructions
http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/Seafood/UCM045647.pdf

Seafood Inspection and EIR Template Tool for FDA Investigators
http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/Seafood/UCM198715.pdf

The Seafood List – FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce
http://www.fda.gov/food/guidanceregulation/ucm113260.htm

Refusal of Inspection
http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm071329.htm

3. PROGRAM CONTACTS

General Program Questions:	Emmanuel Kerry, CFSAN, Office of Compliance, Division of Field Programs and Guidance, Programs Branch, HFS-615, 240-402-3036, FAX (301) 436-2657.
General Investigational Questions:	Chyla Hunter, ORA, ORO Division of Domestic Field Investigations, HFC-130, 301-796-5473
CFSAN Division of Enforcement:	CFSAN/Office of Compliance/Division of Enforcement, HFS-607, Mildred Benjamin at 240-402-1424
Scientific, Technical and Seafood HACCP Policy Questions (Including sample collection):	CFSAN, Office of Food Safety, Division of Seafood Safety, Seafood Processing Technical Policy Branch, (240) 402-2300
General Analytical/ Laboratory Questions:	ORA, ORO, Division of Field Sciences, HFC-141,301/ 827-7605, 7606

Decomposition, organoleptic & chemical	Changyu (Jake) Chae
Filth/Decomposition	----------
Food/Color Additives	Changyu (Jake) Chae
Food Economics, standards, Labeling	Selen Stromgren
Microbiological - Including tests for preservation	Yuelin Shen
Micro analytical (filth,mold, foreign objects)	----------
Seafood toxins (Natural Toxins)	Selen Stromgren
Nutrient Analysis	Changyu (Jake) Chae

CFSAN Analytical Questions

Color Additives Analysis	Office of Cosmetics and Colors, Division of Cosmetics and Color, Division of Cosmetics and Compliance, Bhakti Petigara, HFS-125, 240-402-1025, ext. 1025
Decomposition Analysis	Steve Plakas, Office of Food Science, Division of Seafood Safety, Gulf Coast Sea Laboratory, Dauphin Island (HFS-325), 251-690-2319 ,

Filth Analysis:	Office of Regulatory Science, /Division of Analytical Chemistry, Microanalytical Branch, HFS-315, George Ziobro at 240-402-1965
Food Additives Analysis	Office of Regulatory Science, /Division of Analytical Chemistry, Gregory Diachenko, HFS-705, 240-402-1898
Microbiological analysis	CFSAN, Office of Regulatory Science/ Division of Microbiology, Direct general questions to the Division Director - , specialized questions go to the following at HFS-516

General	Keith Lampel	240-402-2007
E. coli	Peter Feng	(240) 402-1650
Listeria	Anthony D. Hitchins	
Salmonella	Wallace H. Andrews	
Staphylococcus	Reginald W. Bennett	(240) 402-2009
Clostridium	Mary Losikoff	240-402-1412

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

Natural Toxins

PSP
Office of Regulatory Science, Division of Analytical Chemistry, Spectroscopy and Mass Spectrometry Branch, Stacey DeGrasse, HFS-707, 240-402-1470

ASP
Office of Regulatory Science, Division of Analytical Chemistry, Spectroscopy and Mass Spectrometry Branch, Stacey DeGrasse, HFS-707, 240-402-1470, or, Office of Food Safety, Division of Seafood Science and Technology, Chemical Hazards Branch, Steven Plakas, HFS-400, 251-690-3403, or, Alison Robertson, 251-690-3224.

DSP
Office of Regulatory Science, Division of Analytical Chemistry, Spectroscopy and Mass Spectrometry Branch, Jonathan Deeds, HFS-707, 240-402-1474, or, Office of Food Safety, Division of Seafood Science and Technology, Chemical Hazards Branch, Steven Plakas, HFS-400, 251-690-3403, or, Alison Robertson, 251-690-3224.

AZP
(Appropriate GCSL contact)

NSP
Office of Food Safety, Division of Seafood Science and Technology, Chemical Hazards Branch, Steven Plakas, HFS-400, 251-690-3403, or, Ann Abraham, 251-690-3083.

CTX
Office of Food Safety, Division of Seafood Science and Technology, Chemical Hazards Branch, Steven Plakas, HFS-400, 251-690-3403, or, Alison Robertson, 251-690-3224.

TTX
Office of Regulatory Science, Division of Analytical Chemistry, Spectroscopy and Mass Spectrometry Branch, Jonathan Deeds, HFS-707, 240-402-1474

Parasite Analysis — Office of Food Safety, Division of Seafood Safety, Clarke Beaudry, HFS-325, 240-402-2503

Species Substitution — Office of Food Safety, Division of Seafood Safety, Seafood Processing and Technology Policy Branch, Spring Randolph, HFS-325, 240-402-1421, or, Office of Regulatory Science, Division of Analytical Chemistry, Spectroscopy and Mass Spectrometry Branch, Jonathan Deeds, HFS-707, 240-402-1474

Scallops – with added water or hydroscopic chemicals - Office of Food Safety, Division of Seafood Safety, HFS 325, Dale Wohlers at 240-402-2032, or, Patti Ross at 240-402-1587

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.

Table A-1: Sampling Schedules for the Seafood Processors 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 (4.5.3.5.1) shipping instructions for frozen samples and IOM 4.5.3.6 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. Duplicate sample portions are required under 702(b) of the Act UNLESS exempted by CFR 21 Part 2.10 (high cost, sample collected from person named on label who is also the owner, etc.). The samples quantities listed below do not include the duplicate samples.
5. It is important that all collections for Microbiological Analysis be made aseptically (with the exception of molluscan shellfish). 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. Subsamples should generally be collected randomly (IOM. 4.3.7.2) to give the broadest representation of the product within the lot. When a lot contains multiple product codes or daycodes, a sample should include subsamples from multiple codes.

   When the collector has an indication or information that potentially violative products are more likely to be isolated within a particular portion of the lot and the intent of the sample collection is to verify the presence of adulteration, then a less randomized representation may be acceptable under those circumstances. In these situations, the collection record should indicate the collector’s observations, in addition to the sampling method.

   For decomposition: If a collector encounters a situation where it is necessary to collect samples from multiple lots of products (e.g. A warehouse containing lots based on market form, size, species, etc.), generally, individual samples should be selected based on historical susceptibility to decomposition or other applicable knowledge.

Table A-1: Sampling Schedules for the Seafood Processors Inspection Program General Information for Sampling:
6. For Filth/Decomposition: Collect raw material, in-line and finished product samples, if contaminated raw materials are believed to be used or conditions warrant; 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 a 402(a)(4) charge with documentation of the use of these contaminated raw materials in the manufacture of a specific lot or lots of finished product.
7. For Decomposition: In instances where re-sampling additional samples or audit samples are warranted for sensory evaluation, the samples should be directed to a servicing lab with a National Expert in seafood sensory evaluations. If the initial official sample was done at a lab with a National Expert, the additional or audit sample should be directed to a servicing lab with another National Expert in seafood sensory evaluations or, if there is no other available, to a lab designated by a qualified National Expert in seafood sensory evaluations.
8. For Decomposition: Processed products include cooked, canned/pouched, and/or treated with chemicals or additives, including such things as salt, acid, chlorine, smoke, and carbon monoxide. Product treated with sulfites or phosphates may be considered raw unless the compounds are used in excessive levels that could mask decomposition. Dried products and sauce/paste products should not routinely be sampled for decomposition.
9. Special instructions for sampling scombrotoxin-forming species: For refrigerated products (e. g. with ice, gel ice, or refrigeration), if inadequate chilling is suspected, the temperature of the fish (both subsurface and internal temperatures) should be measured. If any product tested shows temperatures over 40 F, a sample from the lot should be collected for organoleptic and histamine analysis. For larger fish, samples should be obtained from the lower anterior portion behind the gills and pectoral fins and above the belly cavity. For smaller fish, multiple fish totaling approximately 1 lb. in weight should be collected for each subsample.
10. For *Listeria monocytogenes*: Do not request analysis on raw products that are not considered ready-to-eat unless there is reason to believe that the product ***will*** be consumed raw and provide an explanation in the "remarks" section describing how this determination was made.
11. For Natural Toxin CFP: Samples should only be collected in response to an illness/ outbreaks. Unused portions of the fish or meal implicated in the illness fish should have the highest priority for sampling and should be discussed with the contacts from DI as to when and how the samples are submitted.

Table A-1: Sampling Schedules for the Seafood Processors Inspection Program
General Information for Sampling:

12. For Decomposition:

In those cases where extremely large fish or frozen fish blocks (greater than 10 pounds) are encountered and the sample cost incurred would be prohibitive:

- **FRESH** (very large fish), each subsample should consist of a minimum of 454 grams (1 lb.) transverse portion cut from the backbone to belly (do not include the belly flap) from the lower anterior end of one side of the fish.

- **FROZEN (**very large fish or large frozen blocks):

  o If a properly trained seafood sensory field investigator or a qualified seafood sensory analyst accompanies the investigator during sampling, up to 18 scombrotoxin-forming fish or fish blocks, or up to 12 non-scombrotoxin-forming fish or fish blocks, may be examined by using the drill method. Collect a minimum of 4 decomposed fish or fish blocks, including any suspected decomposed units, for laboratory examination.

  or

  o If there is no properly trained sensory staff to make an initial field decision or if the state of decomposition is not certain, randomly collect a minimum of 6 subs (large fish or blocks.) Using this approach, the labs should examine a minimum of 5 pounds of the fish in each block while making a sub-by-sub (block-by-block) evaluation.

  or

  o Use a core or plug method to obtain a minimum of 454 grams of flesh per subsample from the lower anterior portion of the fish as described for the transverse section. (Sometimes the owner of the goods can cut out the desired samples from the fish or fish blocks using a band saw or other tool if aseptic technique is not required for the sample.) Collect 18 subsamples of scombrotoxin-forming products or 12 subsamples of non-scombrotoxin-forming fish products for laboratory evaluation.

For very small seafood items, collect multiple items or retail packages to total $\geq$ 454 grams of edible portion per subsample unless otherwise indicated in the schedule.

Table A-1: Sampling Schedules for the Seafood Processors Inspection Program
General Information for Sampling:

13. Prior to collecting samples for Project Area 04 - CHEMICAL CONTAMINANTS, please refer to the Compliance Program Pesticides and Industrial Chemicals in Domestic and foreign 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.

14. **Limited resources are available for Food Economics issues. CFSAN's current priorities focus on food safety. Districts should follow-up on consumer or industry reports of economic fraud; however, general surveillance activities should receive CFSAN concurrence prior to expending District resources.** CFSAN may periodically issue special assignments to address food economics issues.

- Due to the possibility of species mixtures, species identification analysis does not utilize composite sampling. One sample should be collected per lot. Each sample should be comprised of 8 subsamples, preferably 2 subsamples each from 4 randomly selected containers. A subsample is defined as one fillet, steak, or retail package. In the event that the subsample is >1 lb, a 1 lb portion should be taken, where possible. If subsamples are fillets, steaks, or a portion of a retail package, each subsample should be bagged and labeled individually. Label subsamples from each container as 1-4, etc. Label individual fillets from each container as A and B, etc. An ideal sample will be comprised of a 1A, 1B, 2A, 2B, 3A, 3B, 4A, 4B subsample – each bagged and labeled individually. For domestic sampling, the B subsamples can be used as the reserve (702b) samples with only the A portions being analyzed. For import sampling, both the A and the B subsamples can be analyzed. Subsamples should be packaged and labeled for shipment following normal procedures per IOM 4.5. Samples should be frozen until analysis. Ship all samples via overnight delivery to your District's designated laboratory.

- 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.

Table A-1: Sampling Schedules for the Seafood Processors Inspection Program
General Information for Sampling:

10. Intentionally left blank.

11. Sample handling for Molluscan Shellfish - Clams, Mussels, Oysters, Scallops sampled for natural toxin analysis do not need to be collected aseptically.

- In-shell Molluscan Shellfish - Samples of shellfish (12 or more) 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 (12 or more, 100 g). 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 (12 or more, 100 g), 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.
- Special Sampling for Scallops – If scallop adductor only is to be consumed, testing for natural toxins is not needed. If scallops will be sold as roe-on, the gonads must be analyzed (according to sample handling above). If whole scallops will be sold, the gonads and viscera must be analyzed (according to sample handling above).

Table A-1: Sampling Schedules for the Seafood Processors Inspection Program
General Information for Sampling:

18. 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 A-2: Sampling Schedules Domestic and Foreign Fish and Fishery Products Inspection Program

Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842
FINFISH:					
Non-scombrotoxin species, raw - Fresh or Frozen Whole, fillets, portions		15 subs - Minimum of 200g (7 oz.) per sub **OR** If ea. portion is <200g (7 oz), collect enough portions so 1 sub = 200 g (7 oz) per sub Block frozen fillets or portions - Collect 2 blocks. Do not collect fish in round for parasite analysis	12 subsamples - Minimum of [illegible]	General Micro other than *Salmonella*: 10 subs – minimum of 227g (8oz.) per sub. *Salmonella*: 15 subs – Minimum of 114g (4oz.) per sub	Refer to Table #3-1, Chapter 6 in FFPHCG. PSP - 3 subs per sample; 227 grams (8 oz) edible meat per sub
Non-scombrotoxin-forming species Processed products other than LACF/AF	6 subs – Minimum of 900 g -> 1.36 kg (2-3 lb.) per sub		12 subsamples - Minimum of 454 grams (1 lb) per sub Dried products and sauce/paste products should not routinely be sampled for decomposition.	General Micro other than *Salmonella*: 10 subs – minimum of 227g (8oz.) per sub. *Salmonella*: 15 subs – Minimum of 114g (4oz.) per sub	Refer to Table #3-1, Chapter 6 in FFPHCG. PSP - 3 subs per sample; 227 grams (8 oz) meat per sub

TABLE A-2: Sampling Schedules Domestic and Foreign Fish and Fishery Products Inspection Program

Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842
Non-scombrotoxin species other than salmon, LACF/AF	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 subsamples (cans or pouches) If analyses to include decomposition, filth, standards and industrial chemicals, collect 120 cans.		
Scombrotoxin-forming fish, LACF/AF (including canned tuna) (see Table #3-2 in the FFPHCG)	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		Tuna: 24 subsamples - Minimum of 170 grams (6 ounces) per sub; if the units are less than 6 ounces each, collect multiple cans/pouches per sub Non-tuna: 24 sub samples (cans or pouches) 18 subsamples when containers weigh more than 907 grams (2 lbs)		ASP – Unevisceratedanchovies - 3 subs/sample. Min. 227g (8 oz)/sub edible and min. 25 g viscera

TABLE A-2: Sampling Schedules Domestic and Foreign Fish and Fishery Products Inspection Program

Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842
Scombrotoxin-forming fish, processed products other than LACF (see Table #3-2 in the FFPHCG)	6 subs – Minimum 900 g -> 1.36 kg (2-3 lb.) per sub	-	24 subsamples - Minimum of 454 grams (1 lb) per sub Dried products and paste products should not routinely be sampled for decomposition Fish sauce should only be sampled for histamine and should not routinely be sampled for decomposition	General Micro other than *Salmonella*: 10 subs – minimum of 227g (8oz.) per sub. *Salmonella*: 15 – 114g (4oz.) subs from same lot	ASP – Uneviscerated dried anchovies - 3 subs/sample. Min. 227g (8 oz)/sub edible and min. 25 g viscera in duplicate.
Scombrotoxin-forming fish – Fresh & Frozen Whole, fillets, loins, portions, etc. (see Table #3-2 in the FFPHCG)		15 subs - Minimum of 200g (7 oz.) per sub If ea. piece.< 200g (7 oz)., collect enough so 1 sub=200 g (7 oz).	18 subsamples - Minimum of 454 g (1 lb) per sub	Do not test raw seafood products that are not considered ready-to-eat for *Listeria monocytogenes.* All micro other than *Salmonella*: 10 individual fish, min 227g (8oz.) ea *Salmonella*: 15 – 114g (4oz.) subs from same lot	Refer to Table #3-1, in FFPHCG. If the listed hazard is PSP, 3 subs per sample, each sub must be 227 g (8 oz.) **plus** 25 g viscera in duplicate.

TABLE A-2: Sampling Schedules Domestic and Foreign Fish and Fishery Products Inspection Program

Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842
Smoked or salted seafood	6 subs – Minimum 900 g -> 1.36 kg (2-3 lb.) per sub	Fillets, steaks, loins, chunks 15 subs - 200g (7 oz.) per sub, glaze, etc. If ea. piece, < 200g (7 oz)., collect enough so 1 sub=200 g (7 oz).		General Micro other than *Salmonella*: Collect 10 subs from 1 lot. , 454g (1 lb.) each Collect 10 additional. 454 g (1 lb) subs for *C. Botulinum*, unless original sub is greater than 900 g (2 lb) *Salmonella*: 30 subs - Minimum of 114g (4oz) per sub	
Smoked or Salted seafood in ROP(reduced oxygen packaging) e.g., sealed containers, heat sealed containers	6 subs – Minimum 900 g -> 1.36 kg (2-3 lb.) per sub			For water phase salt determination & nitrites collect 10 subs, each 454 g (1 lb)	

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Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842
CRUSTACEAN					
Crab or crabmeat, cooked or pasteurized	Collect 10 - 227g (8 oz) subs		18 subs, 227 grams (8 oz) ea	General Micro other than *Salmonella*: 10 subs – minimum of 227g (8oz.) per sub. If smallest size container > than 5 lbs, collect 3 containers *Salmonella*: 30 subs - Minimum of 114g (4oz) per sub *E. coli*, 6 -227g (8oz.) from same lot.	Collect whole cooked with viscera intact Collect 3 subs, min. 227g (8oz.) edible portion and 25 g viscera per sub If collected for ASP and PSP, double subsample size.
Crabmeat, LACF	Collect 6 cans min., representative of lot		18 subs, 227 grams (8 oz) ea		Collect 3 subs, min. 227g (8oz.) edible portion per sub If collected for ASP and PSP, double subsample size.

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Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842
Whole crab, raw			12 subsamples - Minimum of 454 grams (1 lb) per sub	*Salmonella*: 15 – 114g (4oz.) subs. *E. coli*, 6 -227g (8oz.) from same lot.	Collect whole raw crabs with viscera intact. Collect 3 subs, min. 227g (8oz.) edible portion and 25 g viscera If collected for ASP and PSP, double subsample size.
Cooked - Lobster and lobster meat,	6 subs – Minimum 900 g -> 1.36 kg (2-3 lb.) per sub		18 subs - Minimum of 454 grams (1 lb.) per sub	General Micro other than *Salmonella*: 10 subs – Minimum of 227g (8oz.) per sub *Salmonella*: 30 subs - Minimum of 114g (4oz) per sub	Collect 3 subs, min. 227g (8oz.) edible portion and 25 g viscera per sub
Raw - Lobster and lobster meat	6 subs – Minimum 900 g -> 1.36 kg (2-3 lb.) per sub		12 subs - Minimum of 454 grams (1 lb.) per sub	Raw - *Salmonella*: 15 subs – Minimum of 114g (4oz.) per sub	Collect 3 subs, min. 227g (8oz.) edible portion and 25 g viscera per sub
Cooked - Shrimp	6 subs – Minimum of 900 g -> 1.36 kg (2-3 lb.) per sub		18 subs - Minimum of 454 grams (1 lb.) per sub	General Micro other than *Salmonella*: 10 subs – Minimum of 227g (8oz.) per sub *Salmonella*: 30 subs - Minimum of 114g (4oz) per sub	

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Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842
Raw - Shrimp	6 subs – Minimum of 900 g -> 1.36 kg (2-3 lb.) per sub		12 subsamples. Minimum of 454 grams (1 lb.) per sub	*Salmonella*: 15 subs – Minimum of 114g (4oz) per sub	
Shrimp Canned	48 cans/case; <□□□□□□□□□□□□ >200 cs,96 cans Collect several codes in lot, rep. ea code by min. 16 cans, sample enough codes to give # above.		18 subsamples		
Shrimp, Raw Breaded.	6 subs – Minimum of 900 g -> 1.36 kg (2-3 lb.) per sub		18 subs - Minimum of 454 grams (1 lb) per sub	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]	

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Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842
Shrimp, Freeze dried Shrimp, Dried (sun, air)	Freeze dried: 6 subs - Minimum of 250g (10 oz.) per sub Sun dried: 6 subs – Minimum of 680 g (24 oz.) per sub		Do not routinely sample for decomposition. If unusual circumstances seem to dictate the need to collect dried shrimp for decomposition, contact CFSAN	General Micro other than *Salmonella*: 10 subs - Minimum of 227g (8 oz) per sub *Salmonella*: 30 subs – Minimum of 114g (4 oz.) per sub	
Other Crustacean Products	6 subs – Minimum 900 g -> 1.36 kg (2-3 lb.) per sub		Fresh or Frozen Raw: 12 subs - Minimum of 454 grams (1 lb) per sub Processed: 18 subsamples - Minimum of 454 grams (1 lb) per sub	General Micro other than *Salmonella:* 10 subs – Minimum of 227g (8oz.)per sub *Salmonella* Cooked: 30 subs – Minimum of 114g (4oz) per sub Raw: 15 subs – Minimum of 114 g (4 oz) per sub	

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Seafood	Filth: Macro/ Microscopic 03842B	Filth: Parasites 03842B	Decomposition 03842C	Microbiological 03842D	Natural Toxins 07842
MOLLUSCAN SHELLFISH					
Abalone, Canned			18 cans		
Molluscan Certified: Oysters, clams, mussels, Whole, roe-on-scallops	6 - 114g (4 oz) subs shucked product only,		Raw Fresh or Raw Frozen: 12 subs - Minimum of 454 grams (1 lb) per sub Processed: 18 subsamples. Minimum of 454 grams (1 lb) pet sub Canned: 18 cans	Med. Large in-shell (pacific oysters, surf and hard clams: 5 subs, 12 each, or enough to = 300 g meat and liquid per sub	When collecting samples for multiple toxin testing, collect separate samples for each toxin test. Raw Shucked Fresh or Frozen: Collect 12 subs/sample, 100 grams per sub
Collect aseptically: 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.				Small (olympias, *ostrea lurdia*, little neck clams, mussels): 20 subs – Minimum of 300g (11 oz). meat & liquid per sub Shucked: 5 subs - enough to give 300 g meat and liquid per sub. Shucked product should be kept in same state as it is collected, i.e., either refrigerated or frozen. Blocks: Core or quarter.	Unshucked Shellfish: 12 or more

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Scallops Whole Shucked	Scallops, shucked: 6 subs – Minimum of 227g (8 oz) per sub		Raw Fresh or Raw Frozen: 12 subs - Minimum of 454 grams (1 lb) per sub Processed: 18 subsamples. Minimum of 454 grams (1 lb) per sub Canned: 18 cans	General Micro other than *Salmonella:* 10 subs – Minimum of 227g (8oz.)per sub *Salmonella* Cooked: 30 subs – Minimum of 114g (4oz)per sub Raw: 15 subs – Minimum of 114 g (4 oz) per sub	This work can only be done on whole or roe-on scallops - collect 12 subs - Minimum of 100 grams shucked or whole scallops plus 25 g viscera
OTHER SEAFOOD:					
Squid Surimi analogs Seafood Salads Stuffed Seafood Soups/Chowders Other Seafood Products that do not fit a specific category	6 subs – Minimum of 900 g -> 1.36 kg (2-3 lb.) per sub		Raw Fresh or Raw Frozen: 12 subs - Minimum of 454 grams (1 lb) per sub Processed: 18 subs - Minimum of 454 grams (1 lb) per sub (If canned/retorted, 18 cans/pouches Dried products and sauce/paste products should not routinely be sampled for decomposition.	Micro other than *Salmonella*: 10 subs - Minimum of 227 g (8oz.) per sub *Salmonella* for cooked or RTE: 30 subs – Minimum of 114 grams (4 ounce)per sub *Salmonella* for Raw or non-RTE : 15 subs - – Minimum of 114 gram (4 ounce) per sub	