CHAPTER 03- FOODBORNE HAZARDS

SUBJECT	**SEAFOOD PROCESSOR, PRODUCTS, AND IMPORTER INSPECTION PROGRAM**
IMPLEMENTATION DATE	Upon Receipt

DATA REPORTING

PRODUCT CODES	**NOTE: CP 7303.842 (Seafood Processor Inspection Program) and CP 7303.844 (Imported Seafood Inspection Program) have been combined into a single compliance program – CP 7303.842, Seafood Processor and Products Inspection Program. PAC codes for sampling and analysis will still reflect whether the product is imported or domestic.** INDUSTRY CODE 16, USE APPLICABLE CLASS, SUBCLASS, PIC, AND GROUP PRODUCT CODES For commodities/analyses covered by other CPs, please refer to the applicable CP for appropriate PAC. See Part II for a list of other programs that interact with CP 7303.842. These programs include: Pesticides & Chemicals General Food Labeling AF/LACF Chemotherapeutics Toxic Elements Dietary Supplements

PRODUCT/ASSIGNMENT CODES

REPORT COLLECTIONS AND ANALYSIS USING

IMPORT Code	DOMESTIC Code	Description
03844A	03842A	Chemical Test Decomp (Indole, histamines)
03844B	03842B	Filth
03844C	03842C	Decomposition,Scombrotoxin (histamine)
03844D	03842D	Microbiological (includes % water phase salt (wps), pH, water activity used as microbiological safety control)
Importer HACCP Activity	03842H	HACCP Verification (i.e., verification of adequacy of HACCP plan critical limits)
04844A	04842A	Chemical Contamination
07844	07842	Natural toxins (e.g., ASP, DSP, NSP, AZP, CFP, TTX, and PSP)
09844E	09842E	Color Additives
09844F	09842F	Food Additives
021844	021842	Economically motivated adulteration/Misbranding
21R829	21R829	Nutritional Health Fraud
21005	21005	FPLA

REPORT INSPECTIONS under the following PACs
Report both FDA and State Partnership work under PACs 03842 and 03842H

Code	Description
03842	Documentary samples or seafood inspection activities that are not part of the HACCP assessment.
03842H	Processor HACCP Inspection
03844H	Importer HACCP Inspection
03040	PC training and training records requirements

The following are additional PAC codes for Reporting Purposes:

Code	Description
03R833	Entry Review
99R833	Filer Evaluation OP95
03R824	Follow-up to Refusals
04R824	
07R824	
09R824	

FIELD REPORTING REQUIREMENTS:

Laboratory Reporting

Report the following analytical results into the FACTS Data System:

Biotoxins (Natural Toxins)	Use PAF:	BIO
Color Additives	Use PAF:	COL
Decomposition, Scombrotoxin (histamine)	Use PAF:	DEC
Filth	Use PAF:	FIL
Food Additives	Use PAF:	FAD
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 and few other botulinum neurotoxin producing Clostridial species*	Use sub PAF	GCB
%) Water Phase Salt and Nitrite	Use sub-PAF	WPS-NTR
pH	Use sub-PAF	NAR
Water Activity (Aw)	Use sub-PAF	NAR
Parasites	Use PAF:	PAR
Pesticides	Use PAF:	PES

Economically Motivated Adulteration (or food fraud)

Note: Divisions should follow-up on consumer or industry reports of food fraud; however, general surveillance activities focusing on food fraud issues should receive CFSAN concurrence prior to expending Division resources. CFSAN may periodically issue special assignments to address food fraud issues.

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

Misbranding/Labeling	Use PAF:	FDL
Economics/Standards	Use PAF:	FDF
♦ Economic deception	Use sub-PAF:	FDE
♦ Standard of quality	Use sub-PAF:	FDQ
♦ Standard of identity	Use sub-PAF:	FDI

Inspection/Investigation Reporting

For ***processor or importer inspections*** that were ***classified*** as ***OAI*** and for which the Division is recommending action, submit via MARCS-CMS the scanned hard copy or electronic versions:

- EIR and FDA Form 483
- EIR endorsement - ensure that the computer-generated cover sheet is included

Report content is further described in Part III, Investigational.

Samples Supporting Regulatory Action

When making a submission in support of a detention or for a request for DWPE, submit the following as scanned hardcopy or electronic documents via MARCS-CMS

- Memorandum from the Compliance Officer;
- Product labels must be submitted – if product is in bulk, then photographs or tracings of container labeling must be submitted;
- For detained import samples - entry documents (CBP Form 3461 or 7501, Invoice, Packing slip, Bill of Lading);
- For domestic and domestic import samples – Invoice, Packing slip, Bill of Lading
- Laboratory analytical worksheets (if analytical results are used to support the recommendation, Collection report);
- E-mail communications;
- Other data that is pertinent for the review of the case (if available).

Special HACCP Reporting

This Compliance Program will utilize special HACCP reporting forms, **FDA 3501** (Processors) and **FDA 3502** (Importers)**.** Below the logon, there is a button: "User's Guide". Click on that button and go to page 2 and follow instructions to request User Account and to login. There are different links for creating forms for domestic and foreign establishment inspections. Contracted state inspectors can access their link for **FDA 3501** through ESAF.

A separate seafood HACCP inspection report is to be completed electronically for the HACCP portion of the inspection **for each product evaluated** during an U.S. importer or a domestic or foreign processor inspection, including both observed HACCP evaluations and technical reviews. FDA and contracted state inspectors should complete these forms based on their inspection observations.

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.

Please notice this special definition of **actively processing** 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 actively processing that product. A firm that is a manufacturer, repacker, or re-labeler, must be actively manufacturing, repacking, or relabeling the product listed in Block 9 during the inspection for

it to be classified as actively processing on the **FDA Form 3501**. If a manufacturer, repacker or re-labeler are only holding and storing the product during the inspection, it is not considered to be actively processing even though those activities are defined as "processing" under 123.3(k)
If there are problems using the electronic system, please contact
Rabia Begum, OFS, Division of Seafood Safety at (240) 402-1260.

Special Misbranding and Species Substitution Reporting

Evidence of misbranding should be included in the FDA 483 investigation observations and information documented in the Species Substitution Questionnaire.

Contents

PART I – BACKGROUND

This compliance program provides regulatory coverage of firms, both domestic and foreign, that import or process fish and fishery products to ensure a safe and wholesome domestic seafood supply. This program identifies the necessary training and skills field staff must possess to conduct inspections and provides instructions specific to the inspection of seafood importers, seafood processing facilities, and seafood products. The program also provides prioritizations of products, processes, and establishments for inspection and instructions for the collection and analysis of samples. The current Seafood Processor and Imported Seafood Inspection Program, CP 7303.842, is a combination of the previous compliance programs, the Seafood Processor Inspection Program (CP 7303.842) and the Imported Seafood Inspection Program (CP 7303.844).

FDA currently conducts inspections of both domestic and foreign seafood processors and seafood importers to determine compliance with 21 CFR Part 123, (Procedures for the Safe and Sanitary Processing of Fish and Fishery Products https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-123(referred to as the Seafood HACCP Regulation) and subparts A, B, and F of 21 CFR Part 117 (Current Good Manufacturing Practices, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods). This program addresses the control of the various food safety hazards identified in the seafood HACCP regulation as well as compliance with current Good Manufacturing Practices. These efforts continue under the present program and are important components of the import control strategy. Guidance intended to assist seafood processors in developing their HACCP plans is provided in FDA's "Fish and Fishery Products Hazards and Controls Guidance (the Seafood HACCP Guide or the Guide)."

CFSAN continues to integrate investigational activities for the inspection of importers and the inspection of foreign processors. Data gathered during domestic investigations of importers provide a valuable tool to help CFSAN allocate foreign inspection resources. The names and locations of foreign processors of high-risk products can be obtained during surveillance investigations of domestic importers, inspections of imported seafood, imported seafood data reviews, and direct requests to foreign processors. If foreign processor HACCP plans are available as part of the importer's affirmative steps or are obtained during other regulatory activities, foreign processors that do not appear to have adequate controls can be scheduled for upcoming foreign inspections. HACCP plans that appear inadequate collected during importer inspections should be submitted to CFSAN Division of Enforcement for follow-up.

Conversely, data gathered during foreign investigations of processors can help FDA identify importers that may be accepting product from foreign processors that may not be in compliance with the seafood HACCP regulation, identify specific industries and regions that require additional oversight, and provide insight into the reliability of third-party inspections and foreign certification programs.

PART II - IMPLEMENTATION

1. Objective

The primary objective of this compliance program is to ensure a safe and wholesome supply of fish and fishery products in the U.S. This is done through inspections of seafood importers and domestic and foreign seafood processors for compliance with the requirements of Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations. In addition, this compliance program provides the tools for making risk-based decisions when selecting products, processes, and importers for inspection and guidance on how other compliance programs may apply to a seafood processor or importer.

Program Management Instructions

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 PPS other than 03, unless a substantial amount of time is spent in other specific areas.

- ***Product Prioritization for Inspection by Risk***

  Table 1 prioritizes in descending order specific seafood commodities for inspection based on the hazards associated with the products and industry compliance with FDA requirements. These should be used as a guide when identifying the focus of a seafood HACCP inspection. Table 1 is not all inclusive and captures broad categories of market forms based on potential risk factors. Some products or processes may fall under multiple categories (e.g., Reduced Oxygen Packaged scombrotoxin-forming fish products) and the highest risk category should be the basis for their priority for inspection. Food safety staff should refer to Chapter 3 of the Seafood HACCP Guide to identify potential species and process related hazard for products that do not fall into the categories listed.

Table 1 - Product and Process Priority Ranking

Product or Process Type	Description	Risk
Manufacturers and Refrigerated Warehouses that process: Seafood products packed in Reduced Oxygen Packaging (ROP) Note: Seafood products that are subject to Part 113 or Part 114 are not included in this category.	ROP encompasses a large variety of packaging methods including vacuum packaging, modified atmosphere packaging, hermetically sealed containers (with or without the removal or manipulation of gases), heat sealed plastic or laminated packaging, and packing in oil. By reducing or preventing the exchange of normal ambient oxygen with the environment in the package, a processor introduces the hazard of *Clostridium botulinum*. Examples include seafood packed in cans, jars, lidded plastic containers with a heat-sealed inner liner, heat sealed plastic bags. The following seafood products are typically in ROP • Refrigerated acidified seafood products • Salted, brined, or pickled, seafood products • Hot or cold smoked fish	**HIGHER RISK POTENTIAL** The highest risk biological hazard of concern is ***Clostridium botulinum***. 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 may require multiple critical control points to be listed in HACCP plans to ensure a safe product. See Chapter 13 of the Seafood HACCP Guide and Import Alert 16-125
Manufacturers and Refrigerated Warehouses that process: Uneviscerated or partially eviscerated processed finfish (e.g., cooked, pickled, fermented, salted, dried, or partially dried) Note: Processors of fish larger than 5 inches should be considered for expedited regulatory action when these products or processes are encountered.	Examples include: Kapchunka, Kamchatka, alewives, bloaters, dried sardines, dried anchovies, smoked herring, Tuyo, bokkoms, Bombay duck, Chepa Shutki, fesikh	**HIGHER RISK POTENTIAL** The highest risk biological hazard of concern is ***C. botulinum***. Processing which reduces competing micro-organisms and/or provide potential anaerobic conditions in the gut cavity that increases the opportunity for the neurotoxic clostridial growth and toxin formation in processed un-eviscerated or partially eviscerated fish. Uneviscerated fish less than five inches in length (including nose

Product or Process Type	**Description**	**Risk**
Note: These **do not include** fresh or frozen raw uneviscerated whole fish in their natural state, or products filed under 21 CFR 108/113 or 114.		and tail) typically require several processing controls that are usually complex and require multiple critical control points listed in the HACCP plan to ensure a safe product. See Chapter 13 of the Seafood HACCP Guide and Import Alert 16-74.
Manufacturers and Refrigerated Warehouses that process: Raw molluscan shellfish or products that include raw molluscan shellfish that will not be cooked prior to consumption Note: FDA State contract inspections should not cover raw molluscan shellfish in States participating in the NSSP.	Examples include: • Fresh or frozen, shell-on or shucked clams, mussels, whole scallops, roe-on scallops, oysters) seafood mixes that could contain raw molluscan shellfish • Irradiated shellfish or shellfish that has undergone an HPP process • Raw shellfish in sauces	**HIGHER RISK POTENTIAL/****A significant number of illnesses with serious health consequences have been associated with the consumption of raw molluscan shellfish. Hazards for raw molluscan shellfish include ***Vibrio* **spp., *Salmonella*, *Hepatitis* A virus, norovirus and marine toxins**. See Chapters 4 and 6 of the Seafood HACCP Guide and Im
Manufacturers and refrigerated warehouses that process cooked RTE seafood products: Cooked, hot smoked, pasteurized Note: FDA considers seafood "cooked" and RTE if the fish flesh appears to be coagulated and it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards as stated in the definition of RTE in 21 CFR 117.3.	Examples include: • Heat treated seafood products (e.g., cooked, pasteurized, hot smoked, etc.) • Formulated fishery products that are cooked or contain cooked seafood (e.g., entrees, soups, chowders, salads, pastas, meals, spreads, surimi analogs, dips, sandwiches)	**HIGHER RISK POTENTIAL** Cooked RTE seafood is perceived to be "safer" by consumers and more likely to be consumed by at-risk populations. The highest risk biological hazard of concern is for pathogen survival from an inadequate cook and/or introduction of pathogens by cross-contamination after cooking. These processes typically require at least critical control points for heat treatment (e.g., cooking, pasteurization, or hot smoking) and refrigerated storage of finished product and strict sanitation controls to ensure a safe product.
Manufacturers and refrigerated warehouses that process raw RTE seafood:	Examples include: • Sushi, sashimi, nigiri, ground tuna, Hamachi, Poke, Saku,	**HIGHER RISK POTENTIAL** The hazards are introduced from both the harvest and processing environments. Inadequate

Product or Process Type	Description	Risk
• RTE raw seafood products that have not been cooked and are intended to be consumed without cooking • RTE seafood products that have undergone a process designed to retain raw characteristics (e.g., cold smoking, curing) NOTE: Seafood is considered raw when the flesh of the fish is not coagulated.	urchin roe, herring roe, caviar, salmon roe • Refrigerated pickled or acidified seafood • Cold smoked seafood • Anchovy fillets • Pastes, fish sauce	cooling allows further growth. Pathogens associated with raw seafood products include **hepatitis A virus**, ***Vibrio cholerae***, ***Vibrio spp.***, ***Salmonella***, ***L. monocytogenes***, **parasites**. Fishery products marketed for raw consumption are unlikely to undergo a heating process to eliminate pathogens and parasites. Therefore, strict time, temperature, and sanitation controls must be maintained throughout processing and distribution.
Manufacturers and refrigerated warehouses that process: Scombrotoxin (histamine)forming species	Table 3-2 in the Seafood HACCP Guidance identifies scombrotoxin (histamine) forming species	**HIGHER RISK POTENTIAL** **Scombrotoxin** (histamine) is a heat stable toxin that is not eliminated through thermal processing or acidification. Scombrotoxin poisoning causes a significant number of illnesses in the U.S. each year.
Manufacturers (excluding finished product storage warehouses) of: RTE and non-RTE dried fisheries products	Products include: • RTE dried seafood snacks, dried squid, dried shrimp, bonito flakes, tuna jerky • Dried seafood that is intended to be cooked prior to consumption such as stock fish, fish maws, shark fins, dried cod.	**HIGHER RISK POTENTIAL** The food safety hazards of concern include pathogen growth and toxin formation due to inadequate drying. Drying processes can be complex and require multiple HACCP critical control points and strict sanitation controls to ensure a safe product.
Primary processors of aquacultured seafood	Table 3-A in the Seafood HACCP Guidance will provide the species of concern.	**HIGHER RISK POTENTIAL** The food safety hazard of concern is the unapproved use of **aquaculture drugs**. Primary processors have the responsibility to assure that the fish they process have been handled safety on the farms.

Product or Process Type	Description	Risk
		An increased incidence for detection of unapproved drug residues is associated with imported aquacultured species.
Manufacturers and Refrigerated Warehouses that process: Non-RTE seafood that is intended to be cooked prior to consumption OR Seafood products associated with low regulatory priority hazards OR Seafood products that do not require a HACCP plan	Examples include: • Live seafood • Raw fish that is not sold or intended for raw consumption • Formulated seafood containing multiple ingredients that are traditionally cooked prior to consumption	**LOWER RISK POTENTIAL** The hazards associated with these products are either: Unlikely to present an imminent health hazard. OR Traditionally or commonly cooked by the consumer, eliminating the hazard(s) (e.g., the hazards of pathogens and parasites will be eliminated through cooking).
Frozen and Dry Storage Warehouses: Seafood products that are distributed either shelf-stable or frozen Note: Inspections of these warehouses would be reported under PAC 03842.	Examples include: • Seafood that is stored and distributed frozen • LACF or AF storage facilities • Storage facilities for seafood that is dried or requires no refrigeration	**LOWER RISK POTENTIAL** A HACCP plan is not normally needed in these establishments although sanitation requirements must still be met.

Allergens *are a food safety hazard that can be introduced through product formulation or cross-contact. These are associated with many seafood products. Multi-ingredient products or products where the allergenic ingredient will not be readily apparent to the consumer (e.g., soups, sauces, salads, meals) should be identified as a higher risk than single ingredient products (e.g., fillets, cooked lobsters, whole fish) where the allergen hazard is more easily recognizable.*

Natural marine toxins *are a species related hazard associated with many species processed under the product categories listed above. This hazard should be addressed during inspections of primary processors.*

Lower regulatory priority hazards *are unlikely to result in serious health consequences and where industry compliance with FDA's requirements is consistently good. These include metal fragments, glass fragments, environmental chemicals, and methyl mercury.*

- ***Inspection Prioritization for Establishments (Processor and Importer) by Risk***

  Table 2 is for work planning purposes and further builds upon the product risk ranking. The table provides prioritizations in **descending order** for inspection of processors (domestic and foreign) and importers based on their individual compliance history. The product priorities in Table 1 should be used to prioritize processors and importers by product risk within each category (Row). Priorities for foreign processor inspections may vary from domestic inspections. Foreign inspection priorities can also be influenced by country specific problems, importation data, and emerging issues.

  Note: The number of importer inspections is directed in the ORA workplan. Please perform 90% of the number of planned inspections in the ORA workplan on higher risk importers. The remaining 10% of the number of planned inspections should be made at importers that import less than 100 entry line items per year.

  Note: Frozen storage warehouses, dietary supplement processors, or other low inspection priority facilities that request inspections in order to be added to FDA's Approved List for foreign countries (e.g., European Union, China) or to meet destination country requirements must be inspected. Although not a higher priority, these inspections should be conducted as soon as possible.

  Note: Re-inspections of OAI firms should not be conducted until efforts by the firm to correct and address the significant problems have been completed.

Table 2 – Priorities for Establishment and Importer Inspections

Processors – Domestic and Foreign	**Importers**
Regulatory follow up inspections of **domestic and foreign** processors whose last inspection was classified OAI, are associated with an illness outbreak, received a warning letter, or based on environmental sampling results.	Regulatory follow up inspections of importers whose last inspection was classified OAI based on affirmative step inadequacies, who are associated with an illness outbreak, are associated with safety-related violative entries, or received a warning letter.
Regulatory follow up inspections of **foreign** processors that have been removed from the red list of an import alert, or added to the green list of an import alert	Regulatory follow up inspections of importers whose last inspection was classified VAI based on affirmative step.
Domestic and foreign processors that have never had an FDA or equivalent FDA-contracted State inspection.	Importers of higher risk products that have never had an FDA or that import an average 100 or more lines per year.
Domestic and foreign processors whose last inspection was classified VAI for HACCP violations.	Importers of higher risk products who import less than 100 lines per year
Domestic and foreign processors whose last inspection was classified NAI.	Importers of lower risk products.

- ***Interaction with Other Programs/Assignments***

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

  - Domestic Acidified and Low Acid Canned Foods, CP 7303.803A

    CP 7303.803A covers the food safety hazards associated with the control of *Clostridium botulinum* toxin through the thermal sterilization or acidification processes. Controls for these hazards are covered by 21 CFR part 113 Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF) and 21 CFR Part 114 Acidified Foods (AF) which are intended to control microorganisms of public health significance (*C. botulinum* and other microbiological hazards and not included in a seafood HACCP plan. This program covers HACCP controls addressing hazards that are not eliminated through thermal process or an acidified foods process.

    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 hazards and GMP conditions that are not specifically addressed in parts 113 and 114 are to be reported under this program CP 7303.842.

- Molluscan Shellfish Compliance Program, CP 7318.004

  The Molluscan Shellfish Compliance Program covers the evaluation of state, tribal and foreign shellfish programs and related technical assistance only and is primarily intended for use by Shellfish Specialists and those involved in making admissibility decisions of products covered by the compliance program. CP **7303.842** provides instructions to food safety staff (i.e., State inspectors in participating States) for conducting inspections of establishments and for the collection and analyzing of samples under the NSSP. State inspectors should follow and implement the requirements and guidance included in the Model Ordinance.

  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 at Interstate Certified Shellfish Shippers List (ICSSL) .

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

  NLEA evaluations will be conducted during routine inspections covered by the Seafood Processor Inspection Program, 7303.842. NLEA evaluations will be reported under the compliance program CP 7321.005.

  CP 7303.842 covers the HACCP controls that assure that accurate allergen declarations occur.

- 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. Sampling for pesticides and industry chemicals and regulatory follow up will be covered under CP 7304.004. HACCP controls, GMPs, and evaluations of the HACCP program will be covered under CP 7303.842.

- 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. Toxic elements, including lead, cadmium, and methylmercury have been found to accumulate in certain aquatic organisms. Selected species of finfish and shellfish are of particular interest to CFSAN at this time. Data on levels of these contaminants in bivalve mollusks, finfish and lobster are important for supporting FDA's position on proposed standards for foods in international trade. Sampling for toxic elements and radionuclides and regulatory follow up will be covered under CP 7304.019. HACCP controls, GMPs, and evaluations of the HACCP program will be covered under CP 7303.842.

- 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.

- Dietary Supplements – Import and Domestic, CP 7321.008

  Coverage will be conducted to determine compliance with Part 111 during routine inspections conducted under the Seafood Processor Inspection Program – Domestic and Foreign Facilities inspections of manufacturers of dietary supplements that meet the definition of a seafood processor. Coverage of Part 111 requirements will be reported under the compliance program CP 7321.005. CP 7303.842 covers HACCP controls addressing hazards that are not prevented or eliminated under Part 111 and will be addressed under this program.

- ***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 (FD 249). The inspections must be based on the Seafood HACCP regulation and FDA

recommendations as opposed to local state requirements. Divisions must ensure that state inspectors assigned to do contract HACCP inspections meet minimum training requirements, i.e., they have successfully completed a Seafood HACCP Alliance 3-day course or its equivalent and the Conducting Seafood Inspections Training Course including passing the course examination.

Inspectors conducting contract or partnership seafood HACCP inspections must also complete and submit form FDA 3501.

- ***National Marine Fisheries Services (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 when conducting both domestic and foreign establishment inspections and taking regulatory action.

PART III - INSPECTIONAL

1. **Operations**

Inspections must be conducted by trained food safety staff (either FDA or State) in accordance with the inspection components outlined in the Conducting Seafood Inspections Training Course and FDA's Investigations Operations Manual. Food safety staff who meet the training requirements for conducting seafood HACCP inspections will approach processor inspections following protocols defined in the Conducting Seafood Inspections training course (FD 249). Domestic and foreign seafood HACCP inspections are to be performed according to the instructions that follow, including the completion of a Form FDA 3501 or 3502.

Technical References

For scientific and technical HACCP questions that are not addressed in the Guide during and following inspection, contact the either a subject matter expert, National Expert or the CFSAN Seafood Processing Technology and Policy Branch at (240)402-2300.

For inspectional instructions and procedures, food safety staff are advised to refer to the following references:

- Conducting Seafood Inspections Training Manual – Seafood processors HACCP inspection procedures/activities
- Conducting Seafood Importer Verification Training Manual – Seafood importers inspection procedures/activities
- Fish and Fishery Products Hazards and Controls Guidance (the Seafood HACCP Guide)
- Sanitation Control Procedures for Processing Fish and Fishery Products
- Additional references listed in Part VI

Training Requirements

In addition to the basic training required for food safety staff to conduct establishment inspections, food safety staff performing seafood HACCP inspections must have successfully completed the following courses:

- For all seafood inspections, Seafood HACCP Alliance 3-day course or an equivalent course 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)
- For seafood processor and processor/importer inspections, "FD 249 - Conducting Seafood Inspections" Training Course for seafood HACCP inspections other than raw molluscan shellfish covered under the NSSP.

- For seafood importer inspections, "IM 239 – Conducting Seafood Importer Verification and FD249W200 Seafood HACCP Regulation" Training Courses for seafood HACCP inspections of importers of seafood who are not processors.

It is recommended that food safety staff performing seafood inspections also complete the Seafood HACCP Alliance Sanitation Control Procedures Course.

Processor Inspections

If an inspection is intended to cover a seafood processor where more than one compliance program applies, for example a canned tuna processor, food safety staff should conduct the inspection in accordance with the applicable programs. When limited time is available for a seafood processing facility, such as with a foreign inspection, food safety staff should focus on the seafood HACCP program (PAC 03842H) and conduct limited inspections under other applicable programs if time allows. When time allows, 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 and reporting should reflect this separation of focus and time.

- ***HACCP Program Evaluations***

  HACCP inspections should focus on the highest risk products processed by the firm and be conducted when the firm is known to be in production. Part II of this compliance program provides tools for the identification and selection of higher risk products and processes. In some situations, it may be necessary to consult the firm and determine their production schedule for the product of interest.

  It is important to remember that compliance with 21 CFR 123 is only one element of a seafood processor inspection. Seafood processors must comply with GMPs (subpart B of part 117) and other applicable sections (subparts A, Training, and F, Training records) of part 117. It is equally important to remember that the requirements for subparts C and G of part 117 cannot replace the requirements defined in part 123 for seafood processors. Seafood processors are legally obligated to meet the requirements of part 123 if they meet the definition of a seafood processor.

  During a HACCP inspection, it is important to conduct a walk-through of the facility and observe all steps of the process flow for the selected product, including any step where the product is diverted for rework or other processes. During the walk-through food safety staff should interview employees and observe operations at each process step and obtain information on processing operations, sanitation programs, employee practices, and the implementation of HACCP monitoring, verification, corrective action and sanitation monitoring procedures during production. It is important that the food safety staff be present at the firm to evaluate the entire operation from start-up to finish, including, as necessary, sanitation procedures and the implementation of sanitation monitoring. If it is not possible to watch cleaning procedures or monitoring of sanitation, food safety staff must at least interview employees performing the duties to determine if the procedures and monitoring are adequate. Food safety staff must review and evaluate the firm's written HACCP plan against

their own hazard analysis and the plan's implementation, including interviewing employees and reviewing records associated with that plan.

If the HACCP plan is not adequate or the firm does not have a written HACCP plan, food safety staff should determine if the firm has and is implementing controls to prevent the identified hazards from occurring.

Significant observations are those that will affect the overall integrity of the HACCP program or egregious insanitary conditions. Non-significant conditions and observations that are voluntarily corrected and verified should be included in the EIR as discussion items. Additional inspection instructions are outlined in FDA Supplemental Instructions.

If a question arises about the adequacy of the HACCP plan or implemented controls, the food safety staff is encouraged to seek advice from an SME, National Expert, or CFSAN expert.

Document significant seafood HACCP regulation and GMP deficiencies on the Form FDA 483 in a manner consistent with the Conducting Seafood Inspections Training Course instructions. GMP deficiencies directly related to product safety should be documented as HACCP sanitation monitoring deficiencies whereas non-safety related GMP deficiencies are documented as violations of Part 117, subpart B. As in the past, significant deficiencies will be noted on FDA Form 483 in addition to seafood HACCP deficiencies. Narrative EIRs should be completed as directed by the IOM and existing instructions. The Seafood Inspection and EIR Template Tool can provide insight into the contents of the EIR and the questions to be asked during an inspection. Consistent with such instructions, these narrative reports should describe the firm's HACCP control program, food safety staff observations, discussions with facility management, and verified voluntary corrective actions. Observations should be listed in the 483 and EIR in descending order based on regulatory significance.

In the event food safety staff arrive 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), the food safety staff should walk through the facility, interviewing employees and obtaining information on the processes and procedures and conduct a record review. The record review should include HACCP plan, monitoring, verification, corrective action and sanitation monitoring records. Although it isn't the best situation, the evaluation will still provide valuable information on the compliance of the firm. All deficiencies should still be listed on an FDA 483.

When an evaluation of a previously classified OAI/VAI HACCP inspection of a particular product cannot be accomplished during a re-inspection, the division 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.

- ***Special Instructions for Vessels***

  For logistical reasons, FDA acknowledges that it will be impractical for food safety staff to inspect most processing vessels when they are in operation (at sea). Inspections of these vessels will normally be performed when the vessel is in port and not in operation.

- ***Special Instructions for Economically Motivated Adulteration or Food Fraud***

  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.

  Food fraud in the form of species substitution and misbranding can introduce additional safety concerns. Some species of fish are associated with significant food safety hazards such as marine toxins, allergens, and scombrotoxin which require specific controls to prevent or eliminate the hazard.

- ***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. Foreign facilities are chosen for inspection for the same reasons domestic firms are chosen, product risk and compliance history. Many times, the products identified as the focus for inspection are selected due to violative entries, information obtained from importers, or as a follow-up to an import alert listing which also indicates potential HACCP program inadequacies.

  Investigators conducting foreign inspections must meet the training requirements and must conduct inspections following procedures outlined in the Conducting Seafood Inspections training course. Prior to the inspection investigators will be provided with a list outlining targeted products for each inspection along with entry information and other supporting documents applicable to the firm(s). If the targeted product(s) is not being processed, a product with similar risk and controls should be covered. If the targeted product or a product with identical or similar 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. Investigators should not focus attention on product(s) that are not shipped to the U.S., however, if what the firm is processing has similar hazards and controls, cover those processes, but limit HACCP plan and other record review to products shipped to the U.S. If a comprehensive record review cannot be accomplished because of timeframes for conducting the inspection, investigators should collect copies of HACCP plans and other records for CFSAN review. Many times, these documents will not be in English. Prior to the inspection, investigators may find it helpful to contact the firm and request that translations of the HACCP plan(s) and translated examples of supporting records are available during the inspection. It is crucial that investigators obtain documentary and photographic evidence to accompany their EIR during inspections of foreign processors.

  Investigators should follow procedures outlined in the Conducting Seafood Inspections Training course and should focus their attention on the implementation of the HACCP program for the identified targeted products

- ***NSSP Establishment Inspections***

  Inspections conducted of certified molluscan shellfish firms must be conducted by a shellfish standardized inspector or shellfish standardization officer who has completed both NSSP required classroom and field standardization training. These inspections are to be conducted using the ISSC Form 93-01(A) or an equivalent form. All inspections must be conducted following the requirements outlined in the NSSP Model Ordinance. Inspections must include a thorough review of the firms HACCP plan and associated record keeping, as well as a review of all sanitation monitoring records. In addition to the aforementioned, inspections must also include a thorough walk through of the physical facility, paying close attention to shell-stock storage and processing and potential temperature abuse. Other important areas of the inspection include, but are not limited to, safety of water used in processing (which includes wet storage and depuration), condition and cleanliness of food contact surfaces, prevention from cross-contamination, maintenance of handwashing and toilet facilities, protection from adulterants, proper labeling, use and storage of toxic chemicals, control of employees with adverse health conditions, and exclusion of pests.

  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/federalstatefoodprogra ms/ucm2006753.htm

Importer Inspections

Under the seafood HACCP Regulation, 21 CFR 123.12, importers are required to verify that foreign processors are in compliance with the Seafood HACCP Regulation, 21 CFR 123, and that the food safety hazards associated with their products are adequately controlled to ensure a safe product. This Compliance Program provides direction for reviewing HACCP verification documents during HACCP inspections of seafood importers. Criteria for the selection of importers to inspect are provided in Part II, Table 2. Refer to Part II, Table 1 for selection of products for the focus of the inspection. Inspections of importers for compliance with the verification requirements of 21 CFR 123.12 should be performed by following the procedures contained in the Conducting Seafood Importer Verification Course (FD 239) or Conducting Seafood HACCP Inspections (FD 249). Obtaining and reviewing seafood entries brought in by the importer prior to the inspection will help identify what products will be the focus of the inspection. Products from countries that currently have a food safety MOU with FDA should be excluded from the inspection. Onsite reviewing of the importers' written verification procedures include:

- Confirming written product verification procedures are in place;
- Reviewing the affirmative steps for adequacy;
- Reviewing the product specifications for adequacy; and

- Documenting deviations relating to the affirmative steps on the FDA Form 483. Deviations associated with product specifications and written verification procedures should be included in the EIR as discussion points.

When the processor's HACCP plan is maintained as an affirmative step and it fails to list a significant health hazard identified with the product, then the affirmative step is considered inadequate and that should be recorded on the FDA Form 483. Investigators who have completed FD 249 are qualified to identify if additional potential deficiencies with the controls listed in the plan, however, those HACCP plan deficiencies should not be documented on the FDA 483. When qualified investigators determine there are deficiencies beyond failure to list a hazard are present, they should collect a copy of the HACCP plan to be forwarded to CFSAN for regulatory follow-up with the foreign processor. Do not cite those foreign processor HACCP plan deficiencies on the FDA 483.

Cover as many products as practical under the inspection module provided in the ORA workplan. Products selected for coverage should be the higher risk products identified in Part II, Table 1. An FD 3502 should be completed for each product reviewed. Only qualified investigators (i.e., completed FD 249) should complete the section addressing seafood HACCP plan inadequacies.

Sampling

- ***Domestic "For Cause" Sampling***

  Domestic official samples are to be collected "for cause" only. Because of this, it is not necessary to routinely collect samples of domestic seafood products to support regulatory action for seafood HACCP violations. Collection of samples is appropriate in response to illness outbreaks; as follow-up on consumer or industry complaints; and in response to sampling assignments. Other sampling during domestic inspections should be infrequent. Samples should not be collected not when controls are clearly inadequate. The lack of controls should be clearly stated on the FDA 483 and conditions described in the EIR. If a division thinks a sample is necessary, they should contact CFSAN prior to collecting the samples, to discuss the collection. This type of verification sampling should be infrequent.

  In addition to IOM instructions, Attachment A of this program provides instructions with regards to sample collection and sample sizes. Consult the current ORA Field Work Plan and Laboratory Servicing Table (LST) dashboard to determine appropriate analyzing labs. CFSAN may issue special assignments to address food fraud issues or as targeted assignments for emerging issues.

- ***Imported Seafood Surveillance Sampling***

  The ORA Workplan for each fiscal year for the Import Seafood Products Compliance Program specifies the number of Import Sample Collections for each Division. ORA's automated surveillance system will flag processors and products for sampling; however, the field staff will also be able to manually select products. Entries of product from specific foreign processors or shippers previously found to have safety defects should have the highest priority for sampling.

When reviewing entries for sampling, entry reviewers and compliance officers should refer to Part II, Table 1 of this program to determine the risk and priority of seafood commodities**;** Chapter 3 of the *Fish and Fishery Products Hazards and Controls Guidance* to identify associated hazards of concern; and Attachment A of this program for special sampling instruction. For increased food safety impact, the predominance of samples should be collected from higher risk products, focusing on the food safety hazards associated with those products.

Sample collection instructions can be found in Attachment A. Submit samples to the Division's servicing laboratory specified in the current year's ORA Field workplan. The servicing laboratory may change year to year.

When handling product detained under an import alert, refer to the import alert, import bulletin, or SCOPE assignment, to determine if there are special sampling instructions or conditions for entry.

Note: If multiple analyses will be performed on a sample, contact your servicing laboratory for sample size information.

- ***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 "H") reserved for HACCP verification samples nor are they to count towards division Workplan obligations.

PART IV - ANALYTICAL

1. **Analyzing Laboratories**

Use the methods referenced in the appropriate section of this Part for surveillance sample analysis.

The sections of this part are:

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

B Project 03: **Parasites**

C Project 03: **Decomposition (Scombrotoxin (histamine), indole, organoleptic)**

D Project 03: **Microbiological**

E Project 07: **Natural Toxins**

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

G Project 21: **Food Composition, Standards, Labeling & Fraud**

Note: For all analytical guidance for CHEMOTHERAPEUTICS, including Field Laboratories, Methodology, and Reporting, refer to Part IV Compliance Program Chemotherapeutics in Seafood Compliance Program, CP 7304.018.

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

A. Project 03: FILTH, MOLD AND FOREIGN OBJECTS - MICROSCOPIC and MACROSCOPIC

FIELD LABORATORIES:

Identify a servicing laboratory per the Lab Servicing Table (LST) Dashboard. See IOM SUBCHAPTER 4.5 -SAMPLING: PREPARATION, HANDLING, SHIPPING for detailed shipping instructions. For any technical errors or issues identified in the LST Dashboard, please reach out to ORALabCapacity@fda.hhs.gov. Refer to the current ORA Field Workplan for the correct servicing laboratory.

METHODOLOGY:

Each subsample should be examined individually and not composited.

- AOAC, 18th Ed., Chapter 16, Extraneous Materials: Isolation
- JAOAC (Interim Official First Action Methods)
- FDA Laboratory Bulletin (LIB) # 3172 - Filth in Shrimp, LIB 2288 - Examination of Frozen Peeled and Deveined Shrimp for Fly Contamination, LIB 2957 - Examination of Dried Fish for Microscopic Filth, LIB 3242 Light Filth Analysis of Canned Fish and Fish Products
- Macroanalytical Procedures Manual (MPM)- 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.

CONTACTS:

CFSAN, Office of Food Safety, Monica.pava-Ripoll@fda.hhs.gov, 240-402-1630) or Amy Miller (Amy.Miller@fda.hhs.gov, 240-402-1658).

REPORTING:

Report all results of analytical results in FACTS using Problem Area Flag FIL and PAC 03842B for domestic products and use Problem Area Flag FIL and 03844B for import surveillance.

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:

- ***Hairs***
  Rat or Mouse - Average of 1, 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).

- ***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.

Disease Carrying Insects

Refer to CPG Sec 555.600 Filth from Insects, Rodents, and Other Pests in Foods. A disease-carrying species of insect has all of the following attributes:

- Wild populations known to carry *E. coli*, *Salmonella*, and *Shigella*.
- *Synanthropy* (a preference to live in human settlements).
- *Endophily* (tendency to enter buildings).
- Communicative behavior (oscillating between filth and human food).
- Attraction to both human food and excrement or other pathogen reservoirs.

Recognized 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.

Project 03: PARASITE ANALYSIS

FIELD LABORATORIES: Identify a servicing laboratory per the Lab Servicing Table (LST) Dashboard. For any technical errors or issues identified in the LST Dashboard, please reach out to ORALabCapacity@fda.hhs.gov

METHODOLOGY:
Bacteriological Analytical Manual (BAM) on line at http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/ucm071468.htm Chapter 19, Parasitic Animals in Foods, II. Candling to Detect Parasites in Finfish, page 19.04 - 19.05**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

Parasite Identification

Fix parasites as described in BAM and contact **Heather Hawk at 870-543-4677** (heather.hawk@fda.hhs.gov) 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 copy of the analytical worksheet package in the shipping container.

Parasite Fixation See reference in BAM, Chapter 19.

CONTACTS:

ORA, Office of Regulatory Science, Heather Hawk (870-543-4677) (heather.hawk@fda.hhs.gov) or Michael McLaughlin (301-796-8158)

REPORTING:

Report all analytical results in **FACTS using** PAC 03844B for import surveillance samples, PAC 03842B for domestic surveillance samples, and PAF "PAR".

C. Project 03: DECOMPOSITION ANALYSIS

The recommended number of subsamples in this section apply only to surveillance and audit samples. Sample sizes for reconditioned shipments or shipments detained under import alerts are expected to be more statistically robust to overcome the appearance of adulteration.

***IMPORTANT*:** Resolutions of disputes of findings, reconditioning proposals, or any other decisions with regards to the regulatory action or the disposition of the specific affected article should not be discussed directly with the owner or owner's representatives by agency laboratory personnel unless requested by the Division Compliance Branch having jurisdiction over the affected article. When a sample is classified as Lab Class 3 (Adverse Findings) and regulatory action is initiated by the Division Compliance Branch against the affected article (e.g., detention and refusal) all inquiries, requests and other correspondence related to the article from the owner or the owner's representatives should be directed to and/or referred to the Division Compliance Branch having jurisdiction over the affected article. In the absence of guidance specifically addressing the issues and conditions of an owner's proposals or disputes, the Division Compliance Branches are encouraged to confer with, or, if applicable, submit the owners' submissions to the Center for consideration or review.

FIELD LABORATORIES:

Identify a servicing laboratory per the Lab Servicing Table (LST) Dashboard. For any technical errors or issues identified in the LST Dashboard, please reach out to ORALabCapacity@fda.hhs.gov.

METHODOLOGY:

***Indole*:** Official Methods of Analysis (2019) 21st Ed., AOAC

INTERNATIONAL Rockville, MD, Method 981.07, liquid chromatographic fluorometric method. www.eoma.aoac.org & LIB 4016 Modification of HPLC Method for Indole in Shrimp AOAC 981.07

Histamine: Official Methods of Analysis (2019) 21st Ed.., AOAC INTERNATIONAL, Rockville, MD, Method 977.13, fluorometric method. www.eoma.aoac.org .

Organoleptic: 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 Office of Regulatory Science (contact Heather Hawk or Michael McLaughlin at 870-543-4677 or 301-796-8158, respectively). All of the qualified analysts performing the examination will make a collective assessment regarding each subsample in the sample. In order to fail a subsample, all analysts much reach a unanimous decision.

When products have been treated with chemicals or additives and there is no obvious sensory evidence of decomposition, but the analysts perceive that odors of decomposition may have

been masked, products should be analyzed chemically for decomposition where chemical indicators are applicable to the product (i.e., indole and histamine currently). Ronald Benner, Office of Food Safety, Division of Seafood Science and Technology, Gulf Coast Seafood Laboratory, Dauphin Island (HFS-400), 251-406-8124, can be consulted for appropriate testing methods and applications.

When confirmation of sensory findings by a National Seafood Sensory Expert (NSSE, Level III) is appropriate or directed, if logistically possible, the reserve subsamples from the same sample examined by the initial servicing lab should be examined by an NSSE. An additional sample is a less preferred alternative. When an NSSE confirmation is desired or indicated, it should occur prior to assigning the final Lab Classification for the sample.

Important: When a sample appears to be Lab Class 3 (Adverse Findings) on the basis of sensory findings but where the sensory attributes or findings are unusual, atypical, outside of the characteristic attributes to which the analysts have been exposed during training, or when an analyst has any reservations about the attributes detected in the sample, then it is prudent and advisable to deliver an additional sample, or preferably the reserve sample, to an NSSE (or alternative confirmation analysts designated by the NSSE) for confirmation, or for further confirmation, prior to making a final Lab Class decision on the sample.

Important: Once the sensory analysis is completed and other analyses are not required, a reserve portion will be assembled consisting of all the units assessed as decomposed and representative units equaling at least one subsample with no decomposition assessed (if existing). This sample reserve is held in accordance with the ORA Laboratory Manual. Examining labs should retain the assembled reserve portions from any Lab Class 3 decomposition sample until notification of disposition has been authorized.

Important: **Surveillance sampling of dried fishery products and fermented sauce/paste products** are not routinely recommended for decomposition analysis by either organoleptic examinations or histamine testing; CFSAN Office of Food Safety, Division of Seafood Safety, Seafood Processing and Technology Policy Branch, (Patti Ross at 240-402-1587) or Division of Seafood Science and Technology, Gulf Coast Seafood Laboratory, Dauphin Island (Ronald Benner at 251-406-8124, should be consulted prior to sampling or testing for decomposition analysis of dried or fermented sauce/paste articles if believed warranted.

Note: **Processed products** include cooked, pasteurized, formulated, LACF/AF, and/or products treated with chemicals or additives, including such things as sulfites, sauces, spices, acid (e.g., citric), smoke, and carbon monoxide.

REPORTING REQUIREMENTS:

Enter all analytical results for organoleptic into FACTS using PAF "DEC" and PAC 03842C (domestic "for cause" samples) or PAC 03844C (import surveillance samples). Enter all analytical results for scombrotoxin (histamine) and indole using PAF "DEC" and PAC 03842A (domestic "for cause" samples) or 03844A (import surveillance samples).

When samples are involved in an illness, notify CFSAN Division of Seafood Safety, Seafood Processing and Technology Policy Branch at seafood.illness@fda.hhs.gov and the ORA/ORS Sensory Program Coordinator.

ANALYTICAL RECOMMENDATIONS FOR SURVEILANCE SAMPLES ARE SPECIFIC FOR PRODUCTS AS FOLLOWS:

- ***Scombrotoxin Forming Species (Raw, Fresh, Frozen, or Processed)***:

  To identify scombrotoxin (histamine) forming species, consult the *Fish and Fishery Products Hazards and Controls Guidance*, Chapter 3, Table 3-2.

  - **Organoleptic Examination (Scombrotoxin Forming species)**

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

Scombrotoxin Product Type	Number of Subs
Raw, Fresh or Frozen	18
Processed (e.g., cooked, pasteurized, formulated, LACF/AF, and/or products treated with chemicals or additives, including such things as sulfites, sauces, spices, acid, smoke, and carbon monoxide.	24
Canned/pouched tuna greater than or equal to 1361 grams (3 lbs.) (routine surveillance only)	18

Positive Organoleptic Findings (Scombrotoxin Forming species)

(Sensory evidence)

When an organoleptic analysis is performed and sensory evidence of decomposition is detected by qualified analysts performing collective examination, then the sample is positive.

- If organoleptic analysis is performed and sensory evidence of high temperature abuse consistent with the analysts' training is present in any of the subsamples, then also perform histamine analysis on all subsamples.

  If the subsamples each consist of multiple pieces or portions (e.g., ≥ 2 steaks, fillets, chunks, etc.), the sensory analyst should identify those pieces within each subsample sent forward for histamine testing that had sensory evidence most likely signaling the potential for time-temperature abuse. In such cases, histamine testing should be performed on the pieces or portions, not less than 100 grams, identified by the sensory analyst within each subsample; the entire subsample need not be analyzed for histamine.

A check histamine analysis should be performed on a minimum of two subs showing the highest histamine levels. Use an additional 10-gram aliquot from the same ground subsample portions to perform the check analysis. Analyze all subsamples for histamine if the sample is associated with a scombrotoxin illness investigation.

Negative Organoleptic Findings (Scombrotoxin species) (sample passes the sensory examination)

The procedures that follow are for **surveillance samples only.** All subsamples should typically be analyzed for histamine in applications other than surveillance, for example, an audit sample.

Histamine analysis is to be conducted:

- On a minimum of six subsamples when all subsamples in the sample pass the sensory examination, but with one or more subsamples scoring in the mid-pass or borderline-pass region (i.e., 30 to 49 on the 100 mm sensory training scale). Include subsamples in the mid-pass to borderline-pass regions (i.e., those subsamples that had sensory evidence most likely signaling the potential for time-temperature abuse) in those to be tested for histamine. Analyze the remaining subsamples if histamine greater than or equal to 35 ppm is detected in any of the initial six subsamples. Additional subsamples need not be analyzed if histamine greater than or equal to 500 ppm is detected in one or more of the initial six subsamples. Analyze all subsamples for histamine if the sample is associated with a scombrotoxin illness investigation.

or

- On all subsamples when only one subsample fails the sensory examination.

  If the subsamples each consist of multiple pieces or portions (e.g., ≥ 2 steaks, fillets, chunks, etc.) the sensory analyst should identify those pieces within each subsample sent forward for histamine testing that had sensory evidence most likely signaling the potential for time-temperature abuse. In such cases, histamine testing should be performed on the pieces or portions, not less than 100 grams, identified by the sensory analyst within each subsample; the entire subsample need not be analyzed for histamine.

If the sample does not exhibit sensory evidence of decomposition, and the product is processed with additives or chemical treatments (e.g., sauces, citric acid, smoke, spices) that the analysts perceive may have masked sensory evidence of decomposition, all subsamples in the sample should be analyzed for histamine.

If samples test positive for histamine, a check histamine analysis should be performed on a minimum of two subsamples showing the highest histamine levels when the histamine results are to be used to support a regulatory action (i.e., one subsample ≥ 500 ppm, two subsamples ≥ 50 ppm, or one subsample with sensory evidence of decomposition and another subsample ≥ 50 ppm). Use an additional 10gram aliquot from the same ground subsample portions to perform the check analysis.

Analyze all subsamples for histamine if the sample is associated with a scombrotoxin illness investigation.

- **Histamine analysis (Scombrotoxin Forming species)**

  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 the primary analysis to be performed for decomposition on all surveillance samples of scombrotoxin (histamine)-forming fish and fishery products except where noted above. Follow the instructions above for selection of subsamples when conducting histamine analysis in support of organoleptic findings (positive or negative). In the rare instances where histamine analysis is conducted in the absence of an organoleptic examination, all subsamples in the sample should be analyzed.

  If samples test positive for histamine, a check histamine analysis should be performed on a minimum of two subsamples showing the highest histamine levels when the histamine results are to be used to support a regulatory action (i.e., one subsample ≥ 500 ppm, two subsamples ≥ 50 ppm, or one subsample with sensory evidence of decomposition and another subsample ≥ 50 ppm). Use an additional 10-gram aliquot from the same ground subsample portions to perform the check analysis.

  Analyze all subsamples for histamine if the sample is associated with a scombrotoxin illness investigation.

  Special histamine analysis instructions: Homogenize the specified fish portion in a food grinder or a food processor and remove a 10-gram aliquot from each subsample.

  Note: Histamine analysis should be conducted on all subsamples from samples collected as a consequence of a scombrotoxin illness investigation regardless of the organoleptic results.

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

  - *Breaded/Battered Fish and Fish Portions*: Breading/batter coatings on breaded/battered fish portions is to be removed so that histamine analysis is performed only on the fish component.

  - *Whole Fish, Fillets, and Loins*: Cut a transverse section (approximately 250 to 500 grams) from the anterior end (if it can be determined) of the fish (or fish portion) and grind each subsample (see Table A-1, Appendix). The lower anterior portion from one side of the fish provides the best sample. In sequence, for smaller whole fish, the upper anterior portion and then the lower middle portion (absent the belly flap) from the same side of the fish may be added to the lower anterior portion to obtain 250 grams. Include the same portions from one side of two or more fish if

all 3 portions from the first fish in the subsample would yield less than 250 grams. For very small fish (e.g., anchovies) that would yield less than 250 grams edible product from the entire fish, more than one fish may need to be used to prepare a representative sample of edible portion that may include the entire length from both sides of the fish.

- *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.

  Note: If the subsamples each consist of multiple pieces or portions, e.g., ≥ 2 steaks, fillets, chunks, cans, etc., the sensory analyst should identify those pieces within each subsample sent forward for histamine testing that had sensory evidence most likely signaling the potential for time-temperature abuse. In such cases, histamine testing should be performed on the pieces or portions, not less than 100 grams, identified by the sensory analyst within each subsample; the entire subsample need not be analyzed for histamine.
- *Cans, Cups, and Pouches (Retorted):* Liquid packing media, e.g., water, broth, and oil, should be drained and, when necessary, the meat rinsed.

  - Subsamples ≤ 454 grams*: grind the entire subsample, or drained subsample where applicable.
  - Subsamples > 454 grams*: rough mix the solids, or drained solids where applicable, before collecting and grinding a 250-to-454-gram portion.

  If the subsamples each consist of multiple pieces or portions, e.g., ≥ 2 steaks, fillets, chunks, cans, etc., the sensory analyst should identify those pieces within each subsample sent forward for histamine testing that had sensory evidence most likely signaling the potential for time-temperature abuse. In such cases, histamine testing should be performed on the pieces or portions, not less than 100 grams, identified by the sensory analyst within each subsample; the entire subsample need not be analyzed for histamine.

- **Criteria for Regulatory Action (Scombrotoxin Forming species, Decomp, Histamine)**

  Based on analytical data, refer to CPG Sec. 540.525. As of the implementation date of the program, this CPG is under revision. If a revised CPG has issued, please follow, otherwise contact CFSAN for direction.

- ***Shrimp – Raw (Fresh, Frozen) or Processed*:**

  The procedures that follow are for surveillance and audit samples only.

  - **Organoleptic Examination (Shrimp)**

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

Product Type	Minimum Number of Subs to Examine
Raw, Fresh or Frozen	12
Processed (e.g., cooked, canned/pouched (retorted), and/or treated with chemicals or food additives, including such things as sauces, smoke, citric acid, carbon monoxide or filtered smoke, and spices)	18

Note: Surveillance sampling of dried shrimp products and fermented sauce/paste products is not routinely recommended for decomposition analysis by either organoleptic examinations or indole testing. Contact CFSAN prior to analyzing samples.

Positive Findings (sensory evidence of decomposition present):

If an organoleptic analysis is performed and sensory evidence of decomposition is detected by qualified analysts performing collective examination, then the sample is positive.

When the sample is violative due to presence of sensory odors of decomposition, indole testing is performed at the discretion of the laboratory. When performing indole testing, analyze a minimum of six subsamples including the subsamples exhibiting sensory evidence of decomposition*****. The remaining subsamples should be analyzed if indole is detected at greater than or equal to 15 micrograms/100 grams of shrimp in any of the initial six subsamples. Additional subsamples need not be analyzed if indole greater than or equal to 25 micrograms/100 grams of shrimp is detected in two or more subsamples.

***Note:** The sensory analyst should identify those pieces within each subsample sent forward for indole testing that had sensory evidence most likely signaling the potential for time-temperature abuse. In such cases, indole testing should be performed on the pieces or portions, not less than 100 grams, identified by the sensory analyst within each subsample; the entire subsample need not be analyzed for indole.

When two or more subsamples contain indole at or above 25 micrograms/100 grams, a check indole analysis should be performed on a minimum of two

subsamples showing the highest indole levels. Use an additional aliquot from the same ground subsample portions to perform the check analysis.

Negative Findings (sample passes the sensory examination)**:**

The procedures that follow are for surveillance and audit samples only. All subsamples should typically be analyzed for indole following negative sensory findings in all samples for applications other than surveillance and auditing.

Indole testing following negative sensory findings on shrimp samples should be performed on canned shrimp or shrimp with additives or chemical treatments (e.g., heavy spices or chlorine odors) as follows:

- If only one subsample is determined (by the qualified sensory analysts performing the collective examination) to have sensory evidence of decomposition, indole testing is to be conducted on a minimum of six subsamples;

or

- If all subsamples pass the sensory examination but with one or more subsamples scoring in the low-pass to borderline-pass region (i.e., 40 to 49 on the 100 mm sensory training scale) consistent with the analysts' sensory training, indole testing is to be conducted on a minimum of six subsamples.

Include the subsample that failed or those subsamples in the low-pass to borderline-pass region.*

***Note**: The sensory analyst should identify those pieces within each subsample sent forward for indole testing that had sensory evidence most likely signaling the potential for time-temperature abuse. In such cases, indole testing should be performed on the pieces or portions, not less than 100 grams, identified by the sensory analyst within each subsample; the entire subsample need not be analyzed for indole.

The remaining subsamples should be analyzed if indole is detected at greater than or equal to 15 micrograms/100 grams of shrimp in any of the initial six subsamples. Additional subsamples need not be analyzed if:

- Indole greater than or equal to 25 micrograms/100 grams of shrimp is detected in two or more of the initial six subsamples;
  or
- One subsample failed for sensory evidence of decomposition and indole greater than or equal to 25 micrograms/100 grams is detected in a separate subsample of the initial six subsamples.

If the sample does not exhibit sensory evidence of decomposition and the product is processed with additives or chemical treatments (e.g., sauces, spices,

smoke, citric acid or chlorine odors) that the analysts perceive may have masked sensory evidence of decomposition, all subsamples in the sample should be analyzed for indole.

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

- **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 subsample. If the subsample is larger than 454 grams, rough mix the solids before collecting and grinding a 250-to-454-gram portion. For canned product containing a liquid packing medium, drain and discard the liquid portion before collecting and grinding the drained solid portion.*

***Note**: The sensory analyst should identify those pieces within each subsample sent forward for indole testing that had sensory evidence most likely signaling the potential for time-temperature abuse. In such cases, indole testing should be performed on the pieces or portions, not less than 100 grams, identified by the sensory analyst within each subsample; the entire subsample need not be analyzed for indole.

***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 subsamples showing the highest indole levels. Use an additional aliquot from the same original ground subsample portions to perform the check analysis.

- **Criteria for Regulatory Action (Shrimp, Decomp, Indole):**

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

SEAFOOD PRODUCTS OTHER THAN SCOMBROTOXIN SPECIES AND SHRIMP:

The procedures that follow are for surveillance samples only.

- **Organoleptic Examination:**

  Follow the organoleptic Method and Reporting Requirements as specified in the beginning of Part IV, **DECOMPOSITION ANALYSIS**. The minimum number of surveillance subsamples to be examined organoleptically should be:

Product Type	Minimum Number of Subs to Examine
Raw, Fresh or Frozen	12
Processed (e.g., cooked, canned/pouched (retorted), and/or treated with chemicals, or food additives, including such things as sauces, smoke, citric acid, carbon monoxide or filtered smoke, and spices)	18

  Surveillance sampling and testing of dried products and fermented sauce/paste products is not recommended for decomposition analysis. Contact CFSAN prior to analyzing samples.

  Positive Findings (sensory evidence of decomposition present):

  If an organoleptic analysis is performed and sensory evidence of decomposition is detected by qualified analysts performing collective examination, then the sample is positive.

- **Criteria for Regulatory Action (Other Products):**

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

D. Project 03: MICROBIOLOGICAL ANALYSIS

FIELD LABORATORIES:

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

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

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

GENERAL METHODOLOGY:

- Bacteriological Analytical Manual (BAM) online at http://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm2006949.htm

- AOAC, 18th Ed., (or as updated) Chapter 17, Microbiological Methods
- The laboratories will perform additional analyses in conjunction with those specified by the investigator on the collected samples, if deemed appropriate for regulatory purposes.
- If specified by BAM methodology or by the "Special Methods Instructions" section, composite subsamples for analysis when indicated. Otherwise, analyze each subsample separately

SPECIAL METHODS INSTRUCTIONS:

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

- ***Escherichia coli***

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

- ***Uneviscerated processed fish***

  Import Alert 16-74 prohibits entries of salt-cured, and/or air-dried, un-eviscerated fish uneviscerated or partially eviscerated fish that are either salt-cured, dried, smoked, pickled, fermented or brined, such as Kapchunka, or bloaters (excluding products filed under 21 CFR 108/113 or 114) from processors that are not included on the Green list for the import alert.
    - Small fish, less than 5 inches including head and tail that are not obviously eviscerated, are considered uneviscerated. The belly cavities of the fish do not need to be examined for the presence of viscera by FDA on a routine basis to support action. When investigators encounter fish less than 5 inches during field

assignments or field examinations, they should obtain photographs of the fish against a scale (e.g., ruler), as evidence of the size and lack of evisceration.

- Large fish, 5 inches or more including head and tail should be examined for the presence of viscera. Pictures documenting the size of the fish against a scale and the presence of viscera should be obtained as evidence.

GENERAL METHODS INSTRUCTIONS:

- ***Listeria monocytogenes***

Listeria monocytogenes analysis - will only be performed on seafood products that are considered **ready-to-eat** (i.e., unlikely to be fully cooked by consumers; appears cooked; traditionally consumed without cooking) or when there is evidence that the seafood is marketed or intended to be consumed without cooking.

http://qmis.fda.gov:80/mc/index.cfm?initialRequest=http%3A%2F%2Fqmis.fda.gov%3A80%2Fmc%2Fmain%2Findex.cfm%3Fevent%3DshowFile%26ID%3DD43ZQWGEC5BD5CDXYU%26static%3Dfalse***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.

Compositing/Sample Preparation (*Listeria*):

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.

- 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.

REPORTING *(Listeria monocytogenes)*:

Report all results of analytical results in FACTS using PAC 03844D for import surveillance samples, PAC 03842D for domestic surveillance samples, PAF "MIC", and sub-PAF "GLI".

- ***Salmonella***

Ready-to-eat products should receive a higher priority when allocating resources for testing.

GENERAL METHOD (*Salmonella*):

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.

BAM Chapter 5: Salmonella | FDA

Speciation (*Salmonella*):

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 720799502
Attention: Sina Shojaee
Tel# 87054346216

Isolates from SAN, PRL-NW, PRL-SW and DEN should be sent to:
Denver Division Laboratory
6th Avenue & Kipling Street
DFC Building 20
Denver Colorado 80225-0087
Attention: Doris Farmer

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

REPORTING *(Salmonella)*:

Report all results of analytical results in FACTS using PAC 03844D for import surveillance samples, PAC 03842D for domestic surveillance samples, PAF "MIC", and sub-PAF "GSA".

- ***Staphylococcus aureus and other Staphylococcal* species**

Raw, unprocessed seafood should not be tested for *Staphylococcus aureus or Staphylococcal* enterotoxin.

- Examine individual subsamples
- 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.

Enumeration (*Staphylococcus*):

- Direct Plate Count (DPC), BAM, Chapter 12, *Staphylococcus aureus.*
- 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.

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

- ***Staphylococcal Enterotoxin:***

Enterotoxin in product

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

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.

REPORTING *(Staphylococcus)*:

Report all results of analytical results in FACTS using PAC 03844D for import surveillance samples, PAC 03842D for domestic surveillance samples, and PAF "MIC".

- ***V. cholerae, V. parahaemolyticus, V. vulnificus***

Do not test seafood for *Vibrio spp*. on a routine basis. Only ready to eat seafood should be tested for *Vibrio spp*. Do not test raw product for *Vibrio spp*. unless it is ready to eat or implicated in an illness.

GENERAL INSTRUCTIONS (*Vibrio*):

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).

GENERAL METHOD (*Vibrio*):

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

PCR for toxigenic *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.

Each sample will be analyzed using the BAM, Chapter 9 and for *V. cholerae* sample, Chapter 28 can be used in addition to screen out negative samples.

If the sample is positive for *Vibrio*, notify Jessica Jones at (251) 406-8136 or (251) 599-1779 to determine if the isolates should be sent for confirmation to:

FDA/CFSAN/Office of Food Safety/Division of Seafood Science and Technology, HFF-400
ATTN: Jessica Jones
FDA/Gulf Coast Seafood Laboratory
1 Iberville Drive
Dauphin Island, AL 36528

ALKALINE PEPTONE WATER (APW) LYSATE PREPARATION FOR PCR ANALYSIS (*Vibrio cholerae*):

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*.

Once the appropriate dilutions have been prepared for each of the individual ten (10) subsamples using the BAM method, the samples will be incubated at 35 ±2°C for 6 to 8 h.

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). Boil for 5 min, then freeze.

Re-incubate the samples overnight (total of 18 to 21 h) at 35 ±2°C.

A second set of APW lysate composites will be prepared as above following the overnight incubation period.

See BAM, Chapter 28 for additional details for PCR analysis.

REPORTING *(Vibrio)*:

Report all results of analytical results in FACTS using PAC 03844D for import surveillance samples, PAC 03842D for domestic surveillance samples, PAF "MIC", and use sub-PAFs "GVC" for *V. cholerae* and "GVP" for *V. parahaemolyticus*.

- ***Clostridium botulinum and botulinum toxin producing clostridial species***
    - Examine 10 individual subsamples.
    - Use BAM Chapter 17: *Clostridium botulinum*
    - Do not test for the presence of spores or toxin unless implicated in a food poisoning case, or when microscopic examination show typical *C. botulinum* morphology during incidences of spoilage in canned foods (as described in *BAM Chapter 21A: Examination of Canned Foods*).
    - If there is direct evidence of botulism toxin and/or it is suspected or evidenced in a clinical case, samples should be sent directly to confirmatory lab ARL, which has mouse bioassay testing capability.
    - Select Agent Shipping restrictions apply to the sub-samples/source samples once mouse bioassay testing results are positive during cultural analysis for the clostridia, or when directly tested positive for botulinum toxins, in compliance to the *Federal Select Agent Program* (FSAP)and(*FAQs*)
    - For more information on the BAM method and analysis, contact Shashi Sharma (POC Telephone: 240-402-1570. (Alternative contact: Nagarajan Thirunavukkarasu,240-402-2949)

REPORTING *(Clostridium botulinum)*:

Report all results of analytical results in FACTS using PAC 03844D for import surveillance samples, PAC 03842D for domestic surveillance samples, PAF "MIC", and use sub-PAF "GCB".

ADDITIONAL ANALYSES:

- ***For Smoked, Brined, Salted, Cured, Dried, or Pickled Seafood***
  - **Water Activity** - Methodology for can be found in the analytical section of the Domestic AF & LACF Program, CP 7303.803A.
  - **Water Phase Salt (WPS)**
    - Moisture Content (Total Solids) in Seafood (% moisture)

      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.

    - Salt (Chlorine as Sodium Chloride) in Seafood (% water)

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

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

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

  - **Nitrite**

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

    Examine individual subsamples (10).

    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 botulinum neurotoxin formation (i.e., 100 ppm in smoked fish). Therefore, for the microbiological safety analysis, 10 subsamples are to be each analyzed individually.

    AOAC, 18th Ed., 973.31, Sec. 39.1.21

- ***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.

REPORTING (WPS, Aw, pH, Nitrites):

Report all results of analytical results in FACTS using PAC 03844D for import surveillance samples, PAC 03842D for domestic surveillance samples, PAF "MIC", and use sub-PAF "Nar" for water activity and pH; use "WPS-NTR" for water phase salt and nitrites.

- ***Molluscan Shellfish Sample Preparation/Methods***

  In addition to other fish species, this compliance program applies to raw molluscan shellfish. **FRESH MOLLUSCAN SHELLFISH SAMPLES MUST BE ANALYZED WITHIN 24 HOURS FROM TIME OF COLLECTION.**

  Sample Preparation/Method for Microbiological Analysis (Shellfish):

  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:
  - Weigh 200 g of shell liquor and meats (approximately 10 - 12 medium/large shellfish; approximately 25 small shellfish or ½ lb. shucked shellfish).
  - Grind for 30 seconds. If not possible, blend in sterile blender for 60 sec. It may be necessary to cut meats with sterile scissors or knives prior to grinding/ blending.
  - Remove 25 g of the meat homogenate for *V. parahaemolyticus* and *V. vulnificus* analysis (See BAM Ch 9).
  - Remove two (2) - 25 g meat homogenate portions for *V. cholerae* analysis (See BAM Ch. 9 and 28).
  - 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).

  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 above.

E. Project 07: NATURAL TOXINS

FIELD LABORATORIES:

ORA/ORS should be contacted before sample shipment to identify the correct analyzing laboratories.

GENERAL SAMPLE PREPARATION:

- ***Molluscan Shellfish*:**

  For each subsample (see Attachment A), whole animals (exception: scallop adductor muscles) 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.

  If scallop adductor only is to be consumed, testing for natural toxins is not needed.

- ***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 viscera per sample).

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

- ***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.

- ***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 https://www-s.nist.gov/srmors/certificates/archives/8642.pdf

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

- ***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 Wiggins (240-402-1470) at CFSAN/Office of Food Safety, College Park, MD or Ronald Benner (251-406-8124, CFSAN Gulf Coast Seafood Laboratory, Dauphin Island, AL.

- ***DSP (Okadaic Acid, Dinophysistoxins, and their derivatives)***

  LC-MS/MS is an approved NSSP method for clams.

  Method details and a method checklist are available on the ISSC Laboratory Method References portal.

  Certified reference Okadaic Acid (OA) and Dinophysistoxins 1 and 2 (DTX1, DTX2) can be purchased from the National Research Council Canada (NRC), Institute for Marine Biosciences, Halifax (Refer to Certified reference materials - National Research Council Canada).

  If there are questions about DSP analysis, contact Jonathan Deeds (240-402-1474) at CFSAN/Office of Regulatory Science, College Park, MD or Ronald Benner (251-406-8124), CFSAN Gulf Coast Seafood Laboratory, Dauphin Island, AL.

- ***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 analysis, contact Ronald Benner (251-406-8124) at CFSAN's Gulf Coast Seafood Laboratory, Dauphin Island, AL. Certified reference brevetoxin is not currently available.

- ***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.

  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 (Refer to Certified reference materials - National Research Council Canada).

If there are questions about AZP analysis, contact Jonathan Deeds (240-402-1474) at CFSAN/Office of Regulatory Science, College Park, MD or Ronald Benner (251-406-8124) at CFSAN Gulf Coast Seafood Laboratory, Dauphin Island, AL.

- ***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 Ronald Benner (251-406-8124) at CFSAN's Gulf Coast Seafood Laboratory, Dauphin Island, AL. Certified reference ciguatoxin is not currently available.

- ***TTX (Tetrodotoxin)***

  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).

  The NSSP approved Receptor Binding Assay (RBA) for PSP can also be used for the analysis of TTX.

  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.

REPORTING:

Results should be entered into FACTS using the PAF of "BIO" and PAC 07842 for domestic samples and PAC 07844 for import samples.

If levels are found above the regulatory action level, notify collecting Division'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 Seafood HACCP Guide.

F. Project 09: FOOD AND COLOR ADDITIVES

FIELD LABORATORIES:

- Food and Color Additives: Refer to the current ORA Field Workplan for the correct servicing laboratory.
- Astaxanthin: Division should contact ORA/ORS for placement of samples for astaxanthin analysis. This analysis will require a HPLC chiral column.

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.

- ***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.

  REPORTING (Color Additives):

  Report all results of analytical results in FACTS using PAC 09844E for import surveillance samples, PAC 09842E for domestic surveillance samples, and use PAF "COL".

- ***Food Additives***

  Refer to food additive instructions in the Import Food and Color Additives Compliance Program 7309.006 for current analytical guidance.

  REPORTING (Food Additives):

  Report all results of analytical results in FACTS using PAC 09844F for import surveillance samples, PAC 09842F for domestic surveillance samples

- ***Methods for Food Additives***

  Refer to food additive instructions in the Import Food and Color Additives Compliance Program 7309.006 for current analytical guidance. If sulfites are declared, it is not necessary to analyze for sulfites. 7309.006 for current analytical guidance.

  - Special instructions for Sulfites in Shrimp
  - http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm014548.htm

    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.

    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.

  - Special Instructions for Sulfites In Tuna

    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. The entire solid and liquid contents of each can should be included in the composite.

    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.

    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. 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.

taken.

G. Project 21: FOOD COMPOSITION, STANDARDS, LABELING AND FRAUD

The Program Assignment Code (PAC) for seafood fraud, 21842, will remain in effect and the field should continue to report these activities when performed.

If a division plans any food fraud 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 food 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 division 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 those results in exposure to additional hazards is suspected.

METHODOLOGY:

- ***Net Weight - Overglazing***

  This methodology applies to frozen seafood products whose surface is protected with a frozen water glaze. The procedure requires the analysis of 48 subsamples.

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

CRITERIA FOR REGULATORY ACTION (Net Weight):

Refer to CPG Sec 562.300 Foods - Net Weight.

Consult the current ORA Field Work Plan and Laboratory Servicing Table (LST) dashboard to determine appropriate analyzing labs.

- ***Species Substitution***

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

  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).

  - **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

CRITERIA FOR REGULATORY ACTION (Species substitution):

For servicing lab information, please contact Julia Manetes (ORA/ORS/OFFLO) 718-340-7034 (office) 240-270-4145 (cell).

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.

REPORTING:

- Report resources utilized for all operations except for Fair Packaging Labeling Act (FPLA) against PAC 21842.
- Report resources utilized for NLEA and FPLA against PAC 21005. Do not report inspections under NLEA. See current NLEA Compliance Program for reporting instructions.
- Report resources utilized for nutritional health fraud issues against 21R829.
- Report resources utilized for species substitution against PAC 21842. Use PAF "FDF", Food Fraud 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 division believes that a fish or fishery product poses an imminent public health hazard, the division should contact CFSAN/Office of Compliance/Division of Enforcement to discuss an appropriate response.

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:

- Assign high priority to cases associated with products or processes defined as "Higher risk potential" in Part II.
- Assign a high priority to cases that are regulatory follow-up to OAI inspections or illness events.
- 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.

Table A-3, Seafood HACCP Enforcement Strategy: Ranking of violation, provides information for determining the significance of violations of Part 123.

Table A-3: Seafood HACCP Enforcement Strategy: Ranking of violations Significance must be judged on a case-by-case basis. This ranking is for general guidance.		
Deficiency	**Citation**	**Ranking**
Hazard Analysis		
Hazard analysis not conducted	123.6(a)	Minor
HACCP Plan		
No written plan when one is required	123.6(b)	**Major**
HACCP plan is not implemented • Monitoring procedures/frequency not followed • Monitoring records missing data and observations • Monitoring records missing or not available when requested	123.6(b)	**Major**
Plan not location specific	123.6(b)(1)	Minor
Plan groups fish with different hazards and/or controls together	123.6(b)(2)	Minor
Hazard(s) not listed in the plan	123.6(c)(1)	**Major**
Critical control point(s) not listed in plan	123.6(c)(2)	**Major**
Critical limit(s) is not listed in plan or is inadequate to control hazard	123.6(c)(3)	**Major**
Monitoring procedure(s)/frequency is not listed in plan or is not sufficient to assure critical limit is not exceeded	123.6(c)(4)	**Major**
Monitoring procedure(s)/frequency listed in plan is not followed	123.6(b)	**Major**
Monitoring record data not actual value observed Note: Falsification of records is addressed under Title 18 of the Code of Federal regulations. Title 18 deviations should be referred to the Office of Criminal Investigation.	123.6(c)(7)	Minor
Monitoring observations not listed in monitoring records or not provided	123.6(c)(7)	**Major**
Verification procedure(s)/frequency not listed in plan	123.6(c)(6)	Minor
Recordkeeping system (monitoring records) not identified in plan	123.6(c)(7)	Minor
Recordkeeping system listed in plan not used • No monitoring record or • Monitoring observations not recorded	123.6(b)	**Major**
HACCP plan not signed and/or dated	123.6(d)	Minor
Corrective Actions		
Corrective action(s) not taken when a critical limit deviation occurred	123.7(a)	**Major**
Corrective action(s) taken to address critical limit deviation not appropriate • Do not meet the requirements listed in the corrective actions in the HACCP plan • Do not meet the requirements of 123.7(c) when not listed in HACCP plan	123.7(a)	**Major**
Corrective action(s) listed in HACCP plan not adequate to address the safety of the product and/or the cause of the deviation	123.7(b)	**Major**
Corrective action(s) not documented in records	123.7(d)	**Major**
Verification		
Adequacy of HACCP plan critical limit(s) not verified (Critical limits not validated)	123.8(a)	**Major**
Reassessment of HACCP plan not performed when required	123.8(a)(1)	Minor
Review of safety related consumer complaints not performed	123.8(a)(2(i)	Minor
Calibration of monitoring equipment not performed	123.8(a)(2)(ii)	
Review of critical control point monitoring records not performed within a week of completion	123.8(a)(3)(i)	Minor
Review of calibration records not performed in a timely manner	123.8(a)(3)(iii)	Minor
Corrective action not taken when indicated by a verification procedure	123.8(b)	**Major**
Corrective action taken when indicated by a verification procedure not appropriate	123.8(b)	**Major**
Reassessment of hazard analysis not performed	123.8(c)	Minor
Calibration and end-product testing not documented	123.8(d)	Minor

Deficiency	Citation	Ranking
Records		
Records do not include mandatory descriptive information	123.9(a)	Minor
Record information not recorded in a timely manner (at the time of observation)	123.9(a)(4)	Minor
Records not retained for required time period	123.9(b)(1)	**Major**
Records not available for official review	123.9(c)	**Major**
Training		
Monitoring record verification review and development, reassessment, and modification of HACCP plan not performed by an adequately trained or otherwise qualified individual	123.10(b)	Minor
Sanitation		
Sanitation monitoring not adequate (ready-to-eat products only)	123.11(b)	**Major**
Sanitation monitoring not adequate (other than ready-to-eat products)	123.11(b)	Minor
Sanitation deficiencies not corrected in a timely manner (ready-to-eat products only)	123.11(b)	**Major**
Sanitation deficiencies not corrected in a timely manner (other than ready-to-eat products)	123.11(b)	Minor
Sanitation control records not maintained or are not adequate (ready-to-eat products only)	123.11(c)	**Major**
Sanitation control records not maintained or are not adequate (other than ready-to-eat products)	123.11(c)	Minor
Imported Seafood		
Written verification procedures (summary) not maintained	123.12(a)(2)	Minor
Product specifications missing or inadequate • Food safety hazards missing • Listed safety limits exceed FDA/EPA safety recommendations • Require compliance with FDA GMPs or Part 117, subpart B	123.12(a)(2)(i)	Minor
Affirmative Step is inadequate	123.12(a)(2)(ii)	**Major**
Affirmative Step records are not in English	123.12(c)	**Major**
Assurances could not be provided that the imported seafood was processed in accordance with Part 123 when requested (foreign processor HACCP documentation) • Requested only “for cause” as directed by CFSAN	123.12(d)	**Major**

Ranking Definitions:

Major – A condition, that if left uncorrected, could jeopardize the integrity of the HACCP system and/or significantly increase food safety risk.

Minor - Unsatisfactory conditions that are not unlikely to jeopardize the integrity of the HACCP system or significantly increase food safety risk.

VIOLATIONS OF REGULATIONS OTHER THAN 21 CFR 123

The following instructions apply to deficiencies associated with seafood products encountered at seafood processors that may not be violations of 21 CFR 123 (i.e., seafood HACCP regulation). These include misbranding, economically motivated adulteration, non-scombrotoxin decomposition, non-safety related GMP violations, etc. If significant deviations exist with products or processes subject to FDA's regulation, the division 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 of other regulations and the FD&C Act should also be included when appropriate. Divisions should consult the Compliance Policy Guides (CPG) for direct reference compliance actions.

NATIONAL MARINE FISHERIES SERVICE (NMFS) NOTIFICATION:

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. Division compliance officers and management should review and follow procedures outlined in FMD#-029 following inspections and subsequent regulatory actions involving NMFS contracted processors

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 ORA, Office of Enforcement's intranet site at (See CFSAN section):
http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/Enforcement/ucm023598.htm

DETENTION WITHOUT PHYSICAL EXAMINATION (DWPE):

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.

Refer to the guidance or instructions included in the applicable import alert when evaluating corrective actions or testimony of admissibility.

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 "Mission Accomplishment and Regulatory Compliance Services-Compliance Management Services" (MARCS-CMS)

The procedures include early conversations (Preliminary Assessment Calls, i.e., PAC) and collaboration between ORA and CFSAN's Division of Enforcement, Division of Seafood Safety, DCMO and OCC and are part of the case development for 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. Procedures for the streamlined seizure and injunction process are in Chapters 6 and 10 of the RPM. See https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual(Regulatory Procedures Manual | FDA

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 (OCI).

SPECIES MISBRANDING:

Species misbranding is a violation of the Act [section 403(b) of the FD&C Act or 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 MARCS-CMS. The Division should also contact Carrie Lawlor, Division of Enforcement/Dietary Supplement and Labeling Assessment Branch at Carrie.Lawlor@fda.hhs.gov or (240) 402-0315.

***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 Division should submit a case via CMS to DIOP (HFC-172) for DWPE consideration. DIOP and CFSAN will confer on DWPE recommendations.

CFSAN REGULATORY CONTACTS:

Divisions should contact CFSAN Division of Enforcement, for preliminary discussions concerning possible recommendations for seizures, injunctions, or prosecutions under this program.

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.

REGULATORY GUIDANCE – SOURCES:

Use follow-up activities and 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.
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 located on-line.

RECONDITIONING	Sec. 160.700	Reconditioning of Foods Adulterated Under 402(a)(4)
DECOMPOSITION	Sec. 540.525	Decomposition and Histamine - Raw, Frozen Tuna and 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 (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)

Sec. 540.285 Crabmeat Products Labeling - Crabmeat Products with Added Fish or Other Seafood Ingredients (7108.03)

FOOD FRAUD: Seek CFSAN concurrence prior to devoting resources to food fraud issues.

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)

Sec. 555.875 Water in Food Products (Ingredient or Adulterant)

MICROBIOLOGY Sec. 555.320 Listeria monocytogenes

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. 540.650 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)

ALLERGENS Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens

PARASITES: Sec. 540.590 Prescribes action levels that will be used only for those freshwater fish species listed in that CPG.

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

For any sample of fish referred to CFSAN/OC/DE/Food Adulteration Branch, Maria.Corpuz@fda.hhs.gov HFS-607, Divisions must first send the whole parasites and fragments to the parasite expert for confirmation.

PROGRAM 7303.842

PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

- ATTACHMENTS – Tables A-1 and A-2, Sampling Guide
- REFERENCES
  - Conducting Seafood Inspections Training Manual
  - Fish and Fishery Products Hazards & Controls Guidance (the Guide)
  - Final Rule - Part 123, Seafood HACCP
  - CGMPs, Part 117, Subpart B
  - Sanitation Control Procedures Manual (Seafood HACCP Alliance)
  - Investigations Operations Manual
  - Regulatory Procedures Manual
  - Compliance Policy Guidance Manual
  - Guidance for Industry: Questions and Answers on HACCP Regulation for Fish and Fishery Products | FDA
  - Environmental Sampling for the Detection of Listeria monocytogenes
  - Environmental Sampling for the Detection of Salmonella
  - Draft Guidance for Industry on Reconditioning of Fish and Fishery Products by Segregation
  - Guidance for Industry: The Seafood List | FDA
  - Guidance for Industry: Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products | FDA
  - Guidance for Industry: 1991 Letter to Seafood Manufacturers Regarding the Fraudulent Practice of Including Glaze (ice) as Part of the Weight of Frozen Seafood | FDA
  - Food Defect Levels Handbook (Defect Action Levels)

PROGRAM 7303.842

➢ PROGRAM CONTACTS

***General Program Questions*:**

Jeffery Sumter, DrPh CFSAN, Office of Compliance, Division of Field Programs and Guidance, Programs Branch, HFS-615, 404-253-2279.

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, Maria.Corpuz@fda.hhs.gov

Scientific, Technical and Seafood HACCP Policy Questions (including sample collection:

CFSAN, Office of Food Safety, Division of Seafood Safety, Seafood Processing Technology Policy Branch, (240) 402-2300

***General Analytical/Laboratory Questions**:*

ORA/ORS	301/827-7605,7606

CFSAN Analytical Questions:

Color Additives Analysis	Office of Cosmetics and Colors, Division of Cosmetics and Color, Division of Cosmetics and Compliance, Bhakti Petigara, HFS-Process125, 240-402-1025, ext. 1025
Decomposition Analysis	Patti Ross, Office of Food Science, Division of Seafood Safety, (HFS-325), 240-402-1587
Filth Analysis:	Office of Food Safety Division of Dairy, Egg and Meat Products (DDEMP, Janet McGinn, Janet.McGinn@fda.hhs.gov
Food Additives Analysis	Office of Regulatory Science, /Division of Analytical Chemistry, Lowri DeJager, HFS-705, 240-402-2555
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	Eric Brown	240-402-2020
E. coli	Julie Kase	240- 402-2923
Listeria	Yi Chen	240-402-2783
Salmonella	Hua Wang	240-402-1932

	Staphylococcus	Sandra Tallent 240-402-1619
	Clostridium	Shashi Sharma, 240-402-1570
	(Alternative: *Nagarajan Thirunavukkarasu,* 240 402 2949)	
	Vibrios	Jessica Jones 251-406-8136
Natural Toxins	PSP	Stacey Wiggins, HFS-325, 240-402-1470
	ASP	Stacey Wiggins, HFS-325, 240-402-1470, or, Ronald Benner, HFS-400, 251-406-8124.
	DSP	Jonathan Deeds, HFS-707, 240-402-1474, or, Ronald Benner, HFS-400, 251-406-8124.
	AZP	(Appropriate GCSL contact)
	NSP	Ronald Benner, HFS-400, 251-406-8124
	CTX	Ronald Benner, HFS-400, 251-406-8124
	TTX	Jonathan Deeds, HFS-707, 240-402-1474
Parasite Analysis	Karen Swajian, HFS-325, 240-402-1614Office of Food Safety, Division of Seafood Safety,	
Species Substitution	Karen Swajian, HFS-325, 240-402-1614, Jonathan Deeds, HFS-707, 240-402-1474	
Net Weight / Short Weight	Karen Swajian, HFS-325, 240-402-1614	

Scallops – with added water or hydroscopic chemicals - Emanuel Hignutt, HFS 325, at 240-402-2469

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 fourth year.

ATTACHMENT A –Sampling Information

TABLE A-1: Surveillance Sampling for Fish and Fishery Products

Product	Decomposition 03844C/03842C See #20 below for more information	Microbiological 03844D/03842D See #7, 8, and 9 below for more information
Raw	12 subs - minimum 454 g (1 lb) per sub	Ready-to-Eat (RTE): 30 subs - minimum 227 g (8 oz) per sub. • *L. monocytogenes* analysis from **10** – 114 g (4 oz) subs out of the 30 subs, AND • *Salmonella* analysis from **30** -114 g (4 oz) subs. Not RTE: 15 subs - minimum 114 g (4 oz) per sub. *Salmonella* analysis ONLY.
Processed (see #10 below)	18 subs - minimum 454 g (1 lb) per sub	Ready-to-Eat (RTE): 30 subs - minimum 227 g (8 oz) per sub. • *L. monocytogenes* analysis from **10** – 114 g (4 oz) subs out of the 30 subs, AND • *Salmonella* analysis from **30** -114 g (4 oz) subs. Not RTE: 15 subs - minimum 114 g (4 oz) per sub. *Salmonella* analysis ONLY.
Raw Histamine forming species	18 subs - minimum 454 g (1 lb) per sub	Ready-to-Eat (RTE): 30 subs - minimum 227 g (8 oz) per sub. • *L. monocytogenes* analysis from **10** – 114 g (4 oz) subs out of the 30 subs, AND • *Salmonella* analysis from **30** -114 g (4 oz) subs. Not RTE: 15 subs - minimum 114 g (4 oz) per sub. *Salmonella* analysis ONLY.

Product	**Decomposition 03844C/03842C** **See #20 below for more information**	**Microbiological 03844D/03842D** **See #7, 8, and 9 below for more information**
Processed (see #10 below) Histamine forming species	24 subs - minimum 454 g (1 lb) per sub OR 18 subs for can/pouch tuna containers weighing 1361 g (3 lb) or more.	Ready-to-Eat (RTE): 30 subs - minimum 227 g (8 oz) per sub. • *L. monocytogenes* analysis from **10** – 114 g (4 oz) subs out of the 30 subs, AND • *Salmonella* analysis from **30** -114 g (4 oz) subs. Not RTE: 15 subs - minimum 114 g (4 oz) per sub. *Salmonella* analysis ONLY.

General Information

1. See the current ORA workplan for a list of the **Division servicing laboratories**. This will require either dividing the sample by the laboratory personnel, or collecting a duplicate sample by the field staff. This procedure should be worked out between the two branches prior to sample collection.

2. Utilize Tables 3-2 and 3-3 in the Fish and Fishery Products Hazards & Controls Guidance (the Guide) to identify species related hazards and Table 3-4 to identify potential food safety hazards associated with the end product market form.

3. **Reconditioning:** The sample sizes recommended in Table A-1 are for surveillance and audit purposes only. They should not be recommended as verification that the reconditioning of adulterated imported or domestic product has been successful . Please refer to the Guidance for Industry on Reconditioning of Fish and Fishery Products by Segregation for appropriate reconditioning sample size recommendations.

4. **DWPE Samples:** Placeholder for future guidance.

5. **Domestic HACCP Verification Samples**: CFSAN should be consulted prior to the collection of samples intended to verify implemented food safety (HACCP)controls. The resources for domestic sampling are limited since it is not necessary to collect samples to support HACCP violations.

6. **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 subsample quantities listed below do not include the duplicate samples. It may be necessary for the collecting Division to collect additional (duplicate) subsamples for domestic samples, another servicing lab or for an NSSE for confirmation analysis. Contact the servicing laboratory to determine whether these additional subsamples are necessary.

7. **Microbiological Samples**: It is important that all collections for PAC 03844D/03842D (PAF - MIC) be made aseptically (with the exception of molluscan shellfish). It is necessary that analysis is conducted **within 24 hours** 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 maintained at refrigerated temperatures.

8. **Microbiological Samples:** Surveillance samples should only be routinely collected for *Salmonella* and *Listeria monocytogenes*. Samples for other pathogens should be "for cause" and the Division of Seafood Safety should be consulted prior to collection. When collecting samples of RTE product (i.e., RTE as defined by 21 CFR 117.3) for micro testing, 30 eight (8) oz. samples should be collected to be tested for *Salmonella* and *Listeria monocytogenes*. Non-RTE products are a low regulatory priority for routine micro surveillance sampling and only 15 four (4) oz. subsamples should be collected for *Salmonella* analysis.

General Information (Cont'd)	
9.	***Listeria monocytogenes***: Do not request analysis on products that are not considered ready-to-eat (RTE) unless there is evidence that the product ***will*** be consumed without further cooking and provide an explanation in the "remarks" section describing how this determination was made. Only collect and do *L. monocytogenes* analysis on products that have evidence that they are ready-to-eat (RTE) as defined in 21 CFR 117.3.
10.	**Processed Products** include cooked, pasteurized, formulated, LACF/AF, and/or products treated with chemicals or additives, including such things as sulfites, sauces, spices, acid, smoke, and carbon monoxide or tasteless smoke.
11.	**Filth**: **(Macro/Microscopic)**: Collect only "for cause" when conditions warrant collection. **Do not sample finished products to support Sec. 402(a)(4) violations**. Instead, collect physical "for cause" samples of potentially contaminated raw materials and filth exhibits with documentation of the use of these contaminated raw materials in the manufacture of a specific lot or lots of finished product.
12.	**Subsample Selection:** Subsamples should generally be collected randomly to give the broadest representation of the product within the lot. When a lot contains multiple product codes or day codes, a sample should include subsamples from multiple codes. Where multiple pallets of the lot to be sampled are involved, the subsamples should also provide an appropriate cross-representation of the pallets from the lot. The production/date code of each subsample should be documented. Do not collect multiple subsamples from a single unit (e.g., fish, package). 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.
13.	**Chemical Contaminants**: 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*.
14.	**Natural Toxin CFP**: Samples should only be collected in response to an illness/outbreak. Unused portions of the fish or meal implicated in the illness fish should have the highest priority for sampling. The Gulf Coast Laboratory should be contacted as to when and how the samples are to be submitted.
15.	**Multiple line detention:** When multiple lines of similar products (e.g., different market forms of raw tuna, different sizes of raw shrimp) are included in an entry, a sample from a single entry line is sufficient to detain all other lines of similar product when a violation occurs. Subsamples of a single **surveillance sample** should not be distributed across multiple entry lines. When a sample from the single line is found to be adulterated, additional samples from other similar product lines **are not required to be collected** to support the detention of the unsampled lines.

General Information (Cont'd)

16. Import Alert 16-74, Uneviscerated Finfish

The import alert applies to processed uneviscerated finfish (e.g., cooked, smoked, dried, salted, brined, pickled). The main concern is *C. botulinum* toxin formation due to the reduction of competing microorganisms. The alert does not apply to fresh or frozen uneviscerated raw fish.

- Fish smaller than 5 inches may be assumed to be uneviscerated. If examination is done as a field exam, fish should be measured with a measuring tool and photographed if necessary. The import alert prohibits the importation of these fish if the processor is not on the Green List for the IA.
- There is no known method to safely process uneviscerated fish that are longer than 5 inches. If done as a field examination, fish should be measured from nose to fleshy tip of tail and photographed with measuring tool. Belly cavities should be opened, examined for viscera or portions of viscera, and viscera presence photographed when encountered. A single instance of either the presence of viscera or length less than 5 inches is sufficient to detain the entry and add the processor to the Red List for IA 16-74.
- The number of sub-samples to be collected is listed in the Finfish **Processed Products other than LACF/AF** sections of Attachment A under Filth: Macro/ Microscopic 03844B/03842B PACs.

17. Food Fraud

Divisions should follow-up on consumer or industry reports of food fraud; however, general surveillance activities should receive CFSAN concurrence prior to expending Division resources**.** CFSAN may periodically issue special assignments to address food fraud issues.

- **Overglazing / Net Weight**: 48 subs, if available, from lot
- **Breading Standards**: Collect 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.
- **Species substitution** 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 Division's designated laboratory.

General Information (Cont'd)

18. FOOD AND COLOR ADDITIVES

General Information: The Center is prepared to move quickly against products containing banned, illegal, or improperly used food or color additives. Collect samples of imported seafood products having a known or suspected potential for food and color additive violations. Past food additive problem areas include the following:

- Undeclared sulfites in shrimp
- Undeclared nitrates and nitrites in fishery products
- 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.

- **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.

- **Sample Collection**
  - 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.
  - Color Additives: When sampling, collect at a minimum four (4) subs, each consisting of 127 g (4 oz), of the sampled product.

General Information (Cont'd)

19. RAW MOLLUSCAN SHELLFISH- Clams, Mussels, Oysters, Whole & Roe-on Scallops

- Samples for natural toxin analysis do not need to be collected aseptically.
- Microbiological samples must be analyzed within 24 hrs. of collection. Contact servicing lab prior to sample collection.
- 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 temperatures. **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 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. Samples should be collected aseptically.
- 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 scoring 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.

General Information (Cont'd)

20. General Information – DECOMPOSITION & SCOMBROTOXIN

- **Dried, fermented, or paste: Samples of dried products or fermented sauce/paste products should not be identified for decomposition analysis unless directed by CFSAN.**
- Fish sauce subsamples should only be collected for histamine analysis.
- **Product forms: When collecting a surveillance sample from an entry of fish, such as carbon monoxide treated tuna or mahi, and when the entry consists of multiple product forms, it is generally recommended to select** a form in the following order beginning with the best candidate for sampling to the least desirable sample: scrape/ground meat, pieces, cubes, strips, steaks, saku/loins. The Divisions may, and are encouraged to, periodically stray from the recommendation to ensure that no product forms are exempt from occasional surveillance sampling.
- **Shipment of samples:** Samples should be frozen as soon as possible after collection and shipped frozen to ensure that additional decomposition does not occur while in the possession of FDA.
- **Resampling:** In instances where collecting additional samples from a previously sampled lot is warranted for sensory evaluation, the samples should be directed to a servicing lab with an NSSE. If the initial official sample was done at a lab with an NSSE, the additional sample should be directed to a servicing lab with another NSSE in seafood sensory evaluations or, if there is no other available, to a lab designated by a NSSE in seafood sensory evaluations.
- **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. **Specify on the collection report that both types of testing (organoleptic and histamine) are needed.**

General Information (Cont'd)

20. DECOMPOSITION & SCOMBROTOXIN (continued) - Sampling 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 larger than 10 lbs.):

  - If a properly trained seafood sensory field investigator or a qualified seafood sensory analyst accompanies the investigator during sampling, each subsample may be examined by using the drill method. Collect a minimum of 4 fish or fish blocks, including any suspected decomposed units, for laboratory examination.

  or

  - 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 subsamples (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 subsample-by-subsample (block-by-block) evaluation.

  or

  - Use a core or plug method to obtain a minimum of 454 grams (1 lb.) 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 the recommended number of subsamples listed in Table A-1.

- **FOR VERY SMALL SEAFOOD UNITS,** collect multiple items or retail packages to total $\geq$ 454 grams of edible portion per subsample unless otherwise indicated in the schedule.

General Information (Cont'd)

20. DECOMPOSITION & SCOMBROTOXIN (continued) - Sampling for SCOMBROTOXIN (Histamine)

For histamine sample collections, ≈ 250 grams of muscle meat should be collected from one side of the fish for each subsample in the following preferred target locations:

- A – the preferred location is the lower anterior loin portion;
- B – if the lower anterior loin portion does not yield 250 grams, include the upper anterior loin portion;
- C – if the A & B portions together do not yield 250 grams, include the lower middle loin portion (absent the belly flap);
- If the fish is sufficiently small such that the A, B, & C portions from one side of the fish do not yield 250 grams, it is advisable to include the A, B, & C portions from additional fish in the lot until 250 grams is collected for the subsample.
- When the fish are so small that the entire edible portion of the fish (from both sides of the fish) would yield less than 250 grams, then collect each subsample from the entire edible portion of multiple fish until ≥ 250 grams is obtained.
- Subsamples making up an overall sample should not all be taken from the same side of fish in the lot, i.e., do not collect every subsample from only the left or right side of every fish; the collector should attempt to represent different sides of the fish within the sample collection while collecting muscle from only one side of any individual fish sampled.

TABLE A-1: Surveillance Sampling for Fish and Fishery Products

Product	Decomposition 03844C/03842C See #20 below for more information	Microbiological 03844D/03842D See #7, 8, and 9 below for more information
Raw	12 subs - minimum 454 g (1 lb) per sub	Ready-to-Eat (RTE): 30 subs - minimum 227 g (8 oz) per sub. • *L. monocytogenes* analysis from **10** – 114 g (4 oz) subs out of the 30 subs, AND • *Salmonella* analysis from **30** -114 g (4 oz) subs. Not RTE: 15 subs - minimum 114 g (4 oz) per sub. *Salmonella* analysis ONLY.
Processed (see #10 below)	18 subs - minimum 454 g (1 lb) per sub	Ready-to-Eat (RTE): 30 subs - minimum 227 g (8 oz) per sub. • *L. monocytogenes* analysis from **10** – 114 g (4 oz) subs out of the 30 subs, AND • *Salmonella* analysis from **30** -114 g (4 oz) subs. Not RTE: 15 subs - minimum 114 g (4 oz) per sub. *Salmonella* analysis ONLY.a
Raw Histamine forming species	18 subs - minimum 454 g (1 lb) per sub	Ready-to-Eat (RTE): 30 subs - minimum 227 g (8 oz) per sub. • *L. monocytogenes* analysis from **10** – 114 g (4 oz) subs out of the 30 subs, AND • *Salmonella* analysis from **30** -114 g (4 oz) subs. Not RTE: 15 subs - minimum 114 g (4 oz) per sub. *Salmonella* analysis ONLY.

Product	Decomposition 03844C/03842C See #20 below for more information	Microbiological 03844D/03842D See #7, 8, and 9 below for more information
Processed (see #10 below) Histamine forming species	24 subs - minimum 454 g (1 lb) per sub-OR 18 subs for can/pouch tuna containers weighing 1361 g (3 lb) or more.	Ready-to-Eat (RTE): 30 subs - minimum 227 g (8 oz) per sub. • *L. monocytogenes* analysis from **10** – 114 g (4 oz) subs out of the 30 subs, AND • *Salmonella* analysis from **30** -114 g (4 oz) subs. Not RTE: 15 subs - minimum 114 g (4 oz) per sub. *Salmonella* analysis ONLY.

TABLE A-2: ADDITIONAL SAMPLING INSTRUCTIONS

Non-scombrotoxin finfish species

Seafood Product	Filth: Macro/ Microscopic 03844B/03842B	Filth: Parasites 03844B/03842B	Decomposition 03844C/03842C	Microbiological 03844D/03842D	Natural Toxins 07844/07842
Raw or processed, fresh and frozen **Does not include LACF/AF products** Refer General Instructions for the definition of "processed" Use Chapt. 3 of the Guide to identify non-scombrotoxin species and their associated hazards.	**For Cause only**6 subs – Minimum 900 g -> 1.36 kg (2-3 lb.) per sub Collect samples of potentially uneviscerated fish under this PAC Refer to Table A-1 and Part II, Table 2, of this CP for instructions on uneviscerated fish	Only collect raw products. Do not collect minced fish products, frozen fish products, dried fish, cooked or thermally processed fish. Do not collect whole uneviscerated fish or minced fish products 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 minced fish blocks. **Imported Whitefish:** Refer to Chapt. 4, Table 5 of the IOM	Refer to Table A-1 for specific instructions for decomposition samples and what not to sample. Dried, fermented, and sauce/paste products should not be sampled for decomposition. Contact CFSAN prior to collection.	See Table A-1 for sampling instructions for *L. monocytogenes* and *Salmonella* **ROP Processed and Dried Products other than LACF/AF:** Water activity, pH, water phase salt & nitrites analysis collect 10 subs, each 454 g (1 lb) **Other micro analysis for cause only**	Consult with CFSAN prior to collecting samples. PSP (Puffer fish)-3 subs per sample; 227 grams (8 oz) edible meat per sub ASP (uneviscerated fish consumed whole) 3 subs/sample. Min. 227g (8 oz)/sub edible and min. 25 g viscera Use Table 3-2 of the Guide to identify species associated with hazard

Seafood Product	**Filth: Macro/ Microscopic 03844B/03842B**	**Filth: Parasites 03844B/03842B**	**Decomposition 03844C/03842C**	**Microbiological 03844D/03842D**	**Natural Toxins 07844/07842**
Raw or processed, fresh and frozen Refer to General Instructions for the definition of "processed" **Does not include LACF/AF products** Use Chapt. 3 in the Guide to identify scombrotoxin forming species and associated hazards and their associated hazards.	**For Cause only**6 subs – Minimum 900 g -> 1.36 kg (2-3 lb.) per sub Collect samples of potentially uneviscerated fish under this PAC Refer to Table A-1 and Part II, Table 2, of this CP for instructions on uneviscerated fish	**For Cause only** Do not collect whole, uneviscerated fish as samples Do not sample frozen, dried, cooked or thermally processed products 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 minced fish blocks.	Refer to Table A-1 for specific instructions for decomposition and scombrotoxin (histamine)samples **Dried, fermented, and sauce/paste products should not be sampled for decomposition. Contact CFSAN prior to collection.**	**RTE:** See Table A-1 for special instructions on *L. monocytogenes* and *Salmonella* samples **ROP Processed and Dried Products other than LACF/AF:** Water activity, pH, water phase salt & nitrites analysis collect 10 subs, each 454 g (1 lb) **Other micro analysis for cause only**	Consult with CFSAN prior to collecting samples. ASP (uneviscerated fish consumed whole) 3 subs/sample. Min. 227g (8 oz)/sub edible and min. 25 g viscera Use Table 3-2 in the Guide to identify species associated with hazard

Seafood Product	Filth: Macro/ Microscopic 03844B/03842B	Filth: Parasites 03844B/03842B	Decomposition 03844C/03842C	Microbiological 03844D/03842D	Natural Toxins 07844/07842
Cans, pouches, cups This section applies to products that are subject to 21 CFR 113 and 21 CFR 114. **Refrigerated ROP products should be sampled as instructed in the other commodity sections.**	**For Cause only** If cans <795g (28 oz.): < 50 cases – 24 cans ≥ 50 cases – 48 cans If cans >795g (28 oz.): < 600 cases – 24 cans ≥ 600 cases – 48 cans **Canned Shrimp** Collect several codes in lot, selecting a min. of 16 cans for each code by min. Sample enough codes to result in <200 cs - 48 cans OR >200 cs - 96 cans	Do not collect samples under this program	Refer to Table A-1 for instructions for decomposition samples	Do not collect samples under this program	Consult with CFSAN prior to collecting samples. ASP (Uneviscerated fish consumed whole) - 3 subs/sample. Min. 227g (8 oz)/sub edible and min. 25 g viscera

Seafood Product	**Filth: Macro/ Microscopic 03844B/03842B**	**Filth: Parasites 03844B/03842B**	**Decomposition 03844C/03842C**	**Microbiological 03844D/03842D**	**Natural Toxins 07844/07842**
Shrimp, Crabs, Lobsters, Crawfish, LangostinosRefrigerated ROP is included in this commodity group. **Products other than LACF/AF.**	**For Cause only** 6 subs – Minimum of 900 g -> 1.36 kg (2-3 lb.) per sub **Freeze dried:** 6 subs - Minimum of 250g (10 oz.) per sub **Sun, air dried:** 6 subs – Minimum of 680 g (24 oz.) per sub	Do not collect samples of crustacean shellfish for parasites.	Refer to Table A-1 for instructions for decomposition samples **Dried, fermented, and sauce/paste products should not be sampled for decomposition. Contact CFSAN prior to collection.**	See Table A-1 for special instructions on *Listeria monocytogenes* and *Salmonella* samples **ROP Processed and Dried Products other than LACF/AF:** Water activity, pH, water phase salt & nitrites analysis collect 10 subs, each 454 g (1 lb) **Other micro analysis for cause only**	Contact CFSAN prior to collecting samples. ASP or PSP: 3 subs/sample. Min. 227g (8 oz)/sub edible and min. 25 g viscera **OR** Collect whole raw crabs and lobsters with viscera intact. If collecting for ASP **and** PSP, double subsample size. For crab and lobster, viscera portions will comprise hepatopancreas (e.g., mustard/tomalley)

Seafood Product	**Filth: Macro/ Microscopic 03844B/03842B**	**Filth: Parasites 03844B/03842B**	**Decomposition 03844C/03842C**	**Microbiological 03844D/03842D**	**Natural Toxins 07844/07842**
Shell-on, shucked, fresh, frozen: Oysters, Clams, Mussels, whole or **roe-on** scallops **Note – Micro samples:** Record certificate number of sampled shipment and final destination of shipment in "remarks" section of collection report. This information may be needed to trace back. Refer to Table A-1 for special instructions for raw molluscan shellfish samples	**For Cause only** Shucked Whole Shellfish: 6 - 114g (4 oz) subs	Do not collect samples for parasites	See Table A-1 for instructions for decomposition samples	See Table A-1 for special instructions for *Listeria monocytogenes* and *Salmonella* samples Contact servicing lab prior to 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 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 **Shucked Fresh or Frozen:** Collect 12 subs/sample, 100 grams per sub **Unshucked Shellfish:** 12 or more **Whole or roe-on scallops:** 12 subs - Minimum of 100 grams shucked OR whole scallops plus 25 g viscera

Seafood Product	Filth: Macro/ Microscopic 03844B/03842B	Filth: Parasites 03844B/03842B	Decomposition 03844C/03842C	Microbiological 03844D/03842D	Natural Toxins 07844/07842
• Invertebrates and other species that do not fit into the other categories • Molluscs other than clams, mussels, scallops, oysters • Raw molluscan shellfish that are "processed". • Other seafood products (e.g., raw, dried, processed) that do not fit into a specific seafood category	**For Cause only** 6 subs – Minimum of 900 g -> 1.36 kg (2-3 lb.) per sub	**For Cause only** Refer to Table 3-3 in the Guide to identify species 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 Do not collect samples of frozen, thermally processed (i.e., cooked) or dried products	See Table A-1 for instructions for decomposition samples **Dried, fermented, and sauce/paste products should not be sampled for decomposition. Contact CFSAN prior to collection.**	See Table A-1 for special instructions for *Listeria monocytogenes* samples **ROP Processed and Dried Products other than LACF/AF:** Water activity, water phase salt & nitrites analysis collect 10 subs, each 454 g (1 lb) **Other micro analysis for cause only**	ASP or PSP: 3 subs/sample. Min. 227g (8 oz)/sub edible and min. 25 g viscera When collecting samples for multiple toxin testing, collect separate samples for each toxin test.

Table A-3: Seafood HACCP Enforcement Strategy: Ranking of violations
Significance must be judged on a case-by-case basis. This ranking is for general guidance.

Deficiency	Citation	Ranking
Hazard Analysis		
Hazard analysis not conducted	123.6(a)	Minor
HACCP Plan		
No written plan when one is required	123.6(b)	**Major**
HACCP plan is not implemented • Monitoring procedures/frequency not followed • Monitoring records missing data and observations • Monitoring records missing or not available when requested	123.6(b)	**Major**
Plan not location specific	123.6(b)(1)	Minor
Plan groups fish with different hazards and/or controls together	123.6(b)(2)	Minor
Hazard(s) not listed in the plan	123.6(c)(1)	**Major**
Critical control point(s) not listed in plan	123.6(c)(2)	**Major**
Critical limit(s) is not listed in plan or is inadequate to control hazard	123.6(c)(3)	**Major**
Monitoring procedure(s)/frequency is not listed in plan or is not sufficient to assure critical limit is not exceeded	123.6(c)(4)	**Major**
Monitoring procedure(s)/frequency listed in plan is not followed	123.6(b)	**Major**
Monitoring record data not actual value observed Note: Falsification of records is addressed under Title 18 of the Code of Federal regulations. Title 18 deviations should be referred to the Office of Criminal Investigation.	123.6(c)(7)	Minor
Monitoring observations not listed in monitoring records or not provided	123.6(c)(7)	**Major**
Verification procedure(s)/frequency not listed in plan	123.6(c)(6)	Minor
Recordkeeping system (monitoring records) not identified in plan	123.6(c)(7)	Minor
Recordkeeping system listed in plan not used • No monitoring record or • Monitoring observations not recorded	123.6(b)	**Major**
HACCP plan not signed and/or dated	123.6(d)	Minor

Deficiency	Citation	Ranking
Corrective Actions		
Corrective action(s) not taken when a critical limit deviation occurred	123.7(a)	**Major**
Corrective action(s) taken to address critical limit deviation not appropriate • Do not meet the requirements listed in the corrective actions in the HACCP plan • Do not meet the requirements of 123.7(c) when not listed in HACCP plan	123.7(a)	**Major**
Corrective action(s) listed in HACCP plan not adequate to address the safety of the product and/or the cause of the deviation	123.7(b)	**Major**
Corrective action(s) not documented in records	123.7(d)	**Major**
Verification		
Adequacy of HACCP plan critical limit(s) not verified (Critical limits not validated)	123.8(a)	**Major**
Reassessment of HACCP plan not performed when required	123.8(a)(1)	Minor
Review of safety related consumer complaints not performed	123.8(a)(2(i)	Minor
Calibration of monitoring equipment not performed	123.8(a)(2)(ii)	
Review of critical control point monitoring records not performed within a week of completion	123.8(a)(3)(i)	Minor
Review of calibration records not performed in a timely manner	123.8(a)(3)(iii)	Minor
Corrective action not taken when indicated by a verification procedure	123.8(b)	**Major**
Corrective action taken when indicated by a verification procedure not appropriate	123.8(b)	**Major**
Reassessment of hazard analysis not performed	123.8(c)	Minor
Calibration and end-product testing not documented	123.8(d)	Minor
Records		
Records do not include mandatory descriptive information	123.9(a)	Minor
Record information not recorded in a timely manner (at the time of observation)	123.9(a)(4)	Minor
Records not retained for required time period	123.9(b)(1)	**Major**
Records not available for official review	123.9(c)	**Major**
Training		
Monitoring record verification review and development, reassessment, and modification of HACCP plan not performed by an adequately trained or otherwise qualified individual	123.10(b)	Minor

Deficiency	Citation	Ranking
Sanitation		
Sanitation monitoring not adequate (ready-to-eat products only)	123.11(b)	**Major**
Sanitation monitoring not adequate (other than ready-to-eat products)	123.11(b)	Minor
Sanitation deficiencies not corrected in a timely manner (ready-to-eat products only)	123.11(b)	**Major**
Sanitation deficiencies not corrected in a timely manner (other than ready-to-eat products)	123.11(b)	Minor
Sanitation control records not maintained or are not adequate (ready-to-eat products only)	123.11(c)	**Major**
Sanitation control records not maintained or are not adequate (other than ready-to-eat products)	123.11(c)	Minor
Imported Seafood		
Written verification procedures (summary) not maintained	123.12(a)(2)	Minor
Product specifications missing or inadequate • Food safety hazards missing • Listed safety limits exceed FDA/EPA safety recommendations • Require compliance with FDA GMPs or Part 117, subpart B	123.12(a)(2)(i)	Minor
Affirmative Step is inadequate	123.12(a)(2)(ii)	**Major**
Affirmative Step records are not in English	123.12(c)	**Major**
Assurances could not be provided that the imported seafood was processed in accordance with Part 123 when requested (foreign processor HACCP documentation) • Requested only "for cause" as directed by CFSAN	123.12(d)	**Major**

Ranking Definitions:

Major – A condition, that if left uncorrected, could jeopardize the integrity of the HACCP system and/or significantly increase food safety risk.

Minor - Unsatisfactory conditions that are not unlikely to jeopardize the integrity of the HACCP system or significantly increase food safety risk.