CHAPTER 03 - FOODBORNE BIOLOGICAL HAZARDS

| **SUBJECT:** | **IMPLEMENTATION DATE** |
|---|---|
| IMPORT SEAFOOD PRODUCTS COMPLIANCE PROGRAM FY 07/08/09 | 11/17/06 |
| | **COMPLETION DATE** 9/30/09 |

**DATA REPORTING**

| PRODUCT CODES | PRODUCT/ASSIGNMENT CODES |
|---|---|
| INDUSTRY CODE 16, USE APPROPRIATE PRODUCT CODES | 1. REPORT INSPECTIONS UNDER THE FOLLOWING PACS:<br>03844H HACCP Inspection of Importers<br><br>2. REPORT SAMPLE COLLECTIONS, AUDIT CHECKS, RECALLS, FIELD EXAMS (formerly Wharf Exams), AND INVESTIGATIONS UNDER THE FOLLOWING PACs:<br>03844 Foodborne Biological Hazards<br>07844 Natural Toxins<br>09844E Color Additives<br>09844F Food Additives<br><br>3. REPORT SAMPLE ANALYSIS AND LABEL REVIEW UNDER THE FOLLOWING PACs:<br>03844B Filth<br>03844C Decomposition<br>03844D Microbiological (includes % water phase salt and nitrites)<br>07844 Natural Toxins<br>09844E Color Additives<br>09844F Food Additives<br><br>4. THE FOLLOWING ARE ADDITIONAL PAC CODES FOR REPORTING PURPOSES:<br>03R833 Entry Review<br>99R833 Filer Evaluation OP95<br>03R824 Follow-up to Refusals<br>04R824<br>07R824<br>09R824 |

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

A. HARD COPY REPORTING TO CFSAN

HFS-606 will forward these reports to the appropriate CFSAN office.

1. Inspections

For ***importer inspections*** that were ***classified*** as ***OAI***, submit the hard copy or scanned or electronic:

- EIR
- EIR endorsement, and ensure that the following information is included:
  Computer generated cover sheet
  FDA Form 483
  FDA Form 3502

2. Samples supporting detention or Detention Without Physical Examination (DWPE) request

When making a submission in support of a detention or for a request for DWPE submit the following hardcopy or scanned documents:

- Analytical Worksheets
- OASIS Collection Report and corresponding FACTS Collection Report
- Shipping documentation and foreign certifications
- Copies of entry documentation
- Invoice which identifies the name and address of the manufacturer/processor
- Product labels must be submitted – if product is in bulk, then photographs or tracings of container labeling must be submitted

The above hard copy or scanned reports should be submitted on an as completed basis to:

Food and Drug Administration
CFSAN/Division of Enforcement
Import Branch, HFS-606
Attn: Ronald Pace, Chief Import Branch
5100 Paint Branch Parkway
College Park, MD 20740

mailto: Ronald.Pace@FDA.HHS.GOV

3. Special HACCP **hard copy** Reporting

This compliance program utilizes a special reporting form, the FDA Import Seafood HACCP Report (FDA 3502) for all importer HACCP inspections. The form is to be faxed to a dedicated phone line, **(301) 436-2885**, on an as-completed basis.

In the event that the report cannot be faxed, the original should be sent to Roshelle King at the address listed below:

Food and Drug Administration
CFSAN/Office of Seafood, HFS-417
Attn: Roshelle King
5100 Paint Branch Parkway
College Park, MD 20740

4. When during an importer inspection the investigator reviews a foreign producer's HACCP plan that is, in the inspector's opinion, inadequate, the inspector should obtain a copy of that HACCP Plan.

If the District concurs that the HACCP plan is inadequate, then the plan should be sent to:

Food and Drug Administration
CFSAN/Office of Seafood, HFS-417
Attn: Dixie Kee
5100 Paint Branch Parkway
College Park, MD 20740

**B.** LABORATORY REPORTING

Report the following analytical results into the FACTS Data System:

| | | | |
|---|---|---|---|
| 1. | Biotoxins (Natural Toxins) | Use PAF: | BIO |
| 2. | Color Additives | Use PAF: | COL |
| 3. | Decomposition | Use PAF: | DEC |
| 4. | Filth | Use PAF: | FIL |
| 5. | Food Additives | Use PAF: | FAD |
| 6. | Microbiology | Use PAF: | MIC |
| | Salmonella Speciation | | SAL |
| | Percent (%) Water Phase Salt | | NAR |
| | pH | | NAR |
| 7. | Parasites | Use PAF: | PAR |
| 8. | Pesticides | Use PAF | PES |
| 9. | Salmonella Speciation | Use PAF | SAL |

11. **Note**: No resources have been allocated for Food Economics in the Field Workplan. While some activities in food economics may be necessary, districts should first obtain CFSAN concurrence and hold resource expenditures to a minimum.

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

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

12. GENERAL FOOD LABELING and NLEA coverage for imported seafood will be conducted under the Domestic and Import NLEA, Nutrient Sample Analysis and General Food Labeling Requirements Compliance Program – CP 7321.005

## PART I - BACKGROUND

This Compliance Program provides regulatory coverage of imported fish and fishery products to ensure that a safe and wholesome supply of seafood enters the U.S. Historically, FDA has controlled imports by reviewing customs entries, conducting field exams, collecting samples for laboratory analysis, placing products with a history of problems on detention without physical examination, and conducting a limited number of foreign establishment inspections. This program addresses the control of the various safety hazards identified in the seafood HACCP regulation as well as the occurrence of filth, decomposition, and the illegal use of food or color additives in imported seafood. These efforts continue under the present program, and are important components of the import control strategy.

The Import Seafood Products Compliance Program provides coverage of processors and products that are not covered under the Molluscan Shellfish Evaluation Program (CP 7318.004), and additional coverage of processors and products covered under the Import Acidified and Low Acid Canned Food Compliance Program CP 7303.003(i.e., hermetically sealed low-acid seafood) for hazards that are not addressed in those programs.

Under FDA's HACCP system of controls, the importer and the foreign processor share the responsibility for safety. Foreign processors that ship fish or fishery products to the U.S. must operate in conformance with the 21CFR Part 123, seafood HACCP Regulation. In addition, the HACCP Regulation requires importers to take positive steps to verify that their shipments are obtained from foreign processors that comply with that regulation's requirements.

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. If HACCP plans are available as part of the importer's affirmative step, foreign processors that do not appear to have adequate controls can be scheduled for upcoming foreign inspections.

Conversely, data gathered during foreign investigations of processors can help FDA identify importers that are accepting product from foreign processors that are not in compliance with the seafood HACCP regulation, and also provide insight into the reliability of third party inspections and foreign certification programs.

## PART II - IMPLEMENTATION

### OBJECTIVE

This program is implemented to ensure that a safe and wholesome supply of imported fish and fishery products enters the U.S. This is done by gathering information to determine compliance with the FD&C Act and its regulations by importers and foreign processors involved in the production, storage, and entry of these seafood products.

This will be accomplished:

- by sampling and analyzing imported products at entry to identify commodities that may not be in compliance with the FD&C act and by detaining products as appropriate;
- by inspecting importers to evaluate their compliance with the HACCP Regulation;
- by reviewing and evaluating an importer's affirmative steps, and thus identifying foreign processors as potential candidates for on-site inspections;

### APPROACH

All fish and fishery products that are processed by foreign processors and then offered for entry by importers are subject to the provisions of the seafood HACCP Regulation (21CFR 123.12(d)).

Seafood importers will be considered for inspection using criteria contained in this program. Investigators who conduct importer inspections must be specifically trained in seafood HACCP. They will review importer documentation which is used as a means to ensure evaluate compliance with the Act. Copies of foreign processor's HACCP plans that in the opinion of the investigator appear to be non-compliant with the Act must also be collected when available. That information will provide a basis for future inspections of foreign processors.

Importers who also operate as domestic processors will be evaluated, with regards to their processing activities, under instructions provided in the Domestic Fish and Fishery Products Compliance Program CP 7303.842.

Evaluating the importers' verification procedures and documents during inspection of importers or review of verification documents when they are requested as a condition of reconditioning application approval can only be performed by HACCP trained personnel. These individuals **must** have completed a three (3) day Seafood HACCP Alliance course and two (2) day Seafood HACCP Regulator course, or their equivalents.

### PROGRAM MANAGEMENT INSTRUCTIONS

#### A. Resources

Resources shown in the ORA Work plan for this Compliance Program can be used to cover PMS 03, 07 and 09 use the guidance provided in this program, as well as PMS 21. However, the field should keep operations for Food Labeling and Economics to a minimum.

These resources in the workplan should be used to carry out entry reviews, field exams, sample collections, sample analyses, inspections of importers for verification of HACCP and special collection

assignments.

## B. Product Risk-Potential

This program contains a prioritized list of high potential risk seafood products based on the health hazard they may pose to consumers. The risk status is determined by a combination of the severity of the hazard, its likelihood of occurrence, and previous industry compliance data. These products have a high priority for sample collection and analysis and import field examinations.

1. High-Risk Potential Products in descending order of priority:

   For purposes of this program high-risk potential products are:

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

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

      Reduced 0xygen Packaging (ROP)is oxygen impermeable or oxygen limiting packaging that reduces the transmission of oxygen to unsafe levels (less than 10,000 cc/$m^2$/24 hours)or prevents the transmission of oxygen In addition to hermetically sealed or canned goods requiring refrigeration, packaging where oxygen has been manually or mechanically expressed (vacuum), lidded goods with heat sealed inner films, or deep containers that provide sufficient volume to prevent the exchange of oxygen throughout the package are included in this category.

      Note: Raw, refrigerated fisheries products are covered under Import Alert 16-125. Import Alert 16-125 includes an exemption for certain firms to import raw refrigerated, reduced oxygen packaged products into the United States.

   b. Raw (fresh and fresh frozen) molluscan shellfish from uncertified shippers

      These products are primarily covered by the Molluscan Shellfish Evaluation program, CP 7318.004. Raw molluscan shellfish that are in interstate commerce and have not been processed in a certified facility (i.e., listed in the Interstate Certified Shellfish Shippers list) should be referred to the state shellfish control authority.

      Coverage is provided for these products under this compliance program only when the appropriate state authority cannot or will not provide coverage under the terms of the National Shellfish Sanitation Program. If a notified state authority does not take action to embargo or seize shellfish from uncertified shippers, the District should notify CFSAN, OC, HFS-606, Ronald Pace (301) 436-1742, for further assistance.

The major concern is source and handling controls to prevent contamination. Active shellfish MOU countries are Canada, Chile, Mexico, New Zealand, and South Korea. These MOU's enable the countries to certify their facilities.

c. Ready-to-eat fish or fishery products using any of the following processes:

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

(2) hot or cold smoking process

The major concern is proper processing to prevent toxin formation by ***Staphylococcus aureus*** and illnesses related to possible post-process pathogens, including ***Listeria*** and ***Salmonella that*** will not be destroyed in a cooking step prior to consumption by the consumer.

d. Seafood mixes: Combination of seafood products either all raw, all cooked, or a mixture of raw and cooked product

The major concerns are the inclusion of raw molluscan shellfish from non-MOU sources, and cooked products that have not received an adequate cook.

e. Scombrotoxin-forming (histamine-forming) species (in descending priority):

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

**NOTE:** Preformed scrombrotoxin in tuna used for canning is not eliminated or reduced by the canning process or by acidification, and is covered by this compliance program, C/P 7303.844, rather than by the Import Acidified and Low Acid Canned Foods, 7303.003.

f. Aquacultured seafood

The major concern is the use of unapproved chemotherapeutics in aquacultured fisheries products. Note samples to be collected only under the Chemotherapeutics in Seafood Compliance Program CP 7304.018.

g. Stuffed seafood products

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

h. Ready-to-eat fish or fishery products that have not undergone a heat treatment (such as caviar, urchin roe, or

raw fish intended for sashimi/sushi) that are meant to be consumed raw

The concerns are that these products are subject to the growth of pathogens that will not be destroyed in a cooking step prior to consumption by the consumer and viable parasites may be present.

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

This type of product is a potentially life-threatening acute health hazard because of the possible presence of ***C. botulinum*** toxin.

Examination of any dried head-on fish should determine if the fish is un-eviscerated and if so, if the length of the fish exceeds 5 inches. See Import Alert # 16-74, Detention Without Physical Examination of Salt-Cured Uneviscerated Fish for guidance.

j. Acidified and low acid canned foods (LACF)

This program covers species related hazards, such as histamine formation or parasites, in these products (e.g., scrombrotoxin in canned tuna). The Import Acidified and Low Acid Canned Food Compliance Program CP 7303-003 covers the safety hazards associated with the formation of ***Clostridium botulinum*** toxin.

2. Low-risk Potential Products

For the purposes of this program, low-risk products include all other fish and fishery products not listed as high-risk.

Note: When low-risk products are sampled, they should be analyzed for the problem that presents the greatest potential health hazard. For example, when raw shrimp are sampled, they should be analyzed for undeclared sulfites rather than for ***Salmonella.***

3. Other hazards

The following hazards when detected should be included on the FDA form 483, Inspectional Report:

Allergens
Environmental Chemical (including Methyl Mercury)
Glass Inclusion
Metal Inclusion
Pesticides

## C. Program Priorities for Sampling

OASIS screening criteria have been adjusted to allow the entry reviewers to electronically examine more entries of the high-risk potential products. Consequently, the Districts' accomplishments for the ORA WorkPlans are expected to include a greater percentage of high-risk potential products.

The following list should be used to determine which entries in each seafood product priority grouping (in Section B, 1 & 2 above) to examine first:

1. Entries of product from problem importers, i.e., importers associated with multiple entries previously found to have safety defects

   The field may use their discretion to collect and follow-up on other products from these importers that they have reason to suspect may not be in compliance.

2. Entries of product from specific foreign processors or shippers previously found to have safety defects

   The field may use their discretion to collect and follow-up on other products from these establishments that they have reason to suspect may not be in compliance.

In order to gain sufficient information to determine if a country-wide or geographic-wide problem exists, CFSAN may issue special assignments that will mandate the collection of samples which will take preference over other sampling under this program.

## D. Importer Inspection Priority Criteria

Use the following priority selection criteria to determine which importers to inspect first:

1. Follow-up to physical samples of high risk potential product imported by the importer, in which safety defects were detected

2. Reinspection of importers that had, during their previous HACCP inspection, deviations that if left uncorrected, could jeopardize the integrity of the HACCP system

3. Inspection of importers of high risk potential products for which a foreign inspection raised concerns about their affirmative steps

4. Previously uninspected importers of high risk products

5. Previously uninspected importers of low-risk products

## E. Importer HACCP Inspection Frequency

The number of importer inspections is directed in the ORA workplan.

Please perform # of the number of planned inspections in the ORA Workplan at Importers that average 100 or more entry line items per year. The remaining # of the number of planned inspections should be made at importers that import less than 100 entry line items per year.

Those districts that have few importers who average 100 or more lines per year should inspect those importers that have the highest number of entries per year.
Work with District Compliance Officers to identify problem importers who do not appear to appropriately assure the compliance of products they import.

## F. FDA Import Seafood HACCP Report (FDA 3502)

A separate FDA Import Seafood HACCP Report (FDA 3502) is to be completed for each product, foreign processor, importer combination evaluated during the importer inspection. Always cover high-risk potential products before covering low risk potential products as described above.

These two-copies, multi-page forms, specifically printed for use with the Cardiff system, will be supplied to the field in bulk. It is necessary that the original of each set (which will be identified as District copy) be used for Faxing purposes.

After the inspection has been endorsed, the form should be faxed to the dedicated FAX number: (301) 436-2885. The District copy should then be attached to the file copy of the EIR. Only in the event that an office is unable to FAX the report to the Dedicated FAX number, should the original, after retaining a copy in the District office, be sent to:

FOOD AND DRUG ADMINISTRATION
CFSAN/Office of Seafood, HFS-417
ATTENTION: Roselle King
5100 Paint Branch Parkway
Collage Park, MD 20740

&

## G. Interaction with Other Programs/Assignments

1. Import Acidified and Low Acid Canned Foods, 7303.003

   Resources expended on inspections of firms for compliance with the low acid canned foods regulation (21 CFR 113) or the acidified foods (non-perishable) regulation (21 CFR 114) for imported seafood, must be reported under PACs 03003 and 03003A, respectfully. Inspectional coverage of acidified or canned imported seafood related to safety hazards other than *C. botulinum*, (e.g., histamine, food and color additives, or decomposition) is to be reported under this program, 7303.844.

2. Molluscan Shellfish Evaluation Compliance Program, 7318.004

   The Molluscan Shellfish Evaluation program, 7318.004, covers fresh and fresh frozen molluscan shellfish, from certified shippers, evaluated under the cooperative agreement with the ISSC. That program includes shellfish originating from countries with which FDA has an active shellfish MOU, who are members of the ISSC by virtue of their MOU agreement.

   Instructions pertaining to shellfish offered for entry from uncertified shippers, either in a non-MOU country or an MOU country, is contained in this program, 7303.844.

3. Domestic and Import NLEA, Nutrient Sample Analysis and General Food Labeling Requirements Compliance Program – CP 7321.005

   NLEA coverage for imported seafood will be conducted under the PAC 21005.

4. Pesticides and Industrial Chemicals in Domestic and Imported

Foods, 7304.004

Coverage will be directed under CP 7304.004 to determine pesticide residues and will be directed toward countries and products for which there is little or no information from previous years' sampling, and toward those countries which have a violative history of pesticide or chemical contamination of seafood offered for entry.

5. Toxic Elements in Foods and Foodware, and Radionuclides in Foods, Domestic and Import, 7304.019 and related assignments

   Coverage will be directed under CP 7304.019 to develop broader background level data of certain toxic elements (e.g., lead, cadmium, mercury) in foods, including imported seafood.

6. Chemotherapeutics in Seafood Compliance Program CP 7304.018 and related assignments

   Coverage of seafood products for aquaculture drugs will be directed under CP 7304.018

## PART III - INSPECTIONAL

### A. References

For inspectional guidance and procedures, investigators are advised to refer to the appropriate references:

- 1997 Seafood HACCP Regulator Training Program Manual (HRTM) - HACCP inspection procedures/activities
- Fish and Fishery Products Hazards and Controls Guide (HCG) - Hazards and recommended controls in seafood processing current edition
- FDA Inspectional Methods, October 1996 (Interim Guidance) (IMIG) sampling guidance and reporting
- Investigations Operations Manual (IOM)
- Regulatory Procedures Manual (RPM), Chapter 9, Import Operations and Actions

### B. Import Entry Review

Districts may not routinely request foreign processor HACCP plans or certifications at the time of entry reviews of seafood products.

### C. Reconciliation Exams

An examination of the physical product to verify that it is consistent with declarations on entry documents with regard to the type and quantity of product. These exams should be performed consistent with instructions in the IOM or from the Division of Import Operations/HFC-170. Refer to IOM 530.04 at http://www.fda.gov/ora/inspect_ref/iom/ChapterText/530.04

### D. Field Exams

Field examination procedures are described in the IOM 505.03 at http//www.fda.gov/ora/inspect_ref/iom/ChapterText/500.html

### E. Sampling

1. General instructions

   The ORA Workplan for each fiscal year for the Import Seafood Products Compliance Program specifies the number of Import Sample Collections for each District. This number covers samples collected for analyses for safety hazards and for filth, non-scombrotoxic decomposition, and food and color additives.

2. Products to be sampled in descending priority:

   a. Entries of product from specific foreign processors or shippers previously found to have safety defects

      The field may use their discretion to collect and follow-up on other products from the parties that they have reason to suspect may not be in compliance.

   b. High Potential Risk products as defined in Part II:

(1) Refrigerated seafood products packed in reduced oxygen packaging (ROP)

(2) Samples of raw (fresh and fresh frozen) molluscan shellfish from uncertified shippers are not to be collected.

Refer all entries to the state shellfish authority.

(3) Ready-to-eat fish or fishery products using any of the following processes:

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

(b) hot or cold smoking process

(4) Seafood mixes

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

(6) Stuffed seafood products

(7) Ready-to-eat fish or fishery products that have not undergone a heat treatment (such as, caviar, urchin roe, or raw fish intended for sashimi/sushi) that are meant to be consumed raw.

(8) Do not sample salt-cured, and/or air-dried, un-eviscerated fish, such as Kapchunka, or bloaters. These are prohibited entry unless the processor is included in the exemption list for IA-16.74 and if listed, the district should contact CFSAN prior to collecting a surveillance sample.

(9) Acidified and low acid canned foods (LACF)

c. Entries of product from specific foreign processors previously found to have non-safety defects, i.e., decomposition in non-scrombrotoxin forming species, filth

d. All products not listed in a, b, & c above including low risk potential products

3. Sample collection instruction (number of subs, sample quantities, etc.) can be found in Attachment A.

4. See Inspectional Methods (Interim Guidance) and the IOM for information relating to sample collections.

5. See Import Alerts for seafood products under DWPE and Import

Bulletins for special sampling considerations.

6. Submit samples to the District's servicing laboratory specified in the current year's ORA Field workplan. The servicing laboratory may change year to year.

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

F. Importer HACCP Inspections

Under the seafood HACCP Regulations, 21 CFR 123, importers are required to verify that foreign processors are in compliance with the Seafood HACCP Regulation, 21 CFR 123.12, 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 Importers

  or

- for document review as a precondition to approval of a reconditioning application for seafood products where there is an identified food safety concern

1. Importer HACCP Inspection

Criteria for the selection of importers to inspect are provided in Part II, Item B.2. "Importer Priority Criteria". Inspections of importers for compliance with the verification requirements of 21 CFR 123 should be performed in conformance with existing inspection procedures and include:

- the presentation of FDA credentials
- the issuance of a Notice of Inspection, FDA 482
- the issuance of Inspectional Observations, FDA 483, when warranted

Follow the procedures contained in Chapter 13 of the 1997 HACCP Regulator Training Program Manual for the specific details pertaining to the conduct of the HACCP inspection. These procedures include:

- determining the foreign source of each product to be covered during the inspection (e.g., is the product covered by an MOU or not)
- reviewing importers' written verification procedures;
- reviewing affirmative step documents and verification documents
- reviewing the product safety specifications; and
- documenting objectionable conditions

Cover as many products as practical under the inspection module provided in the ORA workplan. Products selected for coverage should be the high-risk products prioritized in Part II Item B.1. Product Priority List.

G. Hard Copy Reporting

1. FDA Form 483: Document all importer deficiencies relating to the HACCP Regulations on the FDA Form 483 consistent with guidance from TURBO and The Seafood HACCP Regulator training course.

   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 in the Fish & Fisheries Products Hazards & Controls Guidance book, then the failure to list the health hazard should be recorded on the FDA Form 483. It is not the importer's obligation to evaluate either the effectiveness of a HACCP plan's Critical Control Points (CCP) or other aspects of a HACCP plan. Forward a copy of the HACCP plan to OS/CFSAN for appropriate follow-up consideration with the foreign processor.

2. FDA Import Seafood HACCP Report (FDA 3502) Form

   A separate FDA Import Seafood HACCP Report (FDA 3502) form is to be completed for each product-foreign processor-importer combination evaluated during the importer inspection. Always cover high-risk potential products before covering low risk potential products as described above.

   These two-copies, multi-page forms, specifically printed for use with the Cardiff system, will be supplied to the field in bulk. It is necessary that the original of each set (which is identified as District copy) be used for faxing purposes.

   After the inspection has been endorsed, the form should be faxed to the #. The District copy should then be attached to the file copy of the EIR. Only in the event that an office is unable to FAX the report to the dedicated FAX number, should the original, after retaining a copy in the district office, be sent (overnight delivery) to:

   FOOD AND DRUG ADMINISTRATION
   CFSAN/Office of Seafood
   ATTENTION: Roshelle King; HFS-417
   5100 Paint Branch Parkway
   College Park, MD 20740

3. Establishment Inspection Report

   Narrative reports should describe:

   - the importer's HACCP verification procedures, and,
   - the HACCP-related deficiencies noted by the investigator(s):
     - in the importer's documentation and
     - in the foreign processor's documents

4. When the inspector reviews a foreign producer's HACCP plan that is, in the inspector's opinion, inadequate, the inspector **must** obtain a copy of the HACCP Plan. If the District concurs that the HACCP plan contains deficiencies, then the plan should be sent to:

   Food and Drug Administration
   CFSAN/Office of Seafood, HFS-417
   Attn: Dixie Kee
   5100 Paint Branch Parkway
   College Park, MD 20740

## PART IV - ANALYTICAL

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

The sections of this part are:

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

B Project 03: **Parasite**

C Project 03: **Decomposition**

D Project 03: **Microbiological**

E Project 04: **Chemical Contaminants**

F Project 07: **Natural Toxins**

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

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

- Servicing laboratories are not identified in this compliance program. Please consult the current workplan to determine the appropriate laboratory.

Note: As BAM and AOAC methods are updates, the most recent method should be used unless this compliance specifically states not to use updated methods.

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

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

**METHODOLOGY:** AOAC, 17th Ed., Chapter 16, Extraneous Materials: Isolation

JAOAC (Interim Official First Action Methods)

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

Macroanalytical Procedures Manual (MPM)

Note: No specific analytical method exists to determine filth in shucked shellfish; however, depending on the type of filth suspected, adaptations of methods described in the Macroanalytical Procedures Manual (MPM) and in the AOAC, 17th Ed., are appropriate.

**COMMENTS:** Subsamples should be examined individually and not composited.

**CONTACTS:** CFSAN, Office of Plant and Dairy Foods, Division of Natural Products, Microanalytical Branch, HFS-315, George Ziobro, (301/436-1965).

**REPORTING:** Report all results of analytical results in FACTS using Problem Area Flag: FIL and PAC 03844B

B. **PARASITE ANALYSIS**

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

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

1. **Parasite Identification**

Fix parasites as described in BAM and contact Dr. William Jones at (301) 436-1422 to determine where to send them.

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

2. **Report**

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

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

**C. DECOMPOSITION ANALYSIS**

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

**METHODS:** Indole: AOAC, 17th Ed., 981.07, Section 35.1.35, liquid chromatographic fluorometric method.

Histamine: AOAC, 17th Ed., 977.13, Section 35.1.32, fluorometric method

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

Products that have been treated with chemicals or additives, that have no obvious odors of decomposition or where odors may have been masked, should be chemically analyzed for decomposition where chemical indicators of decomposition are applicable. CFSAN's Office of Seafood's Washington Seafood Laboratory at MOD1 (HFS-426) can be consulted for appropriate testing methods and applications. The director of this laboratory is Sherwood Hall at 301-210-2160.

**REPORTING REQUIREMENTS:** Enter all analytical results including organoleptic results into FACTS using PAF DEC and PAC 03844C.

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

**ANALYSIS REQUIREMENTS ARE SPECIFIC FOR PRODUCTS AS FOLLOWS:**

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

   a. **ORGANOLEPTIC EXAMINATION**

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

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

Note: Processed products include cooked, canned, and/or

treated with chemicals or additives, including such things as salt, chlorine, smoke, and carbon monoxide. Dried products and sauce/paste products are not included; CFSAN's Office of Seafood, Washington Seafood Laboratory at MOD1 (HFS-426), should be consulted if decomposition analysis is indicated for dried or sauce/paste articles.

(1) Positive Findings:

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

- An analyst qualified for confirmatory examinations in the appropriate product category as found in ORA's "Sensory Analysts ID List"

  or

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

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

  or

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

(2) Negative Findings:

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

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

b. **HISTAMINE ANALYSIS**

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

examination.

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

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

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

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

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

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

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

c. **Criteria for Regulatory Action: Based on analytical data, refer to CPG 540.525.**

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

a. **ORGANOLEPTIC EXAMINATION:**

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

Note: Processed products include cooked (including pasteurized), canned, and/or treated with chemicals or additives. Product treated with sulfites or phosphates may be considered raw unless the compounds are used in excessive levels in efforts to mask decomposition. Dried products and sauce/paste products are not included; CFSAN's Office of Seafood, Washington Seafood Laboratory at MOD1 (HFS-426), should be consulted if decomposition analysis is indicated for dried or sauce/paste articles.

(1) Positive Findings:

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

- An analyst qualified for confirmatory examinations in the appropriate product category as found in ORA's "Sensory Analysts ID List" maintained by Office of Field Science, HFC-140

or

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

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

or

- Indole analysis

  When confirming positive organoleptic results by indole analysis, analyze a minimum of six subsamples for indole including the subs exhibiting odors of decomposition. The remaining subsamples should be analyzed if indole is detected at 15-24 micrograms /100 grams for shrimp or 20-29 micrograms /100 grams for crabmeat products in any of the initial six subsamples. Additional subs need not be analyzed if two or more subsamples are found to contain 25 micrograms indole/100g or more in shrimp or 30 micrograms indole/100g or more in crabmeat.

(2) Negative Findings:

- If the sample does not exhibit odors of decomposition, or if only one subsample is determined to have odors of decomposition, an indole analysis of at least six subsamples is recommended. The remaining subsamples should be analyzed if indole is detected at 15-24 micrograms /100 grams for shrimp or 20-29 micrograms /100 grams for crabmeat products in any of the initial six subsamples. Additional subs need not be analyzed if two or more subsamples are found to contain 25 micrograms indole/100 grams or more in shrimp or 30 micrograms indole/100 grams or more in crabmeat.

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

b. **INDOLE ANALYSIS**

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

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

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

**Check Analysis:** When two or more subsamples contain indole at or above 25 micrograms/100 grams in shrimp or 30 micrograms/100 grams in crabmeat products, a check indole analysis should be performed on a minimum of two subs showing the highest indole levels using the composites utilized for the original indole analysis. Check analysis of indole findings is also warranted for product with one subsample failed for odors of decomposition and one subsample failed for indole levels.

c. **CRITERIA FOR CONSIDERATION OF REGULATORY ACTION:**

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

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

a. **ORGANOLEPTIC EXAMINATION:**

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

Note: Processed products include cooked, canned, and/or treated with chemicals or additives, including such things as salt, chlorine, and carbon monoxide. Product treated with sulfites or phosphates may be considered raw unless the compounds are used in excessive levels in efforts to mask decomposition. Dried products and sauce/paste products are not included; CFSAN's Office of Seafood, Washington Seafood Laboratory at MOD1 (HFS-426), should be consulted if decomposition analysis is indicated for dried or sauce/paste articles.

Positive Findings:

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

- An analyst qualified for confirmatory examinations in the appropriate product category as found in ORA's "Sensory Analysts ID List" maintained by the Division of Field Science, HFC-140

or

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

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

b. Criteria for Regulatory Action: Based on analytical data, refer to CPG 540.575.

**D. Project 03: MICROBIOLOGICAL ANALYSIS**

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

**NOTE:** Confirmation tests for *Clostridium botulinum*, which require animals, will be performed at SRL and PRL-NW.

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

**GENERAL METHODOLOGY:**

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

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

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

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

**SPECIAL METHODS INSTRUCTIONS**

1. ***Escherichia coli***

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

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

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

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

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

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

b. **Compositing/Sample Preparation Instructions**

*Listeria* analysis will be performed on ready to eat food products that require minimal or no further processing by the consumer.

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

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

Use the following procedure for preparing each composite:

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

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

Once the two composites have been prepared, remove 25 g or mL from each composite for analysis. Mix the 25 g or mL with 225 mL *Listeria* enrichment broth.

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

c. Incubate EB (enrichment broth) mixture according to BAM instructions for a total of 48 hours at 30° C. Proceed with BAM, Chapter 10, Section D. Isolation Procedure.

3. ***Salmonella***

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

b. **Speciation**

If positive for *Salmonella*, prepare BHI slants and provide hardcopy information requested under BAM, E. 11. and send **under seal** for speciation. Prior to sending the slants, please notify recipient by either phone or FAX.

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

Arkansas Regional Laboratory
3900 NCTR Rd., Bldg. 26
Jefferson, AR 72079
Attention: Gwendolyn Anderson

Tel# 870-543-4624

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

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

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

4. ***Staphylococcus aureus***

a. Examine individual subsamples

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

c. Enumeration

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

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

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

**5. *Staphylococcal* enterotoxin Determination**

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

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

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

Follow methodology outlined in the memo **Revised Guidance for**

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

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

a. **General Instructions**

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

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

b. **Methods**

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

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

*Vibrio parahaemolyticus*: Isolation, identification, and enumeration.

*Vibrio vulnificus*: Isolation, identification, and enumeration.

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

(2) If the sample was found to be positive for *Vibrio cholerae*, notify Mahendra Kothary at (301) 827-8616 or (301) 827-8606 and send one set of ALL isolates of *Vibrio cholerae* O1 or non-O1 to the following address for confirmation:

FDA/CFSAN/Division of Virulence Assessment, HFS-025
ATTN: Mahendra Kothary
MOD-1 Facility
8301 Muirkirk Road
Laurel, MD 20708

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

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

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

**NOTE: For products with potential inhibitory effect of the PCR reaction (e.g., oyster, raw shrimp, products with possible high**

**concentration of microflora) APW Lysate composites will be prepared from the original 1:100 APW dilutions.**

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

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

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

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

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

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

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

a. Examine 10 individual subsamples.
b. Use BAM, *Clostridium botulinum*,

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

a. **WATER PHASE SALT**

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

AOAC, 17th Ed., 952.08, Sec. 35.1.13.

**Note:** The above method uses asbestos fibers. In lieu of asbestos fibers, use 10 g of sand.

(2) Water Phase Salt

AOAC, 17th Ed., 937.09, Sec. 35.1.18

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

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

b. **NITRITE**

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

(1) Examine individual subsamples (10).

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

2) AOAC, 17th Ed., 973.31, Sec. 39.1.21

c. Special test for **pickled seafood labeled keep refrigerated**: Check pH. If the pH is greater than or equal to 4.6, check for water phase salt and for nitrite concentration in ppm as above. If pH is less than 4.6, no further analysis is required.

**9. Molluscan Shellfish Sample Preparation**

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

Sample Preparation/Method for Microbiological Analysis

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

For each subsample:

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

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

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

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

e. The remaining approximate 100 g meat homogenate will be blended with 100 mL sterile buffered phosphate water or 0.5%

sterile peptone water for 60 sec. This homogenate will be used for APC, coliforms, fecal coliforms and *E. coli.*

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

**E.** Project 04: **CHEMICAL CONTAMINANTS**

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

For WATER PHASE SALT and NITRATE, see Part IV, section D, 8a and 8b of this program.

**F.** Project 07: **NATURAL TOXINS**

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

**General Sample Preparation**

a. Molluscan Shellfish:

Each subsample will be homogenized and analyzed separately.

b. **Scallops:**

For **each** subsample, separate the adductor muscle from the viscera. The viscera portions will be homogenized and analyzed separately.

c. **Crustaceans:**

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

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

The viscera/head portions will be homogenized and analyzed separately.

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

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

2. **PSP Sample Preparation/Method**

See AOAC, 17th Ed. (or as updated), 959.08, Sec. 49.9.01.

Each subsample will be homogenized and analyzed separately.

Laboratories can obtain a PSP standard through Sherwood Hall, HFS-426 (301) 210-2160.

If you do not have 100 grams of sample, please call Sherwood Hall at (301) 210-2160 at CFSAN to discuss how to use a smaller sample amount.

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

a. ASP Methodology:

Sample Prep:
(1) Weigh out homogenized sample (10g or more)

(2) Add equal weight of water.
(3) Blend thoroughly
(4) Boil 5 Min
(5) Reweigh to obtain final weight to calculate dilution factor.(final weight/initial weight sample=dilution factor)
(6) Centrifuge
(7) Filter (0.22u to 0.45u)
(8) Inject in HPLC

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

HPLC conditions:

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

If there any questions about the method, contact Sherwood Hall at (301) 210-2160 or Stacey Etheridge at (301) 210-2163.

b. Each subsample will be homogenized and analyzed separately. For bivalve mollusks, the entire animal should be homogenized. For other animals, homogenize only the viscera.

4. **REPORTING**

Results should be entered into FACTS using the PAF of "BIO" and PAC 07844

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

- Greater than. 80 micrograms/100 g paralytic shellfish poison in molluscan shellfish
- Greater than. 80 micrograms/100 g paralytic shellfish poison in the edible portion for seafood products other than molluscan shellfish
- Greater than 20 ppm domoic acid, except in the cases of Dungeness crab viscera, where the level is greater than 30 ppm.

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

**ANALYZING LABORATORIES**

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

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

**Analytical Methodology**

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

1. Color Additives

Refer to color instructions 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 JADAC 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 with out prior approval from CFSAN.

2. Sample Preparation for Food Additives

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

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

FRESH Shrimp/Prawns - Remove and discard shells.

b. Compositing:

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

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

3. Methods for Food Additives

a. AOAC, Official Methods of Analysis, 17th Edition, Chapters 47 and 48.

b. Food Additives Analytical Manual, Vol. I and II, 1983 and 198

c. Food Chemicals Codex, 3rd Edition.

d. Nitrites Examine individual subsamples (e.g., 10). Use AOAC, 17th. 973.31, Sec. 39.1.21.

e. Sulfites in Shrimp

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

f. Sulfites In tuna

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

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

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

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

Each laboratory may choose to use the Optimized Monier-Williams Method (Method #990.28. AOAC Official Methods of Analysis, 17th Ed.) for the original and check analysis. If the results are < 10 ppm, no further analysis is needed.

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

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

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

4. Reporting

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

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

| | |
|---|---|
| 09844E | Color Additives |
| 09844F | Food Additives |

Use PAF:

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

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

**With a shrinking resource base, economics work, including seafood economics, is viewed as low priority by CFSAN and no resources have been allocated for this work in the field workplan. While some field activities in the food economics area may be necessary, districts should hold resource expenditures in this area to a minimum. The Program Assignment Code (PAC) for seafood economics, 21844, will remain in effect and the field should continue to report these activities when performed.**

**If a district plans any economic work, they must first obtain DIOP concurrence.**

FACTS REPORTING REQUIREMENTS:

A. Report resources utilized for all operations except for Fair Packaging Labeling Act (FPLA) against PAC 21844.

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

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

## PART V - REGULATORY/ADMINISTRATIVE STRATEGY

Inspections of importers and sample analysis may identify both HACCP and non-HACCP deficiencies. In instances where a district believes that a fish or fishery product poses an imminent public health hazard, the district should contact CFSAN/OC to discuss an appropriate regulatory response.

### A. Sample Evaluation

This program applies to imported fish and fishery products to address deficiencies that relate to the FD&C Act and other regulations under the Act that relate to food safety, sanitation, wholesomeness, and labeling, including nutrition labeling.

Districts should refer to relevant CPGs in determining appropriate regulatory follow up to analytical results reflecting possible deficiencies.

1. Reconditioning:

   If an article is subject to refusal and the owner or consignee applies to recondition the product, the conditions specified in 21 CFR 1.94 (b), 1.95 and 1.96 must be met.

   If an article is refused due to the presence of a safety-related adulteration or misbranding and the applicant applies to recondition the product, the applicant should include the foreign processor's HACCP plan(s) associated with the processing of the detained product along with the reconditioning proposal (FD-766).

   Individuals performing the review of a foreign processor's HACCP documents obtained during the reconditioning application process must be HACCP trained, i.e. must complete the Seafood HACCP Alliance 3-day course or its equivalent and the two-day FDA Seafood HACCP Regulator training course.

   NOTE: When the entry is refused due to a safety issue, the District should schedule an inspection of the importer to determine whether the importer's affirmative step is adequate to control that and other hazards.

2. Recommendation for Addition to an Import Alert for Detention Without Physical Examination (DWPE)

   a. Recommendations for DWPE can be made to the Division of Import Operations and Policy (DIOP) without reference to CFSAN only for Ready to Eat Seafood contaminated with either *Salmonella* or *Listeria,*

   b. All other DWPEs recommendations must first have CFSAN concurrence before recommending, to DIOP, the placing of the combination *Foreign Processor and Product* on DWPE on the appropriate Import Alert.

3. Center's Regulatory Contacts:

   Districts should contact one of the following Compliance Officers in the Import Branch for discussion concerning seizures, injunctions, or prosecutions under this program:

Import Branch, Division of Enforcement (301) 436-2413

The Import Branch will coordinate the discussions with appropriate staff in the Office of Seafood.

**B.** Importer Inspections:

One of the goals of this program is to obtain sufficient evidence to support broad-based enforcement strategies. These would include Import Alerts for Detentions Without Physical Examination (DWPE) for importers, shippers, manufacturers, and countries. We request the field to be aware of detention patterns that could develop into broad-based DWPEs and notify CFSAN, Imports Branch Chief and/or the Regulatory Contact when these situations arise. For example, Districts should consider recommending more stringent enforcement action against problem importers when importers do not appropriately assure the compliance of products they import. Chapter 9 of the Regulatory Procedures Manual contains a section on Priority Enforcement Strategy for Problem Importers (http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9strat.html). The Center intends to refocus its enforcement efforts on Problem Importers to assure they assume appropriate responsibility for the commodities they import. The Center will routinely review import data to identify problem importers that may warrant increased observation and firm based enforcement. CFSAN will consider field assignments to conduct additional sampling and analyses to meet detention criteria for DWPE actions. See the RPM (http://www.fda.gov/ora/compliance_ref/rpm/) for DWPE criteria and procedures.

Dealing with inadequate Foreign Processor HACCP Plans is the responsibility of CFSAN's Office of Seafood: When an importer uses maintaining on file a copy, in English, of the foreign processor's HACCP plan as part of Affirmative step D [21CFR 123.12(a)(2)(ii)(D)]., if the investigator when reviewing the HACCP plan of the foreign processor, determines that the plan is inadequate; and the District concurs, then the District should advise CFSAN, OS, Programs and Enforcement Branch, HFS-417. In such situations, all future correspondence follow up directed to the foreign processor will be initiated by CFSAN.

The District Compliance Branch may utilize any of the actions listed below to either bring the importer into compliance or to eliminate an imminent health hazard.

1. Untitled Letters

2. Warning Letters:

3. Detention without Physical Examination based on Inspectional findings:

C. Regulatory Guidance - Sources

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

1. Appropriate Regulatory Action

To determine whether the districts have been given direct reference authority for detention or whether a detention recommendation must be submitted to CFSAN, consult the Compliance Policy Guides/Code of Federal Regulations listed below:

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

DECOMPOSITION

Sec. 540.375 Canned Salmon - Adulteration Involving Decomposition (7108.10)
Sec. 540.525 Decomposition and Histamine - Raw, Frozen Tuna and Mahi mahi; Canned Tuna; and Related Species (7108.24) (for import products in Domestic Status)
Sec. 540.575 Fish - Fresh and Frozen - Adulteration Involving Decomposition (7108.05)

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)

MICROBIOLOGY

Sec. 540.275 Crabmeat-Fresh and Frozen-Adulteration with Filth, Involving Presence of (E. coli) (7108.02)
Sec. 540.420 Raw Breaded Shrimp - Microbiological Criteria for Evaluating Compliance with Current Good Manufacturing Practice Regulations (7108.25)
Sec. 540.650 Uneviscerated Fish Products that are Salt-cured, dried or Smoked (e.g., Kapchunka) (7108.17)
Sec. 555.300 Food Products- (*except* dairy products) Adulteration with Salmonella (7120.20). This CPG includes direct reference enforcement action criteria for Salmonella in *ready-to-eat* products only. The direct reference does not apply to Salmonella in seafood products that are not ready to eat. Cases involving Salmonella in raw food should be referred to CFSAN for case-by-case consideration.

NATURAL TOXINS

Sec. 540.250 Clams, Mussels, Oysters, Fresh, Frozen or Canned-Paralytic Shellfish Poison (7108.20)

NLEA

**NOTE:** NLEA coverage for imported seafood will be conducted under the Domestic and Import NLEA, Nutrient Sample Analysis and General Food Labeling Requirements Compliance Program – CP 7321.005.

NLEA Health claims related to fishery products that are authorized in the NLEA are:

- 21 CFR 101.73 Dietary Fat and Cancer
- 21 CFR 101.75 Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease

PARASITES

Sec. 540.590 Fish Fresh and Frozen, as Listed – Adulteration by Parasites 7108.06

FOOD ECONOMICS

**NOTE:** Districts are reminded to keep expenditures to a minimum in this area. No resources allocated in the ORA Field Workplan.

Consult with the Division of Enforcement, Import Branch, HFS-606 before preparing any enforcement action involving an economic issue.

4. Case-by-Case Regulatory Actions

In all other instances, contact one of the Center's Regulatory Contacts listed in Section V, *A.* of this Compliance Program. They will coordinate your questions within CFSAN.

a. PARASITES: In the absence of a DAL for unlisted species, CFSAN's Division of Enforcement, HFS-605, will consider enforcement action for parasites on a case-by-case basis.

b. MOLLUSCAN SHELLFISH

Molluscan Shellfish can be offered for entry into the United States by certified and non-certified shippers.

Foreign certified shippers of fresh and fresh frozen molluscan shellfish are evaluated under the Cooperative Agreement with the ISSC and covered by the Molluscan Shellfish Evaluation program, CP7318.004.

**Shellfish from uncertified shippers require special attention.** Uncertified shippers are those that are either in a non-MOU country, or they are shippers that are not certified by the Shellfish Control Authority in a MOU country (e.g., their own country). The Regional Shellfish Specialist and the District import staff should work together. They should contact the state shellfish control authority in the state where the shipment was offered for entry.

If a state chooses not to take action or seize shellfish

from uncertified shippers, the District should notify CFSAN, OC, HFS-606, Ron Pace (301)436-1742, for further assistance.

c. FOOD AND COLOR ADDITIVES

(1) Standard Instructions

Districts are authorized to detain a sampled lot without analysis if the product's labeling lists an illegal food and/or color additive in the ingredient statement. However, many ingredients may be GRAS, but are not listed under 21 CFR Part 182 or 184. Care must be taken to ensure that an ingredient actually is an illegal food or color additive before initiating regulatory action.

Illegal and/or undeclared colors are covered by Import Alert IA #45-02 (http://alpha.ora.fda.gov/www_fiars/files/ia4502.1st)

To determine the status of questionable food or color additives, Districts should contact, CFSAN/Office of:

- Food Additive Safety, Division of Petition Review, HFS-265 or
- Cosmetics and Colors, Division of Cosmetics and Compliance, HFS-125,Richard Jewell at 301-436-1345

When a district has determined a product meets the criteria for detention without physical examination, or the detention has been supported by CFSAN, HFS-606, a district recommendation should be prepared and submitted to ORO, Division of Import Operations and Policy, HFC-170, for inclusion in the appropriate import alert.

(2) Cooked Salad Shrimp

When FD&C Red No. 40 is used to color such a product, 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 21 CFR Section 101.22(k). If the district suspects that the product may contain undeclared FD&C Red No. 40, the product should be sampled and tested in accordance to guidance provided in Part IV, Section G.

Districts should be aware that the use of FD&C Red No. 40 is occasionally used to mask the characteristics of decomposition and that testing for decomposition may be appropriate for some products labeled as containing FD&C Red No. 40.

D. Reporting

Report compliance achievements/voluntary corrections into the Compliance Achievement Reporting System (CARS) once FDA has verified the correction, through written documentation from the firm or by inspectional observation.

## PART VI - ATTACHMENT, REFERENCES, AND PROGRAM CONTACTS

A. **ATTACHMENTS**

| Attachment | Description |
|---|---|
| A | Sampling Schedules |

B. PROGRAM CONTACTS

1. Center for Food Safety and Applied Nutrition

a. General Program Questions,

Andrea Lee Wade, Office of Compliance, Division of Field Programs, Compliance Programs Branch, HFS-636, (301) 436-2079, FAX (301) 436-2657

b. Compliance Matters

, Office of Compliance, Division of Enforcement, Import Branch, HFS-606, (301) 436-1622, Fax (301) 436-2657.

c. Seafood HACCP Questions

The Seafood HACCP Team, Phone - (301) 436-2601

d. Analytical Questions

- Color Additives Analysis
  Office of Cosmetics and Colors, Division of Color Certification and Technology, Color Technology Branch, Sandra Bell, HFS-106, (301) 436-1119

- Decomposition Analysis
  Office of Seafood, Division of Science and Applied Technology, Washington Seafood Laboratory Branch, Walter Staruszkiewicz, HFS-426, (301) 210-2165

- Filth Analysis
  Office of Plant and Dairy Foods, Division of Natural Products, Micro-analytical Branch, George Ziobro, HFS-301; (301) 436-1932

- PSP/ASP
  Molecular Biology and Natural Toxins
  Office of Seafood, Division of Science and Applied Technology, Washington Seafood Laboratory Branch, Sherwood Hall, HFS-425, (301) 210-2160

- Food Additives Analysis
  Office of Food Additive Safety, Division of Chemistry, Research and Environmental Review, Gregory Diachenko, HFS-245, (301) 436-1898

- Microbiological Analysis - General Questions Director, Division of Microbiological Studies, HFS-515, (303) 436-2007

- *Escherichia coli* (toxin, attachment, invasive) **and** *E. coli* LT/ST Enterotoxin

  Peter Feng, CFSAN/Office of Plant and Dairy Foods, HFS-516 at (301) 436-1650

- *Listeria monocytogenes* (isolation)

  Anthony Hitchins, CFSAN/Office of Plant and Dairy Foods, HFS-516, (301) 436-1649

- *Staphylococcus aureus*/Staphylococcal Enterotoxin

  Reginald W. Bennett, CFSAN/Office of Plant and Dairy Foods, HFS-516, (301) 436-2009

- *Salmonella*

  Wallace Andrews, CFSAN/Office of Plant and Dairy Foods, HFS-516 at (301) 436-2008

- *Vibrios: parahaemolyticus, vulnificus*, and *cholerae*

  Angelo DePaola, CFSAN, Office of Seafood (251) 690-3367 or Barbara McCardell Office of Science at (301) 827-8614

- *V. cholerae* PCR Methodology

  Dr. Barbara McCardell, Office of Science, Division of Virulence Assessment, HFS-327, 301-8278614.

- *C. botulinum*
-

  Richard Whiting, Office of Plant and Dairy Foods, HFS-516, at (301) 436-1925

- Parasite Analysis *and* Scallops - with added water or hygroscopic chemicals

  Office of Seafood, Clarke Beaudry, HFS-417, (301) 436-2503

- Species Substitution

  Office of Seafood, Division of Programs and Enforcement Policy, Spring Randolph HFS-416, (301) 436-1421.

2. Center for Veterinary Medicine (CVM) CONTACT

   Technical Inquiries for Chemotherapeutics: Fran Pell, CVM, DVCHD, Tissue Residue Branch, HFV-242, (301) 827-0188

3. Office of Regional Operations

   a. General Investigational and Importing Procedural Questions: Division of Import Operations and Policy, HFC-170,

Doug Randes, or Linda Wisniowski; (301) 443-6553, FAX (301) 594-0413.

b. General Analytical Questions:

Division of Field Science, HFC-140: (301) 827-7605, 7606

| | |
|---|---|
| • Decomposition (organoleptic & chemical) | Don Lech |
| • Filth and Decomposition | Larry D'Hoostelaere |
| • Food and Color Additives | George Salem |
| • Food Economics, Standards, Labeling | George Salem |
| • Microbiological (including tests for preservation) | Lydia I. Rosas-Marty |
| • Microanalytical (filth, mold, foreign objects) | Larry D'Hoostelaere |
| • Seafood Toxins (Natural Toxins) | George Salem |

## PART VII - CENTER RESPONSIBILITIES

Program Evaluation

The Office of Seafood, HFS-400, has the responsibility to prepare periodic formal evaluations of this compliance program. (&)

**IMPORT SEAFOOD PRODUCTS**

Table: Sampling Schedules Import Seafood Products Compliance Program
General Information for Sampling:

1. See the current ORA workplan for a list of the District servicing laboratories. Because of laboratory specialization, the analyses for some samples may be performed in different FDA laboratories. This will require either dividing the sample by the laboratory personnel, or collecting a duplicate sample by the investigator. This procedure should be worked out between the two branches prior to sample collection. See IOM shipping instructions for frozen samples and 452.6 for shipping instructions for refrigerated samples.

2. It may be necessary for the collecting District to collect additional (duplicate) subsamples for another servicing lab or for the national expert in seafood sensory testing for confirmation analysis. Contact the servicing laboratory to determine whether these additional subsamples are necessary.

3. It is important that all collections for Microbiological Analysis be made aseptically. It is necessary that analysis begin quickly after collection; therefore, please contact the servicing laboratory prior to collecting the sample. Additionally, frozen samples should be kept frozen prior to delivery to the lab and all other samples should be kept at refrigerated temperatures.

4. For decomposition: In those cases where extremely large fish are encountered and the sample cost incurred would be prohibitive, each subsample may consist of a minimum of 450 grams (1 lb.) transverse portion cut from the backbone to belly (do not include the belly flap)from the anterior end of one side of the fish. In the case of very large fish:
   - If a properly trained seafood sensory field investigator or a qualified seafood sensory analyst accompanies the investigator during sampling, the fish may be examined by using the drill method and the proportion of decomposed fish in the lot estimated. Collect 1 or 2 passable & a minimum of 3 decomposed fish for laboratory examination; or
   - Use a core or plug method to obtain a minimum of 454 grams of flesh per subsample from the anterior portion of the fish as described for the transverse section. (Sometimes the owner of the goods can cut out the desired samples using a band saw or other tool if aseptic technique is not required for the sample.)
   -

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

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

Table: Sampling Schedules Import Seafood Products Compliance Program
General Information for Sampling Continued:

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

   For species substitution – collect 12 fillets or steaks

   For overglazing: 48 subs, if available, from lot

   Breading Standards: Random, 1 sub from each case, if possible same lot.
   If package size is 10 to 20 ounces, 2 packages per sub and 10 to 30 subs.
   If package size is 454 grams to 2265 grams (1 lb. To 5 lb.) 1 package per sub, 10 – 30 subs
   If package size is 2265 (5 lb) or more, one package per sub and 3 – 15 subs.

7. References: Inspectional Methods (Interim Guidance) - IMIG, October 1996, Chapter 616, Fish and Fishery Products Investigations Operations Manual - OPM - including Chart 1 for Salmonella sampling54Fish & Fisheries Products Hazards & Controls Guide (FFPH&CG), current edition

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



FORM FDA 2438c (5/84)
779/89007 **COMPLIANCE PROGRAM – ATTACHMENT (11 X 8 1/2)**
U.S. GOVERNMENT PRINTING OFFICE: 1993 – 348-

Table: Sampling Schedules Import Seafood Products Compliance Program
General Information for Sampling Continued:

| |
|---|
| 9. Special instructions for sampling scrombrotoxin forming fish: If the product is chilled (e. g. with ice, gel ice, or refrigeration) but inadequate chilling is suspected, the temperature of the fish (deep flesh and near surface at the exposed portions) should be measured. Especially if any fish shows temperature over 40 F, sample the lot for organoleptic and histamine analysis. |
| 10. Do not request analysis for Listeria on products with PIC of B, C, or D unless there is reason to believe that the product ***will*** be consumed raw and in that case, it is necessary to explain that the product probably ***will*** be consumed raw in the remarks section of the collection report |
| 11. For decomposition: Processed products include cooked, canned, and/or treated with chemicals or additives, including such things as salt, chlorine, smoke, and carbon monoxide. Product treated with sulfites or phosphates may be considered raw unless the compounds are used in excessive levels in efforts to mask decomposition. Dried products and sauce/paste products should not routinely be sampled for decomposition. |
| 12. For decomposition: Import shipments often contain more than one line item based on attributes such as species, market form, size of pieces(count), package size (net weight), etc. Within a line item there may be multiple production codes. Generally, for surveillance purposes, it is recommended to collect a sample from a multi-code lot randomly as a commingled lot without isolation on a particular production code. However, the production code of each subsample should be documented if possible. If the shipment consists of numerous line items, more than one sample can be considered for collection. |
| 13. For decomposition, 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. |
| 14. Subsamples should generally be collected randomly to give the broadest representation of the lot (i.e. one subsample per carton/tote/container randomly selected from the lot). More selective sampling, i.e., less randomized representation, may be acceptable only when the collector has specifically identified that potentially violative product appears more likely to be isolated in a particular portion of the lot and the sample is collected for analysis of that violation. In these situations, the collection record should indicate the collector's observations, in addition to the sampling method. |

Table: Sampling Schedules Import Seafood Products Compliance Program
General Information for Sampling Continued:

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

A. The Center is prepared to move quickly against products containing banned, illegal, or improperly used food or color additives.
Past food additive problem areas include the following:

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

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

B. Cooked Salad Shrimp

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

C. Sample Collection

1. Food Additives

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

Canned Tuna for Sulfite Testing

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

2. Color Additives

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



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779/89007 **COMPLIANCE PROGRAM – ATTACHMENT (11 X 8 1/2)**
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TABLE: Sampling Schedules Import Seafood Products Compliance Program

| Seafood | Filth: Macro/ Microscopic 03844B | Filth: Parasites 03844B | Decomposition 03844C | Microbiological 03844D | Natural Toxins 07844 |
|---|---|---|---|---|---|
| FINFISH: | | | | | |
| Non-scombrotoxic species: Fresh raw or Frozen Raw Fish | | Fillets, steaks, loins, chunks, breaded portions<br><br>15 subs; 200g (7 oz.) per sub, excluding breading, glaze, etc.<br>If ea. piece. < 200g (7 oz). collect enough so 1 sub=200 g (7 oz). | 12 sub-samples. Minimum of 454 grams (1 lb) per sub | Note: only do micro on raw fish that is intended to be consumed raw.<br>General Micro.-10 individual fish, duplicate, same lot. Min 227g (8oz.) ea. (for all micro but *Salmonella*).<br>*Salmonell*a: 15 – 114g (4oz.) subs from same lot | Refer to Table #3-1, Chapter 6 in FFPHCG. Only collect samples of fish for which natural toxin is listed as a hazard.; or puffer fish for PSP<br><br>3 subs per sample; 227 grams (8 oz) meat per sub |
| Non-scombrotoxic Species:<br>Fish Blocks/Minced<br>Fish Blocks, Frozen | | Minced, to be processed further; not consumer size.<br>Collect 2 blocks. 18 subs. /lot. | 12 sub samples. Minimum of 454 grams (1 lb) per sub | General Micro: 10 - 227g (8 oz) subs from same lot.<br><br>*Salmonella:* 15 – 114g (4oz.) subs from same lot | |
| Non-scombrotoxic species: Bulk Fish: | | Do not collect fish in round for parasite analysis | 12 sub samples. Minimum of 454grams (1 lb) per sub | Same as fresh frozen. | |
| Non- scombrotoxin species other than salmon:<br>Cans or Retorted Pouches<br><br>If analyses to include decomposition, filth, standards and industrial chemicals, collect 120 cans. | Filth only:<br>If cans < =900 g (2 lb)<br>> 50 cases – 24 cans<br>50 cases or more – 48 cans<br>If cans > 900 g:<br>> 600 cases – 24 cans<br>600 cases or more – 48 cans | | 18 sub-samples, minimum of 6 ounces per sub; collect multiple cans or pouches per sub if less than 6 ounce size containers. | | |
| Canned Salmon | Filth only:<br>If cans < =900 g (2 lb)<br>> 50 cases – 24 cans<br>50 cases or more – 48 cans<br>If cans > 900 g:<br>> 600 cases – 24 cans<br>600 cases or more – 48 cans | | Do not sample for decomposition – canned salmon is examined under an arrangement with the Food Products Association.<br>If unordinary circumstances dictate the need to collect canned salmon for decomposition, collect 18 subsamples as per canned fish instructions | | |

TABLE: Sampling Schedules Import Seafood Products Compliance Program

| Seafood | Filth: Macro/ Microscopic 03844B | Filth: Parasites 03844B | Decomposition 03844C | Microbiological 03844D | Natural Toxins 07844 |
|---|---|---|---|---|---|
| Non- scombrotoxin species processed products other than canned/retorted pouches | | | 18 sub-samples, Minimum of 454 grams (1 lb) per sub | General Micro.-10 individual fish, duplicate, same lot. Min 227g (8oz.) ea. (for all micro but *Salmonella*).<br>*Salmonell*a: 15 – 114g (4oz.) subs from same lot | |
| Fresh raw or Frozen raw Scombrotoxic spec: (Tuna, mahi-mahi, amberjack, blue, mackerel, herring, sardines, etc.) Fillet or steak. | | | 18 sub-samples, Minimum of 454 grams (1 lb) per sub | Note: only do micro on raw fish that is intended to be consumed raw.<br>General Micro.-10 individual fish, duplicate, same lot. Min 227g (8oz.) ea. (for all micro but *Salmonella*).<br>*Salmonell*a: 15 – 114g (4oz.) subs from same lot | |
| Smoked or Salted Fish:<br><br>Seafood products packed in reduced oxygen packaging (e.g., vacuum packaging, modified atmosphere packaging, hermetically sealed containers,) including **smoked fish** and fresh fish in such packaging | | | 18 sub-samples (24 sub-samples if scombrotoxin-forming fish.) Minimum of 454 grams (1 lb) per sub | General Micro: Collect 10 subs from 1 lot. , 454g (1 lb.) each<br>If hermetically/vacuum sealed, take 10 additional. 454 g (1 lb) subs for *C. Botulinum*, unless original sub is greater than 900 g (2 lb)<br>*Salmonella*: 30 - 114g (4oz). subs from same lot. (Use only as follow-up to suspected poisoning.<br>For water phase salt determination & nitrites collect 10 subs, each 454 g (1 lb) | |

TABLE: Sampling Schedules Import Seafood Products Compliance Program

| Seafood | Filth: Macro/ Microscopic 03844B | Filth: Parasites 03844B | Decomposition 03844C | Microbiological 03844D | Natural Toxins 07844 |
|---|---|---|---|---|---|
| Canned or retorted tuna or other canned/retorted scombrotoxin-forming fish | Filth only:<br>If cans < =900 g (2 lb)<br>> 50 cases – 24 cans<br>50 cases or more – 48 cans<br>If cans > 900 g:<br>> 600 cases – 24 cans<br>600 cases or more – 48 cans | | 24 sub-samples, minimum of 170 grams (6 ounces) per sub; if the units are less than 6 ounces each, collect multiple cans/pouches per sub.<br><br>18 sub-samples when containers weigh more than 907 grams (2 lbs)<br>note: can lots can be commingled | | |
| Scombrotoxin-forming fish processed products other than canned/retorted pouches | Filth only:<br>If cans < =900 g (2 lb)<br>> 50 cases – 24 cans<br>50 cases or more – 48 cans<br>If cans > 900 g:<br>> 600 cases – 24 cans<br>600 cases or more – 48 cans | | 24 sub-samples, minimum of 454 grams (1 lb) per sub; | General Micro.-10 individual fish, duplicate, same lot. Min 227g (8oz.) ea. (for all micro but *Salmonella*).<br>*Salmonell*a: 15 – 114g (4oz.) subs from same lot | |
| CRUSTACEANS | | | | | |
| Crabmeat Frozen<br><br>Crab, cooked or pasteurized<br><br>Crab, whole raw<br><br>Crabmeat, canned | Frozen, cooked or raw: Collect 10 - 227g (8 oz) subs.<br><br>canned: Collect 6 cans, min. | | Whole cooked crabs or crabmeat: 18 subs,<br><br>Minimum of 454 grams (1 lb) per sub. (If in cans or plastic cups, minimum of 227g (8 oz) per sub.) | *E. coli*, 6 -227g (8oz.) subs in duplicate from same lot. [<br><br>General Micro:<br>10 - 227 g (8oz.) subs from same lot. If smallest size container > than 5 lbs, collect 3 containers<br><br>*Salmonella* for cooked, parboiled: 30 – 114g (4oz.) subs from same lot.<br><br>*Salmonella* for Fresh, Frozen: 15 – 114g (4oz.) subs from same lot. | If possible, collect whole raw crabs viscera intact.<br><br>If not available, collect cooked with viscera intact crab.<br><br>Collect 3 subs, min. 227g (8oz.) edible portion and 25 g viscera<br><br>If collected for ASP and PSP, double subsample size |

TABLE: Sampling Schedules Import Seafood Products Compliance Program

| Seafood | Filth: Macro/ Microscopic 03844B | Filth: Parasites 03844B | Decomposition 03844C | Microbiological 03844D | Natural Toxins 07844 |
|---|---|---|---|---|---|
| Lobster<br><br>Fresh, Frozen<br><br>Cooked, Parboiled<br><br>Whole, raw | 6 subs min. 900 g -1.36 kg (2-3 lb.) | | Fresh or Frozen Raw: 12 sub-samples. Minimum of 454 grams (1 lb) per sub.<br><br>Processed: 18 sub-samples. Minimum of 454 grams (1 lb) per sub. | General Micro: 10-227g (8oz.) subs from same lot.<br><br>*Salmonella* for cooked, parboiled: 30 – 114g (4oz.) subs from same lot.<br><br>*Salmonella* for Fresh, Frozen: 15 – 114g (4oz.) subs from same lot. | If possible, collect whole raw lobsters with viscera intact. If not available, collect cooked with viscera intact lobster.<br>Collect 3 subs, min. 227g (8oz.) edible portion and 25 g viscera. |
| Shrimp Canned | 48 cans/case;<br>‣200 cs,48 cans<br>>200 cs,96 cans<br><br>Collect (If several codes in lot, rep. ea code by min. 16 cans, sample enough codes to give # above. | | 18 sub-samples, minimum of 170 grams (6 ounces) per sub; collect multiple cans or pouches per sub if less than 6 ounce size containers | | |
| Shrimp<br>Cooked<br>Cooked, frozen<br>Fresh, peeled, raw<br>Fresh, raw<br>Frozen, peeled, raw<br>Frozen, raw<br>Whole, raw, fresh<br><br>in cooked shrimp, for: **Food and Color Additives 09844**, see item 11, page 3 of this attachment | 6 subs, min.900 g - 1.36 kg (2-3 lb.) per sub. | | Fresh or Frozen Raw: 12 sub-samples. Minimum of 454 grams (1 lb) per sub.<br><br>Processed: 18 sub-samples. Minimum of 454 grams (1 lb) per sub. | General Micro: 10 -227g (8oz.) subs in duplicate from same lot.<br><br>For *Salmonella*, if<br>Cooked<br>Cooked, frozen<br>Then: 30 subs @ 114g (4oz) from same lot.<br><br>For *Salmonella* if<br>Fresh, peeled, raw<br>Fresh, raw<br>Frozen, peeled, raw<br>Frozen, raw<br>Whole, raw, fresh<br>Then: 15 subs @ 114g (4oz) from same lot. | Whole Raw (Preferred): (Head and viscera), if possible. If not, collect whole, cooked with viscera and head intact. Collect 3 subs/sample. Min 227g (8oz.)/sub edible portion and 25 g viscera. |

TABLE: Sampling Schedules Import Seafood Products Compliance Program

| Seafood | Filth: Macro/ Microscopic 03844B | Filth: Parasites 03844B | Decomposition 03844C | Microbiological 03844D | Natural Toxins 07844 |
|---|---|---|---|---|---|
| Shrimp, Raw Breaded. | **Min. Of 6 subs, each** 900 g -1.36kg (2-3 lbs.). | | 18 sub-samples. Minimum of 454 grams (1 lb) per sub. | 16 - 150 gram (6 ounce) subs<br><br>For *Salmonella*: 15 -114g (4 oz.) subs from same lot. | |
| Shrimp, Freeze dried<br><br>Shrimp, Sun dried | Freeze dried: 6 subs, 250g (10 oz.)<br>Sun dried: 6 subs. 680 g (24 oz.) from same lot. | | Contact CFSAN's Office of Seafood, Washington Seafood Laboratory, Sherwood Hall at 301-210-2160 if decomposition analysis of dried products is indicated. | General Micro: 10 subs, 227g (8 oz) each from same lot.<br><br>*Salmonella*: 30 -114g (4 oz.) subs from same lot. | |
| Other Crustacean Products | 6 subs, 900 g - 1.36 kg (2-3 lbs)/sub. | | Fresh or Frozen Raw: 12 sub-samples. Minimum of 454 grams (1 lb) per sub.<br><br>Processed: 18 sub-samples. Minimum of 454 grams (1 lb) per sub. | 10 - 227 g (8oz.) subs | |
| **SHELLFISH:** | | | | | |
| Molluscan Shellfish | | | Raw Fresh or Raw Frozen: 12 sub-samples. Minimum of 454 grams (1 lb) per sub.<br><br>Processed: 18 sub-samples. Minimum of 454 grams (1 lb) per sub. (If canned/retorted, Minimum 170 grams (6 ounces) per sub.) | | |
| Molluscan un-Certified: Oysters, clams, mussels, Whole, roe-on scallops | 6 - 114g (4 oz) subs shucked product only. | | See Molluscan Shellfish | Collect aseptically: [See note in first column.<br><br>Med. Large in-shell (pacific oysters, surf and hard clams: 5 subs, 12 each, or enough to = 300 g meat and liquid. | Collect 3 subs/sample<br><br>Med. Large (in-shell) – Pacific oysters, surf and hard clams)<br>12 individual/sub. |

TABLE: Sampling Schedules Import Seafood Products Compliance Program

| Seafood | Filth: Macro/ Microscopic 03844B | Filth: Parasites 03844B | Decomposition 03844C | Microbiological 03844D | Natural Toxins 07844 |
|---|---|---|---|---|---|
| Note: Micro samples must be analyzed within 24 hrs of collections. Contact servicing lab prior to sample collection. | | | | Small (olympias, ostrea lurdia, little neck clams, mussels): Min. of 20. To give at least 300g (11 oz). meat & liquid.<br><br>Shucked: 5 subs - enough to give 300 g meat and liquid. Shucked product should be kept in same state as it is collected, i.e., either refrigerated or frozen.<br><br>Blocks: Core or quarter. | Sm. (in shell) - min. 12 individual - enough to provide. 20 g meat and liquid.<br><br>(Double if doing both ASP and PSP) |
| Scallops:<br><br>Canned<br><br>Fresh<br><br>Frozen<br><br>Shucked | Scallops, shucked: 6 subs 227g (8 oz) min. | | See Molluscan Shellfish | General Micro: 10 - 227g (8oz.) subs from same lot<br><br>*Salmonella*: 30 - 114g (4oz) subs from same lot for canned product<br>15 – 114 g (4 oz) subs from the same lot for fresh, frozen and/or shucked. | This work can only be done on whole scallops, collect 3 subs. Minimum 227 g (8 oz.)/sub edible portion plus 25 g viscera. |
| **OTHER/MISCELLANEOUS SEAFOOD:** | | | | | |
| Anchovies, Sardines, Etc. and uneviscerated fin fish to be consumed whole.) | 6 subs, 900 g - 1.36 kg (2-3 lbs)/sub. | | For scombrotoxin-forming species 24 subsamples<br>For non-scombrotoxin-forming species, 18 subs<br><br>If canned/retorted pouches: – 170 grams (6 ounces) per sub, collect multiple cans/pouches per sub if less than 6 ounce per container<br><br>For all other products: 450 gram (1 pound.) sub-samples | 10 - 227 g (8oz.) subs | 3 subs/sample. Min. 227g (8 oz)/sub edible and min. 25 g viscera. |

TABLE: Sampling Schedules Import Seafood Products Compliance Program

| Seafood | Filth: Macro/ Microscopic 03844B | Filth: Parasites 03844B | Decomposition 03844C | Microbiological 03844D | Natural Toxins 07844 |
|---|---|---|---|---|---|
| Squid<br>Processed Surimi analogs.<br>Seafood Salads<br>Stuffed, RTE<br>Stuffed, not RTE<br>Other Seafood Products that do not fit a specific category | 6 subs, 900 g - 1.36 kg (2-3 lbs)/sub.<br>. | | Raw Fresh or Raw Frozen: 12 sub-samples. Minimum of 454 grams (1 lb) per sub.<br><br>Processed: 18 sub-samples. Minimum of 454 grams (1 lb) per sub. (If canned/retorted, Minimum 170 grams (6 ounces) per sub.) | General Micro: 10 - 227 g (8oz.) subs<br><br>Salmonella for cooked, parboiled: 30 subs – 114 gram (4 ounce) subs<br><br>Salmonella for Fresh, Frozen : 15 subs - – 114 gram (4 ounce) subs | |