CHAPTER 03 - FOODBORNE BIOLOGICAL HAZARDS

SUBJECT:	**IMPLEMENTATION DATE**
IMPORT SEAFOOD PRODUCTS COMPLIANCE PROGRAM FY 01/02/03	UPON RECEIPT **COMPLETION DATE** 9/30/03

DATA REPORTING

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

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.

NOTES:

** The field is requested to keep ECONOMIC ACTIVITIES normally conducted for Import Seafood to a minimum.

GENERAL FOOD LABELING and NLEA coverage for imported seafood will be conducted under the Import NLEA, Nutrient Sample Analysis and General

Food Labeling Program (7321.007). **

A. PROGRAM ASSIGNMENT CODES (PAC) and OPERATION CODES (OPC)

The following PACs and OPCs are to be used for reporting time expended under this Compliance Program (C/P):

1. Inspections (Operations Code: 12)

03844H HACCP Inspection of Importers

2. Sample Collections, Audit Checks, Recalls, Field Exams (formerly Wharf Exams), and Investigations (Operations Codes: 33, 17, 18, 21, and 14)

03844 Foodborne Biological Hazards
07844 Natural Toxins
09844E Color Additives
09844F Food Additives

3. Sample Analyses and Label Review (Operations 43, 52)

03844B Filth
03844C Decomposition
03844D Microbiological (includes % water phase salt and nitrites)
07844 Natural Toxins
09844E Color Additives
09844F Food Additives

** 4. The following are new PAC codes for reporting purposes:

03R833 Entry Review
99R833 Filer Evaluation
04R824 Follow-up to Refusals

B. PROBLEM AREA FLAGs (PAF)

Problem Area	PAFs Collections	PAFs Analyses	
Filth	FIL	FIL	
Decomposition	DEC	DEC	
Parasites	PAR	PAR	
Microbiological	MIC	MIC	
Salmonella Speciation		SAL	
Percent (%) Water Phase Salt		SLT	
pH		NAR	
Natural Toxins	BIO	BIO	
Food Additives	FAD	FAD	
Color Additives	COL	COL	**

C. HARD COPY REPORTING TO CFSAN

The following hard copy reports should be submitted on an as completed basis to:

Food and Drug Administration
CFSAN/Division of Compliance
Import Branch, HFS-606

Attn: Angel Suarez
5100 Paint Branch Parkway
College Park, MD 20740

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

1. Inspections

For ***importer inspections*** that were ***classified*** as ***OAI***, submit the:

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

** 2. Violative Samples

For violative samples only, a hard copy of the Analytical Worksheets must be submitted as part of the case review package. **

3. Special HACCP **hard copy** Reporting

For all importer HACCP inspections, this compliance program utilizes a special reporting form, the FDA Import Seafood HACCP Report (FDA 3502), which is 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 (overnight delivery) to Angel Suarez at the address listed at the beginning of this section, **C. HARD COPY REPORTING TO CFSAN**.

PART I - BACKGROUND

This Compliance Program provides regulatory coverage of imported fish and fishery products to ensure a safe and wholesome supply of seafood entering the U.S. Historically, FDA has controlled imports by reviewing customs entries, conducting field exams, collecting samples for laboratory analysis, and placing products with a history of problems on detention without physical examination. This program addresses the control of pathogens, filth, parasites, decomposition, animal drugs, bio-toxins, and illegal food or color additives in imported seafood. These efforts continue under the present program, and are an important component of the import control strategy.

With the adoption of the Seafood Hazard Analysis Critical Control Point (HACCP) regulation, 21CFR 123, there is now a second component of the import control strategy. Thus the FY 01/02/03 regulatory priority for imported seafood focuses on ensuring the control of food safety hazards in imported seafood through the implementation of the Seafood HACCP Regulations. This regulation became effective December 18, 1997.

Under an 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 seafood HACCP Regulations. In addition, the HACCP Regulations require importers to take positive steps to verify that their shipments are obtained from foreign processors that comply with the regulation requirements.

This Compliance Program provides guidance for ensuring that importers have verified that the products they offer for entry were obtained from foreign processors that are in compliance with the requirements of the Seafood HACCP Regulations.

PART II - IMPLEMENTATION

OBJECTIVE

To ensure a safe and wholesome imported fish and fishery products supply to the U.S., by ensuring 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.

APPROACH

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

In the FY 01/02/03 Import Seafood Products Compliance Program, the Agency continues the inspection of importer HACCP verification activities. Importers will be selected for inspection for HACCP verification, using criteria contained in this program.

Evaluating importers' verification procedures and documents during inspection of importers or for 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 normally conducted for Food Labeling and Economic activities to a minimum.

These resources should be used to carry out entry reviews, field exams, sample collections, sample analyses, and inspections of importers for verification of HACCP.

B. Program Priorities

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NOTE: CFSAN has developed a list of high-risk seafood products because of the imminent health hazard they may pose to consumers. These products have a high priority for sample collection and analysis and import field examinations.

OASIS screening criteria has been adjusted to allow the entry reviewer to visually examine more entries of these High-risk products. Consequently, the Districts' accomplishments for the ORA Workplans are expected to include a greater percentage of high-risk seafood products.

The field may use their discretion to collect and follow-up on other products that they know are or may be violative. **

1. Product Priority List

The seafood product priority list below should be used to determine which entries to examine first:

a. Entries of product previously found violative for safety defects.

b. High-Risk products.

For purposes of this program high-risk products are:

**

- Seafood products packed in reduced oxygen packaging (e.g., vacuum packaging, modified atmospheric packaging, hermetically sealed containers) including cooked seafood, smoked fish, and fresh fish in such packaging. **

  Seafood in such packages is subject to growth of anaerobic bacteria, such as *C. botulinum*, or post-process pathogens.

- fresh and fresh frozen molluscan shellfish from uncertified shippers.

  The major concern is source and handling controls to prevent contamination. Active ** shellfish ** MOU countries are Canada, Chile, New Zealand, and South Korea.

**

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

  (1) heating 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 *Clostridium botulinum* or *Staphylococcus aureus* and infections by possible post-process pathogens, including Listeria. **

  The concern is that these products are subject to the growth of post process contamination by pathogens.

- scombrotoxin-forming (histamine-forming) species (in descending priority) such as:

  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).

NOTE: Scombrotoxin formation in canned tuna, is not eliminated or reduced by the canning process, and is covered by this compliance program, C/P 7303.844, rather than by the Import Acidified and Low Acid Canned Foods, 7303.003.

- salt-cured, air-dried, and uneviscerated 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. See Import Alert # 16-74, Detention Without Physical Examination of Salt-Cured Uneviscerated Fish for guidance.

- stuffed seafood products

  Processing/handling may allow toxin development.

c. Low-risk Products

For the purposes of this program, 7303.844, low-risk products include all other fish and fishery products not listed as high-risk products.

2. **Importers' Priority Criteria**

NOTE: Always cover high-risk products before covering low risk products as described in section B. Product Priority List 1.b. and c. (above).

Always perform re-inspections of importers that had (#) violations, before covering firms with (#) violations.

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

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

b. Reinspection of importers of high-risk products that had, during their initial HACCP inspection, **(#)** deviations (as per Attachment E), excluding parasites.

c. Follow-up to violative physical samples of Low-risk product imported by the importer, in which safety defects were detected.

d. Reinspection of importers of Low-risk products that had, during their initial HACCP inspection, **(#)** deviations (as per Attachment E).

e. Previously uninspected importers of first:
   - high-risk products, then
   - low-risk products.

f. Reinspection of importers that had, during their initial HACCP inspection, **(#)** deviations (as per Attachment E) for high-risk products.

g. Reinspection of importers of high-risk products that had, during their initial HACCP inspection, deviations related to the control of parasites in fishery products to be consumed raw.

h. Reinspection of importers of high-risk products whose last HACCP inspection was in compliance.

i. Reinspection of importers that had, during their initial HACCP inspection, **(#)** deviations (as per Attachment E) for Low-risk products.

j. Reinspection of importers of Low-risk products whose last HACCP inspection was in compliance.

C. Importer HACCP Inspection Frequency

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

Please inspect 90% of the number of planned inspections in the ORA Workplan at Importers whose average entry lists 100 or more lines per year. The remaining 10% of the number of planned inspections should be made at Importers who import less than 100 entry lines.

Those districts that have few Importers who average 100 or more lines per year, or no Importers who average 100 lines per year, should inspect those Importers who have the highest number of entries per year.

D. 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, and importer combination evaluated during the importer inspection.

These two-copy, 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 FDA office, be sent (overnight delivery) to:

FOOD AND DRUG ADMINISTRATION
CFSAN/DIVISION OF Compliance
IMPORT BRANCH, HFS-606
ATTENTION: Angel Suarez
5100 Paint Branch Parkway
Collage Park, MD 20740

E. 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. This import seafood compliance program provides guidance for performing HACCP inspections of importers of LACF and acidified seafood, as well as for other seafood, for compliance with the importer verification requirements of 21 CFR 123, the seafood HACCP Regulations.

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.

   Guidance 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. Nutrition Labeling and Education Act (NLEA) and General Labeling Requirements - Import Program (7321.007)

   NLEA coverage for imported seafood will be conducted under the PAC 21007.

4. Pesticides and Industrial Chemicals in Imported Foods, 7304.016

   Coverage will be conducted under 7304.016 to determine compliance with pesticide residue regulations 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, Domestic and Imported, 7304.019

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

F. Identification of a District Seafood Coordinator

** Each District **MUST** designate a District Seafood Coordinator to CFSAN/Division of Compliance, HFS-605, at the beginning of each fiscal year. **

PART III - INSPECTIONAL

A. References

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

- Seafood HACCP Regulator Training Program Manual (HRTM) - HACCP inspection procedures/activities
- Fish and Fishery Products Hazards and Controls Guide (HCG) - Recommended hazards and controls in seafood processing
- 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

For FY 01/02/03, districts should not request importer HACCP documentation at the time of entry review of seafood products:

- unless directed by this compliance program ,i.e. as a condition for approval of a reconditioning application, or
- the entry is specifically identified for coverage under Import Alerts 16-119 or 16-120.

C. Field Exams

Field examination procedures are described in the IOM.

D. Sampling

1. The ORA Workplan specifies the number of Import Sample Collections for each District. This number covers samples collected for analyses for filth, decomposition, microbes, natural toxins, and food and color additives. In previous years, the ORA Workplan specifically identified the number of samples to collect for three specific categories. These were for Processed Seafood in General, Processed Shrimp, and Seafood for V. cholerae testing.

   The ORA Workplan does not list specific numbers for these categories. Rather, it is the responsibility of the District to assure the collection of samples from these three categories.

2. Sampling information (number of subs, sample quantities, etc.) can be found in Attachment D.

E. Review of Importer HACCP Verification

Under the seafood HACCP Regulations, 21 CFR 123, importers are required to verify that foreign processors have followed the requirements of the Seafood HACCP Regulations, 21CFR 123.12(d). This Compliance Program provides guidance:

- for reviewing HACCP verification documents during HACCP inspections of Importers, or

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

1. Importer HACCP Inspection

Inspectors performing the HACCP review of an importers' verification documents must be HACCP trained, i.e. must complete the Seafood HACCP Alliance 3-day course or its equivalent and the 2-day FDA Seafood HACCP Regulator training course. Criteria for the selection of importers to inspect are provided in Part II, Item B.2. Importers' 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 should 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 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 (e.g., is the product covered by an MOU or not) to be covered during the inspection;
- reviewing importers' written verification procedures;
- reviewing affirmative step documents;
- reviewing the product safety specifications;
- reviewing verification records; 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.

2. Reconditioning

If a sample is found to be violative due to the presence of a safety defect and the importer applies to recondition the product, the importer must supply the HACCP verification documents for the detained product along with the reconditioning proposal. Review of an importer's verification documents as a requirement for reconditioning approval will be the same as performed at an on-site importer HACCP inspection.

The review procedures are described above in Item 1. Importer HACCP Inspection.

Individuals performing the HACCP entry review of an importers' verification documents 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: If the district has conducted an importer seafood HACCP inspection and the results of that importer inspection found the firm was in compliance for verification, etc., for that particular product and foreign supplier, the above procedures may be omitted and considered satisfied. **

F. Reporting

1. 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, and importer combination covered during the inspection. These two-copy, multi-page forms, specifically printed for use with the Cardiff system, will be supplied to the field in bulk by the Center for Food Safety and Applied Nutrition. These forms are designed in such a way that only the original of each set, which will be dedicated the District copy, can be faxed. The form should be faxed to **Dedicated FAX No: (301) 436-2885** only after the Inspection Report has a District Endorsement. 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 in, should the original copy be sent (overnight delivery) to:

FOOD AND DRUG ADMINISTRATION
CFSAN/DIVISION OF Compliance/IMPORT BRANCH
ATTENTION: Angel Suarez, HFS-606
5100 Paint Branch Parkway
College Park, MD 20740

2. Establishment Inspection Report

Narrative EIRs should be completed as directed by existing guidance. Consistent with such guidance, these narrative reports should describe:

- the importer's HACCP verification procedures, and,
- the HACCP-related deficiencies noted:
  - in the importer's documentation, and,
  - in the foreign processor's documents.

Document importer violations of the HACCP Regulations on the FDA 483 consistent with the Seafood HACCP Regulator training course.

PART IV - ANALYTICAL

This program covers seafood products under several Program Management System (PMS) Projects. In order to simplify the Inspectional and Analytical information contained in this program, instructions describing the work to be accomplished under each PMS Area are listed in separate Attachments. The Attachments and PMS Projects covered are as follows:

Attachments	PMS#	PMS Project Name
A-2 thru A-6	03	Foodborne Biological Hazards
B	07	Molecular Biology and Natural Toxins
C	09	Food and Color Additives

NOTES:

- See Part VI - Attachments and Program Contacts for a description of each attachment.
- *Sample Size for Multiple Analysis*: PROJECTS 03, 07, 09

  Whenever a product is collected for multiple analysis, please check the sample size requirements for each analysis. Confirm sample sizes with the laboratory if necessary. Due to the sample size required for each analysis an additional duplicate sample may be required; or in some cases, the sample size for one analysis may provide enough sample for several different analyses.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

This program addresses HACCP and non-HACCP violations. **In instances where a district believes that a fish or fishery product poses an imminent public health hazard, the district should contact OFP/CFSAN to discuss an appropriate regulatory response**. See the following Section B. Non-HACCP Component Regulatory Strategy of this Compliance Program.

The seafood HACCP enforcement area is still an evolving area and the agency will continue to explore effective ways of ensuring that imported seafood products are safe by bringing importers into compliance. The agency has worked with the import industry to provide guidance and training in HACCP Regulations. This continues to be the agency's primary focus. The districts should use telephone calls, meetings, untitled letters, and other informal means, at their discretion, to bring about voluntary compliance by an importer. This is especially important with those importers that are making progress towards implementing an effective HACCP program.

Warning letters to importers should be considered when the District believes that further efforts to obtain voluntary corrections will not be effective.

A. HACCP Component: Inspections and Reconditioning

1. Inspections

   This component provides for the appropriate regulatory language (Attachment F of this program) when serious violations, (Attachment E of this program) of the Seafood HACCP Regulations are encountered. Deviations labeled, as other should be brought to the attention of the firm in the FDA 483, but should not be included in regulatory follow-up at this time.

NOTE: 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], the District should determine whether or not the plan is adequate. If the foreign processor's HACCP plan is not adequate, cite the importer concerning this issue, and refer to OFP/CFSAN for appropriate follow-up with the foreign processor. The importer, in this case, should ONLY be cited for performing an affirmative step was not adequate if the plan does not list a Significant Hazard associated with the product; OR, the importer did not maintain a copy of a written guarantee from the foreign processor.

At his/her discretion, the District Compliance Officer may choose any of the five (5) actions (listed below) to either bring the importer into compliance or to eliminate an imminent health hazard.

a. Warning Letters:

   When serious violations are expected to continue and the informal means described above are not expected to bring about effective corrections by the importer, the District may use warning letters. Though these are also informal and advisory, they can communicate the agency's position for deviations of regulatory significance for which the agency may take enforcement action.

   Attachment F provides regulatory language that the districts may use when writing warning letters to list serious HACCP deviations. Attachment F also contains appropriate regulatory citations for

Warning Letters. Attachment H provides a model warning letter, using plain language, to be sent to the importer.

1) Direct - Reference Warning Letter:

Districts may send direct reference warning letters to importers for serious conditions as described in Attachment E. Attachment I defines high-risk products, and lists situations involving these items where issuance of a warning letter is appropriate. Districts are requested to submit copies of these warning letters to CFSAN, Chief, Import Branch, HFS-606.

2) Center - Approved Warning Letter:

All warning letters not covered by those conditions cited above in section A.1. Direct-Reference Warning Letter must be submitted to CFSAN, Chief, Import Branch, HFS-606, for concurrence.

For instance, when an importer has selected as its affirmative step, either Option A (HACCP monitoring records) or Option D (the foreign processor's HACCP plan) for the imported product, deficiencies noted in these documents may lead to regulatory action against the foreign processor. The deficiencies noted may include:

- Incomplete or inadequate HACCP monitoring records, or
- The HACCP Plan is inadequate or inappropriate because a Hazard(s) is not controlled at a Critical Control Point (CCP), the CCP is inappropriate or not identified, or critical limits are insufficient or inappropriate to control the hazard.

In reviewing the monitoring records or HACCP plan of the foreign processor, the investigator determines the noted deficiencies. The District should recommend further action against the foreign processor to CFSAN when these serious deficiencies are found. In such situations, recommendations for all correspondence to the foreign processor must be sent to CFSAN, Import Branch, and CFSAN will issue any follow-up correspondence and contact the foreign processor.

b. Detention without Physical Examination:

If serious deviations are not corrected after issuance of a warning letter to an importer, the district should:

- detain all future shipments of the product in question, which was processed by the foreign processor involved with the product in question, and imported by the importer; and
- Recommend, to the Division of Import Operations and Policy, placing the combination *Importer, Foreign Processor and Product* on Detention without Physical Examination (DWPE), under Import Alert 16-119.

c. Seizure: (for Import Products in Domestic Status)

All seizure actions must be submitted to CFSAN, Import Branch HFS-606 for concurrence. Please contact CFSAN (see Center's Regulatory Contacts below) to discuss all potential seizure situations when the firm’s product(s) is (are) in Domestic Status. Concurrence will be

considered only if the firm has received a warning letter for the same or related violations of the Seafood HACCP Regulations.

d. Injunction:

All injunction actions must be submitted to CFSAN, Import Branch HFS-606 for concurrence. Please contact CFSAN (see Center's Regulatory Contacts below) to discuss all potential injunction situations. Concurrence will be considered only if the importer has received a warning letter for the same or related violations of the Seafood HACCP Regulations.

e. Prosecution:

Suspected criminal violations, such as falsification of HACCP records should be discussed with CFSAN, Import Branch HFS-606 (see contacts below) and with the Office of Criminal Investigations (OCI).

** 2. Imminent Public Health Hazard Situations

Please contact CFSAN (see Center's Regulatory Contacts below) to discuss.

3. Reconditioning:

Evidence of importer verification, 21 CFR 123.12(a), will be required as a condition for approval of a reconditioning application. If a sample is found to be violative due to the presence of a safety defect and the importer applies to recondition the product, importer verification documents must be presented for FDA review before the proposal can be approved. Where the district has made an importer seafood HACCP inspection covering the specific product and manufacturer, etc., the results of that importer inspection may be used to determine if reconditioning should be approved. **

4. 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:

Angel Suarez	(303) 436-2146
Brian Landesberg	(301) 436-1622

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

B. Non-HACCP Component Regulatory Strategy

This regulatory strategy applies to non-HACCP fish and fishery product compliance to address violations of the FD&C Act and other regulations under the Act that relate to food safety, sanitation, wholesomeness, and labeling, including nutritional content labeling. If violations not related to compliance with HACCP Regulations are encountered during entry review, districts should pursue an appropriate regulatory action.

** For situations involving seafood adulteration due to non-HACCP violations,

the first action of choice should be detention of the entry. If the importer does not make voluntary corrections (e.g. reconditioning), then the entry must be refused. **

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. Routine Regulatory Actions

To determine if the appropriate initial action of choice is detention, or referral 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 (7108.240)

Sec. 540.575 Fish - Fresh and Frozen - Adulteration Involving Decomposition (7108.05)

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 Salt-cured, Air-dried, Uneviscerated Fish (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 (7108.02)

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)

NLEA

NOTE: NLEA coverage for imported seafood will be conducted under the Import NLEA, Nutrient Sample Analysis and General Food Labeling Requirements Program - 7321.007.

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

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

FOOD ECONOMICS

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

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

2. Case-by-Case Regulatory Actions

In the following situations, contact one of the Center's Regulatory Contacts in section *A. HACCP Component* of this C/P. They will coordinate your questions within CFSAN.

a. All fish (as defined in 21 CFR 123.3(d)

(1) Whenever Salmonella is found in either raw or partially prepared but still not ready-to-eat seafood products.

(2) *Staphylococcus aureus*

(a) positive for staphylococcal enterotoxin, OR
(b) *Staphylococcus aureus* level is equal to or greater than 10^4/g (MPN).

(3) *Clostridium botulinum*

(a) Presence of viable spores or vegetative cells in products that will support their growth, OR
(b) Presence of toxin.

Because of the serious health hazards resulting from Clostridium botulinum toxin and the occasional necessity for expert technical advice during an investigation, it is imperative that the Alert System procedures, as defined in Attachment J, are followed. During or IMMEDIATELY after a sample analysis is completed when toxin is detected, HFS-606 must immediately be called, per Attachment J.

(4) *Escherichia coli* - $1x10^4$ or greater organisms per gram.

b. Ready-to-Eat (R-T-E) Seafood

R-T-E is defined as: *product that requires minimal or no cooking by the consumer*. It does not apply to fresh and fresh frozen molluscan shellfish. See Item h. Molluscan Shellfish below.

Guidance Levels:

(1) Enterotoxigenic *E. coli* (ETEC), 1 x 10^3 ETEC/g, LT or ST positive.

(2) *V. cholerae* - presence of toxigenic O1, or toxigenic non-O1.

(3) *V. parahaemolyticus* - levels equal to or greater than 1 x 10^4 per gram.

** (4) *V. vulnificus*, presence **

(5) *L. monocytogenes* - presence of organism (for cause only).

** (6) Sulfites in canned tuna - If a district determines that canned tuna does contain sulfite at levels >10 ppm by either the Ion-Exclusion Method (AOAC method #990.31) or the Ion-Pairing HPLC Method (JAOAC (1989) 72(6), 903-906), the district must send the analytical worksheets to CFSAN Program Contact for review before pursuing any enforcement action. **

c. Refrigerated Smoked Fish

Vacuum or Modified Atmosphere Packaged Smoked Fish or Smoke-flavored Fish:

- Less than 3.5 percent water-phase salt in the loin muscle, OR
- Less than 3.0 percent water-phase salt in the loin muscle and less than 100 ppm nitrite, where appropriate.

d. Domoic Acid (ASP)

Amnesic Shellfish Poison - greater than or equal to 20 ppm Domoic acid, except in the cases of dungeness crab viscera where the level is greater than or equal to 30.0 ppm Domoic acid.

e. Paralytic Shellfish Poison (PSP)

For seafood products other than molluscan shellfish, ≥80 µg per 100 g meat in the edible portion. [CPG 540.250]

f. Other fishery species not specified under CPGs for decomposition

Any sample found to contain odors of decomposition in any subsample or other chemical indices of decomposition, e.g., indole, histamine, putrescine, etc.

g. Parasites

NOTE: Regulatory action will not be considered for parasites found in fish in the round or for dried fish.

CPG 540.590 (7108.06) prescribes action levels that will be used only

for those fresh water fish species listed.

In the absence of a DAL for unlisted species, CFSAN's Division of Compliance, HFS-605, will consider enforcement action for parasites on a case-by-case basis. Therefore, Districts should refer to CFSAN, HFS-605, any fish sample that contains the following levels of parasites:

- A combined total of at least eight (8) or more whole parasites, provided 20% of the fifteen (15) subsamples examined are infected. (Un-fragmented cysts may be counted as whole parasites.)

- If the sample contains less than eight (8) whole parasites, but contains head or tail fragments, the total parasite count may include these fragments as equivalent to whole parasites. (In adding the head or tail fragments to the total count, include **either** the heads or tails, whichever is more numerous. For example, if there are 6 heads and 4 tail fragments, the whole equivalent parasite count would be six (6)). Count only head and tail fragments that are at least 3 mm in length.

Before a case involving parasites in fish is referred to CFSAN, HFS-605, the District must first send the whole parasites and fragments to the parasite expert designated for their Region for confirmation.

h. 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, 7318.004.

Shellfish from uncertified shippers require special attention. Uncertified shippers are either in a non-MOU country, or they are shippers that are not certified by the Shellfish Control Authority in a MOU 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.

The most expeditious course of action is to obtain a state embargo of the product. The importer should be advised that the state will embargo the product if FDA releases it into U.S. commerce. If a state chooses not to take an embargo action or seize shellfish from uncertified shippers, the District should notify CFSAN, OFP, HFS-606, Angel Suarez (301)436-2146, for further assistance.

i. Food and Color Additives

(1) Standard Guidance

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 Section 182 or 184. Care must be taken to ensure that an ingredient actually is an illegal food or color additive before initiating regulatory action.

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

- Pre-Market Approval, Division of Petition Control, HFS-215, Eugene Coleman at (202) 418-3063, for food additives, or

- Cosmetics and Colors, Division Programs and Enforcement Policy, HFS-105, Allen Raphael Halper at (202) 418-3412, color additives.

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 Section 101.22(k).

Districts should check labels of imported cooked shrimp to ascertain that they are accurately and appropriately labeled if color is added. However, if color is used to mask decomposition, this would be in violation of the FD&C Act.

** 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 - ATTACHMENTS, REFERENCES, AND PROGRAM CONTACTS

A. ATTACHMENTS

	Attachment #	Description	
	A-1	Project 03 - Foodborne Biological Hazards – Investigative Activities	
	A-2	Filth, Mold, Foreign Object Analytical Guidance	
	A-3	Parasite Analytical Guidance	
	A-4	Decomposition Analytical Guidance	
	A-5	Microbiological Analytical Guidance	
	A-6	Steak Cut Diagram	
	B	Project 07 - Molecular Biology and Natural Toxins	
	C	Project 09 - Food and Color Additives	
	D	Sampling Schedules	
**	E	Enforcement Strategy: Importers	
	F	Regulatory Citations for Warning and Untitled Letters	**
	G	Untitled Letters Boiler Plate	
**	H	Warning Letter Boiler Plate	
	I	Direct Reference Warning Letters Situations	
	J	Alert System	**

B. PROGRAM CONTACTS

1. Center for Food Safety and Applied Nutrition

   a. General Program Questions,

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

   b. Compliance Matters

      Angel Suarez, Office of Enforcement, Division of Compliance, Import Branch, HFS-606, (301) 436-2146, 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 Science and Applied Technology, Color Technology Branch, Sandra Bell, HFS-126, (202) 205-0291

      - 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 and Beverages, Division of Micro-analytical Evaluations, Alan R. Olsen, HFS-315, (301) 436-1962

      - PSP/ASP

Molecular Biology and Natural Toxins
Office of Seafood, Division of Science and Applied Technology, Washington Seafood Laboratory Branch, Sherwood Hall, HFS-425, (202) 205-4818

- Food Additives Analysis
  Office of Pre-Market Approval, Division of Product Manufacture and Use, Gregory Diachenko, HFS-245, (301) 436-1898

- Microbiological Analysis - General Questions Office of Special Research Skills/Division of Microbiological Studies, Dhirendra B. Shah HFS-515, (303) 436-2007

  - *Escherichia coli* (toxin, attachment, invasive) **and**

  - *E. coli* LT/ST Enterotoxin

    Peter Feng, CFSAN/Office of Science, HFS-237 at (301) 436-1650

  - *Listeria monocytogenes* (isolation)

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

  - *Staphylococcus aureus*/Staphylococcal Enterotoxin

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

  - *Salmonella*

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

  - *Vibrios: parahaemolyticus, vulnificus*, and *cholerae* CFSAN's Angelo DePaola of the 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, 301-827*8614.

  - *C. botulinum*
    Haim Solomon, Office of Plant and Dairy Foods and Beverages, HFS-516, at (301) 436-2013

  - Parasite Analysis *and*
    Scallops - with added water or hygroscopic chemicals
    Office of Seafood, George Hoskin, HFS-425, (301) 436-1402

  - 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

- Filth and Decomposition — Helen Jones
- Food and Color Additives — Elise Murphy
- Microbiological — Marsha Hayden
- Seafood Toxins — George Salem **

PART VII - CENTER RESPONSIBILITIES

Program Evaluation

The Office of Seafood, HFS-400, will submit an evaluation of this program by April 1, of each calendar year to cover the previous Fiscal Year. This evaluation will be developed in conjunction with the Strategic Managers for Microbiology and Nutrition, and the Office Directors for:

Office of Plant and Dairy Foods and Beverages
Office of Pre-Market Approval
Office of Cosmetics and Colors
Office of Nutritional Products, Labeling and Dietary Supplements

This evaluation will be submitted to the Division of Field Programs, Compliance Programs Branch (HFS-636), Attn: Andrea Lee Wade.

Compliance Programs Branch (HFS-606) will forward this evaluation to the Office of Regulatory Affairs (HFC-100) for their information.

IMPORT SEAFOOD PRODUCTS PROGRAM
PROJECT 03 - FOODBORNE BIOLOGICAL HAZARDS
Investigative Activities

Investigations, Audit Checks, Recalls,
Field Exams, and Sample Collections

This attachment covers filth, decomposition, parasites, and microbiological contamination.

I. IMPORT ENTRY REVIEW

A. General Instructions - Products other than Molluscan Shellfish

See Investigations Operations Manual (IOM).

B. Molluscan Shellfish

The Molluscan Shellfish Evaluation program, 7318.004, covers fresh and fresh frozen molluscan shellfish, from certified shippers.

Shellfish offered for entry from **uncertified shippers**, either in a non-MOU country, or from shippers that are not included in the foreign country MOU, will require specific attention. The Regional Shellfish Specialist and the District import staff should work together with the state shellfish control authority in the state of entry to obtain a state embargo of the product, and to advise the importer that the state will embargo the product if FDA releases it into U.S. commerce. In the interest of public health, state intervention should be requested since state intervention is the most desirable, expeditious action.

Each District is responsible for forwarding information relating to shellfish embargoes to the Shellfish Specialist for its Region.

If a notified state does not take action to embargo or seize shellfish from uncertified shippers, the District should notify CFSAN, OFP, HFS-606, Angel Suarez (301) 436-2146, for further assistance.

II. FIELD EXAMS

General Instructions for Filth can be found in IOM.

III. SAMPLING - for Filth, Decomposition and Microbiological Areas

A. General Instructions:

- See Attachment D Sampling Schedules, of this Compliance Program, for sample sizes by product and problem area.
- See Inspectional Methods (Interim Guidance) and the IOM for information and guidance relating to sample collections.
- See Import Alerts and Bulletins, for seafood products to sample or automatically detain.
- Submit samples to laboratories specified in this Compliance

Program.

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

B. Specific Instructions

1. Parasites

NOTE: Do not collect fish in the round, or dried fish for parasite analysis. Regulatory Action will not be considered in these instances.

2. Decomposition Problem Area

NOTE: It may be necessary for the collecting District to collect additional subsamples for the national expert in organoleptic testing for confirmation analysis. Contact the servicing laboratory to determine whether these additional subsamples are necessary.

Fish to Emphasize

Fresh or frozen raw tuna fish and Mahimahi should be collected for histamine analysis.

NOTE: For lots where extremely large fish are involved (sample cost would be prohibitive), each subsample may consist of half a steak, and may be cut from either side of the anterior (head) end of the fish. To cut a steak or sub, a transverse cut, (See Attachment A-6) start approximately 2.5-5.0 cm (e.g., 1-2 inches) from the anterior (head) end of the fish. The transverse cut runs from the backbone of the fish to the belly of the fish. The steak must be at least 2.5 cm (e.g., 2-3 lbs.).

3. Microbiological Problem Area

a. General Instructions

Use aseptic techniques. See IOM.

b. *C. Botulinum* Spores

DO NOT test for the presence of spores or toxin unless implicated in a food illness.

c. Molluscan Shellfish Sampling Instructions

- Shell stock and shucked, unfrozen shellfish samples should have microbiological analyses begun within 24 hours of collection.
- Live 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 or paraffined cardboard cups are suitable types of containers.

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. (See Attachment **D** for Sample Sizes). 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, one or two packages may be taken as a subsample (See Attachment **D** for Sample Sizes). 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.

IV. SAMPLE SUBMISSION AND SHIPMENT

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.

V. ANALYTICAL

List of Analytical Guidance Attachments	Number
Filth, Mold, And Foreign Objects: Microscopic/Macroscopic	A-2
Parasites (Fresh, Refrigerated Fish, Fillets Or Steaks)	A-3
Decomposition	A-4
Microbiological	A-5

VI. REGULATORY/ADMINISTRATIVE STRATEGY

See main body of this Compliance Program PART V - REGULATORY/ ADMINISTRATIVE STRATEGY for further information and guidance.

FILTH, MOLD AND FOREIGN OBJECT ANALYTICAL GUIDANCE
MICROSCOPIC/MACROSCOPIC

I. LABORATORIES:

** Collecting Region/District Analyzing Laboratory

NE	NRL
CE	
BLT, CIN	SRL
CHI, MIN	ARL
NWJ, PHI	NRL
SE	SRL
SW and PA	DFS will identify the servicing Lab **

NOTE: Each subsample should be examined individually.

Unidentifiable items should be submitted to CFSAN, Office of Plant and Dairy Foods and Beverages, Division of Micro-analytical Evaluations, HFS-315, Alan R. Olsen, (301) 436-1962.

II. REPORTING:

** Record all results in FACTS of Analytical Results using Problem Area Flag: FIL; and PAC 03844B. **

III. METHODOLOGY:

A. General Seafood References

- AOAC, 16th Ed., Chapter 16, Extraneous Materials: Isolation
- JAOAC (Interim Official First Action Methods)
- FDA Laboratory Bulletin (LIB) # 3172 - Filth in Shrimp
- Microanalytical Procedures Manual (MAM)

B. Specific Seafood References

Molluscan Shellfish

At the present time, there is no special analytical method to determine filth directly applicable to products covered in this program (fresh/frozen shellfish). However, depending on the type of filth suspected, adaptations of the various methods described in the Micro-analytical Manual and in the 16th edition of the Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC), are appropriate.

PARASITE ANALYTICAL GUIDANCE

I. **FIELD LABORATORIES**:

** Collecting Region/District	Analyzing Laboratory
NE	NRL
CE	
BLT, CIN	SRL
CHI, MIN	ARL
NWJ, PHI	NRL
SE	SRL
SW and PA	DFS will identify the servicing Lab **

II. **METHOD:** BAM, 8th Edition, Revision A, 1998, Chapter 19. Parasitic Animals in Foods, II. Candling to Detect Parasites in Finfish, pp. 19.04-19.05.

III. **REPORTING:**

** Record all results in FACTS of Parasite Analytical Results using Problem Area Flag: PAR; and PAC 03844B. **

IV. **Parasite Identification**

For actionable lots, fix parasites as described in BAM and submit to the parasite expert designated for your region for identification and/or confirmation. 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 hard copy of the FACTS analytical screen in the shipping container.

After contacting Shelagh D. Schopen at (425) 483-4880, ALL regions should ship samples to:

Shelagh D. Schopen
FDA/SEA-DO HFR-PA 360
22201 23rd Drive, SE
Bothell, WA 98021-4421 **

V. **Parasite Fixation**

See reference in BAM, 8th Edition, Revision A, 1998, Chapter 19.

IMPORT SEAFOOD PRODUCTS PROGRAM
DECOMPOSITION ANALYTICAL GUIDANCE
DECOMPOSITION ANALYSIS

I. LABORATORIES:

** Collecting Region/District	Analyzing Laboratory
NE	NRL
CE	
BLT, CIN	SRL
CHI, MIN	ARL
NWJ, PHI	NRL
SE	SRL
SW and PA	DFS will identify the servicing Lab **

II.GENERAL METHODS:

Indole: AOAC, 16th Ed., 981.07, Section 35.1.35, liquid chromatographic fluorometric method.

Histamine: AOAC, 16th Ed., 977.13, Section 35.1.32, fluorometric method, as modified to include 75% methanol for 100% methanol

Organoleptic: Original and confirmatory organoleptic analyses should only be performed by qualified analysts. All subsamples collected for decomposition should be examined. Confirmatory analysis should be conducted on the same subsamples used for the original analysis.

Positive organoleptic findings by a National Expert do **not** require confirmation. Processed products without obvious odors of decomposition must still be chemically analyzed.

III. REPORTING REQUIREMENTS:

** Record all decomposition results in FACTS using:
Problem Area Flag: DEC; and
PAC: 03844C. **

IV. ANALYSIS REQUIREMENTS ARE SPECIFIC FOR PRODUCTS AS FOLLOWS:

1. <u>POTENTIALLY SCOMBROTOXIC SPECIES</u> *(E.G., MAHI MAHI, TUNA)* **RAW FRESH/FROZEN FISH, ONLY**

a. ORGANOLEPTIC

Follow Organoleptic Method and Reporting Requirements as specified in the beginning of this section.

(1) When an original organoleptic analysis is performed and odors of decomposition are detected, original results must be confirmed by organoleptic analysis by a National Expert or by histamine analysis. When confirming positive

organoleptic results by histamine analysis, analyze a minimum of six subsamples for histamine, which should include the subs exhibiting odors of decomposition.

(2) If the sample does not exhibit odors of decomposition, a histamine analysis of six subsamples is required.

b. HISTAMINE

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

Sample Preparation

NOTE: There are no A or B portions.

Fillet: Cut a transverse section (approximately 454 g) from the anterior end (if it can be determined) of the fish fillet and grind the transverse section.

Steaks: Remove bone from the steak and grind the entire subsample.

General Instructions:

Pass the specified fish portion through a food grinder or a food processor and remove a 10 g portion from each subsample.

(1) Histamine Check Analysis:
If any subsample is found to contain histamine greater than or equal to 50 ppm, then perform a check analysis on 10 additional grams from the same ground subsample.

(2) Notification of CFSAN:
When histamine is found in one or more subsamples at greater than or equal to 50 ppm by original and check analysis or when samples are involved in an illness, contact CFSAN/OFP/DOEP/Imports Branch, HFS-606 for further instructions.

2. CANNED TUNA

a. Organoleptic

24 cans must be analyzed organoleptically. When an original organoleptic analysis is performed and odors of decomposition are detected in any subsamples, original results must be confirmed by organoleptic analysis by a National Expert **OR** by histamine analysis. When confirming organoleptic results by histamine analysis, analyze a minimum of six subsamples, which should include the subs exhibiting odors of decomposition.

NOTES:

- In the case of cans larger than one (1) pound, only twelve (12) cans are required for collection. Therefore, only twelve (12) cans will be available for analysis.

- If the servicing laboratory does not have a National Expert, and it is decided to confirm by organoleptic analysis, then send 24 unopened containers from the same can code mix as that of the original examined portion to the National Expert.

- If evidence of decomposition is found in only 1 of 24 cans, analyze the cans for histamine until at least 2 subsamples are found **to** contain 50 or more ppm histamine (by original and check analysis) or until 24 cans are analyzed.

  For all canned tuna samples that exhibit no decomposition in all 24 cans examined organoleptically, analyze a minimum of six (6) cans per can code contained in the sample.

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.

  When 2 or more subsamples contain histamine at or above 50 ppm, a check histamine analysis is to be performed on a minimum of two subs showing the high histamine levels, utilizing the same ground portion used for the original histamine analysis.

  Regulatory action may be recommended if the original and check analyses meet one of the following criteria:

  (1) If at least two (2) cans are found to contain histamine at levels of 50 ppm or greater in both original and check analyses, **or,**

  (2) In the event that the histamine level for one of the six cans analyzed meets or exceeds 50 ppm and is less than 500 ppm , the laboratory **must** continue to analyze additional cans until the criteria in CPG section 540.525 (7108.24) are met, i.e., until one other can is found to contain 50 - 500 ppm histamine or a total of 24 cans are analyzed. No evidence of odor or honeycombing is necessary when these histamine criteria are met. **or,**

  (3) When histamine is found in any subsample at or above 50 mg per 100 g (500 ppm) or when samples are involved in an illness, contact CFSAN, Office of Enforcement, Director, Division of Compliance, HFS-605, (301) 436-2062 for further instructions.

c. CFSAN will continue to support regulatory action on shipments of canned tuna that are found organoleptically decomposed in accordance with CPG Manual Sec. 540.525 (CPG 7108.240). It is not necessary to perform Histamine analysis when a National Expert confirms decomposition.

3. **SHRIMP**

a. Fresh/Frozen Shrimp

(1)Organoleptic Examination:

Follow Organoleptic Method and Reporting Requirements as specified in the beginning of this section. If any of the subsamples contain odors of decomposition, confirm results by organoleptic confirmation analysis, **or,**

(2)Indole:

Confirm organoleptic results by analyzing a minimum of six subsamples for indole. These subsamples should include those subsamples exhibiting odors of decomposition. Using the composites utilized for the original indole analysis, perform a check indole analysis on the two subs that had the highest indole levels in the original indole analysis.

In the absence of finding odors of decomposition by organoleptic analysis **AND** where processing could mask decomposition odor, e.g., heavy chlorine odor, etc., analyze **ALL** subs for indole.

b. Canned Shrimp/Cooked, Frozen Shrimp

(1) Organoleptic Examination:
Follow Organoleptic Method and Reporting Requirements as specified in the beginning of this section. If no odors of decomposition are detected, then analyze a minimum of six subs for indole. If any of the subsamples contain odors of decomposition, confirm results by organoleptic confirmation analysis if a National Expert is available; **or**, if a National Expert is not available,

(2) Indole: Confirm by analyzing the subsamples for indole.

(a) composite the entire sub (drained of liquid), not just the 25 g necessary to run the sample.

(b) Discard any liquid in the can before compositing unless the liquid is intended to be eaten, e.g., canned soup product.

(c) If the sub is significantly larger than 454 g, remove 454 g of the sub and composite this for indole analysis.

(d) If indole is detected, using the original composites analyzed for indole, do a check indole analysis on the two subs that had the highest indole level in the original indole analysis

4. **CANNED ABALONE - LIKE SHELLFISH**; **CRABMEAT**

a. Organoleptic Examination
Follow Organoleptic Method and Reporting Requirements as specified in the beginning of this section. If any of the subsamples contain odors of decomposition, confirm results by organoleptic

confirmation analysis, **or**,

b. Indole Analysis
Confirm organoleptic results by analyzing a minimum of six subsamples for indole. These subsamples should include those samples exhibiting odors of decomposition. Using the original composites analyzed for indole, do a check indole analysis on the two subs that had the highest indole level in the original indole analysis.

5. **MISCELLANEOUS SEAFOOD including:**
ANCHOVIES, SARDINES, ETC., (Planktivorous)
CANNED SALMON
CRAYFISH, LANGASTINOS
FRESH/FROZEN FISH OR FILLETS (Non-Scombrotoxic Fish, only)
LOBSTER
MOLLUSCAN SHELLFISH
SCALLOPS
SQUID

Organoleptic Examination:

Follow Organoleptic Method and Reporting Requirements as specified in the beginning of this section. If any of the subsamples contain odors of decomposition, confirm results by organoleptic confirmation analysis.

MICROBIOLOGICAL ANALYTICAL GUIDANCE

I. **Laboratories**:

**	Collecting Region / District	Analyzing Laboratory	
	NE	NRL	
	CE		
	BLT, CIN	SRL	
	CHI, MIN	ARL	
	NWJ, PHI	NRL	
	SE	SRL	
	SW	DEN	
	PA	District servicing Lab	**

II. **FACTS Reporting Requirements**

** Record all microbiology results in FACTS using:
Problem Area Flag: MIC; and,
PAC: 03844D.

III. **Analysis of Seafood in Sealed Packages**:
(i.e., vacuum packaged, modified atmosphere, pickled)

NOTE: Product package should contain labeling with the statement keep refrigerated, or keep frozen.

A. Vacuum Packaged, Modified Atmosphere Products (smoked fish)

A major concern with this type of product is *C. botulinum*. To control this bacteria's growth in the product, the water-phase-salt (wps) level, that is critical to the food's safety, is adjusted. Nitrite, when permitted, allows a lower level of salt to be used.

Two techniques to control the wps are:

- sufficient salt is added to produce in the loin muscle of the finished product a wps level of at least 3.5%, or
- the finished product contains the combination of at least 3.0% wps in the loin muscle and not less than 100 ppm nitrite.

The following are analytical methods to check salt and nitrite content in the finished product.

1. WATER PHASE SALT

a. For Moisture Content (Total Solids) analysis, use AOAC, 16th Ed., Chapter 35, Section 35.1.13, (952.08).

NOTE: In lieu of the asbestos fibers specified in this method, use 10 g of sand or pumice.

b. For Water-Phase Salt analysis, use AOAC, 16th Ed., Chapter 35, Section 35.1.18, (937.09).

NOTE: Calculate water phase salt, i.e., salt concentration expressed as percent of salt in aqueous portion of the loin muscle by utilizing the formula:

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

2. NITRITES

Method: AOAC, 16th Ed., Chapter 39, Section 39.1.21, (973.31)

Analyze for nitrite only if nitrite is declared on the label or if there is no labeling with the product, to determine if nitrite was used and at what concentration, in ppm.

In determining the safety of smoked fish examine ten (10) individual subsamples for nitrites.

NOTE: Do not use the compositing instructions in CPG 540.200 or 540.500 for determination of nitrites when testing smoked fish products. These CPGs are food additive procedures that test for toxic levels of nitrite. Composite subsamples are used to determine whether a product exceeds the maximum permitted food additive level for nitrite, i.e., 200 ppm. See Attachment **C** - Project 09 Food and Color Additives.

3. *BOTULINUM* SPORES

Do not test for the presence of spores or toxin unless implicated in a food poisoning case.

If there is direct evidence of botulism toxin and it is implicated by clinical evidence, samples should be sent directly to a servicing laboratory with animal capabilities (SRL or PRL-NW). SRL will service NE, CE, and SE Regions. PRL-NW will service the SW and PA Regions.

a. Examine 12 individual subsamples.

b. Use BAM, 8th Ed., Revision A, 1998, Chapter 17, *Clostridium botulinum*, Screening Procedure for *Clostridium botulinum* Type E Spores in Smoked Fish, pages 17.07 - 17.08.)

B. Pickled Seafood (labeled keep refrigerated)

1. Check pH. If the pH $\geq$ 4.6, do 2. and 3. below. Otherwise, the analysis is finished.

2. Check Water Phase Salt as described above in Item A. Vacuum Packaged, Modified Atmosphere Products.

3. Check for Nitrite concentration in PPM using

AOAC, 16th Ed., Chapter 39, Section 39.1.21 (973.31) Nitrites in Cured Meat. **

IV. **General Method References:**

Bacteriological Analytical Manual BAM, 8th Ed., Revision A, 1998.

AOAC, 16th. Ed., Chapter 17, Microbiological Methods

NOTES:

- If deemed appropriate for surveillance data gathering or regulatory purposes, the laboratory branch can perform additional analyses in conjunction with those requested by the investigator.
- Composite for analysis if specified by BAM, or by any of the following special methods instructions. Otherwise, each individual subsample is to be analyzed.

V. Specific Method References:

A. LST-MUG for Detection of *E. coli* and Coliforms (Chapter 4, BAM, 8th Ed., Revision A, 1998).

LST-MUG may be used to examine for coliforms 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).

B. Enterotoxigenic *E. coli* (ETEC), Gene Probe

Do not perform ETEC analysis unless the level of *E. coli* detected is greater than or equal to 10, 000 per gram.

Method: BAM, 8th Ed., Revision A, 1998, Chapter 24, Identification of Foodborne Bacterial Pathogens by Gene Probe, Enterotoxigenic *Escherichia coli*, pages 24.01 - 24.33.

C. Salmonella

** 1. **General Method**: Use BAM, 8th Ed., Revision A, 1998, 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.

2. **Speciation**

If positive for *Salmonella*, prepare BHI slants and provide hardcopy information requested under BAM, 8th Ed., Revision A, 1998, E. 11. and send to ARL(HFR-SW500)**under seal** for speciation:

Doris Farmer, HFR-SW500
U.S. Food & Drug Administration
Arkansas Regional Laboratory
3900 NCTR Rd., Bldg. 14, Room 14C-126
Jefferson, Arkansas 72079-9502

NOTE: Prior to sending the slants, please notify Ms. Farmer at:
Tel# 870-543-7853
Fax# 870-543-7854

D. Listeria

1. **General Method**
BAM, 8th Ed., Revision A, 1998, 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 □ - naphthol, **DO NOT** use □ - Naphthyl amine. 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.

2. **Compositing/Sample Preparation Instructions**

Listeria analysis will be done only on ready to eat food products that require no further or minimal 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 mL or g from each composite for analysis. Mix the 25 mL or g with 225 mL

Listeria enrichment broth.

3. Incubate EB (enrichment broth) mixture for at total of 48 hours at 30° Proceed with BAM, 8th Ed., Revision A, 1998, Chap. 10, p. 10.4, D. Isolation Procedure.

NOTE: If the sample is to be analyzed for both *Listeria* and *Salmonella* then composite subsamples for *Salmonella* as outlined in BAM 8th Ed., Revision A, 1998, Chapter 1, page 3, then randomly select ten (10) subsamples from the original sample to prepare the two composites for *Listeria* analysis as outlined above.

4. Enumeration / Gene Probe / 3 Tube Method

NOTE: If *L. Monocytogenes* is found, regulatory consideration should proceed. Do not wait for the result of the probe.

The increasing importance of risk analysis makes it imperative that *Listeria* positive samples be **enumerated** (see BAM, Chapter 10). This is especially important for smoked Seafood.

If the ready-to-eat product was found to be positive for *L. Monocytogenes* and growth was observed at 24 hours, then enumerate using the **gene probe method** on a composite basis using 1:10 and 1:100 dilutions. Use BAM, 8th Ed., Revision A, 1998, Ch. 24, Identification of Foodborne Bacterial Pathogens by Gene Probe.

Alternatively, samples positive at 24 or 48 hours should be enumerated by the **3 tube MPN selective enrichment method** and/or by direct selective agar plate count. If necessary, consult Tony Hitchins at (301) 436-1649 about enumerating.

E. ***Staphylococcus aureus***

General Methodology

1. Examine individual subsamples

2. Direct microscope examination, BAM, 8th Ed., Revision A, 1998, Chapter 2, Microscopic Examination of Foods. **NOTE: Do not quantitate.** Do smear to get general idea of number of cocci present, only.

3. Direct Plate Count, BAM, 8th Ed., Revision A, 1998, Chapter 12, *Staphylococcus aureus.*

4. Identification, coagulase, ancillary tests, and viable count (MPN) BAM, 8th Ed., Revision A, 1998, Chapter 12, *Staphylococcus aureus*.

NOTES:

- Perform enterotoxin testing if product abuse is suspected, if viable *Staphylococcus* spp. colonies, MPN results or if direct Plate counts indicate a level of 1×10^4.

- 2. Do not perform the MPN method, if the Direct Plate Count (DPC) is used for the analysis. However, CFSAN recommends that both tests be

started at the same time since it is not possible to know if results might be obtained from the DPC method until that test is completed. By the time the DPC method has been completed, it is possible that the sample may no longer be representative of the lot. **

Staphylococcal Enterotoxin Determination

Follow methodology outlined in the memo **Revised Guidance for Staphylococcal enterotoxin Testing in Foods** dated August 1, 1997, issued by the Director, Division of Enforcement and Programs, HFS-605. If you do not have a copy of this memo, please contact Frank Sikorsky, HFS-606, at phone (301) 436-1623, or FAX (301) 436-2716.

F. *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, 8th Ed., Revision A, 1998, Chapter 9, *V. cholerae, V. parahaemolyticus, V. vulnificus,* and Other *Vibrio* spp.

PCR for *V. cholerae*: BAM 8th Ed., Revision A, 1998, Chapter 28.

V. parahaemolyticus: Isolation, identification, and enumeration.

V. vulnificus: Isolation, identification and enumeration.

V. cholerae: Isolation, identification, pathogenicity and PCR.

a. Each sample will be analyzed using the BAM, 8th ED., Revision A, 1998, Chapter 9, *V. cholerae*... et.al. and Chapter 28 - Detection of Enterotoxigenic *V. cholerae* in Foods by PCR.
b. If the sample was found to be positive for *V. cholerae*, send one set of ALL isolates of *V. cholerae* 01 or non-01 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

Call for shipment coordination, (301) 827-8616

c. Alkaline Peptone Water (APW) Lysate Preparation for PCR analysis.

NOTE: Use the following instructions in lieu of Chapter 28, Page 28.04, APW Enrichment Lysate Preparation.

1. 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 micro flora) APW lysate composites will be prepared from the original 1:100 APW dilutions.

2. 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 trough 10 (e.g., composite #1B).

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

4. Prepare a second set of APW lysate composites from original 1:10 or 1:100 dilutions **AFTER** the 6 - 8 hour incubation period at 37 C. Use step 2. above.

   If the sample is **frozen,** prepare the APW lysate composites using step 2. above from the original 1:10 or 1:100 dilutions **AFTER** the 16 - 24 hour incubation.

NOTE: This lysate will be tested first using the PCR test. If this lysate cannot be tested immediately, then freeze until the PCR test can be performed.

5. See BAM, 8th Ed., Revision A, 1998, Chapter 28, for clarification and further instructions for PCR analysis.

G. Molluscan Shellfish Sample Preparation/Methods

NOTE: Fresh molluscan shellfish samples must be analyzed within 24 hours from time of collection.

Sample Preparation/Method for Microbiological Analysis

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

For each subsample:

1. Weigh 200 g of shell liquor and meats (approximately 10 - 12

medium/large shellfish; approximately 25 small shellfish or 1/2 lb. shucked shellfish).

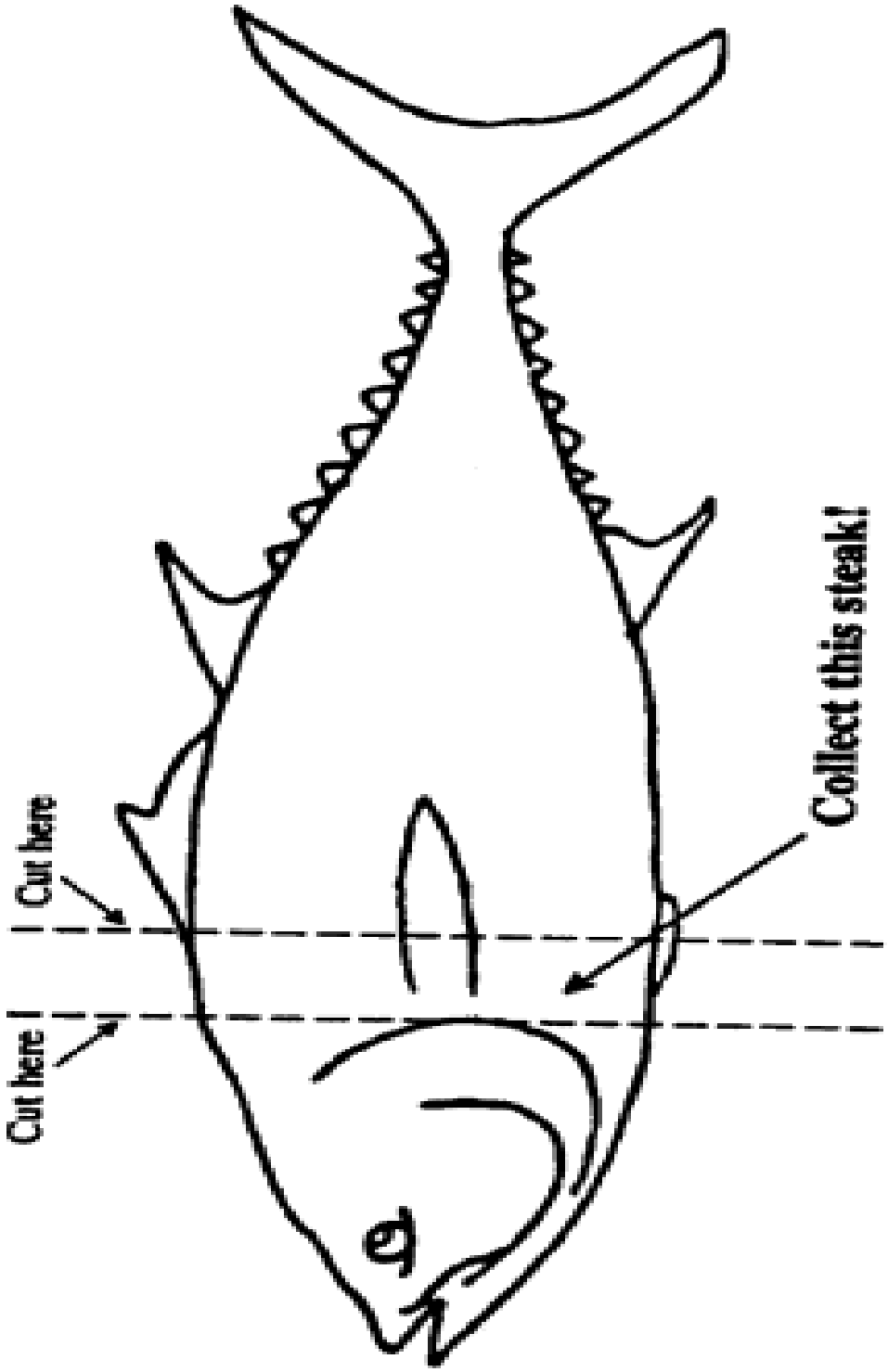
2. Grind for 30 seconds. If not possible, blend in sterile blender for 30 sec. It may be necessary to cut meats with sterile scissors or knives prior to grinding/ blending.

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

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

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

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


Collect this steak!
Cut here
Cut here

IMPORT SEAFOOD PRODUCT PROGRAM
PROJECT 07 - MOLECULAR BIOLOGY AND NATURAL TOXINS
Investigative Activities and Analytical Guidance

I. FACTS REPORTING REQUIREMENTS

** Record all decomposition results in FACTS using Problem Area Flag: BIO; and PAC 07844. **

II. SAMPLE GUIDANCE - Seafood to Sample

Collect whole product, i.e., it must contain the viscera.

Do not sample:

- eviscerated product,
- fresh water species.

Generally, product will be raw frozen or raw iced. Product can also be collected which is canned, cooked, or dried.

Shrimp, Anchovies, and Sardines should only be tested for ASP. All other species can be tested for either ASP, PSP or both. IF THE SPECIES COLLECTED IS FOR BOTH ASP AND PSP ANALYSIS, THEN DOUBLE THE SUBSAMPLE SIZE.

A. Crustaceans

1. Product to Sample

IF AT ALL POSSIBLE, ATTEMPT TO COLLECT WHOLE, RAW CRUSTACEANS (e.g., shrimp with head on, crab and lobster with viscera).

If this is not possible then collect whole, cooked crustaceans with viscera and head intact.

2. Sample Size – See Attachment D.

B. Molluscan Shellfish - Clams, Mussels, Oysters, Scallops

1. Clams, Mussels, Oysters

a. Sample size – See Attachment D.

b. Sample handling

- Samples need not be collected aseptically.

- In-shell Molluscan Shellfish - Samples of shellfish should be collected in clean containers. The container should be waterproof, and be durable enough to withstand the cutting action of the shellfish and abrasion during transportation. Waterproof paper bags, paraffined cardboard cups or plastic bags are suitable types of containers. A tin can with a tight lid is also suitable. Shell-stock samples should be kept in dry storage at refrigerated temperature. Shell stock should not be allowed to come in contact

with ice.

- Shucked Molluscan Shellfish - A sterile wide mouth jar of a suitable capacity with a watertight closure is an acceptable container for subsamples. Consumer size packages are acceptable provided that they contain an adequate number of animals for analysis (10 or more, 20 gm or more each). Samples of shucked shellfish shall be refrigerated immediately after collection by packing in crushed ice and be kept so until examined.

- Frozen Shucked Molluscan Shellfish - If the package contains an adequate number of animals, (see a) Sample Size above) one or two packages may be taken as a subsample. Subsamples from larger blocks may be taken by coring with a suitable instrument or by quartering, using sterile techniques. Cores or quartered sample should be transferred to sterile wide mouth jars for transportation to the laboratory. Keep samples of frozen shucked molluscan shellfish in the frozen state at temperatures close to those at which the stock was maintained. When this is not possible, samples should be packed in crushed ice and kept so until examined.

2. Scallops

Collect only **whole** scallops. See Attachment D.

C. Planktivorous and Uneviscerated Fin Fish (e.g., anchovies, sardines, etc.) (to be consumed whole)

A sample will consist of three (3) subsamples. Each subsample will consist of enough individual fish to yield a minimum of 227 grams (e.g., 1/2 lbs.) edible portion and a minimum of 25 grams (1.0 ounce) of viscera for analyses.

III. ANALYTICAL GUIDANCE

A. Paralytic Shellfish Poison (PSP) **

1. Testing Laboratories

Servicing Laboratories	Collecting Region
SRL	NE
	CE
	SE
PRL-NW	
	SW
	PA **

2. Methodology

AOAC, 16h Ed., Vol. 2, 959.08, Section 49.9.01.

3. Preparation

Each subsample will be homogenized and analyzed separately (e.g., total of three (3) analyses per sample). Laboratories can obtain a PSP standard through Office of Seafood, Division of Science and Applied Technology, Washington Seafood Laboratory Branch, Sherwood Hall, HFS-425, (202) 205-4818.

B. Amnesic Shellfish Poison (ASP)/Domoic Acid **

1. Testing Laboratories

Collecting Region	Servicing Laboratories
NE	SRL
CE	
BLT, CIN, PHI	SRL
CHI, MIN	PRL-NW
SE	SRL
SW	PRL-NW
PA	PRL-NW **

2. Methodology **

a. **ASP Methodology**: The new method Domoic Acid Analysis in Seafood Products using Aqueous Extraction is included in the Domestic Fish and Fishery Products Inspection Compliance Program.

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. **

3. Preparation

a. **Molluscan Shellfish:**

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

b. **Scallops:**

For **each** subsample, separate the adductor muscle from the viscera. The adductor muscle and the viscera portions will be homogenized and analyzed separately (e.g., total of six (6) analyses per sample; three (3) for the adductor muscle and three (3) for the viscera).

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 edible portion and the viscera/head portions will be homogenized and analyzed separately (e.g., total of six (6) analyses per sample; three (3) for the edible portion and three (3) for the viscera/head).

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

For **each** subsample, separate the edible portion from the viscera. The edible portion and the viscera portion will be homogenized and analyzed separately (e.g., total of six (6) analyses per sample; three (3) for the edible portion and three (3) for the viscera/head).

IV. REPORTING

If the following levels are found:

A. notify collecting District's Compliance Branch immediately so the appropriate follow-up action can be initiated:

- ≥ 80 µg/100g paralytic shellfish poison (PSP) in molluscan shellfish;
- ≥ 80 µg in the edible portion for other seafood products;
- ≥ 20 ppm Domoic acid, **EXCEPT** in the case of dungeness crab viscera, where the level is 30 ppm.

B. Report findings into the FACTS analytical screen using PAF: BIO.

V. REGULATORY/ADMINISTRATIVE STRATEGY

See main body of this Compliance Program, Part V - REGULATORY/ ADMINISTRATIVE instructions for guidance.

IMPORT SEAFOOD PRODUCTS PROGRAM
PROJECT 09 - FOOD AND COLOR ADDITIVES
Investigative Activities and Analytical Guidance

I. FACTS REPORTING REQUIREMENTS

A. Program Assignment Codes (PACs)

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

09844E Color Additives
09844F Food Additives

B. Problem Area Flags (PAFs)

Collections and Analyses: FAD - Food Additives
COL - Color Additives

II. SAMPLE GUIDANCE

A. General Information

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:

- 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 Regulatory Procedures Manual, Chapter 9, for procedural guidelines.

CFSAN Assignments, Import Alerts, and Import Bulletins may also be accessed and searched via the FDA Import Alert Retrieval System (FIARS).

Refer to IOM for import sampling procedures. 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. Understand that if color is used to mask

decomposition, however, this would be in violation of the FD&C Act.

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.

D. Sample Shipment

See below, III. ANALYTICAL GUIDANCE, A. Analyzing Laboratories

III. ANALYTICAL GUIDANCE

A. Analyzing Laboratories

Food and Color Additives

**

Collecting Region /District	Servicing Lab
NE	NRL
CE	
BLT, PHI, CIN-Import	NRL
CIN-Domestic	SRL
DET, CHI, MIN ARL	
SE	SRL
SW	ARL
PA	SAN **

B. Analytical Methodology

Use methodology appropriate to the product as well as the additive for which the product is being tested. Various analytical methodology sources are available for food and color additives or 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. Food Additives

- AOAC, Official Methods of Analysis, 16th Edition, Chapters 47 and 48.

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

- Food Chemicals Codex, 3rd Edition.

- Nitrites

  Examine individual subsamples. Use AOAC, 16th., Section 39.1.21 (973.31), or Section 39.1.20 (935.48).

- 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.

  Conduct check analysis on any samples containing 100 ppm sulfur dioxide or greater in the edible portion using the Optimized Monier-Williams method, AOAC, 16th Ed., 990.24, Section 47.3.43.

  Sample Preparation:

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

  FROZEN Shrimp/Prawns - Thaw shrimp at room temperature or in the refrigerator. Allow the liquid to drain. Remove and discard shells. DO NOT THAW BY IMMERSING IN WATER.

  FRESH Shrimp/Prawns - Remove and discard shells.

  Compositing:

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

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

- Sulfites in Canned Tuna

  Methodology:
  Each laboratory may choose to use the Modified Monier-Williams Method (Method #990.28. AOAC Official Methods of Analysis, 16th Ed.) for the original and check analysis. If the results are < 10 ppm, no further analysis is needed.

  Whenever the original analytical results of a Monier-Williams test are ≥ 10 ppm sulfite, a confirmation and check analysis using either the Ion-Exclusion Method (AOAC Method #990.31) or the Ion-Pairing HPLC Method (JAOAC (1989)72(6), 903-906) must be performed.

NOTE: If the servicing laboratory does not have the capability to run the Ion-

Exclusion or Pairing methods, please contact Gregory Diachenko at (301) 436-1898, who will coordinate the analysis of the sample by these methods.

Alternatively, each laboratory may choose only to use either the ion-exclusion method or the ion-pairing HPLC Method for the original and the check analysis.

Preparation:

Prepare a single composite of 6 cans (3 cans for cans weighing 66.5 ozs.) using the entire solid and liquid contents of each can for the composite. Do not over-grind and do not add anything to the composite that is not part of the can contents. Mix the composite thoroughly before weighing out analytical portions.

NOTE: When compositing a sample of 66.5 oz cans of tuna for sulfite analysis, the following steps are recommended:

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 the 3 portions 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 at this point.

2. Color Additives

- AOAC, Official Methods of Analysis, 16th Edition, Chapter 46.

- Attempt to identify any non-permitted colors present. If non-permitted colors are found, check analysis must be conducted. If one non-permitted color is confirmed, identification of the remaining color components in the product is not necessary for initiating regulatory action. However, as resources permit, the identification of the other color(s) present would improve the agency data base concerning color usage.

- NLEA requires the declaration of all certified color additives by name. If non-declared certified colors are found in a sample, perform check analyses to confirm the presence of each non-declared certifiable color additive. Follow reporting instructions for NLEA in the NLEA Enforcement-Imports Compliance Program (7321.007).

- The original or check analysis for the determination of a non-permitted or undeclared color should always include visible spectra, ideally under acidic, basic, and neutral conditions. Standard reference spectra in the same solvents as those for the sample extracts should be attached to the analytical work-sheets. Confirmatory analyses should include alternative characterizing data (e.g. TLC RF-values; HPLC retention times,

etc.) TLC confirmation should include either tables of RF-values, or reproductions of the TLC plates with spots clearly circled and labeled. If black and white reproductions are submitted, the color of the spots should also be reported.

- Do not routinely quantitate colors for which no limits have been established.

- Be aware of the presence and possible separation of subsidiary and isomeric Excessively high levels of subsidiaries in FD&C Yellow No. 5, FD&C Yellow No. 6, and FD&C Red No. 40 (vs. the CFR specification) may indicate the use of non-certified batches of these dyes and should be noted ** in the analytical records. **

C. Reporting

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

1. Food Additives:

   Use Form Code FAD and Flag Code FAD

2. Color Additives:

   Use Form Code COL and Flag Code COL

Sampling Schedules	Import Seafood Products Compliance Program					
Seafood	Filth: Macro 03844B	Filth: Parasites 03844B	Decomposition 03844C	Microbiological 03844D	Natural Toxins 07844 (Do not sample eviscerated or fresh water species.	Economic Fraud 21844 Reminder: No resources allocated.
FINFISH:						
Fresh or Frozen Fish		Fillets, steaks, loins, chunks, breaded portions. Random. 15 subs, . 7 oz.. (200g) (excl. breading, glaze, etc.) If ea. piece <200g (7 oz.), collect enough so 1 sub equals 200g (7 oz).	Only Fillets and packaged. Random samples. 1 sub/cs, if poss. (Pkgs .1 lb, take 2 subs/cs. max.) For Lot .500 lbs; Pkg: .1 lb, 50 subs >1-5lb, 10 subs >5lbs, 5 subs Lot >500 lbs:1 lb., 50 subs >1lb-5lbs, 15 subs >5lbs, 10 subs. Prorate pkg sizes. If firm won't break pkg,>10lbs, sample as bulk.) [IMIG 616.12, B2a, p. 9]	General Micro - Take 10 fish of same lot. Min.= 8 oz. (227 g) per fish. Salmonella- Take 15 fish from same lot. Min. = 8oz./fish, if sampling for micro and/or Salmonella. [IMIG, 616.12, B1a]		Species Substitution Collect 12 fillets or steaks.
Fish Blocks/Minced Fish Blocks, Frozen	`	Minced, to be processed further; not consumer size. Collect 2 blocks.	Collect 2 blocks/lot. 18 - 8 oz subs/ lot.	General Micro.- 10 subs, min 8 oz (227g).ea. Salmonella: Take 15 subs, min. 8 oz. from same lot. [IMIG, Opcit]		
Bulk Fish: Up to 3 lbs.		Do not collect fish in round for parasite anal.		General Micro:-Take 10 subs, min 8 oz. ea. Salmonella: 15 subs,8 oz. min, same lot.[IMIG, Opcit]		

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

Sampling Schedules	Import Seafood Products Compliance Program					
Seafood	Filth: Macro 03844B	Filth: Parasites 03844B	Decomposition 03844C	Microbiological 03844D	Natural Toxins 07844 (Do not sample eviscerated or fresh water species.	Economic Fraud 21844 Reminder: No resources allocated.
Finfish	**Fresh or Frozen continued**					
Over 3 pounds		Do not collect fish in round for parasite analysis.	Random sample. 50 fish/lot. (If cost prohibitive, take 10 fish min.[IMIG, 616.12, B2c, p. 9]	Same as above		
Very large.		Do not collect fish in round for parasite anal.	Collect 1 passable & 1 decomposed fish for lab, if poss. If >20 lbs or larger, take 5 lb portions min, 1 passable and 1 decomposed [IMIG, 616.12, B2d, p.9] See Attach. A-6 for a diagram of cutting a transverse steak.	(Same as above)		
Canned fish (including tuna; excluding Salmon - see below).	Net. Wt. . 2 lbs./can: 0-50 cs, 12 cans >50 cs, 24 cans. Net wt .> 2 lbs,: .600 cs, 12 cans. >600 cs, 18 cans. If lot of fish sampled for standards, decomp., histamines, & filth, collect 78 - 2lb can subs and 54 subs if > 2lbs.		** Single Lot Code: Random sample lot - collect 24 cans. 2 codes: Select as if from 2 separate lots. Collect 24 cans from each code randomly. 3 or More Can Codes: (Consider these as 1 commingled lot) Collect 24 cans at random without regard to can code as one sample from this lot. If can size >1 lb, collect 12 cans. If Organoleptic National Expert utilized, then double			Standards. 48 cans

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

Sampling Schedules	Import Seafood Products Compliance Program					
Seafood	Filth: Macro 03844B	Filth: Parasites 03844B	Decomposition 03844C	Microbiological 03844D	Natural Toxins 07844 (Do not sample eviscerated or fresh water species.	Economic Fraud 21844 Reminder: No resources allocated.
			the number of cans collected. See Attachment . A-1. **			
FINFISH continued:						
Canned Salmon			Decomp by Organoleptic only: ¼ - 1 lb cans: < 100 cases, 50 cans 100-199 cases, 68 cans 200-499 cases, 88 cans 500-799 cases,110 cans 800-999 cases,132 cans 1000-1499 cs,154 cans >1500 cases,176 cans (For uncased lots, sizes based on equiv. of 48 cans/cs.) >1lb-4lb cans: <100 cases, 18 cans 100- 199 cs, 23 cans 200- 499 cs, 30 cans 500- 799 cs, 37 cans 800- 999 cs, 41 cans 1000-1499 cs, 44 cans >1500 cases, 54 cans (For uncased lots, sizes based on equiv. Of 12 cans/case.)			Standard of Fill: 13 - 200 cans, depending on lot size. § 161.170.

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

Sampling Schedules	Import Seafood Products Compliance Program					
Seafood	Filth: Macro 03844B	Filth: Parasites 03844B	Decomposition 03844C	Microbiological 03844D	Natural Toxins 07844 (Do not sample eviscerated or fresh water species.	Economic Fraud 21844 Reminder: No resources allocated.
Finfish continued Scombrotoxic spec: (Tuna, mahi-mahi, amberjack, blue, mackerel, herring, sardines, etc, fresh.			1 a. Iced or refrigerated : Take temp. (Go to 2. below). 1 b. If little or no ice or no refrigeration: Do temperature. probes. If any fish shows Temp . 40□F, sample lot for organo. & histamine. (Go to 2. below). 2. Collect 18 max. fillet/steaks, min. 2 lb ea. per sample. Random if possible. Lot < 18 fish : 1 steak or sub from each fish. Lot . 18 fish : 1 fillet/steak from ea. of 18 fish. (If cost prohib. cut 1/2 steaks - transverse cut 2.54-5.08 cm (1-2 in.) from head (anterior) end of fish. Cut from backbone to belly, a min. 2.54 cm (1 in) thick & 908-1818 gms (2-3 lbs.).			

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

Sampling Schedules	Import Seafood Products Compliance Program					
Seafood	Filth: Macro 03844B	Filth: Parasites 03844B	Decomposition 03844C	Microbiological 03844D	Natural Toxins 07844 (Do not sample eviscerated or fresh water species.	Economic Fraud 21844 Reminder: No resources allocated.
Finfish continued: Smoked/Salted				** General Micro: Collect 10 subs randomly from 1 lot, 453g (1 lb) each. If hermet/vac. sealed, take 12 additional 453(g)(1 lb) subs for C. Botulinum, unless original sub is greater than 900 (g) (2 lb).water phase salt determination and nitrites: Collect 10 subs, 1 lb each (453g).**		
Crustaceans						
Crab meat Frozen	10 subs/sample. Min. 8oz.(227g). Random. (Do not need to be from single code) [IMIG, 616.32,B,p.11]		Collect 18 - 8 oz (227g). subs/sample. Same lot.	General Micro: 10-8oz (227g) subs. Random, from same lot. [IMIG, 616.32. B2, p.11] Salmonella: 15 - 4oz (112g) subs from same lot. [IOM, Chart 1, Category III food]		
Crab, cooked or pasteurized.	Collect 10-8oz (227g). subs randomly. Need not come from 1 production code. [IMIG, 616.32, B, p.11]		Collect 18 - 8 oz (227g). subs/sample, from same lot.	10 subs, 8oz (227g) each. (If smallest size container > 5 lbs, collect 3 containers). [IMIG, 616.32, B2, p. 11]	Whole cooked: (with head & viscera intact) Collect 3 subs, min. 8 oz (227g) edible portion and min 1 oz (25g). viscera.	

Sampling Schedules	Import Seafood Products Compliance Program					
Seafood	Filth: Macro 03844B	Filth: Parasites 03844B	Decomposition 03844C	Microbiological 03844D	Natural Toxins 07844 (Do not sample eviscerated or fresh water species.	Economic Fraud 21844 Reminder: No resources allocated.
Crustaceans cont. Canned crabmeat	Collect 6 cans, minimum, at random.		18 cans/sample.	Cooked or pasteurized: 10 - 8oz (227g)subs. (If smallest container is 5 lbs, collect 3 cntnrs. [IMIG, 616.32, B2, p.11]. Salmonella: 30 - 4 oz (112g) subs from same lot. [IOM, Chart 1, pp185-86, Category II food]		
Crab, whole raw.					Same as above except, if whole raw unavailable, collect whole, cooked with head and viscera intact.)	
Lobster, Fresh, Frozen			Bulk or consumer size pkgs : 2 lbs (900g) / sub min. 1-20 cs/lot, 6 subs 21-100 cases, 12 subs 101 cs, 18 subs	10 subs, 8 oz. (227g) ea. (If smallest container 5 lbs, collect 5 cntnrs.)		Overglazing: 48 subs, if available, from lot= min. of 6 and max. of 12.
Lobster, Cooked, Parboiled			Whether bulk or consumer size: 2 lbs/sub min. 1-20 cs/lot, 6 subs 21-100 cases, 12 subs >101 cs, 18 subs	10 subs, 8oz. (227g) each. (If smallest container >5 lbs, collect 5)	Whole raw (If unavail.,cooked (with viscera & head intact): 3 subs, min. 8 oz. edible portion and min. 1 oz viscera.	
Crustaceans cont.			Whether bulk or consumer size		Whole, viscera &	

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

Sampling Schedules	Import Seafood Products Compliance Program					
Seafood	Filth: Macro 03844B	Filth: Parasites 03844B	Decomposition 03844C	Microbiological 03844D	Natural Toxins 07844 (Do not sample eviscerated or fresh water species.	Economic Fraud 21844 Reminder: No resources allocated.
Lobster, Whole, Raw			consumer size: 2 lbs/sub min. 1-20 cs/lot, 6 subs 21-100 cases, 12 subs . 101 cs, 18 subs		head intact:3 subs, 8 oz. each edible portion, 1 oz. min. viscera.	
Shrimp, Fresh and Frozen, Raw	6 subs, each 2-3 lbs (1-1.5kg)		Larger of 100 ct. min or 2 lbs/sub: Raw: 1-20 cs, 6 subs 21-100 cs, 12 subs . 101 cs, 18 subs Frozen : Collect 18 subs			Overglazing: 48 subs, if available, from lot = min. 6 cs. and max. 12. Random .
Shrimp, Whole Raw or Cooked	Larger of 100 ct, min, or 2 lbs/sub: 1-20 cs, 6 subs 21-100 cs, 12 subs E 101 cs, 18 subs		Larger of 100 ct, min, or 2 lbs/sub: Raw only: 1-20 cs, 6 subs 21-100 cs, 12 subs . 101 cs, 18 subs Cooked: Collect 18 subs	Cooked: 10 subs, 8 oz ea. Salmonella: 30 subs, min 4ox (100 g)). [IOM, Chart 1, pp185-86; Class II food category]	Whole raw, head on: 3 subs, ea. 8 oz. min. edible portion, min. 1 oz. heads.	
Shrimp, Cooked, then Frozen	6 subs, 2-2.5 lbs (1-1.25 kg).		Cooked/peeled shrimp.Larger of 100ct. min or 2 lbs/sub. 18 subs.[Att. A-1, p. 11 & 12]	10-8oz subs. (If smallest container avail .5 lbs collect 5 containers.) Salmonella: 30 subs, min 4 oz (112 g). [IOM, Chart 1, pp185-6; Category II food]	Overglazing: 48 subs, if avail. Random from lot = min 6 and max. 12.	

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

Sampling Schedules	Import Seafood Products Compliance Program					
Seafood	Filth: Macro 03844B	Filth: Parasites 03844B	Decomposition 03844C	Microbiological 03844D	Natural Toxins 07844 (Do not sample eviscerated or fresh water species.	Economic Fraud 21844 Reminder: No resources allocated.
Crustaceans cont. Shrimp, Raw Breaded	6 subs, each 2-3 lbs (1-1.5 kg) Same as fresh and frozen raw)		Raw, headless: Larger of minimum 100 count or 2 lbs/sub 18 subs (raw breaded considered processed. See Att. A-1)	16-6oz (150g) subs. [IMIG, 616.52, A1, p.12] Salmonella: 30 subs, min 4 oz (112g). [IOM, Chart 1, pp185-6, Category II food]		Stds. Breading. Random. 1 sub from each case, if. poss. Same lot. Pkg. sz. = 10 - 12oz. 2pkg/sub; 10-30 subs. Pkg size . 1lb. 10-30 subs. Pkg size = 5 lbs. 3-15 subs.
Shrimp Canned.	Lot size: <200 cs, 48 cans >200 cs, 96 cans (If several codes in lot, ea. code should have min. 16 cans)		18 cans in duplicate for national expert .			
Shrimp, Freeze dried	6 subs, 8oz. each.		Larger of min 100 ct. or 2lbs/sub. 18 subs.			
Shrimp, Sun dried	Need to confirm 6 subs, 20 oz. each.					
Conch, Fresh/Frozen	Min subs = 2lb. 6 subs, 1-20 cs/lot 12 subs,21-100 cs. 18 subs, $101 cs.		Canned: 18 subs.			
Shellfish						
Abalone, Canned			Organoleptic: Min. 18 cans, 8 oz. (227g) min. from same lot .			
Molluscan Uncertified: Oysters, clams, mussels, roe on			Shucked oysters: Up to 64 cs, 8 pts.	Med. Large: 5 subs, 12 each.	Med. large: 3 subs, 10 each.	

Sampling Schedules	Import Seafood Products Compliance Program					
Seafood	Filth: Macro 03844B	Filth: Parasites 03844B	Decomposition 03844C	Microbiological 03844D	Natural Toxins 07844 (Do not sample eviscerated or fresh water species.	Economic Fraud 21844 Reminder: No resources allocated.
mussels, roe-on scallops			Up to 100 cs,16 pts. > 200 cs, 24 pts. Do not sample if shows evidence of freezing. [IMIG, 616.22, B, p. 10)	Small: 5 subs, min. of 20/sub, to give at least 11 oz. meat & liquid.	Small: 3 subs. Min. 12, enough to provide 0.7oz. meat & liquid. each.	
Scallops, Canned	6 subs.		1 can/sub. 18 subs.			
Fresh, frozen scallops	Min. 2 lbs/sub, 6 subs.		Whether sampling bulk or consumer size pkgs, min. 2-lbs (900g)/sub. Lot Size: 6 subs, 1-20 cases 12 subs, 21-100 cases 18 subs, > 101 cases Same as lobster.			Moisture (Added Water): 6 - 1 lb subs.
Scallops, Shucked				Same as filth, [IMIG p. 11]		Moisture. 6 -l lb. subs.
Other Seafood						
Anchovies, Sardines, Etc. (Planktivorous and uneviscerated fin fish to be consumed whole)					3 subs, each min. 8 oz (227g) edible portion, min. 1 oz (25 g). viscera.	
Crayfish, langostinos, cooked, parboiled.					10 subs, 8 oz.(227g) each. If smallest container . 5 lbs., collect 5 containers.	

Miscellaneous Seafood						
Processed Imitation Surimi, analogs.				10 subs, 8 oz. (227g) each. If smallest container .		

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Sampling Schedules	Import Seafood Products Compliance Program					
Seafood	Filth: Macro 03844B	Filth: Parasites 03844B	Decomposition 03844C	Microbiological 03844D	Natural Toxins 07844 (Do not sample eviscerated or fresh water species.	Economic Fraud 21844 Reminder: No resources allocated.
				5 lbs. collect 5 containers.		
Seafood Salads				10 subs, 8 oz.(227g) each. If smallest container . 5 lbs. collect 5 containers.		

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

HACCP Enforcement Strategy: Importers
Ranking is for General Guidance Only.
Actual significance must be judged on a case-by-case basis.

DEFICIENCY	CITATION	(#)
Importer Verification		
No written importer verification procedures when required	123.12(a)(2)	(#)
Product specifications not listed in verification procedures	123.12(a)(2)	(#)
No product specifications	123.12(a)(2)(i)	(#)
Product specifications not adequate	123.12(a)(2)(i)	(#)
Affirmative step(s) not listed in verification procedures	123.12(a)(2)	(#)
Affirmative step not taken	123.12(a)(2)(ii)	(#)
Affirmative step taken not adequate □□	123.12(a)(2)(ii)	(#)
Records		
No affirmative step records	123.12(c)	(#)
Records not in English	123.12(c)	(#)
Records do not include mandatory descriptive information	123.9(a)	(#)
Records not retained for the required time period	123.9(b)(1)	(#)
Record not available for official review	123.9(c)	(#)

□□ Falsification of records is addressed under Title 18 of the Code of Federal Regulations.

Regulatory Citations for Seafood HACCP
Warning Letters and Untitled Letters
Importers
(#)

This language is for general guidance only.

Deficiency (Regulatory Citation)
Importer Verification
You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm **does not have a product specification for [identify product] imported from [identify country].** **[Note: *use when the firm does not have written product specifications*]** **has a product specification for [identify product] imported from [identify country] that does not adequately address the food safety hazard(s) of [identify hazard(s)] that are reasonably likely to be presented by the product.** **[Note: *use when product specifications are not adequate*]**
You must implement an affirmative step which ensures that the fish and fishery product(s) you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm **did not perform an affirmative step for [identify product(s)] manufactured by [identify foreign processor] in [identify country].** **[Note: *use when an affirmative step is not taken*]** **performed an affirmative step of [identify affirmative step] for [identify product] manufactured by [identify foreign processor] in [identify country] that was not adequate.[Explain].** **[Note: *use when the affirmative step taken is not adequate* (refer to the appropriate section of this compliance program when a foreign processor's HACCP plan is not adequate)]**
Records
You must maintain records, in English, that document the performance and results of the affirmative step(s), to comply with 123.12(c). However, your firm **did not have records for [identify product(s)] manufactured by [identify foreign processor] in [identify country].**

Deficiency (Regulatory Citation)
[Note: *use when firm does not have any records*] has records for [identify product(s)] manufactured by [identify foreign processor] in [identify country] that are not in English. [Note: *use when affirmative step documentation records are not in English*]
You must retain records at your place of business for [at least 1 year after the date they were prepared in the case of refrigerated products] and for [at least 2 years after the date they were prepared in the case of frozen products], to comply with 21 CFR 123.9(b)(1). However, your firm's [identify the record(s)] for [identify product] were only retained for [list time]. [Note: *use when records are not retained for the required time period*]
You must provide all mandatory records for official review and copying at reasonable times, to comply with 21 CFR 123.9(c). However, a representative of your firm refused to provide the [identify the record(s)] for [identify product]. [Note: *use when records are not available for official review*]

DRAFT UNTITLED IMPORTER LETTER

On _____, the Food and Drug Administration's (FDA) conducted an inspection of your facility located at _____. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations (21 CFR 123).

The seafood processing regulations, which became effective on December 18, 1997, require that you have and implement written verification procedures to verify that your foreign suppliers have implemented a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP) in accordance with U.S. requirements. These verification procedures must include product specifications to preclude safety hazards and at a minimum one or more affirmative steps (21 CFR 123.12(a)(2)(ii)). Affirmative steps may include the following:

(A) Obtaining from the foreign processor the HACCP and sanitation monitoring records...that relate to the specific lot...offered for import;:

(B) Obtain either a continuing or lot-by-lot certificate from an appropriate foreign government... or third party...;

(C) regularly inspect the foreign processor's facilities...;

(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product was processed in accordance with... (Seafood HACCP);

(E) Periodically testing the imported fish or fishery product, and maintaining on file in English, of a written guarantee from the foreign processor that the imported fish or fishery product was processed in accordance with... (Seafood HACCP);

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

These are the kinds of measures that prudent importers already take. HACCP provides a systematic way of taking measures that demonstrate to FDA, to your customers, and to consumers that you purchase your imported seafood product(s) from foreign suppliers who routinely practice seafood safety by design, and are in compliance with the U.S. food laws and regulations.

During our inspection, the FDA investigator observed shortcomings in your verification procedures that, upon our preliminary review, appear to be deviations from the requirements of the Seafood HACCP Regulations. The FDA investigator also provided you with a copy of the Import Seafood HACCP Report (form FDA 3502), which presents his/her evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

[List the deviations]

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's assessment, you should explain how your system is complying with the regulations. We understand that there may be more than one way to verify compliance with the Seafood HACCP Regulations.

In either case, you should respond to this office on this matter within 30 working days of the receipt of this letter. Upon receipt of your response, we will work with you to resolve any outstanding issues associated with your verification plan. If we do not hear from you, or if your response is inadequate, we will assume that

our preliminary conclusions are correct and we will schedule a follow-up inspection for the immediate future.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention:_____.

If you have questions regarding the implementation of the HACCP Regulations, you may contact _____ at _____ for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program.

Signature

DRAFT IMPORTER WARNING LETTER

On _____, the Food and Drug Administration's (FDA) conducted an inspection of your facility located at _____. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations (21 CFR 123).

During our inspection, the FDA investigator observed _____ _____. The FDA investigator also provided you with a copy of the Import Seafood HACCP Report (form FDA 3502), which presents his/her evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

[List the deviations]

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct this (these) violation(s), including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed with 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention:_____ _____.

If you have questions regarding the implementation of the HACCP Regulations, you may contact _____ at
for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program.

Signature

Direct Reference Warning Letters Situations

High-risk seafood [1/], as defined below, for which any one or more of the following conditions are met:

a The importer has no written product safety specifications.
b The importer has not implemented an affirmative step.

[1/] **High-risk** products are defined as:

1. Seafood packaged in modified atmospheric, reduced oxygen, or vacuum packages;

2. Ready-to-eat fish or fishery products using any of the following processes:
   - heating or pasteurization process (e.g., cooked shrimp, crabmeat, cooked lobster, cooked crayfish, pasteurized crab meat, surimi-based analogs, soups, seafood salads, etc.)
   - hot or cold smoking process

3. Scombrotoxin-forming (histamine-forming) species: mahi-mahi (dolphin fish), tuna, amberjack, anchovies, bluefish, bonito, escolar, jack (e.g., bluerunner, crevalle, rainbow runner, roosterfish, trevally), mackerel (other than atka mackerel), marlin, saury, or yellow tail.

4. Stuffed seafood products - processing/handling may allow toxin development.

5. Molluscan Shellfish from uncertified shippers.

6. Salt cured, air-dried, and uneviscerated fish, such as Kapchunka, or bloaters.

ALERT SYSTEM [1/]

1. If the District concludes upon completion of an inspection that a potential health hazard is possible, the Director, Investigations Branch, with the supervisor and investigator will call CFSAN/Division of Compliance, Import Branch, HFS-606.

2. If HFS-606 concurs that a serious potential health hazard is possible, complete the report as soon as possible and submit it via a one day delivery service to HFS-606.

3. The District may recommend specific regulatory action, but should not delay submitting the EIR while awaiting such recommendation from the Districts' Compliance Branch.

[1/] This is identical to Attachment A of the DOMESTIC ACIDIFIED AND LOW-ACID CANNED FOODS COMPLIANCE PROGRAM 7303.803A.