PART 4 – Policies, Procedures and Requirements for the Inspection of Fisheries Products on a Lot by Lot Basis

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Chapter 1 - Authority

Authority for the USDC Seafood Inspection Program (SIP) to provide product inspection (audit) services can be found within the Agricultural Marketing Act of 1946, the Fish and Wildlife Act of 1956, and the regulations promulgated under these authorities (i.e., 50 CFR Part 260.)

Chapter 2 - Introduction

Lot inspection (audit) and sampling services are performed by the USDC Seafood Inspection Program on a voluntary, fee-for-service basis. Product inspection services can be provided to determine adherence to:

a. Minimum Acceptable Quality (MAQ)
b. U.S. Grade A, B, or C Attributes
c. Buyer Specifications (i.e., Net weight, size, count and/or other product attributes as defined by the buyer)

These services conform to global activities to harmonize inspection protocols. These services are designed to enhance the safety, wholesomeness, economic integrity, and quality of seafood available to consumers. If there are no Buyer Specifications from the applicant, the minimum inspection effort applied to every lot inspection will be adherence to the Minimum Acceptable Quality Standard of Quality and Condition, Flavor and Odor.

Chapter 3 – Scope

The purpose of product inspections is to facilitate the distribution of fish and fishery products that are safe, wholesome, properly labeled, and of desired uniform quality. Any individual, processor, retail operation, warehouse operation, or import/export dealer, foreign or domestic, may use the services of this program.

Chapter 4 - Definitions

1. **Acceptance Number:** The maximum number of non-conforming units allowed in the sample if the lot is to be accepted.
2. **Accuracy Check:** The daily or routine verification of a measuring device against a known standard.
3. **Applicant:** Any interested party who requests inspection service under the regulations in this part.
4. **Belly Burn:** An enzymatic action on the flesh of fish causing a burned or discolored appearance.
5. **Block:** A rectangular or other uniformly-shaped mass of cohering whole fish, fillets, minced fish flesh, or shrimp, or combinations of these products, frozen together into a solid mass and not readily separable into individual pieces.

6. **Calibration:** The process of checking, correcting, adjusting, or standardizing a measuring instrument, usually by comparing it with a verified standard.
7. **Case:** The number of containers (cased or uncased) which, by the particular industry, are ordinarily packed in a shipping container.
8. **Certificate of Sampling:** A statement issued pursuant to the regulations in this part, identifying officially drawn samples, which may include a description of condition of containers and the condition under which the processed product is stored. (**NOAA Form 89-805**)
9. **Chalky:** The abnormal condition wherein a fish product is partly or wholly characterized by a dry, chalky, granular appearance and fiberless structure.
10. **Clump:** A cluster of two or more shrimp or pieces of shrimp frozen together, and which cannot be readily separated.
11. **Condition:** The degree of soundness of the product which may affect its merchantability and includes, but is not limited to, those factors which are subject to change as a result of age or improper preparation, processing, packaging, storage, handling.
12. **Damaged Shrimp:** Any individual shrimp that is crushed or mutilated so as to materially affect its appearance or usability.
13. **Decomposition:** The deterioration of fish, shellfish and their products, including texture breakdown, and causing a persistent and distinct objectionable odor or flavor.
14. **Defect:** A departure of a quality characteristic from its intended level or state that occurs with a severity sufficient to cause an associated product not to satisfy intended normal, or foreseeable, usage requirements.
15. **Dehydration:** The loss of moisture from frozen products through evaporation. This may occur if the products are not properly glazed, packaged or stored. Deep dehydration adversely affects the appearance and surface texture of the product and is commonly known as “freezer burn”.
16. **Deterioration:** Any detectable change from the normal good quality of freshly caught seafood. It is evaluated by noting in the thawed product deviations from the normal odor and appearance of freshly caught product.
17. **Drained Weight:** The weight of the product of a sampled unit after the sample unit has been completely thawed and drained, per AOAC methods.
18. **Establishment:** Any premises, buildings, structures, facilities, and equipment (including vehicles) used in the processing, handling, transporting, and storage of fish and fishery products.
19. **Evisceration:** The cleaning of the belly cavities of fish. All spawn, viscera, and belly strings should be removed.
20. **Extraneous Material:** Any non-edible material such as sticks, seaweed, shrimp thorax, shell pieces, viscera, sand, grit, or other objects that may be accidentally present in the packaging.
21. **Flat:** A can with both ends concave, and remaining in this condition even when the can is brought down sharply on its end on a solid, flat surface.
22. **Flipper:** A can that normally appears flat, but when brought down sharply on its end on a solid flat surface, one end flips out. When pressure is applied to this end, it flips in again and can appear flat.
23. **Girdle:** The inedible bony and cartilaginous structures at the base of the pectoral and pelvic fins that have been inadvertently left on fish steaks.
24. **Glaze:** A layer (coating) of ice applied to a product’s surface to serve as a barrier to air to retard dehydration of the product. It must be removed to determine accurately a packaged product’s net weight.
25. **Glazed Weight:** The weight of the entire package contents (including loose ice, but excluding the weight of packaging material) of a sample unit that has been covered (coated) with a protective layer of ice.
26. **Gross Weight:** The weight of the entire packaged sample unit, including its packaging material.

27. **Hard Swell:** A can bulged at both ends, and so tightly that no indentation can be made with thumb pressure.
28. **Headed:** The condition of fish after the head, gills and pectoral fins have been removed. No gills, gill bones, gill covers, collar bones, or pectoral fins should remain after the fish have been headed.
29. **Honeycombing:** The visible appearance of numerous discrete holes or openings of varying size on the surface of flesh, which results in an overall sponge-like or honeycombed appearance.
30. **Individually Quick Frozen (IQF):** The freezing of each piece of product separately and apart from other pieces of product, i.e., not frozen together in a block or clump. Products frozen in this manner are generally glazed before packaging to delay the onset of dehydration.
31. **Inspection Certificate:** A statement issued pursuant to the regulations in this part, setting forth, in addition to appropriate descriptive information relative to a processed product, and the container thereof, the quality and condition, or any part thereof, of the product and may include a description of the conditions under which the product is stored. (NOAA Form 89-802)
32. **Inspection Service:** (1) The sampling pursuant to the regulations in this part; (2) The determination pursuant to the regulations in this part of: (i) Essential characteristics such as style, type, size, or identity of any processed product which differentiates between major groups of the same kind; (ii) The class, quality, and condition of any processed product, including the condition of the container thereof by the examination of appropriate samples; (3) The issuance of any certificate of sampling, inspection certificates, or certificates of loading of a processed product, or any report relative to any of the foregoing; or (4) Performance by an inspector of any related services such as to observe the preparation of the product from its raw state through each step in the entire process; or observe conditions under which the product is being harvested, prepared, handled, stored, processed, packed, preserved, transported, or held; or observe sanitation as a prerequisite to the inspection of the processed product, either on a contract basis or periodic basis; or checkload the inspected processed product in connection with the marketing of the product, or any other type of service of a consultative or advisory nature related herewith.
33. **Inspector:** Any employee of the National Marine Fisheries Service (NMFS), or any other person licensed by NMFS, authorized to investigate, audit, sample, inspect, and certify in accordance with the regulations in this part to any interested party the class, quality and condition of processed products covered in this part and to perform related duties in connection with the inspection service.
34. **Jellied:** The abnormal condition wherein a fish product is partly or wholly characterized by a gelatinous, glossy, translucent appearance.
35. **Licensed Sampler:** Any person who is authorized by NMFS to draw samples of processed products for inspection, to inspect for identification and condition of containers in a lot, and may, when authorized by NMFS, perform related services under the regulations in this part.
36. **Lot:** Any number of containers of the same size and type, which contain a processed product of the same type, style, grade and identification mark, located in the same or adjacent warehouses, and which are available for inspection at any one time, provided that 1) containers in separate piles which differ from each other as to grade or other factors may be deemed to be separate lots; 2) containers in a pile bearing an identification mark different from other containers of such processed product in that pile, if determined to be of lower grade or deficient in other factors, may be deemed to be a separate lot; and 3) if the applicant requests more than one inspection certificate covering different portions of such processed product, the quantity of the product covered by each certificate shall be deemed to be a separate lot.
37. **Lot Inspection (Contract):** Lot inspection(s), where the user contracts with the USDC SIP for a specified number of contract hours of lot inspection over a specified period of time.

38. **Lot Inspection (Non-contract):** The inspection performed on a specific lot of processed product, not during processing, and the conditions under which the product was produced are not attested to.
39. **Milky:** The abnormal condition wherein a fish product is partly or wholly characterized by a milky-white, excessively mushy, pasty, or fluidized appearance.
40. **Net Contents or Net Weight:** The weight of product in a sample unit which remains after all deductions for tare weight and/or glaze have been made.
41. **Nonconformance:** Any specifically defined variation from a particular requirement. (Formerly defined as "deviation.")
42. **Nonconformity**: A sample unit affected by a departure of a quality characteristic from its intended level or state that occurs with severity sufficient to cause an associated product not to meet a specification requirement. (Formerly defined as a "deviant.")
43. **Official Establishment:** Any establishment which has been approved by the USDC SIP, and utilizes inspection service on a contract basis.
44. **Officially Drawn Sample:** Any sample that has been selected from a particular lot by a USDC SIP inspector, licensed sampler, or by any other person authorized by NMFS pursuant to the regulations in this part.
45. **Processed Product:** Any fishery product or other food product covered under the regulations in this part, which has been altered or preserved by any recognized commercial process, including, but not limited to, filleting, canning, freezing, dehydrating, drying, the addition of chemical substances, or by fermentation.
46. **Pugh Marks:** Holes made in the flesh by a fish fork or pugh.
47. **Quality:** The inherent properties of a product which determine the relative degree of conformance to established standards or specifications of such product, and include the effects of preparation and processing, and may or may not include the effects of packing media or added ingredients.
48. **Rejection Number:** The number associated with a multiple sampling plan that indicates the minimum number of non-conformities in a sample that will cause a lot to fail a specific requirement.
49. **Sample:** A subset of the lot that has approximately the same distribution of characteristics as the population (the total number of containers comprising the lot) from which it was drawn.
50. **Sample Size:** The number of sample units that comprise the sample to be used for inspection prescribed by the sampling plan.
51. **Sample Unit:** A container and/or its entire contents, a portion of the contents of a container or other unit of commodity, or a composite mixture of a product to be used for inspection.
52. **Sampling:** The act of selecting samples of processed products for the purpose of inspection under the regulations in this part.
53. **Sampling Plan:** A specific plan that states the sample size or sizes to be used and the associated acceptance criteria.
54. **Sensory Evaluation:** The method by which evaluation of product attributes (i.e., color, appearance, odor, flavor and texture) is performed.
55. **Shipping Container/Shipper:** An individual container designed for shipping a number of packages or cans ordinarily packed in a container for shipping, or designed for packing unpackaged processed products for shipping.
56. **Sieve:** A utensil of wire mesh or closely perforated metal, used for draining or separating particles of different sizes.
57. **Soft Swell:** A can bulged at both ends, but not so tightly that the ends cannot be pushed in somewhat with thumb pressure.
58. **Springer:** A can with one end permanently bulged. When sufficient pressure is applied to this end, it will flip in, but the other end will flip out.

59. **Tare (Tare Weight):** The weight of the container, wrapper, or other packaging material of a sample unit that is deducted from the gross weight to obtain the net weight.
60. **Trier:** An instrument or a device that sifts, filters, or separates dry ingredients from impurities.
61. **Unofficially Drawn Sample:** Any sample that has been selected by any person other than a USDC SIP inspector or licensed sampler, or by any other person not authorized by NMFS, pursuant to the regulations in this part.
62. **Whole Shrimp:** For shrimp under 70 count per pound, any individual shrimp consisting of at least 5 segments of un-mutilated shrimp flesh; or, for shrimp over 70 count per pound, any individual shrimp consisting of at least 4 segments of un-mutilated shrimp flesh.
63. **Wholesome:** The minimum basis of acceptability for human food purposes, of any fish or fishery product as defined in section 402 of the Federal Food, Drug, and Cosmetic Act, as amended.

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Chapter 5 – Application for Services

Applicants seeking lot inspection services must complete a Request for Inspection Services, NOAA Form 89-814. (Attachment #1) The completed form shall be submitted to the appropriate Regional Inspection Branch or Lot Inspection Office for assignment. It is important for the application to be completed accurately and thoroughly, to ensure prompt and effective product inspection services. It is essential that the applicant clearly state the type of inspection requested (what does the applicant want to know about the product) and what is to be done with the samples following the completion of the inspection. A copy of the request form shall be kept with the inspection report.

Beginning in January, 2011, applicants seeking lot inspection services may also request such services online through the USDC SIP's DSFA system, which can be found at **https://seafoodinspection.nmfs.noaa.gov/customer/customerlogin.html**. First-time users will be directed to create a customer profile and all requests for service will be directed to the appropriate lot inspection office for assignment. It is still the responsibility of the applicant to clearly state the service(s) required and to make the product available for inspection.

ATTACHMENT #1

OMB Control #0648-0266
Expires:9/30/2008

NOAA form 89-814
Prescribed by NOAA Inspection Manual 25

U.S. DEPARTMENT OF COMMERCE
NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

REQUEST FOR INSPECTION SERVICES

CONTRACT NUMBER:
FEDERAL TAX ID #:
TODAY'S DATE:

NAME OF REQUESTER			**SERVICING AGENT'S NAME & PHONE NUMBER**		
STREET ADDRESS			STREET ADDRESS		
CITY	STATE	ZIP CODE	**CITY**	**STATE**	ZIP CODE
CONTACT NAME	PHONE NO.	FAX NO.	TYPE INSPECTION REQUESTED **___ Lot Inspection Certificate** **___ Export Health Certificate** **___ Certificate of Origin** **___ EU Certificate** **___ Other:**		
LOCATION OF PRODUCTS – NAME					
LOCATION OF PRODUCTS – STREET ADDRESS			SPECIAL INSTRUCTIONS (*Buyer Specifications, country requirements, etc.*) **___ Market Specifications:** **___ Product on FDA Hold?**		
CITY	STATE	ZIP CODE			
ASSESS CHARGES TO:			DISPOSITION OF SAMPLES: **___ Return ___ Destroy ___ Charity**		
STREET ADDRESS Same			INSPECTION: **___ Quality & Condition** **___ Minimum U.S. Grade Attributes** **___ U.S. Grade A Attributes** **___ Net Weight** **___ Size or Count** **___ Other: Origin:_____**		
CITY	STATE	ZIP CODE			
CERTIFICATE FORWARDED TO:					
STREET ADDRESS Same					
CITY	STATE	ZIP CODE			
REMARKS					

LOT NUMBER	BRAND	PRODUCT	NUMBER OF CARTONS/ CASES & SIZE	TOTAL POUNDS

NAME OF SHIPPER (*For export only*)		NAME OF CONSIGNEE (*For export only*)	
ADDRESS		ADDRESS	
PORT OF EXPORT	VESSEL OR AIRLINE	PORT OF DESTINATION	
APPLICANT (*Printed Name & Signature*)			DATE

Information Collection Notification – NOAA Form 89-814

This information collection is authorized under 50 CFR §260.15. The information will be used to record applicants requesting inspection services on non-contractual basis. Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden to the Seafood Inspection Program, 1315 East-West Highway, Silver Spring, MD 20910. This information is required in order to receive inspection services on non-contract basis. Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB control Number.

Sample

Chapter 6 – Lot Identification

On the Request for Inspection Services form, the applicant will clearly identify the lot to be inspected, including the lot number, brand, product name, number of cartons/cases and size, and the total pounds. Any additional codes and/or identification marks on the containers should also be noted. The

application will also indicate where the product is physically located, and the applicant is responsible for making sure that the product is available for inspection.

Chapter 7 – Reworked or Reconditioned Product

USDC SIP inspectors and licensed samplers will neither inspect nor certify products which have been reworked or reconditioned for subsequent delivery to other Federal agencies, i.e., Defense Personnel Support Center or U.S. Department of Agriculture, without first having written confirmation from the purchasing agency that reworking or reconditioning of the lot is acceptable. The fact that the lot is derived in whole or in part from reworked or reconditioned product shall be noted on the certificate, as well as specific reference to the letter/document received from the purchasing agency which authorized its use or inclusion.

Chapter 8 – Equipment Checklist

For the accurate and efficient performance of product inspections, each regional office shall have the appropriate and necessary equipment available to perform such audits. Equipment that is required is specific to each Standard or product evaluation, and could include the following:

- Appropriate inspection forms and score sheets
- Balance accurate to 0.01 gram
- Boilable bags
- Box cutter
- Can press
- Candling table/light
- Deep fryer with wire basket
- Digital camera
- Drill – high speed, ¼" bit
- Forceps with blunt points
- Knife
- Magnifying glass with 6X or greater power
- Microwave oven
- Nut pick
- Nylon mesh bags (other materials may be used, as appropriate)
- Packing tape
- Paper towels
- Plastic or glass bowls, various sizes
- Plastic grid marked in ¼", ½", and 1" squares for measuring defects
- Roe tub opener
- Sanitary can opener
- Seam micrometer
- Seam nippers
- Shallow baking pan
- Sieves – U.S. No. 8 (8" and 12"), U.S. No. 20, and U.S. No. 4 (12")
- Sink with cold water and stand pipe
- Spatula, 4" blade with rounded tip
- Stirring device capable of rotating paddle at 120 rpm
- Stop watch or timer, readable to the second
- Thermometer – dial or digital probe
- Thermometer – immersion type, accurate to ±2°F
- Tongs
- Trier
- Two-vaned paddle, each vane measuring about 1" by 3"
- Vacuum gauge
- Water bath
- Wire whip

- 2-gallon container, about 9" diameter

Chapter 9 – Accuracy Checks and Calibration of Equipment

All thermometers, scales, and balances shall be verified according to USDC SIP official accuracy check and calibration procedures, which include equipment calibration at least twice per year, or more frequently depending on storage and usage conditions. Accuracy check and calibration records shall be maintained on file at the local inspection office.

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Chapter 10 – Labeling Policies

Label Review and Approval

The purposes of this section are to 1) establish standard procedures for processing fishery product labels submitted by official establishments for DOC approval, 2) present the new procedures for label review/approval, and 3) standardize the temporary approval and disapproval criteria.

General

Title 50 of the Code of Federal Regulations (CFR) requires that establishments contracting for fishery product inspection service obtain USDC approval of labels prior to use on products that will be processed under federal inspection, regardless of whether or not they bear official inspection or grade marks, and that all labels bearing a Federal inspection mark or statement must be approved prior to use. Additionally, the "**Policy for Advertising Services and Marks"** (https://www.fisheries.noaa.gov/policy-advertising-services-and-use-marks-us-department-commerce)," identifies additional labeling and advertising of marks and services that must be approved prior to use.

EXCEPTIONS:

The Approving Officer, DOC Seafood Inspection Program (SIP), Technical Services Branch, Documentation Approval and Supply Service (DASS) Section, Pascagoula, MS, is responsible for administering the Label Review/Approval System and assuring that this system is operational.

Processing specifications for all non-standardized products shall be submitted for approval concurrently with labels. See Specification Review and Approval Instructions in this document for product specifications for non-standardized products. A copy of previously approved specifications must be submitted with each label submittal.

Submittal Instructions

A. Contracting Party
   1. New and revised labels: The processor is required to submit five label proofs and/or finished labels (CN labeling requires five), prior to use, to the assigned Consumer Safety Inspector (CSI)/Consumer Safety Officer (CSO) or supervisory CSO. Proofs of new or revised labels are not required, but are encouraged. Proof review affords

establishments the opportunity to obtain information on the compliance of the proof with labeling regulations and may prevent the need for modification to finished labels thus reducing costs.

2. All label/proof submittals must be accompanied by NOAA Form 89-819, Specification and Label Submittal Action Request, (see Attachment 1), through the assigned CSI/CSO, or through the immediate supervisor when the CSI/CSO is not available. It is the responsibility of the submitting establishment to complete the NOAA Form 89-819 prior to submitting the package to the assigned CSI/CSO for review. Please read the information concerning the NOAA Form 89-819 at the beginning of Attachment 1. Establishments are reminded to complete separate NOAA Forms 89-819 for institutional labels, case labels (nonretail), retail labels and CN labels. Only one group, for example retail labels, is to be submitted on a NOAA Form 89-819. Use another NOAA Form 89-819 for submitting CN labels and do likewise for institutional and/or case labels. Further, there are to be no more than four different labels of the same group, e.g., institutional labels, on one NOAA Form 89-819.
3. Cancellations: When products are withdrawn from inspection, a completed NOAA Form 89-819, Specification and Label Submittal Action Request, indicating the label approval number, specification number, and approval date is submitted to the assigned CSI/CSO or supervisory CSO for signature. Establishments are encouraged to submit a copy of the original NOAA Form 89-819 on which the label was approved to expedite the process.

Note: For purposes of this manual release, retail labels are defined as any label bearing mandatory nutrition labeling.

4. In the absence of the assigned CSI/CSO, Block 10, USDC Inspector's signature, may be left blank and a statement placed in Block 13, Remarks, indicating the name of the CSI/CSO's supervisor with whom submittal was discussed and who authorized the submittal. Such submittals will be verified by the Approving Officer.
5. HACCP-based inspection establishments are not required to have the NOAA Form 89-819 signed by a CSI/CSO or supervisory CSO. Such establishments may submit labels, depending on group or type, with the form directly to the Approving Officer.
6. After review and signature by the assigned CSI/CSO, the establishment is responsible for mailing the submittal package (labels, specifications, and NOAA Form 89-819). Institutional, case, retail, and CN labels are mailed to the Approving Officer.

Approving Officer
DOC NOAA Fisheries Seafood Inspection Program
Technical Services Branch
Documentation Approval and Supply Service Section
3207 Frederic Street, Suite B
P. O. Drawer 1207
Pascagoula, MS 39568-1207
Phone (228) 762-1892
Fax (228) 769-1436 or 769-2581

B. <u>DOC, SIP, Regional Inspection Branch (RIB), CSI or CSO</u>
The assigned CSI or CSO will:

4. Assure that only those label proofs and/or finished labels which have been authorized for submittal by a properly designated official of the establishment are sent to the Approving Officer, and that separate NOAA Form 89-819's are completed for retail, CN, institution and case labels;
5. Review all label proofs and/or finished labels to assure that the label information agrees with the product represented. Discrepancies should be resolved with the processor. The CSI/CSO will identify any noted discrepancies in Block #13, Remarks, on the NOAA Form 89-819, or by a note attached to the form, or directly on one copy of the label submitted, and sign the noted discrepancies;
6. Determine that the corresponding specification used to prepare the product has been approved or is being submitted for approval with the label;
7. Determine that specifications, and product samples if requested, are submitted in accordance with the instructions contained in Chapter 1, Section 6;
8. Review and sign NOAA Form 89-819 after assuring it is completed in accordance with the instructions, and retain the Field Copy of the form in the office file until approval action has been completed; and
9. Return the signed NOAA Form 89-819 to the establishment for submission to the Approving Officer, DASS.

Note: One-Run Approval. The assigned CSI/CSO or supervisory CSO may give one-run approval for a plant to use a label only after reviewing the label in accordance with these instructions and receiving verbal approval from the Approving Officer.

C. Approving Officer

0. Label Review and Approval, Temporary Approval, or Disapproval

a. Institutional, case, retail, and CN labels will be reviewed by the Approving Officer to determine compliance with the Fair Packaging and Labeling Act, Federal Food, Drug and Cosmetic Act, as amended, Nutritional Labeling and Education Act, and other applicable labeling regulations.
b. The Approving Officer will complete the portion of NOAA Form 89-819 designated "Action Taken," and sign and date the form. Copies will be distributed as follows:
    1. Original and Inspector Copy - To the DOC CSI/CSO stationed at the establishment submitting the labels or proofs. The CSI/CSO will forward the original to the processor, file the Inspector Copy, and discard the Field copy. Copies for HACCP-based inspection establishments will be returned directly to the submitting establishment.
    2. DASS Office Copy - Retained by the Approving Officer, or submitted to DASS by the Regional Consumer Safety Officer.
    3. Regional Office Copy - will be forwarded to the RIB by DASS.

1. Label Cancellation

The Approving Officer will assure that requests for a label cancellation result in proper notation of such labels in the master files. Distribution of NOAA Form 89-819 for cancellation will be the same as that for label approval actions.

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Label and Proof Status as Defined by Action Taken

A. Proofs

1. Proofs submitted for review that comply with the labeling regulations will be "Approved To Print As Is." When the proof is printed, the finished label must be submitted for final approval.
2. Proofs submitted that are not in compliance with the labeling regulations will be "Approved To Print With Changes Noted." When printed with the corrections, finished label(s) must be submitted for final approval.

B. Labels

1. Labels that are submitted and are in compliance with all labeling laws and regulations will be given a "Final Approval." This approval is good for five years, then the labels must be resubmitted for approval to assure and validate that the labels are current and in use.
2. Labels submitted that are not in compliance with the labeling laws and regulations, standards of identity or other applicable regulations will be given a "Temporary Approval" for minor compliance provided that the noncompliance does not warrant a "Disapproval." (Disapproval is identified below). The temporary approval is granted to allow establishments time to correct the label and resubmit the corrected label.
3. Maximum time limits for "Temporary Approval" are:
    a. four months for flat labels (i.e., those affixed to cartons, packages and cases);
    b. nine months for printed bags; and
    c. twelve months for printed cartons.
4. Temporarily approved labels may be resubmitted for an extension of the temporary approval. The processor must provide information on the stock remaining and the expected usage rate before an extension will be granted. Further, a noncompliance may warrant that the label(s) be over-stickered before any additional use of the label is allowed. This condition will be noted on the NOAA Form 89-819, identifying the time-frame for over-stickering.
5. Labels in a noncompliance will be given a "Disapproval" for the following reasons:
    a. Labels bearing USDC Inspection Marks that do not accurately convey the degree of inspection effort. Example: a label bearing a PUFI Mark while the product is lot inspected.
    b. Labels bearing USDC Inspection Marks or references to USDC Inspection that are not approved by the Policy for Use of Official Marks and Advertising.
    c. Labels that fail to bear mandatory nutrition labeling that is not exempt by the regulations.
    d. Labels bearing ingredient statements that do not declare or disclose all ingredients identified by the specification for that product or that fail to declare the use of flavors, artificial colors, preservatives, and/or food additives, or that substantially misidentify an ingredient to the point that it is false or misleading.
    e. Labels that bear nutrient content claims when the claim does not conform to the regulations for nutrient content claims.
    f. Labels bearing identity statements that do not conform to the standard of identity for that product.
    g. Labels bearing a statement of identity that does not identify the product by common or usual name.
    h. Labels that are required to bear Country of Origin labeling and fail to disclose the country of origin or misrepresent the country of origin.
    i. Labels that utilize an information panel and fail to provide all required information without intervening material (information not required).

j. Labels that provide nutrition information and fail to declare the correct serving size in relation to the reference serving size, resulting in a misrepresentation of the nutrient levels and erroneous nutrition information.
k. Labels that contain four or more violations of the requirements contained in the subparts of 21 CFR 101 or other applicable regulations.

Label Review/Approval Conditions that Warrant Billing

A. Rate. As established in the Notice of Charges and Fees for the U.S. Department of Commerce Seafood Inspection Program, establishments submitting labels for review/approval may be charged for the time required. The rate for label review/approval is established as Type I, and the minimum charge is established as one half hour.
B. Conditions. The following are the current conditions that warrant charging for label review/approval:
    1. Nonapplicant review and opinion on labels.
    2. Consultation on labels and specifications for contract and noncontract establishments.
    3. Potential clients of the program that have labels reviewed or approved that do not subsequently enter the program.

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NOAA Form 89-819 Specification and Label Submittal Action Request

A. The information required on NOAA Form 89-819 (see Attachment #1) is to be completed by the submitting establishment and the information required is self-explanatory.
B. Paperwork Reduction Act
    1. NOAA Form 89-819, "Specification and Label Submittal Action Request" is one of several NOAA Forms identified by the Office of Management and Budget (OMB) subject to the Act. Participants in the USDC Seafood Inspection Program are encouraged to read the "Information Collection Notification" by OMB prior to completing the form.
    2. Information Collection Notification, NOAA Form 89-819
        a. This information collection is authorized under 50 CFR §260.97©) (12), (13), and (15). The information will be used to ensure compliance with mandatory labeling regulations established by the U.S. Food and Drug Administration as well as proper use of the official marks of the voluntary NOAA Seafood Inspection Program. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden to the Seafood Inspection Program, 1315 East-West Highway, Silver Spring, MD 20910. This information is required in order to obtain the benefits of the use of official marks [50 CFR §260.86].
        b. Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

LABEL REVIEW LIST

C. The "principal display panel" (PDP) is defined as that part of the label that is most likely to be shown under customary conditions of display for retail sale. The area of the PDP for a rectangular package is the product of the height times width. A cylindrical container or near cylindrical container PDP is 40% of the product of the height times the circumference. In cases of any other shaped container, the PDP area is 40% of the total surface of the container. (21 CFR 101.1).

D. The "information panel" is for additional information required by 21 CFR 101 and means that part of the label immediately contiguous and to the right of the PDP. However, if the panel is too small or otherwise unusable, the panel immediately contiguous and to the right of this part of the label may be used. If the package has alternate principal display panels, the information panel is immediately contiguous and to the right of any principal display panel. If the top of the package/container is the PDP, the information panel is any panel adjacent to the PDP.

NOTE: Specific information is required by regulations in 21 CFR 101 to appear on the principal display panel or the information panel. When required information appears on the information panel, this information must be together without intervening material. Intervening material is defined as any printed matter, picture, vignette, etc. not required by regulation.

The following information, when required to appear on the label of any package, must appear either on the PDP or the information panel. Regulations may specify specific location on the label.

1. Identity labeling of the food - must appear on the PDP.
2. Statement of Ingredients - PDP or Information Panel.
3. Name and place of business of processor, packer, distributor, etc. PDP or information panel.
4. Number of Servings – if nutrition information is present, it is required. On the PDP or on the information panel.
5. Nutrition Information – required on retail labeling unless product or business is exempt. PDP or information panel.
6. Net Quantity of Contents. Must appear on the PDP.

E. Specific requirements for the above information are listed below.

1. Identity labeling of the food, referred to as the Statement of Identity (21 CFR 101.3)
    a. The identity of the food must appear on the PDP.
    b. The identity of the food shall conform to that name established by a standard of identity or other regulation, e.g. raw breaded shrimp; or be the common or usual name of the food, e.g. breaded fish sticks; or be an appropriately descriptive term or fanciful name commonly used by the public for such food.
    c. The identity shall be in bold face type.
    d. The identity of the food shall be in a type size reasonably related to other printed information on the panel.

Note: FDA has determined that this means not less than ½ the type size of the largest type on the PDP.
e. The identity shall be generally parallel to the base on which the package rest.
Note: FDA applies the condition that the identity be not greater than a 22 degree angle from the base.

2. Food, designation of ingredients, (21 CFR 101.4).

a. Ingredients required to be declared by regulation shall be listed by common or usual name.
b. Ingredients shall be declared in descending order of predominance by weight.
c. The descending order of predominance by weight does not apply to ingredients present in amounts of 2 percent or less, however, the statement “contains 2 percent or less of " must precede the ingredients that are listed in other than descending order of predominance by weight.
d. The name of an ingredient shall be a specific name and not a collective (generic) name. Example, Pollock instead of fish, sunflower oil instead of vegetable oil.
e. Specific methods of listing ingredients when in their self are made of other ingredients are found in 21 CFR 101.4(b) (2) (i & ii). In general the ingredients may be listed by common or usual name followed by a parenthetical listing of its ingredients, or by incorporating into the statement of ingredients (descending order of predominance by weight required) the common or usual name of every component of the ingredient without listing the ingredient itself.
f. Listing for specific ingredients is found in 21 CFR 101.4(b) (3-12).
g. And/or listings are allowed for only the following, vegetable oils, leavening agents, yeast nutrients, dough conditioners and firming agents.
h. Specific ingredient labeling for spices, flavorings, color agents and chemical preservatives is located in 21 CFR 101.22.
i. Minimum type size for ingredients is 1/16 inch based on lower case “o” or “e” when both upper and lower case letters are used.

3. Food, Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (Publication 108-282)
    a. Food Allergen Labeling and Consumer Protection Act (FALCPA) directs all foods that are regulated by the Federal Food Drug and Cosmetic Act that are labeled on or after January 1, 2006 must comply with FALCPA.
    b. Under FALCPA, a major food allergen is an ingredient that contains a protein derived from: milk, egg, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans.
    c. FALCPA requires the species be declared for fish (e.g., bass, flounder, or cod), crustacean shellfish (crab, lobster, or shrimp) and tree nuts (e.g., almonds, pecans, or walnuts)
    d. Allergens present in food must be declared with a “Contains” statement immediately below the ingredient statement, in the same size font and print. For example, “Contains Shrimp, wheat, soy” would follow the ingredient statement with no intervening material.
4. Food, name and place of business of manufacturer, packer, or distributor (21 CFR 101.5).
    a. Labels shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

b. Corporations must specify the actual corporation name which may be preceded or followed by the name of the particular division.
c. When the food is not manufactured by the facility whose name appears on the label, it shall be qualified by a phrase which identifies the connection; examples, manufactured for, distributed by, packed for.
d. The statement of the place of business shall include the street address, city, state and zip code. The street address may be omitted if it is shown in a current city directory or telephone directory.
e. Minimum type size is 1/16 inch letter height based on lower case "o" or "e" when upper and lower case letters are used.

5. Labeling of food with number of servings (21 CFR 101.8).
    a. Labels that bear a representation as to the number of servings contained in the package shall bear in immediate conjunction, in the same type size, a statement of the net quantity of each serving.
    b. Statement may be in terms of household units.
    c. Statement must not be misleading in anyway.
    d. If nutrition information is required the serving size and net quantity of this serving shall be consistent with the requirements set forth in the nutrition labeling regulations 21 CFR 101.12.
6. Nutrition labeling of foods (21 CFR 101.9).
    Due to the length of this section, the only major points will be addressed by the review list.
    a. Nutritional information is required on all processed food for retail sale.
    b. Serving Size shall be expressed in terms of household units, except where such units are not applicable, e.g., discrete units such as pieces, portions, etc., or where household units are not applicable, ounces may be used with an appropriate visual unit of measure.
    c. Servings Per Container shall be expressed and be in whole numbers except numbers between 2 and 5 shall be rounded to the nearest 0.5 serving.
    d. Specific nutrients are required to be listed, if present. Calories, Calories from fat, Total fat, Saturated Fat, Trans Fat, Cholesterol, Sodium, Total carbohydrates, Dietary fiber, Sugars, Protein, Vitamin A, Vitamin C, Calcium and Iron. Values are checked per supplied analytical data.
    e. Nutrients shall be listed in the increments required by the regulations for each nutrients requiring listing.
    f. The Nutrition Information shall be displayed in a “Nutrition Facts” panel and the panel will conform to the requirements contained in the regulation.
    g. The letter height and spacing shall conform to the formatting requirements of the regulations.

h. Formatting is dependent space available for Labeling and the correct format for the “Nutrition Fact” panel is evaluated on identified space.

7. Declaration of net quantity of content (21 CFR 101.105).
    a. The statement shall appear on the PDP and may appear on more than one line.
    b. The statement shall be separated by a space equal to the height of the N in net from other printed information appearing above or below the declaration and by a space equal to twice the width of the N in net from other printed matter to the right and left of the statement.
    c. The term “net weight” shall be used when stating the net quantity of contents.
    d. The statement shall appear in the lower 30% of the PDP.
    e. The statement shall be generally parallel to the base of the label.
    f. The statement shall comply with the following type sizes: not less than 1/16 in. height when the PDP is 5 sq. inches or less, or not less than ⅛ in. height when the PDP is more than 5 sq. in. but not more than 25 sq. in., or not less than 3/16 in. letter height when the PDP is more than 25 sq. in. but not more than 100 sq. in., or not less than ¼ in. letter height when the PDP is more than 100 sq. in.; except not less than ½ in. if the PDP is more than 400 sq. in.
    g. When upper and lower case letters are used, the measurement for type size is based on the lower case “o” or “e”.
    h. The statement shall, on packages containing less than 4 pounds, be expressed both in ounces and, if applicable, (l lb or more), be followed in parentheses by pounds. [i.e. 24 oz (1.5 lb)].
    i. The statement shall, on packages containing 4 pounds or more, be expressed in pounds with any remainder in ounces or common or decimal fractions of the pound. Decimal may be carried to no more than two places and common fractions are to be such as ½, 1/3, or ¼.
    j. Metric declaration is optional and is not to be part of the required statement through the use of parentheses.
    Examples: Inch-pound/declaration
    Net Wt. 15 oz - 425g voluntary
    Net Wt. 48 oz (3 lb)
    Net Wt. 4 lb

ATTACHMENT #1

Expires 9/30/2008

NOAA FORM 89-819
(03-06)
Prescribed by NOAA Inspection Manual

U.S. DEPARTMENT OF COMMERCE
NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION
SEAFOOD INSPECTION PROGRAM

SPECIFICATION AND LABEL SUBMITTAL ACTION REQUEST

1. DATE SUBMITTED

2. PLANT CODE(S)

INSTRUCTIONS – Please print for complete by typewriter. Submit a set of 5 specifications and/for labels with each product label indicated on form. All copies except field copy to be submitted to the address below or action. Field copy to be retained by requestor until specifications and/or labels are returned by Approving Officer.

TO: DOCUMENTATION APPROVAL and SUPPLY SERVICES
3209 Frederic Street
PASCAGOULA, MISSISSIPPI 39567

3. PROCESSOR OR PACKER (*Name, address and Phone Number*)

4. DISTRIBUTOR (*Name and full address*)

USDC No. (Item 5) to be assigned by Approving Officer. Indicate USDC Number of approved specifications or labels in Remarks when submitting replacements with minor changes, or when submitting or verification for cancellation. Indicate primary logo, packer or distributor name, or other identification for item 6. Use numbers only or item 9: 1 - No. Shield 2 - Combination Grade A & PUFI., 3 - PUFI Mark, 4 - Grade A, 5 - Lot Inspected Mark

5. USDC NUMBER		6. PRODUCT IDENTIFICATION (*Brand and identifying number if any*)	7. COMMODITY (*Use official terminology including type, style and size; indicate in ounces or count/pounds. Enter 10 digit commodity code*)		8. CONTENT OR NET WEIGHT	9. SHIELD CODE (See Above)
LABEL	SPEC.		PRODUCT	COMMODITY CODE		

10. USDC INSPECTOR (*Signature*) Inspector Number_____HACCP☐

COMPANY OFFICIAL (*Signature*)

11. HAVE SPECIFICATIONS AND/FOR LABELS BEEN REVIEWED FOR COMPLIANCE WITH USDC AND FDA REGULATIONS?
BY INSPECTOR? YES☐ NO☐ BY FIELD INSPECTION OFFICER? YES☐ NO☐

12. ACTION REQUESTED
☐LABEL/SPEC. REVIEW ☐NEW LABEL SKETCH/PROOF REVIEW ☐NEW LABEL APPROVAL (*FINAL*)
☐NEW SPEC. APPROVAL (*FINAL*) ☐REPLACEMENT SPEC. OR LABEL ☐CANCEL APPROVAL ☐OTHER (*SPECIFY IN REMARKS*)
☐USDA/FNS (CN) LABEL OR SPECS ACTION ☐EXTEND TEMPORARY APPROVAL (*SPECIFY IN REMARKS*)

APPROVAL BY THE USDC IS BASED ON THE INFORMATION SUPPLIED AND DOES NOT IMPLY CONCURRENCE FOR ACCEPTANCE BY OTHER FEDERAL STATE FOR LOCAL GOVERNMENTAL AGENCIES UNLESS SPECIFICALLY NOTED, NOR DOES IT RELIEVE THE COMPANY FROM COMPLIANCE WITH OTHER APPLICABLE LAWS, REGULATIONS OR RULINGS. THIS APPROVAL BECOMES VOID IF CHANGES ARE MADE IN THE SPECIFICATION OR LABEL WITHOUT THE CONCURRENCE OF THE USDC APPROVING OFFICER.

13. REMARKS (*Please initial*)

TO BE COMPLETED BY APPROVING OFFICE(S) ONLY

PROOF APPROVED FOR PRINTING ☐AS IS ☐WITH CHANGES NOTED
☐Temporary Approval Expires
(Spec)_____ (Label)_____
☐Final Approval Label ☐Final approval Spec.
☐Disapproved label ☐Disapproved Spec.
☐Extends Approval ☐Cancelled
☐Reviewed

APPROVING OFFICER (*Signature*) DATE:

USDA/FNS USE ONLY
☐SKETCH/PROOF ☐LABEL ☐CONCURRENCE ☐NON-CONCURRENCE

USDA APPROVAL (*Signature*) DATE:

Sample

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PUFI Policy

The Processed Under Federal Inspection (PUFI) Mark identifies fishery products processed under USDC inspection in an approved establishment, inspected for safety, wholesomeness and proper labeling, and conforms to quality and other criteria in an approved specification.

PUFI Statement using the company name:

PROCESSED BY™

UNDER FEDERAL INSPECTION
U.S. DEPT. OF COMMERCE

PUFI Statement:

Processed Under Federal Inspection™

U.S. DEPARTMENT OF COMMERCE

The PUFI Mark may be used for:
- retail packages,
- cases or shipping cartons,
- point-of-sale notices, and
- advertisements/promotional literature.

The use of the PUFI Mark requires that the:
- participant be under USDC contract agreement for in-plant inspection service,
- facility/vessel meets applicable USDC sanitation requirements,
- product specifications and labels be approved by USDC,
- products conform to USDC approved specifications,
- product meets principal display panel declarations,
- PUFI mark or statement be affixed to or next to certified PUFI products only, and
- product be processed and packaged under USDC approved inspection program.

Declaration of Phosphates

This section replaces the Label Alert issued July 24, 1979, subject: Declaring the Food Additive Sodium Tripolyphosphate (STP) on Labels. It provides guidance in the use of phosphate compounds, such as sodium tripolyphosphate and sodium hexametaphosphate, in fishery products, and assures that products containing them are labeled in accordance with the regulations promulgated by the Food and Drug Administration (FDA).

It is NMFS policy to assure that all products processed under USDC inspection contain only FDA-approved ingredients, additives, or substances that are used in accordance with good manufacturing practice, and are declared properly on the product label.

Sodium tripolyphosphate has been used for several years by fishery products processors to reduce the loss of natural moisture in products during processing. Other phosphate compounds have also been used, e.g., sodium hexametaphosphate. These products are approved by FDA as general purpose substances and/or sequestrants which are generally recognized as safe (GRAS) for their intended use, when used in accordance with good manufacturing practice. However, their use in products for which

definitions and standards of identity have been established by FDA is governed by the applicable definition or standard of identity. For example, the use of phosphate compounds is not permitted in the raw shrimp material in the processing of the standardized food, frozen raw breaded shrimp.

Procedure

A. Use in Products
    1. The use of phosphate compounds in foods is governed by regulations promulgated by FDA and published in 21 CFR 182.1(b). This section defines good manufacturing practice to include the following restrictions:
        a. The quantity of a substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and
        b. The quantity of a substance that becomes a component of food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.
        c. The substance is of appropriate food grade and is prepared and handled as a food ingredient.
    2. The quantity of phosphate compounds which may be added to fishery products to meet the aforementioned restrictions, i.e., to comply with the good manufacturing practice definition, should not exceed 0.5 percent by weight.
    3. There is no test method for determining the amount of phosphate added to fishery products readily available to the inspector. However, extreme overuse of these products will result in a translucent appearance of the product.
B. Labeling

Products containing phosphate compounds must have the name of the compound(s) declared on the product label. This is required regardless of whether the product was manufactured from raw material (fishery products) containing them, or whether they were added during the manufacturing process. The common or usual name of the compound(s) added must be used. NOTE: Because they are GRAS substances (see 21 CFR 182.1810 and 21 CFR 182.6760) and are not exempt under 21 CFR 101.100, their presence must be declared to avoid being misbranded under the provisions of section 403 of the Food, Drug, and Cosmetic Act. Their declaration must be either:
1. On the principal display panel as a separate statement, or
2. In the ingredients statement in their descending order of predominance as required in 21 CFR 101.4 and 101.2.

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Date Labeling of Fresh Fish

There is no Federal policy on the date labeling (open dating) of foods. While several states and the District of Columbia have some form of mandatory date labeling, certain products are exempt, e.g., fresh meat, fresh poultry, fresh fish, fresh fruits, and fresh vegetables.

NOAA Fisheries believes that the use of date labeling can be beneficial to both the processor and the consumer. It can encourage better handling practices by processors, wholesalers, retailers, and consumers by drawing attention to expediting the sale and use of fresh products nearing the end of

their shelf life. It can also increase consumer confidence in the freshness of products purchased. In the case of fresh, highly perishable fishery products, however, the processor has limited, if any, control over the factors which affect the shelf life of a product once it enters the distribution chain. To attempt to determine and use the "average" shelf life of a product may discriminate unfairly against a product handled and marketed properly; and, on the other hand, mislead the consumer who purchases an improperly handled and marketed product. NOAA Fisheries can determine and certify the condition (and quality if applicable) of fresh fishery products only at the time of inspection, and grading if appropriate.

It is NOAA policy to not require the date labeling of fresh fishery products which have been packed under USDC inspection, and graded if applicable. In the interest of making fresh products of good quality available to consumers on a continuing basis, it is also the policy of NOAA to encourage and assist official establishments in the development and use of open-date labeling consistent with their products' inherent shelf-life characteristics, the processing, handling, and preservation methods to which they have been exposed, and the degree of quality control exercised by responsible persons in the distribution chain.

In the event NOAA determines that there is chronic abuse of product bearing official inspection mark(s), it will be the policy of NOAA to notify responsible or potentially impacted parties of their findings. This will include parties with identified involvement with the product, such as processors/distributors identified on the label. It is the policy of NOAA to use all available sanctions to remedy such abuse situations.

Metric Declaration of Quantity of Contents

This section is to establish general and specific guidance for the voluntary use of metric units of quantity to state the net quantity of contents on the labeling, including the principal display panel, of a fishery product commodity.

The Metric Conversion Act of 1975 (80 stat 1007) was enacted to voluntarily increase the use of the metric system of weights and measures in the United States. In support of this policy, the FDA has developed guidance on the use of the metric system in declaring the net quantity of contents on the labels of FDA-regulated commodities.

Procedures

A. Policy
    1. A metric declaration of quantity of contents is not considered to be "other printed label information" that would be subject to the separation requirements of 21 CFR 101.105(f). Other printed label information must be separated from the net weight statement.
    2. On packages of foods labeled in English, with an alternate principal display panel in a foreign language, FDA does not object to the foreign language panel bearing only a metric declaration of net contents. This assumes, of course, that the container labeling otherwise complies fully with the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and the regulations promulgated thereunder.
B. Prefixes

1. In symbols or names for units having prefixes, i.e. kilogram, no space is left between letters making up the symbol or the name.

   EXAMPLE: kg, kilogram

2. Prefixes chosen should result in:
   a. numerical values between 0.1 and 1000, and
   b. decimal fractions of no more than two places.

C. Units

1. Unless FDA advises otherwise, a declaration of quantity of contents:
   a. In units of weight, is expressed in terms of the kilogram, gram, milligram, or microgram.
   b. In units of liquid measure, is expressed in terms of the liter or milliliter at 20 C, except for:
      - a commodity that is normally sold and consumed while frozen, the declaration expresses the volume at the frozen temperature, and
      - a commodity that is normally sold in the refrigerated state, the declaration expresses the volume at 4 degrees C.

2. A number of foreign countries use "re" rather that "er" spellings for the ending of metric units of measure (e.g., metre, litre, etc.). The "er" spellings are preferred for all products sold in the U.S. FDA suggests that firms using "re" spellings revise their labels to contain "er" spellings as their labels are reprinted.
3. Unit names, including prefixes, are not capitalized except at the beginning of a sentence and in titles, headings and other instances in which all main words are capitalized.
4. A space is left between a numeral and the unit name or symbol to which it refers.

   EXAMPLE: 22 mg, 22 g

5. The decimal marker is a dot on the line. (This is the practice in the United States and Canada; however, many countries use a comma or a raised dot.)
6. Decimal notation is preferred with metric measurements, but simple fractions are acceptable, such as those where the denominator is 2, 4 and 8. A fraction should be reduced to its lowest terms.
7. A zero before the decimal point should be used in numbers between 1 and -1 to prevent the possibility that a faint decimal point will be overlooked.

   EXAMPLE: The oral expression "point seven five" is written 0.75

D. Symbols

2. The following symbols for metric units are used in the declaration of quantity:

kilogram kg
microgram μg
gram g
liter L
milligram mg
milliliter mL

3. Symbols, except for liter, are not capitalized unless the unit is derived from a proper name. Periods should not be used after the symbol. Symbols for units are the same in singular and plural.

EXAMPLE: 1 m, 100 m

4. The "L" symbol for liter and "mL" symbol for milliliter are preferred. FDA suggests that firms using "l" and "ml" symbols revise their labels to contain "L" and "mL" as their labels are reprinted.

E. Calculations

0. Conversion - The following conversion factors should be used to determine metric equivalents from inch-pound units:

Quantity: VOLUME

Convert From	To	Multiply By
fluid ounce (U.S.)	liter (L)	0.029 573 53
pint (U.S. liquid)	liter (L)	0.473 176 5
quart (U.S. liquid)	liter (L)	0.946 352 9
gallon (U.S. liquid)	liter (L)	3.785 412
cubic foot	liter (L)	28.316 85
bushel (U.S. liquid)	liter (L)	35.239 07

Quantity: MASS (Weight)

Convert From	To	Multiply By
grain	milligram (mg)	64.798 91
ounce (avoirdupois)	gram (g)	28.349 523
ounce (avoirdupois)	kilogram (kg)	0.028 349 52
pound (avoirdupois)	gram (g)	453.592 37
pound (avoirdupois)	kilogram (kg)	0.453 592 37

1. Rounding - When the digits to be discarded begin with a 5 or more, increase by one unit the last digit retained.

EXAMPLE: 8.3745, if rounded to three digits, would be 8.37; 8.3745, if rounded to four digits, would be 8.375.

NOTE: These rounding rules are to be used for conversion of weights to metric units for labeling purposes ONLY. They are not to be confused with USDC Handbook 25 - Chapter 4, Section 12. j. Rounding Rules/Dropping and Retention of Numbers.

2. Significant Digits - significant digits as defined by the American Heritage Dictionary are "digits of the decimal form of a number beginning with the leftmost nonzero digit and extending to the right to include all digits warranted by the accuracy of measuring devices used to obtain the numbers." Although zero digits at the beginning of a number (e.g., 0.1, 0.01) are never significant digits, zero digits at the end of a number (e.g., 0.10, 10, 10 000) may be significant digits if the digit is known to

be reasonably reliable. *The Metric Editorial Guide* advises that "Zeros at the end of a number are not considered significant unless their use results in a number that is closer to the true value than would be the case if the number were increased or decreased by 1." The position of a decimal point in a number does not affect the number of significant digits in that number (e.g., the numbers 2834, 28.34 and 0.0002834 all have four significant digits).

*The Metric Editorial Guid*e provides the following rules concerning significant digits:

a. If the first significant digit of the metric value is EQUAL TO OR LARGER than the first significant digit of the inch-pound value, round the metric value to the SAME NUMBER of significant digits as there are in the inch-pound value.

   EXAMPLE: (1st significant digit underlined.)
   15 oz X 0.02834952 kg/oz = 0.<u>4</u>25 2428 kg
   which rounds to 0.43 kg;
   1 lb X 0.45359237 kg/lb = 0.<u>4</u>5359237 kg
   which rounds to 0.5 kg

b. If the first significant digit of the metric value is SMALLER than the first significant digit of the inch-pound value, round the metric value to ONE MORE significant digit than is in the inch-pound value.

   EXAMPLE: (1st significant digit underlined.)
   42 oz X 0.02834952 kg/oz = <u>1</u>.19067984 kg
   which rounds to 1.19 kg;
   5 lb X 0.45359237 kg/lb = <u>2</u>.26796185 kg
   which rounds to 2.3 kg

F. Placement

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When a metric declaration of quantity of contents appears on a principal display panel (PDP) of an FDA-regulated fishery product commodity within the bottom 30 percent of the area of the PDP, the metric declaration should be placed with the required inch-pound declaration of net quantity of contents.

A metric declaration in the bottom 30 percent of the PDP may appear as the primary declaration of quantity of contents on the PDP. This metric declaration may appear above or below or to the left or the right of the inch-pound declaration of quantity. The inch-pound declaration of quantity should not be omitted from the PDP. However, on an alternate PDP that serves solely as a foreign language PDP, FDA does not object to the foreign language PDP bearing only a metric declaration of net contents. This assumes, of course, that the container labeling otherwise complies fully with the Federal Food, Drug and Cosmetic Act, the Fair Packaging and Labeling Act, and the regulations promulgated thereunder.

A metric declaration in the bottom 30 percent of a PDP should comply with all provisions of FDA regulations [e.g., 21 CFR 101.105 (foods)] pertaining to the required inch-pound declaration of net quantity of contents, except for provisions pertaining to a statement of count or dual statement of count or a dual statement of quantity. Manufacturers should exercise care to assure that the combined inch-pound/metric declaration complies with all regulations and with the principles set forth in this

guide. Because lower case letters are required for most metric symbols, care must be exercised to insure that both upper and lower case letters meet all letter height requirements. In lieu of the symbol, the full name of the metric unit may be used, e.g., "GRAM" or "gram" or "Gram," provided the lower case letters meet type size requirements. Exponents should be one-half the type size of the symbol letters used.

Use the term "Net Weight" or "Net Wt" whenever the required declaration of net quantity of contents is in terms of weight. The metric declaration may be placed before or after such terms.

Whenever the required declaration of net quantity of contents is in terms of fluid measure or numerical count, the terms "net" or "Net Contents" may be used in the declaration. The metric declaration may be placed before or after such terms.

Always use parentheses for the second expression of a dual inch-pound declaration [e.g., net weight 24 oz (1 lb 8 oz)]. Additional parentheses should be used when the metric and U.S. customary declaration appear on one line.

Examples of inch-pound/metric declarations:

a. Net Wt 425 g (15 oz) or Net Weight 15 oz (425 g) assumes ounces are known to 3 significant digits, i.e., 15.0 oz
b. Net Wt 680 g (24 oz) (1 lb 8 oz) or Net Weight 680 g (24 oz (1 lb 8 oz)) or Net Wt 24 oz (1 lb 8 oz) 680 g or NET WEIGHT (680 g) 24 oz (1 lb 8 oz) assumes ounces are known to 3 significant digits, i.e., 24.0 oz

Compliance

All labels are to be submitted to the National Seafood Inspection Laboratory, Division of Documentation Approval and Supply Services for compliance review and program approval.

Policy for Use of Official Marks and Advertising

It is the USDC policy to work cooperatively and constructively with program participants and marketers of inspected products to help them achieve their marketing goals while maintaining compliance with the applicable federal regulations and policies. Violations of the *Policy for Advertising Services and Marks* will be referred to NOAA's Office of the General Counsel for Fisheries on a recommendation for civil or criminal action.

Program participants and marketers are required to comply with the following:

1. Labeling bearing designs, marks, and statements referencing participation in the USDC seafood inspection program must be reviewed and approved by the Seafood Inspection Program.
2. The United States Department of Commerce and the National Oceanic and Atmospheric Administration seals may not be used in advertising and marketing.
3. All designs, marks, and statements must be truthful, not false or misleading, and comply with all federal laws and regulations. For example, the type of services received under the inspection program must be accurately conveyed in all product markings and advertising.

4. Original and private label logos/brand names and their supporting statements may not use, incorporate, reference or closely resemble any official USDC mark, or be displayed in close proximity to an official USDC mark.
5. All products marked at point-of-sale or cited in advertisements as having received USDC inspection services must be supported by USDC approved specifications or U.S. grade standards, and USDC approved labels.
6. When a mix of USDC inspected and non-inspected products is offered at point-of-sale or in advertising, use of official marks or statements must appear on, or next to, inspected products only. Inspected products must be distinguished from non-inspected products.
7. When a mix of U.S. Grade A, PUFI or "lot inspected" products is in advertisements, the majority of product must be U.S. Grade A and/or PUFI in order to use the statements, "Federally Inspected" or "USDC Inspected" over the entire ad, or to reference all products included in the advertisement.
8. When a mix of U.S. Grade A, PUFI and lot inspected products is offered together at point-of-sale or in the same advertisement, it is appropriate to use the phrases "Federally Lot Inspected" or "USDC Lot Inspected" over the entire ad, or to reference all products when the majority of product has received USDC lot inspection services. Facilities that participate in a sanitation only program must not state or infer that their products are USDC inspected.
9. The statement, "U.S. Grade A Available," can be used by Approved Establishments. The statements "USDC Lot Inspection Available" or "Federal Lot Inspection Available," may not be used in advertising and marketing.

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Procedures for Child Nutrition (CN) Label Approval

In order to assure that fishery products are approved to bear a Child Nutrition (CN) label statement and can be credited toward meeting the meal pattern requirements, USDC and USDA/FNS are cooperating in the review and approval process of labels.

To assure acceptance by the schools of seafood products produced under Federal inspection, the products shall bear, at a minimum, the "Processed Under Federal Inspection" (PUFI) mark. The seafood components for all CN labeled products shall possess good flavor and odor characteristic of the species as defined in the appropriate U.S. Standards for Grades of Fishery Products. For those products bearing the PUFI mark only, the product may contain less than the minimum fish flesh requirement identified in the standard, as long as it contains the meat/meat alternate requirement of the CN statement.

Procedures

A. The Contracting Party must:
    1. be a USDC official establishment with an approved contract for a minimum of 4 hours of Type I inspection per week;
    2. submit and receive approval from USDC of specifications used for CN labeled product. Specifications may be submitted prior to or along with CN label approval requests, using NOAA Form 89-819;
    3. follow the USDA procedures, Child Nutrition Labeling for Seafood Products, identified as attachments to this section; and
    4. in the absence of the assigned inspector, may leave Block 11, USDC Inspector's Signature, blank and place a statement in Block 14, Remarks, indicating the name of the

inspector's supervisor with whom the submittal was discussed and who authorized the submittal. Such submittals will be verified by the Approving Officer prior to action.

NOTE: Contracting parties may initially submit a NOAA Form 89-819 with a draft specification and label sketch to the Approving Officer, Documentation Approval and Supply Services Section, for review and comment by NMFS and USDA/FNS before formal submittal. Inquiries regarding the status of the label review are to be directed to the USDC Approving Officer.

B. The assigned inspector will:
   1. review appropriate specification and CN label, and sign application form (NOAA Form 89-819) after ensuring completeness in accordance with the attachments to this section;
   2. forward five (5) copies of all labels and specifications with NOAA Form 89-819 to:

      Approving Officer, Documentation Approval and Supply Services Section
      3207 Frederic Street, Suite B
      P.0. Drawer 1207
      Pascagoula, MS 39568-1207
      3. retain and file the Field Copy of the NOAA Form 89-819 until receipt of approval notice.

C. The Approving Officer will:
   1. review the request for completeness, legibility, and accuracy; sign and forward to USDA/FNS for CN label statement concurrence;
   2. distribute the approved/disapproved request as follows:
      a. Original and Inspector Copy - to the USDC inspector who will forward the Original to the processor, file the Inspector Copy, and discard the Field Copy.
      b. DASS Office Copy - retained by the Approving officer.
      c. Regional Office Copy - forwarded to the Chief of the Regional Inspection Branch.
   3. resubmit the contracting party's corrected application, if necessary.

Chapter 11 – Minimum Inspection Effort for Lot Inspection

The minimum inspection effort applied for lot inspection of fishery products will be Quality and Condition, unless an inspection document requires further investigation of the fishery product, such as a buyer specification, foreign country requirements or an applicant's request. However, should obvious label violations be noted during the lot inspection, they will be reported on the lot inspection certificate along with the results of the quality and condition. Quality and Condition are defined in 50 CFR 260 as follows:

Quality refers to the wholesomeness of the product, or the minimum basis of acceptability for human food purposes. "Quality" means the inherent properties of any processed product which determine the relative degree of excellence of such product, and includes the effects of preparation and processing, and may or may not include the effects of packing media, or added ingredients."

Condition refers to the packaging and the product. "'Condition' means the degree of soundness of the product which may affect its merchantability and includes, but is not limited to those factors which are subject to change as a result of age, improper preparation and processing, improper packaging, improper storage, or improper handling."

On completion of the inspection, the Lot Inspection Certificate will attest to the factors of Quality and Condition found. If weights and counts were not requested as part of the lot inspection, a statement to the effect will be placed on the certificate, "Vendor weights and counts used, but not verified.

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Chapter 12 – Methodology

a. **Sample Selection**
   i. Use of Acceptance Numbers
   ii. Subsample Size (Revised Sub-Sampling Policy for Container Size Group 3 (Table II) – 50 CFR 260.61 Sampling Plan)

   The 50 CFR 260.61 Sampling Plans were created to balance the need for accurate results with the desire to minimize the costs associated with destructive sampling. The 50 CFR 260.61 Sampling Plans permit sub-sampling for Table II - Container Size Groups 4 (over 10 lbs but not over 100 lbs) and 5 (over 100 lbs), but currently do not allow sub-sampling for Table II - Container Size Groups 3 (over 4 lbs but not over 10 lbs).

   During a review of the 50 CFR Part 260.61 Sampling Plans, it was determined that the USDC could decrease destructive sampling associated with Table II - Container Group Size 3 by allowing for sub-sampling without affecting the performance of the Sampling Plan. Effective September 22, 2011, it is now allowed to use 3 pound sub-sampling units from container sizes in Group 3 (over 4 lbs but not over 10 lbs) when using the 50 CFR Part 260.61 Sampling Plan Table II to perform product inspection, grading or other evaluations. All products subject to Container Size Group 3 may be sub-sampled per the instructions for Container Groups 4 and 5 which allows for a three-pound sub sample.

Once the lot has been identified, the sample size is determined using the sampling plans found in **50 CFR Section 260.61** at http://www.gpo.gov/fdsys/pkg/CFR-2004-title50-vol6/pdf/CFR-2004-title50-vol6-sec260-61.pdf . Other validated and internationally recognized sampling plans, such as **Military Standard 1916**, ANSI/ASQ Z1.4 "Sampling Procedures and Tables for Inspection by Attributes," or **Codex Sampling Plans for Prepackaged Foods**, may also be used. For most lot inspections, the single sampling plan format is used. When using the sampling plan from 50 CFR 260.61, select the appropriate Table, depending on the product type, and then identify the sample size depending on the lot size (number of containers). Use the footnotes provided with each Table to determine whether to examine the entire contents of each container or only a portion thereof.

Example: A lot of frozen shrimp (41/50 count) weighing a total of 9,500 pounds, consists of 950 cases. Each case contains 4 2.5-pound bags of shrimp.

1. Use Table II from 50 CFR Section 260.61 for **Frozen** or Similarly Processed Fishery Products, and Products Thereof Containing Units of Such Size and Character as to be **Readily Separable**.
2. The product falls into **Group 2** - Any type of container over 1 pound but not over 4 pounds net weight.
3. The lot size is **3,800 containers**, which falls in the second column of between 1,801 – 8,400 containers: 950cs × 4 bags/cs = 3,800 containers
4. The sample size is **6 sample units**, or 6 2.5-pound bags of shrimp. Examine the entire contents of each bag.

The entire lot must be staged to be readily accessible for sampling. Samples shall be randomly drawn from throughout the entire lot. Representative cases should be selected from random pallets available and from different levels in each pallet, and from among outside and inside positions on the pallets. Individual samples shall be selected from varying locations within the individual cases, with only one sample drawn from any one case whenever possible. If the lot consists of more than one production date code, the inspector should sample as many different codes as possible. To avoid leaving multiple partially filled cases, back-fill each case with product from the first case(s) sampled. When sampling is completed, there should be no more than one partially filled case remaining. Cases from which a sample has been removed are either marked "sampled" or double-stamped, and then resealed with packing tape. 100% of outside of cases (top and four sides) shall be stamped as "Officially Sampled".

Once all samples have been collected, complete the Certificate of Sampling, NOAA Form 89-805. Company and/or warehouse receipts may also be used to identify samples or sample units drawn by the inspector. If samples for inspection are provided by any means other than a USDC SIP inspector or licensed sampler, they shall be accompanied by a Report of Fishery Product Inspection for Unofficial Samples, NOAA Form 89-806.

b. **Container Integrity**

Examine the shipping containers for signs of damage or abuse. Look specifically for evidence of:

- Improper handling – damaged or torn cartons
- Contamination - rodent or insect filth/excreta, foreign material
- Temperature abuse – signs of freeze/thaw damage
- Leakage – water stains, wet packaging, spoilage odors, opened containers

Take photographs of all labels and identifying marks on the outside of the shipping containers to keep with the inspection report. Record any comments on the sampling certificate.

c. **Label Review Procedures**

Labels of all products intended for domestic commerce shall be checked for compliance to the regulations in **21 CFR Part 101, Food Labeling**. Check to ensure the product name, market name, packer, country of origin, weight, count, and size declarations are accurate. For product intended for export, ensure that the labeling meets the minimal requirements for the country to which it is being exported. Take photographs of the product label(s) to keep with the inspection report. Make sure that the information on the product label(s) and the information on the shipping container are in agreement.

All labels bearing a Federal inspection mark or statement must be approved prior to use, in accordance with requirements and procedures of the USDC Seafood Inspection Program, and may only be used on products produced by establishments currently listed on the **USDC Approved Establishments**.

"Approved Establishments" are those processing establishments or vessels that have voluntarily contracted with the NOAA Seafood Inspection Program for inspection services and have been sanitarily inspected, approved, and certified by the program as being capable of producing safe, wholesome products in accordance with specific quality regulations promulgated by the U.S. Department of Commerce.

This list is can be used as a reference for determining which fishery products have been produced in fish establishments approved by the NOAA Seafood Inspection Program.

d. **Net or Drained Weight Determination**

Use the official methods contained in the most current edition of the publication Official Methods of Analysis of AOAC International to determine a product's net weight or drained weight. The procedures and the products to which they apply are as follows:

AOAC 963.26B (a) – Net Contents of Frozen Food Containers – Unglazed Frozen Foods (**Net Contents Method**) This method is used to determine the net weight of packaged, unglazed shrimp and seafood products. Results are reported as net weight.

AOAC Official Method 963.26
Net Contents of Frozen Food Containers

A. Apparatus
   a. *For packages up to 5 lbs. (2268g)*—Use scale of adequate capacity with sensitivity of 0.01 oz (0.284g).
   b. *For packages over 5 lbs*—Use scale of adequate capacity with sensitivity of 0.025 oz (0.71g).
B. Procedure
   Set scale on firm support and level. Adjust 0 load indicator or rest point and check sensitivity.
   a. *Unglazed frozen foods*—Remove package from low temperature storage, remove frost and ice from outside of package, and weight immediately (***W***). Open package; remove contents, including any product particles and frost crystals. Air-dry empty package at room temperature and weigh (***E***). Weight contents = ***W – E***.
   b. *Glazed frozen foods—See* **963.18(a)**.

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AOAC 963.18 (a) – Net Contents of Frozen Seafoods – Drained Weight– Glazed Seafoods (Spray – Deglazed Method)

This method is used to determine the net weight of packaged, glazed, IQF shrimp and seafood products that can be deglazed without thawing or partially thawing some or all of the product. This method is not used for block-frozen shrimp, nor for shrimp that are of such small size that glaze cannot be removed practically without thawing, or partially thawing, some of the shrimp. This method also is not used for IQF products that contain clumps or clusters in excess of 15% by weight of the glazed weight. Results of this method are reported as net weight, regardless of the designation "Drained Weight" in the paragraph heading. The product is not thawed before draining; hence it is not a drained weight.

Note: Exception to method 963.18(a): For large packages, cases, or containers of shrimp, a representative subsample is removed from the total contents to facilitate deglazing and for purposes of grading the product to the standard.

AOAC Official Method 963.18
Net Contents of Frozen Seafoods Drained Weight Procedure

Set scale (*see* **963.26A**) on firm support and level. Adjust 0 load indicator or rest point and check sensitivity.

a. *Glazed seafoods*—Remove package from low temperature storage, open immediately, and place contents under gentle spray of cold H2O. Agitate carefully so product is not broken. Spray until all ice glaze that can be seen or felt is removed. Transfer product to circular No. 8 sieve, 8 in.

(20cm) diameter for 0.9 kg (2lb) and 12 in. (30cm) for >0.9kg (2lb). Without shifting product, incline sieve at angle of 17-20° to facilitate drainage and drain exactly 2 min (stop watch). Immediately transfer product to tared pan (***B***) and weigh (***A***). Weight product = ***A – B***.

b. *Unglazed seafoods*—See **963.26B**.

AOAC 967.13 and 970.60
Drained Weight of Frozen Shrimp and Crabmeat (**Immersion-Thaw Method**)

This method is used to determine the net weight of shrimp or other seafood frozen together in a block. The individual pieces are not readily separable in the frozen state. This method is also used for IQF shrimp of such small size that the glaze cannot be removed practically without thawing or partially thawing at least some of the shrimp. It is also used for IQF products which contain clumps or clusters in excess of 15% by weight of the glazed weight. Results of this method are reported as drained weight.

Note: Exception to methods 967.13 and 970.60: Nylon mesh bags are used in lieu of a wire mesh basket.

AOAC Official Method 967.13
Drained Weight of Frozen Shrimp and Crabmeat

A. Apparatus
   a. *Container*—Wire mesh basket large enough to hold contents of one package and with openings small enough to retain all pieces. Expanded metal test-tube basket or equivalent, fully lined with standard 16 mesh per linear inch insect screen is satisfactory.
   b. *Balance*—Sensitive to 0.25g or 0.01 oz.
   c. *Sieves*—U.S. No. 8, 8 in. (20cm) and 12 in. (30cm) diameter.
B. Determination

Place contents of individual package in wire mesh basket and immerse in ≥ 15L (4 gal.) container of fresh H2O at 26± 3°C (80± 5°F) so that top of basket extends above H2O level. Introduce H2O of same temperature at bottom of container at flow rate of 4-11 L (1-3 gal.)/min. As soon as product thaws, as determined by loss of rigidity, transfer all material to 12 in. (30cm) (for package 450g [1 lb]) or 8 in. (20cm) (for package ≤ 1 lb) No. 8 sieve, distributing evenly. Without shifting material on sieve, incline sieve to ca 30° from horizontal to facilitate drainage. Two min from time placed on sieve, transfer product to previously weighed pan, and weigh. Weight so found minus weight of pan is drained weight of product.

AOAC Official Method 970.60
Drained Weight of Frozen Crabmeat

A. Apparatus
   a. *Balance*—Sensitive to 1 g or 0.01 lb.
   b. *Thermometer*—Accurate in 0-30°C (30-80°F) range.
   c. *Plastic bowls*—Marked at 48 oz (1440mL), 64 oz (1920 mL), or 1 gal. (3840 mL) level for 6 oz, 8 oz, or 1 lb packages, respectively.
B. Determination

Weigh bare block free of all wrappings and record weight. Place block in bowl containing amount of fresh potable water at 27°C (80°F) equal to 8 × declared weight. Leave block in H2O until all ice is melted. Turn block over several times during thawing. The point at which thawing is complete can be determined by probing block apart.

Pour entire thawed test portion into tared 8 in. (20cm) No. 8 sieve. Incline screen to aid drainage, drain exactly 2 min, and weigh. Subtract tare weight of sieve for thawed drained weight of test portion.

Note: Drained weight can be determined whenever requested, however net weight cannot be determined and certified on all lots. When net weight and drained weight can both be determined and the applicant has requested both, the inspector must draw two separate sets of samples, one set for determining the net weight, and one set for determining the drained weight. The applicant must be advised before sampling that two separate sets of samples will be drawn.

The inspector may refuse to perform the spray-deglaze method of determining net weight on shrimp of such small size that the glaze cannot be removed practically without at least partially thawing some of the shrimp. This is a judgment call to be made by the inspector's supervisor, if necessary. If the applicant has requested a net weight determination (not a drained weight determination), and the inspector believes it cannot be performed accurately, the applicant must be so advised, and permission received to perform a drained weight determination in lieu thereof.

It is important that the certificate state exactly what "weight" was determined, i.e., net weight, drained weight, or both. Further, the inspector must include the AOAC method(s) used (by identifying the section number) on the certification along with the number of the edition of the AOAC manual used.

e. Glaze Determination of Frozen Product
f. Fish Flesh Determination
g. On-line Flesh Determination
h. **Procedures for Cooking Samples**

For sensory evaluation of a product in the cooked state, a sample unit is cooked by one of the following procedures, based on the Official Methods of Analysis of AOAC International, section 976.16, most current edition. Each procedure is based on heating the product to an internal temperature of at least 160° F (70° C). Cooking times vary according to the size of the product and the equipment used. To determine cooking time, cook an extra sample using a temperature measuring device to determine the internal temperature, and then cook all test samples in the same manner. It is important not to overcook the samples.

For fish blocks or other unbreaded large samples, cut at least 3 portions from each sample, each approximately 10 x 7.5 x 1.2 cm (4 x 3 x 0.5").

1. **Bake procedure** – Wrap the samples in aluminum foil and distribute evenly on a flat cookie sheet or shallow flat-bottomed pan. Heat in a ventilated oven, preheated to 400° F (240° C), until the internal temperature of the product reaches at least 160° F (70° C).
2. **Boil-in-Bag procedure** – Place the thawed sample in a boilable film-type pouch and seal. Immerse the pouch and contents in boiling water and heat until the internal temperature of the product reaches at least 160° F (70° C).
3. **Steam procedure** – Wrap samples in aluminum foil and place on a wire rack over boiling water in a covered container. Heat until the internal temperature of the product reaches at least 160° F (70° C).
4. **Microwave procedure** – Wrap samples in plastic wrap or microwave food bags with uniform thickness. Some plastic bags impart odors to the product. Check prior to the inspection to ensure no odor is added from the plastic bag. Place on a food-grade paper plate. Rotate plate ¼ turn, halfway through the cook cycle. Heat until the internal temperature of the product reaches at least 160° F (70° C).

5. **Fry procedure (for breaded shrimp)** – Place frozen breaded shrimp into a wire mesh deep-fry basket sufficiently large to hold the shrimp in a single layer without touching one another. Lower the basket into a suitable liquid oil or hydrogenated vegetable oil at 350° – 375° F. Cook for 3 minutes or until the shrimp attain a pleasing golden brown color. Remove the basket from the oil and allow the shrimp to drain for 15 seconds. Place the cooked shrimp on a paper towel or napkin to absorb the excess oil.
6. **Other procedures** – Other cooking procedures may be used if they provide thermal conditions that are acceptable in heating samples to an internal temperature of at least 160° F (70° C) without scorching; and no substances (other than liquid or vegetable oil for frying) are used which alter the natural flavor and odor of the cooked sample. Only breaded samples should be fried.

i. **Determination of Ammonia in Dogfish**

Dogfish (*Squalus acanthias*) develops an odor of ammonia if fish are not properly handled. It has been shown that one of the best indicators of dogfish quality is ammonia content. Belgium and France have established limits for the amount of ammonia permitted in dogfish as determined by chemical testing. On the basis of such testing, a number of U.S. shipments to these countries have been, rejected. Belgium denies entry to dogfish if the concentration of ammonia exceeds 55 milligrams per 100 grams of fish (55 mg percent) as determined by the accelerated microdiffusion method referenced below. In France, the norm for fresh dogfish is considered to be 50 to 70 mg percent ammonia, and the outer limit is 100 mg percent as determined by a chemical method. However, France does not specify a chemical method.

Three methods for ammonia measurement in dogfish were studied. Comparable results were obtained by use of all three methods. A rapid enzymatic method was selected for use by NMFS Inspectors. The other two methods were: A) the Association of Official Analytical Chemists (AOAC) procedure for determining ammonia in crabmeat, Methods of Analysis, AOAC, 13th Edition, 18.027 - 18.030; and B) the accelerated micro-diffusion test of Vyncke described in Fishing News International, July, 1968, pages 49 - 53.

Policy
Dogfish destined for export to France and Belgium, and to other countries with known ammonia content limits, will be sampled and tested for ammonia content by a trained NMFS Inspector prior to certification.

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Responsibility

A. NMFS Inspector - With appropriate training, NMFS Inspectors will perform ammonia analyses on dogfish by means of the enzymatic test kit described herein. Inspectors will order supplies as necessary using the sources listed on Attachment 1.
B. National Seafood Quality and Inspection Laboratory (NSQIL) - NSQIL will provide training in the use of the enzymatic test kit or will assist in locating local laboratories which will perform tests for NMFS.

Procedures
The method to be used by NMFS Inspectors to measure ammonia in dogfish is known as the

"Quantitative Ultraviolet Determination of Ammonia in Plasma at 340 nm". The test is performed with Sigma Chemical Company Kit No. 170-B. It is important that the analyst read and understand the instruction booklet accompanying the kit. The instruction booklet is to be followed with modifications listed below for sample collection, preparation, and ammonia assay procedure.

A. Sample Collection
   From each lot, collect eight sample units and place the sample units in separate plastic bags.
   1. Dogfish backs - Remove one dogfish back from each of eight randomly selected shipping cases. Cut a two- to four-inch section from each end of the dogfish back (anterior and posterior), and place both sections in one plastic bag. Each sample unit then consists of two pieces weighing approximately 90 grams.
   2. Dogfish belly flaps - Remove one flap from each of eight randomly selected cases. Place each sample unit in a plastic bag. Sample units should weigh approximately 70 grams. All sample units must be maintained in the frozen state until chemical analyses are performed.
B. Sample Preparation and Handling
   Dogfish samples shall be prepared for analysis by the kit method as described below. Reusable glassware must be scrupulously cleaned and rinsed with ammonia-free water. All water used in dilutions must be ammonia-free. During blending operations, avoid overheating samples, and avoid splashing samples on the walls of the blender.
   1. Weigh the sample unit, recording the result to the nearest 0.1 gram. Chop the sample unit into small pieces and place the pieces in a Waring-type blender jar. Add three equivalent weights water (e.g., 90.0 grams dogfish, 270 ml water). Blend until homogeneous (approximately two minutes).
   2. Weigh 40.0 grams of the blended dogfish sample. Use a graduated cylinder to measure 360 ml water. Use enough water (60 ml) to completely transfer the 40.0 gram sample to a clean blender jar, then add the remainder of the water to the jar. Blend for one minute.
   3. Filter the homogenate through fluted Whatman #1 paper into a clean container. Save approximately 20 ml of filtrate for analysis. Discard the remainder of the homogenate.
   4. Assay for ammonia immediately or store the filtrate in an airtight container and refrigerate. Filtrates must be frozen if stored overnight. Filtrates must be brought to room temperature before analyses are performed.
C. Ammonia Assay Procedure
   The kit instructions with regard to "Procedure" are modified as follows: Where the instructions are to add "plasma," substitute "dogfish filtrate."
   See Attachment 5 for a full description of reagents and modified procedure.
D. Results and Calculations
   Record test results and calculations on a copy of the attached form entitled, "Results" (Attachment 2). An example of results and calculations is provided as Attachment 3 to this manual release. Attachment 3 also contains important instructions for calculating results. A table is included in this release as Attachment 4 to facilitate calculations and to provide guidelines wherein results are accurate.

Rejections

A lot of dogfish must be rejected when the ammonia content of any sample unit is determined to be in excess of 40 mg percent in both original and check analysis. When the analyst is unsure as to interpretation of results, he or she should consult a chemist at the National Seafood Inspection

Laboratory in Pascagoula, Mississippi. Dogfish may, of course, be rejected for reasons other than ammonia content, such as unfavorable organoleptic results.

Reporting Results
Report the ammonia content as milligram percent ammonia and reference the method used to determine the ammonia content on the USDC Inspection Certificate.

EXAMPLE
Dogfish were analyzed by a chemical method, the "Quantitative Ultraviolet Determination of Ammonia in Plasma at 340 nm". The results in milligrams ammonia per 100 grams dogfish were:

Sample #	mg Percent Ammonia
1	10
2	15
3	10
4	12
5	9
6	11
7	10
8	14

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ATTACHMENT #1

SUPPLIES FOR AMMONIA TEST

Item	Catalog No.	Cost (as of 5-1-81)	Source
Ammonia Kit	170-B	$64.50/kit	Sigma Chemical Company P.O. Box 14508 St. Louis, MO 63178 1-800-325-3010
Disposable Tips, 20Fl, & 200 Fl, Blue	MPT-2	$18.00/500 or $29.50/1000	Same as above
Disposable Tips, 3ml, White	MPT-6	$8.50/100 or $35.00/500	Same as above
Gloucester Lab Only Culture Tubes 20 (cuvets for Turner 350)	T1290-4	$33.57/1000	American Scientific Products Wiggins Avenue Bedford, MA 01730 1-800-842-1208 (in MA)

Seattle Lab Only Disposable Cuvets (cuvets for Beckman DB)	S7360-1	$35.27/500 (on GSA contract)	American Scientific Products 3660 148th Avenue, NE Redmond, WA 98052 1-800-562-8060 (in WA)
Whatman No. 1 filter paper	F2410-125	$1.40/100	American Scientific in Washington, see above. American Scientific in Massachusetts, see above.

ATTACHMENT #2

RESULTS
AMMONIA IN DOGFISH

DATE:_____
ANALYST:_____

	Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Sample	Record	Record	Subtract Col. 2 from Col. 1	Subtract ΔA Blank from Col. 3	Multiply Col. 4 by 44	Multiply Col. 4 by 176
	Initial A340	Final A340	ΔA	Corrected ΔA	μ/ml Ammonia in Control	mg% Ammonia in Sample
Blank						
Control						
Fish #1						
Fish #2						
Fish #3						
Fish #4						
Fish #5						
Fish #6						
Fish #7						

Fish #8						
Fish #9						
Fish #10						
Fish #11						
Fish #12						
Fish #13						
Fish #14						
Fish #15						
Fish #16						
Fish #17						
Fish #18						

ATTACHMENT #3

RESULTS
AMMONIA IN DOGFISH

DATE:_____
ANALYST:_____

	Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Sample	Record	Record	Subtract Col. 2 from Col. 1	Subtract ΔA Blank from Col. 3	Multiply Col. 4 by 44	Multiply Col. 4 by 176
	Initial A340	Final A340	ΔA	Corrected ΔA	µ/ml Ammonia in Control	mg% Ammonia in Sample
Blank	.461	.440	.021			
Control	.460	.330	.130	.109	4.80	
Fish #1	.490	.300	.190	.169		30

Fish #2	.480	.320	.160	.139		25

INSTRUCTIONS FOR CALCULATIONS
Column 1: Record Initial Absorbance.

Column 2: Record Final Absorbance.

Column 3: Calculate Change in Absorbance (ΔA) by subtracting the value in Column 2 from the value in Column 1. Record ΔA in Column 3. CAUTION: ΔA of the Blank must not exceed 0.10.

Column 4: Calculate Corrected ΔA by subtracting the value of the ΔA for the Blank from each ΔA in Column 3. Record Corrected ΔA in Column 4.

Column 5: Calculate the amount of ammonia in the Control by multiplying the value of the Control in Column 4 by 44. Record the calculation in Column 5. CAUTION: The value must be between 4.5 and 5.5.

Column 6: Calculate and record the concentration of ammonia in each dogfish sample by multiplying the value for Corrected ΔA in Column 4 times 176, or refer to Attachment 4 and select the Concentration of Ammonia that corresponds most closely to the Corrected ΔA in said attachment.

CAUTION: If the Corrected ΔA is greater than 0.35, and if it is necessary to determine an accurate value for ammonia concentration, you must make a dilution of the dogfish filtrate and repeat the test on the diluted sample.

Example: A sample is found to have a Corrected ΔA of 0.40. Pipet 1.0 ml of sample into a clean tube. Add 9.0 ml ammonia-free water and mix. Use this solution to run another test. Complete the calculations, then multiply the result by 10 to allow for the dilution.

ATTACHMENT #4

Corrected Change in Absorbance (ΔA) as it relates to Concentration of Ammonia in Dogfish

Corrected ΔA	Concentration of Ammonia In Dogfish (mg %)	Inspector Action
.03	5	Accept a dogfish sample unit containing an ammonia concentration of 40 mg % or less.
.04	7	
.05	9	
.06	11	
.07	12	
.08	14	
.09	16	
.10	18	
.11	19	
.12	21	
.13	23	
.14	25	
.15	26	
.16	28	
.17	30	

.18 .19 .20 .21 .22 .23	32 33 35 37 39 40	
.24 .25 .26 .27 .28 .30 .32 .34	42 44 46 48 49 53 56 60	Reject a dogfish sample unit containing an ammonia concentration greater than 40 mg %.

ATTACHMENT #5

SIGMA CHEMICAL COMPANY
AMMONIA KIT REAGENTS AND MODIFIED PROCEDURE

REAGENTS

A. AMMONIA REAGENT VIALS, Stock No. 170-10

Ammonia Reagent Multi-Assay vial, add 31 ml water.

Swirl gently to dissolve contents. DO NOT SHAKE.

Reconstituted vials are stable for at least 8 hours at room temperature and 2 days when stored in refrigerator at 0-5o C. Freezing extends stability to 1 week.

B. L-GLUTAMIC DEHYDROGENASE SOLUTION, Stock No. 170-4

Store in refrigerator at 0-5o C.

C. AMMONIA CONTROL SOLUTION, Stock No. 170-5

Store in refrigerator at 0-5o C.

D. POTASSIUM DICHROMATE, Stock No. PD-3

Dissolve contents of vial in 100 ml water.

The absorbance of the solution should be approximately 0.40 vs water at 340 nm using a 1 cm light path.

Stable at room temperature.

MODIFIED PROCEDURE

A BLANK and CONTROL are included with each series of assays. The Ammonia Reagent Multi-Assay vial, Stock No. 170-10, is sufficient for a BLANK and CONTROL and for as many as 8 tests performed at one time.

1. Label 3 cuvets, BLANK, CONTROL, TEST.
2.

To BLANK, add:	To CONTROL, add:	To TEST, add:
3.0 ml Ammonia Assay Solution (Reagent A)	3.0 ml Ammonia Assay Solution (Reagent A)	3.0 ml Ammonia Assay Solution (Reagent A)
0.2 ml water	0.2 ml Ammonia Control Solution Stock No. 170-5	0.2 ml Dogfish Filtrate

   Mix and wait 2 - 3 minutes for equilibration.

3. Read and record INITIAL absorbance of each cuvet at 340 nm versus Potassium Dichromate Solution (Reagent D) as reference.
4. Add 0.02 ml L-Glutamic Dehydrogenase, Stock No. 170-4, to all cuvets. Mix by gentle inversion. Let stand for approximately 5 minutes.
5. Read and record FINAL absorbance of each cuvet versus Potassium Dichromate Solution (Reagent D).

Rounding Rules/Dropping and Retention of Numbers

In all inspection functions the dropping or rounding of numbers will be done after computations are completed to minimize the possibility of computation errors in the final results.

When dropping or rounding numbers **only the first two digits immediately following the digit to be retained shall be considered**. In the following examples, the digits in parentheses are to be dropped.

A. If the first digit to be dropped is less than 5, the last digit retained shall be left unchanged.

EXAMPLES:

Observed value	To be rounded to nearest	Rounded value
379.(46) g	1 g	379 g
60.5(37) oz	0.1 oz	60.5 oz
6.2(25) lb	0.1 lb	6.2 lb
91.2(49) %	0.1 %	91.2 %

B. If the first digit to be dropped is more than 5 or is a 5 followed by a digit greater than 0, the last digit retained shall be increased by 1.

EXAMPLES:

Observed value	To be rounded to nearest	Rounded value
379.(56) g	1 g	380 g
60.5(67) oz	0.1 oz	60.6 oz

6.2(69) lb	0.1 lb	6.3 lb
91.2(59) %	0.1 %	91.3 %

C. If the first digit to be dropped is a 5 alone or a 5 followed immediately by a 0 and the last digit to be retained is odd (1, 3, 5, 7, 9), then the last digit to be retained shall be increased by 1.

EXAMPLES:

Observed value	To be rounded to nearest	Rounded value
379.(5) g	1 g	380 g
60.5(50) oz	0.1 oz	60.6 oz
6.3(50) lb	0.1 lb	6.4 lb
91.3(50) %	0.1 %	91.4 %

D. If the first digit to be dropped is a 5 alone or a 5 followed immediately, by a 0 and the last digit to be retained is even (0, 2, 4, 6, 8), then the last digit to be retained shall be left unchanged.

EXAMPLES:

Observed value	To be rounded to nearest	Rounded value
378.(5) g	1 g	378 g
60.4(50) oz	0.1 oz	60.4 oz
6.6(50) lb	0.1 lb	6.6 lb
91.6(50) %	0.1 %	91.6 %

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j. **Rounding Rules/Dropping and Retention of Numbers**

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EXAMPLES:

To be rounded

Observed value	to nearest	Rounded value
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EXAMPLES:

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378.(5) g	1 g	378 g
60.4(50) oz	0.1 oz	60.4 oz
6.6(50) lb	0.1 lb	6.6 lb
91.6(50) %	0.1 %	91.6 %

Chapter 13 – Product (Lot) Inspection Procedures

a. Whole and Dressed Fish (reference grade std)
   i. Fresh
   ii. Frozen (block)
   iii. IQF

b. Fish Fillets (reference grade std)
   i. Fresh
   ii. Frozen (block)
   iii. IQF
c. Fish Steaks and Portions (reference grade std)
   i. Fresh
   ii. IQF
d. Canned/Pouched Tuna and Salmon (reference CID)
e. Shrimp (reference grade std)
   i. Fresh
   ii. Frozen
   iii. Frozen Raw Breaded
   iv. “Hand-Breaded”

v. Determination of Count per Pound in Shrimp
vi. Shrimp Illustration
f. Crustacean Shellfish
i. Frozen Raw
ii. Cooked
g. Molluscan Shellfish - Shucked
h. Scallops (Raw) (reference grade std)
i. Fresh
ii. Frozen
iii. **Scallop Moisture Determination**

Scallop Moisture Determination

To establish uniform inspection procedures when certifying scallops for total moisture content. This policy will only affect scallops for domestic use and will also not be required for lots less than 200 pounds unless other conditions warrant it (e.g., compliance history, buyer's requirements). Product intended for export will be inspected and certified relative to the importing country's requirements.

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General

On August 31, 1992, the Food and Drug Administration (FDA) through the Office of Seafood developed a policy memo entitled "Interim Labeling Policy Established for Scallops." The purpose of the policy was to "…provide consumers with a better indication about the amount of water in the scallop products they buy." At that time the FDA and the Seafood Inspection Program (SIP) along with many sectors of the industry including retailers and consumer groups were concerned that the practice of adding water and phosphate compounds to scallop adductor muscle meats was potentially deceptive, fraudulent and in violation of the Food, Drug and Cosmetic (FD & C) Act as it relates to adulterated food (*21 USCS, § 342(b)(4))*: "A food shall be deemed to be adulterated … if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is."

The FDA "Interim Labeling Policy" established moisture percentages that would differentiate non-treated scallops or what has been referred to as natural scallops from scallops that were subjected to water and/or a phosphate treatment. Scallops less than 80.0% total moisture, if not subjected to processing conditions utilizing excessive water and/or phosphate treatment, could be labeled simply as scallops. As opposed to scallop products whose total moisture analysis demonstrated a percentage of 80.0 % to 84.0% would have to be labeled "X % Water Added Scallop Product" appearing in the principal display panel of the label. The statement, "Processed with Sodium Tripolyphosphate," or any other polyphosphates used, is also to appear in the identity statement if the product has been processed with the ingredient. In addition, the ingredient statement on the labels for these products must include water and sodium tripolyphosphate (or other phosphate, as appropriate). Products having moisture content over 84.0 % were considered adulterated under the FD & C Act.

It has been the SIP's policy since the inception of the FDA policy to test all lots of scallops for total moisture using the "Ohaus method" or the official AOAC method. The results of these analyses are noted on the certificate and the product would have to be labeled accordingly. On May 18, 2004, the FDA rescinded their Interim Labeling Policy of August 1992. In effect, the percentages that FDA used for defining labeling statements are no longer being enforced. However, scallop products that are subjected to processing conditions that will result in added moisture and/or to food additives (e.g.,

phosphates) must be properly labeled both in the identity statement (i.e., on the principal display panel) and in the ingredient statement.

Policy

Because the FDA has rescinded its policy regarding the action levels of moisture content in scallops, the SIP will no longer use that criteria. However because of the concern over improper labeling or misuse of the process, the SIP will continue to require that all lots of scallops over 200 pounds destined for domestic use be tested for total moisture using the "Ohaus method" or the AOAC method for total moisture. The results of the analysis will be noted on the certificate, score sheet or memorandum. If the inspector has definitive knowledge that the product has been treated in some way to add water to the product, the label must reflect that. Also if the product tests over 83.0 % for total moisture, the SIP will assume that the product has been treated and must be properly labeled. This assumption is based on studies and data collected by various governmental agencies, academia, and other organizations that have demonstrated total moisture content of scallops consistently less than 83%.

At this time there is no upper limit for moisture content.

The SIP will closely follow the development of the international Proposed Draft Standard for Quick Frozen Scallop Adductor Muscle Meat under the Codex Alimentarius Commission (the joint Food Standards Programme of the Food and Agriculture Organization of the United Nations and the World Health Organization). The issues of moisture content limits, phosphate usage, and proper labeling are central elements in this draft standard. The SIP will evaluate the data submitted regarding these issues during the development of this international standard, as well as any data that are obtained directly from foreign agencies or other sources with the intent of establishing appropriate moisture content and phosphate usage criteria for use by this Program.

{**Note**: "X%-water-added" is calculated by knowing the natural moisture content (A) and the moisture content after treatment (B). X = (B-A)/(1-B).}

i. Frozen Breaded/Battered Fish (reference grade std)
j. Simulated Seafood Products
k. Cephalopods
l. Roe
m. Live Products
    i. Crustacean Shellfish
    ii. Molluscan Shellfish
        1. Harvester Tag
        2. Dealer Tag
    iii. Miscellaneous Live Fish
n. Dry Ingredients
o. Reworked or Reconditioned Product
p. Inspection of Endangered Species

Chapter 14 – Lot Acceptance/Rejection

The lot is accepted if the number of non-conforming units is less than or equal to the acceptance number for that sample size. Note: There is no acceptance number for decomposition. If the number of non-conforming units exceeds the acceptance number for that sample size, the lot is rendered

nonconforming, or Grade Not Certified. The applicant shall be notified immediately in the case a lot is deemed nonconforming. After the inspection, samples are returned, destroyed, or given to charity, based on the disposition instructions provided on the Request for Inspection Services form.

Chapter 15 - Inspection Requests for Lionfish and Safe Handling Procedures

Background - Lionfish (*Pterois volitans*) are species of fish which originate from the Pacific Ocean. Lionfish are an invasive species in the Western Atlantic Ocean. Though not completely substantiated, it appears that lionfish were brought into Florida as an aquarium fish and were unintentionally introduced. Lionfish are present in the Western Atlantic all the way up to Long Island, NY.[1]

Not only are lionfish permitted to be harvested, many States encourage the harvest and consumption of these non-native species in order to decrease their negative environmental impact on harvest and reef areas.

Lionfish possess venomous spines that must be handled carefully by divers, harvesters, seafood processors and retailers. Typically spines are removed using gloves to protect the food handler from the venom which can cause severe localized pain, swelling and, in some instances, blistering and infection if not treated properly. [2]

Question #1: Lionfish is not listed in the current Fish and Fishery Products, Hazards and Controls guidance (4th edition). Are there any potential species-related hazards associated with lionfish?

> **Response:** Yes; lionfish are affected by the potential species related food safety hazard of Ciguatera Fish poisoning (CFP). The FDA has issued guidance to primary processors regarding lionfish (here); depending upon the harvest area, they are species that can bioaccumulate CFP. Primary processors would be responsible for addressing CFP as a potential species-related hazard.

[1] NOAA Ocean Service Education, last updated July 2017.

[2] National Institutes of Health - US National Library - Denaturing the Lionfish May 23, 2016

Question #2: Does the FDA provide any guidance relative to the non-edible parts of lionfish that contain venom?

Response: Yes. Lionfish are venomous; venom is located in glands and can be transmitted to humans via injury from the pectoral, dorsal and anal spines. Processors are advised to review the venomous fish section of the FDA Bad Bug Book to look at other factors that may increase risk (e.g., processing in such a fashion where cross-contact occurs between venom sacs and meat.) FDA's Bad Bug Book indicates that *"[c]urrently FDA has no specific guidance for seafood processors as to the control of hazards from fish venom. As noted, the potential for harm from consuming this and any of the other known venom-producing fish species has not been adequately investigated."* [3]

It is therefore NOAA IASI policy that processors must control the potential for venomous cross contact through a GMP and an adequate sanitation control program. As always, in addition to potential species-related hazards, processors need to also consider potential process related hazards, per 21 CFR Part 123, the FDA Seafood HACCP Regulation. Processors who may have additional specific questions may want to direct them to the FDA.

Question #3: Can lionfish be inspected by the USDC/NOAA IASI?

Response: Yes. There is no prohibition relative to the harvest and distribution of lionfish; it may be harvested and sold by US seafood processors. Depending upon the contract type, USDC/NOAA IASI may provide grading and/or inspection services to processors of live or processed lionfish.

USDC/NOAA IASI is permitted to:

1. Perform product inspection of lionfish in any form (whole, filleted)
2. Perform product export certification of lionfish in any form (whole, filleted)
    a. Export certification to include the following statement: "Lionfish (*Pterois volitans)* sold with spines intact could present a handling hazard and must be further processed or handled to avoid cross-contact of the venom with the fish flesh."

USDC/NOAA SI Policy regarding - Personal Protection Equipment

[3] FDA Bad Bug Book, Venomous Fish, p. 245.,

When handling fish with venomous spines, it is important to prevent puncture wounds. According to the American Fisheries Society Fisheries Safety Handbook, individuals who handle fish can take precautions by wearing gloves.[4] Either nylon or kevlar gloves may be used. In some cases, biologists and other fish handlers such as NOAA SI field staff, may also wear a pair of latex gloves underneath the outer gloves. In addition, when evaluating fish with the spines intact, individuals should use hand held tools when selecting the fish for evaluation, to minimize the potential for "spining": puncture wounds caused by spines.

Recommendation for Gloves:

(1) HexArmor, Sharps Master II (link here) $41.99/pair, or similar gloves that are puncture resistant.

Recommendation for Hand Held Tools:

(1) Hooked picking tool to select fish
(2) Wire cutters to remove spines prior to evaluation.

[4] Fisheries Safety Handbook, American Fisheries Society, Bethesda, MD, 2008. Fish Handling Safety, p. 28.

Chapter 16 – Certificates

Certificates are issued according to the type of sampling and inspection performed, i.e., Lot Inspection Certificate, Export Health Certificate, Certificate of Origin, Certificate of Sampling, EU Certificate. All certificates must be filled out completely by the inspector performing the services or his/her designee, in ink, and include the inspector's name and ID number, and date of service.

Certificates will attest to the inspection results of the MAQ attributes, grade attributes, or Buyer Specifications. If weights and counts were not requested as part of the lot inspection, a statement to the effect will be placed on the certificate, "Vendor weights and counts used, but not verified". If, however, the inspector suspects short weights and/or counts, s/he is obligated to evaluate and report the results.

The Lot Inspection Certificate will be issued regardless of whether the product is accepted or deemed nonconforming, since it is an official record of the inspection findings. Lot Inspection Certificates shall be completed and distributed as described in the Instructions for Completing Lot Inspection Certificate, Chapter 7, Section 2.

Chapter 17 – Appeal Procedures

An application for an appeal inspection may be made by any interested party who disagrees with the results of an inspection as stated in an inspection certificate, if the lot of processed products can be positively identified by the inspection service as the lot from which officially drawn samples were

[4] Fisheries Safety Handbook, American Fisheries Society, Bethesda, MD, 2008. Fish Handling Safety, p. 28.

previously inspected. Such application shall be made within thirty (30) days following the day on which the initial inspection was performed, unless an extension is approved by the Chief Quality Officer, SIP.

Application for an appeal inspection may be filed with: (1) the inspector who issued the inspection certificate on which the appeal is requested; or (2) the Regional Inspection Branch nearest the place where the processed product is located. The application for appeal inspection shall state 1) the location of the lot of processed products and 2) the reasons for the appeal, as well as 3) the date and serial number of the certificate covering inspection of the processed product on which the appeal is requested. The application may also be accompanied by a copy of the previous inspection certificate and any other information that may facilitate inspection. The application for appeal shall be made in writing.

An application for appeal inspection may be withdrawn by the applicant at any time before the appeal inspection is performed, but the applicant must pay for any time incurred by the inspector in connection with such application, any travel expenses, telephone, or other expenses which have been incurred by the inspection service in connection with such application.

Appeals are granted by the appropriate Regional Branch Chief. An application for an appeal inspection may be refused if it is determined that:

a. The reasons for the appeal inspection are frivolous or not substantial;
b. The quality or condition of the processed product has undergone a material change since the initial inspection;
c. The lot in question is not, or cannot be made accessible for the selection of officially drawn samples;
d. The lot relative to which the appeal inspection is requested cannot be positively identified by the inspector as the lot from which officially drawn samples were previously inspected; or
e. There is a noncompliance with the regulations in this part. Such applicant shall be notified promptly of the reason for such refusal.

An appeal inspection shall be performed by an inspector or inspectors (other than the initial inspector) authorized for this purpose by NMFS and, whenever practical, such appeal inspection shall be conducted jointly by two inspectors. However, the inspector who made the initial inspection may be authorized to draw the samples when another inspector or licensed sampler is not available in the area where the product is located.

After an appeal inspection has been completed, an inspection certificate shall be issued showing the results of the appeal inspection, and such certificate shall supersede the inspection certificate originally issued. Each superseding (appeal) inspection certificate shall clearly identify the number and date of the inspection certificate which it supersedes. The superseded certificate becomes null and void upon the issuance of the superseding (appeal) inspection certificate and shall no longer represent the quality or condition of the processed product described therein.

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Chapter 18 – Fees and Charges

The applicant is responsible for all fees and charges associated with the sampling and inspection of the product. In the event of an appeal inspection, if the applicant for both the initial and appeal inspections is the same and the results of the appeal inspection are in favor of the applicant, there will be no charge to the applicant for the appeal inspection. If, however, the results of the appeal are not in favor of the applicant, the applicant will be charged for the appeal inspection and all related travel expenses. The inspector will complete a Daily Record of Charges, which includes time spent sampling, inspecting, and completing certificates, as well as any travel expenses incurred. The Regional Inspection Branch will, under separate cover, charge the applicant for the associated fees and charges of the inspection and submit the bill to NOAA Finance, with NOAA Finance billing the applicant. The current fee schedule for inspection and analytical services can be found in Chapter One, Section 15a.