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 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 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](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**
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
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.

Chapter 10 – Eligibility Requirements for Use of NOAA SIP Official Insignia (Issue date: 7.15.22)

Introduction

Under the authority of the Agricultural Marketing Act, NOAA Seafood Inspection Program (SIP) offers two quality insignia, the US Grade A Shield and the Processed Under Federal Inspection (PUFI) Mark, as well as the use of associated statements attesting to finished product quality. These marks and associated quality statements are part of what is referred to as Official Insignia.

Scope

The Eligibility Requirements for Use of NOAA SIP Official Insignia policy applies to fish and fishery products that are produced by NOAA SIP Approved Establishments (Approved Establishments).

The following sections outline eligibility requirements, request and approval, and revocation procedures for use of specific NOAA SIP Official Insignia.

Section 1 - Eligibility Requirements for use of Grade A, Processed Under Federal Inspection Marks, and associated statements

Under the authority of the Agricultural Marketing Act, NOAA Seafood Inspection Program (SIP) offers two quality insignia, the US Grade A Shield and the Processed Under Federal Inspection (PUFI) Mark, as well as the use of associated statements attesting to finished product quality. In order to meet eligibility requirements for use of these marks and associated statements, the establishment must be in good standing with NOAA SIP Program Requirements for Approved Establishments (AE) or Approved Establishments with a Quality Management Program (AE QMP) and must satisfy applicable federal compliance and quality conformance criteria established per regulation and by NOAA SIP program requirements.

A. Approved Establishments
For Approved Establishments, eligibility for use of the US Grade A Shield, PUFI Mark, and associated statements is determined on a systems audit and lot-by-lot finished product inspection basis by NOAA SIP. The following conditions must be met:

1. The Approved Establishment must maintain a reliable systems audit rating.
2. NOAA SIP must be present while the designated fish or fishery product lot is being produced, or as otherwise approved by NOAA SIP.
3. NOAA SIP must perform the finished product inspection for each designated production lot.
4. The fish or fishery product offered for certification must meet the applicable Compliance Standard and the applicable US Grade Standard or USDC Approved Specification requirements for use of the requested mark or statement.

B. Approved Establishment with a Quality Management Program

For Approved Establishments and Quality Management Program (AE QMP) participants, eligibility for use of US Grade A Shield, PUFI Mark, and associated statements is determined on a systems audit basis. The following conditions must be met:

1. The AE QMP participant must receive approval from NOAA SIP for the fish or fishery product (or similar group of products) to be included in the firm’s Quality Management Program.
   A quality plan and attendant finished product inspection documents must be submitted by the Approved Establishment and approved by NOAA SIP. The approval process will include document validation and on-site validation of the effectiveness of and adherence to the QMP quality plan.
2. The AE QMP must confirm adherence to the Quality Management Program and Quality Plan and must document that each designated lot meets regulatory compliance criteria and quality conformance criteria commensurate with the specified mark or statement.
3. System assessment and finished product verification performed by NOAA SIP during systems audits will verify that the quality management system is reliable and designated lots were conforming.

Section 2 - Request and Approval Procedures for Use Grade A, Processed Under Federal Inspection Marks, and associated statements.

The procedures to request the use US Grade A Shield, PUFI Mark, and associated statements are outlined below for Approved Establishments and AE QMP participants.

A. Approved Establishment Program (AE) Participants

To request approval to use the US Grade A Shield, PUFI Mark, and associated statements for a designated lot, Approved Establishment participants must:
1) **Submit Request for use of Official Insignia.** All requests must be initiated by using the online Request for Use of NOAA SIP Official Insignia submission form (link).

2) **Schedule Product Inspection with NOAA SIP.** A request must be made to NOAA SIP to schedule and perform an onsite finished product inspection for each designated lot for which the Approved Establishment desires the use of an applicable mark or statement.

3) **Receive Approval/Disapproval from NOAA SIP to use insignia.** Based on finished product inspection and quality assessment results:
   
   a) Lots that meet the *US Grade Standard or USDC Approved Specification* requirements for use of a specified mark or statement will be granted permission for its use by NOAA SIP.
   
   b) Lots that do not meet the *US Grade Standard or USDC Approved Specification* requirements for use of a specified mark or statement will be denied permission for its use by NOAA SIP.

**B. Approved Establishment with a Quality Management Program (AE and QMP) Participants**

To use the US Grade A Shield, PUFI Mark, and associated statements for a designated lot, AE and QMP participants must receive approval for each fish or fishery product processed under their QMP system. To add a fish or fishery product to a Quality Management System, Approved Establishments must:

1) **Submit Request for use of Official Insignia.** All requests must be initiated by using the online Request for Use of NOAA SIP Official Insignia submission form (link).

2) **Submit a Quality Plan and attendant Quality Plan documents.** A quality plan specific for each fish or fishery product (or group of similar products covered by a US Grade Standard or USDC Approved Specification) must be submitted by the AE QMP participant for approval by NOAA SIP. Records used to document Quality Plan Adherence must be submitted for approval by NOAA SIP.
   
   a) Model quality plans will be provided by NOAA SIP and may be used to comply with this requirement.

3) **Submit Finished Product Inspection Documents.** Finished product inspection or verification documents must be submitted by the AE QMP participant and approved by NOAA SIP.
   
   a) E-worksheets are available for determination of compliance and conformance results.

4) **Prepare for an on-site System and Product Validation.** Upon validation of the written quality plan, quality plan documents and finished product inspection
documents, AE QMP Participants must prepare for an on-site System and Product Validation. To do so, AE and QMP Participants must process products under the designated Quality Plan for a minimum of 5 production days, validating the system and verifying the system’s ability to produce products meeting the product inspection and quality criteria commensurate with the requested mark or statement.

Finished product lots produced during this product/process validation period may be eligible for use of the applicable mark or statement when the NOAA SIP Validation Audit results indicate system reliability.

5) **Contact NOAA SIP to Schedule a Validation Audit.** After having completed the Internal Validation, establishments will contact NOAA SIP to schedule a Validation Audit.

6) **Receive Approval/Disapproval to use Official Insignia.** Based on the results from the NOAA SIP on-site Validation Audit:

   a) Establishments that pass the QMP Validation audit for the specific fish or fishery product, or group of similar products will be permitted to process products under the NOAA SIP Audit-based QMP system.

      i) Compliant and conforming lots produced under this system are eligible for use of applicable marks or statements.

      ii) Compliant and conforming lots produced during the establishment’s process and product validation (see C (3) above), may bear the applicable marks or statements.

   b) Quality Management Programs that do not pass the NOAA SIP Validation Audit for the specified fish or fishery product will not be permitted to process products under this system.

**Section 3 - Revocation of Eligibility to Use Grade A, Processed Under Federal Inspection Marks and associated statements for AE and AE with Quality Management Program participants.**

Approval for use of *Official Insignia* may be revoked when the establishment fails to meet NOAA SIP requirements, including the adherence to, validity and efficacy of their Approved Establishment and/or Quality Management Programs.

**Section 4 - Policy for use of Official Insignia in Advertising [Reserved]**

**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.

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](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).

**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.

Back to top
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.

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:

<table>
<thead>
<tr>
<th>Sample #</th>
<th>mg Percent Ammonia</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
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<tr>
<td>4</td>
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<tr>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>14</td>
</tr>
</tbody>
</table>

ATTACHMENT #1

SUPPLIES FOR AMMONIA TEST

<table>
<thead>
<tr>
<th>Item</th>
<th>Catalog No.</th>
<th>Cost (as of 5-1-81)</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonia Kit</td>
<td>170-B</td>
<td>$64.50/kit</td>
<td>Sigma Chemical Company P.O. Box 14508</td>
</tr>
</tbody>
</table>
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: ______________________

<table>
<thead>
<tr>
<th>Sample</th>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
<th>Column 4</th>
<th>Column 5</th>
<th>Column 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Record</td>
<td>Record</td>
<td>Subtract Col. 2 from Col. 1</td>
<td>Subtract ΔA Blank from Col. 3</td>
<td>Multiply Col. 4 by 44</td>
<td>Multiply Col. 4 by 176</td>
</tr>
<tr>
<td>Blank</td>
<td>Initial A340</td>
<td>Final A340</td>
<td>ΔA</td>
<td>Corrected ΔA</td>
<td>μ/ml Ammonia in Control</td>
<td>mg% Ammonia in Sample</td>
</tr>
<tr>
<td>Control</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fish #1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

21
<table>
<thead>
<tr>
<th>Fish #2</th>
<th></th>
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<th></th>
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<td>Fish #4</td>
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<td>Fish #5</td>
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<td>Fish #14</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Fish #15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fish #16</td>
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<td></td>
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<tr>
<td>Fish #17</td>
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<tr>
<td>Fish #18</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

**ATTACHMENT #3**

**RESULTS
AMMONIA IN DOGFISH**

DATE:________________________

ANALYST:_____________________

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
<th>Column 4</th>
<th>Column 5</th>
<th>Column 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample</td>
<td>Record Initial A₃₄₀</td>
<td>Record Final A₃₄₀</td>
<td>Subtract Col. 2 from Col. 1</td>
<td>Subtract ΔA Blank from Col. 3</td>
<td>Multiply Col. 4 by 44</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------</td>
<td>------------------</td>
<td>-----------------------------</td>
<td>-------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Blank</td>
<td>.461</td>
<td>.440</td>
<td>.021</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>.460</td>
<td>.330</td>
<td>.130</td>
<td>.109</td>
<td>4.80</td>
</tr>
<tr>
<td>Fish #1</td>
<td>.490</td>
<td>.300</td>
<td>.190</td>
<td>.169</td>
<td></td>
</tr>
<tr>
<td>Fish #2</td>
<td>.480</td>
<td>.320</td>
<td>.160</td>
<td>.139</td>
<td></td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Corrected ΔA</th>
<th>Concentration of Ammonia in Dogfish (mg %)</th>
<th>Inspector Action</th>
</tr>
</thead>
</table>

23
Accept a dogfish sample unit containing an ammonia concentration of 40 mg % or less.

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

<table>
<thead>
<tr>
<th>Observed value</th>
<th>to nearest</th>
<th>Rounded value</th>
</tr>
</thead>
<tbody>
<tr>
<td>379.(46) g</td>
<td>1 g</td>
<td>379 g</td>
</tr>
<tr>
<td>60.5(37) oz</td>
<td>0.1 oz</td>
<td>60.5 oz</td>
</tr>
<tr>
<td>6.2(25) lb</td>
<td>0.1 lb</td>
<td>6.2 lb</td>
</tr>
<tr>
<td>91.2(49) %</td>
<td>0.1 %</td>
<td>91.2 %</td>
</tr>
</tbody>
</table>

**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:**

<table>
<thead>
<tr>
<th>Observed value</th>
<th>to nearest</th>
<th>Rounded value</th>
</tr>
</thead>
<tbody>
<tr>
<td>379.(56) g</td>
<td>1 g</td>
<td>380 g</td>
</tr>
<tr>
<td>60.5(67) oz</td>
<td>0.1 oz</td>
<td>60.6 oz</td>
</tr>
<tr>
<td>6.2(69) lb</td>
<td>0.1 lb</td>
<td>6.3 lb</td>
</tr>
<tr>
<td>91.2(59) %</td>
<td>0.1 %</td>
<td>91.3 %</td>
</tr>
</tbody>
</table>

**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:**

<table>
<thead>
<tr>
<th>Observed value</th>
<th>to nearest</th>
<th>Rounded value</th>
</tr>
</thead>
<tbody>
<tr>
<td>379.(5) g</td>
<td>1 g</td>
<td>378 g</td>
</tr>
<tr>
<td>60.5(50) oz</td>
<td>0.1 oz</td>
<td>60.6 oz</td>
</tr>
<tr>
<td>6.6(50) lb</td>
<td>0.1 lb</td>
<td>6.6 lb</td>
</tr>
<tr>
<td>91.6(50) %</td>
<td>0.1 %</td>
<td>91.6 %</td>
</tr>
</tbody>
</table>

**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:**

<table>
<thead>
<tr>
<th>Observed value</th>
<th>to nearest</th>
<th>Rounded value</th>
</tr>
</thead>
<tbody>
<tr>
<td>378.(5) g</td>
<td>1 g</td>
<td>378 g</td>
</tr>
<tr>
<td>60.4(50) oz</td>
<td>0.1 oz</td>
<td>60.4 oz</td>
</tr>
<tr>
<td>6.6(50) lb</td>
<td>0.1 lb</td>
<td>6.6 lb</td>
</tr>
<tr>
<td>91.6(50) %</td>
<td>0.1 %</td>
<td>91.6 %</td>
</tr>
</tbody>
</table>

**Back to top**

**j. 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:**

<table>
<thead>
<tr>
<th>Observed value</th>
<th>To be rounded</th>
<th>Rounded value</th>
</tr>
</thead>
<tbody>
<tr>
<td>379.(46) g</td>
<td>1 g</td>
<td>379 g</td>
</tr>
<tr>
<td>60.5(37) oz</td>
<td>0.1 oz</td>
<td>60.5 oz</td>
</tr>
<tr>
<td>6.2(25) lb</td>
<td>0.1 lb</td>
<td>6.2 lb</td>
</tr>
<tr>
<td>91.2(49) %</td>
<td>0.1 %</td>
<td>91.2 %</td>
</tr>
</tbody>
</table>

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:**

<table>
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<tr>
<th>Observed value</th>
<th>To be rounded</th>
<th>Rounded value</th>
</tr>
</thead>
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<td>380 g</td>
</tr>
<tr>
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<td>0.1 oz</td>
<td>60.6 oz</td>
</tr>
<tr>
<td>6.2(69) lb</td>
<td>0.1 lb</td>
<td>6.3 lb</td>
</tr>
<tr>
<td>91.2(59) %</td>
<td>0.1 %</td>
<td>91.3 %</td>
</tr>
</tbody>
</table>

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.

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</thead>
<tbody>
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<td>1 g</td>
<td>380 g</td>
</tr>
<tr>
<td>60.5(50) oz</td>
<td>0.1 oz</td>
<td>60.6 oz</td>
</tr>
<tr>
<td>6.6(50) lb</td>
<td>0.1 lb</td>
<td>6.6 lb</td>
</tr>
<tr>
<td>91.3(50) %</td>
<td>0.1 %</td>
<td>91.4 %</td>
</tr>
</tbody>
</table>

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:**

<table>
<thead>
<tr>
<th>Observed value</th>
<th>To be rounded</th>
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</tr>
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<tbody>
<tr>
<td>378.(5) g</td>
<td>1 g</td>
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</tr>
<tr>
<td>60.4(50) oz</td>
<td>0.1 oz</td>
<td>60.4 oz</td>
</tr>
<tr>
<td>6.6(50) lb</td>
<td>0.1 lb</td>
<td>6.6 lb</td>
</tr>
<tr>
<td>91.6(50) %</td>
<td>0.1 %</td>
<td>91.6 %</td>
</tr>
</tbody>
</table>

**Chapter 13 – Product (Lot) Inspection Procedures**

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

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, due to concerns over improper labeling, NOAA SIP will continue to require that all lots of scallops over 200 pounds destined for domestic use be tested for total moisture using the **AOAC Official Method 950.46-Moisture in Meat** (AOAC Method) or other valid methods and equipment that provide results statistically equivalent to those of 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
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.

**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?

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

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. 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, 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.

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

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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 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.

**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.