

statute until final disposition by an agency Board of Contract Appeals or the United States Court of Federal Claims. Notwithstanding the foregoing, where the head of an agency determines, on a nondelegable basis, following notice to the Contractor that urgent or compelling circumstances will not permit awaiting the decision by such Board of Contract Appeals or the United States Court of Federal Claims, the Contractor or subcontractor agrees that the agency may authorize release or disclosure of the technical data. Such agency determination may be made at any time after issuance of the final decision and will not affect the Contractor's or subcontractor's right to damages against the United States where its asserted restrictions are ultimately upheld or to pursue other relief, if any, as may be provided by law.

\* \* \* \* \*

(i) *Duration of right to challenge.*

(1) The Government may review the validity of any restriction on technical data, delivered or to be delivered under a contract, asserted by the Contractor or subcontractor. During the period within 6 years of final payment on a contract or within 6 years of delivery of the technical data to the Government, whichever is later, the Contracting Officer may review and make a written determination to challenge the restriction. The Government may, however, challenge a restriction on the release, disclosure, or use of technical data at any time if such technical data—

- (i) Are publicly available;
- (ii) Have been furnished to the United States without restriction;
- (iii) Have been otherwise made available without restriction; or
- (iv) Are the subject of a fraudulently asserted use or release restriction.

(2) Only the Contracting Officer's final decision resolving a formal challenge by sustaining the validity of a restrictive marking constitutes "validation" as addressed in 10 U.S.C. 3785(c).

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 260

[Docket No. 240412-0106]

RIN 0648-BH37

#### Inspection and Certification of Establishments, Fishery Products, and Other Marine Ingredients

**AGENCY:** National Marine Fisheries Service (NMFS or Agency), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** The NMFS Office of International Affairs, Trade, and Commerce proposes to revise its current implementing regulations to improve the uniformity and reliability of seafood inspection services by adopting recognized best practices for inspection. NMFS has not significantly revised or updated the existing regulations since first issuing them in 1971, though it has modified many operating procedures since implementation of the current regulations. NMFS anticipates that these revisions will benefit the seafood industry by streamlining seafood inspection services and providing improved, more accurate inspection results, as described below.

**DATES:** Written comments must be received by May 28, 2024.

**ADDRESSES:** Written comments on this action, identified by NOAA-NMFS-2024-0022, may be submitted by either of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to <http://www.regulations.gov/document/NOAA-NMFS-240412-0106>, click the "Comment" icon, complete the required fields, and enter or attach your comments.

- *Mail:* Steven Wilson, Chief, Seafood Inspection Program, Office of International Affairs, Trade, and Commerce, 1315 East-West Highway, Silver Spring, MD 20910. All comments received are a part of the public record and will generally be posted to <https://www.regulations.gov> without change. All personal identifying information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

NMFS will accept anonymous comments. Enter N/A in the required fields if you wish to remain anonymous. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe portable document file (PDF) formats only.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to the NMFS Office of International Affairs, Trade, and Commerce and by email to: [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov) or fax to (202) 395-7285.

**FOR FURTHER INFORMATION CONTACT:** Steven Wilson, Chief, Seafood Inspection Program, by email at [Steven.Wilson@noaa.gov](mailto:Steven.Wilson@noaa.gov) or by phone at 301-427-8312.

#### SUPPLEMENTARY INFORMATION:

##### Background

Under the authority of the Agricultural Marketing Act (AMA) of 1946 (7 U.S.C. 1621 *et seq.*), and in accordance with the Reorganization Plan Number 4 of 1970 (84 Stat. 2090), NOAA administers a voluntary Seafood Inspection Program (SIP or Program) which offers inspection and grading services for seafood and other marine products, as well as audit and consultative services to domestic and international processors, importers, and international competent food safety authorities. SIP also authorizes the use of certain marks and shields to processors meeting specific safety, quality, and other program requirements. The existing regulations codified at 50 CFR part 260 have not been significantly revised or updated since NMFS first issued them in 1971, 36 FR 21037 (November 3, 1971), and currently do not reflect the changes in industry practices or the expanding role of SIP since that time. On October 15, 2019, NMFS issued an advance notice of proposed rulemaking (ANPR) requesting input from stakeholders and interested parties on focused areas of the Seafood Inspection Program regulations. Based on the eight public comments received and NMFS' overall assessment of the current program, NMFS proposes these comprehensive updates to the existing regulations. NMFS looks forward to receiving comments on the updates and modernizations proposed here.

The revisions proposed herein incorporate the significant changes and updates that SIP has already made and those that it still needs to implement to simplify its administrative, inspection, and certification procedures. These changes and updates will lead to

increased uniformity of and efficiencies associated with inspections, while retaining the reliability and validity of inspection results. In an effort to minimize costs, streamline operations, and enable updates in a cost-effective and timely fashion, SIP is proposing to remove certain provisions from 50 CFR part 260 and place them in the NMFS Fishery Products Inspection Manual (SIP Manual), which can be found online at <https://www.fisheries.noaa.gov/national/seafood-commerce-certification/seafood-inspection-manual>. The proposed rule does not change the way SIP currently operates but removes outdated regulatory text, adds relevant text to incorporate current practices, and moves certain provisions to the SIP Manual so that the regulations would both more accurately reflect current industry practices and allow for adaptation to potential changes in technologies and product requirements. NMFS anticipates that these revisions will benefit the seafood industry by clarifying and simplifying the procedures for obtaining seafood inspection services and providing improved, more accurate and consistent inspection results, as compared with the current published regulations. Table 1 below summarizes the proposed rule's impacts on section number and title changes, as well as identifying provisions that would be deleted from the regulations.

### 1. Modernize Definitions and Administrative Procedures

With respect to administrative procedures, NMFS proposes to remove specific provisions that are no longer in use, such as the option to request inspection service via telegraph, from the regulatory text. The requirement to request inspection services would be retained, while the specific, detailed procedures for requesting such service would be moved from the regulatory text to the online SIP Manual, where they can more readily be updated and modified as new technologies and procedures are implemented. Putting these strictly procedural matters in the online manual would make implementing cost-neutral and cost-saving procedural changes more timely and efficient for both government and industry.

#### Definitions

The proposed rule would update definitions in § 260.6 (proposed § 260.2) to reflect the current use and meaning of certain terms used throughout part 260 and in general use in industry. Terms such as “Approved

Establishment,” “Fish,” “Fishery Product,” “Marine Ingredient,” “NMFS Fishery Products Inspection Manual (SIP Manual),” “Processing,” and “Product” would be added to align with current SIP policies and procedures, as well as current U.S. Standards for Grades (50 CFR part 261), Food and Drug Administration (FDA) Hazard Analysis and Critical Control Point (HACCP) regulations (21 CFR part 123), and Good Manufacturing Practices (GMPs) (21 CFR part 117). Other terms, such as “Deviant,” “Deviation,” and “Plant” would be removed because they are either no longer commonly used in the context of seafood inspection or are more accurately defined in other terms. In general, only terms that pertain specifically to the regulations in this part are defined therein.

#### Inspection Service and Appeal Inspection

The existing regulations at §§ 260.12–260.41 are out of date and inconsistent with current procedures for requesting inspection services, performance of inspections and product grading activities, issuance of certificates, and appeal of inspection results. The proposed regulations reflect the now-common use of the internet and the online Seafood Inspection Services Portal (online portal) system for requesting SIP inspection services, as well as the use of electronic documents (e.g., inspection certificates), which the current regulations do not address. The online portal, first deployed in 2008 for inspection services requests and issuance of certificates and reports, enables SIP staff to address the needs of industry in a more timely and consistent manner. Tracking service requests through the online portal system also enables SIP management to better allocate resources to meet the needs of its customers. Public comment on the ANPR supported the increased use of the online portal for requesting all inspection services and continued electronic transfer of records. In addition to the increases in efficiency, the use of the online portal for the generation of official inspection certificates, whether printed on water-marked paper or delivered electronically, has reduced government costs by eliminating the need to print and secure the old carbon-copy controlled certificate books, whereby each inspector or office had to secure a log and retain a copy of each certificate type issued.

While the proposed regulations would still allow for inspection services to be requested by fax, the move to the online portal system reduces the cost to

seafood businesses by allowing computer access to all services in one account, storing information, reducing the amount of time required to make a request, and eliminating the need to have a separate fax machine, which many smaller businesses do not otherwise use or need. The proposed rule would consolidate the current sections associated with applying for service (§§ 260.14–260.17) into a new § 260.6, with language updated to reflect the current practice of applying for inspection services through the online portal system per the instructions in the SIP Manual, found in part 1, chapter 12. The regulatory language in § 260.21(b)(1–5) (proposed § 260.10(b)(1–4)) would be updated to reflect the current product inspection grade and compliance assessment practices. SIP's intent is to consolidate and harmonize the current U.S. Grade Standards outside of this rulemaking action, and to keep current product inspection and quality assessment procedures detailed in the SIP Manual. This shift will allow SIP to keep current with changes and improvements in inspection techniques, as well as any changes to finished product specifications and the approval process of buyer and customer specifications.

NMFS proposes removing § 260.23, Postponement of Inspection Service, from regulatory text, and placing this procedure in the SIP Manual, part 1, chapter 12. This specific activity is strictly procedural in nature and does not need to be regulated in part 260.

The proposed rule would modify the existing provisions for requesting and performing appeal inspections found in §§ 260.36–260.41 by removing the procedures to file the request for appeal (§ 260.36; proposed § 260.19) and the mechanics of numbering and dating the appeal inspection certificates (§ 260.41; proposed § 260.23) from part 260 and placing them in the SIP Manual, part 1, chapter 14. NMFS proposes to leave the remainder of the appeal process in regulatory text and add provisions for appeals of audits and other services (the current regulations only address appeal of fishery product inspections) to ensure that all customers get equitable and consistent treatment, regardless of their level of participation in SIP. For example, a person requesting one lot inspection would have the same right to appeal as a company with multiple facilities and vessels participating in SIP as an Approved Establishment.

#### Fees and Charges

NMFS proposes to consolidate the current subgroup Fees and Charges (§§ 260.69–260.81) into a new § 260.30,

Inspection Fees, Payment Guarantees, Charges and Payments, and remove the details of individual fees and charges from regulatory text. The current fees for all SIP services are available in the SIP Manual, part 1, chapter 13 and on the SIP website at <https://www.fisheries.noaa.gov/national/seafood-commerce-trade/inspection-and-analytical-services-fees>. Putting the specific fees and charges in the SIP Manual, rather than in the regulatory text, would allow for annual updates and any modifications to the fee structure to be accurately reflected in a timely manner without additional rulemaking. SIP would continue to provide notice of fee updates and modifications to the fee structure in the **Federal Register** consistent with existing §§ 260.70 and 260.81.

In response to the ANPR, one commenter suggested that travel costs be the same for all participants in SIP and not based on their contract/non-contract type or level of participation. The commenter also suggested that HACCP contract rates have become too high for many small businesses and that when a participant regularly demonstrates compliance and minimal deficiencies in an audit, the frequency of HACCP audits should be reduced to twice yearly. Another comment suggested that with the online portal system, where most certificate information is filled out online by the requestor instead of SIP staff, the cost of certificates should be reduced, while another commenter suggested that the fees charged for scoresheets and duplicate certificates should be re-evaluated. NMFS also received one comment suggesting that SIP clarify its billing processes and activity time charges and make them consistent across the regions and offices. The same commenter expressed concern that any changes made to sampling plans not increase the cost of inspection.

While there may be an incremental cost increase for small entities choosing to participate in the activities of SIP, all of the fees assessed by SIP are analyzed and updated regularly and are set in such a way as to offset the costs of the program while not generating a profit per the Financial Policy outlined in the SIP Manual in part 1, chapter 13. This includes certificate fees, whether or not issued through the online portal. All travel costs incurred with inspection services, including mileage, transportation, travel time, and lodging and per diem when required, are billed to the requestor. Lodging, per diem, and the personal vehicle mileage rate are set annually by the U.S. General Services Administration (GSA) and are applied

equally to all users, so any disparity in these charges between regions can be attributed to cost variations in different parts of the country. Billing for travel-related costs is detailed in the SIP Manual, part 4, chapter 18, and in part 1, chapter 14. Any changes proposed to sampling plans resulting from this proposed rule are expected to have a positive impact on associated costs and will be detailed in the SIP Manual, part 4, chapter 19. These positive impacts could include using smaller sample sizes and less destructive sampling, which would decrease both the cost of the samples themselves as well as the time required for sampling and inspecting said samples. The frequency of HACCP and surveillance audits is established and detailed in the SIP Manual in part 3, chapters 11 and 12 and appendix 1. Audit frequency may be increased or tightened based on the results of an audit as determined by the Regional Inspection Branch. NMFS has set the minimum audit frequency at levels appropriate to ensure that federal regulations and Program requirements are being met.

#### *Policies and Procedures*

The proposed rule would update the current § 260.84, Policies and procedures (see proposed § 260.34), to reflect that NOAA no longer publishes a hard-copy inspection manual, formerly known as NOAA Handbook 25. All SIP policies and procedures are now contained in the SIP Manual, which is publicly available online at <https://www.fisheries.noaa.gov/national/seafood-commerce-certification/seafood-inspection-manual>. The SIP Manual moved to the online format over a decade ago to allow for updates and corrections in real time. The online version is always current and available to inspection staff, program participants, and the general public at all times and in any location with internet access. Any update to a policy or procedure can be uploaded to the SIP Manual and broadcast to all users within hours. The move to the online format also saves the government money by eliminating the costs of printing and postage, as well as eliminating the need for inspectors to spend time each quarter manually removing old pages and adding new pages to the hard-copy handbook.

NMFS is proposing to remove the section on Political Activity (currently § 260.88), since it is now specifically governed through the Hatch Act, as amended (see 5 U.S.C. 7321–7326), and its inclusion in the updated SIP regulations is redundant.

A few minor updates are proposed to § 260.93, Debarment and suspension

(proposed § 260.39), to reflect the use of more modern terms (*i.e.*, “Grade A Equivalent” and “processing establishment” instead of “plant”). In addition, the requirement to file five copies of all documents would be removed from § 260.93(h)(1), as that practice is no longer necessary. Any documents filed today are likely to be converted to electronic format, if not submitted electronically.

#### *Approved Establishments*

Under the proposed rule, the provisions regarding Approved Establishments would be moved and updated. Requirements for Plants Operating Under Continuous Inspection on a Contract Basis, currently §§ 260.96–260.104, would be renumbered §§ 260.31–260.33 and retitled Requirements for Approved Establishments for purposes of clarity and to reflect current practices. In this proposed format, the requirements for becoming an Approved Establishment are set out prior to specifying the benefits of being an Approved Establishment, such as the ability to use marks and official statements on seafood products, providing a more logical flow for these provisions. Section 260.96, Application for fishery products inspection service on a contract basis at official establishments, would be retitled Application for SIP Approved Establishment and re-numbered as § 260.31. The requirement to submit an application to SIP for inspection services would remain in the part 260 regulations, but the specific details of the application procedures would be placed into the SIP Manual, part 3, chapter 5. This movement aligns directly with the Agency’s goal of keeping the operational requirements and procedures of SIP up to date as technologies and methods of communication change, as well as staying current with industry practices.

Sections 260.97(a) and § 260.97(b) would be modified to reflect that the requirements for receiving inspection services at establishments are based on an establishment’s good standing, which is assessed by the Agency through the combination of systems, process and product auditing and inspection activities. Approved Establishments are included in a list published on the Program’s website and periodically in hard copy. Inclusion on this list is contingent upon the firm’s continued adherence to the Program requirements, which are addressed in detail in the SIP Manual at part 3. They also include FDA and U.S. Department of Commerce (USDC) regulations governing the construction and maintenance of

facilities and equipment, processing techniques, and employee practices, all of which are verified by on-site facility and product audits. The provisions in § 260.97(b) would be retained in proposed § 260.32(c). Sub-sections 260.97(c)(3–6) and (14) regarding the use of labels and other NOAA marks would be addressed in the proposed §§ 260.35 and 260.36. Sub-sections 260.97(c)(1–2), regarding raw materials and lot identification, and 260.97(c)(8–10), regarding office and lab space and laundry service, would be moved to § 260.32(d)(1–4). The procedures currently at § 260.97(c)(7), (12–13), and (15–16) detailing furnishing NOAA with reports, product specifications, label proofs, and other insignia, would also be removed entirely from the regulations in this part and placed in the SIP Manual, parts 3 and 4. Again, this move from regulatory text to the SIP Manual is an effort to align with the Agency's goal of being able to adapt to changes in policies and industry practices in real time. Section 260.97(c)(11) would be removed completely from the rule since the practice of having contracting parties provide clerical and stenographic assistance to the Agency is obsolete.

For purposes of clarity, § 260.97(c)(17) (proposed § 260.32(d)(5)) would be reworded to cover all inspection services, and § 260.97(d), Termination of Inspection Services, would be moved to § 260.32(f). Current section 260.97(d)(1)(iii) would be separated into two sub-items: § 260.32(f)(1)(iii) would detail how service may be terminated due to failure of the contracting party to meet financial obligations and § 260.32(f)(1)(iv) would detail how service may be terminated due to failure of the contracting party to meet statutory or regulatory requirements, including the provisions of the regulations in this part.

With one exception, §§ 260.98–260.104 would be condensed into one new § 260.33, Compliance with Statutory and Regulatory Requirements, which would read: “Approved Establishments shall comply with all statutory and regulatory requirements and provisions pertaining to the production of fish and fishery products and other marine ingredients for human or animal consumption.” This provision would underscore that participation as an Approved Establishment does not exempt an establishment from any statutory or regulatory requirements. The audit criteria for Approved Establishments detailed in the SIP Manual, part 3, encompasses all of the requirements previously covered in regulatory text in these sections

regarding premises, buildings and structures, facilities, lavatory accommodations, equipment, effective sanitation programs, and personnel. The Agency is not adopting by reference other agencies' regulations as part of this rulemaking, specifically FDA HACCP regulations (21 CFR part 123) and GMPs (21 CFR part 117), which already cover the requirements for premises, sanitation programs, and personnel.

The current § 260.103(f) detailing the authority of NMFS to reject product and retain equipment would be relocated to § 260.32(e). This move aligns with NMFS' goal of streamlining the regulatory text and consolidating the requirements for Approved Establishments but in no way diminishes the authority of NMFS to identify, isolate, and hold any product that has been deemed mislabeled or unwholesome or any equipment that has been deemed unsanitary or likely to contaminate processed product in any way. Any product or equipment that has been placed on such hold and identified with the word “RETAINED” may not be used or disposed of until inspection or testing has been completed and the NMFS inspector has removed the “RETAINED” identification.

## 2. Modernize Sampling Plan and Lot Compliance Determination Procedures

NMFS proposes several adjustments to the current section “Licensing of Samplers and Inspectors” (§§ 260.47–260.51). The text currently at § 260.48 regarding the application to become a licensed sampler would be removed. The Agency no longer requires formal application for a person to become a licensed sampler, though the person's qualifications must still meet the standards outlined in the SIP Manual, part 1, chapter 6, and be approved by an authorized employee of the Agency. The current sections on Licensed Sampler (§ 260.47) and Inspectors (§ 260.49) would be reversed in order and renumbered as § 260.24–25. The intent of this renumbering is to emphasize the role of inspectors, NOAA employees who are qualified to perform the full catalog of inspection services, over the role of licensed samplers, who are only authorized to pull samples.

### Sampling

The changes proposed to the section Sampling, currently under §§ 260.57–260.63 (proposed §§ 260.28–29), are intended to make sampling less restrictive and more flexible for both industry and government. The opportunity and flexibility to use different sampling plans for lot

inspections is detailed in the SIP Manual in part 4, chapter 19, and for grading standards in part 5, chapter 5. The use of more flexible sampling plans is expected to reduce the amount of destructive sampling and the time and costs associated with the act of sampling itself and increase the reliability of the results based on the samples used. Since 1966, when the current sampling plan (§ 260.61) was established, many improvements have been made by both industry and government in terms of sampling and lot compliance determination. NMFS has determined that using a static sample size of six and acceptance number of zero, regardless of the lot size, will both simplify the sampling procedures and maintain the statistical validity of the inspection results. With the current sampling plans, the sample size can range from 3 to over 72 sample units and often involves destruction of the product and packaging. Having a uniform sample size of six would reduce the time needed to select samples in most cases and minimize the destruction and loss of product due to sampling. Determining lot compliance would also be easier, since the assessment of the lowest performing sample unit would apply to the entire lot with an acceptance number of zero. This would mean the lot must have zero non-conforming sample units to be accepted. In other words, if one sample unit does not meet the inspection requirements, the entire lot is rendered non-conforming. Removing the specific sampling procedures and sampling plans from the regulatory text in this part and placing them in the SIP Manual aligns with the Agency's goal of being more adaptable to changes in industry practice and applying new techniques as they become available. It would also allow SIP to keep up to date with the Codex Alimentarius (CODEX) and other internationally agreed upon standards as they are improved and updated without requiring new regulatory action. When finished product inspection is required, a SIP inspector would follow the Sampling Procedures and Sampling Plans set forth in the SIP Manual, part 4, chapters 12 and 19.

The following requirements related to lot identification and sampling are unchanged in the rulemaking updates proposed here (§ 260.60–61; proposed § 260.28–29): all product must be readily identifiable and accessible for sufficient sampling; officially drawn samples shall be marked by the Agency representative so they can be properly identified for inspection; a certificate of sampling shall be prepared and signed

by the inspector or licensed sampler; any lot not readily identifiable shall be marked by the Agency representative in a manner prescribed by the Agency; and any samples that require shipment to an Inspection Office shall be shipped in a manner to avoid, if possible, any material change in the quality or condition of the fish or fishery product or other marine ingredient. All costs associated with furnishing samples for inspection and shipments shall be at the expense of the applicant.

NMFS proposes to remove from regulatory text the single and multiple sampling plans and procedures for determining lot compliance, currently found in § 260.61, and adopt internationally recognized standards and specifications for sampling practices, sample sizes, and lot compliance determinations. These standards and specifications would continue to be housed and detailed in the SIP Manual, part 4, chapter 12 and 19 for lot inspections and in part 5, chapter 5 for grading standards rather than in regulatory text. One comment received on the ANPR suggested that NMFS consult with the National Institute for Standards and Technology (NIST) to ensure that any modified sampling plans align with their procedures and provide uniformity between states' and SIP's inspection results regarding net weight compliance. The commenter also suggested that NMFS use information from the research of the CODEX Committee on Methods of Analysis and Sampling (CCMAS) as a benchmark to align SIP's sample size and lot compliance procedures with other globally accepted methods. NMFS works closely with NIST, agrees with the goal of alignment with other globally accepted procedures, and seeks additional comment specifically on modifications to sampling plans, sample sizes, and lot compliance determination, as found in the SIP Manual, part 4, chapter 19.

### 3. Modernize Use of Inspection and Certification Marks

The section on marks and official statements (§ 260.86; proposed § 260.35) would be updated to reflect the changes associated with the development of Approved Establishments and their associated marks and statements. Products may bear a mark showing they were processed in an approved facility and/or a mark showing that they meet applicable SIP-approved specifications or inspections as prescribed in part 3, chapter 16, and part 4, chapter 10, of the SIP Manual. The "USDC Lot Inspected Shield" would be removed, as it is antiquated and no longer in use.

Proposed § 260.36 would be added to clearly identify the terms for revocation of approval to use inspection marks and statements. The outdated mention of any marks referencing the U.S. Department of the Interior would be removed.

One public comment suggested using a special mark to identify product sourced sustainably, such as aquaculture grown in a safe and sustainable manner, stating that certification standards reflecting more sustainable practices would be recognized by consumers and help influence industry guidelines to reflect more sustainable practices. NMFS fully supports sustainability in all aspects of fisheries, but the Agricultural Marketing Act of 1946 only authorizes NMFS to certify the quality, quantity, and condition of products. Sustainability claims are out of the scope and authority of SIP at this time. One commenter suggested that NMFS survey current program users to see what value SIP marks still have, if any, given the numerous third-party program available today, and then develop and implement a new communication effort to improve the understanding among consumers of what the marks actually signify. SIP marks continue to be sought-after by industry participants, and the agency publicizes the value of SIP-inspected products as resources permit.

Another commenter added that the value of existing labeling would be increased if it was simplified and made clearer to consumers and included an assessment of the facility(ies) involved. While NMFS appreciates the suggestions for making SIP marks more effective and recognizable to the consumer, we believe the Approved Establishment marks and statements already convey such an assessment. In order to qualify to bear these marks, a facility must comply with all the requirements spelled out in the SIP Manual, part 3, regarding approved establishments and maintain a level of compliance assessed through regular auditing.

### 4. Extension of Services to Product Forms Beyond Those for Human Consumption

The proposed rule expands the scope of service to include certain foods for animal consumption such as fishmeal, fish bone meal, fish for bait and some types of pet food for cats and dogs, but it does not include products such as food for aquarium fish. This proposed expansion also covers other products of marine origin, such as seaweed, kelp, algae, fish-based fertilizers, and other fishery by-products whether or not

intended for human consumption. The expansion of SIP to non-consumer and other marine products is an expansion of opportunity and markets and helps to facilitate trade for U.S. businesses. By including non-human-consumption fish and fishery products and other marine ingredients to the program, U.S. businesses are better able to compete with industry members from other countries in providing these valuable resources to the worldwide marketplace. Some countries, such as China and the Republic of Korea, already require both physical product inspection and participation in SIP in order to export fish and fishery products to those countries, including items such as fish meal and fishery by-products. At the request of industry, SIP has been providing these services for several years, so there is little to no cost increase to the Agency or industry to include these products through this proposed rule. Specifically, adding inspection and certification services for non-food, by-products, and other marine ingredients in the revised SIP regulations would enable SIP to provide services to businesses trading in marine products that traditionally the FDA and the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) do not provide. While NMFS does propose to expand inspection and certification services to include fish food for aquaculture operations, the Agency does not propose to expand services to pet foods, such as fish food for aquarium fish, or to ornamental/brood stock/research animals, as these products fall under the regulatory authority of the USDA Animal and Plant Health Inspection Service (APHIS).

The fish oil market is growing at 5.8 percent annually and is expected to reach \$3.34 billion by 2030 (Reports and Data, February 2023). To facilitate trade with foreign nations, U.S. suppliers must effectively identify the sourcing history of their products, which could be satisfied if NMFS continued and expanded its support for the trade and certification of fishery by-products, including fish oils. Multiple commenters supported and encouraged the efforts of SIP to provide certification services for inedible fishery products, including aquatic fish food, the latter of which the Agency lacks the authority to inspect.

### 5. Modernize U.S. Grade Standards

In the ANPR (84 FR 55130, October 15, 2019), NMFS also requested comment on the modernization of the U.S. Grade Standards found in 50 CFR part 261. Comments from industry

members generally support the maintenance of U.S. Grade Standards in the SIP Manual, currently in part 5, and encourage the development of simplified grading documentation and harmonizing of the grading standards across regions, stakeholders, and products. Based on comments received and NMFS' internal review, the Agency has decided not to update the U.S. Grade Standards as part of this proposed rulemaking but may address changes to 50 CFR part 261 in future rulemaking. Currently, NMFS intends to reduce the existing grade standards down to seven or eight consolidated U.S. Standards for fishery products and to adopt a uniform

sample size of six with zero non-conformities for lot acceptance. This means that for all lot sizes, six sample units would be selected for inspection, and each sample unit must meet the regulatory or quality criteria for the lot to be accepted.

The changes proposed to "Basis of inspection, grade, and compliance assessment" currently at § 260.21 (proposed § 260.10) would enable SIP to perform finished product inspections based on specifications and procedures found in the SIP Manual, parts 4 and 5, and compliance would be determined according to the inspection and assessment procedures outlined in the SIP Manual in parts 4 and 5.

General public comments on the ANPR also included a request for NMFS to continue its outreach to program participants, including hosting webinars and public meetings where industry could provide more input on the efforts to modernize the SIP. NMFS encourages and actively seeks public comment on all of the modernization efforts proposed here. Any public meetings and/or webinars will be posted on our website and announced through the current communication channels to all program participants and interested industry members. See table 1 below for details of all the proposed section number and title changes.

**TABLE 1—PROPOSED RE-ORDERING OF PART 260  
PART 260—INSPECTION AND CERTIFICATION**

Current Subpart A—Inspection and Certification of Establishments and Fishery Products for Human Consumption  
Proposed Subpart A—Inspection and Certification of Establishments, Fishery Products, and Other Marine Ingredients

Current section	Current section title	Proposed section	Proposed section title
260.1	Administration of regulations.	260.1	Administration of regulations.
Definitions 260.6–260.7		Definitions 260.2–260.3	
260.6	Terms defined.	260.2	Terms defined.
260.7	Designation of official certificates, memoranda, marks, other identifications, and devices for purposes of the Agricultural Marketing Act.	260.3	Designation and use of official certificates, memoranda, marks, other identifications, and devices for purposes of the Agricultural Marketing Act.
Inspection Service 260.12–260.30		Inspection Service 260.4–260.18	
260.12	Where inspection service is offered.	260.4	Where inspection service is offered.
260.13	Who may obtain inspection service.	260.5	Who may obtain inspection service.
260.14	How to make application.	260.6	Application for inspection service.
260.15	Information required in connection with application.		Deleted.
260.16	Filing of application		Deleted.
260.17	Record of filing time.		Deleted.
260.18	When application may be rejected.	260.7	Rejection of application for inspection service.
260.19	When application may be withdrawn.	260.8	Withdrawal of an application for inspection service.
260.20	Disposition of inspected sample.	260.9	Disposition of inspected samples.
260.21	Basis of inspection and grade or compliance determination.	260.10	Basis of inspection grade and compliance assessment.
260.22	Order of inspection service.	260.11	Order of inspection service.
260.23	Postponing inspection service		Deleted.
260.24	Financial interest of inspector.	260.12	Financial interest of inspector.
260.25	Forms of certificates.	260.13	Official forms for inspection services.
260.26	Issuance of certificates.	260.14	Issuance of certificates.
260.27	Issuance of corrected certificates.	260.15	Issuance of corrected certificates.
260.28	Issuance of an inspection report in lieu of an inspection certificate.	260.16	Issuance of an inspection report in lieu of an inspection certificate.
260.29	Disposition of inspection certificates.	260.17	Retention and provision of inspection certificates.
260.30	Report of inspection results prior to issuance of formal report.	260.18	Report of inspection results prior to issuance of formal report.
Appeal Inspection 260.36–260.41		Appeal Service 260.19–260.23	
260.36	When appeal inspection may be requested.	260.19	Requesting an appeal.
260.37	Where to file for an appeal inspection and information required.		Deleted.
260.38	When an application for an appeal inspection may be withdrawn.	260.20	Withdrawing an appeal application.
260.39	When appeal inspection may be refused.	260.21	Declining an appeal application.
260.40	Who shall perform appeal inspection.	260.22	Appeal inspector selection protocol.
260.41	Appeal inspection certificate.	260.23	Appeal documentation.
Licensing of Samplers and Inspectors 260.47–260.51		Licensing of Inspectors and Samplers 260.24–260.27	
260.47	Who may become licensed sampler.	260.25	Licensed sampler.
260.48	Application to become a licensed sampler.		Deleted.
260.49	Inspectors.	260.24	Inspectors.
260.50	Suspension or revocation of license of licensed sampler or licensed inspector.	260.26	Suspension or revocation of licensed inspector or licensed sampler.
260.51	Surrender of license.	260.27	Surrender of license.

TABLE 1—PROPOSED RE-ORDERING OF PART 260—Continued  
PART 260—INSPECTION AND CERTIFICATION

Current Subpart A—Inspection and Certification of Establishments and Fishery Products for Human Consumption  
Proposed Subpart A—Inspection and Certification of Establishments, Fishery Products, and Other Marine Ingredients

Current section	Current section title	Proposed section	Proposed section title
Sampling 260.57–260.63		Sampling 260.28–260.29	
260.57 .....	How samples are drawn by inspectors or licensed samplers.	.....	Deleted.
260.58 .....	Accessibility for sampling.	.....	Deleted.
260.59 .....	How officially drawn samples are to be identified.	.....	Deleted.
260.60 .....	How samples are to be shipped.	260.29 .....	Shipment of samples.
260.61 .....	Sampling plans and procedures for determining lot compliance.	260.28 .....	Sampling plans and procedures.
260.62 .....	Issuance of certificate of sampling.	.....	Deleted.
260.63 .....	Identification of lots sampled.	.....	Deleted.
Fees and Charges 260.69–260.81		Fees and Charges 260.30	
260.69 .....	Payment fees and charges.	260.30 .....	Inspection fees, payment guarantees, charges and payments.
260.70 .....	Schedule of fees.	.....	Deleted.
260.71 .....	[Reserved]	.....	Deleted.
260.72 .....	Fees for inspection service performed under cooperative agreement.	.....	Deleted.
260.73 .....	Disposition of fees for inspections made under cooperative agreement.	.....	Deleted.
260.74 .....	Fee for appeal inspection.	.....	Deleted.
260.76 .....	[Reserved]	.....	Deleted.
260.77 .....	Fees for score sheets.	.....	Deleted.
260.78 .....	Fees for additional copies of inspection certificates.	.....	Deleted.
260.79 .....	Travel and other expenses.	.....	Deleted.
260.80 .....	Charges for inspection service on a contract basis.	.....	Deleted.
260.81 .....	Readjustment and increase in hourly rates of fees.	.....	Deleted.
Miscellaneous 260.84–260.93		Miscellaneous 260.34–260.39	
260.84 .....	Policies and procedures.	260.34 .....	Policies and procedures.
260.86 .....	Approved identification.	260.35 .....	Approved marks, shields, stamps and official statements.
.....	.....	260.36 .....	Revocation of approval to use inspection marks and statements.
260.88 .....	Political activity.	.....	Deleted.
260.90 .....	Compliance with other laws.	260.37 .....	Compliance with other laws.
260.91 .....	Identification.	260.38 .....	Identification.
260.93 .....	Debarment and suspension.	260.39 .....	Debarment and suspension.
Requirements for Plants Operating Under Continuous Inspection on a Contract Basis 260.96–260.104		Requirements for Approved Establishments 260.31–260.33	
260.96 .....	Application for fishery products inspection service on a contract basis at official establishments.	260.31 .....	Application for SIP Approved Establishment.
260.97 .....	Conditions for providing fishery products inspection service at official establishments.	260.32 .....	Requirements for the provision of inspection services for Approved Establishments.
260.98 .....	Premises.	.....	Deleted.
260.99 .....	Buildings and structures.	.....	Deleted.
260.100 .....	Facilities.	.....	Deleted.
260.101 .....	Lavatory accommodations.	.....	Deleted.
260.102 .....	Equipment.	.....	Deleted.
260.103 .....	Operations and operating procedures shall be in accordance with an effective sanitation program.	260.33 .....	Compliance with statutory and regulatory requirements.
260.104 .....	Personnel	.....	Deleted.
Labeling Requirements 260.200		Deleted	
260.200–260.201 ..	[Reserved]	.....	Deleted.

**Classification**

This proposed rule is published under the authority of the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 *et seq.*). The NMFS Assistant Administrator has determined that this proposed action is consistent with the provisions of this and other applicable laws, subject to further consideration after public comment.

*Executive Order 12866*

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866.

*Regulatory Flexibility Act*

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted,

would not have a significant economic impact on a substantial number of small entities. A description of the factual basis for this determination follows.

The regulatory action being considered is described in the preamble of this proposed rule and includes updates, deletions, and additions to the regulations currently found at 50 CFR part 260. The proposed action reflects the significant changes and updates SIP

has already made to simplify its administrative, inspection, and certification procedures, which will result in increased uniformity of inspection results and efficiencies associated with inspection effort, while retaining the reliability and validity of inspection results, detailed in the above sections. Many of the changes proposed here are not actual changes to the way SIP currently operates, but merely a removal of outdated regulatory text, so the regulations both more accurately reflect current Program and industry practices and remain adaptable to potential future changes in technologies and product requirements.

Even though SIP operates as a fee-for-service program, it must adhere to the regulatory authority of the FDA under which all seafood processors in the United States operate, regardless of their status or participation in SIP. The proposed rule clarifies the authority SIP has to provide services for fishery products, regardless of intended end-use, and allows SIP the flexibility to keep its policies and operational procedures current with both industry practices and international standards by housing the day-to-day operational details in the online SIP Manual versus in regulatory text.

The entities affected by this rulemaking include all seafood harvesters, processors, brokers, importers, exporters, storage facilities, and other entities who utilize the fee-based services provided by the SIP. This group includes both businesses that choose to contract with the Agency for certain services and those who wish to export seafood products that require certification that only SIP can provide. SIP services both domestic and foreign businesses. Per the RFA’s definition of

small business and regulations issued by the SBA, impacts on “a business entity organized for profit, with a place of business located in the United States, and which operates primarily with the United States or which makes a significant contribution to the U.S. economy through payment of taxes or use of American products, material or labor” will be analyzed below.

Small entities include “small businesses,” “small organizations,” and “small governmental jurisdictions.” The SBA has established size standards for all major industry sectors using the North American Industry Classification System (NAICS). Size thresholds can be based on either a company’s number of employees or its sales, depending on SBA’s criteria for that industry. On December 29, 2015, NMFS issued a final rule establishing a small business size standard of \$11 million in annual gross receipts for all businesses primarily engaged in the commercial fishing industry (NAICS 11411) for RFA compliance purposes only (80 FR 81194). The \$11 million standard became effective on July 1, 2016, and is to be used in place of the U.S. NAICS 114111, 114112, and 114119 sectors of the U.S. commercial fishing industry in all NMFS rules subject to the RFA after July 1, 2016. *Id.* at 81194.

Based on the list of SIP businesses requesting services in 2021, 64 NAICS industries were identified. This analysis applies those SBA/NMFS small business definitions to the 64 6-digit NAICS industries. For the purposes of this analysis, it is assumed that the choice to participate in SIP is not correlated with business size, and thus the estimated number of small entities is the fraction of that NAICS industry that is considered small multiplied by

the number of entities in that industry participating in SIP. The total number of entities that are small for NAICS with employment-based small entity definitions is calculated using the 2021 Statistics of U.S. Businesses (SUSB) by detailed employment size (U.S. Census Bureau 2023). In some cases, the small business threshold is somewhere in the middle of a SUSB bracket, in which case an adjustment is necessary. Assuming that firms are uniformly distributed within an employment size bracket, the number of small firms from the subdivided bracket is estimated based on the proportion of the bracket below the threshold. For example, if the small business threshold is 125 employees and SUSB reports 40 businesses in the 100–149 employee bracket, it is assumed that 20 of the businesses are small because half of the bracket is below the 125-employee threshold. However, if the small business threshold is in the top bracket (*e.g.* a threshold of 750 employees with a top bracket of 500+ employees), then a conservative estimate is made that all the affected entities are small. The percentage of businesses that are small for NAICS with revenue-based small business definitions is calculated using the 2017 SUSB by revenue,<sup>1</sup> with revenues inflated to 2022 dollars using the Consumer Price Index Inflation. The same proportional rules are applied here when the threshold lies somewhere in the data bracket.

A complete list of the NAICS codes, NAICS descriptions, the corresponding SBA size standard thresholds, total entities and the number of entities determined to be small entities affected by this rule is provided in table 2.

TABLE 2—NAICS CODES, SMALL BUSINESS THRESHOLDS AND ENTITY TOTALS

NAICS Code	NAICS description	Small business threshold	Total entities by NAICS	Estimated small entities
11411	Commercial Fishing Industry	11 million	18	18
112511	Finfish Farming and Fish Hatcheries	3.75 million	4	4
112519	Other Aquaculture	3.75 million	2	2
311119	Other Animal Food Manufacturing	650 employees	4	4
311412	Frozen Specialty Food Manufacturing	1250 employees	5	5
311423	Dry and Dehydrated Food Manufacturing	750 employees	2	2
311615	Poultry Processing	1250 employees	3	3
311710	Seafood Product and Preparation and Packaging	750 employees	80	78
311942	Spice and Extract Manufacturing	650 employees	1	1
311999	All Other Miscellaneous Food Manufacturing	700 employees	5	5
325311	Nitrogenous Fertilizer Manufacturing	1050 employees	1	1
325411	Medicinal and Botanical Manufacturing	1000 employees	3	3
325412	Pharmaceutical Preparation Manufacturing	1300 employees	4	4
325414	Biological Product (except Diagnostic) Manufacturing	1250 employees	1	1
325612	Polish and Other Sanitation Good Manufacturing	900 employees	1	1

<sup>1</sup> The 2019 and 2021 SUSB updates do not include data by revenue, so this is the most recent available.



TABLE 2—NAICS CODES, SMALL BUSINESS THRESHOLDS AND ENTITY TOTALS—Continued

NAICS Code	NAICS description	Small business threshold	Total entities by NAICS	Estimated small entities
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing.	650 employees	2	2
333241	Food Product Machinery Manufacturing	500 employees	1	1
333998	All Other Miscellaneous General Purpose Machinery Manufacturing.	700 employees	3	3
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers.	200 employees	1	1
423740	Refrigeration Equipment and Supplies Merchant Wholesalers.	125 employees	1	1
424210	Drugs and Druggists' Sundries Merchant Wholesalers.	250 employees	3	3
424410	General Line Grocery Merchant Wholesalers	250 employees	18	17
424420	Packaged Frozen Food Merchant Wholesalers	200 employees	15	14
424440	Poultry and Poultry Product Merchant Wholesalers	150 employees	4	4
424460	Fish and Seafood Merchant Wholesalers	100 employees	233	228
424470	Meat and Meat Product Merchant Wholesalers	150 employees	10	10
424480	Fresh Fruit and Vegetable Merchant Wholesalers	100 employees	2	2
424490	Other Grocery and Related Products Merchant Wholesalers.	250 employees	16	16
424910	Farm Supplies Merchant Wholesalers	200 employees	1	1
424990	Other miscellaneous nondurable goods merchant wholesalers.	100 employees	15	15
445110	Supermarkets and Other Grocery (except Convenience) Stores Retailers.	40 million	3	3
445210	Meat Markets Retailers	500 employees	2	2
445250	Fish and Seafood Markets Retailers	9 million	11	11
445298	All Other Specialty Food Retailers	10 million	4	4
456110	Pharmacies and Drug Stores Retailers	37.5 million	1	1
456191	Food Health Supplement Stores Retailers	22.5 million	5	5
459110	Sporting Goods Stores Retailers	26.5 million	1	1
459910	Pet and Pet Supplies Stores Retailers	32 million	2	2
455219	All Other General Merchandise Stores Retailers	40 million	2	2
483111	Deep Sea Freight Transportation	1050 employees	1	1
483113	Coastal and Great Lakes Freight Transportation	800 employees	1	1
484110	General Freight Trucking, Local	34 million	1	1
488210	Support Activities for Rail Transportation	34 million	1	1
488320	Marine Cargo Handling	47 million	1	1
488510	Freight Transportation Arrangement	20 million	29	27
488999	All Other Support Activities for Transportation	25 million	2	2
493110	General Warehousing and Storage	34 million	7	5
493120	Refrigerated Warehousing and Storage	36.5 million	5	5
523160	Commodity Contracts Dealing Intermediation	47 million	1	1
523910	Miscellaneous Intermediation	47 million	1	1
523991	Trust, Fiduciary, and Custody Activities	47 million	1	1
541611	Administrative Management and General Management Consulting Services.	24.5 million	3	3
541890	Other Services Related to Advertising	19 million	1	1
541990	All Other Professional, Scientific, and Technical Services.	19.5 million	1	1
561110	Office Administrative Services	12.5 million	3	3
561499	All Other Business Support Services	21.5 million	5	5
561510	Travel Agencies	25 million	2	2
561910	Packaging and Labeling Service	19.5 million	1	1
561990	All Other Support Services	16.5 million	1	1
721199	All Other Traveler Accommodation	9 million	1	1
721214	Recreational and Vacation Camps (except Campgrounds).	9 million	1	1
722511	Full-Service Restaurants	11.5 million	15	15
813319	Other Social Advocacy Organizations	18 million	1	1
	Non-classifiable Establishments	n/a	1	1
	TOTAL		577	553

Source: U.S. Small Business Administration Table of Small Business Size Standards (Effective date January 1, 2022). Available at: <https://www.sba.gov/document/support-table-size-standards>.

Based on the information above, NMFS expects approximately 553 small entities ranging across 64 NAICS sectors would be directly affected by this rule

upon implementation. As more entities participate in the services, including those expanded services proposed in the

rule, the number of entities is likely to increase marginally over time.

This proposed action would not establish any new reporting,

recordkeeping, or other compliance requirements for small entities. The proposed rule would add or amend definitions, clarify the authority SIP has to provide services for fishery products (regardless of intended end-use), and allow SIP the flexibility to keep its policies and operational procedures current with both industry practices and international standards by housing the day-to-day operational details in the online SIP Manual versus in regulatory text. The actions proposed would not change the way SIP currently operates but merely remove outdated regulatory text so the regulations both more accurately reflect current industry practices and remain adaptable to potential changes in technologies and product requirements. Thus, no small business or local government would be required to undertake any additional reporting, recordkeeping, or other affirmative actions in order to comply with the proposed rule. No duplicative, overlapping, or conflicting federal rules have been identified.

Using the 2021 SUSB by detailed employment size (U.S. Census Bureau 2023) and 2017 SUSB by revenue, most of the entities affected represent less than one percent of the total number of firms in their NAICS sector. Those industries in NAICS code sectors that had five or fewer entities participating in the SIP programs were assumed to be well below one percent of the total number of firms in the sector since sectors generally contain many hundreds of entities.

Only two NAICS sectors exceeded one percent, Seafood Product Preparation and Packaging (311710) with 13.6 percent and Fish and Seafood Merchant Wholesalers (424460) with 11.2 percent. The affected small entities do not represent a large portion of their sectors, but the total number of affected small entities (78 and 228, respectively) could be considered a substantial number.

NMFS anticipates some small entities affected by the rule would likely incur some compliance cost associated with familiarizing themselves with the relocated text in the online manual. The SIP Manual was moved online over a

decade ago, allowing for updates and corrections to be made in real time. The online version is routinely updated and available to inspection staff, program participants, and the general public at all times, and in any location with internet access. Based on existing participants' knowledge and current use of the online manual, NMFS anticipates small entities will likely incur 2 burden hours associated with rule, definition, and online manual familiarization associated with changes proposed in the rule. Table 3 provides the most common services and the occupation title most associated with those requesting services. Wage rates for Office Clerks (General) and Food Service Managers are from the U.S. Bureau of Labor Statistics' (BLS) Employer Costs for Employee Compensation (ECEC) historical data for May 2022 (BLS 2022a). The estimate and cost per firm is provided in table 4. The affected small businesses subject to the rule are likely to incur 2 burden hours at an average cost of \$59.54 per firm, for a total of \$32,925.62.

TABLE 3—SUMMARY OF ESTIMATED BURDEN HOURS AND COST FOR USERS REQUESTING COMMON SERVICES

Common services	Type of user (e.g., occupational title)	Average burden (hour)	Mean hourly wage rate <sup>1</sup> (for type of user)	Total annual wage burden costs
§ 260.15 (prop. § 260.6) Application for Inspection Services.	Office Clerks, General (43–9061) .....	2.00	\$19.78	\$39.56
§ 260.36 (prop. § 260.19) Application for appeal .....	Food Service Managers (11–9051) .....	2.00	32.27	64.54
§ 260.96 (prop. § 260.31) Contract Completion .....	Food Service Managers (11–9051) .....	2.00	32.27	64.54
§ 260.97(c)(12), (13), and (15) (prop. § 260.32) Label and Specification Submission.	Food Service Managers (11–9051) .....	2.00	32.27	64.54
HACCP Participants .....	Food Service Managers (11–9051) .....	2.00	32.27	64.54
Average per Firm .....			29.77	59.54

<sup>1</sup> Source: BLS 2022.

TABLE 4—SUMMARY OF COMPLIANCE COST BY ACTIVITY

Activity	Number of affected firms	Average burden per firm (hours)	Total burden (hours)	Average cost per firm (2022\$)	Total cost (2022\$)
Rule Familiarization .....	553	0.5	276.5	\$14.89	\$8,231.41
Definition Familiarization .....	553	0.5	276.5	14.89	8,231.41
SIP Online Manual Familiarization .....	553	1	553	29.77	16,462.81
Total Cost for all activities .....				59.55	32,925.62

While NMFS does not have firm level information on profit, an annual cost of \$59.55 can reasonably be assumed to be well below 1 percent of total profit for the affected entities. For the 553 small entities subject to the rule, 100 percent are expected to have cost impacts of less than 1 percent of their annual revenues. Therefore, NMFS does not expect the

cost associated with the proposed rule to represent a significant impact to small entities.

NMFS believes the actions contained in this rule would not create a competitive disadvantage for small entities vis-a-vis large entities. The proposed rule, if finalized, would help ensure that all entities regardless of size

get equitable and consistent treatment, regardless of their level of participation in the SIP. A person requesting one lot inspection has the same access to information and available services, as well as the equal right to an appeal inspection, as a company with multiple facilities and vessels.

While unable to quantify cost savings, NMFS assumes the overall impact of the rule to be neutral to marginally positive on profitability for all entities, is not expected to significantly reduce profits for a substantial number of small entities, and does not create a significant competitive disadvantage to small entities. While it is debatable if the number of affected small entities may qualify as “substantial,” the economic impact of this rule is very small. Therefore, NMFS does not expect the proposed rule, if finalized, to have a significant economic impact on a substantial number of small entities. An initial regulatory flexibility analysis is not required, and none has been prepared.

#### *National Environmental Policy Act*

Under NOAA Administrative Order (NAO 216–6A), the promulgation of regulations that are administrative, financial, legal, technical or procedural in nature are categorically excluded from the requirement to prepare an Environmental Assessment. These proposed regulations to update 50 CFR part 260 are procedural and administrative in nature, in that they merely reflect the actual operations of the SIP today. Neither fishing activity nor trade in seafood products are further restricted relative to any existing laws or regulations, either foreign or domestic. Given the procedural and administrative nature of this rulemaking, an Environmental Assessment was not prepared.

#### *Paperwork Reduction Act*

This proposed rule does not contain a change to a collection of information requirement for purposes of the Paperwork Reduction Act of 1995. The existing collection of information requirements would continue to apply under the following OMB Control Number: 0648–0266, Seafood Inspection and Certification Requirements.

#### **List of Subjects in 50 CFR Part 260**

Inspection, Inspection Services, Certification, Approved Establishment, Sampling, Imports, Exports, Fish and Fisheries Products, Marine Ingredients, Grade Standards, Marks.

Dated: April 18, 2024.

**Samuel D. Rauch III,**

*Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.*

For the reasons set out in the preamble, NOAA proposes to revise part 260 of title 50 of the Code of Federal Regulations to read as follows:

## **PART 260—INSPECTION AND CERTIFICATION**

### **Subpart A—Inspection and Certification of Establishments, Fishery Products, and Other Marine Ingredients**

Sec.

260.1 Administration of regulations.

#### **Definitions**

260.2 Terms defined.

260.3 Designation and use of official certificates, memoranda, marks, other identifications, and devices for purposes of the Agricultural Marketing Act.

#### **Inspection Service**

260.4 Where inspection service is offered.

260.5 Who may obtain inspection service.

260.6 Application for inspection service.

260.7 Rejection of application for inspection service.

260.8 Withdrawal of an application for inspection service.

260.9 Disposition of inspected samples.

260.10 Basis of inspection, grade and compliance assessment.

260.11 Order of inspection service.

260.12 Financial interest of inspector.

260.13 Official forms for inspection services.

260.14 Issuance of certificates.

260.15 Issuance of corrected certificates.

260.16 Issuance of an inspection report in lieu of an inspection certificate.

260.17 Retention and provision of inspection certificates.

260.18 Report of inspection results prior to issuance of formal report.

#### **Appeal Service**

260.19 Requesting an appeal.

260.20 Withdrawing an appeal application.

260.21 Declining an appeal application.

260.22 Appeal inspector selection protocol.

260.23 Appeal documentation.

#### **Licensing of Inspectors and Samplers**

260.24 Inspectors.

260.25 Licensed sampler.

260.26 Suspension or revocation of licensed inspector or licensed sampler.

260.27 Surrender of license.

#### **Sampling**

260.28 Sampling plans and procedures.

260.29 Shipment of samples.

#### **Fees and Charges**

260.30 Inspection fees, payment guarantees, charges and payments.

#### **Requirements for Approved Establishments**

260.31 Application for SIP Approved Establishment.

260.32 Requirements for the provision of Inspection Services for Approved Establishments.

260.33 Compliance with statutory and regulatory requirements.

#### **Miscellaneous**

260.34 Policies and procedures.

260.35 Approved marks, shields, stamps and official statements.

260.36 Revocation of approval to use inspection marks and statements.

260.37 Compliance with other laws.

260.38 Identification.

260.39 Debarment and suspension.

**Authority:** Sec. 6, 70 Stat. 1122, 16 U.S.C. 742e; secs. 203, 205, 60 Stat. 1087, 1090 as amended; 7 U.S.C. 1622, 1624; Reorganization Plan No. 4 of 1970 (84 Stat. 2090).

### **Subpart A—Inspection and Certification of Establishments, Fishery Products, and Other Marine Ingredients**

#### **§ 260.1 Administration of regulations.**

The Secretary of the Department of Commerce is charged by the Agricultural Marketing Act of 1946 with the administration of the regulations in this part, except that they may delegate any or all of such functions to any officer or employee of the National Marine Fisheries Service (the *Agency*) of the Department at their discretion.

#### **Definitions**

##### **§ 260.2 Terms defined.**

Words in the regulations in this part in the singular form shall be deemed to import the plural and vice versa, as the case may demand. For the purposes of the regulations in this part, unless the context otherwise requires, the following terms shall have the following meanings:

*Acceptance number* means the number in a sampling plan that indicates the maximum number of nonconformities permitted in a sample of a lot that meets a specific requirement.

*Act* means the applicable provisions of the Agricultural Marketing Act of 1946 (60 Stat. 1087 *et seq.*, as amended; 7 U.S.C. 1621 *et seq.*) or any other act of Congress conferring like authority.

*Administrator* means the Administrator of NOAA (Under Secretary of Commerce for Oceans and Atmosphere) or a designee.

*Agency* means the National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce.

*Applicant* means any interested party who requests inspection service under the regulations in this part.

*Approved Establishment* means an establishment which has been approved by the Agency pursuant to this Part and the NMFS Fishery Products Inspection Manual (SIP Manual) and utilizes inspection service on a contract basis.

*Certificate of loading* means an official certificate or document that makes a statement relative to check-loading of a fish or fishery product or other marine ingredient subsequent to inspection thereof issued pursuant to the regulations in this part.

*Certificate of sampling* means an official certificate or document that makes a statement pursuant to the regulations in this part identifying officially drawn samples and may include a description of the condition of containers and the condition under which the fish or fishery product or other marine ingredient is stored.

*Class* means a grade or rank of quality.

*Condition* means the degree of soundness of the product that may affect its merchantability and includes but is not limited to those factors that are subject to change due to age, improper preparation and processing, improper packaging, improper storage, or improper handling.

*Cross-Licensed Inspector* means a qualified person employed and licensed by the agency to perform specified inspection services under a joint Federal-State inspection service arrangement.

*Department* means the U.S. Department of Commerce.

*Director* means the Assistant Administrator for Fisheries, NOAA, or a designee.

*Establishment* means the premises, buildings, structures, facilities, and equipment (including machines, utensils, fixtures and transit vehicles) used with respect to the receipt, processing and transport of fish and fishery products and other marine ingredients.

*Fish* means a fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and including all mollusks, where such animal life is intended for human or animal consumption or for other non-food uses.

*Fishery product* means any human food product in which fish is a characterizing ingredient.

*Inspection certificate* means a statement, either written or printed, issued pursuant to the regulations in this part, setting forth the quality and condition of the product, or any part thereof, in addition to appropriate descriptive information relative to a fish, fishery product, or other marine ingredient, and the container thereof. It may also include a description of the conditions under which the product is stored.

*Inspection service* means:

- (1) The performance of sampling pursuant to the regulations in this part;
- (2) The determination pursuant to the regulations and requirements in this part:

- (i) Assessing compliance with statutory and regulatory requirements pertaining to the interstate commerce of fish and fishery products or other marine ingredients for human or animal food;

- (ii) Identifying the essential characteristics such as style, type, size, or identity of any fish or fishery product or other marine ingredient; or
- (iii) Assessing the class, quality, and condition of any fish or fishery product or other marine ingredient, including the condition of the container thereof by the examination of appropriate samples;

- (3) The issuance of any certificates of sampling, inspection certificates, or certificates of loading of a fish or fishery product or other marine ingredient, or any report relative to any of the foregoing; or

- (4) The performance by an inspector of any related services, such as:

- (i) Observing the preparation of the product from its raw state through each step in the entire process;

- (ii) Observing the conditions under which the product is being harvested, prepared, handled, stored, processed, packed, preserved, transported, or held;

- (iii) Observing the sanitation conditions as a prerequisite to the inspection of the processed product, either on a contract basis or periodic basis;

- (iv) Check-loading the inspected processed product in connection with the marketing of the product; or

- (v) Conducting any other type of service of a consultative or advisory nature related herewith as outlined in the NMFS Fishery Products Inspection Manual.

*Inspector* means any employee of the Department authorized by the Secretary or any other person licensed by the Secretary to investigate, 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.

*Interested party* means any person who has a financial interest in the fish or fishery product or other marine ingredient involved.

*Licensed sampler* means any person who is authorized by the Secretary to draw samples of fish and fishery products or other marine ingredients for inspection service, to confirm the identification and condition of containers in a lot, and may, when authorized by the Secretary, perform other related services under the act and the regulations in this part.

*Lot* means a defined quantity of product accumulated under conditions

considered uniform for sampling purposes.

- (1) For processors who manufacture fish and fishery products or other marine ingredients, a lot is a production unit as defined by mutual agreement between the processor and SIP, consisting of fish or fishery products or other marine ingredients of the same type, style, form and size, which have been marked or labeled as such and produced under conditions as nearly uniform as possible, during a single 8 hour shift (or as defined and approved) on an individual processing line.

- (2) For establishments that receive fish or fishery products or other marine ingredients and perform no additional processing, such as distribution warehouses and foodservice distributors, a lot is defined by mutual agreement between the establishment and SIP and must consist of fish or fishery products or other marine ingredients located in a discrete grouping that consists of fish or fishery products or other marine ingredients of the same type, style and size and are marked or labeled as such. Except that: Fish or fishery products or other marine ingredients located in separate groups that differ from each other as to grade or other factors may be deemed as separate lots in some cases, for example:

- (i) Fish or fishery products or other marine ingredients located in the same group bearing an identification mark different from other containers in that group may be deemed as separate lots;

- (ii) Containers of fish or fishery products or other marine ingredients in a group bearing an identification mark different from other containers in that group, if determined to be of lower grade or deficient in other factors, may be deemed as separate lots; or

- (iii) If the applicant requests more than one inspection certificate covering different portions of a lot, the quantity of the product covered by each certificate shall be deemed a separate lot.

*Marine ingredient* means any product of marine origin, whether or not intended for human consumption, including, but not limited to, fishmeal, fish oil, fish-based fertilizer, seaweed, kelp, and algae.

*NMFS Fishery Products Inspection Manual (SIP Manual)* means the online handbook, housed at <https://www.fisheries.noaa.gov/national/seafood-commerce-certification/seafood-inspection-manual>, that provides procedures of how services shall be scheduled, planned, conducted, and documented and describes services that conform to global activities that harmonize inspection protocols.

*Officially drawn sample* means any sample that has been selected from a particular lot by an inspector, licensed sampler, or by any other person authorized by the Secretary pursuant to the regulations in this part.

*Person* means any individual, partnership, association, business trust, corporation, any organized group of persons (whether incorporated or not); the United States (including, but not limited to, any corporate agencies thereof) any State, county, or municipal government; any common carrier; and any authorized agent of any of the foregoing.

*Processing* means, with respect to fish and fishery products and other marine ingredients, activities that an establishment engages in including handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding. *Product* means any fish or fishery product or other marine ingredient, whether or not destined for human consumption, presented to NMFS for inspection and/or certification service.

*Quality* means the inherent properties of any processed product that determine the relative degree of excellence of such product, includes the effects of preparation and processing, and may or may not include the effects of packing media or added ingredients.

*Rejection number* means the smallest number of nonconformities, defectives (or defects) in the sample or samples under consideration that will require rejection of the lot.

*Sample* means the number of sample units drawn from a lot for purposes of inspection to reach a decision regarding acceptance of the lot and for purposes of quality to reach a conclusion regarding conformity of the lot.

*Sample unit* means a "unit of product", a primary container and its contents that makes up the sample that is inspected to determine whether it complies with regulatory criteria and that is quality assessed to determine whether it conforms to quality criteria.

*Sampling* means the process of selecting sample units that comprise the sample for the purpose of inspection and quality assessment under the regulations of this part.

*Seafood Inspection Program (SIP)* means the program within the U.S. Department of Commerce, National Oceanic and Atmospheric Administration, which offers inspection and grading services for seafood and other marine products as well as audit and consultative services to domestic

and international processors, importers, and international competent food safety authorities.

*Secretary* means the Secretary of the Department of Commerce or any other officer or employee of the Department authorized to exercise the powers and to perform the duties of the Secretary with respect to the matters covered by the regulations in this part.

*Shipping container* means an individual container designed for shipping a number of packages or cans ordinarily packed in a container for shipping or designed for packing unpackaged fish or fishery products or other marine ingredients for shipping.

*Unofficially drawn sample* means any sample that has been selected by any person other than an inspector or licensed sampler.

*Wholesome* means the minimum basis of acceptability for human food purposes of any fish or fishery product or other marine ingredient as defined in section 402 of the Federal Food, Drug, and Cosmetic Act, as amended.

**§ 260.3 Designation and use of official certificates, memoranda, marks, other identifications, and devices for purposes of the Agricultural Marketing Act.**

Section 203(h) of the Agricultural Marketing Act of 1946 provides criminal penalties for various specified offenses relating to the misuse of official certificates, memoranda, marks or other identifications and devices for making such marks or identifications, issued or authorized under section 203 of said Act, and certain misrepresentations concerning the inspection or grading of agricultural products under said section. For the purposes of said section and the provisions in this part, the terms listed below shall have the respective meanings specified:

*Official certificate* means any form of written, printed or electronic certification, including those defined in § 260.2, used under this part to document and/or certify the compliance of fish or fishery products and other marine ingredients to applicable specifications with respect to inspection compliance and conformity to class, grade, quality, size, quantity, or condition requirements.

*Official device* means a mechanically or manually operated tool, appliance or other means approved by the Agency to apply an official mark or other identification to any product or the packaging material thereof that is approved by the Director, including, but not limited to, a stamping appliance, branding device, stencil, or printed label.

*Official identification* means any designation of class, grade, quality, size, quantity, condition, or attribute specified by this part or any symbol, stamp, label, seal, or official statement indicating that the product has been inspected or graded using specifications deemed appropriate by SIP or otherwise evaluated for any buyer specified attribute.

*Official insignia* means a grade mark, inspection mark, combined inspection and grade mark, shield, stamp, other emblem, and/or official statement approved by the Secretary, authorized by the Agency, and used in accordance with the NMFS Fishery Products Inspection Manual (SIP Manual).

*Official document* means a record of findings made by an authorized person having performed any inspection, certification, grading, audit or any other service pursuant to this part.

**Inspection Service**

**§ 260.4 Where inspection service is offered.**

Inspection services may be furnished where an inspector, cross-licensed inspector, or licensed sampler is available and when the establishment's facilities and conditions are appropriate for the conduct of such service. This location can include, but is not limited to, SIP regional and field offices, warehouses, processing facilities, docks, and vessels, as detailed in the SIP Manual.

**§ 260.5 Who may obtain inspection service.**

Any person engaged in the processing, shipping or receiving of fish and fishery products or other marine ingredients in interstate commerce may apply for inspection service.

**§ 260.6 Application for inspection service.**

Prospective service participants must submit an application for inspection service per the Application for Inspection Services procedures in the SIP Manual. To be considered for approval, applications for inspection service must be complete and conform to all SIP inspection service requirements as specified in the SIP Manual.

**§ 260.7 Rejection of application for inspection service.**

Applicants will be notified if an Application for Inspection Service is rejected. Inspection Service applications may be rejected when: (a) the application is incomplete or in contravention of regulations and/or policy; (b) there is a noncompliance with NOAA financial policy, such as

nonpayment for previous inspection services rendered; (c) the fish or fishery product or other marine ingredient is not properly identified; or (d) it appears that the performance of the inspection service would not be in the best interests of the Government.

**§ 260.8 Withdrawal of an application for inspection service.**

The applicant may withdraw an Application for Inspection Service at any time before the inspection is performed, provided that the applicant shall pay for all costs and expenses which have been incurred by the inspection service in connection with such application.

**§ 260.9 Disposition of inspected samples.**

Any product sample that has been used for inspection may be returned to the applicant, at its request and expense; otherwise it shall be destroyed or, when appropriate, diverted to a charitable institution.

**§ 260.10 Basis of inspection, grade and compliance assessment.**

(a) Finished product inspection and certification services shall be performed on the basis of the specifications deemed appropriate by SIP.

(b) Unless otherwise approved by SIP, compliance with the appropriate specifications shall be determined by evaluating the product, or sample, in accordance with the product inspection and quality assessment procedures outlined in the SIP Manual. *Provided*, That:

(1) Such sample complies with the applicable standards of quality promulgated under the Federal Food, Drug, and Cosmetic Act;

(2) Such sample complies with the product description;

(3) Such sample meets the indicated grade with respect to factors of quality which are not rated by score points; and

(4) The number of sample units classed as deviants does not exceed the applicable acceptance number indicated in the sampling plans approved and used. A “deviant,” as used in this paragraph, means a sample unit that falls below the indicated grade or specification parameter.

**§ 260.11 Order of inspection service.**

Inspection services shall be performed, insofar as practicable, in the order in which Application for Inspection Service is made, except that precedence is given first to the United States (including, but not limited to, any instrumentality or agency thereof); second, to an inspection contract holder; and third, to an interested party without an inspection contract.

**§ 260.12 Financial interest of inspector.**

No inspector shall inspect any product in which s/he has a direct or indirect financial interest.

**§ 260.13 Official forms for inspection services.**

Inspection certificates, memoranda, reports and other documents associated with inspection services shall only be issued on forms approved by the Agency.

**§ 260.14 Issuance of certificates.**

Inspection Certificates and Certificates of Loading may be issued by an inspector authorized by the Agency to affix their signature to a certificate that has been prepared in accordance with the documented evidence in connection with the inspection service provided.

**§ 260.15 Issuance of corrected certificates.**

When an issued inspection certificate contains errors or otherwise requires revision, the inspector who issued the original document or another employee of the Agency may issue a corrected inspection certificate. The corrected certificate will supersede the original document, which will become null and void after the issuance of the corrected certificate.

**§ 260.16 Issuance of an inspection report in lieu of an inspection certificate.**

A written report in lieu of an inspection certificate may be issued by an inspector when such action appears to be more suitable than an inspection certificate.

**§ 260.17 Retention and provision of inspection certificates.**

Inspection certificate copies or other documents issued under the regulations in this part shall be retained by the Agency in accordance with Agency record retention policies. The original certificate (electronic or other) or copy is provided to the inspection service requester, and copies may be provided to other interested parties as identified by the Agency.

**§ 260.18 Report of inspection results prior to issuance of formal report. Upon request by any interested party and approval by the Agency, the interim inspection findings may be provided.**

**Appeal Service**

**§ 260.19 Requesting an appeal.**

(a) An application for an appeal may be made by any interested party who has cause to disagree with the results of a product inspection or audit finding. An official appeal inspection of a product inspection may only be

performed when the lot of fish or fishery products or other marine ingredients can be positively identified by the inspection service as the lot from which officially drawn samples were previously inspected.

(b) Such application shall be made in adherence with the SIP Manual and shall be made within 30 days following the day on which the previous result was communicated, except that upon approval by SIP the time may be extended.

**§ 260.20 Withdrawing an appeal application.**

An application for appeal may be withdrawn by the applicant at any time before the appeal service is performed, provided that the applicant shall pay for all costs and expenses which have been incurred by the inspection service in connection with such application.

**§ 260.21 Declining an appeal application.**

A request for an appeal may be declined when:

(a) The reasons for the appeal are frivolous or not substantial;

(b) The quality or condition of the product has undergone a material change since the inspection covering the product on which an appeal inspection is requested;

(c) The lot relative to which an appeal inspection is requested is not, or cannot be made, accessible for the selection of officially drawn samples;

(d) The lot relative to which an 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 noncompliance with the regulations in this part. The applicant shall be notified promptly if a request for appeal is declined, as outlined in the SIP Manual.

**§ 260.22 Appeal inspector selection protocol.**

(a) An inspector who did not perform the original product inspection shall be assigned to perform the appeal service; provided that the inspector who made the original product inspection on which an appeal is requested may be authorized to draw the samples when another inspector or licensed sampler is not available in the area where the product is located.

(b) Whenever practical, the appeal service shall be conducted jointly by two inspectors.

**§ 260.23 Appeal documentation.**

(a) After an appeal service has been completed, the results will be recorded on an appropriate document, as outlined in the SIP Manual. Any appeal

document shall supersede the certificate or report previously issued for the product or establishment involved.

(b) The superseded document shall become null and void upon the issuance of the appeal document and shall no longer represent the quality or condition of the product, system, or establishment described therein.

(c) If the original document and all copies have not been returned to the inspector(s) performing the appeal service, the appeal document shall be issued to the person(s) the inspector(s) considers necessary to prevent misuse of the superseded document.

(d) All provisions in this regulation concerning the use, issuance and disposition of inspection certificates shall apply to appeal inspection certificates, except that electronic copies of the appeal inspection certificates shall be furnished to all interested parties who received the superseded certificate.

#### Licensing of Inspectors and Samplers

##### § 260.24 Inspectors.

(a) Federal Government employees licensed or authorized as inspectors will perform inspections.

(b) In addition, qualified persons may be employed and licensed (Cross-Licensee) by the Agency to perform specified inspection services under a joint Federal-State inspection service arrangement.

(c) An Inspector or Cross-Licensee shall perform their duties pursuant to the regulations in this part as directed by the Director.

##### § 260.25 Licensed sampler.

(a) Any person deemed to have the necessary qualifications may be approved as a licensed sampler.

(b) Licensed samplers are authorized to draw samples, to confirm the identity of the lot, and assess the condition of containers in the lot.

(c) Licensed samplers are not authorized to inspect fish or fishery products or other marine ingredients.

##### § 260.26 Suspension or revocation of licensed inspector or licensed sampler.

In adherence to Federal and Agency requirements, the Agency may suspend or revoke the license of a licensed inspector or licensed sampler when deemed necessary, as outlined in the SIP Manual.

##### § 260.27 Surrender of license.

Upon suspension, revocation and/or termination of the services of a licensed inspector and/or licensed sampler, or in the case of an expired license, the licensee shall surrender their license to the Agency.

#### Sampling

##### § 260.28 Sampling plans and procedures.

(a) When finished product inspections of fish and fishery products and other marine ingredients are performed, the Sampling Plans and Sampling Procedures set forth in the SIP Manual will be followed.

(b) Defined lots of product must be accessible, allowing thorough and proper sampling in accordance with the regulations of this part. Failure to make lots accessible for proper sampling shall be sufficient cause for postponing or canceling inspection service.

(c) Lots must be readily identifiable; if lots to be sampled are not suitably identified, the inspector or licensed sampler will mark the lot in a manner prescribed by the agency in the regulations and in the SIP Manual.

(d) Samples shall be furnished for inspection at no cost to the Agency.

(e) A certificate of sampling shall be prepared and signed by the inspector or licensed sampler.

(f) Officially drawn samples shall be marked by the Agency representative so such samples can be properly identified for inspection.

##### § 260.29 Shipment of samples.

Samples that require shipment to an Inspection Office shall be shipped in a manner to avoid, if possible, any material change in the quality or condition of the product. Costs associated with shipments shall be at the expense of the applicant.

#### Fees and Charges

##### § 260.30 Inspection fees, payment guarantees, charges and payments.

(a) A schedule of fees, charges, payment guarantees and payments for inspection services shall be made in accordance with the applicable provisions of the regulations in this part and the Financial Policy provided in the SIP Manual.

(b) The Schedule of Fees to be charged and collected for any inspection service performed under the regulations of this part will be determined annually, or as required, and published as a Notice in the **Federal Register**.

(c) Fees for inspection under a cooperative agreement with any State or person shall be transferred and collected in accordance with the terms of such agreement. Such portion of the fees collected under a cooperative agreement as may be due the United States shall be remitted in accordance with this section and the Financial Policy as provided in the SIP Manual.

(d) Charges may be made to cover the cost of travel and other expenses

incurred in connection with the performance of any inspection service, including appeal inspections, as provided in the SIP Manual.

(e) Inspection services may be made on a contract basis or via a memorandum of understanding with other Federal and State entities pursuant to the Agricultural Marketing Act of 1946, provided the Agency is reimbursed for the full cost of such service.

(f) For each calendar year, SIP will calculate the rate for services, per hour per program employee, using the following formulas:

(1) *Regular rate.* The total SIP inspection program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service. The regular rate shall be the contract rate.

(2) *Overtime rate.* The total SIP inspection program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5 plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(3) *Holiday rate.* The total SIP inspection program personnel direct pay divided by direct hours which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(g) For each calendar year, based on previous fiscal year/historical actual costs, SIP will calculate the benefits, operating, and allowance for bad debt components of the regular, overtime and holiday rates as follows:

(1) *Benefits rate.* The total SIP inspection program direct benefits costs divided by the total hours (regular, overtime, and holiday) worked, which is then multiplied by the next calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan (TSP) retirement basic and matching contributions.

(2) *Operating rate.* The total SIP inspection program operating costs divided by total hours (regular, overtime, and holiday) worked, which is

then multiplied by the percentage of inflation.

(3) *Allowance for bad debt rate.* Total allowance for bad debt divided by total hours (regular, overtime, and holiday) worked.

(h) The calendar year cost of living expenses and percentage of inflation factors used in the formulas in this section are based on the most recent Office of Management and Budget's Presidential Economic Assumptions.

(1) When an inspection is delayed because product is not available or readily accessible, a charge for waiting time shall be determined using the formulas in this section.

### Requirements for Approved Establishments

#### § 260.31 Application for SIP Approved Establishment.

Any person desiring to process and pack fish and fishery products and other marine ingredients as an SIP Approved Establishment must receive approval of their written and implemented food management system per the application procedures which are detailed in the SIP Manual.

#### § 260.32 Requirements for the provision of Inspection Services for Approved Establishments.

All establishments must remain in good standing in order to receive services per this Part.

(a) The determination as to the inspection effort required to adequately provide inspection service at any establishment will be made by NMFS. The person-hours required may vary at different establishments due to factors such as, but not limited to, size and complexity of operations, volume and variety of products produced, and adequacy of control systems and cooperation. The inspection effort requirement may be reevaluated when the contracting party or NMFS deems there is sufficient change in production, equipment and change of quality control input to warrant reevaluation. Inspectors will not be available to perform any of the employee or management duties; however, they will be available for consultation purposes. NMFS reserves the right to reassign inspectors as it deems necessary.

(b) Assessment of an establishment's good standing will be made by the Agency through systems, process, and product auditing and inspection activities, which are further specified in the SIP manual.

(c) The Agency shall not be held responsible:

(1) For damages occurring through any act of commission or omission on

the part of its inspectors when engaged in performing services; or

(2) For production errors, such as processing temperatures, length of process, or misbranding of products; or

(3) For failure to supply enough inspection effort during any period of service.

(d) Approved Establishments shall:

(1) Use, handle, process, store and distribute only raw materials and finished products that meet processing and sanitation statutory and regulatory requirements for food safety, wholesomeness and labeling;

(2) Adequately code each primary container and master case of products sold or otherwise distributed from a manufacturing, processing, packing, or repackaging activity to enable lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use;

(3) Provide adequate office space in the designated establishment, if required by the Agency, and furnish suitable desks, office equipment, internet services access, laboratory facilities and equipment required to perform product verification and inspection, as prescribed by the Agency;

(4) Furnish and provide laundry service for coats, trousers, smocks, and towels used by inspectors during performance of duty in establishments if required by the Agency; and

(5) During all reasonable times, provide representatives of the Agency free and immediate access to the establishment under the applicant's control for the purpose of performing any and all inspection services.

(e) Retention tags:

(1) Any equipment such as, but not limited to, conveyors, tillers, sorters, choppers, and containers which fail to meet appropriate and adequate sanitation requirements will be identified by the inspector in an appropriate and conspicuous manner with the word "RETAINED." Following such identification, the equipment shall not be used until the discrepancy has been resolved, the equipment re-inspected and approved by the inspector and the "RETAINED" identification removed by the inspector.

(2) Lot(s) of processed products that may be considered to be mislabeled and/or unwholesome by reason of contaminants, or which may otherwise be in such condition as to require further evaluation or testing to determine that the product is properly labeled and/or wholesome, will be identified by the inspector in an appropriate and conspicuous manner

with the word "RETAINED." Such lot(s) of product shall be held for re-inspection or testing. Final disposition of the lot(s) shall be determined by NMFS and the removal of the "RETAINED" identification shall be performed by the inspector.

(f) Termination of inspection services:

(1) The fishery products inspection service, including the issuance of inspection reports, shall be rendered from the date of the commencement specified in the contract and continue until suspended or terminated:

(i) by mutual consent;

(ii) by either party giving the other party 60 days' written notice specifying the date of suspension or termination;

(iii) by written notice by the Agency in the event the applicant does not meet financial obligations;

(iv) by written notice by the Agency, terminating service in the event the applicant fails to meet statutory and/or regulatory requirements, or in the event the applicant fails to comply with any provisions of the regulations contained in this part;

(v) by automatic termination in case of bankruptcy, closing out of business, or change in controlling ownership.

(2) In case the contracting party wishes to terminate the fishery products inspection service under the terms of paragraph (f)(1)(i) or (ii) of this section:

(i) the service must be continued until all unused containers, labels, and advertising material on hand or in possession of his supplier bearing official identification marks or reference to the fishery products inspection service have been used;

(ii) all unused containers, labels, and advertising material bearing official identification marks or reference to the fishery products inspection service must be destroyed;

(iii) official identification marks and all other reference to the fishery products inspection service on all unused containers, labels, advertising material must be obliterated; or

(iv) assurance satisfactory to NMFS must be furnished that all unused containers, labels, and advertising material bearing official identification marks or reference to the fishery products inspection service will not be used in violation of any of the provisions of the regulations in the part.

(3) In case the fishery products inspection service is terminated for cause by NMFS under the terms of paragraph (f)(1)(iii) or (iv) of this section, or in case of automatic termination under terms of paragraph (f)(1)(v) of this section, the contracting party must destroy all unused containers, labels, and advertising



material on hand bearing official identification marks or reference to the fishery products inspection service or must obliterate official identification marks and all reference to the fishery products inspection service on said containers, labels and advertising material. After termination of the fishery products inspection service, NMFS may, at such time or times as it may determine to be necessary, during regular business hours, enter the establishment(s) or other facilities in order to ascertain that the containers, labels, and advertising material have been altered or disposed of in the manner provided herein, to the satisfaction of NMFS.

#### § 260.33 Compliance with statutory and regulatory requirements.

Approved Establishments shall comply with all statutory and regulatory requirements and provisions pertaining to the production of fish and fishery products and other marine ingredients for human or animal consumption.

#### Miscellaneous

#### § 260.34 Policies and procedures.

The policies and procedures pertaining to the Agency's inspection services are contained within the SIP Manual.

#### § 260.35 Approved marks, shields, stamps and official statements.

As prescribed by the SIP Manual, Inspection Service participants meeting the requirements may request approval to utilize specified SIP Grade Marks, Shields, Stamps and Official Statements (collectively *SIP Insignia*).

##### (a) Participants as Approved Establishments

(1) Fish and Fishery products and other marine ingredients that are processed under Federal inspection to assure compliance with all applicable regulatory requirements through the SIP Approved Establishments Program may be eligible to bear an:

- (i) Approved Establishment inspection mark; and/or,
- (ii) Approved Establishment Official Statement.

#### Figure 1 to Paragraph (a)(1)(ii)—USDC Approved Establishment Inspection Mark

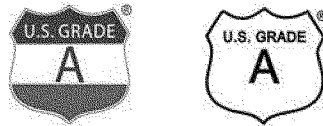


(2) Fish and Fishery products and other marine ingredients that are (1)

processed under Federal inspection to ensure compliance with all applicable regulatory requirements through the SIP Approved Establishments Program and (2) certified by an inspector as meeting the requirements of the applicable Approved Specification additionally may be eligible to bear (as applicable):

- (i) Grade A shield;
- (ii) Processed Under Federal Inspection (PUFI) mark; and/or
- (iii) Other official statements and/or marks, as approved by SIP, e.g.

#### Figure 2 to Paragraph (a)(2)(i)—U.S. Grade A Shield



#### Figure 3 to Paragraph (a)(2)(ii)—Processed Under Federal Inspection (PUFI) Mark



(3) Approved Establishments will not make deceptive, fraudulent, or unauthorized use in advertising, or otherwise, of the fishery products inspection service marks, the inspection certificates or reports issued, or the containers on which official identification marks are embossed or otherwise identified, in connection with the sale of any processed products;

##### (b) Lot Inspection Marks

(1) Fish and fishery products and other marine ingredients that have not been processed under Federal inspection may not be approved for the use of Grade or Inspection Marks. Such products may, however, be inspected on a Lot Inspection basis.

(2) Master cases and inspection certificates for products that are (1) submitted for inspection through the lot inspection process identified in the SIP Manual and are (2) certified by an inspector as meeting the requirements of the applicable USDC Approved Specification corresponding with the shield, may bear one or more of the following:

- (i) USDC Accepted Per Specifications shield;
- (ii) Officially Sampled shield, e.g.

#### Figure 4 to Paragraph (b)(2)(i)—USDC Accepted Per Specifications Shield



#### Figure 5 to Paragraph (b)(2)(ii)—Officially Sampled Shield



#### § 260.36 Revocation of approval to use inspection marks and statements.

(a) Approval for use of SIP inspection marks, statements, and insignia will be rescinded when evidence indicates that processing conditions and/or product lots do not meet applicable regulatory, inspection and/or quality requirements per the SIP Manual.

(b) Any affected lot(s) shall be retained and may not enter commerce unless the lot meets minimum regulatory requirements to enter commerce and the SIP insignia is removed.

(c) The establishment or processor shall obtain written clearance from the Agency for the release of product lots that have been put on hold under this part.

#### § 260.37 Compliance with other laws.

None of the requirements in the regulations in this part shall excuse failure to comply with any Federal, State, county, or municipal laws applicable to the operation of food processing establishments and to processed food products.

#### § 260.38 Identification.

Each inspector and licensed sampler shall have a means of identification furnished by the Agency in his/her possession and, while on duty, present such identification upon request.

#### § 260.39 Debarment and suspension.

(a) *Debarment.* Any person may be debarred from using or benefiting from the inspection service provided under the regulations of this subchapter or under the terms of any inspection contract, and such debarment may apply to one or more processing establishments under their control, if such person engages in one or more of the following acts or activities:

- (1) Misrepresenting, misstating, or withholding any material or relevant facts or information in conjunction with any application or request for an

inspection contract, inspection service, inspection appeal, lot inspection, or other service provided for under the regulations of this subchapter.

(2) Using on a fish or fishery or other marine ingredient product any label that displays any official identification, official device, or official mark, when the label is not currently approved for use by the Director or his/her delegate.

(3) Using on a fish or fishery product or other marine ingredient any label that displays the words "USDC Approved Establishment" or "Processed Under Federal Inspection, U.S. Department of Commerce"; any official mark, official device, or official identification; or a facsimile of the foregoing, when such product has not been inspected under the regulations of this subchapter.

(4) Making any statement or reference to the U.S. Grade of any product or any inspection service provided under the regulations of this subchapter on the label or in the advertising of any product when such product has not been inspected under the regulations of this subchapter.

(5) Making, using, issuing or attempting to issue or use in conjunction with the sale, shipment, transfer or advertisement of a product any certificate of loading, certificate of sampling, inspection certificate, official device, official identification, official mark, official document, or score sheet which has not been issued, approved, or authorized for use with such product by an inspector.

(6) Using any of the terms "United States," "Officially graded," "Officially inspected," "Government inspected," "Federally inspected," "Officially sampled," "Grade A Equivalent" or words of similar import or meanings, or using any official device, official identification, or official mark on the label, on the shipping container, or in the advertising of any fish or fishery product or other marine ingredient, when such product has not been inspected under the regulations of this subchapter.

(7) Using, attempting to use, altering or reproducing any certificate, certificate form, design, insignia, mark, shield, device, or figure which simulates in whole or in part any official mark, official device, official identification, certificate of loading, certificate of sampling, inspection certificate or other official certificate issued pursuant to the regulations of this subchapter.

(8) Assaulting, harassing, interfering, obstructing or attempting to interfere with or obstruct any inspector or licensed sampler in the performance of their duties under the regulations of this subchapter.

(9) Violating any one or more of the terms of any inspection contract or the provisions of the regulations of this subchapter.

(10) Engaging in acts or activities which destroy or interfere with the purposes of the inspection program or which have the effect of undermining the integrity of the inspection program.

(b) *Temporary suspension.*

(1) Whenever the Director has reasonable cause to believe that any person has engaged in any act or activity described in paragraph

(a) of this section and such act or activity, in the judgment of the Director, would cause serious and irreparable injury to the inspection program and services provided under the regulations of this subchapter, the Director may, without a hearing, temporarily suspend, either before or after the institution of a debarment hearing, the inspection service provided under the regulations of this subchapter or under any inspection contract for one or more processing establishments under the control of such person. Notice of suspension shall be served by registered or certified mail, return receipt requested, and the notice shall specifically state those acts or activities of such person that are the basis for the suspension. The suspension shall become effective 5 days after receipt of the notice.

(2) Once a person has received a notice of a temporary suspension, a debarment hearing will be set for 30 days after the effective date of the suspension. Within 60 days after the completion of the debarment hearing, the Hearing Examiner shall determine, based upon evidence of record, whether the temporary suspension shall be continued or terminated. A temporary suspension shall be terminated by the Hearing Examiner if they determine that the acts or activities that were the bases for the suspension did not occur or will not cause serious and irreparable injury to the inspection program and services provided under the regulations of this subchapter. This determination of the Hearing Examiner on the continuation or termination of the temporary suspension shall be final, and there shall be no appeal of this determination. The initial decision by the Hearing Examiner on the debarment shall be made in accordance with paragraph (b)(1), *Decisions*, of this section.

(3) After a debarment hearing has been instituted against any person by a suspension, such suspension will remain in effect until a final decision is rendered on the debarment in accordance with the regulations of this

section or the temporary suspension is terminated by the Hearing Examiner.

(4) When a debarment hearing has been instituted against any person not under suspension, the Director may, in accordance with the regulations of this paragraph (b), of this section, temporarily suspend such person, and the suspension will remain in effect until a final decision on the debarment is rendered in accordance with the regulations of this section or the temporary suspension is terminated by the Hearing Examiner.

(c) *Hearing Examiner.* All hearings shall be held before a Hearing Examiner appointed by the Secretary or the Director.

(d) *Hearing.* If one or more of the acts or activities described in paragraph

(a) of this section have occurred, the Director may institute a hearing to determine the length of time during which the person shall be debarred and those processing establishments to which the debarment shall apply. No person may be debarred unless there is a hearing, as prescribed in this section, and it has been determined by the Hearing Examiner, based on evidence of record, that one or more of the activities described in paragraph

(a) of this section have occurred. Any debarment or suspension must be instituted within 2 years of the time when such acts or activities described in paragraph (a) of this section have occurred.

(e) *Notice of hearing.* The Director shall notify such person of the debarment hearing by registered or certified mail, return receipt requested. The notice shall set forth the time and place of the hearing, the specific acts or activities which are the basis for the debarment hearing, the time period of debarment being sought, and those processing establishments to which the debarment shall apply. Except for the debarment hearing provided for in paragraph (b) of this section the hearing will be set for a time not longer than 120 days after receipt of the notice of hearing.

(f) *Time and place of hearing.* The hearing shall be held at a time and place fixed by the Director: *Provided*, however, the Hearing Examiner may, upon a proper showing of inconvenience, change the time and place of the hearing. Motions for change of time or place of the hearing must be mailed to or served upon the Hearing Examiner no later than 10 days before the hearing.

(g) *Right to counsel.* In all proceedings under this section, all persons and the Department of Commerce shall have the right to be represented by counsel, in

accordance with the rules and regulations set forth in title 15, Code of Federal Regulations, Part 906.

(h) *Form, execution, and service of documents.*

(1) All papers to be filed under the regulations in this section shall be clear and legible; and shall be dated, signed in ink, contain the docket description and title of the proceeding, if any, and the address of the signatory. Documents filed shall be executed by:

(i) The person or persons filing same;

(ii) An authorized officer thereof if it be a corporation; or

(iii) An attorney or other person having authority with respect thereto.

(2) All documents, when filed, shall show that service has been made upon all parties to the proceeding. Such service shall be made by delivering one copy to each party in person or by mailing by first-class mail, properly addressed with postage prepaid. When a party has appeared by attorney or other representative, service on such attorney or other representative will be deemed service upon the party. The date of service of document shall be the day when the matter served is deposited in the U.S. mail, shown by the postmark thereon, or is delivered in person, as the case may be.

(3) A person is deemed to have appeared in a hearing by filing with the Director a written notice of their appearance or their authority to appear on behalf of one of the parties to the hearing.

(4) The original of every document filed under this section and required to be served upon all parties to a proceeding shall be accompanied by a certificate of service signed by the party making service, stating that such service has been made upon each party to the proceeding. Certificates of service may be in substantially the following form:

I hereby certify that I have this day served the foregoing document upon all parties of record in this proceeding by:

(1) Mailing postage prepaid, (2) delivering in person, or (3) electronically delivering a copy to each party.

Dated at \_\_\_\_\_ this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_

Signature \_\_\_\_\_

(i) *Procedures and evidence.*

(1) All parties to a hearing shall be entitled to introduce all relevant evidence on the issues as stated in the notice for hearing or as determined by the Hearing Examiner at the outset of or during the hearing.

(2) Technical rules of evidence shall not apply to hearings conducted pursuant to this section, but rules or

principles designed to assure production of the most credible evidence available and to subject testimony to test by cross-examination shall be applied where reasonably necessary.

(j) *Duties of Hearing Examiner.* The Hearing Examiner shall have the authority to:

(1) Take depositions or cause depositions to be taken;

(2) Regulate the course of the hearings;

(3) Prescribe the order in which evidence shall be presented;

(4) Dispose of procedural requests or similar matters;

(5) Hear and initially rule upon all motions and petitions before them;

(6) Administer oaths and affirmations;

(7) Rule upon offers of proof and receive competent, relevant, material, reliable, and probative evidence;

(8) Prevent the admission of irrelevant, immaterial, incompetent, unreliable, repetitious, or cumulative evidence;

(9) Hear oral arguments if the Hearing Examiner determined such requirement is necessary;

(10) Fix the time for filing briefs, motions, and other documents to be filed in connection with hearings;

(11) Issue the initial decision and dispose of any other pertinent matters that normally and properly arise in the course of proceedings; and

(12) Do all other things necessary for an orderly and impartial hearing.

(k) *The record.*

(1) The Director will designate an official reporter for all hearings. The official transcript of testimony taken, together with any exhibits and briefs filed therewith, shall be filed with the Director. Transcripts of testimony will be available in any proceeding under the regulations of this section at rates fixed by the contract between the United States of America and the reporter. If the reporter is an employee of the Department of Commerce, the Director will fix the rate.

(2) The transcript of testimony and exhibits, together with all briefs, papers, and all rulings by the Hearing Examiner shall constitute the record. The initial decision will be predicated on the same record, as will the final decision.

(l) *Decisions.*

(1) The Hearing Examiner shall render the initial decision in all debarment proceedings before them. The same Hearing Examiner who presides at the hearing shall render the initial decision except when such Examiner becomes unavailable to the Department of Commerce. In such case, another Hearing Examiner will be designated by

the Secretary or Director to render the initial decision. Briefs or other documents to be submitted after the hearing must be received not later than 20 days after the hearing unless otherwise extended by the Hearing Examiner upon motion by a party. The initial decision shall be made within 60 days after the receipt of all briefs. If no appeal from the initial decision is served upon the Director within 10 days of the date of the initial decision, it will become the final decision on the 20th day following the date of the initial decision. If an appeal is received, the appeal will be transmitted to the Secretary who will render the final decision after considering the record and the appeal.

(2) All initial and final decisions shall include a statement of findings and conclusions, as well as the reasons or bases therefore, upon the material issues presented. A copy of each decision shall be served on the parties to the proceeding and furnished to interested persons upon request.

(3) It shall be the duty of the Hearing Examiner, and the Secretary where there is an appeal, to determine whether the person has engaged in one or more of the acts or activities described in paragraph (a) of this section, and, if there is a finding that the person has engaged in such acts or activities, the length of time the person shall be debarred and the processing establishments to which the debarment shall apply.

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 300

[Docket No. 240417-0110]

RIN 0648-BM67

#### International Fisheries; Pacific Tuna Fisheries; Safe Handling and Release Practices for Sharks on Longline Vessels and Revision to Vessel Monitoring System Requirements in the Eastern Pacific Ocean

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** NMFS is proposing regulations under the Tuna Conventions