

SUPPORTING STATEMENT
U.S. Department of Commerce
National Oceanic & Atmospheric Administration
Seafood Inspection and Certification Requirements
OMB Control No. 0648-0266

Abstract

This request is for the extension of a current information collection. The National Marine Fisheries Service operates a fee-for-service Seafood Inspection Program (SIP), available to all segments of the seafood industry. Participants request services such as product inspection, export and health certification, and facility approval. Information is collected from participants to confirm the identity of products being inspected and certified, as well as to show compliance with Program requirements.

Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The National Marine Fisheries Service (NMFS) operates the fee-for-service Seafood Inspection Program (SIP) under the authorities of the [Agricultural Marketing Act of 1946](#), as amended, the [Fish and Wildlife Act of 1956](#), and the [Reorganization Plan No. 4 of 1970](#). The regulations for the SIP are contained in [50 CFR Part 260](#). The SIP offers inspection, grading and certification services, including the use of official grade marks and statements which indicate that specific products have been federally inspected. The SIP is the only Federal entity which establishes quality grade standards for seafood marketed in the United States, and is the competent authority for the United States for issuing export health and catch certificates for seafood and certain other marine ingredients. Qualified participants are permitted to use SIP's official grade marks and statements on their products to facilitate the domestic and global trade of fishery products and other marine ingredients.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

Participation in the SIP is open to all segments of the seafood industry, from harvesters and growers to retailers. When inspection service is desired, participants are required to submit specific information pertaining to the type of service needed (§ 260.15). This includes the type of products to be inspected, the quantity, the location of the product, and the date when the inspection is needed. Customers complete the NOAA Form 89-814 [Request for Inspection Services](#) and submit it to their local inspection office via e-mail or over the phone. There are also application requirements (i.e., a letter from the participant) if there is an appeal on previous service results (§ 260.36). Participants requesting regular inspection services on a contractual basis submit a contract using the NOAA Form 89-800 (§ 260.96). Any changes to the contract require a contract amendment, using the same form.

Approved Establishments must meet NOAA SIP system policies and procedures and the regulatory and quality requirements outlined by U.S. Grade Standards or USDC Approved Specifications in

order to use official grade marks and statements (§§ 260.86). Current regulations state requirements for approval of drawings and specifications prior to approval of facilities (§260.97(c)(12), (13), (14) and (15)). There are no respondents under this section. The Program is amending this part of the regulations in a future action, expected to be completed in 2022. SIP is discontinuing the use of the Specification and Label Submittal Action Request (NOAA Form 89-819). It is the responsibility of the processor to ensure their labels are in compliance with mandatory labeling regulations established by the U.S. Food and Drug Administration (FDA) (21 CFR 110). SIP does continue to approve labels and marks for the USDA Child Nutrition (USDA CN) and military purchase programs. Those labels and marks are currently submitted for review via NOAA Form 89-819, but SIP is planning on shifting that process to an online format in the upcoming rulemaking.

When export or certain other forms of certification is desired, applicants are required to submit specific information regarding the consignment and the type of documents required, including details about the product, the shipper and the destination of the consignment, through an online portal system.

In July 1992, NMFS announced new inspection services, which were fully based on guidelines recommended by the National Academy of Sciences, known as Hazard Analysis Critical Control Point (HACCP). The information collection requirements fall under § 260.15 of the regulations. These guidelines require that a facility's quality control system have a written plan of the operation, identification of control points with acceptance criteria and a corrective action plan, as well as personnel identified with responsibility for oversight of the system.

HACCP requires continuous monitoring and record keeping by the facility's personnel. Although HACCP involves substantial self-monitoring by the industry, the HACCP-based program is not a self-certification program. It relies on unannounced system audits by NMFS. The frequency of audits is determined by the ability of the firm to monitor its operation. By means of these audits, NMFS reviews the records produced through the program participant's self-monitoring. The audits determine whether the participant's HACCP-based system is in compliance by checking for overall sanitation, accordance with good manufacturing practices, labeling, and other requirements. In addition, in-process reviews, end-product sampling, and laboratory analyses are performed by NMFS at frequencies based on the potential consumer risk associated with the product and/or the firm's history of compliance with the program's criteria.

The information collected is used to determine a participant's compliance with the program. The reported information, a HACCP plan, is needed only once, but must be reviewed regularly and modified if needed. Other information is collected and kept by the participant as part of its routine monitoring activities. NMFS audits the participant's records on unannounced frequencies to further determine compliance.

The FDA implemented mandatory HACCP seafood safety requirements in December 1997. The FDA regulations (21 CFR Part 123) include some of the same reporting elements as the NMFS HACCP program. However, one of the significant differences is that the FDA regulation is mandatory for all seafood processors and focuses on seafood safety only. The NMFS HACCP program is voluntary, is available to all segments of the seafood industry (from harvesters to retailers), and addresses not only food safety, but also wholesomeness (hygiene), economic integrity and food quality. There is a NMFS HACCP mark available to participants to assist them in marketing their products. FDA's mandatory program has no mark. Further, the FDA regulations require a HACCP plan only if a hazard analysis reveals a seafood safety hazard. NMFS requires a

HACCP plan for all participants in the HACCP Program. The NMFS HACCP program also assures participants compliance with international trade standards.

The burden hours identified are those beyond the FDA’s mandatory HACCP requirements to ensure seafood safety. HACCP-related burden hours are identified separately below and are based on an estimate of 15 new HACCP facilities a year and include annual monitoring and record keeping estimates for 400 facilities already in the Program.

National Oceanic and Atmospheric Administration, National Marine Fisheries Service (NOAA, NMFS) will retain control over the information and safeguard it from improper access, modification, and destruction, consistent with NOAA standards for confidentiality, privacy, and electronic information. See response #10 of this Supporting Statement for more information on confidentiality and privacy. The information collection is designed to yield data that meet all applicable information quality guidelines. Prior to dissemination, the information will be subjected to quality control measures and a pre-dissemination review pursuant to [Section 515 of Public Law 106-554](#).

Table 1: Information Requirements and Needs and Uses of Information Collected

Item #	Requirement	Statute	Regulation	Form #	Needs and Uses
1	Service Requests	77 U.S.C. 1621 <i>et seq.</i>	50 CFR 260.15	89-814	Used by SIP to determine what service to provide to applicant and issue appropriate certificates
2	New and amended contracts	77 U.S.C. 1621 <i>et seq.</i>	50 CFR 260.96	89-800	Used by SIP to provide regular service to applicant and ensure available manpower to cover those services
3	Appeals	77 U.S.C. 1621 <i>et seq.</i>	50 CFR 260.36	n/a	Used by SIP to re-evaluate results from a previous service
4	Approved Establishment Applications	77 U.S.C. 1621 <i>et seq.</i>	50 CFR 260.96	n/a	Used by SIP to ensure compliance to Program requirements
5	CN Label and Specification Submissions	77 U.S.C. 1621 <i>et seq.</i>	50 CFR 260.96	89-819	Used by SIP to approve labels and specifications for the USDA Child Nutrition Program

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also, describe any consideration of using information technology to reduce burden.

The information collected involves the use of automated, electronic or other technological techniques, in addition to mail and over the phone requests by SIP inspection personnel. Examples of labels and specifications are generally submitted in hard copy or via email to the Program’s review staff for approval. The fillable form for Request for Inspection Services is available from the SIP web site at <https://www.fisheries.noaa.gov/topic/seafood-commerce-certification#seafood-inspection>. The program

has developed and implemented an [online portal system](#), which is our primary source for gathering information. Once an account is created in the online portal, users need not re-enter business information for each new request, and much of the product information can also be stored for re-use.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Question 2

As mentioned in Question 2, the FDA HACCP regulations require some of the same reporting elements as the NMFS HACCP program. This statement includes reporting burden beyond what is required under the FDA regulations to better ensure seafood safety. In other words, an applicant's NMFS HACCP plan is acceptable under the FDA regulations so that no additional plan is needed for FDA. If, however, the applicant wishes to participate in the NMFS HACCP program and has an FDA HACCP plan, the FDA HACCP plan would be expanded to include the NMFS requirements which address not only seafood safety, but also wholesomeness (hygiene), economic fraud, and seafood quality.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

Small businesses may voluntarily participate in the SIP and respond to the collection. Specific instructions are provided, where needed, to all businesses to prevent submission of unnecessary information and to minimize the burden.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If the collection were not conducted, efficient operation of the Program would be jeopardized and SIP would not be able to sufficiently serve the customers for whom it is intended.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner that is inconsistent with OMB guidelines.

For participants to continue to obtain the benefits of advertising the official Program marks and to ensure the Program's marks are being used with integrity, some of the collections are done at a frequency inconsistent with the Office of Management and Budget (OMB) guidelines. For example, HACCP participants submit their HACCP plan only once, but changes in the plan may occur whenever their processing operations dictate, which may be outside of the OMB guidelines. In addition, monitoring of the HACCP plan is an ongoing activity which is then audited by SIP personnel at varying frequencies to determine the participant's compliance with the Program requirements. Participants that are non-compliant may be audited more frequently.

8. If applicable, provide a copy and identify the date and page number of publications in the Federal Register of the agency's notice, required by 5 CFR 1320.8 (d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

A [Federal Register Notice](#) was published on May 25, 2021 (86 FR 28081) for public comment. No

public comments were received.

NMFS reached out to several stakeholders in an effort to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. No responses were received.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payments or gifts are made.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

Participants in the SIP are assured of the confidentiality of certain information, such as records of sanitation, HACCP plans and supply chain relationships, which may contain privileged trade information. The Department of Commerce, with the concurrence of the U.S. Department of Justice, determined that this information is protected from disclosure pursuant to the [Freedom of Information Act](#) Exemption (b)(4), 5 U.S.C. § 552(b)(4), which applies to trade secrets and commercial or financial information obtained from a person that is privileged or confidential. The information is covered by the Privacy Act Systems of Records Notice, NOAA-19.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

No sensitive questions are asked.

12. Provide estimates of the hour burden of the collection of information.

Estimated number of respondents, response times, and burden. The estimates below are based on a 3-year average as reported by our field offices.

§260.15 Application for Inspection Services and Certificates. The estimated time per response is an average based on the wide range of applicants. Regular applicants, for example, have made extra copies of Form 89-814 with the standard information completed so that they simply fill in several additional blocks, which would likely require much less than 5 minutes, then fax or email it to the inspection office. New applicants, on the other hand, may take longer. They may provide the information over the phone or we may fax them a blank form which they complete and fax in return. Also, not all of the blocks on the form are required to be completed before inspection services can be provided. Missing information may be inserted by the inspector at a later date and kept as an internal record. Requests for most certificates are done via the online portal, and are also estimated to take about 5 minutes each. Once a customer creates an online portal account, most of their information is stored and re-usable, so only certain details unique to each shipment need to be added at the time of request. Most of these requests are expected to be completed by a general office clerk, with an average hourly salary of \$18.16.

Estimated Number of Respondents: 1,012
Estimated Number of Responses: 72,575
Estimated Time Per Response: 5 minutes
Estimated Total Annual Burden Hours: 6,048

§260.36 Application for appeal of previous inspection results: As mentioned in Question 2, this is simply a short letter notifying the inspection office that an appeal is requested. These requests are expected to be completed by someone at a Food Service Manager level, with an average hourly salary of \$29.33.

Estimated Number of Respondents and Responses: 36
Estimated Time Per Response: 30 minutes
Estimated Total Annual Burden Hours: 18

§260.96 Contract Completion. This estimate includes new requests, estimated at about 35 annually, and current participants who amend their contracts (Form 89-800) during the year. The burden estimate is considered equal for both situations, and they would also be completed by someone at a Food Service Manager level.

Estimated Number of Respondents and Responses: 95
Estimated Time Per Response: 5 minutes
Estimated Total Annual Burden Hours: 8

§260.97(c)(12), (13), and (15) Label and Specification Submission. This estimate includes not only completing the Form 89-819, but also the time to compile and package the submission by someone at a Food Service Manager level.

Estimated Number of Respondents: 5
Estimated Number of Responses: 115
Estimated Time Per Response: 60 minutes
Estimated Total Annual Burden Hours: 115

HACCP Participants

New Respondents. These are applicants that are not currently in the NMFS HACCP Program, who need to develop a NMFS HACCP Plan, which as explained previously, is required only once, unless a hazard analysis reveals a seafood safety hazard. It is possible that if the applicant has an FDA HACCP plan, expansion of it to include NMFS requirements may take a little less time. The burden reflected considers both situations as equal, and is expected to be completed by someone at a Food Service Manager level.

Estimated Number of Respondents and Responses: 15
Estimated Time Per Response: 60 hours
Estimated Total Annual Burden Hours: 900

Current Respondents. These are participants already in the NMFS HACCP Program, with an operating HACCP Plan. These participants are responsible for certain monitoring and record keeping functions as described in the SIP Manual, performed by someone at a Food Service Manager level.

Estimated Number of Respondents and Responses: 400
 Estimated Time Per Response: 40 hours
 Estimated Total Annual Burden Hours: 16,000

TOTAL RESPONDENTS (unduplicated): 1,012

TOTAL RESPONSES: 73,236

TOTAL BURDEN HOURS: 23,089

Information Collection	Type of Respondent (e.g., Occupational Title)	# of Respondents/year (a)	Annual # of Responses / Respondent (b)	Total # of Annual Responses (c) = (a) x (b)	Burden Hrs / Response (d)	Total Annual Burden Hrs (e) = (c) x (d)	Hourly Wage Rate (for Type of Respondent) (f)	Total Annual Wage Burden Costs (g) = (e) x (f)
\$260.15 Application for Inspection Services	Office Clerks, General	1,012	72	72,575	0.0833	6,048	18.16	109,832
\$260.36 Application for appeal	Food Service Managers	36	1	36	.5	18	29.33	528
\$260.96 Contract Completion	Food Service Managers	95	1	95	0.0833	8	29.33	235
\$260.97(c)(12), (13), and (15) Label and Specification Submission	Food Service Managers	5	23	115	1	115	29.33	3,373
HACCP Participants - New Respondents	Food Service Managers	15	1	15	60	900	29.33	26,397
HACCP Participants - Current Respondents	Food Service Managers	400	1	400	40	16,000	29.33	469,280
Totals				73,236		23,089		609,645

BLS's *Occupational Outlook Handbook* was used as a wage source (<https://www.bls.gov/bls/blswage.htm>). The large increase in number of responses is due mostly to the increase in the number of certificates requested over the last few years, as more marine products need certification and more countries require unique certificates that only the SIP can provide.

13. Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

The costs previously reported in this collection were an administrative error. Those are costs related to participating in the Seafood Inspection Program in general, not necessarily related to the information collection. The only capital costs or operating and maintenance costs associated with this information collection are for recordkeeping. An estimated 10% of service requests come in via paper format, and costs associated with copying/ mailing those are included below.

Information Collection	# of Respondents (a)	Annual # of Responses / Respondent (b)	Total # of Annual Responses (c) = (a) x (b)	Cost Burden / Respondent (h)	Total Annual Cost Burden (i) = (c) x (h)
\$260.15 Application for Inspection Services	1,012	72	72,575	.065	4,717
\$260.36 Application for appeal	36	1	36	.065	2
\$260.96 Contract Completion	95	1	95	.065	6
\$260.97(c)(12), (13), and (15) Label and Specification Submission	5	23	115	.065	7
HACCP Participants - New Respondents	15	1	15	.065	1
HACCP Participants - Current Respondents	400	1	400	.065	26
TOTALS			73,236		4,759

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information.

As a fee-for-service program, as explained in Question 1, all of the costs to the Federal government for the collection are paid by the users of this program. Total annual program costs are approximately \$20 million. Fees in addition to those shown in Question 13 are charged for other program services that do not involve collection of information from respondents.

15. Explain the reasons for any program changes or adjustments reported in ROCIS.

Over the last several years, the Seafood Inspection Program has been shifting from end product inspection to a systems based approach to food safety and quality. Our program users no longer are required to provide information on an inspection by inspection basis; alternatively, information is gathered at the system level during periodic audits. Completing fewer inspections also resulted in fewer appeal inspections, but the converse is true for audits. We have also been inspecting and certifying more types of products, including fishmeal (not for human consumption) and other marine ingredients, which has led to a large increase in the number of certificate requests overall. In addition, the program completed development and implementation of an online portal, which is now the primary source for gathering billing information, requesting certificates, and providing response to program users. This system is not only much more streamlined than the previous mail/fax method it also has the added feature of reuse values which allows for industry to prepare forms in a fraction of the time it took previously. Previously a single page form would have required an estimated 20-30 minutes to complete and then fax or mail; with the portal, the estimate is 5-10 minutes or even less when they are able to use

the reuse values option. The online portal has reduced the time burden for both program users and providers. The combined impact of a shift from product inspection to system auditing and the implementation of our automated online system for document needs and information gathering is demonstrated in the numbers below.

Table 3: Adjustments to Burden Hours

Information Collection	Respondents		Responses		Burden Hours		Reason for change or adjustment
	Current Renewal / Revision	Previous Renewal / Revision	Current Renewal / Revision	Previous Renewal / Revision	Current Renewal / Revision	Previous Renewal / Revision	
\$260.15 Application for Inspection Services	1,012	122	72,575	3,676	6,048	306	The use of the online portal for requesting certificates was not previously included, and the number of certificate requests in general has increased greatly
\$260.36 Application for appeal	36	10	36	10	18	5	Adjusted to reflect actual numbers over the past three years
\$260.96 Contract Completion	95	57	95	57	8	57	The way contracts are completed and billed has changed, which led to a larger than usual number of amended contracts over the past year.
\$260.97(c)(12), (13), and (15) Label and Specification Submission	5	200	115	200	115	100	Adjusted to reflect actual numbers over the past three years
HACCP Participants - New Respondents	15	57	15	57	900	570	Adjusted to reflect actual numbers over the past three years
HACCP Participants - Current Respondents	400	1,050	400	4,200	16,000	2,100	Previous respondents/responses were based on 1,050 responses X 4 times per year, which does not accurately reflect the burden; we have about 400 approved facilities, and region administrators estimate the amount of time needed to provide the information at about 40 hours per year for each facility
Total for Collection	1,563	1,496	73,236	8,200	23,089	3,138	
Difference	67		65,036		19,951		

Table 4: Adjustments to Burden Costs

Information Collection	Labor Costs		Miscellaneous Costs		Reason for change or adjustment
	Current	Previous	Current	Previous	
\$260.15 Application for Inspection Services	109,832	n/a	4,717	122,160	Labor costs not previously included. Miscellaneous costs corrected as previous administrative error included costs for the whole program, not for just the information collection aspect.
\$260.36 Application for appeal	528	n/a	2	7	
\$260.96 Contract Completion	235	n/a	6	42	
\$260.97(c)(12), (13), and (15) Label and Specification Submission	3,373	n/a	7	146	
HACCP Participants - New Respondents	26,397	n/a	1	15,413	
HACCP Participants - Current Respondents	469,280	n/a	26	1,135,702	
Total for Collection	609,645	n/a	4,761	1,273,470	

Difference	609,645	-1,268,709	
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16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

Results will not be published.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

The agency plans to display the expiration date for OMB approval of the information collection on all instruments.

18. Explain each exception to the certification statement identified in "Certification for Paperwork Reduction Act Submissions."

The agency certifies compliance with [5 CFR 1320.9](#) and the related provisions of [5 CFR 1320.8\(b\)\(3\)](#).