

**SUPPORTING STATEMENT
SEAFOOD INSPECTION AND CERTIFICATION REQUIREMENTS
OMB CONTROL NO. 0648-0266**

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary.

This request is for extension of a current information collection.

The National Marine Fisheries Service (NMFS) operates a voluntary fee-for-service seafood inspection program under the authorities of the [Agricultural Marketing Act of 1946](#), as amended, the [Fish and Wildlife Act of 1956](#), and [Reorganization Plan No. 4 of 1970](#). The regulations for the program are contained in [50 CFR Part 260](#). The program offers inspection, grading, and certification services, including the use of official quality grade marks which indicate that specific products have been federally inspected. In addition, the NMFS inspection program is the only Federal entity which establishes quality grade standards for seafood marketed in the United States (U.S.). Qualified participants are permitted to use the program's official quality grade marks on their products to facilitate trade of fishery products.

2. Explain how, by whom, how frequently, and for what purpose the information will be used.

Participants in the Program include all segments of the seafood industry from harvesters to retailers.

When inspection services are desired, participants are requested to submit specific information pertaining to the type of inspection service needed [§260.15]. That is, applicants provide the Program information regarding the type of products to be inspected, the quantity, the location of the product, and the date when the inspection is needed.

There are also application requirements (i.e., a letter from the participant), if there is an appeal on previous inspection results [§260.36].

Participants requesting regular inspection services on a contractual basis submit a contract [§260.96]. Any changes to the contract require a contract amendment, using the same form.

Participants interested in using official grade marks are required to submit product labels and specifications for review and approval to ensure compliance with mandatory labeling regulations established by the U.S. Food and Drug Administration (FDA), as well as proper use of the Program's marks [§260.97(c)(12), (13), (14) and (15)].

Current regulations state requirements for approval of drawings and specifications prior to approval of facilities [§260.96(b) and (c)]. There are no respondents under this section. The Program will amend this part of the regulations in a future action.

Plan requirement: 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 required 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 identified personnel responsible for oversight of the system. The document entitled "Development, Assessment, Approval, and Continuing Compliance Evaluation of HACCP-based Inspection Systems", a chapter from the NMFS Fishery Products Inspection Manual, describes in detail the requirements for participants choosing to receive NMFS HACCP-based inspection services.

HACCP requires continuing 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. 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 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 seafood safety, but also wholesomeness (hygiene), economic integrity and seafood quality. There is a NMFS HACCP mark available to participants to assist them in marketing their products. The FDA's mandatory program has no mark. Further, the FDA regulations require a revised HACCP plan only if a hazard analysis reveals a seafood safety hazard. 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 35 new HACCP facilities a year and include annual monitoring and record keeping estimates for 100 facilities already in the Program.

As explained in the preceding paragraphs, the information gathered has utility. The National Oceanic and Atmospheric Administration (NOAA) Fisheries 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 to Question 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](#).

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology.

The information collected does not involve the use of automated, electronic or other technological techniques. Much of the information for inspection requests is gathered over the phone and documented by the Program's inspection personnel. Examples of labels and specifications are generally submitted in hard copy to the Program's review staff for approval. Electronic submissions, via attachments to email, for example, are also acceptable. The fillable form for Request for Inspection Services is available from the Program's Web site: <http://www.seafood.nmfs.noaa.gov>.

4. Describe efforts to identify duplication.

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 involves small businesses or other small entities, describe the methods used to minimize burden.

Small businesses may voluntarily participate in the Program 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 consequences to the Federal program or policy activities if the collection is not conducted or is conducted less frequently.

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

7. Explain any special circumstances that require the collection to be conducted in a manner 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 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 Program personnel at varying frequencies to determine the participant's compliance with the Program requirements.

The regulations for label approval [§260.97(b)(13) and (15)] require an original label and four copies, one more copy than recommended by OMB. The labels, once approved, are distributed to the applicant, the inspector in the facility, the regional inspection office, and the label approving officer for their records and future reference, which can be critical particularly if there is a question or dispute.

8. Provide information on the PRA Federal Register Notice that solicited public comments on the information collection prior to this submission. Summarize the public comments received in response to that notice and describe the actions taken by the agency in response to those comments. Describe the efforts to consult with persons outside the agency 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.

A Federal Register Notice published on September 7, 2011 (76 FR 55363) solicited public comments. No public comments were received.

9. Explain any decisions to provide payments or gifts 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 assurance in statute, regulation, or agency policy.

Participants in the Program are assured of the confidentiality of certain information, such as records of sanitation and HACCP plans, 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.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

No sensitive questions are asked.

12. Provide an estimate in hours of the burden of the collection of information.

Estimated number of respondents, response times, and burden: The estimates below are based on a 3-year average.

§260.15 Application for Inspection Services. The estimated time per response is an average based on the wide range of applicants. Regular applicants, for example, have made extra copies of the form 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 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.

Estimated Number of Respondents: 2,390
Estimated Number of Responses: 7,490
Estimated Time Per Response: 5 minutes
Estimated Total Annual Burden Hours: 624

§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.

Estimated Number of Respondents and Responses: 62
Estimated Time Per Response: 5 minutes
Estimated Total Annual Burden Hours: 5

§260.96 Contract Completion. This estimate includes new requests, estimated at about 35 annually, and current participants who amend their contracts during the year. The burden estimate is considered equal for both situations.

Estimated Number of Respondents and Responses: 205
Estimated Time Per Response: 5 minutes
Estimated Total Annual Burden Hours: 17

§260.97(c)(12), (13), and (15) Label and Specification Submission. This estimate includes not only completing the form, but also the estimate to develop a new specification or revise an existing one. The estimate also includes the time to compile, duplicate, and package the submission.

Estimated Number of Respondents: 542
Estimated Number of Responses: 2,986
Estimated Time Per Response: 30 minutes
Estimated Total Annual Burden Hours: 1,493

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 equal.

Estimated Number of Respondents and Responses: 20
Estimated Time Per Response: 60 hours
Estimated Total Annual Burden Hours: 1,200

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 manual release.

Estimated Number of Respondents and Responses: 120
Estimated Time Per Response: 40 hours
Estimated Total Annual Burden Hours: 4,800

TOTAL RESPONDENTS (unduplicated): 3,339.
TOTAL RESPONSES: 10,883
TOTAL BURDEN HOURS: 8,139.

13. Provide an estimate of the total annual cost burden to the respondents or record-keepers resulting from the collection (excluding the value of the burden hours in Question 12 above).

Inspection fees are \$88 per hour and average 6 hours. For 7,490 inspections, at 6 x \$88, or \$528, the total fees would be \$3,954,720.

Recordkeeping/reporting: Some of the information is faxed and some is mailed. The combined annual costs for copying, faxing or mailing total approximately \$6,000.

Total costs: \$3,960,720 (rounded down to \$3,960,719 in ROCIS).

14. Provide estimates of annualized cost to the Federal government.

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 \$25 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.

There are no program changes.

Adjustment: previously, inspection fees, although in effect, were not counted in Question 13. For consistency with other information collections, they are now being included. This adds \$3,954,720 for inspection services (\$528 per inspection).

16. For collections whose results will be published, outline the plans for tabulation and publication.

Results are not published.

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

Not Applicable.

18. Explain each exception to the certification statement.

Not Applicable.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection does not employ statistical methods.