Procedures for the Safe Processing and Importing of Fish and Fishery Products

OMB Control No. 0910-0354

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA regulations in part 123 (21 CFR part 123) mandate the application of hazard analysis and critical control point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety, including section 402(a)(1) and (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and (a)(4)).

Certain provisions in part 123 require that processors and importers of seafood collect and record information. The HACCP records compiled and maintained by a seafood processor primarily consist of the periodic observations recorded at selected monitoring points during processing and packaging operations, as called for in a processor's HACCP plan (e.g., the values for processing times, temperatures, acidity, etc., as observed at critical control points).

We request the extension of OMB approval for the following collection of information requirements:

21 CFR 123.6(a),(b), and (c) -- Recordkeeping
Requires that processors conduct a hazard analysis and, if that analysis reveals that one or more food safety hazards are reasonably likely to occur, requires that processors prepare and implement a written HACCP plan; Specifies elements required in HACCP plan.

21 CFR 123.6(c)(5) -- Recordkeeping
Requires processors to include in the HACCP plan any corrective action plans developed in accordance with § 123.7(b).

21 CFR 123.8(a)(1) and (c) -- Recordkeeping
Requires processors to verify that their HACCP plan is adequate to control food safety hazards that are reasonably likely to occur by annual reassessment of the HACCP plan and the hazard analysis, and to modify the HACCP plan as necessary.

21 CFR 123.12(a)(2)(ii) -- Recordkeeping
Requires that importers of seafood products take affirmative steps to verify compliance of imports, and to maintain records of their verification activities.

21 CFR 123.6(c)(7) -- Recordkeeping
Requires that processors implement a recordkeeping system that documents the monitoring of the critical control points.

21 CFR 123.7(d) – Recordkeeping
Requires that processors maintain records of any corrective actions taken when a deviation from a critical limit occurs.

21 CFR 123.8(d) – Recordkeeping
Requires that processors maintain records of the calibration of process-monitoring instruments and the performing of any periodic end-product and in-process testing.

21 CFR 123.11(c) -- Recordkeeping
Requires that processors maintain sanitation control records.

21 CFR 123.12(c) – Recordkeeping
Requires that importers of seafood products maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123.

21 CFR 123.12(a)(2) -- Recordkeeping
Requires that importers of seafood products have and implement written verification procedures that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123.

2. Purpose and Use of the Information Collection

Seafood processors and importers maintain the HACCP records required by part 123. The primary purpose of HACCP records is to permit a processor to verify that products have been produced within carefully established processing parameters (critical limits) that ensure that hazards have been avoided.

HACCP records are normally reviewed by appropriately trained employees at the end of a production lot or at the end of a day or week of production to verify that control limits have been maintained, or that appropriate corrective actions were taken if the critical limits were not maintained. Such verification activities are essential to ensure that the HACCP system is working as planned. FDA may also review HACCP records. A review of these records during the conduct of periodic plant inspections permits FDA to determine whether the products have been consistently processed in conformance with appropriate HACCP food safety controls.

Section 123.12 requires that importers of seafood products take affirmative steps and maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123. These records are also to be made available for review by FDA as provided in § 123.12(c).

Description of respondents: Respondents to this collection of information include processors and importers of seafood. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

Many of the observations required to document HACCP control point parameters (times, temperatures, acidity, etc.) are amenable to modern data acquisition and processing technology.

The agency encourages the application of this technology for monitoring and record keeping operations to minimize the paperwork burden and labor costs, and also to enhance the organization and retrievability of the records. Under § 123.9(f) (21 CFR 123.9(f)), records maintained as computer files are acceptable when controls are implemented to ensure the integrity of the system.

FDA estimates that ten percent (10%) of the respondents will use electronic means to record the required information.

4. Efforts to Identify Duplication and Use of Similar Information

There is no likelihood of Federal duplication of effort. Seafood processors that currently process low-acid canned fishery products under the provisions of 21 CFR part 113 are using HACCP procedures and record keeping to avoid the hazard of botulinum toxin that can result from the improper thermal processing of low-acid canned food. These processors are exempted from the HACCP requirements of part 123 with regard to that specific hazard (§ 123.6(e)).

5. Impact on Small Businesses or Other Small Entities

FDA recognizes that a substantial proportion, approximately seventy-five percent (75%) of seafood processors affected by part 123, are small businesses. Small businesses are assisted in the preparation of HACCP plans primarily through the publication of the agency's "Fish and Fishery Products Hazards and Controls Guide" (available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm). This publication contains model HACCP plans, example forms, and commodity information to assist processors in identifying hazards and suggest preventive measures for their control. FDA also participates in an alliance with industry and academia (The Seafood Alliance) that has designed a curriculum and provided uniform HACCP training nationwide.

6. Consequences of Collecting the Information Less Frequently

Under a HACCP plan, data collection by each processor occurs periodically during daily food processing operations. Frequency of observation and recordkeeping will vary considerably for different processors, depending on the nature and the number of hazards controlled under the HACCP plan. Once a HACCP plan has been implemented, the collection of information must be continuous. There is no apparent way to minimize the collection burdens. Data collection may occur hourly, daily, weekly, monthly or yearly.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the Federal Register of April 9, 2010 (75 FR 18211), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received no comments.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

FDA may consult a firm's HACCP records during periodic plant inspections. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). Thus, HACCP records that the agency may copy or take possession of, such as in the event of a traceback or recall, would be protected from disclosure under FOIA..

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

The time and costs of these recordkeeping activities will vary considerably among processors and importers of fish and fishery products, depending on the type and number of products involved, and on the nature of the equipment or instruments required to monitor critical control points. The burden estimate in Table 1 of this document includes only those collections of information under the seafood HACCP regulations that are not already required under other statutes and regulations. The estimate also does not include collections of information that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (21 CFR 1240.60) is a customary and usual practice among seafood processors. Consequently, the estimates in Table 1 account only for information collection and recording requirements attributable to part 123.

Description of respondents: Respondents to this collection of information include processors and importers of seafood.

FDA estimates the burden of this collection of information as follows:

Table 1. -- Estimated Annual Recordkeeping Burden[1]

21 CFR Section[2]	No. of Recordkeepers	Annual Frequency of Recordkeeping[3]	Total Annual Records	Hours per Record[4]	Total Hours
123.6(a),(b), and (c)	50	1	50	16.00	800
123.6(c)(5)	15,000	4	60,000	0.30	18,000
123.8(a)(1) and (c)	15,000	1	15,000	4.00	60,000
123.12(a)(2)(ii)	4,100	80	328,000	0.20	65,600
123.6(c)(7)	15,000	280	4,200,000	0.30	1,260,000
123.7(d)	6,000	4	24,000	0.10	2,400

123.8(d)	15,000	47	705,000	0.10	70,500
123.11(c)	15,000	280	4,200,000	0.10	420,000
123.12(c)	4,100	80	328,000	0.10	32,800
123.12(a)(2)	41	1	41	4.00	164
Total					1,930,264

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] These estimates include the information collection requirements in the following sections:
§ 123.16 -- Smoked Fish—process controls (see § 123.6(b));
§ 123.28(a)—Source Controls—molluscan shellfish (see § 123.6(b));
§ 123.28(c) and (d)—Records—molluscan shellfish (see § 123.6(c)(7)).

[3] Based on an estimated 280 working days per year.

[4] Estimated average time per 8-hour work day unless one-time response.

FDA bases this hour burden estimate on its experience with the application of HACCP principles in food processing. Further, the burdens have been estimated using typical small seafood processing firms as a model because these firms represent a significant proportion of the industry. The hour burden of HACCP recordkeeping activities will vary considerably among processors and importers of fish and fishery products, depending on the size of the facility and complexity of the HACCP control scheme (i.e., the number of products and the number of hazards controlled); the daily frequency that control points are monitored and values recorded; and also on the extent that data recording time and cost are minimized by the use of automated data logging technology. The burden estimate does not include burden hours for activities that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (21 CFR 1240.60) is a customary and usual practice among seafood processors.

Based on its records, FDA estimates that there are 15,000 processors and 4,100 importers.

FDA estimates that 50 processors will undertake the initial preparation of a hazard analysis and HAACP plan (§ 123.6(a),(b), and (c)). FDA estimates the burden for the initial preparation of a hazard analysis and HAACP plan to be 16 hours per processor for a total burden of 800 hours. FDA estimates that all processors (15,000 processors) will undertake and keep records of four corrective action plans (§ 123.6(c)(5)) for a total of 60,000 records. FDA estimates the burden for the preparation of each record to be 0.30 hours for a total burden of 18,000 hours.

FDA estimates that all processors (15,000 processors) will annually reassess their hazard analysis and HACCP plan (§ 123.8(a)(1) and (c)). FDA estimates the burden for the reassessment of the hazard analysis and HAACP plan to be 4 hours per processor for a total burden of 60,000 hours.

FDA estimates that all importers (4,100 importers) will take affirmative steps to verify compliance of imports and prepare 80 records of their verification activities (§123.12(a)(2)(ii)) for a total of 328,000 records. FDA estimates the burden for the preparation of each record to be 0.20 hours for a total burden of 65,600 hours.

FDA estimates that all processors (15,000 processors) will document the monitoring of critical control points (§ 123.6(c)(7)) at 280 records per processor for a total of 4,200,000 records. FDA estimates the burden for the preparation of each record to be 0.30 hours for a total burden of 1,260,000 hours.

FDA estimates that 40 percent of all processors (6,000 processors) will maintain records of any corrective actions taken due to a deviation from a critical limit (§ 123.7(d) at four records per processor for a total of 24,000 records. FDA estimates the burden for the preparation of each record to be 0.10 hours for a total burden of 2,400 hours.

FDA estimates that all processors (15,000 processors) will maintain records of the calibration of process-monitoring instruments and the performing of any periodic end-product and in-process testing (§ 123.8(d)) at 47 records per processor for a total of 705,000 records. FDA estimates the burden for the preparation of each record to be 0.10 hours for a total burden of 70,500 hours.

FDA estimates that all processors (15,000 processors) will maintain sanitation control records (§ 123.11(c)) at 280 records per processor for a total of 4,200,000 records. FDA estimates the burden for the preparation of each record to be 0.10 hours for a total burden of 420,000 hours.

FDA estimates that all importers (4,100 importers) will maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123 (§123.12(c)). FDA estimates that 80 records will be prepared per importer for a total of 328,000 records. FDA estimates the burden for the preparation of each record to be 0.10 hours for a total burden of 32,800 hours.

FDA estimates that one percent of all importers (41 importers) will require new written verification procedures to verify compliance of imports (§123.12(a)(2)). FDA estimates the burden for preparing the new procedures to be 4 hours per importer for a total burden of 164 hours.

12 b. Annualized Cost Burden Estimate

Costs were estimated for the collection of HACCP data for each type of recordkeeping activity using an average labor costa Federal government employee at the GS-5/Step-1 rate for the Washington-Baltimore locality pay area for the year 2010, which is $16.33 per hour; 1,930,264 hours x $16.33 = $31,521,211.12.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

FDA's review of the retained records would generally occur as part of its routine or for cause establishment inspection activities. In addition, some of these inspections would be carried out under contract or in partnership with state agencies. FDA estimates that its review of the retained records would take five hours per inspection. FDA estimates the hourly cost for review and evaluation to be $42.66 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2010. To account for overhead, this cost is increased by 100 percent, making the total cost $85.32 per hour. Thus, FDA estimates the cost to the Federal Government for the review of records to be $426.60 per review ($85.32/hour x 5 hours). FDA estimates that it reviews records for an average of 1,500 inspections per year. Thus, FDA estimates that the total annual cost to the

Federal Government would be $639,900 ($426.60 x 1,500 inspections).

15. Explanation for Program Changes or Adjustments

The increase in burden is due to the overall increase in the number of processors and importers, although there was a decrease in the estimated number of processors (from 275 to 50), expected to undertake the initial preparation of a hazard analysis and HAACP plan, as well as a decrease in the estimated number of importers (from 55 to 41) expected to prepare new written verification procedures to verify compliance of imports.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.