SUPPORTING STATEMENT
PROCEDURES FOR THE SAFE PROCESSING AND IMPORTING OF FISH AND FISHERY PRODUCTS

OMB No. 0910-0354

A. JUSTIFICATION

1. Need and Legal Basis

FDA regulations in part 123 (21 CFR part 123) (Attachment A) mandate the application of hazard analysis and critical control point (HACCP) principles to the processing of seafood. The regulations were issued under FDA's statutory authority to regulate food safety, including the adulteration provisions in section 402 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342) (Attachment B).

HACCP is a preventive system of hazard control designed to help ensure the safety of foods. HACCP procedures yield products that are known, with a high degree of confidence, to be free of the hazards controlled by a processor's plan. Thus, HACCP procedures can largely eliminate the need for extensive testing of finished products.

Part 123 mandates recordkeeping related to seafood processing and sanitation, but the regulation does not require any reporting of this data to FDA or any other government agency. The HACCP records compiled and maintained by a seafood processor or importer 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. Information Users

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.

3. Improved Information Technology

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.

4. Duplication of Similar Information

There is no likelihood of Federal duplication of effort. A 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. Small Businesses

FDA recognizes that a substantial proportion 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." 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. Less Frequent Collection

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 short of not implementing a seafood HACCP program.

7. Special Circumstances

There are no special circumstances associated with this information collection.

8. *Federal Register* Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), in the FEDERAL REGISTER of September 26, 2006 (71 FR 56154), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received no comments.

9. Payment/Gift to Respondent

This information collection does not provide for payment or gifts to respondents.

10. Confidentiality

FDA may consult a firm's HACCP records during periodic plant inspections. Any 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 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).

11. Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

12. Burden Estimate (Total Hours and Wages)

Description of respondents: processors and importers of seafood.

The total annual estimated burden imposed by this collection of information is 702,350 hours, as follows:

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)	275	1	275	16.00	4,400
123.6(c)(5)	5,500	4	22,000	0.30	6,600
123.8(a)(1) and (c)	5,500	1	5,500	4.00	22,000
123.12(a)(2)(ii)	1,100	80	88,000	0.20	17,600
123.6(c)(7)	5,500	280	1,540,000	0.30	462,000
123.7(d)	2,200	4	8800	0.10	880
123.8(d)	5,500	47	258,500	0.10	25,850
123.11(c)	5,500	280	1,540,000	0.10	154,000
123.12(c)	1,100	80	88,000	0.10	8,800
123.12(a)(2)	55	1	55	4.00	220
Total					702,350

[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.

FDA estimates that five percent of all processors (275 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 4,400 hours.

FDA estimates that all processors (5,500 processors) will undertake and keep records of four corrective action plans (§ 123.6(c)(5)) for a total of 22,000 records. FDA estimates the burden for the preparation of each record to be 0.30 hours for a total burden of 6,600 hours.

FDA estimates that all processors (5,500 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 22,000 hours. FDA estimates that all importers (1,100 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 88,000 records. FDA estimates the burden for the preparation of each record to be 0.20 hours for a total burden of 17,600 hours.

FDA estimates that all processors (5,500 processors) will document the monitoring of critical control points (§ 123.6(c)(7)) at 280 records per processor for a total of 1,540,000 records. FDA estimates the burden for the preparation of each record to be 0.30 hours for a total burden of 462,000 hours.

FDA estimates that 40 percent of all processors (2,200 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 8,800 records. FDA estimates the burden for the preparation of each record to be 0.10 hours for a total burden of 880 hours.

FDA estimates that all processors (5,500 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 258,500 records. FDA estimates the burden for the preparation of each record to be 0.10 hours for a total burden of 25,850 hours.

FDA estimates that all processors (5,500 processors) will maintain sanitation control records (§ 123.11(c)) at 280 records per processor for a total of 1,540,000 records. FDA estimates the burden for the preparation of each record to be 0.10 hours for a total burden of 154,000 hours.

FDA estimates that all importers (1,100 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 88,000 records. FDA estimates the burden for the preparation of each record to be 0.10 hours for a total burden of 8,800 hours.

FDA estimates that one percent of all importers (55 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 220 hours.

Estimated Annualized Cost for the Burden Hours

Costs were estimated for the collection of HACCP data for each type of recordkeeping activity using an average labor cost of $15.00 per hour; 708,950 hours x $15 = $10,634,250.

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs or operating and maintenance costs associated with this collection.

14. Cost to Federal Government

FDA estimates that the annualized cost to the Federal Government for the review and evaluation of the records generated under part 123 will not significantly increase the current annual expenditures for ongoing food establishment inspections.

15. Program or Burden Changes

The increase in burden is due to the increase in the number of processors and importers.

16. Publication and Tabulation Dates

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

17. Display of OMB Approval Date

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”

No exception is requested to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions" of OMB Form 83-1.