

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0879]

Agency Information Collection Activities; Proposed Collection; Comment Request; Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies must publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and allow 60 days for public comment. This notice invites comments on the information collection provisions of our regulations requiring reporting and recordkeeping for processors and importers of fish and fishery products.

DATES: Submit either electronic or written comments on the collection of information by October 7, 2013.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, domini.bean@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products—21 CFR Part 123 (OMB Control Number 0910-0354)—Extension

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). 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. A review of these records during the conduct of periodic plant inspections also 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).

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 BURDEN¹

21 CFR Section ²	Number of recordkeepers	Number of records per recordkeeper ³	Total annual records	Average burden per recordkeeping ⁴	Total hours
123.6(a),(b), and (c); Prepare hazard analysis and HACCP plan.	50	1	50	16	800
123.6(c)(5); Undertake and prepare records of corrective actions.	15,000	4	60,000	0.30 (18 minutes)	18,000
123.8(a)(1) and (c); Reassess hazard analysis and HACCP plan.	15,000	1	15,000	4	60,000
123.12(a)(2)(ii); Verify compliance of imports and prepare records of verification activities.	4,100	80	328,000	0.20 (12 minutes)	65,600
123.6(c)(7); Document monitoring of critical control points.	15,000	280	4,200,000	0.30 (18 minutes)	1,260,000
123.7(d); Undertake and prepare records of corrective actions due to a deviation from a critical limit.	6,000	4	24,000	0.10 (6 minutes)	2,400
123.8(d); Maintain records of the calibration of process-monitoring instruments and the performing of any periodic end-product and in-process testing.	15,000	47	705,000	0.10 (6 minutes)	70,500
123.11(c); Maintain sanitation control records	15,000	280	4,200,000	0.10 (6 minutes)	420,000
123.12(c); 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.	4,100	80	328,000	0.10 (6 minutes)	32,800
123.12(a)(2); Prepare new written verification procedures to verify compliance of imports.	41	1	41	4	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.

We base 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 our records, we estimate that there are 15,000 processors and 4,100 importers. We estimate that 50

processors will undertake the initial preparation of a hazard analysis and HACCP plan (§ 123.6(a), (b), and (c)). We estimate the burden for the initial preparation of a hazard analysis and HACCP plan to be 16 hours per processor for a total burden of 800 hours. We estimate 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. We estimate the burden for the preparation of each record to be 0.30 hours for a total burden of 18,000 hours.

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

We estimate 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. We estimate the burden for the preparation of each record to be 0.20 hours for a total burden of 65,600 hours.

We estimate 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. We estimate the burden for the preparation of each record to be 0.30 hours for a total burden of 1,260,000 hours.

We estimate 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. We estimate the burden for the preparation of each record to be 0.10 hours for a total burden of 2,400 hours.

We estimate 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. We estimate the burden for the preparation of each record to be 0.10 hours for a total burden of 70,500 hours.

We estimate 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. We estimate the burden for the preparation of each record to be 0.10 hours for a total burden of 420,000 hours.

We estimate 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 § 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.

We estimate that 1 percent of all importers (41 importers) will require new written verification procedures to verify compliance of imports (§ 123.12(a)(2)). We estimate the burden for preparing the new procedures to be 4 hours per importer for a total burden of 164 hours.

Dated: July 31, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0451] (formerly 2004N-0226)

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 031

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled “Modifications to the List of Recognized Standards, Recognition List Number: 031” (Recognition List Number: 031), will assist manufacturers

who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of “Modifications to the List of Recognized Standards, Recognition List Number: 031” to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301-847-8149. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by email: standards@cdhr.fda.gov. This document may also be accessed on FDA’s Internet site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>. See section VI for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 031 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 3632, Silver Spring, MD 20993, 301-796-6287.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled “Recognition and Use of Consensus Standards.” The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>.

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains “hypertext markup language (HTML)” and “portable document format (PDF)” versions of the list of “FDA Recognized Consensus Standards.” Both versions are publicly accessible at the Agency’s Internet site. See section VI for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 031

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in premarket submissions and other requirements for devices. FDA will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency’s searchable database. FDA will use the term “Recognition List Number: 031” to identify these current modifications.

In table 1, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, if applicable; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III, FDA lists modifications the Agency is making that involve the initial addition of standards not previously recognized by FDA.