

and 2). For example, 41 percent of U.S. consumers say they have never looked for any recalled product in their home (Ref. 2). Conversely, some consumers overreact to the announcement of a foodborne illness outbreak or food recall. In response to the 2006 fresh, bagged spinach recall which followed a multistate outbreak of *Escherichia coli* O157: H7 infections (Ref. 3), 18 percent of consumers said they stopped buying other bagged, fresh produce because of the spinach recall (Ref. 1).

Research shows that emotion plays a large role in decisionmaking, and that individuals may not be conscious of its effects on their behavior (Ref. 4). For example, when people are angry they are likely to place blame, take action, and want justice to be served (Ref. 5). If a particular food recall engenders widespread anger and the anger is coupled with behavior that is less than desirable from a food safety or

nutritional standpoint, it is possible that anger will be the lens through which future food recall situations are viewed, thus resulting in similar undesirable behaviors. Findings from this study will help FDA understand the emotional response to food recalls. This will help FDA to design more effective consumer food recall messages during and after a recall.

FDA conducts research and educational and public information programs relating to food safety under its broad statutory authority, set forth in section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)), to protect the public health by ensuring that foods are "safe, wholesome, sanitary, and properly labeled," and in section 903(d)(2)(C), to conduct research relating to foods, drugs, cosmetics, and devices in carrying out the act.

FDA plans to survey U.S. consumers using a Web-based panel of U.S.

households to collect information on consumers' cognitive and emotional reaction to food recalls. The survey will query consumers on their recollection of food recalls within the past 5 years; attitude toward recalled foods; knowledge about particular food recalls; behavior during the food recall; assessment and appraisals of susceptibility, severity, satisfaction, and self-efficacy.

The data will be collected using an online survey. A pool of 10,000 consumers from a Web-based consumer panel will be screened for eligibility based on age (18+ years) and familiarity with recent food recalls. One thousand of those screened consumers will be randomly selected to participate in the survey. The results of the survey will not be used to generate population estimates.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	10,000	1	10,000	.006	60
Pre-test	40	1	40	.167	7
Survey	1,000	1	1,000	.167	167
Total	11,040	1	11,040		234

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

Ten thousand members of a Web-based consumer panel will be screened. We estimate that it will take a respondent 20 seconds (.006 hours) to complete the screening questions, for a total of 60 hours. We will conduct a pre-test of the survey with 40 respondents; we estimate that it will take a respondent 10 minutes (.167 hours) to complete the pre-test, for a total of 7 hours. One thousand (1,000) respondents will complete the survey. We estimate that it will take a respondent 10 minutes (.167 hours) to complete the survey, for a total of 167 hours. Thus, the total estimated burden is 234 hours.

II. References

1. Cuite, C., S. Condry, M. Nucci, et al., "Public Response to the Contaminated Spinach Recall of 2006," Publication number RR-0107-013, New Brunswick, NJ: Rutgers, the State University of New Jersey, Food Policy Institute, 2007.

2. Hallman, W., C. Cuite, and N. Hooker, "Consumer Responses to Food Recalls: 2009 National Survey Report," Publication number RR-0109-018, New Brunswick, NJ: Rutgers,

the State University of New Jersey, Food Policy Institute, 2009.

3. Acheson, D., "Outbreak of *Escherichia coli* O157 Infections Associated With Fresh Spinach—United States, August-September 2006," 2007 (http://first.fda.gov/cafdas/documents/Acheson_Spinach_Outbreak_2006_FDA_pres.ppt).

4. Han, S., J. S. Lerner, and D. Keltner, "Feelings and Consumer Decision Making: The Appraisal-Tendency Framework," *Journal of Consumer Psychology*, 17(3) 158-168, 2007.

5. Lazarus, R. S., "Emotion and Adaptation," New York: Oxford University Press, 1991.

Dated: June 14, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0182]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 19, 2010.

ADDRESSES: To ensure that comments on the information collection are received,

OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0354. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products—(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 (§ 1240.60 (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. Respondents to this collection of information include processors and importers of seafood.

In the **Federal Register** of April 9, 2010 (75 FR 18211), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

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)).

³Based on an estimated 280 working days per year.

⁴Estimated average time per 8-hour workday 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 (§ 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 4 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 4 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 1 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.

Dated: June 14, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; National Institute of Diabetes and Digestive and Kidney Diseases Information Clearinghouses Customer Satisfaction Survey

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH), is giving public notice that the agency proposes to request reinstatement of an information collection activity for which approval expired on February 28, 2010.

Proposed Collection

Title: NIDDK Information Clearinghouses Customer Satisfaction Survey. *Type of Information Requested:* Reinstatement, with change, of a previously approved collection for which approval has expired. The OMB control number 0925-0480 expired on February 28, 2010. *Need and Use of Information Collection:* NIDDK is conducting a survey to assess the efficiency and effectiveness of services provided by NIDDK's three clearinghouses: The National Diabetes Information Clearinghouse (NDIC); the National Digestive Diseases Information Clearinghouse (NDDIC); and the National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC). The survey responds to Executive Order 12821, "Setting Customer Service Standards," which requires agencies and departments to identify and survey their "customers to determine the kind and quality of service they want and their level of satisfaction with existing services." *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; business and for profit organizations; not-for-profit agencies. *Type of Respondents:* Physicians, health care professionals, patients, family and friends of patients.

The annual reporting burden is as follows: Estimated number of respondents: 7,079; estimated number of responses per respondent: 1; estimated average burden hours per response: 0.025; and estimated total annual burden hours requested: 177. The