Food Safety Survey

0910-0345—Reinstatement

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Approval is requested for Cycle V of the Food and Drug Administration-Food Safety and Inspection Service of U.S. Department of Agriculture (FDA-FSIS) Food Safety Survey (FSS). The FSS is widely accepted as a unique data base on consumer food handling practices, food safety-related knowledge and attitudes and is used as the definitive source of this information by both Healthy People 2010, Healthy People 2020, and by the 2010 US Dietary Guidelines Food Safety Subcommittee**.** Under sections 903(d)(2)(C) and 903(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 393(d)(2)(C) and 393(d)(2)(D)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply.

Telephone interviews are planned with a random sample of approximately 4000 US adults, including at least 500 Hispanics. Data from the survey will be used in support of the Agency's regulatory policy in diverse areas dealing with food safety and will support consumer education by enabling the Agency to track consumer knowledge, attitudes, and practices concerning food safety. The data will also be used to measure progress on two Healthy People 2010 consumer objectives for food safety: (1) increase the proportion of consumers who follow key food safety practices (Objective 10-5), and (2) reduce severe allergic reactions to food among adults (Objective 10-4b). Data from Cycle V of the Food Safety Survey will also serve as the baseline for two planned Healthy People 2020 food safety objectives similar to the Healthy People 2010 objectives. The survey methodology is largely identical to Cycle IV as approved by OMB (No. 0910-0345). The questionnaire (copy attached) has been updated to reflect current issues for consumers and food safety.

Since 2006, there have been several high profile recalls of FDA-regulated food due to contamination. Information about food recalls does not always reach the intended audience (Refs. 1, 2, 3). The FSS planned for 2009 will look specifically at reasons why consumers do not always heed food recall alerts. New questions will be added to learn about how recent food recalls have affected consumer confidence in the food supply and what effect, if any, they have on consumers'

home food safety behaviors. This information will help FDA develop strategies to more effectively communicate food recall information to the public.

2. Purpose and Use of the Information Collection

Data will be collected using an independently drawn and randomized, nationally representative sample of telephone numbers with an over-sample of Hispanics. The sample will be drawn, and data collected, by RTI International, a large marketing firm.

The primary users of the data will be staff in the Division of Social Sciences (DSS) of the Center for Food Safety and Applied Nutrition (CFSAN) and staff in FSIS. DSS staff will analyze the data in consultation with other units of the Center including the food safety educators, risk assessors and risk communicators. Survey questions on food handling behaviors and food allergies will serve as measures of progress toward two Healthy People 2010 objectives and also as the baseline for two planned Healthy People 2020 objectives.

Staff in FDA and FSIS will use the data to track, and to better understand, consumers' food handling and preparation practices, food consumption practices related to food safety (such as consumption of raw or undercooked foods of animal origin) and related attitudes, concerns, knowledge, and sources of information. Because many of the questions were asked in the 1993, 1998, 2001, and 2006 FSSs, staff will compare the results over time to estimate extent and nature of changes that occurred in any of these areas. Trend analysis will also be conducted by demographic characteristics to evaluate disparities in practices and attitudes over time. Current estimates of the safety of consumer food handling and consumption practices will be used in risk assessments.

3. Use of Improved Information Technology and Burden Reduction

The proposed data collection effort will involve telephone surveys. The computer-assisted telephone interviewing (CATI) methodology proposed for the survey duplicates the method used for the 1993, 1998, 2001, and 2006 surveys, with which the data will be compared. CATI is also the most cost-effective approach to acquiring the needed information. Telephone interviews are less intrusive than face-to-face interviews and are considerably less expensive. Self-administered surveys sent by mail are not appropriate for questionnaires with skip patterns such as used here.

4. Efforts to Identify Duplication and Use of Similar Information

The FSS is a unique survey instrument. The value of asking the core FSS questions with the same data collection method as the previous waves of the FSS has increased substantially, now that four data collections have been completed. No other consumer survey of consumer food handling practices can satisfy the criteria needed to provide current national estimates of consumer food handling practices, knowledge and attitudes or to enable a comparison with the previous FSS results. The collaboration between FDA and FSIS avoids duplication that would result from independent surveys.

5. Impact on Small Businesses or Other Small Entities

No small businesses would be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

Without this data collection, national estimates of current knowledge, attitudes, and the safety of consumer food handling practices will not be available. This is important because the 2006 FSS results most likely do not adequately reflect the current state of consumer knowledge, attitudes, and practices in regard to food safety.

A data collection in 2009 will also serve the data needs of Healthy People 2020. Data from the 2009 Food Safety Survey will serve as a baseline for two planned objectives on consumer food preparation and consumer allergen experiences.

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

The collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection. The study will not require respondents to: report the information more often than quarterly; provide a written response in less than 30 days; submit more than one original plus 2 copies of the information; or, retain records for more than 3 years. The design of the statistical survey will not produce results that cannot be generalized to the universe of study. The study will not use statistical data that has not yet been reviewed or approved by OMB. The study will not include a pledge of confidentiality that is (1) not supported by authority established in statute or regulation; (2) not supported by disclosure and data security policies that are consistent with the pledge; or (3) which unnecessarily impedes sharing of data with other agencies for compatible confidential use. Finally, the study does not involve the submission of trade secrets, proprietary information or other confidential 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, September 17, 2008 (73 FR 53878), FDA published a 60-day notice requesting public comment on the proposed information collection. The agency received one comment that did not address the information collection provisions.

In August 2009, FDA presented the proposed new questions on food recalls to FDA's Risk Communications Advisory Council, a group of mostly academicians, several of whom are "audience experts" familiar with the perspectives of patients, consumers, and health care professionals. Feedback from this committee was incorporated in the final questionnaire.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be made to respondents.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the respondents' answers will remain confidential. The survey questionnaire and screener contain a statement that responses will be kept confidential. Confidential 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).

Prior to starting data collection, FDA's Institutional Review Board (IRB) will review the survey protocol to ensure that human subjects are protected and that confidentiality procedures are adequate. An independent contractor for FDA, RTI, will collect the data and will not provide FDA with identifying information on the respondents. Respondents will be promised that their data will be treated as confidential and released to the public only in the form of aggregate statistics that cannot be associated with any individual or household. Interviewing staff are required to sign a pledge of confidentiality that reinforces confidentiality requirements of the study and states that any procedural violation that jeopardizes a respondent's privacy will be grounds for immediate termination and possible legal action. Once response editing and interview validation are completed for the survey data, respondents' names and other identifying information will be permanently dissociated from interview data.

All data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

The survey instrument does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

The respondents are US adults, age 18 and older. The total estimated burden imposed by this collection of information is 1,541 hours (Table 1).

TABLE 1 -- ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive Interview	20	1	20	1	20
Pretest	27	1	27	0.5	14
Screener	10,000	1	10,000	.0167	167
Survey	4,000	1	4,000	.33	1,320
Non-response	200	1	200	.10	20
Total					1,541

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

Prior to finalizing the survey, FDA will conduct 20 cognitive interviews each requiring an average of 1 hour per respondent for a total of 20 hours. Before the survey is fielded, a small pretest of 27 individuals, each lasting half an hour (0.5 hour), will be conducted (See section B4). The survey screener is estimated to take 1 minute or less per response for a total screener burden of 4000 (respondents) + 6000 (ineligibles screened) x .0167 hours = 167 hours. The survey will require an average of 20 minutes (0.33 hours) per respondent and we expect that the variation

in burden across respondents will be small. This estimate is based on average interview time for the 2006 Food Safety Survey. The proposed number of respondents is 4,000, each of whom will be asked to complete a one-time telephone interview that requires no preparation time. Additionally, 200 initial non-respondents will be asked to participate in a short version of the survey to conduct a non-response analysis. This is expected to take 6 minutes (0.10 hours). Therefore, the total estimated public reporting burden is 1,541 hours.

We have revised the burden table. In the 60-day notice published on September 17, 2008, we estimated the total burden to be 1,421 hours. The total burden of 1,541 hours estimated in table 1 of this document includes an additional 120 hours, which resulted from correcting a typographical error in line 4 of the table. The hours per response in line 4 of table 1 changed from 0.3 to 0.33.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to the Federal Government

The estimated cost to the federal government is $600,000. This cost includes costs paid to the contractor to draw the sample, collect the survey data, create a database of the data, tabulate and summarize the survey data, and prepare a final report. This cost also includes FDA staff time to manage the study.

15. Explanation for Program Changes or Adjustments

This survey is a repeat, with modifications, of the 2006 Food Safety Survey, previously approved as OMB Control Number 0910-0345. We discontinued the approval for this collection in March 2008. We are now seeking to reinstate the approval for Cycle V of the survey. The estimated burden hours have increased from 1401 hours to 1541 hours. This is due primarily to the addition of 120 hours resulting from changing the hours per response in line 4 of table 1 from 0.3 to 0.33, and the addition of 20 hours for cognitive interviews.

16. Plans for Tabulation and Publication and Project Time Schedule

Activities associated with the outcomes of this research will primarily consist of a top-line report summarizing the survey findings posted on the FDA Web site, articles published in peer reviewed journals, and presentations at national conferences on food safety and public health.

Table A.2 Project Schedule

Date	Activity
Within 1 day after receipt of OMB approval of collection of information	Notification to contractor to proceed with data collection activities
Within 150 days after receipt of OMB approval of collection of information	Completion of data collection and delivery of data by contractor
Within 120 days after completion of data collection	Completion of preliminary analyses
Within 60 days after completion of preliminary analyses	Posting of top-line report on FDA Web site

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

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions requested.

REFERENCES

1. Cuite, C.L., S.C. Condry, M.L. Nucci, W.K. Hallman. 2007. Public Response to the Contaminated Spinach Recall of 2006. (Publication number RR-0107-013). New Brunswick, New Jersey: Rutgers, the State University of New Jersey, Food Policy Institute.
2. Mahon, B.E., L. Slutsker, L. Hutwagner, C. Drenzek, K. Maloney, K. Toomey, P.M. Griffin. 1999. Consequences in Georgia of a Nationwide Outbreak of *Salmonella* Infections: What You Don't Know Might Hurt You. *American Journal of Public Health.* 89(1):31-35.
3. Patrick, M.E., P.M. Griffin, A.C. Voetsch, P.S. Mead. 2007. Effectiveness of recall notification: Community response to a nationwide recall of hot dogs and deli meats. *Journal of Food Protection*. 70(10):2373-2376.