

Food Safety, Health, and Diet Survey

0910-0345

SUPPORTING STATEMENT

Terms of Clearance: This collection is a combination and reinstatement of OMB Collection Numbers 0910-0345 and 0910-0545. Terms for OMB No. 0910-0345 stated, “Note that respondents should be informed that their responses will be kept “secure to the extent permitted by law” and that “confidentiality” cannot be assured absent explicit statutory authority.

Terms for 0910-0545 stated, “this generic clearance for the Health and Diet Survey is approved for 3-years under the following conditions: (1) For individual collections, FDA shall submit a generic IC in ROCIS along with: (a) an abbreviated supporting statement in the template agreed to by OMB and FDA (including a statement of need, intended use of information, description of respondents, date(s) and location(s), collection procedures, number of surveys or interviews, justification for any proposed incentive, and estimated burden); (b) the participant screener, and (c) any moderator guides. (2) OMB will respond with clearance or questions within 10 working days.”

A. Justification

1. Circumstances Making the Collection of Information Necessary

The authority for FDA’s collection of information derives from the FDA Commissioner’s authority provided in section 1003(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)), which authorizes the FDA to conduct food research and educational and public information programs relating to the safety of the nation’s food supply. Previously, FDA conducted two separate surveys, OMB Nos. 0910-0345 (the Food Safety survey) and 0910-0545 (the Health and Diet survey), to measure consumers’ knowledge, attitudes, and beliefs about food safety and nutritional issues. FDA believes combining these two surveys will provide a more holistic picture of how and why consumers make food choices and determine which food safety and nutrition issues are most salient to their lives. Additionally, combining these two survey efforts more efficiently uses staff time and saves operational costs.

2. Purpose and Use of the Information Collection

This voluntary survey is being completed to measure consumers' knowledge, attitudes, beliefs, and reported behavior about food safety various topics related to health, nutrition, and physical activity.

The Centers for Disease Control and Prevention (CDC) estimates 48 million people get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases each year in the United States. Consumers play an important role in the safety of the food they eat and are the last line of defense for preventing foodborne disease. Safe in-home food preparation

practices can reduce the risk of illness. Since the late 1990s, most consumer food safety education has focused on one or more behaviors that consumers can practice at home to reduce foodborne illness. Although each food safety education campaign is unique, many include information encouraging consumers to wash their hands often while cooking and to think about and take preventive actions to mitigate the transfer of pathogens from raw foods onto hands and food contact surfaces such as cutting boards, and to use food thermometers.

Improving safe consumer food handling practices in the home continues to be an important goal for improving human health. To help achieve this goal, the Partnership for Food Safety Education (PFSE) was created in 1997 as a not-for-profit organization that unites industry associations, professional societies in food science, nutrition and health, consumer groups, and the U.S. government to educate the public about safe food handling. PFSE works with an active network of 13,000 health and food safety educators (BAC Fighters) and supports them by making their work more visible, collaborative, and effective. These BAC Fighters are connecting each year with an estimated 7.5 million consumers –helping them to protect their health through safe food handling and hand hygiene.

Data from previous Food Safety Surveys has been used to measure progress toward five Healthy People 2020 objectives related to consumer food handling (Clean, Cook, Separate, and Chill) and one related to food allergy experiences, and data from the upcoming survey are being proposed as a baseline for measuring the same four consumer food handling objectives for Healthy People 2030. The goal of these objectives for both Healthy People 2020 and Healthy People 2030 is to measure what consumers are doing in their homes when they prepare food. To measure progress on these goals, the survey has detailed questions asking consumers if and how they: 1) wash their hands before and during the cooking process (CLEAN); 2) use a food thermometer to determine the doneness of meat, poultry, and seafood (COOK); 3) wash cooking surfaces such as cutting boards (SEPARATE); 4) and refrigerate foods within two hours of preparing (CHILL).

The information collected is expected to help evaluate and develop strategies and programs to encourage and help consumers adopt healthy lifestyles. The information will also help FDA and other federal agencies to evaluate and track consumer awareness and behavior as outcome measures of their achievement in improving public health, especially as it relates to helping consumers use the new Nutrition Facts label and new menu labeling information. Additionally, survey data will be used to measure trends in consumers' attitudes and risk perceptions toward food safety.

The combined FDA Food Safety, Health, and Diet Survey will contain many of the same questions and topics as the surveys previously collected under OMB No. 0910-0345 and 0910-0545, to facilitate measuring trends in food safety, diet knowledge, attitudes, and reported behaviors over time. The combined survey is designed around three major themes relative to consumers' experience with food: Eat, Shop, and Prepare. "Eat" is comprised of questions related to eating at restaurants, including the frequency of eating

at restaurants, awareness of menu labeling, and use of restaurant inspection scores. “Eat” will also include questions about consumers’ overall dietary patterns, consumption of potentially risky foods, and perceptions of food safety risks.

“Shop” is comprised of questions about use of the Nutrition Facts label, claims made on the front of food packages, and perceptions related to organic and genetically engineered foods.

Finally, “Prepare” is comprised of questions about food handling practices related to cleaning hands and kitchen surfaces, separating meat and other foods to be eaten raw, using food thermometers, preparing ready- and non-ready-to eat foods, and properly chilling foods.

This survey is directed towards individual consumers or households.

3. Use of Improved Information Technology and Burden Reduction

The proposed data collection effort will involve telephone surveys – both landline and cell phone – and an address-based, mail push-to-web survey. The computer-assisted telephone interviewing (CATI) methodology proposed for the telephone survey duplicates the method used for the previous Food Safety and Health and Diet surveys, with which the data will be compared. CATI is the most cost-effective approach for telephone surveys. Telephone interviews are less intrusive than face-to-face interviews and are considerably less expensive.

The address-based, mail-push-to-web survey methodology is designed to encourage respondents to fill out the survey via an online web survey. Respondents are contacted via mail with an initial notification letter asking them to go to the web to complete the survey. After follow-up mailings, non-responding households will be sent a paper mail questionnaire they can complete as an alternative to the web survey. We expect that over half of the respondents will take the survey via the web.

The agency estimates that ninety-five percent (95%) of all respondents will use either the telephone or Web to complete this survey.

4. Efforts to Identify Duplication and Use of Similar Information

The Food Safety, Health, and Diet Survey is a unique survey instrument. Many of the topics are of special interest to FDA, and are not addressed by any other public- or privately- sponsored national surveys. There are no other consumer surveys of consumer food handling and diet practices that can satisfy the criteria needed to provide current national estimates and that would enable a comparison with the previous Food Safety Survey and Health and Diet Survey results. FDA collaborated with other federal agencies when developing the draft survey. The collaboration avoids duplication that would result from each agency conducting independent surveys. FDA met with experts across FDA as well as from USDA/FSIS, USDA/CNPP, HHS/ODPHP, and CDC. Each

of these entities contributed questions, suggested edits to existing questions, or provided comments that helped to improve the draft survey.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

Without this data collection, current national estimates of knowledge, attitudes, beliefs, and reported behavior related to food safety, health and diet will not be available. A new collection is important because data from the most recent Food Safety Survey and Health and Diet Survey do not adequately reflect the current state of consumer knowledge, attitudes, beliefs, and practices regarding food safety, health and diet.

A data collection in 2018-2019 will also serve the data needs of Healthy People 2030. Data collected from the 2018-2019 Food Safety, Health and Diet Survey is being proposed as the baseline for the four Healthy People 2030 objectives on consumer food preparation.

Not conducting this new, updated data collection will severely limit FDA's ability to promote and protect the public health.

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.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of July 3, 2017 (82 FR 30871) for the Food Safety Survey, OMB No. 0910-0345. FDA received two comments. One commenter discussed the importance of food safety, for which FDA agrees, and one commenter provided a comment unrelated to the information collection. FDA also published a 60-day notice for public comment in the FEDERAL REGISTER of July 18, 2017 (82 FR 32832) for the Health and Diet Survey, OMB No. 0910-0545. FDA received no comments for this collection. After evaluating these comments, FDA has decided not to revise the information collection.

FDA has also collaborated with other federal agencies when developing this draft survey to avoid duplicating efforts that may result from each agency conducting independent surveys. FDA met with experts across FDA as well as from USDA/FSIS, USDA/CNPP, HHS/ODPHP, and CDC to discuss additional questions, edit existing questions, or provide comments to help improve the survey.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be offered to telephone respondents. If cell phone respondents request money to offset the cost to them of paying for the phone minutes needed to take the survey, a ten-dollar incentive will be offered. Two \$1 bills (\$2 total per sampled respondent) will be included in the invitation letter for the address-based sample. Studies have shown that small pre-paid incentives are effective at increasing survey response.

10. Assurance of Confidentiality Provided to Respondents

The survey questionnaire and screener contain a statement that responses will be kept private to the extent allowed by law. 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). Identifying information will not be included in the data files delivered by contractors to the agency. Information will be kept private to the extent permitted by law.

Prior to starting data collection, FDA's Institutional Review Board will review the survey protocol to ensure that human subjects are protected and that confidentiality procedures are adequate. An independent contractor for FDA will collect survey responses using respondent contact information already maintained by the contractor (not collected de novo in performance of the contract). Responses to interview questions are not expected to include any names or other personal identifiers and questions are designed not to solicit identifying information. Moreover, the contractor will not provide FDA with identifying information on the respondents. The contractor advises respondents that their data (responses) will be treated as private and provided to FDA/CFSAN and/or 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 privacy that reinforces privacy 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, the contractor will permanently dissociate respondents' names and other identifying information from interview (response) 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.

Privacy Act

In developing this proposed collection, staff from FDA's Center for Food Safety and Applied Nutrition (CFSAN) consulted the FDA Privacy Officer to identify potential risks to the privacy of individuals whose information may be handled by or on behalf of FDA. In this case, the subject information collection does not utilize any FDA forms and does not involve solicitation or collection of personally identifiable information (PII) by or on behalf of FDA/CFSAN. No personally identifiable information (PII) will be collected and maintained by FDA/CFSAN. Specifically, FDA/CFSAN does not intend to collect PII

and will not maintain records subject to the Privacy Act or otherwise operate a Privacy Act System of Records in relation to this proposed collection.

11. Justification for Sensitive Questions

The study does not include any questions that are of a sensitive nature. However, respondents are queried on their height, weight, and perception of their risk of chronic illnesses. The agency's experience with these questions suggests that the overwhelming majority of respondents feel comfortable providing this information. For example, when these questions were asked in the last Health and Diet Survey (2008), the item non-response rates due to refusal were lower than 3%.

To mitigate potential privacy concerns on the telephone survey, the following sentence is read immediately prior to the group of questions concerning health status: "The next few questions may seem a bit personal. But we need this information because this survey is about nutrition and health." It is likely that the low item non-response rates mentioned above were attributable to this sentence.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1. Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cognitive interview screener (phone survey)	75	1	75	0.083 (5 minutes)	6
Cognitive interview screener (mail survey)	75	1	75	0.083 (5 minutes)	6
Cognitive interview (phone survey)	9	1	9	1 (60 minutes)	9
Cognitive interview (mail survey)	9	1	9	1 (60 minutes)	9

Table 1. Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pretest screener (phone survey)	100	1	100	0.0167 (1 minute)	2
Pretest screener (mail survey)	100	1	100	0.0167 (1 minute)	2
Pretest (phone survey)	40	1	40	0.25 (15 minutes)	10
Pretest (mail survey)	25	1	25	0.33 (20 minutes)	9
Survey screener (phone survey)	20,000	1	20,000	0.0167 (1 minute)	334
Survey screener (mail survey)	40,000	1	40,000	0.0167 (1 minute)	668
Phone survey	2,000	1	2,000	0.25 (15 minutes)	500
Mail survey	4,000	1	4,000	0.33 (20 minutes)	1,320
Non-Response phone survey screener	200	1	200	0.0167 (1 minute)	3
Non-Response mail survey screener	200	1	200	0.0167 (1 minute)	3
Non-Response phone survey	100	1	100	0.167 (10 minutes)	16
Non-Response mail survey	100	1	100	0.167 (10 minutes)	16
Total					2,913

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

FDA's burden estimate is based on the Agency's prior experience with the Food Safety Survey and the Health and Diet Survey. We will use a cognitive interview screener with

75 individuals for each of the phone and mail surveys to recruit prospective interview participants for a total of 150 individuals. We estimate that it will take a screener respondent approximately 5 minutes (0.08 hours) to complete the cognitive interview screener, for a total of 12 hours for both surveys. We will conduct cognitive interviews with 18 participants, 9 for each survey. We estimate that it will take a participant approximately 1 hour to complete the interview, for a total of 18 hours. Prior to the administration of the surveys, the Agency plans to conduct a pretest to identify and resolve potential survey administration problems. We will use a pretest screener with 175 individuals total; we estimate that it will take a respondent approximately 1 minute (0.0167 hours) to complete the pretest screener, for a total of 4 hours. The pretest will be conducted with 65 total participants (40 phone and 25 mail); we estimate that it will take a participant 15 minutes (0.25 hours) to complete the phone pretest and 20 minutes (0.33 hours) for the mail pretest for a total of 19 hours. We will use a survey screener to select an eligible adult respondent in each household to participate in the survey. A total of 60,000 individuals in the 50 states and the District of Columbia will be screened by telephone or mail. We estimate that it will take a respondent 1 minute (0.0167 hours) to complete the screening, for a total of 1,002 hours for both phone and mail surveys. We estimate that 2,000 eligible adults will participate in the phone survey and 4,000 eligible adults will participate in the mail survey, the phone survey taking 15 minutes (0.25 hours) and the mail survey taking 20 minutes (0.33 hours), for a total of 1,820 hours. We will use a non-response survey screener to select an eligible adult respondent in each household to participate in a non-response survey. A total of 400 participants in the 50 states and the District of Columbia will be screened by telephone or mail. We estimate that it will take a respondent 1 minute (0.0167 hours) to complete the screening, for a total of 6 hours for both the phone and mail surveys. We estimate that 200 respondents total, 100 for the phone survey and 100 for the mail survey, will complete the nonresponse survey taking 10 minutes (0.167 hours) for a total of 32 hours. Thus, the total estimated burden is 2,913 hours.

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is \$58,260 (2,913 x \$20.00) at the 2017 median wage rate in the United States.¹

Table 2. Estimated Annual Reporting Cost Burden			
Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Responding to Survey	2,913	\$20.00	\$58,260.00

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

¹ http://www.bls.gov/oes/current/oes_nat.htm, accessed October, 2017.

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

14. Annualized Cost to the Federal Government

The estimated cost to the federal government is \$1,300,000.00. This cost includes costs paid to the contractor to draw the samples, 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 develop and manage the study.

15. Explanation for Program Changes or Adjustments

This request for reinstatement with change combines/consolidates two previously approved ICRs: 0910-0345 and 0910-0545. This program change is a result of the efficiencies realized by the use of the methodologies to be undertaken by this combined collection and the use of telephone and web-based technologies used to conduct this survey.

Since the last approval for both ICRs in 2014 the number of responses has increased. The overall burden, however, has decreased. This is due to program changes--combining like questions and incorporating new technologies to conduct the survey.

For purposes of entering the ICR into ROCIS the ICs were combined/consolidated decreasing from eight to five.

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 Website, articles published in peer reviewed journals, and presentations at national conferences on food safety and public health. The planned schedule for project activities is shown in Table 3.

Table 3. Project Schedule

Date	Activity	Audience
Within 3 days after receipt of OMB approval of collection of information	Notification to the contractor to proceed with data collection activities	Not applicable
Within 150 days after notification to contractor	Completion of data collection	Not applicable
Within 180 days after notification to contractor	Delivery by the contractor of final data files	Not applicable
Within 6 months after receipt of final data files	Posting of top-line report to FDA Website.	FDA

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

No exemption is requested. FDA is not seeking approval to not display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.