Comparing Food Safety Knowledge, Attitude and Behavior Among English-dominant Hispanics, Spanish-dominant Hispanics, and Other Consumers

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration has the responsibility to protect public health by assuring the safety and security of our nation's food supply and by assuring that food labels are truthful and not misleading. In addition, we are responsible for advancing public health by helping the public to get the accurate, science-based information they need to use foods to improve health. As a member Agency, we support the Department of Health and Human Services policies related to infant and child health, nutrition, and obesity prevention.

We conduct research, educational and public information programs relating to food safety pursuant to its broad statutory authority, set forth in section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (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 1003(d)(2)(C) (21 U.S.C. 393 (d)(2)(C)), to conduct research relating to foods, drugs, cosmetics, devices and tobacco products.

We need an understanding of how different population groups perceive and behave in terms of food safety and food handling to inform development of possible measures that we may take to better protect public health and to help consumers practice safe food handling. We, however, are aware of no consumer research on a nationwide level on how different population groups understand, perceive and practice food safety and food handling. This data collection is aimed at filling the knowledge gaps.

Our current food safety education and outreach programs and materials generally are developed and provided for the English-speaking population in the United States (U.S.) (Ref. 1). To better protect public health and to help consumers practice safe food handling, we need empirical data on how different population groups understand, perceive and practice food safety and food handling. An emerging and important demographic trend in the United States is the increase in Hispanics. Recent estimates suggest that Hispanics (defined as those who identify themselves as of Hispanic or Latino origin) are the largest and fastest growing minority group in the nation; the proportion of the U.S. population that was Hispanic was 14 percent in 2005 and is projected to increase to 29 percent in 2050 (Ref. 2). Data from the Centers for Disease Control and Prevention (CDC) indicate that, in the past two decades, Hispanics were one of the population groups that often experienced higher incidence rates (per 100,000 population) of bacterial

causes of foodborne illness than Caucasians (Ref. 3). These bacterial causes include Campylobacter, Listeria monocytogenes (Listeria), Shigella, and Salmonella. While some Hispanics living in the United States use the English language exclusively or more often than Spanish (English-dominant Hispanics), other U.S. Hispanics predominantly use the Spanish language in their daily lives (Spanish-dominant Hispanics) (Ref. 4). Since most U.S. food labels, including safe food handling instructions, are in English, Spanish-dominant Hispanics' understanding and use of safe food handling instructions may differ from that of English-dominant Hispanics and of non-Hispanics who use English exclusively.

2. Purpose and Use of the Information Collection

This study is intended to provide initial answers to research questions such as whether and how much Spanish-dominant Hispanics, English-dominant Hispanics, and English-speaking non-Hispanics differ in their knowledge, attitude, and behavior toward selected food safety and food handling and the role that demographic and other factors such as one's health conditions and allergies may play in any differences. The study instrument will collect data on the following topics:

- Food consumption - including eating experience at various types of restaurants and with various types of food that may be more susceptible to contamination (e.g., Mexican salsa, raw eggs, undercooked hamburgers, soft cheeses), and hamburger cooking practice;
- Food handling practices - including preparation of some of the foods (e.g., Mexican salsa), handwashing practice, raw meat/chicken handling practices, cutting board and food preparation surface cleaning practices, and use of food thermometers for food preparation;
- Food safety information - preferred and trusted sources and language of the information;
- Risk perceptions and foodborne illness - perceived risk of unsafe food preparation and consumption practices, perceptions of various food safety issues, foodborne illness experience and reaction, and awareness of mercury and seafood safety; and
- Personal background information – (Hispanic participants only) an acculturation index (language preferences) and Hispanic/Latin heritage, general health, and food allergies.

In addition, we will obtain from the contractor participants' socioeconomic characteristics such as age, gender, education, race/ethnicity, household size and composition, marital status, income, and employment status. The characteristics will be retrieved from participants' profiles maintained by the contractor.

We plan to use the results of the study to develop follow-up quantitative and qualitative research to gauge the prevalence and extent of differences in food safety knowledge and behaviors between the three mentioned population groups. We plan to use the results of the follow-up research to help inform the design of effective education and outreach

initiatives aimed at helping reduce the risk of foodborne illness for the general U.S. population as well as Hispanics.

We will not use the results of the study to develop population estimates.

3. Use of Improved Information Technology and Burden Reduction

We will collect the information online from participants using a Web-based questionnaire. The technology is non-intrusive and allows participants to interact with the questionnaire freely and minimizes participant burden.

4. Efforts to Identify Duplication and Use of Similar Information

The proposed research is not duplicative of existing information.

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

This is a one-time data collection. If this information is not collected, we will not obtain an understanding of how different population groups perceive and behave in terms of food safety and food handling to inform development of possible measures that we may take to better protect public health and to help consumers practice safe food handling.

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

There are no special circumstances for this collection of information.

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

In the Federal Register of November 28, 2014 (79 FR 70875), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

The use of incentives is a standard practice in data collection in general (see the American Association of Public Opinion Research Best Practices Guidelines at http://www.aapor.org/Best_Practices1.htm#best9). To ensure adequate participation and high data quality, and to help ensure that participants are reasonably diverse in age, gender, and education, we propose the following incentive approaches. These approaches are determined based on information provided by our contractor about the current practice by the planned consumer panels as well as the going rates offered to participants in the D.C. metropolitan area, for consumer research of similar type, scope, and length of time.

We will recruit from members on the GfK's KnowledgePanel and KnowledgePanel Latino to participate in the data collection. GfK operates an ongoing modest incentive

program, primarily through the use of point system, to encourage participation and create member loyalty. Members can redeem their points for cash, merchandise, gift cards or game entries. Generally, panel members are invited to complete one survey per week. On average, panel members complete two to three surveys per month with typical durations of 10 to 15 minutes per survey.

KnowledgePanel members can receive two types of incentives: non-survey-specific and survey-specific incentives. Non-specific survey incentives are used to maintain a high degree of panel loyalty and to prevent attrition from the panel. For the households that are provided Internet appliances and an Internet connection by GfK, their 'panel loyalty' incentive is the hardware and Internet service that GfK provides free. For households using their own personal computers and Internet service for survey participation, GfK enrolls the panelists into a points program that is analogous to a 'frequent flyer' program, in that respondents are credited with points in proportion to their regular participation in surveys. Panelists receive cash-equivalent checks approximately every four to six months in amounts reflecting their level of participation in the panel, which commonly results in distributions in the range of $4 to $6 per month.

For this data collection, a $5 survey-specific incentive will be paid to Spanish-dominant participants because GfK has found this is essential for obtaining the cooperation of these individuals.

Full details of GfK's incentive protocol are available at http://www.knowledgenetworks.com/ganp/irbsupport/.

Because a significant proportion of the study participants will be Spanish speakers, it is imperative that they can understand and respond to the study instrument, which will be in both Spanish and English. Thus, we plan to conduct cognitive interviews with primarily Spanish-speaking adults. Cognitive interviewees will be recruited and interviewed in-person in the Washington, D.C. metropolitan area. Participants will each be offered$75 for their participation in a 90-minute interview. According to recruitment facility, $75 is the appropriate standard incentive for similar consumers participating in studies lasting 60-90 minutes in the study location. This rate is appropriate because Spanish-speaking participants are harder to recruit and this rate is necessary because a lower rate would prevent the study from taking into consideration potential cognitive responses of an important proportion of the intended participants, which may in turn hurt the quality of data finally collected. The $75 rate is also based on the following estimate of costs to participate in the research and the principles suggested in the 2006 OMB Memorandum, "Guidance on Agency Survey and Statistical Information Collections": transportation (public transportation and/or parking) to and from the interview facility — $15; child care (three hours, including travel time and interview time) at $16/hour (from care.com) — $48; incidental expenses (food, drink, etc) — $12.

10. Assurance of Confidentiality Provided to Respondents

The information will be kept in a secured fashion that will not permit unauthorized access. Throughout the research, any hard-copy files will be stored in a locked file cabinet in the Project Manager's office, and electronic files will be stored on the contractor's password-protected server, which allows only project team members access to the files. All data will be collected with an assurance that the respondents' answers will remain secure to the extent provided by law. The questionnaire will contain a statement that responses will be kept confidential. Identifying information will not be included in the data files delivered by the contractor to us. We will keep the study data secure to the extent permitted by law.

The privacy of the information submitted 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). The proposed data collection has received an exempt status from our contractor's Institutional Review Board (IRB) as well as FDA's Research Involving Human Subjects Committee (RIHSC).

All electronic data will be maintained in a manner consistent with the Department of Health and Human Services' ADP Systems Security Policy as described in the DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also 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 studies do not include any questions that are of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We base our estimates on prior experience with research that is similar to this proposed study. We will use a cognitive interview screener with 72 individuals to recruit prospective interview participants. We estimate that it will take a screener respondent approximately 5 minutes (0.083 hours) to complete the cognitive interview screener, for a total of 5.976 hours, rounded to 6 hours. We will conduct cognitive interviews with nine participants. We estimate that it will take a participant approximately 90 minutes to complete the interview, for a total of 13.5 hours, rounded to 14 hours. We also plan to conduct a pretest to identify and resolve potential survey administration problems. We will send a pretest invitation to 1,440 prospective pretest participants and estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the invitation, for a total of 47.52 hours, rounded to 48 hours. We will administer the pretest with 180 participants and estimate that it will take a participant 15 minutes (0.25 hours) to complete the pretest, for a total of 45 hours. We will send a study invitation to 24,000 prospective participants and estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the invitation, for a total of 792 hours. We will administer the study with 3,000 participants and estimate that it will take a participant 15 minutes (0.25 hours) to complete the study, for a total of 750 hours. The total estimated burden for all the study activities is 1,655 hours; this estimate is 9 hours higher than that

shown in the 60-day notice due to revised hours for cognitive interviews, from 30 minutes (0.5 hours) to 90 minutes (1.5 hours) each interview to reflect a more realistic estimate of the hour burden.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cognitive interview screener (Appendix F)	72	1	72	0.083 (5 minutes)	6
Cognitive interview (Appendix G)	9	1	9	1.5 (90 minutes)	14
Pretest invitation (Appendices A and E)	1,440	1	1,440	0.033 (2 minutes)	48
Pretest (Appendix B)	180	1	180	0.25 (15 minutes)	45
Study invitation (Appendices C and E)	24,000	1	24,000	0.033 (2 minutes)	792
Study (Appendix D)	3,000	1	3,000	0.25 (15 minutes)	750
Total					1,655

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $28,284 (1,655 hours x $17.09/hour) at the May 2014 median wage rate in the U.S.[1]

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

[1] http://www.bls.gov/oes/current/oes_nat.htm, accessed April 2013.

The estimated total cost to the Federal Government for this information collection $200,000. This includes the value of a task order to execute the collection of information and the value of a Full-Time employee to develop, monitor and analyze the study.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. Final results of the study may be reported to the Agency internally, in peer-reviewed scientific journals and presentations at professional conferences. The planned project schedule is shown in Table 2.

Table 2. -- 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 60 days after notification to contractor	Completion of data collection	Not applicable
Within 90 days after notification to contractor	Delivery by the contractor of final data files	Not applicable
Within 4 months after receipt of final data files	Delivery of oral and written preliminary summaries	FDA
Within 12 months after receipt of final data files	Delivery of a written final report of summaries and analytical findings	FDA
Within 18 months after receipt of final data files and as needed	Response to information requests	FDA and public
Within 24 months after receipt of final data files	Submission of manuscript(s) of journal article(s) to disseminate information and analytical findings	Public

FDA will disseminate the results of this study strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public." In describing the data collected and results of the analysis, FDA will clearly acknowledge that the studies are not intended or to be used for developing nationally representative population estimates of consumer attitudes, knowledge, or behaviors and that the studies provide valid and quantitative estimates of differences across experimental conditions.

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

The OMB approval and expiration date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References:

1. U.S. Food and Drug Administration. "Foodborne Illness & Contaminants." June 9, 2014. (http://www.fda.gov/Food/FoodborneIllnessContaminants/default.htm).
2. Passel, J.S. and C. D'Vera. "U.S. Population Projections: 2005-2050." Pew Research Center. February 11, 2008. (http://pewhispanic.org/files/reports/85.pdf).

3. Quinlan, J.J. "Foodborne Illness Incidence Rates and Food Safety Risks for Populations of Low Socioeconomic Status and Minority Race/Ethnicity: A review of the Literature." International Journal of Environmental Research and Public Health 10(8): 3634-3652, 2013.

4. Taylor, P., M.H. Lopez, J. Martínez and G.Velasco. "Language Use Among Latinos." Pew Research Center. April 4, 2012. (http://www.pewhispanic.org/2012/04/04/iv-language-use-among-latinos/).