Request for OMB Review

Supporting Statement for

Mental Models Study of Food Terrorism Risk Awareness

Submitted by:

Office of Regulations and Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services

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Mental Models Study of Food Terrorism Risk Awareness

A. JUSTIFICATION

1. Legal Basis and Necessity for the Information Collection

The proposed information collection will help FDA protect the public from food terrorism by preparing the agency to take appropriate action in the event of a crisis. Under the Federal Food, Drug, and Cosmetic Act of 1938, as amended, FDA has authority to act to protect the safety of the nation's food supply. Under title 42 of the Public Health Service Act (1944), FDA has authority to act to protect the public health. In addition, title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188), FDA has authority to act to improve the ability of the United States to prevent, prepare for, and respond to terrorism and other public health emergencies.

FDA has crafted and disseminated messages intended to raise the awareness of state and local government agency and industry representatives regarding food defense issues and preparedness, but FDA does not currently have similar initiatives for consumers. Extensive research exists in disaster preparedness and in effective communication to the public of risk or crisis information by government or non-government entities. However, additional research is needed to help FDA design communications that will increase consumer awareness of the potential for food terrorism and help consumers to make good decisions in the event of a food terrorism emergency.

Approval is requested for a study to assess consumers' perceptions of the risk of food terrorism, entitled Mental Models Study of Food Terrorism Risk Awareness (the "Mental Models study").

2. How, by whom, and the Purpose for Collecting this Information

The proposed information collection will use "mental modeling," a qualitative research method wherein the decision-making processes of a group of consumer respondents concerning food terrorism are modeled and compared to a model based on expert knowledge and experience in food terrorism. The information will be collected via a telephone interview concerning the factors that influence the perceptions and motivations related to the threat of food terrorism. The method will help to identify consumers' misperceptions and erroneous beliefs about food terrorism. A comparison between expert and consumer models based on the collected information may identify "consequential knowledge gaps" that can be redressed through messages or information campaigns designed by FDA. Thus, the information to be collected will be used by FDA to develop messaging and information campaigns.

FDA/CFSAN has contracted with Decision Partners, a world leader in risk perception research, to develop and conduct the Mental Models study, which they will do with the aid and input of the FDA project officer, an expert in social science research. The first step in the mental models process is to conduct background research to develop a model based on both experts' current knowledge and extant literature on food terrorism awareness. The resulting "simple expert

model" is a mapping of decision-making factors, relationships and influences, and is used to develop an interview protocol for a day-long workshop with experts, hereafter referred to as the "expert elicitation."

The expert elicitation was conducted January 31, 2007. It included 17 experts from a variety of fields related to risk communication and food terrorism (e.g., food distribution systems, food defense, food safety, toxicology, mental health, nutritionist, state health departments, and public affairs officers). Nine experts were professionals from academia or the private sector. , and eight experts were from the Federal government. The expert elicitation process does not solicit advice, opinions, or recommendations from the group, but instead tries to determine how each expert perceives the factors related to consumer decision-making, from their particular expert field. Results from the expert elicitation are used to develop the expert model, which generally includes adding new concepts and supporting details to the existing simple expert model. The new, draft expert model is validated during a subsequent teleconference with the same group of experts about a month following the initial elicitation. Following the validation, the project team finalizes the expert model.

The expert model informs the development of the consumer interview guide for consumer telephone interviews. The consumer research sample will consist of adults, ages 18 years or older, with at least one child age four to 13 years residing in the home at least half-time. Respondents also will have to self-identify as one of the primary food shoppers in the home. The sample will be divided by gender. The first sample criterion is based on the belief that adults providing care to school age children are more likely to have greater concerns about health and food-safety than adults in households without children. Families with children ages 4 to 13 will be selected because of the high likelihood that children in this age group eat the same foods as the rest of the household. The second criterion derives from our research experience tells us that household, primary food shoppers are better able to discuss food products and food safety issues than people that do not shop regularly. Cognitive interviews will be conducted with five consumers. The one-on-one interviews will last approximately 45 minutes each. The results of the cognitive interviews will be used to refine the consumer interview guide.

When OMB clearance is received, trained interviewers will conduct 40 one-on-one, in-depth consumer telephone interviews. Decision Partners will use a "Snowball Sampling Technique" to generate a list of potential interviewees. This technique is involves asking people who are known to be active and engaged in the community, to provide contact information for other people who may wish to participate in an interview. Unlike random dialing methods, the Snowball Sampling tends to generate lists of people who are more willing to provide depth and richness in their responses to interview questions. A sample size of 40 is sufficiently large for the qualitative findings to capture a wide depth and range of people's thinking. Like the cognitive interviews, the consumer interviews will last approximately 45 minutes.

The consumer interviews will be used to create a mental model of consumer decision-making factors with respect to food terrorism threats. Based on the comparison between the consumer and expert models, Decision Partners will identify the gaps and inconsistencies between the models and provide recommendations on the areas that will be important for planning a communication strategy. At the conclusion of the study, the contractor will produce expert and consumer decision-making models and prepare a final project report containing recommendations.

3. Improved Information Technology

The study does not use electronic collection of information. Qualitative interview guides are often unstructured. The questions are generally open-ended, allowing interviewees to respond without restriction. As opposed to structured questionnaires, the goal of a qualitative inquiry is to discover the range of meaningful themes and categories, which are often used in follow-up, quantitative research. Typically, a qualitative interview requires some interaction between the respondent and the interviewer. While for some qualitative studies it may be appropriate to engage in an electronic interaction through a computer interface, mental modeling interviews rely on the subtleties that can only be detected through verbal conversation. The consumer interviews for this research are conducted over the telephone, which minimizes respondent burden that would be incurred through time and travel.

4. Duplication of Similar Information

There is no likelihood of Federal duplication of effort across agencies. The U.S. Department of Homeland Security's Science and Technology Directorate created a national consortium for the Study of Terrorism and Responses to Terror (START) (http://www.start.umd.edu/). START is tasked with using state-of-the-art theories, methods, and data from the social and behavioral sciences to improve understanding of the origins, dynamics, and social and psychological impact of terrorism. One of START's three thematic working groups does research under the rubric of Societal Responses to Terrorist Threats and Attacks. The research conducted there includes about twenty different studies, including a household survey on disaster preparedness and community emergency preparedness. While the studies conducted through START grants have been, and will be, helpful for providing background and supporting information, currently none of the projects duplicates the research proposed here. Certainly, global concepts for risk communication are applicable and will be used to contribute to this research and any follow-up risk communication strategy. However, FDA's information needs are unique and require a targeted research strategy.

5. Small Businesses

This study will have no impact on small businesses.

6. Less Frequent Collection

This is a one time information collection. Without the data collection, FDA would not have the knowledge or understanding of how best to communicate with consumers about preparedness for food terrorism threats.

7. Special Circumstances

This collection fully complies with 5 CFR 1320.5. The only special circumstance associated with this information collection is the assurance of confidentiality for the information collected from consumers. Please see section 10 below for a discussion on confidentiality.

8. Federal Register Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), on March 30, 2007, in Volume 72, page 15140, a 60-day notice for public comment was published in the *Federal Register*. No comments were received from the public.

The following is a sampling of the people from the private sector, industry, and academia who were consulted on this data collection:

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9. Payment/Gift to Respondent

Decision Partners typically offers an honorarium to interviewees for participation in a research project. Honoraria are usually in the order of $25 - $30. To ensure that interviewee responses are not influenced by the token of appreciation, no mention is made of an honorarium until after the interview has been fully completed. If an interviewee happens to ask about the possibility of being paid for his or her involvement in the research, Decision Partners will decline to interview the respondent.

10. Confidentiality

Decision Partners will collect information for the sample list for the sole purpose of inviting people to participate in an interview. The information is stored securely and will not be used unless the person opts to participate in an interview. Under no circumstance is contact information ever released to a third party.

The information collected from consumers in this research is confidential and respondents are given assurances of confidentiality. Confidentiality will be assured by using an independent contractor to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants. Identifying information will not be included on the data files delivered to FDA. Confidentiality 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). In addition, this study has been reviewed by the FDA Research in Human Subjects Committee Center liaison and has been approved for six months, subject to reevaluation and continued approval. Part of the criteria for approved status includes ensuring that identifying information is stripped from the data and that appropriate security procedures are in place. Respondents are also informed of their rights to privacy and their right to refuse to participate, to quit at any time and to skip any questions they want.

11. Sensitive Questions

No questions of a sensitive nature are asked in this information collection.

12. Burden Estimate (Total Hours and Wages)

FDA estimates the total annual burden for this one-time collection of information to be 33.75 hours. FDA estimates that respondents will take 45 minutes (0.75 hours) to complete both the screening and participation. There will be a total of no more than 45 respondents, five for pre-tests and 40 for the data collection.

Estimated Annual Reporting Burden[1]					
Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours

Study	45	1	45	0.75	34

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

13. Capital Costs (Maintenance of Capital Costs)

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

14. Cost to Federal Government

The total cost to the Federal government for this data collection is $125,000.00. This includes fees paid to the contractor to design the study, draw the sample, collect the data, produce expert and consumer decision-making models and prepare a final project report containing recommendations.

15. Program or Burden Changes

This is a new information collection.

16. Publication and Tabulation Dates

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 summarized for publication in a peer-reviewed scientific journal. Currently, there are no plans to publish summaries or final reports in either hard copy or on the Internet.

17. Display of OMB Approval Date

The OMB Approval date will be displayed on all materials associated with the study.

18. Exceptions to "Certification for Paperwork Reduction Act Submissions"

No exceptions are requested.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This information collection will not employ statistical methods. It is a qualitative data collection. The information collected can be used to inform a quantitative data collection, however, that is not the current plan. Please see section number A2 above for respondent universe and data collection information.