**SURVEY TO EVALUATE**

**FDA'S FOOD DEFENSE AWARENESS INITIATIVE ALERT**

**SUPPORTING STATEMENT**

**OMB No. 0910-NEW**

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary

The proposed "Survey to Evaluate FDA's Food Defense Awareness Initiative ALERT" will be conducted under a cooperative agreement between the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and the Center for Risk Communication Research (CRCR) at the University of Maryland (UMD). The Institute, established in 1996, is a public and private partnership between the U.S. Food and Drug Administration (FDA) and UMD. The Institute jointly administers multidisciplinary research and education programs to foster the missions of FDA and the University to increase the quantity and quality of research.

In July 2006, FDA announced its Food Defense Awareness Initiative, called ALERT (the letters stand for the five key components of the initiative: assure, look, employees, report, and threat). The purpose of the ALERT initiative is to raise the awareness of state and local government agencies and the food industry regarding food defense issues. ALERT identifies five key points that industry and businesses can use to decrease the risk of intentional food contamination at their facility. The ALERT web-based training module and more information on ALERT are available at www.cfsan.fda.gov/~dms/defterr.html.

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 393 (b)(2)), 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. Under this authority, FDA is planning to conduct a survey of first line supervisors working in a range of capacities in the food industry about their awareness and perceptions of the agency's ALERT initiative and the ALERT initiative informational materials.

### 2. Purpose and Use of the Information Collection

The CRCR will contact a statistical sample of businesses drawn from purchased lists of seven food-related industries. The industries of interest are growers, packers, processors, warehouses, transporters, retailers, and food service operators. Participation will be voluntary and information that would associate specific responses to specific businesses will not be accessible to FDA. The purpose of the survey is to help FDA evaluate ALERT informational materials and to gauge whether the ALERT principles or ALERT materials succeed in informing food industry personnel about the risk of intentional food contamination and in motivating them to engage in protective behaviors.

FDA plans to use the information collected from the survey to learn about the food defense practices of the food industry. The survey results will be used assess how knowledge and awareness, threat perceptions, attitudes, norms, benefits and barriers affect the implementation of the ALERT initiative or its principles. This is a new, one-time data collection. FDA does not plan to collect data on food defense practices in the food industry on an ongoing basis.

**3. Use of Improved Information Technology and Burden Reduction**

The CRCR will utilize a mixed-mode approach using both the Internet and U.S Postal Service mail. They will use an Internet survey to collect the information from targeted respondents that prefer responding by Internet. With a custom-designed online survey system, responses will be entered directly into a computer database, eliminating the need for additional coding and data entry operations. In addition, the system will ensure that conditional questions are asked in proper order, freeing the respondent from the need to keep track of the question order and skip patterns. The data quality will be high because the instrument will contain built-in edits, prompts, and data validation features. CRCR selected the Internet survey method due to the following considerations: (1) the Internet survey method is the least costly to the agency when compared with other modes of collection and generates the timeliest responses; (2) the Internet survey will impose a relatively modest reporting burden on small entities. For respondents that lack Internet connectivity or that prefer a mail survey, CRCR will use the U.S Postal Service mail to administer the survey.

**4. Efforts to Identify Duplication and Use of Similar Information**

There is no duplicative collection of this information. No comparable data have been collected by any other means. There is some literature on studies of food defense in the food supply chain. In particular, Kinsey, Kaynts, and Ghosh (2007) report on findings from a three year study on food defense practices and readiness of food firms to protect their assets from terrorist attack. This study, however, is not an evaluation of the FDA ALERT campaign. Insights from the literature will be used to help inform the study. The survey will provide valuable information on industry perceptions of the ALERT campaign.

**5. Impact on Small Businesses or Other Small Entities**

An effort will be made to include large, medium, and small businesses in this study. It is important to determine how organizations of all sizes have responded to the ALERT campaign. The CRCR is utilizing the Internet and the US Postal Service as its modes of data collection based on the preference of the individual small entities.

The survey instrument contains built-in skip logic, prompts, and edits that will minimize the time required to answer the questions. The mail instrument will be specially designed to be easily read with a logic pattern that will also minimize the time for completion. As a result, the reporting burden by small entities will be modest. No further reductions in respondent burden are possible without rendering the survey ineffective.

## 6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. If this information were not collected, FDA would have no knowledge about the influence and effects of the ALERT campaign. This lack of information would negatively affect the FDA's educational and public information programs relating to the food defense.

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

The collection fully complies with 5 CFR 1320.5(d) (2). All respondents will be assured that the information they provide is confidential. FDA can show we have procedures to protect the respondent's confidentiality. The study will not require respondents to 1) report the information more often than quarterly, 2) provide a written response in less than 30 days, 3) submit more than one original plus two copies of the information, or 4) 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 May 22, 2007 (73 FR 29759), FDA published a 60-day notice requesting public comment on the proposed information collection. The FDA received no comments on this research.

The following individuals have been consulted for input on the survey method, the questionnaire, and the sampling plan.

Anthony Flood
Director, Food Safety Communications
IFIC
Email: flood@ific.org
Phone: 202.296.4630

Timothy L. Sellnow, Ph.D.
University of Kentucky
Department of Communication
249 Grehan Building
Lexington, KY 40506-0042
Email: tim.sellnow@uky.edu

Phone: 859.257.2295
FAX: 859.257.4103

Sandi Smith, Ph.D.
Director, Health & Risk Communication Center
Professor, Department of Communication
573 Communication Arts and Sciences
Michigan State University
East Lansing, MI 48824
email: smiths@msu.edu
Phone: 517.353.3715
FAX: 517.432.1192

**9. Explanation of Any Payment or Gift to Respondents**

Respondents will not receive any type of payment or gift for participation in this collection of information. However, the CRCR will offer a copy of the survey report to all respondents as an incentive to participate.

**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). The survey will include a pledge of confidentiality regarding CRCR's use of the data provided by the respondents. All data will be collected and compiled by CRCR. The terms of the research proposal restrict CRCR from providing FDA with raw or other data that has identifiers that would permit the association of specific responses to a given respondent. CRCR will provide FDA personnel only with a summary of data (aggregated statistical data) compiled in the course of the study. The raw data generated by the survey will not be owned by FDA, will not be an FDA record, and will not be provided, or otherwise made available, to FDA.

The CRCR will assure confidentiality by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants. The CRCR has a privacy policy that precludes them from sharing personal information on participants with any third party without the participant's express permission unless it is required by law or necessary to protect their rights or to comply with judicial proceedings, court order, or other legal process. Identifying information will not be included in data files that may be delivered to the agency.

The CRCR will maintain all electronic data 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 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 of Sensitive Questions**

The survey does not include any questions that are of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters commonly considered private.

**12. Estimates of Annualized Burden Hours and Costs**

*Description of Respondents:* The universe for the sample is owner/operators, food defense decision-makers, or first-line supervisors in the following food industries: growers, packers, processors, warehouses, transporters, retailers, and food service operators. FDA has included in its estimate the time needed to obtain permission from the respondent's supervisor.

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

| Table 1.--Estimated Annual Reporting Burden[1] | | | | | |
|---|---|---|---|---|---|
| Activity | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
| Cognitive Interviews | 7 | 1 | 7 | 1 | 7 |
| Telephone Interview - Pre-test Invitation | 28 | 1 | 28 | 0.10 | 3 |
| Completed Pre-test | 14 | 1 | 14 | 0.25 | 4 |
| Telephone Interview – Survey Invitation | 5,000 | 1 | 5,000 | 0.10 | 500 |
| Completed Survey | 2,500 | 1 | 2,500 | 0.25 | 625 |
| Total | | | | | 1139 |

Cognitive interviews will be conducted with seven participants. We estimate that the cognitive interviews will take 60 minutes (1 hour) to complete for a total of 7 hours. An invitation to take a pre-test will be extended to 28 food-defense decision-makers; we estimate that it will take respondents 6 minutes (0.10 hours) to respond to the invitation and make arrangements to complete the pretest, for a total of 2.8 hours (rounded to 3). Fourteen (14) respondents will complete the pre-test; we estimate that it will take respondents 15 minutes (0.25 hour) to complete the pretest for a total of 3.5 hours (rounded to 4). An invitation to take the survey will be extended to 5,000 food defense decision-makers; we estimate that it will take 6 minutes (0.10 hours) to respond to the invitation and make arrangements to complete the survey, for a total of 500 hours. Twenty-five hundred respondents will complete the survey. We estimate that it will take a respondent 15 minutes (0.25 hours) to complete the entire survey, for a total of 625 hours. Thus, the total estimated burden is 1139 hours. FDA's burden estimate is based on prior experience with surveys that are similar to this proposed survey.

**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 Federal Government**

The estimated total cost to the Federal Government for this information collection $135,000. This estimate consists of (1) $9,000 for 1 FTE of FDA professional staff to manage the project, and other informational products to be described in A.16, and (2) $126,000 for data collection.

**15. Explanation for Program Changes or Adjustments**

This is a new data collection. The new burden hours are due to a one-time survey and its related cognitive interviews, pre-test and screener.

**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 summarized for publication in a peer-reviewed scientific journal. The planned schedule for project activities 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 contractor to proceed with data collection activities | Not applicable |
| Within 135 days after the start of data collection | Completion of data collection | Not applicable |
| Within 6 months after receipt of final data files | Delivery of oral and written preliminary summaries | FDA |
| Within 18 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 | 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 |

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

The CRCR and FDA will display the OMB approval and expiration date on all materials associated with the study.

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

The CRCR and FDA do not request exceptions.

References

Gagné, P. E., & Hancock, G. R. (2006). Measurement model quality, sample size, and solution propriety in confirmatory factor models. *Multivariate Behavioral Research*, 41, 65-83.

Kinsey, J., Kaynts K., , and Ghosh, K. (2007) Defending the Food Supply Chain: Retail Food, Foodservice and their Wholesale Suppliers. *The Food Industry Center.* University of Minnesota.