MENTAL MODELS STUDY OF FARMERS' UNDERSTANDING AND IMPLEMENTATION OF GOOD AGRICULTURAL PRACTICES

OMB No. 0910-NEW

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The proposed information collection will help FDA protect the public from foodborne illness by increasing the agency's understanding of how farmers and growers use Good Agricultural Practices (GAPs) to address common risk factors in their operations and thereby minimize food safety hazards potentially associated with fresh produce. Fresh fruits and vegetables are those that are likely to be sold to consumers in an unprocessed or minimally processed (i.e., raw) form and that are reasonably likely to be consumed raw. 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 Title 42 of the Public Health Service Act (1944), FDA has authority to act to protect the public health.

In 1998, FDA issued a guidance document entitled "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," available at http://www.cfsan.fda.gov/~dms/prodguid.html. The guidance addresses microbial food safety hazards and good agricultural and good management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form. There is evidence that growers have not fully implemented the GAPs to reduce production risks, despite intensive GAPS training programs.

Approval is requested to conduct a study to determine growers' decision-making processes with regard to understanding and implementing GAPs on the farm to more fully understand the barriers and constraints associated with GAPs implementation.

2. Purpose and Use of the Information Collection

The data will be collected using one-on-one interviews in person and on the telephone, using a mental models approach, a qualitative research method wherein the decision-making processes of a group of respondents (described below) are modeled and compared to a model based on expert knowledge and experience. The data will be collected by trained interviewers employed by a hired contractor (Decision Partners).

The purpose of this information collection is to learn farmers' understanding about GAPs, the decisions involved in implementing GAPS, and the barriers and constraints they face in implementing GAPs. This knowledge will help FDA design communications about GAPs and inform the development of GAPs training materials.

Findings from this study will provide a preliminary framework to help FDA decide whether it would be useful to pursue quantitative studies to test the extent of any knowledge gaps and whether changes to FDA communications would remedy any problems identified. We expect this work to facilitate improved decision making by produce farmers and GAPs trainers to decrease the incidence of microbial contamination on the farm.

3. Improved Information Technology and Burden Reduction

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. While for some qualitative studies, it may be appropriate to engage in electronic interaction through a computer interface, mental modeling interviews rely on the subtleties that can only be detected through verbal conversation. The farmer and trainer interviews for this research are conducted over the telephone, which minimizes respondent burden that would be incurred through time and travel.

4. Efforts to Identify Duplication and Use of Similar Information

There is no likelihood of Federal duplication of effort across agencies. 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.

For this project, FDA was able to build upon similar background research conducted by the contractor and its collaborators at the Ohio Agricultural Research and Development Center in support of a USDA National Integrated Food Safety Initiative special emphasis grant on microbial risks to fresh and fresh-cut produce. To inform that research, the contractor and its collaborators developed an expert model, entitled "Influences on Farmers' Decision Making Regarding Safety of Fresh and Fresh Cut Produce." This model was developed based on input from an expert elicitation workshop held March, 2007, with approximately 20 academic, industrial and governmental experts who spoke to a range of issues related to microbial food safety, GAPs and agricultural management. 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 farmer/GAPs trainer decision-making, from their particular expert field. Results from the expert elicitation were used to develop the expert model. A draft expert model was constructed and validated during a subsequent teleconference with the same group of experts about a month following the initial elicitation. Following the validation, the project team finalized the expert model. This model then served as the foundation for the design and analysis of the subsequent mental models research conducted as part of that research project.

Because this project shares many common goals, utilizes the same expert models and mental models research methodology and requires the same background research, it is appropriate and efficient to build upon that research and utilize the same expert model, with slight modifications, as the foundation for the present FDA research. Small variations were made to the expert model to enhance specific expert understanding of the role of GAPs in minimizing food safety risks and factors that influence farmers' adoptions of GAPs. These modifications were made by the contractor in consultation with FDA and a few external experts.

5. Impact on Small Businesses or Other Small Entities

This study will not have a significant impact on small businesses or other small entities. The information collection is voluntary, and produce farmers and GAPs trainers can complete the interview at a time most convenient for them.

6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection. If this information is not collected, FDA will have no knowledge or understanding of how best to communicate with produce farmers and GAPS trainers about the appropriate implementation of GAPs. This lack of information could impede the agency's educational and information programs relating to the safety of the nation's food supply.

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

This collection fully complies with 5 CFR 1320.5. 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 study will not use statistical data. 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 July 1, 2008 (73 FR 37464), FDA published a 60-day notice requesting public comment on the proposed information collection. FDA received one letter in response to the notice, containing one or more comments. One comment recommended that FDA increase the sample size and ensure that key subsets of the produce industry are surveyed. FDA responds that the proposed study is qualitative in nature. FDA does not intend the results of this study to be a quantitative estimate of the prevalence of the use of GAPs across the produce industry. The proposed sample size is sufficient to enable FDA to construct mental models of the barriers and constraints related to GAPs implementation. FDA agrees with the recommendation to ensure key subsets of the industry are included in the study.

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. Explanation of Any Payment or Gift to Respondents

The contractor typically offers an honorarium in the order of $25 - $30 to interviewees for participation in a research project.

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).

Confidentiality will be assured by using an independent contractor (Decision Partners) 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. Decision Partners will not share personal information regarding 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 the data files delivered to the agency.

All electronic 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 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 survey does not include any questions that are of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. Further, we are only asking respondents to speak within the context of their professional capacities.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: The respondents are farmers or growers of fruits and vegetables, GAPs trainers, and retail buyer or grower association representatives.

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

Table 3.--Estimated Annual Reporting Burden[1]					
Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	80	1	80	0.02	2
Pre-tests/ Cognitive Interviews	9	1	9	.75	7
Farmers/ Growers	24	1	24	.75	18
GAPs Trainers	24	1	24	.75	18
Retail Buyers/ Growers Assn. Reps.	12	1	12	.75	9
Total					54

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

Approximately 80 respondents will be screened. We estimate that it will take a respondent 1.2 minutes (0.02 hours) to complete the screening questions, for a total of 2 hours. FDA will conduct 9 pretests; we estimate that it will take respondents 45 minutes (0.75 hours) to complete the pretest, for a total of 7 hours. Sixty (60) respondents will complete the interview. We estimate that it will take respondents 45 minutes (0.75 hours) to complete the entire interview, for a total of 45 hours. Thus, the total estimated burden is 54 hours. FDA's burden estimate is based on prior experience with mental models research that is similar to this proposed study.

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 total estimated cost of this research is $209,000. This includes $200,000 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. In addition, FDA estimates the cost of salaries for the FDA staff involved in the project development,

implementation and monitoring to be $9,000, for a total estimated cost of $209,000.

15. Explanation for Program Changes or Adjustments

This is a new data collection. The new burden hours are due to a one-time interview and its related 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.

Table 4. *Project Schedule*

Date	**Activity**	**Audience**
Within 3 days after receipt of OMB approval of collection of information	Notification to Decision Partners to proceed with data collection activities	Not applicable
Within 135 days after notification to Decision Partners	Completion of data collection	Not applicable
Within 180 days after completion of data collection	Delivery by Decision Partners of final data files	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

Activities associated with the outcomes of this research will primarily consist of written and oral presentations as well as a written final report. In addition, journal manuscripts and oral and/or poster presentations will be planned to disseminate the information to the public, including professional, academic, industry and consumer organizations. The dialogues will help improve the effectiveness of the agency's regulatory and education initiatives in promoting and protecting the public health.

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"

No exceptions are requested.