Experiment to Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak

0910-NEW

SUPPORTING STATEMENT

PART A

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) has the responsibility to protect public health by assuring the safety and security of our nation's food supply and by assuring that foods are effectively labeled. In addition, the FDA is 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 part of its regulatory responsibility for safety of the food supply, the FDA develops and disseminates consumer messages about food safety and nutrition. As a member agency, the FDA supports the Department of Health and Human Services policies related to infant and child health, nutrition, and obesity prevention.

FDA conducts research and educational and public information programs relating to food safety pursuant to its broad statutory authority, set forth in section 903(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 903(d)(2)(C) (21 U.S.C. 393 (d)(2)(C)), to conduct research relating to foods, drugs, cosmetics and devices in carrying out the act.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

This proposed collection of information entitled "Experiment to Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak" 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. JIFSAN was established in 1996 and is a public and private partnership between FDA and the University of Maryland. The CRCR will design and administer the study.

The purpose of this research is to help FDA better understand whether the magnitude and duration of the decline in commodity consumption following food recalls can be partly explained by grower and retailer speculations and projections

about consumers' attitudes toward food recalls resulting from foodborne illness outbreaks. This research will be used to assess how grower, retailer, and consumer perceptions, attitudes, knowledge, and beliefs affect market recovery after a hypothetical fresh spinach recall.

2. Purpose and Use of the Information Collection

Epidemiologists define foodborne illness outbreaks as two or more cases of a similar illness resulting from the ingestion of a common food (Ref. 1). Because many foodborne illness cases are mild, most outbreaks are never recognized or brought to the attention of public health authorities. When the outbreaks are large in scale or cause hospitalization, serious illness, or death, public health officials will inform the public in order to try to stop the spread of disease. A food recall can occur when a particular food in the marketplace is found to have a known contaminant, because either people have become sickened by it or pathogen testing has revealed contamination (2). The purpose of a food recall is to rid retail establishments of the product and to inform consumers that they should discard the product if they have it in their homes. Although the purpose of a food recall is to keep consumers from becoming ill, food recalls can be costly to all sectors of the food distribution chain (3). The goal of the proposed project is to test, by experimental study, whether the psychological tendency called "attribution error," contributes to unnecessarily prolonging the economic effects of a food recall. "Attribution error" is the tendency people have of overestimating others' negative response to situations compared to their own response. If industry decision-makers' measures of consumer response are biased by "attribution error," industry could be contributing to its own slow recovery after a food recall.

When a widespread foodborne illness outbreak results in a food recall, the product can be out of the marketplace for an extended period of time; this occurred when fresh, bagged spinach was recalled in 2006 (3). Tomatoes were also less available following the Salmonella Saintpaul outbreak in 2008 (4). Although growers and retailers want to provide safe foods, decisions surrounding production, wholesale, and retail sales forecasting in response to a food recall affects how quickly the food is again available for consumption. We hypothesize that industry's over-attribution of consumers' fear of the food after such a food recall would result in the food being kept off of the market longer than necessary.

The CRCR plans to conduct an experiment using a Web-based questionnaire. The center will use a convenience sample of 900 participants (180 growers, 180 retailers, 540 consumers) drawn from industry networks (for the growers and retailers), and a Web-based panel of U.S. households (for the consumers). Participation in the study is voluntary.

This study will help FDA better understand the reasons for the time between a food recall resulting from a foodborne illness outbreak and market recovery. In order to understand the complexities of market recovery process, the CRCR will

compare understandings and reactions of growers, retailers, and consumers to a hypothetical food recall resulting from a hypothetical foodborne illness outbreak. To make this comparison, individuals in each group will be assigned to one of the following experimental conditions (consisting of vignettes in the form of news articles on a hypothetical food recall): An "anger" scenario, a "fear" scenario, or a "control" scenario. After reading the news article, participants will complete a questionnaire assessing their emotional response, appraisals, attribution of responsibility, perceptions about the safety of the affected produce, intentions to grow, sell, or buy the affected produce, perceived probability of a repeat event, and a measure of their innate ability to effectively respond to the information in the article.

Information will be collected from individuals.

3. Use of Improved Information Technology and Burden Reduction

The study will use a web-based questionnaire. Web-based questionnaires not only reduce the burden on respondents, but also minimize possible administration errors and expedite the timeliness of data processing. Compared to face-to-face interviews, web-based questionnaires are less intrusive and less costly.

FDA estimates that 100% of the respondents will use the Web-based questionnaire to participate in the study.

4. Efforts to Identify Duplication and Use of Similar Information

A literature review indicates there has been very limited research on the topics we are interested in examining. In particular, there have been almost no studies that specifically investigate retailers' and growers' responses to food recalls. Additionally, how retailers and growers perceive consumers' reactions to food recalls is not well understood. A recent study (5) demonstrates that consumers exhibit the so-called third person effect, perceiving others to be more strongly influenced by news of food recalls than themselves. Our study will examine whether retailers and growers show a similar bias. If so, their unwillingness to restock and grow recalled products may be partly due to an overestimation of consumers' negative reactions.

5. Impact on Small Businesses or Other Small Entities

None (0%) of the respondents are small businesses, thus, no small businesses or other small entities will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. Without this study, FDA will not have information needed for better understanding the reasons for the time between a food recall resulting from a foodborne illness outbreak and market recovery.

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

No special circumstances will occur in the data collection.

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

8a. Publication in the FEDERAL REGISTER

In accordance with 5 CFR 1320.8(d), in the Federal Register of April 15, 2011 (76 FR 21379), FDA published a 60-day notice requesting public comment on the proposed collection of information. The agency received two comments. The comments, and the agency's responses, are discussed in the following paragraphs.

(Comment 1) One comment suggested that the FDA should include the foodservice distributor community in the study.

(Response 1) FDA disagrees. FDA is not including the foodservice distributor community as a study sample because the foodservice distributor community is responsive to retail's demands for product. The retail sector is included in the study.

(Comment 2) One comment questioned the need for FDA to apply government resources toward the research question, which was characterized in the comment as a survey of consumers' reactions to food recalls.

(Response 2) FDA disagrees that the research data is not needed. The proposed study utilizes an experimental design to assess how well industry predicts consumer reaction to a food recall. This information will help the FDA in their risk management role during and following a food recall. Risk management involves communicating both with industry and consumers about the important health and economic consequences related to the recall.

8b. Outside Consultation

The FDA Primary Investigator consulted by telephone with Will Daniels of EarthBound Farms in 2009. Mr. Daniels reviewed an early draft of the study protocol and questionnaire.

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The FDA Primary Investigator consulted in person and by e-mail with Jim Gorny, FDA's produce expert in 2010 and 2011.

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9. Explanation of Any Payment or Gift to Respondents

There will be no payment or gift to respondents. The Center for Risk Communication Research will contract with Knowledge Networks' Web-based Panel to procure the consumer sample. The panel is routinely sent inexpensive gifts to show appreciation for their efforts in answering the questionnaires.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the respondents' answers will remain confidential. The study 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).

Knowledge Networks, has procedures in place to prevent unauthorized access to respondent information. The firm stores Internet panel members' personal identifiable information on separate servers from survey response data, uses firewalls to secure its servers, maintains audit records of log-ins, file accesses and other security incidents, and conducts its work in a high security building.

The information accompanying a link to the questionnaire will contain a statement that responses will be kept confidential. Identifying information will not be included in the data files.

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 questionnaire 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.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Estimated Annual Reporting Burden

Activity	No. of	No. of	Total Annual	Average	Total

	Respondents	Responses per Respondent	Respondents	Burden per Response (in Hours)[2]	Hours
Cognitive Interview Recruitment	25	1	25	.08 (5 minutes)	2
Cognitive Interviews	10	1	10	1 (60 minutes)	10
Consumer Panel Screener	800	1	800	.03 (2 minutes	24
Grower Screener	360	1	360	03 (2 minutes	11
Retailer Screener	360	1	360	03 (2 minutes	11
Pre-tests	24	1	24	.17 (10 minutes)	5
Experiment	900	1	900	.17 (10 minutes)	153
Total					216

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

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $5,950. (130 hours at $16 per hour and 86 hours at $45 per hour) (the 2009 median wage rate in the U.S. overall and for General and Operations Managers) See http://www.bls.gov/oes/current/oes_nat.htm#00-0000, dated May 14, 2010, the latest estimate available as of July 2011.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General and Operations Managers	86	$45.00	$3,870
Consumers	130	$16.00	$2,080.
Total			$5,950.

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

The estimated total cost to the Federal Government for this information collection is $200,000. This is the total of the cooperative agreement between JIFSAN and The Center for Risk Communication Research to conduct the research.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

15. Plans for Tabulation and Publication and Project Time Schedule

Conventional statistical techniques for experimental analysis will be used. These will include generalized linear models and other techniques appropriate to the specific research questions.

The Agency anticipates disseminating the results of the study after the data analysis is completed, reviewed, and cleared. Final results of the study will 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**	**Expected Duration**
Within 1 month after receipt of OMB approval of collection of information	Conduct cognitive interviews/pretests	1-1.5 months
Within 3 months after receipt of OMB approval of collection of information	Finalize questionnaires for the main study	1-1.5 months
Within 7 months after receipt of OMB approval of collection of information	Collect data for the main study	4 months
Within 1 month after completion of data collection	Receive data and methods report from contractor	1 month
Within 3 months after receipt of final data files	Delivery of a written top line report of findings	3 months
Within 24 months after receipt of final data files	Submission of manuscript(s) to professional journals to disseminate information and analytical findings	24 months

16. 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. No exemption is requested.

17. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References:

(1) Olsen, S., L. MacKinon, et al., "Surveillance for Foodborne Disease Outbreaks--United States, 1993 to1997," Morbidity and Mortality Weekly Report 49(SS01), pp. 1-51, 2000.

(2) FDA 101: Product Recalls--From First Alert to Effectiveness Checks, Available at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm.

(3) Calvin, L., "Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices," Amber Waves 5(3), pp. 24-31, 2007.

(4) Lucier, G. and R. Dettmann, "Vegetables and Melons Outlook," A Report From the United States Department of Agriculture, Economic Research Service, VGS-327, June 26, 2008.

(5) Ran, W., Ven-Hwei, L., & Hung-Yi, L. (2010). The third-person effect of tainted food product recall news: Examining the role of credibility, attention and elaboration for college students in Taiwan. *Journalism & Mass Communication Quarterly*, 87(3/4), 598-614. Retrieved from EBSCO*host*.