REQUEST FOR OMB REVIEW

Supporting Statement A

SURVEY OF CURRENT MANUFACTURING PRACTICES IN THE FOOD INDUSTRY

Submitted by

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Food and Drug Administration

Department of Health and Human Services

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A JUSTIFICATION

A.1 Need and Legal Basis

FDA's regulations in part 110 of Title 21 of the Code of Federal Regulations (21 CFR part 110) describe the methods, equipment, facilities and controls for producing processed food, hereafter referred to as food CGMPs. As the minimum sanitary and processing requirements for producing safe and wholesome food, CGMPs are an important part of regulatory control of the nation's food supply. FDA believes that it is necessary to revisit and modernize the food CGMPs. Since the food CGMPs were last revised in 1986, there have been significant changes in food production technology and important advances in the understanding of foodborne illnesses. Accordingly, the agency will rigorously assess the impacts of any modernization policies on food facilities. To assess the impacts of the modernization policy, information is needed to help understand baseline or current industry practice. At present, however, FDA lacks baseline information on the nature of current manufacturing practices that would serve as part of a regulatory impact analysis.

FDA plans to conduct a mixed mode Internet and U.S. Postal Service mail statistical survey of all domestic FDA-registered facilities that primarily manufacture or process food. The mixed mode statistical survey and will solicit detailed information about six key topics relevant to the food CGMPs modernization effort: employee training, sanitation and personal hygiene, allergen controls, process controls, post-production processing, and recordkeeping. Additionally, FDA will collect information on establishment characteristics, such as facility size and industry, which are expected to correlate with the presence or absence of various manufacturing practices, such as electronic recordkeeping, ongoing employee training in food safety, and product-to-label conformance procedures.

The authority for FDA to collect the information derives from the FDA Commissioner's authority to conduct research, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

A.2.1 Information Users

The survey will be sent to a statistical sample of FDA-registered facilities in the United States that primarily manufacture or process food products. Participation will be voluntary and the respondent identifiers that would permit an association of specific responses to specific respondents will not be accessible to FDA. FDA plans to use the information collected from the mixed mode statistical survey to learn about the baseline practices of the industry. The results of the survey will enable FDA to make an informed decision about how to revise the food CGMPs in the most cost-effective manner. FDA will evaluate the impact of any proposed revisions to the food CGMPs by assessing different regulatory options. To assess different options, FDA must (1) rigorously characterize the types of training, sanitation and personal hygiene, allergen controls, process controls, and recordkeeping practices that food manufacturers/processors currently use; and (2) determine the costs and other barriers to adopting desirable practices. This is a new, one-time data collection. FDA does not plan to collect data on manufacturing practices in the food industry on an ongoing basis.

A2.2 **Users and Use of Information**

A2.2.1 *Information items.* The instrument proposed for this collection of information (Attachment B) includes the following topics.

- Facility Profile
- Training
- Sanitation and Personal Hygiene
- Allergen Controls
- Process Controls
- Recordkeeping

The key information to be collected includes responses to questions about the following: (1) training procedures and practices for food production managers, production supervisors, quality control personnel, sanitation and cleaning supervisors and production line employees on the topics of food safety, basic cleaning, sanitizing, sanitation, personal hygiene, specific product and equipment training and allergen control; (2) pest control and sanitation procedures and practices for food contact surfaces, non-food contact surfaces, production areas and warehouses; (3) allergen control procedures and practices for soybean or soybean-based ingredients, peanuts or peanut-based ingredients, finfish and crustacea, tree nuts, milk and other diary products, eggs, and wheat or wheat-based products; (4) process controls, including written procedures for handling incoming raw materials, approving vendors, the calibration of operating equipment, pathogen control, and a Hazard Analysis and Critical Control Point system; (5) recordkeeping practices; (6) the primary operation characteristics conducted at the facility, such as the type of food manufactured or processed for human consumption; and (7) fresh produce and ready to eat packing practice and post harvest operations.

A.2.2.2. and A2.2.3 *Users and Use of the Information.* FDA will be the user of the information to be collected. The agency will use the information to evaluate regulatory options before promulgating revisions to the existing rules.

A2.3 **Plan of Analysis**

A2.3.1 *Purpose of analysis.* FDA plans to use the information collected to understand the food industry's current or baseline manufacturing practices.

A2.3.2 *Analytical approach.* FDA expects to analyze the data on manufacturing practices in the food industry to develop a variety of descriptive and relational statistics, such as frequencies and proportions applicable to the food industry.

A.3 Improved Information Technology

FDA will utilize a mixed-mode approach using both the Internet and U.S. Postal Service mail. FDA will use an Internet survey to electronically collect the information from targeted respondents that have an e-mail address and that prefer to be contacted electronically. 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. Also, 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 also be higher because the instrument will contain built-in edits, prompts, and data validation features. The Internet survey method was selected due to the following considerations: (1) E-mail addresses of the respondents are available from the FDA Food Facility Registration database for approximately 80 percent of the potential respondents and they are continuously validated by FDA; (2) the Internet survey method is the least costly to the agency when compared with other modes of collection and generates the timeliest responses; (3) the Internet survey will impose a relatively modest reporting burden on small entities. For respondents that lack an e-mail address or that prefer a mail survey, FDA will use the U.S. Postal Service mail to administer the survey.

A.4 Duplication of Similar Information

FDA undertook a thorough review of existing studies and other literature on current manufacturing practices in the food industry. As a result of this review, FDA identified a total of six mostly small-scale, non-statistical surveys by professional organizations and other groups on various aspects of manufacturing practices in the food industry (see Table A-1). There are, however, major limitations to the usefulness of the data collected from these surveys. First, assessing the validity of findings is not possible, as none of the studies attempted to define precise survey statistics. Second, most of the surveys reported had very low response rates. Third, all of the studies used convenience samples that are not representative of the population of interest.[1] Finally, none of these surveys included questions on various key areas, such as allergen controls and specific sanitation practices that are of greatest concern to FDA. Thus, FDA needs reliable, broader, and more detailed information on current manufacturing practices in the food industry to evaluate the impacts of its future policies in this area.

Table A-1: Industry Surveys of Food Manufacturing Practices

Year	Mode	Sample Frame	Response Rate
Food Processing 2002 Manufacturing Trends Survey (Ennen, 2002)			
2002	Email	Readers	NA
Food Processing 2003 Manufacturing Trends Survey (Ennen, 2003)			
2003	Email	Readers	NA
Food Processing 2004 Manufacturing Trends Survey (Fusaro, 2004)			
2004	Email	149 Readers from circulation list	NA
3rd Annual Best Manufacturing Practices Survey (Gregerson, 2002)			

[1] Convenience samples are typically drawn from units of the population of interest that are close at hand or willing to participate with little or no effort made to ensure that the samples are representative. Thus, the results of convenience samples cannot be generalized to the target population of interest.

2002	Mail	Readers	13% (130/1,000)
2nd Annual Best Manufacturing Practices Survey (Morris, 2001b)			
2001	Mail	Readers	13% (132/1,000)
1st Annual Best Manufacturing Practices Survey (Morris, 2000a)			
2000	Mail	Readers	11% (112/1,000)
A Survey of Automation Practices in the Food Industry (Ilyukhin et al., 2001a)			
2001	Mail	U.S. food manufacturers (as well as system integrators and equipment suppliers)	54% (27/50)
A Survey of Control System Validation Practices in the Food Industry (Ilyukhin et al., 2001b)			
2001	Mail	U.S. food manufacturers (as well as system integrators and equipment suppliers)	54% (27/50)
A Survey on the Use of Computer-Integrated Manufacturing in Food Processing Companies (Aly, 1989)			
1989	Mail	Food processing companies in central California	32% (31/98)
Survey of Practices of Maryland Cider Producers (Senkel et al., 1999)			
1999	Mail	U.S. cider producers	100% (11/11)

A.5 Small Businesses

The proposed survey will cover food-manufacturing facilities of all sizes, including small entities (as they are defined in the Small Business Size Standards published by the Small Business Administration (SBA)). FDA has developed a highly focused survey instrument and is utilizing the Internet and the U.S. Postal Service as its modes of data collection based on the preferences 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.

A.6 Less Frequent Collection

Without this survey, FDA will lack information about the baseline or current manufacturing practices in the food industry and ultimately about the potential impact of FDA's future policies on these practices. Without this knowledge, FDA would be impeded from developing cost effective strategies for modernizing the food CGMPs.

A.7 Special Circumstances

This collection fully complies with 5 CFR 1320.5(d)(2). There are no special circumstances associated with this information collection.

A.8 *Federal Register* Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), on September 14, 2005 (70 FR 54390), FDA published in the *Federal Register* a 60-day notice requesting public comment on the proposed information collection. We received comments from three respondents. One of the respondents' comments was received after the 60-day comment period closed and is not addressed.

Comment 1: One industry respondent wanted assurances from FDA that individual company information was not subject to release under the Freedom of Information Act (FOIA).

Response 1: The survey includes a pledge of confidentiality regarding the data provided by the respondent. All data will be collected, compiled and owned by Eastern Research Group, Inc. (ERG), an independent consulting firm contracted by FDA. ERG is contractually obligated to retain the raw data and to not provide FDA with access to it. ERG will provide FDA personnel only with anonymous summary and aggregate statistical data compiled during the course of the study; ERG is contractually restricted from providing FDA with raw or other data that has identifiers that would permit the association of specific responses to a given respondent. Data that FDA does not own cannot be requested through the Freedom of Information Act.

Comment 2: The respondent requests that only one contact be made for each individual firm through the parent company contact listed on the firm's facility registration form and not to each location where the firm has a production facility.

Response 2: We recognize the additional burden this places on a firm but because we need current information from each manufacturing plant we do not believe that we have an alternative approach. Not every facility processes the same types of foods with the same preventive controls even when the parent company is the same. We need to get an idea of current good manufacturing practices at each facility location. Having a parent company respond could give us inaccurate information.

Comment 3: The respondent requests that each firm (facility) receive only one solicitation for information.

Response 3: Response to this survey is voluntary. For the sake of statistical reliability, we must contact non-responders more than just initially or our survey data result could be subject to a non-response bias. Non-response bias is affected by both the proportion of non-responders and the extent to which non-respondents and respondents differ on key questions being measured in the survey. To reduce the bias, it is necessary to reduce the number of non-responders by contacting them multiple times. It also helps to obtain information about non-responders to assess whether their socio-demographic characteristics differ systematically from survey

responders. Survey researchers should always try to follow up with individuals who do not consent to participate in a survey and ascertain their reasons for non-response. We do recognize that there should be an upper limit for the number of times a non-responder should be contacted before being dropped. From our experience, data quality will not be improved significantly by more than 6 contacts, so we will set our upper limit at 6 contacts.

Comment 4: One respondent opposes investigating foreign manufacturers.

Response 4: If we decide to survey foreign facilitates, we will not be investigating foreign manufacturers; we will be surveying them to get an idea about their manufacturing practices. Nearly 20% of all imports into the U.S. are food and food products; imported fresh produce and seafood make up a large percentage of these imports. All food, including imported and domestic food, must follow the same manufacturing regulations, thus information on foreign manufacturing processes is desirable and relevant to help inform us about how to modernize our regulation on current good manufacturing practices for food facilities.

- **Consultation Outside the Agency**

FDA consulted Eastern Research Group, Inc. (ERG), an independent consulting firm specializing in the analysis of FDA-regulated industries. ERG has conducted numerous studies for FDA, including: a literature review of preventive controls for microbiological, chemical, and physical food safety problems in the food processing industry; a Delphi study of the common food safety problems and preventive controls; and, an assessment of the costs and benefits of recordkeeping in different size food manufacturing facilities. ERG has been performing work for several offices in FDA for over 14 years and has managed or had major responsibilities in multiple FDA survey efforts. ERG, therefore, is well qualified to consult on this data gathering effort.

Additionally, ERG contracted two individuals to provide technical and operational expertise regarding manufacturing practices in the food industry. These individuals are:

> *William R. Sanders*, former Vice President of Quality at Nestle USA, Inc., has a total of 28 years of experience in the food industry devoted to technical support and technical management. Mr. Sanders has spent 21 years working with quality systems both at the plant, division and corporate level. During this time, he has had various responsibilities, including the implementation and maintenance of comprehensive quality programs in large multi-plant (14 to 525 facilities) operations. Mr. Sanders' work experience includes highly diverse food technologies: dry cereals, infant foods, frozen foods, low and high acid canned foods, milk and milk powders, acidified foods, pet foods, refrigerated foods, and beverages.
>
> *John R. Manoush*, President of Manoush Associates, is an independent food safety and quality consultant, who recently retired from B&G Foods where he served for over 27 years as Manager of Quality and R&D for the maker of nationally known *B&M Baked Beans*. During his tenure with B&M, Mr. Manoush was responsible for the full range of food quality and R&D services, with particular emphasis on the Hazard Analysis and Critical Control Point (HACCP) system and low-acid canning. He is certified by the Pillsbury Co., founder of the HACCP system, as a HACCP leader and trainer. His other

areas of expertise include design of experiments, statistical process control, vendor and co-packer auditing, sanitation and employee training. Mr. Manoush is thoroughly familiar with the FDA food CGMPs, low-acid regulations, and AIB guidelines for sanitation and pest control.

As directed by OMB, FDA reopened the comment period requesting public comments on the proposed information collection by publishing in the *Federal Register* a 60-day notice on July 19, 2007 (72 FR 39623). No comments were received.

A.9 Payment/Gift to Respondents

No payment, gifts, or other remuneration will be offered to respondents. FDA will, however, offer a copy of the survey report to all respondents as an incentive to participate.

A.10 Confidentiality

The survey includes a pledge of confidentiality regarding the contractor's use of the data provided by the respondents. All data will be collected and compiled by Eastern Research Group, Inc. (ERG), an independent consulting firm contracted by FDA. ERG will provide FDA personnel only with a summary of data (aggregated statistical data) compiled in the course of the study. No reports will have information about individual facility's participation or lack of participation, or information that enables FDA to determine individual responses. In keeping with longstanding FDA practice, ERG will not provide FDA with identifiers that would permit the association of specific responses with a given respondent. Responses will not be the property of the Federal government. 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.

A.11 Sensitive Questions

The survey does not include any questions of a sensitive nature.

A.12 Burden Estimate (Total Hours and Wages)

FDA estimates the total burden for this one-time collection of information to be 1,257 hours. FDA estimates that respondents will take 4 minutes (.067 hours) to complete the screening questions and 45 minutes (0.75 hours) to complete the entire survey. We anticipate that approximately 1,538 domestic facilities will respond, as shown in Table A-2. The hour burden estimates are based on a pretest of the preliminary survey instrument administered to two industry experts, William R. Sanders and John R. Manoush. The time required to complete the survey may vary based on the various characteristics of the responding facility, such as whether it processes any products containing allergens, whether it packages fresh fruits and vegetables, and whether it has a training program for its employees. However, since we do not expect the differences to be substantial, the table presents point estimates of the hour burden for this information collection rather than range estimates.

Table A-2: Estimated Hour Burden

Activity	No. of Respondents	Annual Frequency	Total Annual	Hours per Response	Total Hours

		per Response	Responses		
Internet Survey Invitation	1,230	1	1,230	.067	82
Completed Internet Survey		1		.75	923
U.S. Postal Service Survey Invitation	308	1	308	.067	21
Completed U.S. Postal Service Survey		1		.75	231
Total	**1,538**		**1,538**		**1,257**

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

Costs to Respondents. FDA estimates that the average hourly wage of the employee who will be assigned to respond to the survey is $23 per hour. Multiplying by 1.5 of this wage to account for overhead costs, FDA estimates the hourly cost to respondents to be $34.50. The overall estimated cost incurred by the respondents is $43,000 (1,257 burden hours x $34.50/hr = $43,367; rounding up to 2 significant digits = $43,000).

A.13 Capital Costs (Maintenance of Capital Costs)

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

A.14 Cost to the Federal Government

The total estimated cost of this research is $375,000. This includes fees paid to the contractor to design and test the survey instrument, collect the data, and create a written report, as presented in Table A-3.

Activity	Labor Hours	Operational Expenses [a]
Internet Survey		
Survey instrument design/testing	420	$45,852
Online functionality development/testing	615	$67,140
FDA registration and Dun and Bradstreet data matching	220	$24,017
Send survey invitation		
Email	20	$2,183
U.S. Postal Service Mail	80	$8,734
Conduct survey	620	$67,686
Data Processing	840	$91,703
Survey analysis and written report	500	$54,585
Additional administrative costs [e]	120	$13,100
Total	3,435	$375,000

[a] Consists of contractor costs estimated at $109.17 per hour on average, including labor and overhead charges.

[e] These include sample frame data clean up, QA/QC, telephone, and postage charges.

A.15 Program or Burden Changes

This is a new information collection. The increase in burden hours reflects the total number of hours necessary for the respondents to complete this new Internet survey.

A.16 Publication and Tabulation Dates

Following OMB approval, the data collection contractor will conduct pretests, collect the information and prepare the deliverables in accordance with the contract requirements. The schedule is shown in Table A-4.

Table A-4: Project Schedule

Date	Activity	Audience
Within 5 days after receipt of OMB approval of collection of information	• Notification to contractor to proceed with data collection activities	Not applicable
Within 150 days after notification to contractor	• Completion of data collection	Not applicable
Within 90 days after completion of data collection	• Delivery by contractor of draft report	Not applicable
Within 60 days after receipt of draft final report	• Delivery of completed final report	FDA

The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. The exact timing and nature of any such dissemination has not been determined, but may include presentations and articles at trade and academic conferences, publications, and Internet posting.

A.17 Display of OMB Approval Date

The expiration date will be displayed. No exemption is requested.

A.18 Exceptions to the Certification Statement of OMB Form 83-I

Not applicable (Form 83-I is no longer used).