

B. Statistical Methods (used for collection of information employing statistical methods)

1. Respondent Universe and Sampling Methods

The total respondent universe as mentioned will be approximately 1391 respondents comprised of State and local health and agriculture agencies. This number was established by the FDA from our count of current State and local government agencies within the United States that have a program currently conducting inspections for food safety and food defense under their own financially self-supported programs. These agencies under their own rules, laws or ordinances inspect food facility within their established jurisdiction.

The goal of this collection is to acquire standardized information from all 1391 respondents. FDA plans to conduct a census of the entire respondent population. FDA has chosen to conduct a census rather than a survey of sampled units from the respondent, because of the following considerations: a census from a state program may provide higher quality information with little cost difference to the agency since this is being conducted under a cooperative agreement; the *Food Safety Modernization Act* needs the information from each and every individual agency in order to better understand the current capacities within their agencies and the survey is considered short, precise and not considered burdensome; and the concerns of some State and local agencies that were not included in any other type of survey method being used have been considered and why this method has been determined as the delivery method of the survey.

The collected information will help FDA better understand the current capacities of State and local agencies which will allow for the development and implementation of strategies to leverage and enhance the food safety and defense capacities of these agencies in regards to foodborne illness outbreak prevention, response and containment.

2. Procedures for the Collection of Information

As mentioned, the collection of information will be facilitated under a cooperative agreement with the Association of Food and Drug Officials (AFDO). AFDO has developed the survey in an electronic format for information to be gathered and compiled in a spreadsheet that can be analyzed and the findings collected to support work currently being conducted with the *Public Law 111-353, 124 Stat.3885, Food Safety Modernization Act (FSMA)*. AFDO has converted the survey to an Adobe PDF form that can be completed using Adobe Reader software, which is available for free download at www.adobe.com. Instructions to the respondent will state:

- The Program Director that is most knowledgeable of the Food/Feed Inspections Program is the targeted respondent and to whom the survey will be addressed to for completion as per list of FDA established Food agencies with established jurisdictions.
- The survey should be completed on behalf of the agency. If possible, coordinate data from other divisions or sections if necessary within the agency and submit only one (1) survey form per agency.
- If you need to send a partially completed survey to another employee please click *File > Save As* and save a copy to your hard drive (e.g. Desktop, My Computer). Then open a new email message and attach the partially completed survey

- If parts of the survey do not apply, or are not within your agency's scope of jurisdiction, simply leave them blank.
- When completed, click on the *Submit Form Button* and the form will be automatically submitted to the appropriate party.
- If you encounter difficulties using the *Submit Form Button*, please attach your completed survey to a new email message and send to survey@afdo.org.
- If you have questions about the survey or need further clarification, submit your questions to survey@afdo.org.

3. Methods to Maximize Response Rates and Deal with Non-response

FDA will implement several procedures to maximize participation. The survey will be distributed to the State and local officials and given a period of approximately two weeks to complete. The survey is expected to take an average of one hour to complete (see Appendix A for survey). Survey participants will be sent a cover memo, along with the survey, requesting their participation and outlining the importance of the survey (See Appendix B for cover memo). After two weeks, a reminder email will be sent to those who have not completed their survey every three days during the two-month open period beginning from the time the survey is introduced to State or local official. (See Appendix C for the reminder). The deadline for submission will be determined by the return of surveys, working toward a goal of eighty-percent completion as outlined by the Office of Management and Budget. In addition, AFDO will send reminders and regularly monitor sampling output and returns to solve any problems daily throughout the course of the collection of information.

The survey development team will also be able to solicit completion of surveys from the respondents via telephone if needed. The survey development team is primarily comprised of FDA-Division of Federal-State Relations employees who have existing contacts within regions, districts, states, and localities that can solicit the completion of the survey. The FDA Regions and Districts work with the State and local agencies on a regular basis and can share the importance of completing the survey.

Information regarding the survey has been shared at meetings with State and local agencies to make them aware of the importance in the collection of this information. We will continue to conduct outreach with relevant stakeholders up to the time the survey is disseminated to State and local agencies.

4. Test of Procedures on Methods to be Undertaken

The group that developed this survey was comprised of a multitude of individuals including State and local officials, Federal employees, and members of key national association partners. The variety of group members allowed a wide range of questions due to the differing perspectives of each individual. Over the course of six months, these group members discussed possible survey questions and decided on the final 55 survey questions. The 55 questions will help bridge the gap between current information sources currently identified and will allow us to create a complete report identifying gaps in capacities among State and local agencies.

The survey plans to use categories that ask participants questions in the order listed below (see Appendix A for survey):

- Food and Feed Safety
- Food Defense
- Information Technology
- Interagency Agreements

Each respondent will be asked to complete all 55 questions with a “check box” type of response. The survey development group determined that a “fill in the blank” type of response was not wanted in this survey. The survey is designed to determine the presence or absence of specific capacities, as defined in each question, without the need to collect opinions or comments on each question. The respondent will click the box or boxes to provide answers that best fit their program or fill in the blank with the current data identified by their program. No information will be recorded on how long it takes to complete an answer or to complete the entire survey.

The survey will be re-tested before dissemination on six current FDA employees that were former State employees with extensive knowledge and experience in each of the fields contained within the survey. This will serve to address any unforeseen problems in administration of the survey. The test employees each came from a different area of the nation which provides FDA a wider sample size to better estimate the burden. On average, the survey has taken less than an hour to complete. There will be conference calls and/or face-to face contact with State and local agencies to make them aware of the importance of this collection of information.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Tressa Madden
FDA/ORR/OP
RP-OKLA CITY, RM SUITE-029
Oklahoma Fed Building - 301 NW 6th
Oklahoma City, OK 73102
(405) 609-8738 office
(240) 479-8591 cell