Improving Food Safety and Defense Capacity of the State and Local Level:
Review of State and Local Capacities

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Public Law 111-353, 124 Stat. 3885, Food Safety Modernization Act, Section 205(c)2

The Food Safety Modernization Act (FSMA), under Sections 205(c)2 and 110(a), requires that a review of state and local capacities be executed and analyzed. This requirement had a statutory deadline of January 4, 2012. FDA conducted a review, but determined that an additional information collection, in the form of a survey, from State and local health and agriculture employees is necessary. This survey will be used to develop and implement future strategies to enhance the food safety and defense capacities of State and local agencies, which will provide a foundation for building an integrated food safety system.

The Food and Drug Administration (FDA) is requesting approval from the Office of Management and Budget (OMB) for the information collection requirements contained in:

FSMA 205(c)1
"(c) Improving Food Safety and Defense Capacity at the State and Local Level.--
(1) In general. <<NOTE: Strategies.>> --The Secretary shall develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies in order to achieve the following goals:
(A) Improve foodborne illness outbreak response and containment.
(B) Accelerate foodborne illness surveillance and outbreak investigation, including rapid shipment of clinical isolates from clinical laboratories to appropriate State laboratories, and conducting more standardized illness outbreak interviews.
(C) Strengthen the capacity of State and local agencies to carry out inspections and enforce safety standards.
(D) Improve the effectiveness of Federal, State, and local partnerships to coordinate food safety and defense resources and reduce the incidence of foodborne illness.
(E) Share information on a timely basis among public health and food regulatory agencies, with the food industry, with health care providers, and with the public.
(F) Strengthen the capacity of State and local agencies to achieve the goals described in section 108."

FSMA 205(c)2:

"Review. <<NOTE: Deadline.>> --In developing of the strategies required by paragraph (1)(205(c)1), the Secretary shall, not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, complete a review of State and local capacities, and needs for enhancement, which may include a survey with respect to--
(A) staffing levels and expertise available to perform food safety and defense functions;
(B) laboratory capacity to support surveillance, outbreak response, inspection, and enforcement activities;
(C) information systems to support data management and sharing of food safety and defense information among State and local agencies and with counterparts at the Federal level; and
(D) other State and local activities and needs as determined appropriate by the Secretary."

The deadline for this review was January 4, 2012. From this review, it was deemed necessary to conduct a survey to establish and analyze possible gaps in the areas of food safety, food defense, laboratories, and information technology. The information will be used to develop future strategies to support capacity building and continue efforts underway to build an integrated food safety system.

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

2. Purpose and Use of the Information Collection

The information gathered from this survey will be used to initiate the development of strategies for implementing various provisions of FSMA, specifically section 205(c)1. This survey will serve as an assessment to guide future work and discussions amongst Federal, State, and local government agencies with responsibility for food safety and public health. This assessment will allow FDA to better understand the current capacities and procedural systems of State and local agencies which will allow FDA to operate more efficiently and effectively with its partners.

This survey will be distributed to health and agriculture departments only in State and local agencies. There will not be any soliciation to the private sector or to individuals.

3. Use of Improved Information Technology and Burden Reduction

Under a cooperative agreement, the Association of Food and Drug Officials (AFDO) will work with the survey development team to create an electronic means to distribute the survey. AFDO is developing an online survey that will allow participants to respond at their convenience by creating a 'save' feature. The survey will also be able to be accessed by multiple users in the event that assistance by other subject matter experts within the agency is required for certain questions. AFDO will tabulate the results and submit them to FDA.

4. Efforts to Identify Duplication and Use of Similar Information

A review of current Federal, State, local, and trade association surveys was conducted by this survey's development team. The current surveys did not fulfill the needs outlined in FSMA, specifically in the areas of information technology, laboratory, food safety, and food defense. Food defense is the effort to protect the nation's food supply from intentional acts of contamination or tampering. Intentional contamination can be in the form of chemical, biological, radiological, or nuclear agents. Food defense differs from food safety, which is protecting against the accidental contamination of food.. While intentional contamination is typically thought of only in terms of a foreign terrorist threat, there are other threats for intentional contamination, including disgruntled employees, domestic terrorists/activist organizations, economic adulteration, and counterfeiting/diversion/tampering. This survey will enable us to determine what gaps exist in State and local capacities. Once the responses have been received and analyzed, the information will be used to further develop and improve strategies and procedures, called for under FSMA section 205(c)1. The goals of the future strategy development will be to improve foodborne illness outbreak response, accelerate foodborne illness surveillance, carry out inspections, improve effectiveness of partnerships to coordinate food safety and defense resources, and share information among partner agencies in a more timely manner.

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 provided for a wide range of questions due the differing perspectives of each individual. Over the course of six months, the group members discussed possible survey questions and decided on the final 55 survey questions. The 55 questions help bridge the gap between current information sources and will allow us to create a complete report of current capacity at the State and local level.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

Due to the nature of this survey, this team will only request that the survey be completed once. There are no legal obstacles to reduce the burden.

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

There are no special circumstances for this collection of 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), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 02/24/2012 (77 FR 11132). FDA received six comments. The comments, and the Agency's response, are discussed in the following paragraphs.

(Comment 1) FDA conducted a review of existing surveys.

(Response 1) Although helpful, these surveys did not fully address factors such as laboratory capacity and information technology in State and local agencies. Therefore, this survey will be used to fill the gaps of various other surveys so that FDA can meet its objective as congressionally mandated in the Food Safety Modernization Act.

(Comment 2) The proposed information collection is necessary for the proper performance of FDA's functions.

(Response 2) FDA agrees.

(Comment 3) NACCHO recommends FDA builds upon information gathered from existing food safety and defense assessments and surveys.

(Response 3) Prior to developing this survey, FDA conducted a systematic review of current and past surveys conducted by Federal, State and local agencies, academia, industry, and associations such as the Association of Food and Drug Officials (AFDO), the Association of State and Territorial Health Officials (ASTHO), and NACCHO's 2008 survey regarding budget cuts and reductions of State and local agencies. This review revealed that the current and past surveys did not contain sufficient information for FDA to establish and analyze possible gaps in the areas of food safety, food defense, laboratories, and information technology. The results of the review of current and past surveys were conveyed to an FDA working group focused on drafting a report to Congress that is specified by Food Safety Modernization Act (FSMA) Section 110. Under Section 110, FDA has a congressionally mandated deadline to conduct a more extensive review by January 4, 2013. This team plans to contribute further to this review; however, the main focus of this survey will be to provide a current snapshot of State and local capacities for FSMA Section 205(c)1. FDA was aware that NACCHO was conducting a survey but due to time restrictions, FDA could not wait for NACCHO's survey to be made public prior to developing the current survey. Also, FDA did not know the content of NACCHO's survey and how it would address the needs of obtaining information to support FSMA section 205(c)2.

(Comment 4) FDA should survey 1,391 State and local agencies at minimum instead of focusing on 1,391 state and local employees.

(Response 4) FDA is proposing to survey 1,391 State and local agencies. The involvement of single or multiple individuals from a single agency will be left to the discretion of the responding entity.

(Comment 5) NACCHO recommends that the assessment be designed to allow multiple employees within an agency access the survey on multiple occasions to fully and accurately complete the survey.

(Response 5) FDA has an arrangement with AFDO, through a cooperative agreement, to deliver the survey. The survey will be delivered online. NACCHO's suggestion of

developing a web-based portal with log-in capability to allow multiple users to log into the same survey to increase the efficiency of completing the survey has been considered and will be implemented. In addition, hard copies of the survey can be made available upon request.

(Comment 6) The assessment should be conducted on a routine basis.

(Response 6) FDA agrees with NACCHO in its statement that a survey, such as this one, should be conducted on a more regular basis to track and trend gaps. At this time, this survey is intended to be a one-time collection of information. FDA could consider conducting future surveys depending on Agency resources and priorities.

There was no outside consultation for the information request or a requirement of the request.

9. Explanation of Any Payment or Gift to Respondents

There will be no payments to the respondents.

10. Assurance of Confidentiality Provided to Respondents

Due to the nature of an anonymous survey, the confidentiality of the respondents is protected. Furthermore, there is no personally identifying information in the survey. The survey will be offered to Congress where it may choose whether or not to publicize it.

11. Justification for Sensitive Questions

There are no sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Current State and Local Governments Agencies	1,391	1	1,391	1	1,391

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

The survey development team asked six FDA employees who were former state employees to complete the survey and, from those results, concluded, that it should take no longer than one hour for each of the 1,391 current State and local government agencies to complete the survey. Therefore, the total burden is 1,391 hours.

The number of agencies to receive this survey is based on a previous FDA study that found how many jurisdictions conduct their own food safety and food defense inspections. To qualify, these jurisdictions must be able to self-sustain their inspection programs under their own laws or adopted laws.

12b. Annualized Cost Burden Estimate

The cost associated with this collection is directly related to the speed at which a respondent can complete the survey. Based on previous deductions of one hour for each respondent, there will be a total of 1,391 hours used for this survey as there are 1,391 respondents. A study by the U.S. Bureau of Labor Statistics in 2011 found that the average state employee earns $40.76 per hour. This includes the total wages and other compensation as well as benefits like health insurance and retirement contributions.

Estimates of annualized cost burden are provided in the chart below:

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State and Local	1,391	$40.76[2]	$56,697.16

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 annual cost to the Federal Government is directly related to the job duties of the survey development team. Additional costs associated with electronically distributing the survey are covered under current agreements with the Association of Food and Drug Officials.

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

It is possible that this information could be published by Congress at a later date. However, the purpose of this survey is to determine what gaps exist in various fields of state and local government capacity. Once the gaps are identified, FSMA implementation teams will be able to develop and execute strategies to enhance the food safety system.

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

We are not seeking approval to exempt display of the OMB approval date on any documents that are associated with this information collection.

[2] United States Bureau of Labor Statistics. (2011). Employer Costs for Employee Compensation. Retrieved from http://www.bls.gov/news.release/pdf/ecec.pdf.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.