

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

0910-0726

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This survey will measure the outcomes of funding programs and other collaborative actions taken to improve State and local food safety and defense capacities in response to the results from the 2011-2012 Review of State and Local Capacities, issued under OMB Control #0910-0726. The first survey was mandated by the statutes below:

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

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 -- 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:

“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 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 was used to develop and implement future strategies to enhance the food safety and defense capacities of State and local agencies, and to provide a foundation for building an integrated food safety system.

Following the initial collection, conducted under OMB Control 0910-0726, it was determined that a follow-on collection was required in order to evaluate progress, report measurable outcomes of actions taken, and determine what action is necessary to continue building an integrated food safety system through uniformity of standards and protocols.

2. Purpose and Use of the Information Collection

This survey will serve as a review of past work and 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. Additionally, it will provide the opportunity to measure the progress that has been made since FSMA first mandated these actions.

This survey will be distributed to health and agriculture departments only in State and local agencies. There will not be any solicitation 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 timelier 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.

The original intent was to solicit survey responses only once; however, the results of that first collection prompted a number of actions to improve the food safety and defense capacities of those respondents who needed it most. FDA and its State and local partners will therefore significantly benefit from a second iteration of the survey, which will provide a second dataset by which to measure progress and determine follow-on actions.

This IC is fillable and fileable, but not signable. 100% of the respondents have the option to complete the survey in electronic format, however those who do not have the capability or the desire to do so may request a hard copy.

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

The two iterations of this IC are separated by approximately three years. Reducing this frequency would make work-planning and resource allocation difficult or impossible.

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 08/03/2015 (80 FR 46025). No comments were received.

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

Current State and Local Government Agencies	1,391	1	1,391	1	1,391
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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	\$44.22 ²	\$61,510.00

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.

² United States Bureau of Labor Statistics. (2015). Employer Costs for Employee Compensation. Retrieved from <http://www.bls.gov/news.release/pdf/ecec.pdf>.

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.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.