

including gaining feedback on the flow of items and their relevance to the respondents' experience, assessing the effectiveness of the questionnaire instructions, and obtaining recommendations for improving the questions. Data captured in the pretest were used to identify areas for questionnaire improvement and recommendations for maximizing the performance of the full survey.

The proposed survey will be based upon a probability sample of approximately 300 of the 675 underground coal mines in the United States. A stratified random sample of mines will be drawn to ensure representativeness on important dimensions such as mine size and region of the country. Sampling a large proportion of the underground coal

mines will ensure low rates of sampling error and increase confidence in the resulting survey estimates. Over-sampling some kinds of mines, such as those operating longwall sections, will be necessary to ensure enough cases are available to conduct meaningful analysis of these mine types.

Allowing mine operators to complete the survey using the method they find convenient is expected to enhance the overall response rate. Therefore, both a Web-based and a print version of the questionnaire will be provided to sampled respondents. Mine operators unable to complete the survey through one of these two methods will be contacted and asked to complete the survey over the telephone. Using these multiple methods of administration, NIOSH expects to achieve an 80% rate

of response to the survey. An additional method that will be used to reduce the overall burden on respondents will be to collect certain types of supplementary information (e.g., the mine's dates of operation, annual coal production) on each sampled mine from publicly-available data collected by the Mine Safety and Health Administration (MSHA).

Once the study is completed, NIOSH will provide a copy of the final report to each sampled mining operation, and use the survey data to improve the adoption of important safety and health practices throughout the coal mine industry. NIOSH expects to complete data collection in the spring of 2009. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Responding eligible coal mine operators	240	1	30/60	120

Dated: July 10, 2008.

Maryam Danneshvar,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0362]

Directory of State and Local Officials and State Food Safety Resource Survey Support Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations (DFSR) is announcing the availability of a Sole Source to the Association of Food and Drug Officials (AFDO) to provide funding for a 3-year cooperative agreement award to support a Special Project Cooperative Agreement program. No other applications are solicited. This cooperative agreement is intended to have AFDO update and maintain the FDA Directory of State and Local Officials and to update the AFDO document "State Food Safety Resource

Survey (2000)" by providing funding for additional personnel, equipment, and supplies to support activities related to these projects.

DATES: Receipt Date: Applications are due within 30 days after the publication of the funding opportunity in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: *For issues regarding the administrative and financial management aspects of this notice:* Marc Pitts, Division of Acquisition Support and Grants, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301-827-7162, e-mail: Marc.Pitts@fda.hhs.gov.

For issues regarding the programmatic or technical aspects of this notice: Jennifer Gabb, Division of Federal-State Relations (HFC-150), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rm. 12-07, Rockville, MD 20857, 301-827-2899, e-mail: jennifer.gabb@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Announcement Type: New Cooperative Agreement (U18)
Request for Applications (RFA) Number: FD-08-011 Sole Source
Catalog of Federal Domestic Assistance Number: 93.103

In 2007 and 2008, the Food and Drug Administration Amendments Act of 2007 (FDAAA), the Food Protection Plan, and the Import Strategic Action

Plan addressed FDA's relationship with the States in food protection activities. In addition, the Food Protection Plan lays out new goals specific to protecting the food supply and responding to incidents in a rapid and coordinated manner.

A. Food Protection Plan 2007

In May 2007, the Secretary of Health and Human Services and the Commissioner of Food and Drugs charged FDA with developing a comprehensive and integrated Food Protection Plan to keep the nation's food supply safe from both unintentional and deliberate contamination. Driven by science and modern information technology, the Food Protection Plan aims to identify potential hazards and counter them before they can do harm. A cornerstone of this forward-thinking effort is an increased focus on prevention.

B. Project Emphasis

FDA's integrated approach within the Food Protection Plan encompasses three core elements: Prevention, intervention and response.

Core Element 1: Prevention

The prevention element involves promoting increased corporate responsibility so that food problems do not occur in the first place. By comprehensively reviewing food supply vulnerabilities and developing and implementing risk reduction measures

with industry and other stakeholders, we can best address critical weaknesses.

Core Element 2: Intervention

The intervention element focuses on risk-based inspections, sampling, and surveillance at high-risk points in the food supply chain. These interventions must verify that the preventive measures are being implemented and implemented correctly.

Core Element 3: Response

The response element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency. This element also includes the idea of better communication with other Federal, State, and local government agencies and industry during and after emergencies. Whether contamination is unintentional or deliberate, there is a need to respond quickly and to communicate clearly with consumers and other stakeholders. The communication should emphasize identifying products of concern as well as informing the public of what is safe to consume.

C. Food and Drug Administration Amendments Act of 2007

Under the Food and Drug Administration Amendment Act of 2007 (FDAAA), FDA is required to work with the states to improve food safety. Section 1004 of the FDAAA states:

“(a) IN GENERAL—The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of food, including fresh and processed produce, so that State food safety programs and activities conducted by the Secretary function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of State food safety programs is not unsafe for human consumption.”

D. Import Safety Action Plan

The Import Safety Action Plan (ISAP) acknowledges the value of mutual leveraging of State and Federal resources and recommends consideration of cooperative agreements to increase information sharing. Specifically, the ISAP provides the following recommendations:

Federal-State Rapid Response

Recommendation 12—Maximize Federal-State Collaboration

The roles of and the resources used by the Federal Government and the States in import safety are complementary. States possess legislative authority and resources to respond to unsafe imported products within their jurisdiction. The Federal Government can take steps to interdict unsafe imported goods at ports of entry. Should an unsafe product enter domestic commerce, federal departments and agencies often work with State authorities to track it down, seize it, notify the public if it has already been purchased by consumers, and impose appropriate penalties on domestic entities who violate U.S. law. Also, both the Federal Government and States may have access to information relevant to protecting consumers that the other does not possess. For example, Federal departments and agencies may have relevant information about the foreign source of the imported product and about the importer. This information can help State officials track down an unsafe imported product within their jurisdiction. On the other hand, State officials may identify an unsafe imported product during transport or at the point of sale, if the product does get into the country, and can tip off Federal officials to prevent future shipments from entering domestic commerce.

Several Federal departments and agencies already collaborate closely with State authorities to protect consumers. For example, FDA has contracts and cooperative agreements with State Governments to share information, conduct joint inspections, and collaborate on laboratory analyses. Greater mutual leveraging of State and Federal resources can further enhance consumer protection.

Recommendation 12.1 states: “Consider cooperative agreements between the federal inspection agencies and their state counterparts for greater information-sharing.” Such cooperative agreements would not infringe on the statutory authorities of Federal or State regulators and would encourage a coordinated effort that would result in a more rapid and effective response. Establishing clear procedures and points of contact for information sharing and joint enforcement efforts can further enhance the effectiveness of Federal-State actions to limit exposure and potential harm to consumers if an unsafe imported product enters domestic commerce.

II. Award Information

Mechanism of Support

Support will be in the form of a Sole Source cooperative agreement U18 Mechanism. Substantive involvement by the awarding agency is inherent in the cooperative agreement award. Accordingly, FDA will have substantial involvement in the program activities of the project funded by the cooperative agreement.

III. Eligibility Information

A. Eligible Applicants

ORA is offering this sole source cooperative agreement to AFDO to improve and update the Directory of State and Local Officials (current version is from 2004) to provide information for Rapid Response and information sharing. AFDO will also update the data in the AFDO State Food Safety Resource Survey including recall and foodborne illness investigation information to identify and to support Risk Management and information sharing. Assistance will be provided only to the AFDO. No other applications are solicited.

B. Applicability

AFDO is uniquely qualified for this cooperative agreement. AFDO (<http://www.afdo.org/>) conducted a nationwide survey of State and local food safety programs in 2000 and, with the National Center for Food Protection and Defense, has been an active partner in the FoodSHIELD project (<http://www.afdo.org/afdo/upload/061025-FoodSHIELD%20Brochure.pdf>, <http://www.foodshield.org/>), during which AFDO has collected contact information of State and local jurisdictions comparable to the FDA Directory of State and Local Officials (http://www.fda.gov/ora/fed_state/directorytable.htm). AFDO is the organization qualified for conducting this work because:

- AFDO is the only national organization that represents the State and local food protection regulatory agencies. AFDO's principal purpose is to act as a leader and a resource to State and local regulatory agencies in developing strategies to resolve and promote public health and consumer protection related to the regulation of foods, drugs, medical devices, and consumer products. Regular members are officials of State and local regulatory agencies that administer these programs in conjunction and collaboration with FDA.

- AFDO has always focused on the administration of the nation's food

protection programs. Thus, unlike other organizations, AFDO has a unique perspective on the infrastructure, capacity, strengths, and needs of State and local food protection programs.

- AFDO has successful experience in carrying out national efforts that focus on the needs of State and local regulatory agencies. FDA has used the data from the initial AFDO State Food Safety Resource Survey, AFDO model codes, and training programs such as the Seafood HACCP training program certified through AFDO. AFDO has also developed the AFDO Recall Manual and many other training programs and initiatives with the Centers for Disease Control, the U.S. Department of Agriculture, and others in meat and poultry processing at retail. AFDO also has industry associate members.

C. Award Amount

The total amount of funding available for fiscal years 2008 through 2010 is \$250,000. This cooperative agreement will award up to \$250,000 in total (direct plus indirect) costs for a 3-year cooperative agreement.

D. Length of Support

The length of support for this project will be 3 years.

E. Cost Sharing or Matching

Cost sharing is not required.

IV. Application and Submission

A. Application Information

Applications must be prepared using the most current SF424 (Research and Related) (also referred to as the "SF424 (R&R)", which is part of the Public Health Service, PHS 5161-1 form. Applications must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling 866-705-5711 or through the Web site at <http://www.dnb.com/us/>. (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Applications must be prepared using the forms found in the SF424 R&R instructions for preparing a nonmodular research grant application. Submit a signed, typewritten original of the paper application, including the checklist, three signed photocopies, and appendix material in one package to: Marc Pitts (see **FOR FURTHER INFORMATION CONTACT**).

If you experience technical difficulties with your online

submission, you should contact either Marc Pitts (see **FOR FURTHER INFORMATION CONTACT**), or the Grants.gov Customer Support Center by e-mail at support@grants.gov or by phone at 1-800-518-4726.

Information collection requirements requested on Form (SF-424) PHS 5161-1, expiration date of January 31, 2009, have been sent by the PHS to the Office of Management and Budget (OMB) and have been approved and assigned OMB control number OS-4040-0004.

B. Submission Dates and Times

The application receipt date is 30 days after the publication of the funding opportunity in the **Federal Register**. Applications will be accepted from 8 a.m. to 4:30 p.m. e.s.t., Monday through Friday, until the established receipt date. Applications submitted electronically must be received by the close of business on the established receipt date. No addendum material will be accepted after the established receipt date.

C. Intergovernmental Review

The regulations issued under Executive Order 12372, Intergovernmental Review of Federal Programs (45 CFR part 100) apply. Applicants (other than federally recognized tribal governments) should contact the State's Single Point of Contact (SPOC) as early as possible to alert the SPOC to the prospective application(s) and to receive any necessary instructions on the State's review process. A current listing of SPOCs is located at <http://www.whitehouse.gov/omb/grants/spoc.html>. The SPOC should send any State review process recommendations to the FDA administrative contact (see **FOR FURTHER INFORMATION CONTACT**). The due date for the State process recommendations is no later than 60 days after the application receipt date. FDA does not guarantee accommodation or explanation of SPOC comments that are received after the 60-day cutoff.

D. Funding Restrictions

This cooperative agreement is not to fund annual, regional, or State meetings of AFDO, travel for other than project employees, equipment other than consumables or as outlined in the application, or any remodeling or capital improvement to office location or space.

E. Central Contractor Registration

Applicants must register with the Central Contractor Registration (CCR) database. This database is a government-wide warehouse of commercial and

financial information for all organizations conducting business with the Federal Government. Registration with CCR is a mandatory requirement and is consistent with the government-wide management reform to create a citizen-centered Web presence and to build e-gov infrastructures in and across agencies to establish a "single face to industry." The preferred method for completing a registration is through the World Wide Web at <http://www.ccr.gov>. This Web site provides a CCR handbook with detailed information on data you will need prior to beginning the online preregistration, as well as steps to walk you through the registration process. You must have a DUNS number to begin your registration. The CCR registration process can also be found under the "Organization Registration" page of Grants.gov at http://www.grants.gov/applicants/organization_registration.jsp.

F. Copyright Material

Applicant and applicants' subgrantees and subcontractors must ensure that any projects developed in whole or in part with Federal funds may be made available to other State, territorial, local, and tribal regulatory agencies by FDA or its agents. Any copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal Government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal Government purposes.

Dated: July 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0359]

Food Safety and Security Monitoring Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations (DFSR), is announcing the availability of cooperative agreements for equipment, supplies, personnel, training, and facility upgrades to Food Emergency