

strategies for managing areas affected by toxic algal blooms.

(8) FDA will continue to work with ISSC to establish improved mechanisms for incorporating new lab methods into the NSSP.

(9) FDA will work with the ISSC to develop NSSP Model Ordinance interpretations.

(10) FDA will take any action that may be necessary to ensure compliance with this cooperative agreement including, but not limited to the pursuit of science-based HACCP controls for managing the risk of *Vibrios*, and developing patrol, growing area classification, and plant inspection criteria.

C. Eligibility Information

Competition is limited to ISSC because it has unique capacity found nowhere else. ISSC is the primary voluntary National organization of State shellfish regulatory officials that provides guidance and counsel to the States and industry on matters of sanitary control of molluscan shellfish. ISSC is the only organization that has the established formal structure, procedures, and expertise to direct all components (public health, environmental, resource management, and enforcement) of an effective National shellfish safety program, and has operated satisfactorily in this capacity since 1993. This effort will enhance FDA's molluscan shellfish safety program and provide the public greater assurance of the quality and safety of shellfish products.

II. Award Information/Funds Available

A. Award Amount

The annual allocation to the ISSC under this cooperative agreement, including support in the amount of \$75,000.00 from the National Marine Fisheries Services will be \$325,000.00.

Subject to the availability of Federal funds and successful performance, 4 additional years of support will be available. CFSAN intends to fund 1 year of award to begin in September 1, 2011. Subject to annual appropriations and successful performance, 4 additional years of noncompetitive award will be available.

B. Length of Support

September 1, 2011, to August 31, 2016.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to the funding opportunity announcement (FOA), applicants should first review the full

announcement located at <http://www.fda.gov/Food/NewsEvents/default.htm>. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) Persons interested in applying for a grant may obtain an application at <http://grants2.nih.gov/grants/funding/phs398/phs398.html>. For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet Data Universal Numbering System (DUNS) Number
- Step 2: Register With Central Contractor Registration
- Step 3: Register With Electronic Research Administration (eRA) Commons

Steps 1 and 2, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. Step 3, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>.

After you have followed these steps, submit paper applications to: Gladys Melendez-Bohler, Office of Acquisition and Grants Services (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, 301-827-7175, e-mail: gladys.bohler@fda.hhs.gov.

Dated: June 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0010]

Cooperative Agreement With the World Health Organization Department of Food Safety and Zoonoses in Support of Strategies That Address Food Safety Problems That Align Domestically and Globally (U01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of a sole source cooperative agreement with the World Health Organization (WHO). The goal of the Food and Drug Administration, Office of the Commissioner and the Office of International Programs, Center for Food

Safety and Nutrition, and the Center for Veterinary Medicine is to contribute to the knowledge base of the current state of food safety globally, including challenges, risks and emerging trends, through an integrated information system based on WHO's existing network efforts.

DATES: Important dates are as follows

1. The application due date is July 20, 2011.

2. The anticipated start date is September, 2011.

3. The opening date is the date the notice is published in the **Federal Register**.

4. The expiration date is July 21, 2011.

FOR FURTHER INFORMATION AND

ADDITIONAL REQUIREMENTS CONTACT: For programmatic questions and concerns

contact: Katherine Bond, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8318; e-mail:

Katherine.bond@fda.hhs.gov.

For financial and administrative questions and concerns contact: Gladys M. Bohler, Office of Acquisition and Grant Services, Food and Drug Administration, 5630 Fishers Lane, rm. 1078 (HFA 500), Rockville, MD 20857, 301-827-7175; e-mail:

gladys.bohler@fda.hhs.gov.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at <http://www.fda.gov/InternationalPrograms/CapacityBuilding/default.htm>.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-11-021,
93.103: 93.103.

A. Background

WHO has responsibility for the provision of technical cooperation to its 193 Member States (national governments) in the area of food safety and zoonotic diseases. Among the focus areas are: Surveillance for food borne disease; identification of food contamination; management of mechanisms for information sharing; and systems for emergency response, including outbreak investigations and governments' food product recalls which may potentially have a global impact or cross national boundaries, and which may fall within the requirements of the International Health Regulations. WHO's technical support complements a paradigm shift that is emerging around the globe; a shift from a focus on food safety interventions at

ports-of-entry toward an approach that emphasizes preventive, risk-based efforts. This shift entails increasing accountability of entities along the supply chain that grow, harvest, manufacture, process, store, transport, distribute, and/or import foods for ensuring the safety of their products, while at the same time strengthening national authorities' capacity and systems to be able to regulate these products efficiently and effectively. Along with the Food and Agriculture Organization of the United Nations (FAO), WHO also has a responsibility in relation to harmonizing international science-based food safety standards (e.g., as one of the founding institutions and technical advisory bodies to the Codex Alimentarius Commission (Codex)). Codex was founded in 1963 to develop food standards, guidelines, and other related texts, such as codes of practice, under the Joint FAO/WHO Food Standards Programme. Currently, 185 Member States, including the United States through FDA and other U.S. Government agency technical and scientific experts, actively participate in Codex.

The goal of the Food and Drug Administration, Office of the Commissioner and the Office of International Programs, Center for Food Safety and Nutrition, and the Center for Veterinary Medicine is to contribute to the knowledge base of the current state of food safety globally, including challenges, risks and emerging trends, through an integrated information system based on WHO's existing network efforts, such as the Global Foodborne Infections Network (GFN), International Food Safety Authorities Network (INFOSAN), Global Environment Monitoring System for Food (GEMS/Food), Global Early Warning Systems for Animal Diseases Including Zoonoses (GLEWS), and the Initiative to Estimate the Global Burden of Foodborne Diseases (FERG), as well as programs currently under development, such as the Global Laboratory Directory (GLaD); enable the sharing of scientific findings and data through expert meetings and technical consultations; enhance capacity at international and national levels in such areas of laboratory analyses, surveillance, and risk assessment/risk management, including through the Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR); contribute to the scientific, standard-setting work of the Codex Alimentarius Commission (Codex) through scientific advisory groups including the Joint FAO/WHO

Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meetings on Pesticide Residues (JMPR), the FAO/WHO Joint Meetings on Microbiological Risk Assessment (JEMRA), and the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) currently in development phase; and enable participation of Member States through the Codex Trust Fund.

A significant outcome of the 63rd World Health Assembly in May 2010 was a consensus resolution on advancing food safety initiatives, which, among other items, acknowledged the continuing need for closer collaboration between the health sector and other sectors, and increased action on food safety at the international and national levels, across the full length of the food-production chain, in order to reduce significantly the incidence of food borne disease. This resolution also closed a ten year gap in WHO governance dialogue on global food safety challenges, providing all Member States with a general pathway for global collaboration and enforcing the Secretariat's role in technical cooperation.

In support of the resolution's implementation, FDA awarded two cooperative agreements in fiscal year (FY) 2010 to WHO's Department of Food Safety and Zoonoses (FOS) to: (1) support the development of a plan that delineates a global integrated information system to better report and utilize information and data that are timely, accurate, and comparable; and, through such data, increase understanding of risk factors and safety standards relative to public health outcomes; and (2) support WHO's Advisory Group on Integrated Surveillance for Antimicrobial Resistance (AGISAR), which is part of WHO's effort to minimize the public health impact of antimicrobial resistance associated with the use of antimicrobials in food animals.

For nearly 30 years, FDA, through the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM), has participated with WHO's International Programme on Chemical Safety (IPCS) in a Cooperative Agreement that supported WHO's work in international risk assessment and its standard-setting activities for food ingredients, contaminants, and veterinary drug residues in food, including the Joint FAO/WHO Expert Committee on Food Additives (JECFA). JECFA contributes internationally-recognized science-based risk assessments of food additives, contaminants, and residues of veterinary drug residue in food. This

Cooperative Agreement has also supported Joint FAO/WHO Expert Consultations on risk assessments for emerging or cross-cutting issues (e.g., the use of active chlorine species in food processing, bisphenol-A). The evaluations that are produced by JECFA and the Expert Consultations provide a sound scientific basis for Codex's standard-setting activities that contribute to improved public health and food safety worldwide.

The 63rd Health Assembly also called the continuation of sustainable preventive measures through food safety education programs such as the FIVE KEYS to safer food developed by WHO in collaboration with FDA. The WHO Five Keys to Safer Food global message and training materials for consumers in the home are now recognized as an international source for conducting national food safety education programs. In 2008, a joint Food and Agriculture Organization (FAO)/WHO Expert Meeting on the microbiological hazards in fresh leafy vegetables and herbs also acknowledged the success of the FIVE KEYS to safe food as it reviewed the scientific data and made recommendations for limiting the risks associated with microbial contamination of these products. An important recommendation from the meeting was the suggestion that WHO develop training and educational materials based on the FIVE KEYS TO SAFER FOOD concept. As a result, WHO, working together with FDA, developed FIVE KEYS to Growing Safer Fruits and Vegetables: Promoting Health by Decreasing Microbial Contamination, a training program designed for educating rural workers who grow fresh fruits and vegetables for themselves, their families and for sale in local markets.

Many of the network "building blocks" to address elements of preventive risk-base approaches to food safety reside within WHO. For example:

- The International Networks of Food Safety Authorities (INFOSAN), a joint FAO/WHO program consisting of 177 Member States, which aims to promote the rapid exchange of information during food safety related events, promote partnership and collaboration between countries, and help countries to strengthen their capacity to manage food safety risks;

- The Global Foodborne Infections Network (GFN), a network of over 1,500 individuals from 700 institutions in 177 countries, that provide human resource expertise to promote integrated, laboratory-based surveillance and intersectoral collaboration in human

health, veterinary, and food-related disciplines;

- The Global Early Warning Systems for Animal Diseases Including Zoonoses (GLEWS), a joint system that coordinates alert mechanisms of the WHO, the FAO, and the World Organization for Animal Health (OIE) to assist in prediction, prevention, and control of zoonotic disease threats;

- The Global Laboratory Directory (GLaD), a support system for building, connecting, and sustaining laboratory and surveillance networks (currently in development phase);

- The Global Environment Monitoring System for Food (GEMS/Food), a program, which focuses on data collection and training related to dietary exposure of chemical hazards and involves a network of WHO Collaborating Center and national institutions from around the globe;

- The Foodborne Disease Burden Epidemiology Reference Group (FERG), established to provide guidance to WHO on the burden of foodborne disease to countries, with an anticipated publication of Global Report within the next several years;

- JECFA, the Joint FAO/WHO Meetings on Pesticide Residues (JMPR), the Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA), and the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) currently in development phase, that serve as technical advisory bodies to Codex;

- The management of the Codex Trust Fund; and

- The FIVE KEYS to safer food training materials developed to educate food handlers in safe food handling practices.

B. Research Objectives

The Funding Opportunity

The Cooperative Agreement announced in this FOA represents the continuation of a long-standing collaboration between WHO and FDA in support of strategies and approaches that align well domestically and globally to address food safety problems. Relevant strategies include: (1) Efforts to strengthen data and information systems so they are comparable, comprehensive, and robust, thereby allowing for better decision-making for all Member States; (2) enhanced capacity around the globe to improve detection of and response to food safety threats through preventive controls, data, information, surveillance systems, and risk-based approaches; and (3) global harmonization of science-based standards and adoption or

adaptation of international standards by national authorities.

This Cooperative Agreement is expected to support the following types of collaboration:

- Contribute to the knowledge base of the current state of food safety globally, including challenges, risks, and emerging trends, through an integrated information system based on WHO's existing network efforts, such as the GFN, INFOSAN, GEMS/Food, GLEWS, and FERG, as well as programs currently under development, such as GLaD;

- Enable the sharing of scientific findings and data through expert meetings and technical consultations;

- Enhance capacity at international and national levels in such areas of laboratory analyses, surveillance, and risk assessment/risk management, including through AGISAR;

- Contribute to the scientific, standard-setting work of Codex through scientific advisory groups including JECFA, JMPR, JEMRA, and JEMNU currently in development phase; and
- Enable participation of Member States through the Codex Trust Fund.

Inherent in the cooperative agreement award is substantive involvement by the awarding agency. Accordingly, FDA will be actively engaged in the programmatic activities of the entire project funded by this cooperative agreement, including but not limited, to the following items:

- FDA will appoint a project officer who will actively monitor the FDA-supported program under this award and work closely and collaboratively with a core group of experts. This core group of technical experts (CG/TE) from CFSAN, CVM, the Office of Regulatory Affairs (ORA) and relevant offices of the Office of the Commissioner (OC) will provide technical guidance and advice, as appropriate, to WHO in the implementation of this cooperative agreement. Support can be from various sources including in-kind participation.

- Appropriate participation of FDA in multinational advisory group(s) that are working to address food safety regulatory systems, the development and implementation of science-based standards and norms, and strengthening the existing capacity of Member States in the area of food safety and preventive controls.

C. Eligibility Information

The World Health Organization (WHO) Department of Food Safety and Zoonoses (FOS). Competition is limited to WHO because, as the only global health organization with a well-established trusted presence and high-level access to appropriate regulatory

authorities in its 193 Member Countries and Territories and with its ability to coordinate programs at both the regional and international levels, it is uniquely qualified to further the food safety objectives of this cooperative agreement. This ability to advance the objectives of this cooperative agreement through Member-State participation and intersectoral action is requisite for the success of this program.

II. Award Information/Funds Available

A. Award Amount

The total funding available is up to \$260,000 (total costs including indirect costs) in fiscal year 2011 in support of this project. One award will be made.

B. Length of Support

Funding will be provided for 1 year, with the possibility of up to 4 additional years of support, contingent upon successful performance and the availability of funds.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at <http://www.fda.gov/InternationalPrograms/CapacityBuilding/default.htm>. Persons interested in applying for a grant may obtain an application <http://grants2.nih.gov/grants/funding/phs398/phs398.html>.

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Dated: June 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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