

Enteritidis (SE) prevention measures, how to sample for SE, and how to maintain records documenting compliance with the final rule.

DATES: Although you can comment on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))), to ensure that the agency considers your comments on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 12, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Plant and Dairy Food Safety/Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301-436-1070. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nancy Bufano, Center for Food Safety and Applied Nutrition (HFS-316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1493.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 9, 2009 (74 FR 33030), FDA issued the final rule requiring shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, and requiring these producers to maintain records concerning their compliance with the final rule and to register with FDA. The final rule became effective September 8, 2009.

FDA is issuing the draft guidance as a level 1 draft guidance consistent with FDA's good guidance practices regulation (§ 10.115). The draft guidance, when finalized, will represent the agency's current thinking on how to comply with certain measures designed to prevent SE from contaminating eggs on the farm, as well as how to sample for SE and maintain records documenting compliance with the final rule. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An

alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 118.5, 118.6, 118.10, and 118.11 have been approved under OMB control number 0910-0660.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>.

Dated: August 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Intent To Award Patient Protection and Affordable Care Act Funding to Approved But Unfunded Applications (ABU) Formerly Received in Response to the American Recovery and Reinvestment Act of 2009 (ARRA) Centers for Disease Control and Prevention Funding Opportunity DP09-912ARRA09, "Communities Putting Prevention to Work (CPPW)"

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice provides notice of CDC's intent to fund additional

Approved but Unfunded (ABU) cooperative agreement applications previously received and competed in response to CDC Funding Opportunity, CDC-RFA-DP09-912ARRA09, "Communities Putting Prevention to Work" (CPPW). It is the intent of CDC to fund additional previously received applications with Patient Protection Affordable Care Act (PPACA), Section 4002, appropriations. To this end, CDC will remove the following ARRA-Specific Requirements published in the aforementioned funding opportunity announcement:

—Catalogue of Domestic Assistance Number 93.724

—*Recovery Act-Specific Reporting Requirements*

Recipients of Federal awards from funds authorized under Division A of the Recovery Act must comply with all requirements specified in Division A of the Recovery Act (Pub. L. 111-5), including reporting requirements outlined in Section 1512 of the Act and designated Recovery Act outcome and output measures as detailed at the end of this section. For purposes of reporting, Recovery Act recipients must report on Recovery Act sub-recipient (sub-grantee and sub-contractor) activities as specified below.

Not later than 10 days after the end of each calendar quarter, starting with the quarter ending ____; and reporting by ____, the recipient must submit quarterly reports to HHS that will posted to Recovery.gov, containing the following information:

a. The total amount of Recovery Act funds under this award;

b. The amount of Recovery Act funds received under this award that were obligated and expended to projects or activities;

c. The amount of unobligated award balances;

d. A detailed list of all projects or activities for which Recovery Act funds under this award were obligated and expended, including

- The name of the project or activity;
- A description of the project or activity;
- An evaluation of the completion status of the project or activity;
- An estimate of the number of jobs created and the number of jobs retained by the project or activity (see OMB Guidance M-09-21, June 22, 2009) and;
- For infrastructure investments made by State and local governments, the purpose, total cost, and rationale of the agency for funding the infrastructure investment with funds made available under this Act, and the name of the person to contact at the agency if there

are concerns with the infrastructure investment.

e. Detailed information on any sub-awards (sub-contracts or sub-grants) made by the grant recipient to include the data elements required to comply with the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282).

For any sub-award equal to or larger than \$25,000, the following information:

- The name of the entity receiving the sub-award;

- The amount of the sub-award;
- The transaction type;
- The North American Industry

Classification System code or Catalog of Federal Domestic Assistance (CFDA) number;

- Program source;
- An award title descriptive of the purpose of each funding action;
- The location of the entity receiving the award;
- The primary location of performance under the award, including the city, State, congressional district, and county.

- A unique identifier of the entity receiving the award and of the parent entity of the recipient, should the entity be owned by another entity;

- The date the sub-award was issued;
- The term of the sub-award (start/end dates);

- The scope/activities of the sub-award;

- The amount of the total sub-award that has been obligated or disbursed by the sub-recipient; and

- The amount of the total sub-award that remains unobligated by the sub-recipient.

f. All sub-awards less than \$25,000 or to individuals may be reported in the aggregate, as prescribed by HHS.

g. Recipients must account for each Recovery Act award and sub-award (sub-grant and sub-contract) separately. Recipients will draw down Recovery Act funds on an award-specific basis. Pooling of Recovery Act award funds with other funds for drawdown or other purposes is not permitted.

h. Recipients must account for each Recovery Act award separately by referencing the assigned CFDA number for each award.

The definition of terms and data elements, as well as any specific instructions for reporting, including required formats, will be provided in subsequent guidance issued by HHS.

Buy American—Use of American Iron, Steel, and Manufactured Goods

Recipients may not use any funds obligated under this award for the construction, alteration, maintenance, or

repair of a public building or public work unless all of the iron, steel, and manufactured goods used in the project are produced in the United States unless HHS waives the application of this provision. (Recovery Act Sec. 1605)

Wage Rate Requirements

[This term and condition shall not apply to tribal contracts funded with this appropriation. (Recovery Act Title VII—Interior, Environment, and Related Agencies, Department of Health and Human Services, Indian Health Facilities)] Subject to further clarification issued by the Office of Management and Budget, and notwithstanding any other provision of law and in a manner consistent with other provisions of Recovery Act, all laborers and mechanics employed by contractors and subcontractors on projects funded directly by or assisted in whole or in part by and through the Federal Government pursuant to this award shall be paid wages at rates not less than those prevailing on projects of a character similar in the locality as determined by the Secretary of Labor in accordance with subchapter IV of chapter 31 of title 40, United States Code. With respect to the labor standards specified in this section, the Secretary of Labor shall have the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (64 Stat. 1267; 5 U.S.C. App.) and section 3145 of title 40, United States Code. (Recovery Act Sec. 1606)

Preference for Quick Start Activities (Recovery Act)

In using funds for this award for infrastructure investment, recipients shall give preference to activities that can be started and completed expeditiously, including a goal of using at least 50 percent of the funds for activities that can be initiated not later than 120 days after the date of the enactment of Recovery Act. Recipients shall also use grant funds in a manner that maximizes job creation and economic benefit. (Recovery Act Sec. 1602)

Limit on Funds (Recovery Act)

None of the funds appropriated or otherwise made available in Recovery Act may be used by any State or local government, or any private entity, for any casino or other gambling establishment, aquarium, zoo, golf course, or swimming pool. (Recovery Act Sec. 1604)

Disclosure of Fraud or Misconduct

Each recipient or sub-recipient awarded funds made available under

the Recovery Act shall promptly refer to the HHS Office of Inspector General any credible evidence that a principal, employee, agent, contractor, sub-recipient, subcontractor, or other person has submitted a false claim under the False Claims Act or has committed a criminal or civil violation of laws pertaining to fraud, conflict of interest, bribery, gratuity, or similar misconduct involving those funds. The HHS Office of Inspector General can be reached at <http://www.oig.hhs.gov/fraud/hotline/>

Recovery Act: One-Time Funding

Unless otherwise specified, Recovery Act funding to existent or new awardees should be considered one-time funding.

Schedule of Expenditures of Federal Awards

Recipients agree to separately identify the expenditures for each grant award funded under Recovery Act on the Schedule of Expenditures of Federal Awards (SEFA) and the Data Collection Form (SF–SAC) required by Office of Management and Budget Circular A–133, “Audits of States, Local Governments, and Non-Profit Organizations.” This identification on the SEFA and SF–SAC shall include the Federal award number, the Catalog of Federal Domestic Assistance (CFDA) number, and amount such that separate accountability and disclosure is provided for Recovery Act funds by Federal award number consistent with the recipient reports required by Recovery Act Section 1512(c). (2 CFR 215.26, 45 CFR 74.26, and 45 CFR 92.26)

Responsibilities for Informing Sub-Recipients

Recipients agree to separately identify to each sub-recipient, and document at the time of sub-award and at the time of disbursement of funds, the Federal award number, any special CFDA number assigned for Recovery Act purposes, and amount of Recovery Act funds. (2 CFR 215.26, 45 CFR 74.26, and 45 CFR 92.26)

Reporting Jobs Creation

HHS’ recipients of Recovery Act funding who are subject to Section 1512 reporting should report job-created data as prescribed in Section 5 of the Office of Management and Budget (OMB) guidance M–09–21. HHS will not accept statistical sampling methods to estimate the number of jobs created and retained. All recipients must report a direct and comprehensive count of jobs, as specified by OMB guidance M–09–21. See Section 5.3 of the OMB guidance for more information on calculating jobs,

including job estimation examples. For the full OMB guidance, please visit: http://www.whitehouse.gov/omb/assets/memoranda_fy2009/m09-21.pdf.

Conclusion of Recovery Act-Specific Reporting Requirements

Recipient Reporting Requirements under PPACA

The removal of ARRA Section 1512 Reporting Requirements does not absolve the applicant from reporting project status as well as the other terms and conditions set forth in the above-referenced CPPW FOA and the Notice of Cooperative Agreement Award. Recipients funded with PPACA appropriations will be required to report project status on a semi-annual basis. Specific reporting requirements will be detailed in the Terms and Conditions of the Notice of Cooperative Agreement Award.

CFDA Number 93.520 is the PPACA-specific CFDA number for this initiative. It will replace CFDA Number 93.724 published in the above-referenced CPPW Funding Opportunity Announcement (FOA).

Award Information:

Approximate Current Fiscal Year

Funding: \$34,000,000.

Approximate Number of Awards: 11.

Approximate Average Award: \$3,000,000.

Fiscal Year Funds: Patient Protection and Affordable Health Care Act of 2010.
Anticipated Award Date: 30 Sep 2010.
Budget Period: 24 months.

Project Period: 24 months.

Application Selection Process: CDC will apply the same selection methodology published in the CPPW FOA, CDC-RFA-DP09-912ARRA09.

Applications will be funded in order by score and rank determined by the previously held review panel.

In addition, as was referenced in the CPPW FOA, funding decisions may be made to ensure:

- Representation of tobacco and obesity/physical activity/nutrition across communities, including a varied type of interventions and evidence-based strategies.
- Geographic distribution of The Communities Putting Prevention to Work Initiative nationwide.
- Inclusion of communities of varying sizes, including rural, suburban, and urban communities.
- Inclusion of populations disproportionately affected by chronic disease and associated risk factors.

CDC will provide justification for any decision to fund out of rank order.

CDC will add the following Authority to that which is reflected in the published Funding Opportunity:

—Section 4002 of the Patient Protection and Affordability Care Act (Public Law 111-148.)

DATES: The effective date for this action is August 12, 2010 and remains in effect until the expiration of the project period of the PPACA funded applications.

FOR FURTHER INFORMATION CONTACT: Elmira Benson, Deputy Director, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341, telephone: (770) 488-2802, e-mail: EBenson@cdc.gov

SUPPLEMENTARY INFORMATION: On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (PPACA). PPACA is designed to improve and expand the scope of health care coverage for Americans. Cost savings through disease prevention is an important element of this legislation and PPACA has established a Prevention and Public Health Fund (PPHF) for this purpose. Specifically, the legislation states in Section 4002 that the PPHF is to “provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs”. PPACA and the Prevention and Public Health Fund make improving public health a priority with investments to improve public health.

The PPHF states that the Secretary shall transfer amounts in the Fund to accounts within the Department of Health and Human Services to increase funding, over the fiscal year 2008 level, for programs authorized by the Public Health Services Act, for prevention, wellness and public health activities including prevention research and health screenings, such as the Community Transformation Grant Program, the Education and Outreach Campaign for Preventative Benefits, and Immunization Programs.

Both ARRA and PPACA legislation affords an important opportunity to advance public health across the lifespan and to reduce health disparities by supporting an intensive community approach to chronic disease prevention and control. Therefore, awarding cooperative agreements with PPACA funds under PPHF to ABUs to carry out CPPW objectives is consistent with the purpose of PPHF, as stated above, to provide for the expanded and sustained national investment in prevention and public health programs. Further, the Secretary allocated funds to CDC, pursuant to the PPHF, for the types of activities that the CPPW initiative is designed to carry out.

Therefore, the CPPW program activities CDC proposes to fund with PPACA appropriations are authorized by the amendment to the Public Health Services Act which authorized the Prevention and Wellness Program as embodied in CDC RFA DP09-912ARRA09.

Dated: August 5, 2010.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, Epi R01s, Data Analysis R21s, and K99 Applications.

Date: August 23, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, 1 Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: SAMUEL RAWLINGS, PhD, Chief, Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301-451-2020, rawlings@nei.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Eye Institute Special Emphasis Panel, Clinical Trials.

Date: August 24-25, 2010.

Time: 8 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NEI Division of Extramural Research, 5635 Fishers Lane, Bethesda, MD 20892, (Virtual Meeting).