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#### List of Subjects

Environmental protection, NPPTAC, Pollution prevention, toxics, Toxic chemicals, and Chemical health and safety.

Dated: September 8, 2006.

**Ann E. Goode,**

*Acting Director, Office of Pollution Prevention and Toxics*

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BILLING CODE 6560-50-S

#### ENVIRONMENTAL PROTECTION AGENCY

[FRL-8220-2; EPA-HQ-Docket ID No. EPA-ORD-2006-0666]

#### Approaches To Estimating the Waterborne Disease Outbreak Burden in the United States: Uses and Limitations of the Waterborne Disease Outbreak Surveillance System; External Review Draft

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of public comment period.

**SUMMARY:** EPA is announcing a 30-day public comment period for the draft document titled, *Approaches To Estimating the Waterborne Disease Outbreak Burden in the United States: Uses and Limitations of the Waterborne Disease Outbreak Surveillance System* (EPA/600/R-06/069). The document was prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development.

EPA is releasing this draft document solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. This document has not been formally disseminated by EPA. It does not represent and should not be construed to represent any Agency policy or determination. EPA will consider any public comments submitted in accordance with this notice when revising the document.

**DATES:** The 30-day public comment period begins September 15, 2006, and ends October 16, 2006. Technical comments should be in writing and

must be received by EPA by October 16, 2006.

**ADDRESSES:** The draft *Approaches To Estimating the Waterborne Disease Outbreak Burden in the United States: Uses and Limitations of the Waterborne Disease Outbreak Surveillance System* (EPA/600/R-06/069) is available primarily via the Internet on the National Center for Environmental Assessment's home page under the Recent Additions and Publications menus at <http://www.epa.gov/ncea>. A limited number of paper copies are available from Ms. Donna Tucker, Technical Information Manager, NCEA-Cincinnati; telephone: 513-569-7257; facsimile: 513-569-7916; e-mail: [tucker.donna@epa.gov](mailto:tucker.donna@epa.gov). If you are requesting a paper copy, please provide your name, your mailing address, and the document title, *Approaches To Estimating the Waterborne Disease Outbreak Burden in the United States: Uses and Limitations of the Waterborne Disease Outbreak Surveillance System* (EPA/600/R-06/069).

Comments may be submitted electronically via EPA's E-Docket, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions provided in the Supplementary Information section of this notice.

**FOR FURTHER INFORMATION CONTACT:** For information on the public comment period, contact the Office of Environmental Information Docket; telephone: 202-566-1752; facsimile: 202-566-1753; or e-mail: [ORD.Docket@epa.gov](mailto:ORD.Docket@epa.gov).

For technical information, contact Glenn Rice, NCEA; telephone: 513-569-7813; facsimile: 513-487-2539; or e-mail: [rice.glenn@epa.gov](mailto:rice.glenn@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Information About the Project/ Document

Information about waterborne disease outbreaks (WBDOs) in the United States is voluntarily reported by State, territorial and local public health agencies to the Centers for Disease Control and Prevention (CDC). CDC and EPA jointly maintain a WBDO database. The database describes outbreak attributes including, among other things, the drinking water system deficiency, the etiologic agent, and the number of individuals who became ill. Underreporting of such events is assumed but the magnitude of underreporting is unknown.

This draft document presents an approach for estimating the epidemiologic and economic burden of disease associated with 665 WBDOs

reported in the U.S. between 1971 and 2000. The term *disease burden* broadly refers to the magnitude of the impact incurred by society as a consequence of disease in the community (e.g., decrements in a population's health or the associated economic effects) and there are various metrics that can be employed by analysts to quantify burden. In order to capture some of the benefits of drinking water regulations, EPA has typically expressed waterborne disease impacts in terms of epidemiologic and monetary measures; this WBDO burden analysis employs those same measures. Because not all WBDOs in the United States and associated cases of illness are reported, the WBDO database on which this draft document is based is not comprehensive. The extent to which WBDOs are not recognized is unknown and is not examined in this analysis. This draft report develops several quantitative sensitivity analyses to characterize some of the uncertainty in the burden estimates but does not provide an evaluation of the potential impact of under- or overreporting of WBDOs or their associated severity characteristics. The draft report includes recommendations for the collection and reporting of additional outbreak information that would improve the usefulness of the WBDO database for future disease burden estimates.

##### II. How To Submit Technical Comments to EPA's E-Docket

Submit your comments, identified by Docket ID No. EPA-ORD-2006-0666 by one of the following methods:

- [www.regulations.gov](http://www.regulations.gov): Follow the on-line instructions for submitting comments.

- *E-mail:* [ORD.Docket@epa.gov](mailto:ORD.Docket@epa.gov).

- *Fax:* 202-566-1753.

- *Mail:* Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The phone number is 202-566-1752.

If you provide comments by mail, please submit one unbound original with pages numbered consecutively, and three copies. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

- *Hand Delivery:* The OEI Docket is located in the Headquarters EPA Docket Center, EPA/DC; EPA West Building, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal

holidays. The telephone number for the Public Reading Room is 202-566-1744. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

**Instructions:** Direct your comments to Docket ID No. EPA-ORD-2006-0666. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

**Docket:** All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

**Note:** The EPA Docket Center suffered damage due to flooding during the last week of June 2006. The Docket Center is continuing to operate. However, during the

cleanup, there will be temporary changes to Docket Center telephone numbers, addresses, and hours of operation for people who wish to make hand deliveries or visit the Public Reading Room to view documents. Consult EPA's **Federal Register** notice at 71 FR 38147 (July 5, 2006) or the EPA Web site at [www.epa.gov/epahome/dockets.htm](http://www.epa.gov/epahome/dockets.htm) for current information on docket operations, locations and telephone numbers. U.S. mail and the procedures for submitting comments to [www.regulations.gov](http://www.regulations.gov) are not affected by the flooding and will remain the same.

Dated: September 7, 2006.

**Peter W. Preuss,**

*Director, National Center for Environmental Assessment.*

[FR Doc. E6-15335 Filed 9-14-06; 8:45 am]

**BILLING CODE 6560-50-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### International Development of H5N1 Influenza Vaccines; Funding Opportunity

**AGENCY:** Office of the Secretary, Office of Public Health Emergency Preparedness.

**ACTION:** Notice.

*Funding Opportunity Title:* International Development of H5N1 Influenza Vaccines.

*Announcement Type:* Single-Source Cooperative Agreement.

*Catalog of Federal Domestic Assistance Number:* The Office of Management and Budget (OMB) Catalog of Federal Domestic Assistance number is 93.019.

**SUMMARY:** The objective of this project is to mitigate any potential global shortage of influenza vaccines and the manufacturing of this vaccine in the event of an influenza pandemic. The Office of Public Health Emergency Preparedness (OPHEP) requires the World Health Organization (WHO) to perform activities related to pandemic influenza preparedness and planning, particularly in the international development of H5N1 human vaccines (and other pandemic influenza vaccine candidates) and influenza vaccine manufacturing infrastructure building in countries where resources for vaccine acquisition and manufacturing may be limited. The specific countries in which the WHO Secretariat will carry out these activities are Argentina, Brazil, India, Indonesia, Mexico, Romania, Russia, South Africa, and Tunisia. Activities include pre-clinical safety and immunogenicity testing, toxicology testing, clinical vaccine lot manufacturing, scale-up and process

development, analytical lot release assay development and validation, and clinical immunogenicity assay development and validation.

**DATES:** To receive consideration, applications must be received no later than 5 p.m., Eastern Time, on September 29, 2006.

**ADDRESSES:** The Office of Grants Management within the Office of Public Health and Science of the U.S. Department of Health and Human Services, located at 1101 Wootton Parkway, Rockville, MD 20857, must receive all applications.

**SUPPLEMENTARY INFORMATION:** In the last century, three influenza pandemics have struck the United States and the world, and viruses from birds contributed to all of them. In 1918, the first pandemic infected one-third of the U.S. population, killed over half a million Americans, reduced American life expectancy by 13 years, and killed more than 20 million people worldwide. Following the 1918 outbreak, influenza pandemics in 1957 and 1968 also killed tens of thousands of Americans and millions across the world. The recent limited outbreak of Severe Acute Respiratory Syndrome (SARS) in 2003 suggests the danger that a modern pandemic would present.

The H5N1 strain of avian influenza has become the most threatening influenza virus in the world, and any large scale outbreak of this disease among humans would have grave consequences for global public health. Influenza experts have warned that the reassortment of different H5N1 viruses over the past seven years greatly increases the potential for the viruses to be transmitted more easily from person to person. Medical practitioners have also discovered several other, new avian viruses that can be transmitted to humans.

The U.S. Government is concerned that a new influenza virus could become efficiently transmissible among humans. Now spreading through bird populations across Asia, reaching into Europe, the Middle East and, most recently, Africa, the H5N1 strain has infected domesticated birds, such as ducks and chickens, and long range migratory birds. In 1997, the first recorded H5N1 outbreak in humans took place in Hong Kong. H5N1 struck again in late 2003, and has, as of August 17, 2006, resulted in 239 confirmed cases and 140 deaths world-wide, a 59 percent mortality rate. As of now, the H5N1 avian influenza is primarily an animal disease; H5N1 infection in humans has been the result of contact with sick poultry. Unless people come