

Background

Bisphenol A (CAS RN: 80-5-07) is a high production volume chemical used in the production of epoxy resins, polyester resins, polysulfone resins, polyacrylate resins, polycarbonate plastics, and flame retardants. Polycarbonate plastics are used in food and drink packaging; resins are used as lacquers to coat metal products such as food cans, bottle tops, and water supply pipes. Some polymers used in dental sealants and tooth coatings contain bisphenol A. Exposure to the general population can occur through direct contact to bisphenol A or by exposure to food or drink that has been in contact with a material containing bisphenol A. CERHR selected this chemical for evaluation because of (1) high production volume, (2) widespread human exposure, (3) evidence of reproductive toxicity in laboratory animal studies, and (4) public concern.

The CERHR convened an expert panel on March 5-7, 2007, and on August 6-8, 2007, to review and revise the draft and interim draft expert panel reports and reach conclusions regarding whether exposure to bisphenol A is a hazard to human development or reproduction. The expert panel also identified data gaps and research needs. CERHR solicited public comments on drafts of the expert panel report several times (FR, December 12, 2006, Vol. 71, No. 238 pp. 74534-74536; FR, April 2, 2007, Vol. 72, No. 62 pp. 15695-15696; FR, May 1, 2007, Vol. 72, No. 83 pp. 23833-23834).

Following receipt of public comments on the final bisphenol A expert panel report, CERHR staff will prepare the NTP-CERHR monograph. NTP-CERHR monographs are divided into four major sections: (1) The NTP Brief that provides the NTP's interpretation of the potential for the chemical to cause adverse reproductive and/or developmental effects in exposed humans, (2) a roster of expert panel members, (3) the final expert panel report, and (4) public comments received on that report. The NTP Brief is based on the expert panel report, public comments on that report, public and peer review comments on the draft NTP Brief, and any new, relevant information that becomes available after the expert panel meetings.

Request for Comments

CERHR invites written public comments on the bisphenol A expert panel report. Written comments should be sent to Dr. Michael Shelby (see **ADDRESSES** above). Persons submitting written comments are asked to include

their name and contact information (affiliation, mailing address, telephone and facsimile numbers, e-mail, and sponsoring organization, if any). Any comments received will be posted on the CERHR Web site and included in the NTP CERHR monograph on this chemical. All public comments will be considered by the NTP during preparation of the NTP Brief (see "Background" above).

Background Information on CERHR

The NTP established the CERHR in June 1998 [FR, December 14, 1998 (Vol. 63, No. 239, pp. 68782)]. CERHR is a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with exposure to environmental and/or occupational exposures. Expert panels conduct scientific evaluations of agents selected by CERHR in public forums.

CERHR invites the nomination of agents for review or scientists for its expert registry. Information about CERHR and the nomination process can be obtained from its Web site (<http://cerhr.niehs.nih.gov>) or by contacting Dr. Shelby (see **ADDRESSES** above). CERHR selects chemicals for evaluation based upon several factors including production volume, potential for human exposure from use and occurrence in the environment, extent of public concern, and extent of data from reproductive and developmental toxicity studies.

CERHR follows a formal, multi-step process for review and evaluation of selected chemicals. A description of the evaluation process is available on the CERHR Web site under "About CERHR" or in printed copy from CERHR.

Dated: November 15, 2007.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Amendment to January 26, 2007 Declaration Under the Public Readiness and Emergency Preparedness Act

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), HHS.

ACTION: Amendment (to the January 26, 2007 Declaration under the Public

Readiness and Emergency Preparedness Act).

SUMMARY: Declaration pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d) to provide targeted liability protections for pandemic countermeasures based on a credible risk that avian influenza viruses spread and evolve into strains capable of causing a pandemic of human influenza.

Amendment: Whereas, the H7 and H9 subtypes of avian influenza viruses are viewed as likely candidates to evolve into an influenza virus strain capable of causing a pandemic of human influenza; and

*Whereas, in accordance with section 319F-3(b)(6) of the Public Health Service Act (42 U.S.C. 247d-6d(b)) ("the Act"), I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacturing and product formulation, labeling, distribution, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of these additional medical countermeasures with respect to the category of diseases and population described in sections II and IV of the declaration published in **Federal Register** on February 1, 2007 (72 FR 4710) ("the Original Declaration");*

Therefore, pursuant to section 319F-3(b) of the Act, I have determined there is a credible risk that the spread of the H7 and H9 subtypes of avian influenza viruses and resulting disease could in the future constitute a public health emergency. In order to reflect the addition of medical countermeasures specific to the H7 and H9 subtypes of influenza viruses, the Original Declaration is hereby amended as follows:

First "whereas" clause, first sentence, insert "H7 and H9 vaccines" following "(H5N1)."

*Second "whereas" clause, first sentence, insert "H7 and H9" following "H5N1" to read "Whereas an H5N1, [H7 and H9] avian influenza virus(es) may evolve into strain[s] * * *."*

In Section I, paragraph 2, first sentence insert "H7 and H9" following "(H5N1)" to read " * * pandemic countermeasure influenza A (H5N1, [H7 and H9]) vaccine[s]."*

In Section I, paragraph 2, third sentence insert "H7 and H9" following "(H5N1)" to read " * * pandemic countermeasure influenza A (H5N1, [H7 and H9]) vaccine[s] * * *."*

In Section II, paragraph 1, insert "or an H7 or H9" following "(H5N1)."

In Section VIII, strike the sentence "This Declaration has not previously been amended." and replace it with: "This is the first amendment to this Declaration. The Original Declaration was published in the **Federal Register** at 72 FR 4710."

All other provisions of the Original declaration remain in full force.

This amendment to the Declaration will be published in the **Federal Register** pursuant to section 319F-3(b)(4) of the Act.

DATES: This notice and the attached declaration are effective November 30, 2007.

FOR FURTHER INFORMATION CONTACT: RADM W. Craig Vanderwage, MD, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll-free number).

Dated: November 21, 2007.

Michael O. Leavitt,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) allow the renewal of the generic information collection project: "AHRQ Grants Reporting System (GRS)." In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by December 31, 2007.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, 540 Gaither Road, Room #5036, Rockville,

MD 20850, or by e-mail at doris.lefkowitz@ahrq.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from AHRQ's Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ, Reports Clearance Officer, (301) 427-1477.

SUPPLEMENTARY INFORMATION:

Proposed Project

"*AHRQ Grants Reporting System (GRS)*"

AHRQ has identified the need to establish a systematic method for its grantees to report project progress and important preliminary findings for grants funded by the Agency. The proposed system will address the shortfalls in the current reporting process and establish a consistent and comprehensive grants reporting solution for AHRQ. Currently, AHRQ receives grants continuation applications on an annual basis from all grantees. The progress report, which represents a portion of the annual continuation application, is inadequate because it is too infrequent and does not necessarily capture the information that AHRQ requires to respond to internal and external inquiries. The reporting system will also provide a centralized repository of grants research information that can be used to support initiatives within the Agency's research plans for the future and to support activities such as performance monitoring, budgeting, knowledge transfer as well as strategic planning. AHRQ currently conducts quarterly conference calls with some grantees. The content, frequency, and focus of these calls vary. In some grant programs, the number of participants on these calls may be so large as to prohibit quarterly updates from all participants in order to avoid creating an extremely lengthy conference call and to allow the Agency to address other important issues during these calls. The GRS will support the timely collection of important information related to the life cycle of a grant. This information includes: Significant changes in project goals, methods, study design, sample or subjects, interventions, evaluation, dissemination, training, key personnel, key preliminary findings; significant problems and resolutions; publications and presentations; tools and products; and new collaborations/partnerships with AHRQ grantees or others conducting related research. Collecting

this information in a systematic manner will:

- Promote the transfer of critical information more frequently and efficiently which will enhance the Agency's ability to support research designed to improve the outcomes and quality of health care, reduce its costs, and broaden access to effective services.
- Increase the efficiency of the Agency in responding to ad-hoc information requests, Freedom of Information Act requests, and producing responses related to federally mandated programs and regulations.
- Establish a consistent approach throughout the Agency for information collection about grant progress and a systematic basis for oversight and for facilitating potential collaboration with or among grantees.
- Decrease the inconvenience and burden on grantees of unanticipated adhoc requests for information by the Agency in response to particular (one-time) internal and external requests for information.

This proposed information collection was previously published in the **Federal Register** on September 17th, 2007 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. This project was previously approved by OMB on November 10th, 2004. The OMB control number is 0935-0122 and will expire on November 30th, 2007.

Data Confidentiality Provisions

Confidential commercial information will be protected in accordance with 18 U.S.C. 1905. Information about Principal Investigators will be maintained in accordance with the Privacy Act, 5 U.S.C. 552a. Also, individuals and organizations will be assured of the confidentiality of their data under section 934(c) of the Healthcare Research and Quality Act of 1999. The submitted reports will be printed and included in the official file for each grant. All of these files will be retained according to existing agency policies and procedures and archived as required. The data will be collected using a Web based reporting interface developed specifically for the purpose of collecting information quarterly. To reduce burden and to the extent possible, these forms will be prepopulated with reoccurring information needed to specifically identify the institution, project, principal investigator, and other similar information.