

Dated: January 25, 2005.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP); Center for the Evaluation of Risks to Human Reproduction (CERHR); Announcement of Plans for Future Evaluation of Di(2-ethylhexyl)phthalate; Request for Public Comments on this Chemical; and Solicitation for the Nomination of Scientists Qualified to Serve on an Expert Panel

AGENCY: National Institute for Environmental Health Sciences (NIEHS); National Institutes of Health (NIH), Department of Health and Human Services (HHS).

ACTION: Notice of expert panel evaluation of the reproductive and developmental toxicities of di(2-ethylhexyl)phthalate.

SUMMARY: The CERHR plans to convene an expert panel to evaluate the scientific evidence regarding the potential reproductive and/or developmental toxicity associated with exposure to di(2-ethylhexyl)phthalate (DEHP). The expert panel will consist of approximately 8-12 scientists selected for their scientific expertise in various aspects of reproductive and developmental toxicology and other relevant areas of science. The CERHR invites the submission of public comments on DEHP and the nomination of scientists to serve on the expert panel for its evaluation (*see SUPPLEMENTARY INFORMATION* below). This meeting is tentatively scheduled for fall 2005, although the exact date and location are not yet established. As plans are finalized, they will be announced in the **Federal Register** and posted on the CERHR Web site (<http://cerhr.niehs.nih.gov>). CERHR expert panel meetings are open to the public with time scheduled for oral public comment.

DATES: Information and comments received by March 21, 2005, will be made available to the CERHR staff and the expert panel for consideration in the evaluation and posted on the CERHR Web site. Nominations of scientists received by March 21, 2005, will be

considered for this panel and for inclusion in the CERHR Expert Registry.

ADDRESSES: Information and comments should be sent to Dr. Michael D. Shelby, CERHR Director, NIEHS, P.O. Box 12233, MD EC-32, Research Triangle Park, NC 27709 (mail), (919) 316-4511 (fax), or shelby@niehs.nih.gov (e-mail). Courier address: CERHR, 79 T.W. Alexander Drive, Building 4401, Room 103, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Dr. Michael D. Shelby, CERHR Director, (919) 541-3455, shelby@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

DEHP is a high production chemical used as a plasticizer of polyvinyl chloride in the manufacturer of a wide variety of consumer products, such as building products, car products, clothing, food packaging, children's products (but not in toys intended for mouthing) and in polyvinyl chloride medical devices. In 1999-2000, a NTP-CERHR expert panel evaluated DEHP and six other phthalates for reproductive and developmental toxicities. Since release of the NTP-CERHR expert panel report on DEHP in 2000, approximately 70 papers relevant to human exposure and reproductive and/or developmental toxicity of DEHP have been published. Because this is a chemical with wide human exposure and public and government interest, CERHR plans to convene an expert panel to conduct an updated evaluation of the potential reproductive and developmental toxicities of DEHP.

Request for Comments

The CERHR invites the public and other interested parties to submit information and comments on DEHP including toxicology information from completed and ongoing studies, information on planned studies, and information about current production levels, human exposure, use patterns, and environmental occurrence.

Request for the Nomination of Scientist for the Expert Panel

The CERHR invites nominations of qualified scientists to serve on the expert panel. Panelists are primarily drawn from the CERHR Expert Registry and/or the nomination of other scientists who meet the criteria for listing in that registry which include: formal academic training and experience in a relevant scientific field, publications in peer-reviewed journals, membership in relevant professional societies, and certification by an appropriate scientific board or other

entities. Expert panel members are required to sign conflict of interest forms in accordance with Federal Advisory Committee Act Guidelines (5 U.S.C. Appendix 2).

All panel members serve as individual experts and not as representatives of their employers or other organizations. Scientists on the expert panel will be selected to represent a wide range of expertise including, but not limited to, developmental toxicology, reproductive toxicology, epidemiology, general toxicology, pharmacokinetics, exposure assessment, and biostatistics. Nominations should include contact information and a current curriculum vitae (if possible) and be forwarded to the CERHR at the address given above.

Background Information on the CERHR

The NTP established the CERHR in June 1998 (**Federal Register**, December 14, 1998: Volume 63, Number 239, page 68782). The CERHR is a publicly accessible resource for information about adverse reproductive and developmental health effects associated with environmental exposures. Expert panels conduct scientific evaluations of agents selected by the CERHR in public forums.

Information about CERHR and its process for nominating agents for review or scientists for its expert registry can be obtained from its Web site (<http://cerhr.niehs.nih.gov>) or by contacting Dr. Shelby (contact information provided above). The CERHR selects chemicals for evaluation based upon several factors, including production volume, extent of human exposure, public concern, and extent of the database on reproductive or developmental toxicity studies.

CERHR follows a formal, multi-step process for review and evaluation of selected chemicals. The formal evaluation process was published in the **Federal Register** (July 16, 2001: Volume 66, Number 136, pages 37047-37048) and is available on the CERHR Web site under "About CERHR" or in printed copy from the CERHR.

Dated: January 27, 2005.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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