NATIONAL TOXICOLOGY PROGRAM
FACT SHEET
Headquartered at the National Institute of Environmental Health Sciences • NIH • DHHS

NTP Center for the Evaluation of Risks to Human Reproduction

Year 2003

The **N**ational **T**oxicology **P**rogram (NTP) and the **N**ational **I**nstitute of **E**nvironmental **H**ealth **S**ciences (NIEHS) established the NTP **C**enter for the **E**valuation of **R**isks to **H**uman **R**eproduction (CERHR) in 1998. The CERHR is an environmental health resource for the public, as well as regulatory and health agencies. The CERHR provides accessible, scientifically based, uniform assessments of adverse effects and potential adverse effects on human reproduction and development, as a result of chemical exposures.

The CERHR was established in response to growing concern among health professionals, environmental scientists, and the general public, that such exposure(s) may be factors in the following:

- Nearly 50 percent of pregnancies are not successfully completed
- 5-10 percent of couples desiring children encounter problems achieving pregnancy
- 3-5 percent of newborns have major birth defects.

Who Provides Oversight to the CERHR?

Directed by Dr. Michael Shelby, the CERHR has a Core Committee composed of representatives from NTP-participating agencies to offer expertise on expert panel members and chemicals being considered for evaluation. The NTP Board of Scientific Counselors provides oversight to the CERHR on priorities, directions, and the adequacy of the review process.

What Chemicals Have Been Reviewed to Date?

The CERHR has held expert panel meetings on the chemicals listed in the table below. Expert panel reports from these meetings, as available, are posted electronically on CERHR website or available from the CERHR.

Chemical	Use	Year
Phthalates (7)*	Primary plasticizers in wide range of polyvinyl chloride-based consumer products	2000
Methanol	Chemical synthesis, racecar fuels, potential as vehicle fuel or fuel additive	2001-02
1-Bromopropane	Solvent, in spray adhesives & cold bath degreaser; potential use as a replacement for ozone depleting hydrochlorofluorocarbons & chlorinated solvents	2001-02
2-Bromopropane	Contaminant in 1-bromopropane, synthesis of pharmaceuticals & dyes	2001-02
Ethylene glycol	High-production-volume chemical; used chiefly in production of polyester compounds, widely used in antifreeze (heating & cooling systems)	2003
Propylene glycol	Production of polyester resins, used in antifreeze, de-icing solution; paints & coatings, also approved for use as a food additive & in some drugs & cosmetics	2003

Note: CERHR plans a workshop on "Thyroid Toxicants: Assessing Reproductive Health Effects" on April 28-29, 2003 in Alexandria, VA. The workshop will address appropriate designs for toxicity tests in detecting adverse thyroid effects. In addition, there will be a discussion of the relevance of rodent effects for predicting adverse effects in humans. Information on this workshop is available on the CERHR website.

* butyl benzyl phthalate, di(2-ethylhexyl) phthalate, di-isodecyl phthalate, di-isononyl phthalate, di-*n*-butyl phthalate, di-*n*-hexyl phthalate, and di-*n*-octyl phthalate.

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WEB SITE http://ntp-server.niehs.nih.gov/
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Where Can I Go for Information about CERHR Activities?

The CERHR web site (http://cerhr.niehs.nih.gov) provides information on the center's structure and activities including expert panel reports, press releases, meeting announcements, and Federal Register notices. The web site is a source for information on a wide range of common questions and concerns regarding fertility, healthy pregnancy, and the potential of various exposures that adversely affect development of the unborn child. Hardcopies may be obtained by contacting the CERHR.

What Is the CERHR Review Process?

Nomination, selection and evaluation of chemicals follow an open, yet formal process. Details about the process can be found on the CERHR website (http://cerhr.niehs.nih.gov) or by contacting the CERHR director. The CERHR invites the nomination of chemicals for evaluation from public and private sectors, including industry, academia, environmental groups, labor, and federal, state and local government agencies. The Core Committee gives input on selected nominations and public is invited to comment. The NTP reviews this information and makes the final selection of chemicals for evaluation based on several factors:

- Production volume
- Extent of human exposure
- Public concern about hazards
- Availability of reproductive toxicity data
- Other relevant information

The CERHR evaluates 2-3 chemicals each year. The goals of these assessments are to:

- Interpret for and provide the general public with information from scientific evidence that a given exposure or exposure circumstance poses a hazard to reproduction, or the health and welfare of children.
- Provide regulatory agencies with objective and sound scientific assessments of effects on reproductive/developmental health associated with exposure to specific chemicals or classes of chemicals and outline any uncertainties associated with the assessment of such hazards.
- Identify knowledge gaps to establish research and testing priorities.

The CERHR convenes a scientific expert panel that follows rigorous guidelines to evaluate the scientific literature on a chemical or chemical mixture. The panel develops a report and provides the CERHR its expert opinion about the possibility for harmful effects to human reproduction and/or developmental health resulting from exposure to the chemical. Panel meetings are open to the public and include the opportunity for public comment. Following an expert panel meeting, reports are finalized and made available to the public for comment. NTP staff then prepares the NTP-CERHR monograph on the chemical evaluated, consisting of the NTP brief, expert panel report, and all public comments. The NTP brief provides the NTP's interpretation of the potential for the chemical to affect adversely human reproductive health or the health of children. Monographs are distributed to appropriate regulatory and health agencies and are available to the public.

How is the Public Invited to Be Part of the Process?

Public comment is welcome and is solicited through Federal Register notices. Public input can occur in multiple ways:

- Nomination of chemicals for evaluation
- Submission of comments on nominated chemicals, draft expert panel reports, and expert panel reports
- Presentation of comment at an expert panel meeting
- Nomination of scientists for the expert panels

Nominations of scientists for the CERHR Expert Registry or chemicals for evaluation can be submitted through the web site or by contacting the Center director. Chemical nominations should be accompanied by a rationale for the nomination and, whenever possible, appropriate background information, data, or literature citations. Suggestions for expert panel members need to be accompanied by a description of their expertise and curriculum vitae.

Forward nominations and requests for reports and other information to:
Dr. Michael Shelby, CERHR, NIEHS, P.O. Box 12233, MD EC-32, Research Triangle Park, NC 27709
Phone: 919/541-3455, E-mail: shelby@niehs.nih.gov or Visit the CERHR web site at: http://cerhr.niehs.nih.gov