

NTP CENTER FOR THE EVALUATION OF RISKS TO HUMAN REPRODUCTION

Year 2005

The National Toxicology Program (NTP) and the National Institute of Environmental Health Sciences (NIEHS) established the NTP Center for the Evaluation of Risks to Human Reproduction (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 the adverse effects and potential adverse effects on human reproduction and development resulting from chemical and other exposures.

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

- 35 to 50 percent of pregnancies are not successfully completed.
- 5 to 10 percent of couples desiring children encounter problems achieving pregnancy.
- 3 to 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 advice 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 conducted expert panel evaluations on the chemicals listed in the table below. Expert panel evaluations of 1) genistein and soy formula and 2) Di(2-ethylhexyl)phthalate are planned for late 2005.

Chemical	Use	Year
Phthalates (7)*	Primary plasticizers in a wide range of polyvinyl chloride-based consumer products.	2000
Methanol	Chemical synthesis, racecar fuels, and potential use as a vehicle fuel or fuel additive.	2001
1-Bromopropane	Solvent in spray adhesives and cold bath degreaser; potential use as a replacement for ozone-depleting hydrochlorofluorocarbons and chlorinated solvents.	2001
2-Bromopropane	Contaminant in 1-bromopropane; used in synthesis of Pharmaceuticals and dyes.	2001
Ethylene glycol	High production volume chemical used chiefly in production of polyester compounds and widely as antifreeze for heating and cooling systems.	2003
Propylene glycol	Production of polyester resins, as antifreeze and de-icing solution, and in paints and coatings; also approved for use as a food additive and in some drugs & cosmetics.	2003
Fluoxetine	Used primarily as an antidepressant in adults, is approved for use in children 7-17 years old; also used to treat premenstrual dysphoric disorder.	2004
Acrylamide	Used in production of polyacrylamide that is used in water treatment, pulp and paper production, and mineral processing; also used in synthesis of dyes, adhesives, contact lenses, soil conditioners, and permanent press fabrics and electrophoresis.	2004
Styrene	High production volume chemical used in the production of polystyrene resins; found in foam cups, dental fillings, ion exchange filters, construction materials.	2005
Amphetamines	Central nervous system stimulants. Amphetamine is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) and narcolepsy; methamphetamine is indicated for the treatment of ADHD and for short-term treatment of obesity.	2005
Methylphenidate	A central nervous system stimulant approved by the Food and Drug Administration for the treatment of ADHD and narcolepsy in persons six years of age and older.	2005

* 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.

Where Can I Go for Information about CERHR Activities?

The CERHR web site (<http://cerhr.niehs.nih.gov>) provides access to expert panel reports, monographs, press releases, meeting announcements, and Federal Register notices. It is also a source for information on common questions and concerns regarding fertility, healthy pregnancy, and the potential of various exposures to adversely affect development of the unborn child. Hardcopies of panel reports and monographs may be obtained by contacting the CERHR.

What Is the CERHR Review Process?

Nomination, selection, and evaluation of chemicals follow an open, formal process. Details about the process can be found on the CERHR web site or by contacting the CERHR director. The CERHR invites the nomination of chemicals for evaluation from public and private sectors. The Core Committee gives input on all nominations and the 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.
- Extent of literature on reproductive toxicity testing.

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

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

The CERHR convenes an independent, 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 for public 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 on the report. 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 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>

Printed on recycled paper