

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Public Health Service****National Toxicology Program**

The National Toxicology Program (NTP) and the National Institute of Environmental Health Sciences (NIEHS) announces the establishment of the NTP Center for the Evaluation of Risks to Human Reproduction; solicits nominations of chemicals and/or chemical mixtures to be evaluated by the Center; and requests suggestions for scientists to be added to an Expert Registry from which reviewers will be appointed to serve on ad hoc panels that will assess the reproductive and developmental toxicity of selected agents.

Background

There currently is no readily and publicly available, scientifically authoritative mechanism for the evaluation of human and experimental evidence for adverse effects on reproduction, including development, caused by agents to which humans may be exposed. In the absence of uniform, authoritative, independent reviews, there is a lack of consistency in risk evaluations involving reproductive toxicants. The need for such evaluations of reproductive hazards is clear, especially evaluations that are readily available and understandable to the public. Although the etiology is largely unknown, an infertility rate of approximately 5–10 percent exists among couples who desire children, approximately 50 percent of pregnancies are not successfully completed, there is a birth defect rate of 3–5 percent, and a decline in human sperm counts over recent decades has been reported but not confirmed.

In line with the goal of the National Toxicology Program to provide toxicological evaluation on substances of public health concern, the Center is being established to provide a strictly scientifically-based, uniform assessment of the evidence for reproductive and developmental toxicity of man-made or naturally occurring chemicals or chemical mixtures. The reports produced through the Center will provide a timely, scientifically sound source of information to the public and the scientific communities on the reproductive risks of environmental agents. A special effort will be made to summarize these reports in terms that can be understood by these who are not scientifically trained.

NTP Center Operations

Nominations of chemicals to be evaluated through the Center are solicited from the public and scientific communities, including industry, Federal, state, and local governments, academia, environmental groups, citizens, and workers. All nominations will be considered and prioritized based on a preliminary evaluation which will include literature searches and review by the core committee described below. A listing of exposures under consideration for evaluation will be published in the **Federal Register**, the NTP newsletter, and through press advisories with the request for public review and comment.

The initial capacity for conducting assessments will be limited to 2–3 per year. Chemicals selected for evaluation will be reviewed by expert panels of approximately 10–15 scientists selected for their expertise in various aspects of reproductive toxicology and other relevant areas. These panels will develop reports addressing the reproductive health risks to the human population of a specific chemical or a chemical mixture. Panel meetings will be open to the public and will include the opportunity for public comment.

The goals of the individual assessments are to (1) interpret for and provide to the general public information about the strength of scientific evidence that a given exposure or exposure circumstance poses a hazard to reproduction and the health and welfare of children; (2) provide regulatory agencies with objective and scientifically credible assessments of reproductive/developmental health effects associated with exposure to specific chemicals or classes of chemicals, including descriptions of any uncertainties associated with the assessment of risks; and (3) identify knowledge gaps to help establish research and testing priorities.

The Executive Summary and the final report of the expert panel will be published in Environmental Health Perspectives and will be announced and disseminated widely. Each assessment will appear as well on the CERHR website, linked to the NIEHS and NTP websites.

Scientists representing NTP agencies and Sciences International, Inc., the contractor who will support the Center, will constitute a core committee which will provide the initial review for nominations, select the expert panel membership and establish the meeting agenda.

External Oversight

Oversight will be provided through the NTP Board of Scientific Counselors, a chartered peer review group of scientific experts primarily outside the government, who will provide advice on priorities, directions, and the adequacy of the process and will facilitate public input into the process. Center activities and priorities will be presented to the Board at least annually. All Board meetings will be held in open session and will include opportunity for public comment.

Public Input Solicited and Encouraged

The process includes opportunities for the public to (1) nominate chemicals for evaluation, (2) comment on nominations and the prioritizing and selecting of chemical nominations for evaluation, (3) comment on the evaluation of any particular chemical at the time of the expert panel meetings. The public is encouraged in this initial phase of the Center operations and on a continuing basis to nominate chemicals or chemical mixtures for review through the Center and/or suggest scientists to be added to an Expert Registry from which reviewers will be appointed to serve on ad hoc panels that will assess the reproductive and developmental toxicity of selected agents.

Nominations of chemicals or chemical mixtures should be accompanied by the reason for the nomination and, whenever possible, appropriate background information, data, or literature citations.

Suggestions for scientists to be added to the Expert Registry should be accompanied by a description of their expertise and a curriculum vitae.

All chemical nominations and suggestions for scientists to be added to the Expert Registry should be forwarded to: NTP Center for the Evaluation of Risks to Human Reproduction, 1800 Diagonal Road, Suite 500, Alexandria, VA 22314.

The Center Program will be directed by Dr. Michael D. Shelby of the NIEHS, RTP, NC. Center support and scientific expertise will be provided through a contract with Sciences International, Inc. Alexandria, VA where Dr. John A. Moore is principal investigator on the project.

Dated: December 4, 1998.

Kenneth Olden,

Director, National Toxicology Program.

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