

U.S. Consumer Product Safety Commission, U.S. Department of Defense, U.S. Environmental Protection Agency, U.S. Food and Drug Administration's National Center for Toxicological Research, National Institutes of Health's (NIH) National Cancer Institute, National Center for Environmental Health, NIH's National Institute of Environmental Health Sciences (NIEHS), National Institute for Occupational Safety and Health, NIH's National Library of Medicine, and the Occupational Safety and Health Administration. The ICCEC meets once or twice annually to evaluate groups of new study nominations and to make recommendations with respect to both specific types of studies and testing priorities.

### Request for Public Comment

Interested parties are invited to submit written comments or supplementary information on the nominated substances and study recommendations that appear in the accompanying tables. The NTP welcomes toxicology and carcinogenesis study information from completed, ongoing, or anticipated studies, as well as information on current U.S. production levels, use or consumption patterns, human exposure, environmental occurrence, or public health concerns for any of the nominated substances. The NTP is also interested in identifying appropriate new animal and non-animal models for mechanistic based research, including genetically modified rodents, and as such, solicits comments regarding the use of specific *in vivo* and *in vitro* experimental models to address scientific questions relevant to the nominated substances or issues under consideration. All information received will be considered by the NTP in its continued review of these nominations. Comments or information should be sent to Dr. Scott Masten (contact information below) by September 15, 2003. Persons responding to this request should include their name, affiliation, mailing address, phone, fax, e-mail address and sponsoring organization (if

any) with the submission. Written submissions will be made available electronically on the NTP Web site as they are received.

An electronic copy of this announcement, Internet links to electronic versions of supporting documents for each nomination, and further information on the NTP and the NTP Chemical Nomination and Selection Process can be accessed through the NTP Web site: <http://ntp-server.niehs.nih.gov>.

Send comments or information to Dr. Scott A. Masten, Office of Chemical Nomination and Selection, NIEHS/NTP, PO Box 12233, MD A3-07, Research Triangle Park, North Carolina 27709; telephone: (919) 541-5710; Fax: (919) 541-3647; e-mail: [masten@niehs.nih.gov](mailto:masten@niehs.nih.gov).

### Background

The NTP actively seeks to identify and select for study chemicals and other agents for which sufficient information is not available to adequately evaluate potential human health hazards. The NTP accomplishes this goal through a formal open nomination and selection process. Substances considered appropriate for study generally fall into two broad yet overlapping categories: (1) Substances judged to have high concern as a possible public health hazard based on the extent of human exposure and/or suspicion of toxicity and (2) substances for which toxicological data gaps exist and additional studies would aid in assessing potential human health risks, *e.g.* by facilitating cross-species extrapolation or evaluating dose-response relationships. Input is also solicited regarding the nomination of studies that permit the testing of hypotheses to enhance the predictive ability of future NTP studies, address mechanisms of toxicity, or fill significant gaps in the knowledge of the toxicity of classes of chemical, biological, or physical substances. Substances may be studied to evaluate a variety of health-related effects, including but not limited to reproductive and developmental toxicity, genotoxicity, immunotoxicity, neurotoxicity, metabolism and

disposition, and carcinogenicity. In reviewing and selecting nominated substances, the NTP also considers legislative mandates that require responsible private sector commercial organizations to evaluate their products for health and environmental effects. The possible human health consequences of anticipated or known human exposure, however, remain the over-riding factor in the NTP's decision to study a particular substance.

The review and selection of substances nominated for study is a multi-step process. A broad range of concerns are addressed during this process through the participation of representatives from the NIEHS, other Federal agencies, the NTP Board of Scientific Counselors—an external scientific advisory body, the NTP Executive Committee—the NTP Federal interagency policy body, and the public. This process is described in further detail in a March 2, 2000 **Federal Register** announcement (Volume 65, Number 42, pages 11329–11331). This multi-step evaluative process provides the NTP with direction and guidance to ensure that its testing program addresses toxicological concerns relative to all areas of public health, and furthermore, that there is balance among the types of substances selected for study (*e.g.*, industrial chemicals, consumer products, therapeutic agents). As such, it should be recognized that at any given time, the new study nominations under consideration do not necessarily reflect the overall balance of substances historically or currently being evaluated by the NTP in its toxicology testing program. For further information on NTP toxicology studies (previous or in progress) visit the NTP Web site at <http://ntp-server.niehs.nih.gov>.

Dated: July 7, 2003.

**Samuel Wilson,**

*Deputy Director, National Institute of Environmental Health Sciences.*

**Substances Nominated to the NTP for Toxicological Studies and Recommendations Made by the ICCEC on June 10, 2003**