

NOMINATION OF SUBSTANCES FOR TOXICOLOGICAL STUDIES

Year 2006

The National Toxicology Program's (NTP) formal process for soliciting, reviewing and selecting substances for toxicological studies is integral to its effective operation and success. This process allows the NTP to best use its resources for testing substances of greatest public health concern using current methodologies, for developing and validating new testing methodologies, and for evaluating new concepts regarding mechanisms of toxicity.

Who Can Nominate a Substance for Study?

The NTP has an open nomination process that invites and encourages the nomination of chemicals and other substances for study from both the public and private sectors. NTP member agencies: the National Center for Toxicological Research (NCTR), the National Institute of Environmental Health Sciences (NIEHS), and the National Institute for Occupational Safety and Health (NIOSH), as well as other federal agencies are the primary sources for nominations. The NTP also welcomes study nominations from state agencies, private citizens, labor and industry groups, and academia. The NTP asks that each nomination (1) include the name of the substance, (2) identify the particular toxicological studies being recommended, and (3) provide a rationale for the nomination. The NTP also requests that the nomination include, when available, supporting background information on production, use, human exposure, environmental occurrence, and extent of available toxicological data. The NTP recognizes that some nominating individuals and organizations may not have the resources to provide all of the requested information. The NTP still welcomes the nomination and will consider all nominations received regardless of the extent of supporting information submitted.

How are Study Nominations Reviewed?

Each nomination goes through a review and selection process to prioritize substances for study. The NTP Office of Chemical Nomination and Selection reviews substances or issues nominated for study to determine which ones have been adequately investigated, which ones are already being studied or are scheduled for study, and which ones have been previously considered by the NTP for study, but deemed of low priority. The nominations next undergo interagency review by the Interagency Committee for Chemical Evaluation and Coordination. Preliminary study recommendations are then published in the Federal Register along with a request for additional relevant information and for public comment on the nominated substances and study recommendations. Next, the NTP Board of Scientific Counselors reviews the nominations and study recommendations and receives any additional public comments at an open, public meeting. Following this review the NTP Executive Committee evaluates the nominations and makes a recommendation to the NTP to study, not to study at this time, or to defer study until additional information is received and considered. Once a nomination is selected for study, an NTP project team develops a research program for the nomination and implements studies as time and resources permit.

What Factors are Considered in Selecting a Nomination for Study?

Substances selected for study generally fall into two broad overlapping categories, as follows:

1. Those substances or issues of greatest concern for public or occupational health based on the extent of human exposure and/or suspicion of toxicity.

2. Those substances or issues for which toxicological data gaps exist and additional studies would aid in assessing potential human health risks. Examples include studies performed to facilitate cross-species extrapolation or better define dose-response relationships.

Particular assistance is also sought for 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 chemicals. NTP studies are designed to address a variety of health-related effects including but not limited to reproductive and developmental toxicity, genotoxicity, immunotoxicity, neurotoxicity, metabolism, tissue disposition, and carcinogenicity. In evaluating and selecting nominations for study, the NTP also considers legislative mandates that require responsible private sector commercial organizations to evaluate their products for health and environmental effects. The possibility of adverse human health consequences from anticipated or known human exposure to a particular substance, however, remains the overriding factor in the NTP's decision to study a substance. The original nominating individual or organization is kept informed of the status of their nominations throughout the selection process and are informed of the results of each study conducted. For more detailed information on the NTP Chemical Nomination and Selection process, visit the NTP web site at <http://ntp.niehs.nih.gov>; select *Nominations to the Testing Program*.

How is Information about Studies Made Available?

Once the NTP initiates a study, this information is entered into a NTP database that is publicly accessible on the NTP web site at <http://ntp.niehs.nih.gov>, select *Testing Status of Agents at NTP*. The NTP Board of Scientific Counselors Technical Reports Review Subcommittee peer reviews the results of toxicology and carcinogenesis studies in an open public meeting. Once reviewed, these results are published as NTP Technical Reports and often also in the open scientific literature. The abstracts for all NTP studies and full reports for NTP Toxicity and Technical Reports are available on the NTP web site (<http://ntp.niehs.nih.gov>, select *NTP Study Reports*). The electronic files (PDFs) of these reports are publicly accessible free-of-charge.

Nominations for toxicological studies can be made through the NTP web site at <http://ntp.niehs.nih.gov>; select *Nominations to the Testing Program* and then select *Online Nomination Form*

For further information contact:

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