

Nomination of Substances for Toxicological Studies

Year 2003

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 chemicals and other 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 Food and Drug Administration (FDA), the National Institute of Environmental Health Sciences (NIEHS), and the National Institute for Occupational Safety and Health (OSHA), 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 document include, when available, supporting background information on production, use, human exposure, environmental occurrence, and extent of available toxicological data. The NTP recognizes that some potential nomination sources 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 NIEHS Nominations Faculty reviews nominations to determine which have been adequately tested, 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. The committee's study recommendations are 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 test, not to test at this time, or to defer testing until additional information is received and considered. Once a nomination is approved for testing, an NTP research 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 of greatest concern for public or occupational health based on the extent of human exposure and/or suspicion of toxicity; and
2. those substances for which toxicological data gaps exist and additional studies would aid in assessing potential human health risks. This would be done by facilitating cross-species extrapolation or evaluating 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. Substances may be studied for 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 substances 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-server.niehs.nih.gov/>, select *How to Nominate Substances*.

How is Study Information 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-server.niehs.nih.gov/>, select *NTP Study Information, Results and Status Search*. The NTP Board of Scientific Counselor 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/or in the open scientific literature. The abstracts for NTP reports are available on its web site (<http://ntp-server.niehs.nih.gov/>, select *NTP Study Information Abstracts*) and **ehpOnline** maintains the library of NTP Technical Reports and NTP Toxicity Reports and adds new reports as available. The electronic files (PDFs) of these reports are publicly accessible free-of-charge. There is a charge for printed reports. To gain access to these reports, contact ehpOnline at <http://ehp.niehs.nih.gov/> or e-mail ehpOnline at <http://ehp.niehs.nih.gov/> or call 866/541-3841 or 919/653-2595.

Nominations for toxicological studies should be addressed to: Dr. Scott Masten, Office of Chemical Nomination and Selection, NIEHS, P.O. Box 12233, MD A3-07, Research Triangle Park, NC, 27709; Phone: 919-541-5710 or Email: NTPNomin@niehs.nih.gov

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