

Total annual hour burden (for all respondents)	Union respondents ¹	Management respondents ²	Total costs
1250 minutes (21 hours total annually) ...	\$18.07/hour × 21 hour = \$379.47	\$42.94/hour × 21 hours = \$901.74	\$1281.21

¹ The average hourly wage was derived from BLS' "Employer Costs for Employee Compensation 4th Quarter 2004," from the hourly wage calculation across all occupations nationwide.

² The average management wage rate is derived from BLS' "General and operations managers" classification mean hourly wage estimates.

Request for Comments: In accordance with the Paperwork Reduction Act, comments on the FMCS RDT survey are requested with regard to any of the following:

(a) Whether the proposed collection of information is necessary for the proper performance of functions of the Agency, including whether the information will have practical utility;

(b) The accuracy of the Agency's estimate of the burden (including hours and costs) of the proposed collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and,

(d) Ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: April 29, 2005.

Scot Beckenbaugh,

Acting Director.

[FR Doc. 05-8915 Filed 5-4-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program; Office of Chemical Nomination and Selection; Announcement of and Request for Public Comment on Toxicological Study Nominations to the National Toxicology Program

AGENCY: National Institute of Environmental Health Sciences, National Institutes of Health.

ACTION: Notice; request for comments.

SUMMARY: The National Toxicology Program (NTP) continuously solicits and accepts nominations for toxicological studies to be undertaken by the program. Nominations of substances of potential human health concern are received from federal agencies, the public and other interested parties. These nominations are subject to several levels of review before

selections for testing are made and toxicological studies are designed and implemented. This notice (1) provides brief background information and study recommendations regarding 15 nominations for NTP study (Table 1), (2) solicits public comment on the nominations and study recommendations, and (3) requests the submission of additional relevant information for consideration by the NTP in its continued evaluation of these nominations. 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 Study Nomination and Review Process can be accessed through the NTP Web site (<http://ntp.niehs.nih.gov/>; select "Nominations to the Testing Program").

DATES: Comments or information should be submitted by June 6, 2005.

ADDRESSES: Send comments or information to Dr. Scott A. Masten, Office of Chemical Nomination and Selection, NIEHS/NTP, 111 T.W. Alexander Drive, P.O. Box 12233, Research Triangle Park, North Carolina 27709; telephone: (919) 541-5710; FAX: (919) 541-3647; e-mail:

masten@niehs.nih.gov. Supporting documents for these nominations are available at the NTP Web site (<http://ntp.niehs.nih.gov/> select "Nominations to the Testing Program").

FOR FURTHER INFORMATION CONTACT: See contact information for Dr. Masten under **ADDRESSES** above.

SUPPLEMENTARY INFORMATION:

Background Information on NTP Study Nominations and the NTP Office of Chemical Nomination and Selection

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 possible public health hazards 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. Nominations are also solicited for 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.

Study nominations may entail the evaluation of a variety of health-related effects including, but not limited to, reproductive and developmental toxicity, genetic toxicity, immunotoxicity, neurotoxicity, metabolism and disposition, and carcinogenicity in appropriate experimental models. In reviewing 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 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.

Nominations undergo a multi-step, formal process of review. During the entire nomination review and selection process, the NTP works actively with regulatory agencies, its advisors, and interested parties to supplement information about nominated substances and ensure that regulatory and public health needs are addressed. The nomination review and selection process is accomplished through the participation of representatives from the National Institute of Environmental Health Sciences (NIEHS), other federal agencies represented on the Interagency Committee for Chemical Evaluation and Coordination (ICCEC), the NTP Board of Scientific Counselors—an external scientific advisory body, the NTP Executive Committee—the NTP federal interagency policy body, and the public. Study recommendations are initially developed and refined by the nominator, NTP staff, and the ICCEC. Individual study recommendations for the nominations listed in Table 1 may be further refined as the formal review

process continues. The nomination review and selection process is described in further detail on the NTP Web site (<http://ntp.niehs.nih.gov/>; select "Nominations to the Testing Program").

The NTP Office of Chemical Nomination and Selection (OCNS) manages the solicitation, receipt, and review of NTP toxicology study nominations. The OCNS conducts an initial review of each study nomination received to determine whether the substance or issue has been adequately studied or has been previously considered by the NTP. For nominations not eliminated from consideration or deferred at this stage, the OCNS initiates a formal review process, as described above. The OCNS also ensures adequate background information is available to support the review for each nomination. For further information on the OCNS visit the NTP Web site (<http://ntp.niehs.nih.gov> select "Nominations

to the Testing Program") or contact Dr. Masten (see **ADDRESSES** above).

Request for Comments and Additional Information

The NTP invites interested parties to submit written comments or supplementary information on the nominated substances and study recommendations that appear in Table 1. 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 interested in identifying appropriate, novel, animal and non-animal experimental models for mechanistic-based research, including genetically modified rodents and higher-throughput in vitro test methods, and as such, solicits comments regarding the use of

specific in vivo and in vitro experimental approaches to address questions relevant to the nominated substances and issues under consideration. The NTP will not respond to submitted comments; however, all information received will become part of the official record that the NTP considers in its ongoing review of these nominations. Persons submitting comments 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 publicly available electronically on the NTP Web site as they are received (<http://ntp.niehs.nih.gov/> select "Nominations to the Testing Program").

Dated: April 22, 2005.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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Table 1. Study Recommendations for Substances Nominated to the NTP for Toxicological Studies

Substance [CAS No.]	Nominated by	Rationale for Nomination	Study Recommendations*
Acetyl-L-carnitine hydrochloride [5080-50-2] and α -Lipoic acid [62-46-4]	National Cancer Institute	Consumer exposure through increasing dietary supplement use; lack of adequate toxicological data	-Subchronic toxicity studies (individual and combination studies)
Antimony trioxide [1309-64-4]	National Institute of Environmental Health Sciences	Significant human exposure in occupational settings and lack of adequate two-year exposure carcinogenicity studies	-Chronic toxicity and carcinogenicity studies -Cardiotoxicity studies
Antimony trisulfide [1345-04-6]	National Cancer Institute	Significant human exposure in occupational settings and suspicion of carcinogenicity	No additional studies at this time due to presumed lower workplace exposures relative to other antimony compounds
4-Bromofluorobenzene [460-00-4]	National Institute of Environmental Health Sciences	High production volume and use; lack of adequate toxicological data; suspicion of toxicity based on chemical structure	Defer pending review of anticipated submissions on exposure and toxicity information to the U.S. Environmental Protection Agency and possible sponsorship in the High Production Volume Challenge Program
Butylparaben [94-26-8]	National Institute of Environmental Health Sciences	Widespread use in foods, cosmetics, and pharmaceuticals; potential reproductive toxicant; lack of adequate toxicological data	-Toxicological characterization including reproductive toxicity studies
2,6-Diaminopyridine [141-86-6]	National Cancer Institute	Moderate production and industrial use; lack of adequate toxicological data	Defer pending review of additional information on uses and potential exposure from hair dyes
1,3-Dichloropropanol [96-23-1]	National Institute of Environmental Health Sciences	High production volume and use; occurrence in foods; reproductive toxicity and carcinogenicity demonstrated but not adequately characterized	-Toxicological characterization -Metabolism and disposition studies -Reproductive toxicity studies -Carcinogenicity studies -Coordinate studies with voluntary data development activities of the U.S. Environmental Protection Agency
2,5-Dimercapto-1,3,4-thiadiazole [1072-71-5]	Chemonics Industries, Inc.	Component of wildland fire retardant formulations; moderate production and industrial use; lack of adequate toxicological data	-Genotoxicity studies -Metabolism and disposition studies -Subchronic toxicity studies
3-Dimethylaminopropylamine [109-55-7]	National Cancer Institute	Significant and increasing use in personal care products; widespread industrial use; lack of information on chronic toxicity; evidence of toxicity in exposed workers	- <i>In vitro</i> genotoxicity studies (in combination with a nitrosating agent) -Dermal absorption and metabolism studies with focus on nitrosamine formation

Substance [CAS No.]	Nominated by	Rationale for Nomination	Study Recommendations*
<i>Garcinia cambogia</i> extract [90045-23-1]	National Cancer Institute	Consumer exposure through increasing dietary supplement use; lack of adequate toxicological data	Defer pending further review of recently published studies
Gum guggul extract [No CAS No.]	National Institute of Environmental Health Sciences	Consumer exposure through increasing dietary supplement use; demonstrated metabolic and hormonal effects; lack of adequate toxicological data	-Toxicological characterization
Imidazolidinyl urea [39236-46-9]	National Cancer Institute	Widely used preservative in personal care products; mutagenic potential; lack of adequate carcinogenicity data	-Genotoxicity studies -Dermal absorption studies -Evaluation of potential degradation products (e.g., diazolidinyl urea and formaldehyde)
Permanent makeup inks [No CAS No.]	U.S. Food and Drug Administration	Rapidly growing practice in the United States; lack of adequate toxicological data; numerous human adverse event reports	For representative Premier Products True Color pigments: - <i>In vitro</i> and <i>in vivo</i> allergenicity, photoallergenicity, and phototoxicity studies -Chemical characterization studies
Usnic acid [125-46-2] and <i>Usnea</i> herb [No CAS No.]	U.S. Food and Drug Administration	Widely used in dietary supplement and personal care products; lack of adequate toxicological data; numerous human adverse event reports	-Toxicological characterization including genotoxicity, pharmacokinetic, and developmental and reproductive toxicity studies - <i>In vitro</i> mitochondrial toxicity studies
Vincamine [1617-90-9]	National Cancer Institute	Consumer exposure through dietary supplement use; suspicion of toxicity; lack of adequate toxicological data	-Integrate into current NTP research program on QT interval prolongation

* The term "toxicological characterization" in this table includes studies for genotoxicity, subchronic toxicity, and chronic toxicity/carcinogenicity as determined to be appropriate during the conceptualization and design of a research program to address toxicological data needs. Though other types of studies (e.g., metabolism and disposition, immunotoxicity, and reproductive and developmental toxicity) may be conducted as part of a complete toxicological characterization, these types of studies are not listed unless they are specifically recommended.