NICEATM prefers data to be submitted as copies of pages from applicable study notebooks and/or study reports, if available. Each submission for a chemical should preferably include the following information, as appropriate:

- Common and trade name
- Chemical Abstracts Service Registry Number (CASRN)
- Chemical and/or product class
- Commercial source
- Rabbit skin/eye test protocol used
- Human skin/eye test protocol used
- Individual animal/human responses at each observation time
- The extent to which the study complied with National or International Good Laboratory Practice (GLP) guidelines
- Date and testing organization

Those persons submitting data on chemicals tested for skin and/or ocular irritancy in rabbits are referred to the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) Report No. 66: Skin Irritation and Corrosion: Reference Chemicals Data Bank (March 1995) and ECETOC Technical Report No. 48: Eye Irritation: Reference Chemicals Data Bank (Second Edition, June 1998), respectively, for examples of the experimental animal study information and data that are requested in this notice. Both reports may be ordered from the ECETOC Web site at: *http://www.ecetoc.org.* Those persons submitting data on chemicals tested for skin irritation in humans are referred to Phillips, *et al.* (1972) for examples of the types of human study information and data that are requested in this notice.

The NICEATM will compile information and test data received by the deadline for consideration by ICCVAM and the ICCVAM Dermal Corrosivity and Irritancy Working Group (DCIWG). These groups will review the data and identify chemicals that might be appropriate for use in the upcoming validation study on *in vitro* test methods for dermal irritation.

Background Information on ICCVAM and NICEATM

ICCVAM was established in 1997 by NIEHS to coordinate the interagency evaluation of proposed new and alternative test methods, and to coordinate cross-agency issues relating to the validation, acceptance, and national/international harmonization of toxicological testing methods. Composed of representatives from fifteen Federal regulatory and research agencies that use or generate toxicological information, ICCVAM promotes the scientific validation and regulatory acceptance of toxicological test methods that improve agencies' ability to make decisions on health risks, while refining, reducing, and replacing animal use wherever possible. ICCVAM was authorized as a permanent interagency committee of the NIEHS, under the NICEATM, on December 19, 2000, through passage of the ICCVAM Authorization Act of 2000 (Pub. L. 106–545, available at *http://iccvam.niehs.nih.gov/PL106545.htm*). Pub. L. 106–545 directs the ICCVAM to coordinate the technical review of new, revised, and alternative test methods of interagency interest. NICEATM provides operational and scientific support for ICCVAM and ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found at the following Web site: *http://iccvam.niehs.nih.gov.*

References

EPA. 1998a. Health Effects Test Guidelines, OPPTS 870.2500, Acute Dermal Irritation, EPA 712–C–98–196. Available: *http://www.epa.gov/opptsfrs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Drafts/870–2400.pdf.*

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OECD. 2001. Harmonized Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures [ENV/JM/MONO(2001)6] Available: *http://www.oecd.org.*

Phillips L, Steinberg M, Maibach HI, Akers WA. 1972. A comparison of rabbit and human skin response to certain irritants. Toxicology and Applied Pharmacology. Mar; 21(3): 369–82.

Dated: July 9, 2003.

Samuel Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; Announcement of and Request for Public Comments on Substances Nominated to the National Toxicology Program (NTP) for Toxicological Studies and Study Recommendations Made by the NTP Interagency Committee for Chemical Evaluation and Coordination (ICCEC)

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. Evaluation by the NTP Interagency Committee for Chemical Evaluation and Coordination (ICCEC) is the initial external review step in the NTP's formal selection process for NTP study nominations. On June 10, 2003, the ICCEC met to review 14 new nominations and make study recommendations. This announcement (1) Provides brief background information regarding the substances nominated to the NTP for study, (2) presents the ICCEC's study recommendations from its June 10, 2003 meeting, (3) solicits public comment on the nominations and study recommendations, and (4) requests the submission of additional relevant information for consideration by the NTP in its continued evaluation of these nominations.

Review of Study Nominations

Evaluation by the ICCEC is the initial external step in the NTP's formal selection process for NTP study nominations. At it's meeting on June 10, 2003, the ICCEC reviewed 14 new nominations for NTP studies. For 13 of these nominations, the ICCEC recommended one or more types of toxicological studies, and for one nomination, no studies were recommended at this time. The nominated substances with CAS numbers, nomination source, nomination rationale, and specific study recommendations are given in the accompanying tables.

The ICCEC is composed of representatives from the Agency for Toxic Substances and Disease Registry,

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.*

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 it's 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 it's 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

TABLE 1.—SUBSTANCES RECOMMENDED FOR STUDY

Substance [CAS No.]	Nominated by	Nomination rationale	Recommendations for toxicological studies
Acrylamide [79–06–1] and Glycidamide [5694–00–8].	U.S. Food and Drug Administration.	Inadequate information available to accurately assess human health risks from exposure to acrylamide in foodstuffs; a properly designed well-conducted, GLP-compliant bioassay with appropriate ancillary studies is needed to provide dose-response information and account for the food matrix through which humans are exposed.	—Toxicological characterization. —Toxicokinetics. —Mechanistic (hemoglobin adducts). —Carcinogenicity. —Bioavailability from food and drinking water.
Antimony trisulfide [1345–04–6]	National Cancer Institute.	Significant human exposure in occupational settings and suspicion of carcinogenicity.	Chronic toxicity/carcinogenicity.
Cadmium telluride [1306–25–8]	U.S. Department of Energy, Brookhaven National Laboratory, National Renewable Energy Laboratory, First Solar, Inc.	Potential for widespread applications in photovoltaic energy generation; anticipated increase in human exposures; further data needed to address health and safety issues related to manufacture and use.	—Toxicological characterization. —Chemical disposition (oral and inhalation routes).
Cedarwood oil, Virginia [8000–27–9].	National Cancer Institute	Widespread occupational and consumer exposure; lack of basic toxicology data.	—Toxicological characterization. —Developmental toxicity.
Chondroitin sulfate [9007–28–7]	National Cancer Institute	Widespread long-term use as a dietary supplement and inadequate data to assess safety.	—Chronic toxicity/carcinogenicity. —Carcinogenicity of chondroitin sulfate and glucosamine combined.
Dimethylethanolamine [108–01–0]	National Institute of Environmental Health Sciences.	Potential for widespread human exposure through its use in industrial and consumer products; inadequate toxicological database; some ethanolamines can interfere with choline uptake and utilization and may also generate nitrosamines.	—Metabolism.
Drugs positive for QT Interval Prolongation/Induction of *Torsade* Proarrhythmia [No CAS No.].	U.S. Food and Drug Administration.	QT interval prolongation and *torsade de pointes* is a high priority cause for concern in drug development and regulatory safety evaluation; a clear definition of the strengths, limitations, and future performance characteristics of the canine telemetry model for pre-clinical safety assessment is needed.	—Initiate a study program to develop *in vitro* and *in vivo* test systems for assessing QT interval prolongation.
Glucosamine [3416–24–8]	National Cancer Institute	Widespread long-term use as a dietary supplement and inadequate data to assess safety.	—Chronic toxicity/carcinogenicity. —Carcinogenicity of chondroitin sulfate and glucosamine combined.
Nanoscale materials. [No CAS No.].	Rice University Center for Biological and Environmental Nanotechnology.	Intense current and anticipated future research and development focus; further studies and development of appropriate toxicological methods are needed to adequately assess health effects.	—Size—and composition—dependent biological disposition of nanocrystalline fluorescent semiconductor materials. —Toxicological characterization of high aspect ratio carbon nanomaterials. —Role of particle core and surface composition in the immunotoxicity of the above listed materials. —Phototoxicity of representative metal oxide nanoparticles.

TABLE 1.—SUBSTANCES RECOMMENDED FOR STUDY—Continued

Substance [CAS No.]	Nominated by	Nomination rationale	Recommendations for toxicological studies
trans—Resveratrol [501–36–0]	National Institute of Environmental Health Sciences.	Widespread human exposure from natural dietary sources and use of dietary supplements; suspicion of toxicity based on estrogenic and genotoxic activity; insufficient data available to characterize safety.	—Toxicological characterization. —Carcinogenicity. —Reproductive toxicity.
Tetrabromobisphenol A [79–94–7]	National Institute of Environmental Health Sciences.	High production volume; widespread human exposure and suspicion of thyroid toxicity/tumorigenicity.	—Toxicological characterization. —Neurodevelopmental toxicity. —Carcinogencity.
Tetrabromobisphenol A bis(2,3-dibromopropyl ether) [21850–44–2].	National Institute of Environmental Health Sciences.	High production volume; little toxicity data available; suspicion of carcinogenic potential due to 2,3-dibromo-1-propanol substructure.	—Toxicological characterization. —*In vivo* genotoxicity. —Metabolism. —Carcinogenicity.
Tungsten [7440–33–7]	National Center for Environmental Health.	Important industrial materials; insufficient data to assess human health implications of elevated urinary tungsten levels.	—Toxicological characterization. —Carcinogenicity. —Studies should focus on a representative soluble tungsten compound.

TABLE 2.—SUBSTANCE FOR WHICH NO STUDY IS RECOMMENDED AT THIS TIME

Substance [CAS No.]	Nominated by	Nominated for	Nomination rationale	Rationale for recommending no toxicological studies
4-Phenylcyclohexene [4994–16–5].	Private Individuals	—Toxicological characterization including genotoxicity and neurotoxicity.	Present in indoor environments primarily from carpet emissions; concern that it has not been adequately tested for potential health effects.	Low suspicion of hazard based on available human exposure and toxicity information.

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Citizenship and Immigration Services

[CIS No. 2279–03]

RIN 1615–AA04

Extension of the Designation of El Salvador Under Temporary Protected Status Program; Automatic Extension of Employment Authorization Documentation for El Salvador

AGENCY: Bureau of Citizenship and Immigration Services, Homeland Security.

ACTION: Notice.

SUMMARY: The designation of El Salvador under the Temporary Protected Status (TPS) Program will expire on September 9, 2003. This notice extends the Secretary of Homeland Security's designation of El Salvador for 18 months until March 9, 2005, and sets forth procedures necessary for nationals of El Salvador (or aliens having no nationality who last habitually resided in El Salvador) with TPS to re-register and to apply for an extension of their employment authorization documentation for the additional 18-month period. Re-registration is limited to persons who registered under the initial designation (which ended on September 9, 2002) and also timely re-registered under the extensions of designation. Certain nationals of El Salvador (or aliens having no nationality who last habitually resided in El Salvador) who previously have not applied for TPS may be eligible to apply under the late initial registration provisions.

Given the large number of Salvadorans affected by this notice, the Department of Homeland Security (DHS) recognizes that many re-registrants will not receive their new Employment Authorization Documents (EADs) until after their current EADs expire on September 9, 2003. Accordingly, this notice automatically extends, until March 9, 2004, the validity of EADs issued pursuant to the El Salvador TPS program, and explains how TPS beneficiaries or their employers may determine which EADs are automatically extended.

EFFECTIVE DATES: The extension of El Salvador's TPS designation is effective September 9, 2003, and will remain in effect until March 9, 2005. The 60-day re-registration period begins July 16, 2003 and will remain in effect until September 15, 2003.

FOR FURTHER INFORMATION CONTACT: Jonathan Mills, Department of Homeland Security, Bureau of Citizenship and Immigration Services, 425 ''I'' Street, NW., Room 3040, Washington, DC 20536, telephone (202) 514–4754.

SUPPLEMENTARY INFORMATION:

What Authority Does the Secretary of the Homeland Security Have To Extend the Designation of El Salvador Under the TPS Program?

On March 1, 2003, the functions of the Immigration and Naturalization Service (Service) transferred from the Department of Justice to the Department of Homeland Security (DHS) pursuant to the Homeland Security Act of 2002,