Dated: July 18, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

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 undergo several levels of review before selections for testing are made and toxicological studies are designed and implemented. The NTP Interagency Committee for Chemical Evaluation and Coordination (ICCEC) serves as the first level of review for NTP nominations. At the 8 May 2001 ICCEC meeting, 13 new nominations were reviewed and testing recommendations were made. To inform the public and to obtain input for consideration when selecting chemicals for toxicological evaluation, the NTP routinely seeks public comment on the nominated substances and the ICCEC's testing recommendations. This announcement (1) provides brief background information regarding the substances nominated to NTP for study, (2) presents the ICCEC's testing recommendations from its 8 May 2001 meeting, (3) solicits public comment on the nominations and recommendations, and (4) requests the submission of additional relevant information for consideration by the NTP in its continued evaluation of these nominations.

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 chemical nomination and selection process. Substances selected for study generally fall into two broad overlapping categories: (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) 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. 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 and disposition, and carcinogenicity. In evaluating 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 chemical or agent.

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 Federal agencies, the NTP Board of Scientific Counselors—an external scientific advisory body, the NTP Executive Committee—the NTP Federal interagency policy body, and a public comment period. This process is described in further detail in a 2 March 2000 **Federal Register** announcement (Volume 65, Number 42, pages 11329–11331). This multi-step evaluative process provides the NTP 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, etc.). As such, it should be recognized that for any given committee review, the new testing nominations under consideration do not necessarily reflect the overall balance of substances historically or currently being evaluated by NTP in it's testing program. For further information on NTP studies (previous or in progress) visit the NTP web site at *http://ntp-server.niehs.nih.gov.*

Nominated Substances and Interagency Review

The ICCEC is composed of representatives from the Agency for Toxic Substances and Disease Registry, Consumer Product Safety Commission, Department of Defense, Environmental Protection Agency, Food and Drug Administration's National Center for Toxicological Research, National Cancer Institute, National Institute of Environmental Health Sciences, National Institute for Occupational Safety and Health, National Library of Medicine, and the Occupational Safety and Health Administration. The ICCEC meets once or twice annually to evaluate groups of new nominations and to make testing recommendations with respect to both specific types of studies and testing priorities. At its meeting on 8 May 2001, the ICCEC reviewed 13 new nominations for NTP studies. For eight of these nominations, one or more types of testing was recommended, and for three nominations, no testing was recommended at this time. A testing recommendation for two nominations was deferred pending receipt of (1) additional information or data from the nominator or other organizations on related studies completed, anticipated or in progress, or (2) additional information on production, human exposure, use patterns, or regulatory needs. The nominated substances with CAS numbers, nomination source, nomination rationale, specific study recommendations, and other information are given in the attached tables.

Request for Public Comment

Interested parties are invited to submit comments or supplementary information on the nominated substances and recommendations identified in the attached tables. The NTP would welcome receiving toxicology and carcinogenesis information from completed, ongoing, or planned studies, as well as information on current production levels, use patterns, human exposure, environmental occurrence, or public health concerns for any of the nominated substances. Comments or information should be sent to Dr. Scott Masten at the address given below through September 24, 2001. Persons responding to this request are asked to include their name, affiliation, mailing address, phone, fax, e-mail address and sponsoring organization (if any) with

the submission. An electronic copy of this announcement as well as 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.*

Contact may be made by mail to Dr. Scott Masten, Office of Chemical Nomination and Selection, NIEHS/NTP, P.O. Box 12233, Research Triangle Park, North Carolina 27709; by telephone at (919) 541–5710; by FAX at (919) 558–7067; or by email to masten@niehs.nih.gov.

Dated: June 14, 2001.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

Substances Nominated to the NTP for Toxicological Studies and Testing Recommendations Made by the ICCEC on 8 May 2001

TABLE 1.—SUBSTANCES RECOMMENDED FOR TESTING

Substance [CAS No.]	Nominated by	Nomination rationale; other information	ICCEC recommendations for toxicological studies
Bladderwrack [68917–51–1] [84696–13–9]	National Cancer Institute	Significant human exposure through use as a dietary supplement; safety concern due to potential thyroid stimulation; limited available toxicity information.	—Chemical characterization (iodine content). —Subchronic toxicity testing with evaluation of reproductive parameters.
Cylindrospermopsin [14345–90–8]	National Institute of Environmental Health Sciences.	Cyanobacterial toxin with potential for widespread human exposure through drinking water; high acute toxicity; limited available toxicity information.	—Complete toxicological characterization including chronic toxicity and carcinogenicity testing.
Epigallocatechin-3-gallate [989–51–5].	National Cancer Institute	Major polyphenol in green tea and green tea extract dietary supplements; potential chemopreventive agent; limited available toxicity information.	—Genotoxicity testing. —Subchronic toxicity testing. —Consider testing green tea extract.
2-Ethylhexyl-p-dimethylaminobenzoic acid [21245–02–3].	Private Individual	High production volume chemical with industrial and consumer (sunscreen) uses; evidence for phototoxicity and testicular toxicity; limited available toxicity information.	—Subchronic toxicity and developmental and reproductive toxicity testing by the dermal route of exposure. —Phototoxicity and photocarcinogenicity testing.
Grape seed and pine bark extracts	National Cancer Institute	Significant human exposure through use as a dietary supplement; limited available toxicity information.	—Genotoxicity testing. —Subchronic toxicity testing. —Developmental and reproductive toxicity testing. —Select a standardized commercial pine bark extract for study.
Metalworking fluids	National Institute for Occupational Safety and Health.	High production volume; large number of occupationally-exposed workers; lack of carcinogenicity and chronic toxicity data.	—In vitro, short-term in vivo and subchronic toxicity studies aimed at evaluating toxicity and carcinogenicity potential of multiple commercial formulations. —The ICCEC will make recommendations regarding further testing after reviewing the results of NTP preliminary studies.
Methyl tetrahydrofuran [96–47–9]	National Cancer Institute	Increasing use in alternative fuels; suspicion of toxicity and carcinogenicity based on structure; limited available toxicity information.	—Genotoxicity testing —Short-term toxicity testing. —Consider dermal and inhalation routes of exposure.
Polybrominated diphenyl ethers .... Pentabromodiphenyl ether (technical) [32534–81–9] Octabromodiphenyl ether (technical) [32536–52–0] 2,2',4,4'-Tetrabromodiphenyl ether [5436–43–1] 2,2',4,4',5-Pentabromodiphenyl ether [60348–60–9] 2,2',4,4',5,5'-Hexabromodiphenyl ether [68631–49–2]	Private Individuals, California Environmental Protection Agency.	High production volume flame retardants; widespread human exposure occupationally and as environmental contaminants; persistent and bioaccumulative; evidence for toxicity but significant knowledge gaps remain.	—Subchronic toxicity, developmental neurotoxicity and chronic toxicity testing of selected individual congeners —No testing of technical mixtures.

TABLE 2.—SUBSTANCES FOR WHICH NO TESTING IS RECOMMENDED AT THIS TIME

Substance [CAS No.]	Nominated by	Nominated for	Nomination rationale; other information	ICCEC rationale for not recommending toxicological studies
Apigenin [520–36–5]	National Cancer Institute ..	—Genotoxicity testing ..... —Developmental toxicity testing.	Naturally occurring flavonoid with potential oxidant and estrogenic activity; lack of toxicity information.	Insufficient toxicity and exposure potential.
Dibenzofuran [132–64–9] ..	National Cancer Institute ..	—Genotoxicity testing ..... —Carcinogenicity testing.	Widespread human exposure as an environmental contaminant; potential for carcinogenicity; lack of toxicity information.	Low commercial production volume; low potential for human exposure.
Diphenolic acid [126–00–1]	National Cancer Institute ..	—Genotoxicity testing ..... —Subchronic toxicity testing.	Industrial chemical potential for increasing use; structurally related bisphenol A; lack of toxicity information.	Low commercial production volume; low potential for human exposure.

TABLE 3.—SUBSTANCES FOR WHICH A TESTING RECOMMENDATION IS DEFERRED PENDING RECEIPT AND CONSIDERATION OF ADDITIONAL INFORMATION

Substance [CAS No.]	Nominated by	Nominated for	Nomination rationale; other Information	Additional information needed
n-Butyl bromide [109–65–9].	National Cancer Institute ..	—Subchronic toxicity testing. —Reproductive toxicity testing.	Industrial chemical with significant production volume and human exposure potential; mutagenic; potential for carcinogenicity; lack of toxicity information.	Manufacturers' voluntary testing plans.
Methyl soyate [67784–80–9].	National Cancer Institute ..	—Genotoxicity testing ..... —Subchronic toxicity testing by the dermal route of exposure.	Increasing production volume as an alternative fuel (biodiesel); lack of toxicity information.	Toxicity data development plans through existing or future regulatory programs.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4649–N–16]

Notice of Proposed Information Collection for Public Comment; Environmental Review Procedures for Entities Assuming HUD Environmental Responsibilities

AGENCY: Office of the Assistant Secretary for Community Planning and Development (HUD).

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* September 24, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Sheila Jones, Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street, SW., Room 7232, Washington, DC 20410–7000.

FOR FURTHER INFORMATION CONTACT: Richard H. Broun, Director, Office of Community Viability, Department of Housing and Urban Development, Room 7240, 451 Seventh Street, SW., Washington, DC 20410–7000. For telephone communication, contact Walter Prybyla, Deputy Director for Policy, Environmental Review Division, (202) 708–1201 x4466 or e-mail: *Walter_Prybyla@hud.gov.* This phone number is not toll-free. Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Environmental Review Procedures for Entities