Non-Asbestiform) changes on the agenda from number seven to number six; and Estrogens, Steroidal changes from number five to number seven for review. Summary data and the revised, preliminary order for review of the nominations are listed in the table below:

SUMMARY DATA FOR NOMINATIONS TO BE REVIEWED AT THE MEETING OF THE NTP BOARD OF SCIENTIFIC COUNSELORS' REPORT ON CARCINOGENS SUBCOMMITTEE—DECEMBER 13, 14, & 15, 2000

Nomination to be reviewed/cas number	Primary uses or exposures	To be reviewed for	Tentative review order
Broad Spectrum UV Radiation and UVA, UVB and UVC.	Solar and artificial sources of ultraviolet radiation	Listing in the 10th Report.	1
Chloramphenicol/(56–75–7)	Used widely as an antibiotic since the 1950s	Listing in the 10th Report.	5
Estrogens, Sterodial	Estrogens are widely used in post-menopausal therapy and in oral contraceptives for women.	Listing in the 10th Report.	7
Metallic Nickel & Nickel Alloys	Widely used in commercial applications for over 100 years.	Listing in the 10th Report.	4
Methyleugenol/(93–15–2)	Flavoring agent used in jellies, baked goods, nonalcholoic beverages, chewing gum, candy, and ice cream. Also used as a fragrance for many perfumes, lotions, detergents and soaps.	Listing in the 10th Report.	3
Talc/(14807–96–6) (Asbestiform and (Non-Asbestiform).	Asbestiform talc (i.e. talc containing Asbestiform fibers) occurs in various geological settings around the world. Occupational exposure occurs during mining, milling and processing. Non-asbestiform talc (i.e. talc not containing asbestiform fibers) occurs in various geological settings around the world. Occupational exposure occurs during mining, milling and processing. Exposure to general population occurs through use of products such as cosmetics.	Listing in the 10th Report.	6
Trichloroethylene (TCE)/(79–01–6)	Trichloroethylene is widely used as a solvent with 80–90% used worldwide for degreasing metals.	Upgrade to Known	2
Wood Dust	It is estimated that at least two million people are routinely exposed occupationally to wood dust worldwide. Non-occupational exposure also occurs. The highest exposures have generally been reported in wood furniture and cabinet manufacturer, especially during machine sanding and similar operations.	Listing in the 10th Report.	8

The RoC Subcommittee will provide separate recommendations for each of the agents, substances, mixtures or exposure circumstance listed in the table above. This includes separate recommendations for Broad Spectrum UV Radiation and for UVA, for UVB, and for UVC; for Metallic Nickel and for Nickel Alloys, and for Talc Asbestiform and for Talc Non-Asbestiform.

The agenda and a roster of Subcommittee members is available on the NTP web homepage at *http://ntp-server.niehs.nih.gov/* and upon request from Dr. Wolfe (Dr. Mary S. Wolfe, P.O. Box 12233, A3–07, Research Triangle Park, NC 27709 (telephone 919/541–3971; FAX 919/541–0295; email wolfe@niehs.nih.gov). Summary minutes for the previous meeting are available on the NTP web homepage and upon request from Dr. Wolfe.

Dated: November 21, 2000.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; 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 (ICCEC)

Summary

The National Toxicology Program (NTP) routinely solicits, accepts and reviews for consideration nominations for toxicological studies to be undertaken by the Program on substances of potential human health concern. Nominations are solicited widely from Federal agencies, the public, and other interested parties and those received undergo several levels of review before 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 October 27, 2000 ICCEC meeting, 18 new nominations were reviewed and testing recommendations were made. As part of an effort to inform the public and to obtain input for consideration when selecting chemicals for evaluation, the NTP routinely seeks public comment on (1) substances nominated to the Program for toxicological studies and (2) the testing recommendations made by the ICCEC. This announcement provides brief background information about the nomination of substances for NTP study; presents the ICCEC's testing recommendations from the October 27, 2000 meeting; solicits public comment on those nominations and recommendations; and requests the submission of additional relevant information for consideration by the NTP in its subsequent evaluation of the nominations.

Background

The NTP actively seeks to identify and select for study chemicals and agents with the highest potential for

adversely impacting public health. The nomination process is open to all interested parties and 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 suspicion of toxicity; and (2) substances for which toxicological data gaps exist and additional studies would aid in assessing potential human health risks by facilitating cross-species extrapolation and evaluation of 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 chemicals or 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, metabolism and disposition, as well as carcinogenicity. Selections for NTP testing also consider legislative mandates that require responsible manufacturers to evaluate their own chemicals or agents for health and environmental effects. The possible human health consequences of anticipated or known human exposure, however, remain the over-riding factor in the decision to study a particular chemical or agent.

The review and selection of substances nominated for study is a multi-level 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 March 2, 2000 **Federal Register** Announcement (Volume 65, Number 42, pages 11329–11331). As a result of this multi-step evaluative process for NTP nominations, the Program receives appropriate 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 must be recognized that for any given committee review, the substances being considered for new testing 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 page at the URL listed at the end of this announcement.

Nominated Substances and ICCEC Review

The NTP Interagency Committee for Chemical Evaluation and Coordination (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. As part of the review and selection process for nominations, the ICCEC meets once or twice annually to review and evaluate the nominations and to make testing recommendations with respect to both specific types of studies and testing priorities. At its meeting on October 27, 2000, the ICCEC reviewed 18 new nominations for NTP studies. For 15 of these nominations, pharmacokinetic, toxicity, and/or carcinogenicity studies were recommended. A testing recommendation for three 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, exposure, use patterns, and regulatory needs. The nominated substances with CAS numbers, nomination source, types of studies recommended, study rationale and other information are given in the attached tables.

Request for Comment

Interested parties are encouraged to provide comments or supplementary information on the nominated substances and recommendations identified in this announcement. The NTP would welcome receiving toxicology and carcinogenesis information from completed, ongoing, or planned studies, as well as information on current production levels, human exposure, use patterns, environmental occurrence, or public health concerns for any of the substances listed in the attached tables. Comments or information should be sent to Dr. Scott Masten at the address given below within 60 days of the publication date of this announcement. 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. The URL for the NTP homepage is http://ntp-server.niehs.nih.gov.

Contact may be made by mail to Dr. Scott Masten, 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: November 20, 2000.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

Attachment—Substances Nominated to the NTP for Study and Testing Recommendations Made by the ICCEC on October 27, 2000

TABLE 1.—SUBSTANCES RECOMMENDED FOR TESTING

Substance [CAS Number]	Nominated by	ICCEC recommendations	Study rationale; other information
Aluminum complexes found in drinking water, Aluminum fluoride, [7784–18–1], Aluminum citrate, [31142–56–0].	Environmental Protection Agency; National Institute of Environmental Health Sciences.	Long-term drinking water studies to address pharmacokinetics, neurotoxicity, bone development, and reproduction and developmental toxicity. —Consider testing in transgenic animal models of neurodegenerative disease.	Drinking water contaminants with a high health research priority; known neurotoxicity of aluminum; need for better understanding of pharmacokinetics and toxicity of aluminum species occurring in drinking water.

TABLE 1.—SUBSTANCES RECOMMENDED FOR TESTING—Continued

Substance [CAS Number]	Nominated by	ICCEC recommendations	Study rationale; other information
Bilberry fruit extract, [84082–34–8].	National Cancer Institute	—*In vitro* and *in vivo* genotoxicity testing ..	Widespread human exposure through use as a dietary supplement; lack of toxicity information.
Black cohosh, [84776–26–1].	National Cancer Institute; National Institute of Environmental Health Sciences.	—Subchronic toxicity testing in young and aged female animals. —Two-generation reproductive and developmental toxicity study.	Widespread human exposure through use as a dietary supplement; reported estrogenic activity; inadequate toxicity information.
Blue-Green algae (dietary supplements and selected toxins).	National Cancer Institute	—Subchronic toxicity and neurotoxicity studies of commercial blue-green algae dietary supplements. —Consider testing specific cyanobacterial toxins pending results of Blue-Green algae dietary supplement and microcystin-LR studies.	Widespread human exposure through drinking water and via contamination of algal dietary supplements; demonstrated acute toxicity but only limited chronic toxicity information available.
Cefuroxime, [55268–75–2]	Food and Drug Administration.	—Genotoxicity testing (Syrian hamster embryo *in vitro* cell transformation assay; *in vivo* micronucleus assay).	Prescription drug with widespread and potentially long-term use; lack of chronic toxicity data for any member of this class of drugs.
Clarithromycin, [81103–11–9].	Food and Drug Administration.	—Genotoxicity testing (Syrian hamster embryo *in vitro* cell transformation assay; *in vivo* micronucleus assay).	Prescription drug with widespread and potentially long-term use; numerous known toxicities in short-term studies; lack of chronic toxicity data.
D&C Red No. 27, [13473–26–2] and D&C Red No. 28, [18472–87–2].	Food and Drug Administration.	—*In vitro* percutaneous absorption testing —Photocarcinogenicity testing dependent on results of absorption studies.	Approved colorings for drugs and cosmetics that can lead to DNA damage; lack of sufficient data on long-term phototoxicity or photocarcinogenicity.
N,N-Dimethyl-*p*-toluidine, [99–97–8].	National Cancer Institute	—Subchronic toxicity testing pending review of industry test plans and/or data developed under EPA's High Production Volume Chemical Challenge Program.	High production volume chemical with potential for widespread human exposure and limited chronic toxicity or carcinogenicity data; genotoxic; suspicion of carcinogenicity.
Lemon Oil, [8008–56–8] and Lime Oil, [8008–26–2].	Food and Drug Administration.	—Photogenotoxicity testing ..... —Photocarcinogenicity testing dependent on results of phototogenotoxicity studies.	Widespread consumer exposure as a fragrance component; known phototoxicity; long-term toxicity unknown.
Local anesthetics that metabolize to 2,6-xylidine or *o*-toluidine, Bupivacaine, [38396–39–3], Prilocaine, [721–50–6].	Private Individual; National Institute of Environmental Health Sciences.	—Short-term *in vitro/in vivo* mechanistic studies to evaluate carcinogenic metabolite formation and genotoxicity of representative local anesthetic compounds.	Widespread clinical use and human exposure; potentially metabolized to carcinogenic and neurotoxic intermediates; little available quantitative metabolism or genotoxicity data.
Microcystin-LR, [101043–37–2].	National Institute of Environmental Health Sciences.	—Toxicokinetic, subchronic, reproductive toxicity, chronic toxicity and carcinogenicity studies including doses relevant to environmental concentrations in drinking water. —Consider carcinogenicity testing in Japanese Medaka fish model.	Cyanobacteria and their toxins are drinking water contaminants with a high health research priority; many have high acute toxicity and known hepatotoxicity and hepatocarcinogenicity.
Organotins occurring in drinking water, Monomethyltin trichloride, [993–16–8], Dimethyltin dichloride, [753–73–1], Monobutyltin trichloride, [1118–46–3], Dibutyltin dichloride, [683–18–1].	Environmental Protection Agency; National Institute of Environmental Health Sciences.	—Long-term single chemical and binary mixture drinking water studies to address pharmacokinetics, neurotoxicity, immunotoxicity, and reproductive and developmental toxicity. —Consider testing in transgenic animal models of neurodegenerative disease.	Drinking water contaminants with a high health research priority; numerous organotins have demonstrated a broad spectrum of toxicity; chronic toxicity information on organotin species primarily found in drinking water is limited.
All-*trans*-retinyl palmitate, [79–81–2].	Food and Drug Administration.	—Phototoxicity and photocarcinogenicity testing.	Widespread use in cosmetic products; known biochemical and histological cutaneous alterations; other retinoids known to enhance photocarcinogenesis.

TABLE 1.—SUBSTANCES RECOMMENDED FOR TESTING—Continued

Substance [CAS Number]	Nominated by	ICCEC recommendations	Study rationale; other information
S-Adenosylmethionine, [29908–03–0].	National Cancer Institute	—*In vitro* genotoxicity testing (Syrian hamster embryo cell transformation and DNA alkylation assays). —Subchronic toxicity testing dependent on results of genotoxicity studies.	Widespread exogenous human exposure through use as a dietary supplement; limited toxicity data available.
Senna [8013–11–4]	Food and Drug Administration	—Carcinogenicity testing in p53 transgenic mouse model	Data needed to complete safety evaluation of stimulant laxatives; transgenic studies will complement manufacturer sponsored carcinogenicity studies.

TABLE 2.—SUBSTANCES FOR WHICH A TESTING RECOMMENDATION IS DEFERRED PENDING RECEIPT AND CONSIDERATION OF ADDITIONAL INFORMATION

Substance [CAS Number]	Nominated by	Nominated for	Nomination rationale	Additional information needed
1,3-Dichloropropane, [142–28–9], 2,2-Dichloropropane, [594–20–7], 1,1-Dichloropropene, [563–58–6].	Environmental Protection Agency; National Institute of Environmental Health Sciences.	—Short-term comprehensive drinking water toxicity studies. —Pharmacokinetics —Medaka studies .... —Testing in human bladder cell transformation model.	Drinking water contaminants with high health research priority; very limited toxicity data; known toxicity and carcinogenicity of structurally similar compounds.	Additional drinking water occurrence data; production volumes; potential sources of drinking water contamination; anticipated regulatory value of additional toxicity data.
Hydergine, [8067–24–1].	National Cancer Institute.	—Genotoxicity testing.	Ergot alkaloid prescription drug with recent increase in ''off label'' and dietary supplement use in healthy individuals; lack of available information on toxicity and carcinogenicity.	Dietary supplement sales and use information; regulatory agency information needs.
Yohimbe bark extract, [85117–22–2], Yohimbine, [146–48–5].	National Cancer Institute.	—Micronucleus assay.	Significant human exposure through use as a dietary supplement; suspicion of carcinogenicity of yohimbine based on structural similarity to reserpine.	Dietary supplement use levels and patterns; regulatory agency informaiton needs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Treatment Improvement Protocols (TIPs) Evaluation Project—Prospective Study—New—Since 1993, SAMHSA's Center for Substance Abuse Treatment has published 37 Treatment Improvement Protocols, which provide administrative and clinical practice guidance to the substance abuse treatment field. This is the third of three major studies and is designed to assess readers' use of TIPs and the impact of TIPs on changing substance abuse treatment practices.

The Prospective Study seeks to determine the most cost effective level of support needed by substance abuse treatment providers to implement in practice the information contained in TIPs. Specifically, this study will examine the use of TIP # 35, ''Enhancing Motivation for Change in Substance Abuse Treatment,'' by treatment professionals in four different areas of the country. The study will use a pretest/post-test experimental design in which treatment facilities will be randomly assigned to one of four conditions: (1) The control group (which will receive the TIP and no additional support); (2) a TIP-plus curriculum group; (3) a TIP-plus curriculum and training group; and (4) a TIP-plus curriculum, training, and ongoing support group.

Data will be collected at baseline and follow-up. Measures will include providers' awareness of TIP 35, their knowledge of the content contained in this TIP, their attitudes toward the TIP and its content, and their use of this TIP and its impact on practices within their facilities. Burden for State substance abuse (SSA) agency directors in the four areas of the country chosen will consist of information gathering by telephone. Burden for other respondents will consist of completing the pretest and post-test questionnaires. The total estimated burden for this project, to be completed in a 1-year period, is summarized below.