

Dated: April 20, 2000.

LaVerne Y. Stringfield,
*Director, Office of Federal Advisory
Committee Policy.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; Meeting of the NTP Board of Scientific Counselors

Pursuant to Public Law 92-463, notice is hereby given of a meeting of the National Toxicology Program (NTP) Board of Scientific Counselors, U.S. Public Health Service, in the Rodbell Auditorium, Building 101, South Campus, National Institute of Environmental Health Sciences (NIEHS), 111 T.W. Alexander Drive, Research Triangle Park, North Carolina, on May 24, 2000.

The NTP Board of Scientific Counselors is composed of scientists from the public and private sector. The Board provides primary scientific oversight to the NTP.

Agenda

The meeting is open to the public from 8:30 a.m. to adjournment with attendance limited only by space available. A draft agenda with a tentative schedule is provided below. There are three primary agenda topics: (1) An update on the NTP Center for the Evaluation of Risks to Human Reproduction (CERHR) including a discussion of its progress, the phthalates review, and its procedures for nomination, selection and review of chemicals; (2) presentations about current initiatives for NTP toxicology studies; and (3) recommendations of substances by the Interagency Committee for future NTP studies. Also in the afternoon, there will be reports on activities of the Report on Carcinogens and Technical Reports Review Subcommittees. The Board will review a concept proposal for the continued use of a contract mechanism to perform NTP toxicology and carcinogenesis studies.

Information about the CERHR including the chemicals currently under consideration for Expert Panel evaluation and the evaluation process are described in a **Federal Register** notice [March 20, 2000, Volume 65, Number 54, pages 14997-14998]. The opportunity for submission of written public comments on those candidate chemicals is provided through May 4,

2000. A copy of this notice is available on-line at the NTP web site (<http://ntp-server.niehs.nih.gov>) and CERHR web site (<http://cerhr.niehs.nih.gov>) or by contacting the Executive Secretary (address given below). The chemicals under consideration include: 1-Bromopropane, 2-Bromopropane, Dimethyl Methyl Phosphonate, Ethylene glycol, Glycol ethers, Glyphosate, Methanol, Nicotine, Phenol, Thimerosal, and Toluene. This meeting provides an additional opportunity for the public to present any comments to the NTP Board of Scientific Counselors and NTP staff. However, if written comments were submitted in response to the March 20th **Federal Register** announcement they are being considered and do not need to be resubmitted or readdressed.

The NTP has a broad mandate to provide toxicological characterization for chemicals and agents of public health concern and strives to balance the selection of agents for study. Current NTP initiatives include water disinfection by-products, DNA-based products, herbal/dietary supplements, phototoxicology studies and occupational exposures and mixtures.

Information about substances nominated to the NTP for toxicology studies and recommendations for testing by the NTP Interagency Committee for Chemical Evaluation and Coordination (ICCEC) are provided in the **Federal Register** notice dated March 2, 2000 (Volume 65, Number 42, Pages 11329-11331). The opportunity for submission of written public comments on those candidate chemicals is provided through April 30, 2000. Substances currently under consideration include: Substances recommended for testing: 1-Bromopropane and 2-Bromopropane, Chitosan, DNA-based products, Juglone, Potassium ferricyanide, and Radio frequency radiation emissions of wireless communication devices; Substances for which no testing is recommended at this time: Cafestol and Plumbagin; Substances for which a testing recommendation is deferred pending receipt and consideration of additional information: Ethylenebis(tetrabromo-phthalimide), Terpinolene, Tetrabromophthalic anhydride, and Texanol benzyl phthalate. Testing recommendations from the ICCEC are given in the referenced **Federal Register** notice. This meeting provides an additional opportunity for the public to comment to the NTP Board and staff. However, if written comments were submitted in response to the March 2nd **Federal Register** announcement, they are under

consideration and do not need to be resubmitted or readdressed.

Public Comment Encouraged

Public input at the meeting is welcome and time is set aside in the agenda for presentation of public comments on any agenda topic. Seven minutes are allotted for each formal oral presentation. To facilitate planning for the meeting, persons interested in providing formal written or oral comments are asked to notify the Executive Secretary, Dr. Mary S. Wolfe, NIEHS, P.O. Box 12233 MD A3-07, Research Triangle Park, NC 27709 (telephone 919/541-3971, fax 919/541-0295, and email wolfe@niehs.nih.gov). Written comments submitted for consideration by the Board and NTP staff prior to the meeting must be received by May 15, 2000. Persons wishing to register to make a formal presentation during a public comment period are asked to notify the Executive Secretary preferably no later than May 22, 2000, and, if possible, to provide a copy of the statement in advance of the meeting for distribution to the Board and NTP staff. Individuals will also be able to register to give oral public comments on-site at the meeting. However, if registering on-site and reading from written text, please bring 25 copies of the statement to the meeting for distribution to the Board and NTP staff and to supplement the record. Persons registering to make oral comments or submitting written comments are asked to provide their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any).

Additional Information About Meeting

Prior to the meeting, a copy of the agenda and a roster of the Board members will be available from the Executive Secretary. Following the meeting, summary minutes will be prepared and available upon request to Central Data Management, NIEHS, P.O. Box 12233 MD E1-02, Research Triangle Park, NC 27709; telephone 919/541-3419; fax 919/541-3687; and email CDM@niehs.nih.gov.

Dated: April 19, 2000.

Samuel H. Wilson,

Deputy Director, National Institute for Environmental Health Sciences.

Draft Agenda; National Toxicology Program (NTP) Board of Scientific Counselors

May 24, 2000

Rodbell Auditorium, Building 101, South Campus, National Institute of Environmental Health Sciences (NIEHS), Research Triangle Park, North Carolina

8:30 a.m.—Welcome

8:50 a.m.—NTP Update

9:00 a.m.—NTP Center for the Evaluation of Risks to Human Reproduction (CERHR)

- Role of CERHR in meeting the goals of the NTP
- Response to last years Board Review of CERHR

9:30 a.m.—CERHR Processes and Criteria

- Nomination and selection of agents for review
- Evaluation of selected agents
- Communication with public

10:00 a.m.—Break

10:15 a.m.—Public Comments

10:30 a.m.—Board Discussion

11:00 a.m.—Perspectives on the Process (e.g. Phthalates Review)

- Expert Panel
- Regulatory Agencies
- NTP Board of Scientific Counselors
- Public Comments

Noon—Lunch

1:00 p.m.—Current Trends in NTP Toxicology Testing

- Water disinfection by-products
- DNA-based products
- Herbals/dietary supplements

2:15 p.m.—Break

2:30 p.m.—Current Trends in NTP Toxicology Testing (continued)

- Phototoxicology studies and the NTP Center

- Occupational chemicals and mixtures

3:20 p.m.—Concept Review

- Board Discussion and ACTION

3:50 p.m.—Testing Recommendations from the Interagency Committee for Chemical Evaluation and Coordination

- Public Comments

- Board Discussion

4:35 p.m.—NTP Board Subcommittee Reviews—Updates

- Report on Carcinogens

- Technical Reports

- Board Discussion

5:20 p.m.—Adjourn

Substances Nominated to the NTP for Study and Testing Recommendations Made by the ICCEC on December 13, 1999

TABLE 1.—SUBSTANCES RECOMMENDED FOR TESTING

Substance [CAS No.]	Nominated by	ICCEC recommendations	Study rationale; other information
1-Bromopropane [106–94–5] and 2-Bromopropane [75–26–3].	OSHA NIOSH	<i>1-Bromopropane</i> —Carcinogenicity —Reproductive and developmental toxicity. —Toxicokinetics —Mechanistic studies —Neurotoxicity —Genotoxicity —Exposure studies in workers ... <i>2-Bromopropane</i> —Subchronic toxicity. —Mechanistic studies to evaluate vitamin E and mineral depletion.	Reported increasing production and use in many industrial applications as an alternative to ozone depleting substances; available data from limited repeat dose studies indicate toxicity to multiple organ systems. 2-Bromopropane is a contaminant in reagent grade. 1-Bromopropane with known reproductive toxicity.
Chitosan [9012–76–4]	NCI	—Mechanistic studies to evaluate vitamin E and mineral depletion.	Significant human exposure through use as a dietary supplement and other commercial applications; potential for toxicity from interference with dietary fat absorption.
DNA-based products	FDA	—Establish joint NIEHS/FDA program to evaluate long-term toxicity in anticipation of regulatory needs.	Rapidly growing market for DNA-based therapeutic agents and a lack of adequate mechanisms and methodologies for evaluating safety.
Juglone [481–39–0]	NCI	—Mechanistic studies —Metabolism studies —Mouse lymphoma assay —Mammalian mutagenicity —Carcinogenicity testing pending results of preliminary studies.	Potential human exposure resulting from use of walnut-based products as dietary supplements and natural dyes and stains; suspicion of carcinogenicity based on quinone structure.
Potassium ferricyanide [13746–66–2]	NCI	—Genotoxicity —Subchronic toxicity	Potential consumer and worker exposure resulting from use in photographic processing; suspicion of toxicity based on potential for redox cycling; inadequate toxicity information available.
Radio frequency radiation emissions of wireless communication devices.	FDA	—Establish interagency program to design studies assessing cancer and non-cancer health effects to fulfill regulatory needs.	Widespread consumer and worker exposure; available data is inadequate to properly assess safety.

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

Substance [CAS No.]	Nominated by	Nominated for	Rationale for not testing
Cafestol [469–83–0] and Kahweol [6894–43–5].	Private individual.	—Toxicity and carcinogenicity testing.	Anti-carcinogenic effects demonstrated in animal studies; limited data indicate low potential for toxicity; other natural products with higher potential for toxicity and human exposure exist; ongoing research efforts as opposed to new testing may provide basis for determining relevance of metabolic modulatory effects to chronic toxicity.
Plumbagin [481–42–5]	NCI	—Mechanistic studies —Metabolism studies —Mouse lymphoma assay —Mammalian mutagenicity —Carcinogenicity	Structurally similar to Juglone which is selected for study; low magnitude and/or prevalence of human exposure; adequate evidence of acute and reproductive toxicity.

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

Substance [CAS No.]	Nominated by	Nominated for	Additional information needed
Ethylenebis(tetrabromo-phthalimide) [32588–76–4].	NIEHS	—Toxicity and carcinogenicity testing.	Ongoing and planned industry testing efforts; better characterization of uses and potential human exposures.
Terpinolene [586–62–9]	NIEHS	—Toxicity and carcinogenicity testing.	Ongoing and planned industry testing efforts; better characterization of uses and potential human exposures; study results for structurally related compounds.
Tetrabromophthalic anhydride [632–79–1]	NIEHS	—Toxicity and carcinogenicity testing.	Ongoing and planned industry testing efforts; better characterization of uses and potential human exposures.
Texanol benzyl phthalate [16883–83–3] or [32333–99–6].	NIEHS	—Toxicity and carcinogenicity testing.	Ongoing and planned industry testing efforts; better characterization of uses and potential human exposures.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given of a joint meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) five advisory committees (SAMHSA National Advisory Council, Center for Mental Health Services National Advisory Council, Center for Substance Abuse Prevention National Advisory Council, Center for Substance Abuse Treatment National Advisory Council, and the Advisory Committee for Women's Services) in May 2000.

The organizing theme of the Year 2000 Joint Council Meeting is "Spirit of Collaboration from Prevention through Treatment." The session on May 10 will be open and will include presentations by several representatives from the Department of Health and Human

Services Programs. On May 11, there will be presentations by the U.S. Department of Education and the Department of Justice, a presentation on the effects of the Olmstead Decision and its relationship to the Institute for Mental Disease exclusion, a presentation on economic analysis and depression and an update on the National Congress for Hispanic Mental Health.

Attendance by the public will be limited to space available. Public comments are welcome, and interested persons may present information or views, orally or in writing, on issues pending before the committees. Those desiring to make formal presentations should contact Toian Vaughn, Executive Secretary, Office of Extramural Programs, SAMHSA, 5600 Fishers Lane, Room 12C–06, Rockville, Maryland 20857, prior to April 28, 2000, and submit a brief statement of: the general nature of the information or arguments they wish to present, the names, addresses, and telephone number of proposed participants, identification of organizational affiliation, and an indication of the approximate time required to make their comments. Time

for presentations may be limited by the number of requests. Photocopies, up to five pages of material, may be distributed at the meeting through the SAMHSA National Advisory Council Executive Secretary, if provided by April 28.

A summary of the meeting and/or a roster of committee members may be obtained from Toian Vaughn, Executive Secretary, SAMHSA National Advisory Council, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone (301) 443–4266, e-mail: tvaughn@samhsa.gov.

Substantive program information and information pertaining to special accommodations for persons with disabilities may be obtained from the contact whose name and telephone number are listed below.

Committee Names: Substance Abuse and Mental Health Services Administration National Advisory Council, Center for Mental Health Services National Advisory Council, Center for Substance Abuse Prevention National Advisory Council, Center for Substance Abuse Treatment National