

**Public Health Service**

**National Toxicology Program; National Toxicology Program (NTP) Board of Scientific Counselors' Meeting; Review of Substances for Listing in the 8th Biennial Report on Carcinogens**

**Background**

The Director, NTP, initiated a public review in 1994 of the process for preparation of the Biennial Report on Carcinogens (BRC) to broaden input to its preparation, broaden the scope of scientific review associated with the Report, and provide review of the criteria used for inclusion of substances in the BRC. As a result of an extensive public as well as Federal interagency review, the criteria were revised with the revised criteria recently approved by the Secretary, Department of Health and Human Services, (Federal Register Vol. 61, No. 188, 50499-50500). The major change in the BRC which will occur as a result of the criteria revision will be to include consideration of all relevant information, including mechanistic data, in the decision to list substances in or delist substances from future volumes of the BRC. To broaden the scope of scientific review, a new standing subcommittee of the NTP Board of Scientific Counselors was established and held an organizational and informational meeting on May 8, 1996. The Biennial Report on Carcinogens (BRC) Subcommittee will meet once or twice a year, in public session, to review nominations for listing and/or delisting substances and to receive public comments. A November 18 and 19, 1996, meeting will be the first where review of nominations takes place. Finally, to broaden input to preparation of the BRC, the NTP will use a number of mechanisms to communicate to the public the revised criteria and the process for listing and delisting substances in the BRC, and to solicit nominations for listing or delisting. Announcements will be published in the Federal Register and appropriate publications such as the NIEHS journal, Environmental Health Perspectives, and various trade publications and journals. Direct

mailings from the NTP Liaison Office will target persons and organizations who have requested to be on a mailing list for NTP information and specifically for information regarding the BRC. A list of new petitions for listing or delisting, soliciting public comment, will be disseminated through the same media.

**November 18-19 Meeting**

Pursuant to Public Law 92-463, notice is hereby given of the next meeting of the NTP Board of Scientific Counselors' Biennial Report on Carcinogens Subcommittee to be held in the Conference Center, Building 101, South Campus, National Institute of Environmental Health Sciences (NIEHS), 111 Alexander Drive, Research Triangle Park, North Carolina. The meeting will begin at 8:30 a.m. and is open to the public. The agenda topic is the peer review of substances nominated for listing in the 8th Biennial Report on Carcinogens. Also under review will be revisions to the Introduction to the 8th BRC and changes to the structure of the report. These include a.) the addition of a table of substances considered, but rejected for inclusion in the BRC as known or reasonably anticipated human carcinogens and b.) the addition of a table of substances nominated but not yet reviewed for listing in a subsequent Report. There will also be a review of the reference in the draft 8th BRC Introduction to certain manufacturing processes and occupations which the International Agency for Research on Cancer (IARC) has determined are associated with increased incidences of cancer in workers in these settings but which do not qualify for formal review for BRC listing because no specific agent, substance or mixture has been identified with the exposures involved. This will include a discussion of the appropriateness of having this reference in the BRC and, if so, should it remain in the Introduction or be listed separately in an appendix in the Report.

Tentatively scheduled to be peer reviewed on November 18-19 are 15 substances, listed alphabetically, along with supporting information in the attached table. The order of review is

given in the far right column of the table. Copies of the draft introduction for the 8th BRC, or copies of a draft summary document which contains the background data and information used to evaluate the nomination for listing a substance may be obtained, as available, from: Dr. C. W. Jameson, Biennial Report on Carcinogens, MD WC-05, P.O. Box 12233, Research Triangle Park, NC 27709 (919/541-4096; FAX 919/541-2242).

**Public Comment**

Persons wanting to make a formal presentation concerning proposed changes to the BRC or regarding a particular nominated substance must notify the Executive Secretary, Dr. Larry G. Hart, by telephone, by FAX, or by mail (see contact information below) no later than November 13, 1996. A written copy of comments is requested in advance of the meeting so that copies can be distributed to all Subcommittee members and staff and made available at the meeting. Written statements should supplement and may expand upon the oral presentation. Oral presentations must be limited to no more than five minutes. In lieu of an oral presentation, written statements may be submitted. These should be received by the Executive Secretary by November 13.

The program would welcome receiving carcinogenesis information from completed, ongoing, or planned studies, as well as current production data, human exposure information, and use patterns for any of the substances listed in this announcement. Please contact Dr. C. W. Jameson at the address given above.

Upon request the Executive Secretary, Dr. Larry G. Hart, P.O. Box 12233, Research Triangle Park, North Carolina 27709 (telephone 919/541-3971; FAX 919/541-0295), will furnish an agenda and a roster of Subcommittee members prior to the meeting. Summary minutes subsequent to the meeting will be available upon request.

**Attachment**

Dated: October 16, 1996.

Kenneth Olden,

*Director, National Toxicology Program.*

**SUMMARY DATA FOR SUBSTANCES TENTATIVELY SCHEDULED FOR REVIEW AT THE MEETING OF THE NTP BOARD OF SCIENTIFIC COUNSELORS' BIENNIAL REPORT ON CARCINOGENS SUBCOMMITTEE, NOVEMBER 18-19, 1996**

Azacitidine .....	CAS Number 320-67-2 .....	Review order: 3.
Primary Uses .....	Used as a cytostatic agent in the treatment of acute leukemia.	
Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	
p-Chloro-o-Toluidine and its HCl salt .....	CAS Number 95-69-2 .....	Review order: 4.
Primary Uses .....	Used to produce azo dyes for cotton, silk acetate and nylon and as intermediate in production of Pigment Red 7 and Pigment Yellow 49. Also an impurity in and a metabolite of the pesticide chlordimeform.	

SUMMARY DATA FOR SUBSTANCES TENTATIVELY SCHEDULED FOR REVIEW AT THE MEETING OF THE NTP BOARD OF SCIENTIFIC COUNSELORS' BIENNIAL REPORT ON CARCINOGENS SUBCOMMITTEE, NOVEMBER 18-19, 1996—Continued

Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	
Chlorozotocin .....	CAS Number 54749-90-5 .....	Review order: 5.
Primary Uses .....	Used as a cytostatic agent in the treatment of cancers of the stomach, large intestine pancreas and lung; melanoma; and multiple myeloma.	
Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	
Cyclosporin .....	CAS Number 59865-13-3 .....	Review order: 1.
Primary Uses .....	Used as an immunosuppressive agent in the prevention and treatment of graft-vs-host reactions in bone marrow transplantation and for the prevention of rejection of kidney, heart, and liver transplants.	
Nominated as .....	Known to be a Human Carcinogen.	
Danthron (1,8-Dihydroxyanthraquinone) .....	CAS Number 117-10-2 .....	Review order: 12.
Primary Uses .....	Used as a laxative and as an intermediate in the manufacture of dyes.	
Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	
1,6-Dinitropyrene .....	CAS Number 42397-64-8 .....	Review order: 9.
Primary Uses .....	Not used commercially, detected in ambient atmospheric samples and as a constituent of diesel exhaust.	
Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	
1,8-Dinitropyrene .....	CAS Number 42397-65-9 .....	Review order: 10.
Primary Uses .....	Not used commercially, detected in ambient atmospheric samples and as a constituent of diesel exhaust.	
Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	
Disperse Blue 1 (1,4,5,8-Tetraaminoanthraquinone) .....	CAS Number 2475-45-8 .....	Review order: 13.
Primary Uses .....	Used as an anthraquinone based dyestuff in hair color formulations and in coloring fabrics and plastics.	
Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	
Furan .....	CAS Number 100-00-9 .....	Review order: 6.
Primary Uses .....	Used as an intermediate in the synthesis and production of other organic compounds..	
Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	
o-Nitroanisole .....	CAS Number 91-23-6 .....	Review order: 14.
Primary Uses .....	Used as a precursor in the synthesis of o-anisidine which is used in the manufacture of over 100 azo dyes.	
Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	
6-Nitrochrysene .....	CAS Number 7495-02-8 .....	Review order: 11.
Primary Uses .....	Not used commercially, detected in ambient atmospheric samples.	
Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	
1-Nitropyrene .....	CAS Number 5522-43-0 .....	Review order: 7.
Primary Uses .....	Not used commercially, detected in ambient atmospheric samples and as a constituent of diesel and gasoline engine exhaust.	
Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	
4-Nitropyrene .....	CAS Number 57835-92-4 .....	Review order: 8.
Primary Uses .....	Not used commercially, detected in ambient atmospheric samples.	
Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	
Thiotepa .....	CAS Number 52-24-4 .....	Review order: 2.
Primary Uses .....	Used as a cytostatic agent in the treatment of lymphomas and a variety of solid tumors, such as breast and ovary. It has also been used at high doses in combination chemotherapy with cyclophosphamide in patients with refractory malignancies treated with autologous bone transplantation.	
Nominated as .....	Known to be a Human Carcinogen.	
1,2,3-Trichloropropane .....	CAS Number 96-18-4 .....	Review order: 15.
Primary Uses .....	Used as a polymer crosslinking agent, paint and varnish remover, solvent and degreasing agent. It has been found as an impurity in certain nematocides and soil fumigants and has been detected in drinking and ground water in various parts of the United States.	
Nominated as .....	Reasonably Anticipated to be a Human Carcinogen.	

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**Substance Abuse and Mental Health Services Administration**

**Center for Substance Abuse Prevention; Notice of Meeting**

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Drug Testing Advisory Board of the

Center for Substance Abuse Prevention in December 1996.

A portion of the meeting will be open and will include a roll call, general announcements, and a discussion of various program, procedural, and technical issues. Public comments are welcome during the open session.