

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Public Health Service****National Toxicology Program; National Toxicology Program (NTP) Board of Scientific Counselors' Meeting; Review of Nominations for Listing in or Delisting From the 10th Report on Carcinogens**

Pursuant to Pub. L. 92-463, notice is hereby given of the next meeting of the NTP Board of Scientific Counselors' Report on Carcinogens (RoC) Subcommittee to be held on January 20 & 21, 2000, at the Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, VA 22202. On January 20, registration will begin at 9 a.m. and the meeting will begin at 9:30 a.m. On January 21, the meeting will begin at 8:30 a.m. Pre-registration is not required; however, persons requesting time to make oral, public comments are asked to notify Dr. Mary S. Wolfe, Executive Secretary, prior to the meeting (contact information given below). The agenda covers the peer review of substances, mixtures, or exposure circumstances nominated for listing in the 10th Report on Carcinogens, and includes an opportunity for public input.

Background

The Department of Health and Human Services (DHHS) Report on Carcinogens (RoC) is a public information document prepared for the US Congress by the National Toxicology Program (NTP) in response to Section 301(b)(4) of the Public Health Service Act, as amended. The intent of the document is to provide a listing of those agents, substances, or exposure circumstances that are either "known" or "reasonably anticipated" to cause cancer in humans and to which a significant number of people in the United States are exposed. The process for preparation of the RoC has three levels of scientific peer review. Central to the evaluations of the review groups is the use of criteria for inclusion in or removal of substances from the Report. The current criteria for listing in or delisting from the Report were approved by the Secretary, DHHS, in September 1996. The major change in the RoC, which occurred as a result of the criteria revision, was to include consideration of all relevant information, including mechanistic data, in the decision to list in or delist from future editions. The review process for listing in or delisting from the RoC begins with initial scientific review by the National Institute of Environmental Health

Sciences (NIEHS)/NTP Report on Carcinogens Review Committee (RG1), which is comprised of NIEHS/NTP staff scientists. The second scientific review group is comprised of representatives from the Federal health research and regulatory agencies that are members of the NTP Executive Committee. Following external public review by the NTP Board RoC Subcommittee and solicitation of public comments through announcements in the **Federal Register** and other media, the independent recommendations of the three scientific peer review groups and all public comments are presented to the NTP Executive Committee for review and comment. All recommendations and public comments are submitted to the Director, NTP, who reviews them and makes a final recommendation to the Secretary, DHHS, concerning the listing or delisting of chemicals or exposure circumstances in the RoC. The Secretary has final review and approval for the Report.

Agenda

The meeting of the NTP RoC Subcommittee is scheduled for January 20 & 21, 2000. Tentatively scheduled to be peer reviewed are nine nominated chemicals or exposure circumstances. These nominations are listed alphabetically in the attached table, along with supporting information and a tentative order of presentation and review. Background summary documents for each of the nominations are available to the public and include (1) A summary of the scientific data and information used to evaluate the nomination, (2) a recommendation for listing either as "known to be a human carcinogen" or as "reasonably anticipated to be a human carcinogen," or (3) the upgrading or delisting of a current listing in the RoC. Copies of a draft background summary document for each of these nominations are available on the NTP web homepage at <http://ntp-server.niehs.nih.gov/> and the Environmental Health Information Service website at <http://ehis.niehs.nih.gov/> or can be obtained in hard copy, as available, from: Dr. C.W. Jameson, Report on Carcinogens, NIEHS, MD EC-14, 79 Alexander Drive, Building 4401, Room 3127, P.O. Box 12233, Research Triangle Park, NC 27709 (919/541-4096; FAX 919/541-2242; email jameson@niehs.nih.gov).

The April 2, 1999 **Federal Register** Announcement (Volume 64, Number 63, Page 15983-15984) calling for public comments on the nominations to be reviewed in 1999 for listing in or delisting (removing) from the 10th RoC, indicated that UV Radiation (separate

consideration of three segments of the wavelength spectrum: UVA (315-400 nm), UVB (280-315 nm), and UVC (100-280 nm)) and Toluene Diisocyanate (CAS Number 26471-62-5) would be among the nominations to be reviewed. The initial review of the UV Radiation nomination by NTP staff found an extensive published database for this nomination and there was insufficient time to prepare adequately a comprehensive summary background document for its review in 1999. Therefore, the nomination of UV Radiation (separate consideration of three segments of the wavelength spectrum: UVA (315-400 nm), UVB (280-315 nm), and UVC (100-280 nm)) was deferred for review until later in 2000.

Toluene Diisocyanate (TDI) was nominated by the Diisocyanates Panel of the Chemical Manufacturers Association for review and delisting from the RoC. As outlined in the published listing/delisting procedures for the RoC, the RG1 reviewed the nomination and data provided by the Diisocyanates Panel. Based on its review of the available information concerning the carcinogenicity of TDI, the RG1 determined that there is no new, relevant data to support the delisting of TDI from the RoC. RG1 recommended that the nomination to delist TDI from the RoC not proceed any further through the review process. Therefore, TDI is not on the agenda for review at the January 20-21 RoC Subcommittee meeting. The Diisocyanates Panel was notified of this action and invited to resubmit the nomination to delist TDI from the RoC providing additional justification and relevant new data to support the nomination. The RG2, NTP Board of Scientific Counselors RoC Subcommittee, and the NTP Executive Committee were notified of this action.

Solicitation of Public Comment

The NTP Board of Scientific Counselors RoC Subcommittee meeting is open to the public, and time will be provided for public comment on each of the nominations under review. In order to facilitate planning for the meeting, persons requesting time for an oral presentation regarding a particular nomination should notify the Executive Secretary, 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) no later than January 7, 2000. Persons registering to make comments are asked to provide, if possible, a written copy of their statement by January 7th so copies can be made and distributed to

Subcommittee for their timely review prior to the meeting. Written statements can supplement and expand the oral presentation, and each speaker is asked to provide his/her name, affiliation, mailing address, phone, fax, e-mail and supporting organization (if any). At least seven minutes will be allotted to each speaker, and if time permits, can be extended to 10 minutes. Individuals who register to make oral presentations by January 7th will be notified about the time available for their presentation at least one week prior to the meeting. Registration for making public comments will also be available on-site. If registering on-site to speak and reading oral comments from printed copy, the speaker is asked to bring 25

copies of the text. These copies will be distributed to the Chair and Subcommittee members and supplement the record.

Written comments, in lieu of making oral comments, are welcome. All comments must include name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization (if any) and should be received by January 7th for distribution to the Subcommittee. Written comments received after January 7th will not be considered by Subcommittee members in their reviews.

The NTP would welcome receiving information from completed, ongoing, or planned human or experimental animal cancer studies, or studies of mechanism of cancer formation, as well

as current production data, human exposure information, and use patterns for any of the nominations listed in this announcement. Organizations or individuals that wish to provide information should contact Dr. C.W. Jameson at the address given above.

The agenda and a roster of Subcommittee members will be available prior to the meeting on the NTP web homepage at <http://ntp-server.niehs.nih.gov/> and upon request from Dr. Wolfe. Summary minutes from the previous meeting are available on the NTP web homepage and upon request from Dr. Wolfe.

Dated: November 10, 1999.

Samuel H. Wilson,
Deputy Director, NIEHS and NTP.

SUMMARY DATA FOR NOMINATIONS TENTATIVELY SCHEDULED FOR REVIEW AT THE MEETING OF THE NTP BOARD OF SCIENTIFIC COUNSELORS' REPORT ON CARCINOGENS SUBCOMMITTEE JANUARY 20-21, 2000

Nomination to be reviewed/CAS No.	Primary uses or exposures	To be reviewed for	Tentative review order
Beryllium and Beryllium Compounds/7440-41-7.	Fiber optics and cellular network communications systems, aerospace, defense and other industry applications.	Possible updating of current listing of beryllium and certain beryllium compounds to a known human carcinogen.	3
2,2-bis-(bromomethyl) -1,3-propanediol/3296-90-9.	Used as a fire retardant in unsaturated polyester resins, in molded products, and in rigid polyurethane foam.	Listing in the 10th Report	2
2,3-Dibromo-1-Propanol/96-13-9	Used as a flame retardant, as an intermediate in the preparation of the flame retardant tris(2,3-dibromopropyl) phosphate, and as an intermediate in the manufacture of pesticides and pharmaceutical preparations.	Listing in the 10th Report	1
Dyes Metabolized to Dimethoxybenzidine (Dimethoxybenzidine Dyes as a Class).	Dyes widely used for leather, paper, plastics, rubber, and textile industries.	Listing in the 10th Report	4
Dyes Metabolized to Dimethylbenzidine (Dimethylbenzidine Dyes as a Class).	Dyes widely used for leather, paper, plastics, rubber, and textile industries.	Listing in the 10th Report	5
IQ (2-Amino-3-methylimidazo[4,5-f]quinoline)/76180-96-6.	Found in cooked meat and fish	Listing in the 10th Report	6
Styrene-7,8-oxide/96-09-3	Used mainly in the preparation of fragrances and in some epoxy resin formulations.	Listing in the 10th Report	7
Vinyl Bromide/593-60-2	Used commercially since 1968, primarily in the manufacture of flame retardant synthetic fibers.	Listing in the 10th Report	8
Vinyl Fluoride/75-02-5	Used commercially since the 1960s, in the production of polyvinylfluoride, which is used for plastics.	Listing in the 10th Report	9

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Review Phthalates Meeting Notice

National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), Center for the Evaluation of Risks to Human Reproduction, announces the second

meeting of an expert panel to review phthalates, December 15-17, 1999. The meeting will be held at Hawthorn Suites Hotel, 300 Meredith Drive, Durham, NC (near the intersection of highways 54 and 55 in Research Triangle Park) and will begin at 8:30 a.m. each day.

Background

The NTP and the NIEHS established the NTP Center for the Evaluation of Risks to Human Reproduction (CERHR) (63 FR 68782, No 239) in June 1998. The purpose of the Center is to provide timely and unbiased, scientifically

sound evaluations of human and experimental evidence for adverse effects on reproduction, including development, which may be caused by agents to which humans are exposed. The evaluations produced through the Center will be published as monographs in *Environmental Health Perspectives* (EHP); a special effort will be made to summarize the reports in non-scientific terms for use by the general public. These documents will be available on the CERHR website (<http://cerhr.niehs.nih.gov>) or in hardcopy by contacting Ms. Peggy Sheren (contact