

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Public Health Service****National Toxicology Program**

National Toxicology Program (NTP) Board of Scientific Counselors' Meeting; Review of Substances for Listing in or Delisting from the 9th 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 Subcommittee to be held on October 30 & 31, 1997, 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. both days and is open to the public. The agenda are the peer review of substances nominated for listing in or delisting from the 9th Report on Carcinogens (formerly the Biennial Report on Carcinogens), and provision of an opportunity for public input.

**Background**

Over the past three years, there was an extensive public and Federal interagency review of the process for the preparation of the Report on Carcinogens (RC) to broaden input to its preparation, broaden the scope of scientific review, and provide review of the criteria used for inclusion in or removal of substances from the Report. As a result, the criteria were revised and approved in September 1996 by the Secretary, Department of Health and Human Services. The major change in the RC 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 substances in or delist substances from future volumes. To broaden the scope of scientific review, a new standing subcommittee of the NTP Board of Scientific Counselors was established. A November 1996 meeting of the Report on Carcinogens (RC) Subcommittee was the first where public review of nominations took place, and using the

revised criteria. Thus, the current review process for review of petitions considered by the NTP for listing in or delisting from the Report begins with initial scientific review by the NIEHS/NTP Report on Carcinogens Review Committee (RG1). The RG1 makes a formal recommendation for those petitions determined to contain sufficient information for listing or delisting in the Report. The second scientific review is done by the NTP Executive Committee's Working Group for the Report on Carcinogens (RG2). RG2 is comprised of representatives of the Federal health research and regulatory agencies on the NTP Executive Committee. Following external scientific peer review by the RC Subcommittee in public session and solicitation of public comments through announcements in the **Federal Register** and other media, the independent recommendations of the three review groups and all public comments are presented to the NTP Executive Committee for review and comment. The Director, NTP, receives the four independent recommendations and makes the final decision to submit the Report to the Secretary for review and approval.

**Agenda**

Tentatively scheduled to be peer reviewed on October 30 & 31, are 14 agents, substances, mixtures or exposure circumstances listed alphabetically, along with supporting information in the attached table. The table lists the nominations in the tentative order of their presentation and review, and gives their primary uses or exposures and the category for which they were originally nominated. Background summary documents on each of the substances will be provided to reviewers around October 1, and will be available to the public at that time as well. Background documents include (1) a summary of the background data and information used to evaluate the nomination, and (2) the recommendation for: listing as "known to be a human carcinogen" or as "reasonably anticipated to be a human carcinogen"; the upgrading of a current listing; or the removal from the Report. Copies of draft background documents

can be obtained, as available, from: the Executive Secretary, Dr. Larry G. Hart, P.O. Box 12233, Research Triangle Park, NC 27709 (telephone 919/541-3971; FAX 919/541-0295; email hart@niehs.nih.gov.

**Public Input Encouraged**

The entire meeting is open to the public and time will be provided for public comment on each of the substances being reviewed. In order to facilitate planning for the meeting, persons wanting to make a formal presentation regarding a particular nominated substance must notify the Executive Secretary by telephone, by FAX, by mail, or by email no later than October 23, 1997, and provide a written copy in advance of the meeting. Written statements should supplement and may expand on the oral presentation, or may be submitted in lieu of an oral presentation, and should be received by October 27 so copies can be made for distribution to Subcommittee members and staff and made available for the public. *Oral presentation should be limited to no more than five minutes. Should the requests for time exceed the likely available time, the time may have to be limited to three minutes and presenters will be contacted.*

The program would welcome receiving carcinogenesis information from completed, ongoing, or planned studies by others, 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, Report on Carcinogens, MD EC-14, P.O. Box 12233, Research Triangle Park, NC 27709 (919/541-4096; FAX 919/541-2242).

The Executive Secretary, Dr. Larry G. Hart, at the address given above, will furnish agenda and a roster of Subcommittee members prior to the meeting. Summary minutes subsequent to the meeting will be available upon request.

Dated: September 23, 1997.

**Samuel H. Wilson,**

*Deputy Director, National Toxicology Program.*

SUMMARY DATA FOR AGENTS, SUBSTANCES, MIXTURES OR EXPOSURE CIRCUMSTANCES TENTATIVELY SCHEDULED FOR REVIEW AT THE MEETING OF THE NTP BOARD OF SCIENTIFIC COUNSELORS' REPORT ON CARCINOGENS SUBCOMMITTEE OCTOBER 30, AND 31, 1997

Substance or exposure circumstance/CAS No.	Primary uses or exposures	Nominated for <sup>1</sup>	Tentative review order
Dyes metabolized to benzidine (Benzidine dyes as a class).	Benzidine-based dyes are used primarily for dyeing textiles, paper and leather products. More than 250 benzidine-based dyes have been reported by the Society of Dyers and Colorists.	Listing as Known to be a Human Carcinogen in the 9th Report.	14
1,3-Butadiene/106-99-0 .....	Used primarily as a chemical intermediate and polymer component in the manufacture of synthetic rubber.	Upgrading current listing to Known to be a Human Carcinogen in the 9th Report.	4
Cadmium and cadmium compounds/7440-43-9.	Used in batteries, coating and plating, plastic and synthetic products and in alloys.	Upgrading current listing to Known to be a Human Carcinogen in the 9th Report.	2
Chloroprene/126-99-8 .....	Used as a monomer for neoprene elastomers, industrial rubber products, and as a component of adhesives in food packaging.	Listing as Reasonably Anticipated to be a Human Carcinogen in the 9th Report.	3
Phenolphthalein/77-09-8 .....	Used as a laboratory reagent and acid-base indicator and as a cathartic drug in over-the-counter laxative preparations.	Listing as Reasonably Anticipated to be a Human Carcinogen in the 9th Report.	10
Saccharin/281-44-9 .....	Used primarily as a nonnutritive sweetening agent ...	Removal from the Report on Carcinogens.	11
Smokeless tobacco .....	Oral use of smokeless tobacco products .....	Listing as Known to be a Human Carcinogen in the 9th Report.	7
Strong inorganic acid mists containing sulfuric acid.	Used in the manufacture of fertilizers, rayon, and other fibers, pigments and colors, explosives, plastics, coal-tar products such as dyes and drugs, storage batteries, synthetic detergents, natural and synthetic rubber, pulp and paper, cellophane and catalysts. It is also used in petroleum refining, pickling iron, steel and other metals and in ore concentration.	Listing as Known to be a Human Carcinogen in the 9th Report.	8
Tamoxifen/10540-29-1 .....	Used as an anti-estrogen drug and in the palliative treatment of breast cancer.	Listing as Known to be a Human Carcinogen in the 9th Report.	9
2,3,7,8-Tetrachlorodibenzo-P-Dioxin (TCDD)/1746-01-6.	Not used commercially, used only as a research chemical. Potential exposure from municipal incinerators, dump sites and contaminated soil.	Upgrading current listing to Known to be a Human Carcinogen in the 9th Report.	12
Tetrafluoroethylene/116-14-3 .....	Used in the production of polytetrafluoroethylene (Teflon) and other polymers. Has also been used as a propellant for food product aerosols.	Listing as Reasonably Anticipated to be a Human Carcinogen in the 9th Report.	1
Tobacco smoking .....	Inhalation of tobacco smoke .....	Listing as Known to be a Human Carcinogen in the 9th Report.	6
Trichloroethylene/79-01-6 .....	Used as an industrial solvent for vapor degreasing and cold cleaning of fabricated metal parts. Has also been used as a carrier solvent for the active ingredients of insecticides and fungicides, as a solvent for waxes, fats, resins, and oils, as an anesthetic for medical and dental use, and as an extractant for spice oleoresins and for caffeine from coffee.	Listing as Reasonably Anticipated to be a Human Carcinogen in the 9th Report.	13
UV radiation .....	Solar and artificial sources of ultraviolet radiation ...	Listing as Known to be a Human Carcinogen in the 9th Report.	5

<sup>1</sup> Nomination does not necessarily reflect the final recommendation of the two NTP Scientific Review Committees for the Report on Carcinogens.

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**DEPARTMENT OF THE INTERIOR**  
**Fish and Wildlife Service**

**Notice of Receipt of Applications for Permit**

The following applicants have applied for a permit to conduct certain activities with endangered species. This

notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT-834504

*Applicant:* Zoological Society of San Diego, San Diego, CA

The applicant requests a permit to import one captive-born Black-footed cat (*Felis nigripes nigripes*) from the Frankfurt Zoo, Frankfurt, Germany, for the purpose of enhancement of the species through captive propagation.

PRT-831854

*Applicant:* Thure Cerling, University of Utah, Salt Lake City, UT

The applicant requests a permit to import molar fragments from Black rhinoceros (*Diceros bicornis*) collected in the wild in Kenya, from skeletal remains found in the National Parks of Kenya, or from existing material archived in the National Museums of Kenya, for scientific research.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management