

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; Call for Public Comments on 8 Nominations, Proposed for Listing in or Delisting From the Report on Carcinogens, Tenth Edition

Background

The National Toxicology Program (NTP) solicits final public comments on agents, substances, mixtures and exposure circumstances reviewed in 2000 for listing in or delisting from the Report on Carcinogens, Tenth Edition. This Report (previously known as the Annual Report on Carcinogens) is a Congressionally mandated listing of known human carcinogens and reasonably anticipated human carcinogens and its preparation is delegated to the National Toxicology Program by the Secretary, Department of Health and Human Services (DHHS). Section 301(b)(4) of the Public Health Service Act, as amended, provides that the Secretary, (DHHS), shall publish a biennial report which contains a list of all substances (1) which either are known to be human carcinogens or may reasonably be anticipated to be human carcinogens; and (2) to which a significant number of persons residing in the United States (US) are exposed. The law also states that the reports should provide available information on

the nature of exposures, the estimated number of persons exposed and the extent to which the implementation of Federal regulations decreases the risk to public health from exposure to these chemicals.

In 2000, eight nominations were reviewed for listing in the Tenth Report. This review included two Federal and one non-government, scientific peer reviews and public comment and review. The three scientific review committees evaluated all available data relevant to the criteria for inclusion of candidate nominations in the Report. The criteria used in the review process and a detailed description of the review procedures, including the steps in the current formal review process, can be obtained from the NTP Home Page web site at <http://ntp-server.niehs.nih.gov/> or by contacting: Dr. C.W. Jameson, National Toxicology Program, Report on Carcinogens, MD EC-14, P.O. Box 12233, Research Triangle Park, NC 27709; phone: (919) 541-4096, fax: (919) 541-0144, email: jameson@niehs.nih.gov.

Public Comment Requested

The nominations reviewed in 2000 are provided in the following table with their Chemical Abstracts Services (CAS) Registry numbers (where available) and the recommendations from the three scientific peer reviews of the nominations. The NTP will be making a final recommendation in 2001 for these eight nominations for listing in, or

changing the current listing from reasonably anticipated to be a human carcinogen to the known to be a human carcinogen category in the Tenth Report.

Background documents provided to the review committees and the public are available on the web in PDF-format at the address above. Hard copies of these documents are also available upon request. The NTP will review the recommendations from each of the review committees and consider the public comments received throughout the process in making decisions regarding the NTP recommendations to the Secretary, DHHS, for listing of the nominated substances in the Tenth Edition of the Report on Carcinogens. The NTP solicits final public comment to supplement any previously submitted comments or to provide comments for the first time on any substance in the following table. Comments will be accepted for 60 days from the publication date of this announcement and should be directed to Dr. C.W. Jameson at the address listed above. Individuals submitting public comments are asked to include relevant contact information [name, affiliation (if any), address, telephone, fax, and e-mail].

Attachment

Dated: February 21, 2001.

Kenneth Olden,

Director, National Toxicology Program.

SUMMARY OF RG1,⁹ RG2² AND NTP BOARD SUBCOMMITTEE³ RECOMMENDATIONS FOR THE AGENTS, SUBSTANCES, MIXTURES OR EXPOSURE CIRCUMSTANCES REVIEWED IN 2000 FOR LISTING IN, DELISTING FROM, OR UPGRADING IN THE REPORT ON CARCINOGENS,⁴ 10TH EDITION

Nomination/CAS No.	Primary uses or exposures	RG1 action	RG2 action	NTP board subcommittee action
Broad Spectrum UV Radiation (UVR) and UVA, and UVB, and UVC.	Solar and artificial sources of ultraviolet radiation.	Motion to list UVR as known to be a human carcinogen passed by unanimous vote (6/0). Motion to list UVA, UVB and UVC as reasonably anticipated to be human carcinogens passed by unanimous vote (6/0).	Motion list UVR as known to be a human carcinogen passed by unanimous vote (8/0). Motion to list UVA, UVB and UVC as reasonably anticipated to be human carcinogens passed by unanimous vote (8/0).	Motion to list UVR as known to be a human carcinogen passed by unanimous vote (10/0). Motion to list UVA as reasonably anticipated to be human carcinogen passed by unanimous vote (10/0). Motion to list UVB as reasonably anticipated to be human carcinogen passed by vote of 7 yes to 3 no. Negative votes (3) cast because members felt data meets criteria to list as known human carcinogen.

SUMMARY OF RG1,⁹ RG2² AND NTP BOARD SUBCOMMITTEE³ RECOMMENDATIONS FOR THE AGENTS, SUBSTANCES, MIXTURES OR EXPOSURE CIRCUMSTANCES REVIEWED IN 2000 FOR LISTING IN, DELISTING FROM, OR UPGRADING IN THE REPORT ON CARCINOGENS,⁴ 10TH EDITION—Continued

Nomination/CAS No.	Primary uses or exposures	RG1 action	RG2 action	NTP board subcommittee action
Chloramphenicol (56-75-7).	Chloramphenicol has been used an antibiotic since the 1950s.	Motion to list Chloramphenicol as reasonably anticipated to be human carcinogen passed by unanimous vote (7/0).	Motion to list Chloramphenicol reasonably anticipated to be human carcinogen passed by vote of 7 yes to 0 no with 1 abstention. Abstention (1) was because member felt data concerning link between aplastic anemia and leukemia was not compelling.	Motion to list UVC as reasonably anticipated to be human carcinogen passed by vote of 9 yes to 1 no. Negative vote (1) cast because member felt insufficient human data to list as reasonably anticipated carcinogen. Motion to list Chloramphenicol as reasonably anticipated to be human carcinogen passed by unanimous vote (10/0).
Estrogens, Steroidal	Estrogens are widely used in post-menopausal therapy and in oral contraceptives for women.	Motion to list Steroidal Estrogens as known to be a human carcinogen passed by unanimous vote (7/0).	Motion to list Steroidal Estrogens as known to be a human carcinogen passed by unanimous vote (8/0).	Motion to list Steroidal Estrogens as known to be a human carcinogen passed by a vote of 8 yes to 1 no. Negative vote (1) cast because member felt insufficient human data to list all steroidal estrogens in the Report.
Methyleugenol (93-15-2) ..	Methyleugenol are flavoring agents used in jellies, baked goods, nonalcoholic beverages, chewing gum, candy, and ice cream. Also used as fragrance for many perfumes, lotions, detergents and soaps.	Motion to list Methyleugenol as reasonably anticipated to be human carcinogen passed by unanimous vote (7/0).	Motion to list Methyleugenol as reasonably anticipated to be human carcinogen passed by unanimous vote (8/0).	Motion to list Methyleugenol as reasonably anticipated to be human carcinogen passed by a vote of 9 yes to 1 no. Negative vote (1) cast because member felt insufficient human data to list in the Report.
Nickel (metallic) and Certain Nickel Alloys.	Metallic Nickel and Nickel Alloys have been used in commercial applications for over 100 years.	Motion to list Metallic Nickel and Certain Nickel alloys as reasonably anticipated to be human carcinogen passed by a vote of 6 yes to 2 no. Negative votes (2) cast because members did not agree with the use of term "certain" in the listing of Nickel alloys.	Motion to list Metallic Nickel as reasonably anticipated to be human carcinogen passed by a vote of 7 yes to 1 no. Negative vote (1) cast because member felt the animal data not persuasive to list in the Report as reasonably anticipated human carcinogens because of inappropriate routes of exposure.	Motion to list Metallic Nickel as reasonably anticipated to be human carcinogen passed by a vote of 7 yes to 3 no. Negative votes (3) cast because members felt that the human and animal data not persuasive to list in the Report as reasonably anticipated human carcinogens.

SUMMARY OF RG1,⁹ RG2² AND NTP BOARD SUBCOMMITTEE³ RECOMMENDATIONS FOR THE AGENTS, SUBSTANCES, MIXTURES OR EXPOSURE CIRCUMSTANCES REVIEWED IN 2000 FOR LISTING IN, DELISTING FROM, OR UPGRADING IN THE REPORT ON CARCINOGENS,⁴ 10TH EDITION—Continued

Nomination/CAS No.	Primary uses or exposures	RG1 action	RG2 action	NTP board subcommittee action
Talc (14807-96-6) Asbestiform and Non-Asbestiform.	Both Asbestiform talc (i.e., talc containing asbestiform fibers) and non-asbestiform talc (i.e. talc not containing asbestiform fibers) occur in various geological settings around the world. Occupational exposure to both forms occurs during mining, milling, and processing. Exposure to non-asbestiform talc by the general population occurs through the use of products such as cosmetics.	<p>Motion to list Talc containing asbestiform fibers as known to be a human carcinogen passed by unanimous vote (7/0).</p> <p>Motion to list Talc not containing asbestiform fibers as reasonably anticipated to be a human carcinogen passed by a vote of 6 yes to 1 no. Negative vote (1) cast because member questioned the biological plausibility of talc using causing ovarian neoplasms in women.</p>	<p>Motion <i>not</i> to list Talc containing asbestiform fibers as known to be a human carcinogen was defeated by a vote of 2 yes to 6 no. Negative votes (6) cast because members felt human data were not sufficient to list as a known human carcinogen because asbestiform fibers were not considered to include asbestos contamination.</p>	<p>Motion to list Certain Nickel Alloys as reasonably anticipated to be human carcinogen was defeated by a vote of 3 yes to 7 no. in RoC. Negative votes (7) cast because members felt available data not persuasive to list in the Report as reasonably anticipated human carcinogens.</p> <p>Motion <i>not</i> to list Certain Nickel Alloys in RoC was passed by a vote of 9 yes 1 no. Negative votes (1) cast because member felt data meets criteria to list as reasonably anticipated to be a human carcinogen.</p> <p>Motion to list Talc containing asbestiform fibers as reasonably anticipated to be a human carcinogen resulted in a tie vote (5 yes to 5 no). Negative votes (4) cast because members felt human and animal data not sufficient to list in Report. Other negative (1) cast because member felt action should be deferred.</p>

SUMMARY OF RG1,⁹ RG2² AND NTP BOARD SUBCOMMITTEE³ RECOMMENDATIONS FOR THE AGENTS, SUBSTANCES, MIXTURES OR EXPOSURE CIRCUMSTANCES REVIEWED IN 2000 FOR LISTING IN, DELISTING FROM, OR UPGRADING IN THE REPORT ON CARCINOGENS,⁴ 10TH EDITION—Continued

Nomination/CAS No.	Primary uses or exposures	RG1 action	RG2 action	NTP board subcommittee action
Trichloroethylene (TCE) (79-01-6).	Trichloroethylene is widely used as a solvent with 80-90% used worldwide for degreasing metals.	Motion to list TCE as known to be a human carcinogen passed by unanimous vote (7/0).	<p>Motion to list Talc containing asbestiform fibers as reasonably anticipated to be a human carcinogen passed by a vote of 6 yes to 2 no. Negative vote (1) cast because member felt data sufficient to list as a known human carcinogen. Other negative vote (1) cast because member felt evidence not adequate to list in the Report.</p> <p>Motion to list Talc not containing asbestiform fibers as reasonably anticipated to be human carcinogen passed by a vote of 7 yes to 1 no. Negative vote (1) cast because member felt animal data not sufficient and human data confounded because of the uncertainty of possible contamination of talc with asbestos.</p> <p>Motion to list TCE as known to be a human carcinogen was defeated by a vote of 3 yes to 4 no. Negative votes (4) cast because members felt the human data did not meet the criteria for listing as a known human carcinogen because the exposures in the human studies may not have been specific for TCE.</p>	<p>Motion <i>not</i> to list talc not containing asbestiform fibers as reasonably anticipated to be a human carcinogen passed by a vote of 7 yes to 3 no. Negative votes cast either because the member felt that data meets criteria to list talc not containing asbestiform fibers as reasonability anticipated to be a human carcinogen or that ovarian cancer studies should have been considered in the evaluation. The Subcommittee did not consider the ovarian cancer studies in the evaluation of talc not containing asbestiform fibers because it was unclear if the talc used in these studies might have been contaminated with asbestos.</p> <p>Motion that the listing of TCE should remain as reasonably anticipated to be a human carcinogen passed by a vote of 9 yes to 1 no. Negative vote (1) because member felt human data sufficient to list as a known human carcinogen.</p>
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 manufacture, especially during machine sanding and similar operations..	Motion to list Wood Dust as known to be a human carcinogen passed by unanimous vote (⁸⁰).	Motion to list Wood as known to be a human carcinogen passed by unanimous vote (⁷⁰).	Motion to list Wood Dust as known to be a human carcinogen passed by unanimous vote (⁸⁰).

¹ The NIEHS Review Committee for the Report on Carcinogens (RG1).

² The NTP Executive Committee (Agencies from the NTP Executive Committee represented on RG2 include: Agency for Toxic Substances and Disease Registry (ATSDR), Consumer Product Safety Commission (CPSC), Environmental Protection Agency (EPA), National Center for Environmental Health of the Centers for Disease Control and Prevention (NCEH/CDC), National Center for Toxicological Research of the Food and Drug Administration (NCTR/FDA), National Institute for Occupational Safety and Health/CDC (NIOSH/CDC), Occupational Safety and Health Administration (OSHA), National Cancer Institute of the National Institutes of Health (NCI/NIH), and National Institute of Environmental Health Sciences/NIH(NIEHS/NIH) Interagency Working Group for the Report on Carcinogens (RG2).

³ The NTP Board of Scientific Counselors Report on Carcinogens Subcommittee (the External Peer Review Group).

⁴ RoC—Report on Carcinogens.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This Notice is also available on the internet at the following website: <http://www.health.org/workplace>.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443-6014, Fax: (301) 443-3031.

Special Note: Please use the above address for all surface mail and correspondence. For all overnight mail service use the following address: Division of Workplace Programs, 5515 Security Lane, Room 815, Rockville, Maryland 20852.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100-71. Subpart C of the Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal

agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414-328-7840/800-877-7016 (Formerly: Bayshore Clinical Laboratory)
Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901-794-5770/888-290-1150
Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615-255-2400
Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800-541-4931/334-263-5745
Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513-585-9000 (Formerly: Jewish Hospital of Cincinnati, Inc.)
American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 20151, 703-802-6900
Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119-5412, 702-733-7866/800-433-2750
Baptist Medical Center—Toxicology Laboratory, 9601 I-630, Exit 7, Little Rock, AR 72205-7299, 501-202-2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)
Clinical Laboratory Partners, LLC, 129 East Cedar St., Newington, CT 06111, 860-696-8115 (Formerly: Hartford Hospital Toxicology Laboratory)
Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215-2802, 800-445-6917
Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800-876-3652/417-269-3093 (Formerly: Cox Medical Centers)
Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, Building 38-H, P.O. Box 88-6819, Great Lakes, IL 60088-6819, 847-688-2045/847-688-4171

Diagnostic Services Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 941-561-8200/800-735-5416
Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31602, 912-244-4468

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206-386-2672/800-898-0180 (Formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215-674-9310

Dynacare Kasper Medical Laboratories,* 14940-123 Ave., Edmonton, Alberta, Canada T5V 1B4, 780-451-3702/800-661-9876

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 662-236-2609

Express Analytical Labs, 1301 18th Ave NW, Suite 110, Austin, MN 55912, 507-437-7322

Gamma-Dynacare Medical Laboratories,* A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall St., London, ONT, Canada N6A 1P4, 519-679-1630

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608-267-6267

Integrated Regional Laboratories, 5361 NW 33rd Avenue, Fort Lauderdale, FL 33309, 954-777-0018, 800-522-0232, (Formerly: Cedars Medical Center, Department of Pathology)

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504-361-8989/800-433-3823, (Formerly: Laboratory Specialists, Inc.)

LabOne, Inc., 10101 Renner Blvd., Lenexa, KS 66219, 913-888-3927/800-728-4064, (Formerly: Center for Laboratory Services, a Division of LabOne, Inc.)

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713-856-8288/800-800-2387

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919-572-6900/800-833-3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 4022 Willow Lake Blvd., Memphis, TN 38118, 866-827-8042/