

Dated: March 29, 2000.

LaVerne Y. Stringfield,

*Director, Office of Federal Advisory
Committee Policy.*

[FR Doc. 00-8317 Filed 4-4-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Noticed of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel.

Date: April 7, 2000.

Time: 8 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Kenwood Country Club, 5601 River Road, Bethesda, MD 20816.

Contact Person: John R. Lymangrover, PHD, Scientific Review Administrator, National Institutes of Health, NIAMS, Natcher Bldg., Room 5As25N, Bethesda, MD 20892, 301-594-4952.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: March 29, 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; Call for Public Comments on Substances, Mixtures and Exposure Circumstances Proposed for Listing in the Report on Carcinogens, Tenth Edition

Background

The National Toxicology Program (NTP) announces its intent to review additional agents, substances, mixtures and exposure circumstances for possible listing in the Report on Carcinogens (RoC), 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 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.

The scientific review of the nominated agents, substances, mixtures or exposure circumstances involves three separate scientific reviews: two Federal review groups and one non-government peer review body (a subcommittee of the NTP Board of Scientific Counselors) that meets in an open, public forum. Throughout the review process, multiple opportunities are provided for public input including at the Subcommittee meeting. In reviewing nominations for the RoC, all available data and public comments, which are relevant to application of the criteria for inclusion or removal of candidate agents, substances, mixtures or exposure circumstances or for a change in a candidate's classification, are evaluated. The criteria used in the review process are as follows:

Known To Be Human Carcinogens

There is sufficient evidence of carcinogenicity from studies in humans

which indicates a causal relationship between exposure to the agent, substance or mixture and human cancer.

Reasonably Anticipated To Be Human Carcinogens

There is limited evidence of carcinogenicity from studies in humans which indicates that causal interpretation is credible but that alternative explanations such as chance, bias or confounding factors could not adequately be excluded; or

There is sufficient evidence of carcinogenicity from studies in experimental animals which indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors: (1) in multiple species, or at multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an unusual degree with regard to incidence, site or type of tumor or at onset; or

There is less than sufficient evidence of carcinogenicity in humans or laboratory animals; However, the agent, substance or mixture belongs to a well defined, structurally-related class of substances whose members are listed in a previous Report on Carcinogens as either a known to be human carcinogen, or reasonably anticipated to be human carcinogen or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive subpopulations, genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals but there are compelling data indicating that the agent acts through mechanisms which do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans.

A detailed description of the review procedures, including the steps in the formal review process, is available at <http://ntp-server.niehs.nih.gov> or can be obtained 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 NTP is considering 11 agents, substances, mixtures and exposure circumstances for possible review in 2000, as either a new 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. These nominations are provided in the following table with their Chemical Abstracts Services (CAS) Registry numbers (where available) and pending review action. The NTP solicits public input on these 11 nominations and asks for relevant information anyone may have concerning their carcinogenesis, as well as current production data, use patterns, or human exposure information. The NTP also invites interested parties to identify any

scientific issues related to the listing of a specific nomination in the RoC that they feel should be addressed during the reviews. Comments concerning these nominations for listing in, changing the current listing in, or delisting from the Tenth Report on Carcinogens will be accepted through June 5, 2000. Individuals submitting public comments are asked to include relevant contact information (name, affiliation (if any), address, telephone, fax, and email). Comments or questions should be directed to Dr. C. W. Jameson at the address listed above.

Additional Nominations for Delisting or Listing Encouraged

The NTP solicits and encourages the broadest participation from interested individuals or parties in nominating

agents, substances, or mixtures for listing in or delisting from the Tenth and future RoCs. Nominations should contain a rationale for listing or delisting. Appropriate background information and relevant data (e.g. Journal articles, NTP Technical Reports, IARC listings, exposure surveys, release inventories, etc.), which support a nomination, should be provided or referenced when possible. Contact information for the nominator should also be included (name, affiliation (if any), address, telephone, fax, and email). Nominations should be sent to Dr. Jameson's attention at the address given above.

Dated: March 27, 2000.

Kenneth Olden,

Director, National Toxicology Program.

SUMMARY FOR NOMINATIONS TO BE REVIEWED IN 2000 FOR CONSIDERATION OF LISTING IN OR DELISTING FROM THE TENTH REPORT ON CARCINOGENS

Nomination/CAS No.	Primary uses or exposures	To be reviewed for	Basis of nomination
Chloramphenicol (56-75-7)	Used widely as an antibiotic since the 1950s. Veterinary use of chloramphenicol has resulted in the occurrence of residues in animal-derived food.	Listing in the 10th Report.	Nominated by RG1 ¹ based on the IARC ² identification of chloramphenicol as a Group 2A-Probable Human Carcinogen (Vol. 50, 1990). IARC listing based on findings of limited evidence of carcinogenicity in humans based on case reports, which described an unusual succession of leukemia following chloramphenicol-induced aplastic anemia and bone-marrow depression.
Human Papillomaviruses (HPVs)	HPVs are small, non-enveloped viruses that contain a double-stranded, circular 8 kb DNA genome. HPV infections are common throughout the world, are highly host-specific and, with the exception of some ungulate papillomaviruses, infect only epithelial cells.	Listing in the 10th Report.	Nominated by RG1 ¹ based on IARC ² finding of sufficient evidence of carcinogenicity in human epidemiology studies and identifying certain human papillomaviruses as a Group 1—Known Human Carcinogen (Vol. 64, 1995). HPVs are found in over 90% of all invasive cervical cancers and in a high proportion of certain other anogenital cancers. Carcinogenicity in humans has been most firmly established for HPV-16, but strong evidence of carcinogenicity also exists for certain other HPV types.
Lead and Lead Compounds	Widespread uses which have included use in pipes for water distribution, lead-based paints, lead additives in gasoline, and many other applications.	Listing in the 10th Report.	Nominated by RG1 ¹ based on recent published data that indicate an excess of cancers in workers exposed to lead and lead compounds.
Methyleugenol (93-15-2)	Flavoring agent used in jellies, baked goods, nonalcoholic beverages, chewing gum, candy, and ice cream. Also used as a fragrance for many perfumes, lotions, detergents and soaps.	Listing in the 10th Report.	Nominated by RG1 ¹ based on recent NTP Technical Report (TR 491, 1998) reporting clear evidence of carcinogenic activity of methyleugenol in rats and mice based on the increased incidences of liver neoplasms in rats and mice, neuroendocrine tumors of the glandular stomach in male and female rats and male mice, and the increased incidences of kidney neoplasms, malignant mesothelioma, mammary gland fibroadenoma, and subcutaneous fibroma and fibroma or fibrosarcoma (combined) in male rats.
Nickel and Nickel Compounds including Metallic Nickel & Nickel Alloys.	Widely used in commercial applications for over 100 years.	Listing in the 10th Report.	Action required to complete review of Nickel and Nickel Compounds. This review will be of metallic nickel and nickel alloys. Review of nickel compounds for listing in the Report on Carcinogens was completed in 1998.

SUMMARY FOR NOMINATIONS TO BE REVIEWED IN 2000 FOR CONSIDERATION OF LISTING IN OR DELISTING FROM THE TENTH REPORT ON CARCINOGENS—Continued

Nomination/CAS No.	Primary uses or exposures	To be reviewed for	Basis of nomination
Estrogens, steroidal	Estrogens are widely used in oral contraceptives and in post-menopausal therapy for women.	Listing in the 10th Report.	Nominated by RG1 ¹ based on IARC ² identification of Estrogens, Steroidal as a Group 1—Known Human Carcinogen (Vol. 72, 1999) IARC listing based on a consistent, strongly positive association between exposure to a number of estrogenic substances and risk of endometrial and breast cancer in women.
Talc (14807–96–6) (Non-Asbestiform).	Talc (non-asbestiform) occurs in various geological settings around the world. Occupational exposure occurs during mining, milling and processing. Exposure to general population occurs through use of products such as cosmetics.	Listing in the 10th Report.	Nominated by RG1 ¹ based on NTP Technical Report (TR 421, 1993) which reported clear evidence of carcinogenic activity of talc (non-asbestiform) based on increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung in female rats and also recently published epidemiology studies that suggests that talc exposure among pottery workers has been associated with lung cancer, and ovarian neoplasms in women.
Talc (14807–96–6) (Containing Asbestiform Fibers).	Talc (containing asbestiform fibers) occurs in various geological settings around the world. Occupational exposure occurs during mining, milling and processing.	Listing in the 10th Report.	Nominated by RG1 ¹ based on IARC ² identification of talc (containing asbestiform fibers) as a Group 1—Known Human Carcinogen (Sup 7, 1987). IARC listing based on the observed association between exposure to talc containing asbestiform fibers and mesothelioma in humans.
Trichloroethylene (TCE) (79–01–6).	Trichloroethylene is widely used as a solvent with 80–90% used worldwide for degreasing metals.	Upgrade to Known	Recommended by RG1 ¹ to be upgraded to a known human carcinogen based on recent published data that indicate an excess of kidney cancers in workers exposed to trichloroethylene.
Broad Spectrum UV Radiation ...	Solar and artificial sources of ultraviolet radiation.	Listing in the 10th Report.	Review of UVA, UVB and UVC recommended by RG2 ³ based on earlier Report on Carcinogens review of solar UV radiation.
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.	Listing in the 10th Report.	Nominated by the Occupational Safety and Health Administration based on IARC ² identification of wood dust as a Group 1—Known Human Carcinogen (Vol. 62, 1995). IARC listing based on increases in cancer, particularly cancer of the nasal cavities and paranasal sinuses, associated with exposure to wood dust.

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

² International Agency For Research On Cancer (IARC).

³ The NTP Executive Committee* Interagency Working Group for the Report on Carcinogens (RG2).

*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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; Call for Public Comments on 9 Substances Proposed for Listing in or Delisting from the Report on Carcinogens, Tenth Edition

Background

The National Toxicology Program (NTP) solicits final public comments on additional agents, substances, mixtures and exposure circumstances 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, (HHS), shall publish a biennial report which contains a list of all substances (1) which either are