This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 20, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–24730 Filed 9–25–96; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Office of Cancer Communications; Notice of Partnership Initiative

Pursuant to Pub. L. 92–463, notice is hereby given that the Office of Cancer Communications, National Cancer Institute, is seeking partnerships with non-Federal organizations to conduct public awareness programs on cancer research, patient education, clinical trials, screening, prevention, genetics education, and cancer risk communication. The goal is to strengthen the National Cancer Program by forming partnerships with private sector organizations. These cooperative efforts are intended to bring the resources of several partners to bear on cancer-related problems that are too complex or massive for any one organization to handle alone.

Note: Partnerships between NCI and outside organizations will be formalized through Memorandum of Agreements and will not involve grants or contracts.

Date of Effectiveness: Beginning immediately.

For more information, please contact John Burklow, Office of Cancer Communications, National Cancer Institute, at (301) 496–6631.

Dated: September 12, 1996.

Philip D. Amoruso,

Director, Office of Extramural Management.

[JR Dos. 96–24625 Filed 9–25–96; 8:45 am]

BILLING CODE 4140–01–M

Public Health Service

The National Toxicology Program (NTP) Revised Criteria and Process for Listing Substances in the Biennial Report on Carcinogens

AGENCY: National Institute of Environmental Health Sciences, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services is providing this notice of changes in the criteria for listing carcinogens in the Biennial Report on Carcinogens. The process for developing these changes was public and included participation of a broad base of interested parties. The revised criteria will be used to develop the eighth annual report.

FOR FURTHER INFORMATION CONTACT: Dr. C.W. Jameson, NIEHS/NTP, Biennial Report on Carcinogens, MD WC–05, P.O. Box 12233, Research Triangle Park, North Carolina 27709: fax 919 541–2242; internet Jameson@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

Section 301(b)(4) of the Public Health Service Act, as amended, provides that the Secretary, Department of Health and Human Services (HHS), 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 Biennial Report on Carcinogens is prepared by the National Toxicology Program (NTP).

A review of the criteria used to list substances in the Report was initiated by the Director, NTP in late 1994. The process for the review was public and included participation of a broad base of interested persons including Academia, Industry, Labor, Federal, State and Local Agencies and Private Organizations. During 1995 the review included two open, public meetings by the NTP Board of Scientific Counselors and a number of internal reviews by HHS and the NTP Executive Committee agencies.

At each step of the review there was concurrence with the following points: (1) the current criteria should be revised; (2) mechanistic information should be used as part of the listing criteria; (3) the categories (known to be human carcinogens and reasonably anticipated to be human carcinogens) should remain the same as described in the original legislation; and (4) there should be a formal mechanism which allows for the removal of substances from the BRC. Based on these recommendations, revised criteria and a new procedure for applying these criteria for inclusion or removal of substances in the BRC were prepared by the NTP with the assistance of NTP participating agencies.

Revised Criteria

A point by point comparison of the former BRC criteria to the revised criteria follows. Sections that have been deleted from the former BRC criteria are in brackets []. The changes/additions in the revised criteria are highlighted by underlining.

Former BRC Criteria Known To Be Carcinogens

There is sufficient evidence of carcinogenicity from studies in humans which indicates a causal relationship between the agent and human cancer.

Revised BRC Criteria 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.

Former BRC Criteria Reasonably Anticipated To Be Carcinogens

[a.] 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, could not adequately be excluded, or

[b.] There is sufficient evidence of carcinogenicity from studies in experimental animals which indicates that there is an increased incidence of malignant tumors: (a) in multiple species [or strains], or (b) [in multiple experiments (preferably with different routes of administration or using different dose levels)], or (c) to an unusual degree with regard to incidence, site or type of tumor, or age at onset. Additional evidence may be provided by data concerning dose-response effects, as well as information on mutagenicity or chemical structure.]

Revised BRC Criteria 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, could not adequately be excluded, or

There is sufficient evidence of carcinogenicity from studies in experimental animals which indicates that there is an increased incidence of malignant *and/or combined benign and malignant tumors:* (a) in multiple species *or at multiple tissue sites,* or *(b) by multiple routes of exposure,* or (c) to an unusual degree with regard to incidence, site or type of tumor, or age 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 Annual or Biennial 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.

The following descriptive paragraph has been added to the criteria:

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 sub populations, 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 reasonably be anticipated not to cause cancer in humans.

Expanded Review Procedure

External peer review is added to the review process through the establishment of a new, standing subcommittee of the NTP Board of Scientific Counselors. The BRC Subcommittee will meet twice a year, in public session, to review nominations for listing and /or delisting and to receive public comment.

Listing/Delisting Procedures

Nominations of chemicals for listing or delisting will be solicited from government, industry, academia, Federal, State and local agencies, and the general public. However, nominations can be submitted to the National Toxicology Program at any time. Interested persons should send nominations which contain a justification for listing or delisting the agent, substance, or mixture in the BRC to the: National Toxicology Program, Biennial Report on Carcinogens, MD WC–05, P.O. Box 12233, Research Triangle Park, NC 27709. To the extent feasible, all appropriate background information and relevant data (e.g. scientific journal publications, NTP reports, IARC listings, exposure surveys, release inventories, etc.) that support the nomination should be provided or fully referenced to permit retrieval. Nominations will be reviewed as expeditiously as possible. A list of new petitions for listing or delisting will be routinely published in appropriate publications, including the Federal Register, trade journals, and the NTP Liaison Office mail-outs, soliciting public comment and input on the nominations.

Dated: August 15, 1996.

Kenneth Olden,

Director National Institute of Environmental Health Sciences and the National Toxicology Program.

Dated: September 12, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–24227 Filed 9–25–96; 8:45 am]

BILLING CODE 4140–01–P

National Toxicology Program; Availability of Technical Report of Comparative Initiation/Promotion Skin Paint Studies of B6C3F$_1$ Mice, Swiss (CD–1®) Mice, and SENCAR Mice

The HHS' National Toxicology Program announces the availability of the NTP Technical Report on the Comparative Initiation/Promotion Skin Paint Studies of B6C3F$_1$ Mice, Swiss (CD–1®) Mice, and SENCAR Mice.

All three strains of mice demonstrated sensitivity by developing skin tumors after topical application of the chemicals under study (7,12–dimethylbenz(a)anthracene (DMBA), N-methyl-N′-nitro-N-nitrosoguanidine (MNNG), 12-O-tetradecanoylphorbol-13-acetate (TPA), and benzoyl peroxide (BPO). The most sensitive of the three strains appeared to be SENCAR mice, in the sense that lower doses of the test chemical were generally required to produce effects equivalent to those in the other two strains. Skin tumors also tended to develop earlier and with greater multiplicity in SENCAR mice than in the other two strains. By these criteria, the overall sensitivity of Swiss (CD–1®) mice was intermediate, and B6C3F$_1$ mice showed the least overall sensitivity to dermal carcinogenicity.

The 1-year complete carcinogen studies used repeated applications of low concentrations of the carcinogens DMBA and MNNG. There was a high incidence of skin tumors in all three strains with both carcinogens. More B6C3F$_1$ and SENCAR mice developed skin tumors and averaged more tumors per mouse than did Swiss (CD–1®) mice. Skin tumors developed earlier in SENCAR mice than in B6C3F$_1$ and Swiss (CD–1®) mice. Although B6C3F$_1$ mice exhibited the lowest overall sensitivity to the initiation/promotion protocol when compared to Swiss (CD–1®) and SENCAR mice, the response of B6C3F$_1$ mice was similar to Swiss (CD–1®) and SENCAR mice for complete carcinogen studies.

Questions or comments about the Technical Report should be directed to Central Data Management at NIEHS, MD E1–02, P.O. Box 12233, Research Triangle Park, NC 27709 or telephone (919) 541–3419.

Copies of the *Comparative Initiation/Promotion Skin Paint Studies of B6C3F$_1$ Mice, Swiss (CD–1®) Mice, and SENCAR Mice* (TR–441) are available without charge from Central Data Management, NIEHS, MD E1–02, P.O. Box 12233, Research Triangle Park, NC 27709; telephone (919) 541–3419.

Dated: August 21, 1996.

Kenneth Olden,

Director, National Toxicology Program.

[FR Doc. 96–24626 Filed 9–25–96; 8:45 am]

BILLING CODE 4140–01–M

National Toxicology Program; Availability of Technical Report on Toxicology and Carcinogenesis Studies of Acetonitrile

The HHS' National Toxicology Program announces the availability of the NTP Technical Report on the toxicology and carcinogenesis studies of acetonitrile. Acetonitrile is used primarily as a solvent in extractive distillation and crystallization of pharmaceutical and agricultural products and as a catalyst in chemical reactions.

Toxicology and carcinogenicity studies were conducted by administration of acetonitrile by inhalation to groups of 56 F344/N rats of each sex at doses of 0, 100, 200, or 400 ppm (equivalent to 0, 168, 335, or 670 mg/m^3) and 60 B6C3F$_1$ mice of each sex were exposed at doses of 0, 50, 100, or 200 ppm (equivalent to 0, 84, 168, or 335 mg/m^3) for 6 hours per day, 5 days per week for 2 years.

Under the conditions of these 2-year inhalation studies, there was equivocal evidence of carcinogenic activity [1] of acetonitrile in male F344/N rats based on marginally increased incidences of hepatocellular adenoma and carcinoma. There was no evidence of carcinogenic activity of acetonitrile in female F344/

[1] The NTP uses five categories of evidence of carcinogenic activity observed in each animal study: two categories for positive results (''clear evidence'' and ''some evidence''), one category for uncertain findings (''equivocal evidence''), one category for no observable effect (''no evidence''), and one category for studies that cannot be evaluated because of major flaws (''inadequate study'').