

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]

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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,