DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program (NTP) Proposed Revised Criteria for Listing Substances in the Biennial Report on Carcinogens (BRC) and Notice of Meeting of the NTP Board of Scientific Counselors

Background

A public meeting of the NTP Board of Scientific Counselors' ad hoc Working Group to Review the Criteria for Listing Substances in the Biennial Report on Carcinogens (BRC) was held on April 24 and 25, 1995, at the Washington Hilton and Towers Hotel, 1919 Connecticut Avenue NW., Washington DC. The purpose of the meeting was to receive public comments on the current criteria for listing substances in the BRC, and to review and make recommendations on these criteria. The issues addressed by this ad hoc group were: (1) The adequacy of existing criteria for listing substances in future Reports; and (2) the incorporation of mechanistic data as part of the criteria for listing substances in future Reports which may include the consideration of sensitive subpopulations as well as procedures to upgrade or downgrade the evaluation of the results of animal bioassay or epidemiology studies. A background and discussion document prepared by the NTP for use by the ad hoc working group and also for review and comment by the public, is available upon request. Copies of this document can be obtained by contacting the NTP Liaison Office at NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709, or by FAX to (919) 541–0295.

This meeting was the first step in the review of the criteria and was open to the public. The meeting began with a plenary session which provided background on the BRC and a public comment session. The working group then broke into three breakout groups, with each breakout group addressing the same above listed issues. The final session of the meeting was a plenary session at which time each breakout group reported on their deliberations. The chairperson, rapporteur, and facilitator of the three breakout groups completed draft reports of their group's discussions and recommendations and submitted it to the Chairperson of the ad hoc working group. The Chairperson, working with NIEHS/NTP staff, completed a draft summary report of the criteria review meeting which subsequently was sent to all ad hoc working group members for editing and

corrections. A copy of the revised summary report is printed below. Also printed below are the current and proposed revised criteria developed by the NIEHS/NTP based on the input of the NTP Board of Scientific Counselors' ad hoc working group.

Action-Request for Public Input on the Proposed Revised Criteria

The NTP seeks comments and views on the proposed revised criteria which follows. Public input concerning the proposed revised criteria for listing a substance in the BRC is important to the review process and is encouraged. A further opportunity for comment will be provided during a meeting of the NTP Board of Scientific Counselors in the NIEHS Conference Center, Building 101, South Campus, National Institute of Environmental Health Sciences, 111 Alexander Drive, Research Triangle Park, North Carolina, on June 29, 1995. The primary agenda topic for this meeting concerns the summary report and recommendations of the ad hoc working group of the NTP Board from their review of the criteria for listing substances in the BRC on April 24 and 25, 1995. This meeting is open to the public, and public input concerning the criteria for listing a substance in the **Biennial Report on Carcinogens is** encouraged. Formal oral comments during the NTP Board meeting will be limited to five minutes to permit maximum participation. Written comments accompanying oral statements are encouraged. To assure consideration by the Board at this meeting, written comments must be submitted to Dr. Larry G. Hart, Executive Secretary for the NTP Board of Scientific Counselors and received by June 23, 1995. Registration to attend is not required; however, to ensure adequate seating, we ask that those planning to attend let us know. To register, submit written comments or announce intention to make oral comments on the criteria review report, receive information on the agenda, or be put on the mailing list for summary minutes subsequent to the meeting, please contact: Dr. L. G. Hart, P.O. Box 12233, Research Triangle Park, NC 27709; telephone: (919) 541-3971; FAX: (919) 541-0719.

Dated: May 30, 1995.

Kenneth Olden,

Director, National Toxicology Program.

Attachments

Summary Report of the Meeting of the National Toxicology Program's Board of Scientific Counselors' Ad Hoc Working Group To Review the Criteria for Listing Substances in the Biennial Report on Carcinogens, Washington Hilton and Towers Hotel, Washington, D.C., April 24 and 25, 1995

Background

The Biennial Report on Carcinogens is prepared in response to Section 301(b)(4) of the Public Health Service Act which stipulates that the Secretary of the Department of Health and Human Services shall publish a report which contains a list of all substances (i) which either are known to be human carcinogens or may reasonably be anticipated to be human carcinogens; and (ii) to which a significant number of persons residing in the United States are exposed. This responsibility has been delegated by the Secretary to the Director, National Toxicology Program (NTP). Dr. Ken Olden, Director of the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program, has initiated a review of the BRC to broaden input to its preparation, broaden the scope of scientific review associated with the Report, and provide review of the criteria used for inclusion of substances in the BRC.

An ad hoc working group of the NTP Board of Scientific Counselors was established to receive public comments on the existing criteria and review and make recommendations on the criteria for listing substances in the BRC. This ad hoc working group had a balance of expertise and views and included representatives from Academia; Industry; Labor; Federal, State and Local Agencies; and Private Organizations. The working group reviewed the criteria in an open, public meeting in Washington, D.C. on April 24 & 25, 1995.

Meeting Summary

The ad hoc working group was chaired by NTP Board of Scientific Counselors member Dr. Arnold Brown of the University of Wisconsin. The working group was divided into three breakout groups to allow for a more in depth discussion of the criteria and the public comments received. Each of the breakout groups were asked to address the following issues in their review of the criteria:

(a) The adequacy of existing criteria for listing substances in future Reports; and

(b) The incorporation of mechanistic data as part of the criteria for listing substances in future Reports that may include the consideration of sensitive sub-populations as well as procedures to upgrade or downgrade the evaluation of the results of animal bioassay or epidemiology studies.

Plenary Session I was chaired by Dr. George Lucier, Director, Environmental Toxicology Program, NIEHS/NTP and allowed for opening and background presentations by Dr. Kenneth Olden, Director, NIEHS and NTP, Dr. C. W. Jameson, NIEHS/NTP, and Dr. Marilyn Wind, CPSC (NTP Executive Committee BRC Working Group representative). Dr. Lucier then gave the charge to the ad hoc working group to