

Dated: July 10, 2001.

LaVerne Y. Stringfield,
Director, Office of Federal Advisory
Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Draft Methanol Expert Panel Report and Meeting

National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), Center for the Evaluation of Risks to Human Reproduction (CERHR), announces:

(1) Availability of the Draft Methanol Expert Panel Report—Public comments are solicited on the draft report and the deadline for written comments is September 7, 2001.

(2) Methanol Expert Panel Meeting scheduled for October 15–17, 2001—The meeting is open to the public and will be held at the Radisson Hotel in Old Town Alexandria in Alexandria, Virginia.

Background

The NTP and the NIEHS established the NTP Center for the Evaluation of Risks to Human Reproduction (CERHR) [Federal Register (FR), December 14, 1998 (Volume 63, Number 239, page 68782)] in June 1998. The purpose of the Center is to provide scientifically-based, uniform assessments of the potential for adverse effects on reproduction and development caused by agents to which humans may be exposed. Expert panels conduct scientific evaluations of agents selected by the Center in public forums. The agent currently under evaluation is methanol. Additional details about CERHR and the formal review process are provided below (see Additional Information about CERHR).

Methanol (CASRN: 67-56-1) is a commercially important, high production volume chemical (10.54 billion pounds, US production, 1993), with high potential for occupational, consumer, and environmental exposure. Methanol is used in chemical syntheses and as an industrial solvent. It is found in a variety of consumer products such as paints, antifreeze, cleaning solutions, and adhesives and is a by-product of sewage treatment, fermentation, and paper production. Methanol is used in racing car fuels, and there is the potential for the expanded use of methanol as a vehicle fuel or fuel additive. There is a large toxicity

database on reproductive and developmental effects of methanol, including a recently completed study in primates.

Draft Methanol Expert Panel Report Available

The Draft Methanol Draft Expert Panel Report is composed of the following sections:

- 1.0 Chemistry, Use, and Human Exposure
- 2.0 General Toxicological and Biological Effects
- 3.0 Developmental Toxicity Data
- 4.0 Reproductive Toxicity Data
- 5.0 Summary, Conclusions, and Critical Data Needs

Sections 1–4 will be available to the public by July 9. Copies can be obtained electronically on the CERHR web site (<http://cerhr.niehs.nih.gov>) or in hard copy by contacting Dr. Michael Shelby, CERHR Director (NIEHS, 79 T.W. Alexander Drive, Building 4401, Room 103, P.O. Box 12233, MD EC-32, Research Triangle Park, NC 27709, Phone: (919) 541-3455; Fax: (919) 316-4511; shelby@niehs.nih.gov).

Request for Written Comments on Draft Methanol Expert Panel Report

The CERHR invites written public comments on Sections 1–4 of the Draft Methanol Expert Panel Report. Comments can be submitted in hard copy or electronic format and must be received by the Center by September 7, 2001. These comments will be distributed to CERHR staff and the Methanol Expert Panel for consideration in reviewing the draft report and in preparing for the Methanol Expert Panel Meeting (see below). These comments should be sent to Dr. Michael Shelby at the address provided above. Persons submitting written comments are asked to include their name and contact information (affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, if any).

Expert Panel Will Review Methanol

An expert panel (the Panel) of 13 independent scientists selected for their scientific expertise in reproductive and developmental toxicology and other relevant areas of science are conducting this review. The roster of experts follows:

Methanol Expert Panel (Name and Affiliation)

Eula Bingham, Ph.D. (Chair), University of Cincinnati, Cincinnati, Ohio
Stanley Barone, Ph.D. US EPA, Research Triangle Park, NC
David Bellinger, Ph.D., Children's Hospital, Boston, MA

Gary Burin, Ph.D., Technology Sciences Group, Washington, DC
Robert Chapin, Ph.D., DuPont Pharmaceuticals, Newark, DE
J. Michael Davis, Ph.D., US EPA, Research Triangle Park, NC
David Dorman, DVM, Ph.D., CIIT Centers for Health Research, Research Triangle Park, NC
John R. Glowa, Ph.D., LSU Medical Center, Shreveport, LA
Deborah K. Hansen, Ph.D., National Center for Toxicological Research, Jefferson, AR
H.B. (Skip) Matthews, Ph.D., Consultant, Durham, NC
Mark Miller, M.D., MPH Cal EPA, Oakland, CA
Kathleen M. Nauss, Ph.D., Consultant, Sudbury, MA
John M. Rogers, Ph.D., US EPA, Research Triangle Park, NC

Public Meeting of the Methanol Expert Panel

This meeting is open to the public and attendance is limited only by the availability of space. This meeting will take place from October 15–17, 2001 in the Washington Ballroom of the Radisson Hotel Old Town Alexandria, 901 N. Fairfax Street, Alexandria, Virginia, telephone (703) 683-6000, fax (703) 683-7597.

Preliminary Meeting Agenda

The meeting begins each day at 8:30 a.m. It is anticipated that a lunch break will occur from 12–1 p.m. daily and that adjournment will be between 5 and 6 p.m. each day.

October 15, 2001 (8:30 a.m.)

Opening comments—Public Comment comment session

- The Panel will receive comments from the public (up to seven minutes per speaker; details are given below).
- Review of Sections 1–4 of the Draft Methanol Expert Panel Report
Discussion of Section 5.0 Summary, Conclusions, and Critical Data Needs

October 16, 2001 (8:30 a.m.)

Discussion of Section 5.0 Summary, Conclusions, and Critical Data Needs
Preparation of draft summaries and conclusion statements

October 17, 2001 (8:30 a.m.)

Presentation and discussion of and agreement on summaries and conclusions
Closing comments

Oral Comments Can Be Presented at the Expert Panel Meeting

Time is set aside on October 15 for presentation of oral public comments at

the Methanol Expert Panel Meeting. To facilitate planning of this meeting, those persons wishing to make oral public comments are asked to contact the CERHR Director by October 10 [Dr. Michael Shelby, NIEHS, 79 T.W. Alexander Drive, Building 4401, Room 103, P.O. Box 12233, MD EC-32, Research Triangle Park, NC 27709, Phone: (919) 541-3455; Fax (919) 316-4511; shelby@niehs.nih.gov]. Seven minutes will be available for each speaker (one speaker per organization). When registering to comment orally, please provide your name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization (if any). If possible, also send a copy of the statement or talking points to CERHR by October 10. This information will be provided to the Expert Panel and will assist the Panel in identifying issues for discussion. Registration for presentation of oral comments will also be available at the meeting on October 15 (7:30—8:30 a.m.). Those registering at the meeting are asked to bring 20 copies of their statement or talking points. In lieu of making an oral presentation at the meeting, the public is invited to submit a written statement to CERHR by October 10. This statement will be distributed to CERHR staff and the Methanol Expert Panel and noted in the meeting record.

Post-Meeting Public Comments

Following the Methanol Expert Panel Meeting and completion of the Expert Panel Report, public comment will be solicited. This solicitation will be announced in a future **Federal Register** notice.

For other questions about the Draft Methanol Report or the Methanol Expert Panel Meeting, contact Dr. Michael Shelby [CERHR, NIEHS, 79 T.W. Alexander Drive, Building 4401, Room 103, P.O. Box 12233, MD EC-32, Research Triangle Park, NC 27709, Phone: (919) 541-3455; Fax (919) 316-4511; shelby@niehs.nih.gov.]

Additional Information About CERHR

CERHR invites the nomination of agents for review or scientists for its expert registry. Information about CERHR and the nomination process can be obtained from its homepage (<http://cerhr.niehs.nih.gov>) or by contacting the Center Director, Dr. Shelby (contact information provided above). The Center selects chemicals for evaluation based upon several factors including production volume, extent of human exposure, public concern, and published evidence of reproductive or developmental toxicity. The Center establishes an expert panel to review the

scientific evidence on the chemical(s) under review, to receive public comments, and to prepare a report on the chemical(s). This draft Expert Panel Report is made publicly available for comment on the CERHR web site and upon request from CERHR, and an Expert Panel Meeting is held to discuss and evaluate the draft report. Following the Expert Panel Meeting and completion of the Expert Panel Report, public comment is solicited again.

After this public comment period ends, the NTP staff prepares a NTP Center Report on the evaluated chemical(s) that integrates background information on the chemical(s), findings of the expert panel, and a discussion of any additional, recent studies. The NTP Center Report includes all public comments received on the Expert Panel Report. The final NTP Center Report is made publicly available and distributed to interested stakeholders and to appropriate regulatory and research agencies. The formal evaluation process is outlined below.

CERHR Review Process

- Chemical Nominations. Open nomination process includes interested individuals, NTP Executive Committee, Federal Agencies, NTP Staff, Labor Unions, Industry
- CERHR Multi-agency Core Committee.
- Nominations reviewed quarterly by Core Committee made up of NTP agency representatives
- Highest priority chemicals identified based on production volume, evidence of reproductive or developmental toxicity, human exposure, public concern
- Center staff prepares dossiers on priority chemicals for review by Core Committee
- Core Committee recommends candidate chemicals to be considered for evaluation
- Candidate chemicals approved by Associate Director, NTP
 - First Solicitation of Public Comment.
- Notice of candidate chemicals and request for public comment published in **Federal Register**, NTP Newsletter and listserv, and CERHR web site
- Center staff compiles public comments for review by the Core Committee
 - CERHR Core Committee Review.
- Reviews dossiers and material submitted in public comments
- Recommends list of prioritized chemicals to Associate Director, NTP, for final selection

- Second Solicitation of Public Comment.

—**Federal Register** notice announces selected chemical(s) and solicits public comment, new data, information on exposure, and nominations of individuals qualified to serve on the Expert Panel

- Third Solicitation of Public Comment.

—**Federal Register** notice announces availability of sections 1–4 of the Draft Expert Panel Report, requests public comments, and announces the Expert Panel Meeting

- Expert Panel Meeting.
- The Panel meets in public session to discuss their review of the literature and to prepare the final panel report
- The meeting includes time for presentation of public comments
 - Final Solicitation of Public Comment.
- Federal Register** notice announces availability of Expert Panel Report and requests public comment
 - NTP Center Report Transmitted.

—NTP staff prepares an NTP Center Report on the chemical(s). This report integrates background information on the chemical evaluated, the findings in the Expert Panel Report, a discussion of any recent relevant study findings, public comments, and an executive summary that includes conclusions intended for a readership of non-scientists

—The Center Report is distributed to Federal and state agencies, interested stakeholders, and the public

Dated: July 2, 2001.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information