

Agenda items include highlights of the Office of Children's Health Protection (OCHP) activities and reports from the Science and Regulatory Work Group. Other potential agenda items include an EPA briefing on Information Quality Guidelines and an informational panel on human milk contamination.

**FOR FURTHER INFORMATION CONTACT:**

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Dated: February 26, 2003.

**Elizabeth Blackburn,**

*Acting Designated Federal Official.*

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**ENVIRONMENTAL PROTECTION AGENCY**

[FRL-7457-2]

**Notice of Availability and Opportunity To Provide Comment on the Draft Final Guidelines for Carcinogen Risk Assessment and the Draft Supplemental Guidance for Assessing Cancer Susceptibility From Early-Life Exposure to Carcinogens**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of availability and public comment period.

**SUMMARY:** EPA is today announcing the availability of, and opportunity to comment on, the Draft Final Guidelines for Carcinogen Risk Assessment and the draft Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens.

In 1996, EPA published for public comment proposed revisions to EPA's 1986 Guidelines for Carcinogen Risk Assessment. Since the 1996 proposal, the Agency has benefitted from extensive public comment and scientific peer review, including three reviews by EPA's Science Advisory Board (SAB). The major issues currently being considered by EPA as it proceeds to issue final Guidelines are identified in the Supplementary Information section of this notice. As announced in November 2001, the July 1999 draft revised Guidelines will continue to serve as EPA's interim guidance to EPA risk assessors preparing cancer risk assessments until final Guidelines are issued.

The Draft Final Guidelines issued today for comment explicitly call for consideration of possible sensitive subpopulations and/or lifestages (such

as childhood). Therefore, concurrent with release of the Draft Final Guidelines, EPA is also requesting public comment on draft supplemental guidance describing possible approaches that could be used to assess risks resulting from early life exposure to potential carcinogens. This draft supplemental guidance will be peer reviewed by the Agency's Science Advisory Board at a public meeting that will be announced in a separate **Federal Register** notice. The supplemental guidance is separate from the Guidelines so that it may be more easily updated in a timely manner given the expected rapid evolution of scientific understanding about the effects of early-life exposures.

**DATES:** Comments must be received by Thursday, May 1, 2003.

**ADDRESSES:**

**Document Availability**

The Draft Final Guidelines for Carcinogen Risk Assessment (February 2003, NCEA-F-0644A) and the draft Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens (EPA/630/R-03/003) are available via the Internet from <http://www.epa.gov/ncea/raf/cancer2003.htm>. A limited number of paper copies of the documents are available from the Technical Information Staff (8623D), NCEA-W, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: 202-564-3261; facsimile: 202-565-0050.

**Submitting Comments**

One of three methods may be chosen to submit comments, and comments may be in electronic or paper copy format. First, comments may be submitted through EPA's electronic public docket and comment system, EPA Dockets. EPA Dockets is available at <http://www.epa.gov/edocket/>. Once in the system, select "search," then key in the appropriate docket identification number (OAR-2003-0008). Second, comments may be submitted via e-mail to "[a-and-r-Docket@epa.gov](mailto:a-and-r-Docket@epa.gov)." Third, paper copies of comments may be submitted (in duplicate if possible) to the Air Docket at the Environmental Protection Agency, EPA Docket Center (EPA/DC), Office of Air and Radiation, Mail Code 6102T, 1200 Pennsylvania Avenue NW., Washington, DC 20460. Please refer to Public Docket Number OAR-2003-0008 in e-mail and in paper correspondence. Acknowledgments will not be sent for electronic or paper comment submissions. Persons providing information or comments

should not submit personal information (such as medical data or home address), Confidential Business Information, or information protected by copyright because all comments will be made available for public viewing.

**Viewing Public Comments**

Public comments pertaining to this notice may be viewed by using EPA Dockets, or by visiting EPA's Air Docket. EPA intends to make all comments received in response to this **Federal Register** Notice available in EPA Dockets (<http://www.epa.gov/edocket/>), including documents originally submitted in paper format. To view comments select "search," then key in the appropriate docket identification number (OAR-2003-0008). Also, paper copies of materials related to this notice are available for review under Public Docket No. OAR-2003-0008 at EPA's Air Docket. EPA's Air Docket also makes available for review the comments received on the 1996 Proposed Guidelines under Public Docket No. ORD-CAN-96-02 and comments received on the 1999 draft revised Guidelines during the November 2001 public comment period under Public Docket No. ORD-CAN-2001. EPA's Air Docket is located at the following address: U.S. Environmental Protection Agency (EPA), Public Reading Room, Room B102 EPA West Building, 1301 Constitution Avenue NW., Washington, DC 20460. The Reading Room is open between 8 a.m. and 4:30 p.m., Monday through Friday, except on legal holidays. Visitors to the Public Reading Room are required to show photographic identification and sign the Agency's visitor log. There may be a reasonable fee for copying docket materials, as provided in 40 CFR part 2. You can reach the Air Docket by telephone at 202-566-1742, and by facsimile at 202-566-1741.

**FOR FURTHER INFORMATION CONTACT:** Dr. William P. Wood, Risk Assessment Forum (mail code 8601D), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460, telephone 202-564-3361, or send electronic mail inquiries to [risk.forum@epa.gov](mailto:risk.forum@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

In 1983, the National Academy of Sciences/National Research Council (NRC) published its report entitled, Risk Assessment in the Federal Government: Managing the Process. In that report, the NRC recommended that Federal regulatory agencies establish "inference guidelines" to promote consistency and