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: Contact Joanne Rodman, Office of Children's Health Protection, USEPA, MC 1107A, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, (202) 564–2188, *rodman.joanne@epa.gov*.

Dated: February 26, 2003.

Elizabeth Blackburn,

Acting Designated Federal Official.

[FR Doc. 03–4915 Filed 2–28–03; 8:45 am]

BILLING CODE 6560–50–P

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*.'' 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*.

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

technical quality in risk assessments and to ensure that the risk assessment process was maintained as a scientific effort separate from risk management. EPA responded to this recommendation by publishing a set of risk assessment guidelines in 1986, including Guidelines for Carcinogen Risk Assessment (51 FR 33992, September 24, 1986). These Guidelines set forth principles and procedures to guide EPA scientists in assessing the cancer risks from chemicals or other agents in the environment and to inform the public about these procedures. EPA continues to revise its risk assessment guidelines and to develop new guidelines as experience and scientific understanding evolve. Revisions to the Guidelines for Carcinogen Risk Assessment are intended to make greater use of the increasing scientific understanding of the mechanisms that underlie the carcinogenic process. As part of that process, the Agency published Proposed Guidelines for Carcinogen Risk Assessment in 1996 (61 FR 17960, April 23, 1996).

The draft revisions to the Guidelines have been subject to extensive public comment and scientific peer review, including three reviews by EPA's Science Advisory Board (SAB). In 2001, EPA published a notice (66 FR 59593, November 29, 2001) providing an additional opportunity for public comment on a 1999 draft of the Guidelines. Comments were invited on experience gained in applying previous draft revised Guidelines and on issues raised in previous comments by the SAB and the public. EPA has also considered the recommendations of the NRC (Science and Judgment in Risk Assessment, 1994) in revising the Guidelines. EPA's approach to the recommendations is reflected in the Guidelines themselves. Draft EPA responses to the NRC recommendations were presented in the preamble to the 1996 draft of these revised Guidelines (61 FR 18003, April 23, 1996). EPA anticipates issuing final responses to the NRC recommendations when it issues final Guidelines.

Role of Risk Assessment Guidelines at EPA

The final Guidelines will be guidance only. They will not establish any substantive ''rules'' under the Administrative Procedure Act or any other law and will have no binding effect on EPA or any regulated entity, but instead will represent a non-binding statement of policy. EPA believes that the Draft Final Guidelines represent a sound and up-to-date approach to cancer risk assessment, and the final Guidelines will enhance the application of the best available science in EPA's risk assessments. However, EPA cancer risk assessments may be conducted differently than envisioned in the final Guidelines for many reasons, including (but not limited to) new information, new scientific understanding, or new science policy judgment. The science of risk assessment continues to develop rapidly, and specific components of the final Guidelines may become outdated or may otherwise require modification in individual settings. Use of the final Guidelines in future risk assessments will be based on decisions by EPA that approaches from the final Guidelines are suitable and appropriate in the context of those particular risk assessments. These judgments will be tested through peer review, and risk assessments will be modified to use different approaches if appropriate.

Even though the final Guidelines will not be binding rules, EPA is issuing them in a manner consistent with the procedures in the Administrative Procedure Act that are generally applicable to rulemaking, including providing an opportunity for public comment. EPA will consider and respond to all significant public comments as it prepares the final Guidelines, and will send a copy of the final Guidelines to Congress. EPA certifies that the Draft Final Guidelines will not have a significant impact on a substantial number of small entities because the Guidelines are for the benefit of EPA and impose no requirements or costs on small entities.

Issues Identified in 2001 Public Comments

A range of views were expressed in the comments submitted to EPA in response to the 2001 notice (66 FR 59593, November 29, 2001) (see the Addresses section for information on viewing these comments). Comments on four issues of interest identified by EPA in the 2001 notice included the following:

(1) Default assumptions. Default assumptions are options that EPA can apply in risk assessments when information about the effects of a substance on human health is unavailable, limited, or of insufficient quality. (For example, if no information is available on the effects of a chemical on humans, a common default assumption is that adverse effects observed in animals due to chemical exposure have the potential to occur in humans as well.) Commenters differed on whether default assumptions should be (a) built into each risk assessment unless sufficient evidence is available to depart from them, or (b) invoked only when determined to be necessary given the data available in a particular risk assessment. Commenters also differed on whether EPA's proposed default assumptions should be more protective of public health versus already being excessively conservative.

(2) Hazard descriptors. Under the 1999 draft Guidelines, one or more standard descriptors (*e.g.*, ''Likely to be Carcinogenic to Humans'') were used to express conclusions about the weight of evidence for human carcinogenic potential. Many commenters generally agreed with EPA's approach for the descriptors, but most recommended that EPA refine the phrases and descriptions to enhance their clarity. Two commenters preferred that descriptors not be used at all. A number of commenters advised the Agency to use the ''Carcinogenic to Humans'' descriptor only when epidemiological evidence of carcinogenicity is conclusive.

(3) Mode of action. EPA's draft 1999 Guidelines emphasized the value of understanding a chemical's ''mode of action,'' which refers to the series of steps and processes that lead to cancer formation. Many commenters disagreed with EPA's proposal that confirmatory data be available or a ''cogent biological rationale'' be developed before a mode of action identified in adults (or mature animals) could be considered applicable to children as well. On the other hand, several commenters stated that EPA should require much stronger evidence before concluding that a particular mode of action operates in both adults and children.

(4) Margin of exposure analysis. A margin of exposure analysis is an approach described in the 1999 draft Guidelines to inform decision-makers about cancer risks at relatively low levels of exposure. The 1999 draft Guidelines suggested its use in the case of certain carcinogens where mode of action data support a nonlinear approach for describing the relationship between dose and response for the chemical. Several commenters expressed concern that the margin of exposure analysis as described by EPA would not be sufficiently protective of public health. Other commenters stated that it inappropriately mixed risk assessment and risk management considerations and was problematic because it removed quantitative estimation of cancer risk from risk assessment.

Key Features of the Draft Final Guidelines

EPA's guiding principle for revisions to the Guidelines is that Agency cancer risk assessments be both public health protective and scientifically sound. By public health protective, EPA means that risk assessments should consider a range of susceptibilities among the human population and, in the absence of complete knowledge, employ assumptions that will reflect the risks to susceptible subpopulations and lifestages. By scientifically sound, EPA means that risk assessments should reflect current and evolving scientific practice and describe risks in a clear, consistent, and reasonable manner. In particular, the revisions to the Guidelines are intended to make greater use of the increasing scientific understanding of the mechanisms that underlie the carcinogenic process. EPA has also designed the Guidelines to be flexible enough to accommodate future scientific advances in science and risk assessment practices. EPA is particularly interested in public comments on the following areas that have been the focus of the Agency's attention in preparing today's Draft Final Guidelines:

(1) Use of default options. The Draft Final Guidelines clarify the role of default options (default assumptions) in the Agency's risk assessments. Rather than view default options as the starting point from which departures may be justified by new scientific information, the Guidelines emphasize that assessments begin with a critical analysis of the available data, and defaults would be invoked as needed when too much uncertainty exists or critical data are missing. In keeping with EPA's mission and the advice of numerous scientific advisory panels, the Agency's default options are constructed to be public health protective. The decision to invoke a default option would be determined on a case-by-case basis. Given the multitude of different types of risk assessments and potential default options, it is neither possible nor desirable to specify step-by-step criteria for decisions to invoke a default option. The Guidelines, however, identify general principles for invoking default options (as originally articulated by the National Research Council): Such decisions should be scientifically defensible, consistent with EPA's statutory mission, and responsive to the needs of decision-makers.

(2) Hazard descriptors. The Draft Final Guidelines continue to emphasize the importance of weighing all of the evidence in reaching conclusions about the human carcinogenic potential of agents, with hazard descriptors used to facilitate clarity in describing carcinogenicity conclusions. Several of the hazard descriptors presented in the Draft Final Guidelines have been modified from previous drafts of the Guidelines, and the discussion of when they would apply has been strengthened. Descriptors may apply only to certain routes of exposure, dose ranges, and durations of exposure. The following five descriptors are discussed in the Guidelines: Carcinogenic to Humans; Likely to Be Carcinogenic to Humans; Suggestive Evidence of Carcinogenic Potential; Inadequate Information to Assess Carcinogenic Potential; and Not Likely to Be Carcinogenic to Humans.

(3) Mode of action. The use of mode of action in the assessment of potential carcinogens is the main thrust of the Draft Final Guidelines. This area of emphasis arose because of scientific breakthroughs concerning the causes of cancer induction. As discussed in the Draft Final Guidelines, an important use of mode-of-action information is to identify susceptible populations and lifestages. Because it is rare to have epidemiologic studies or animal bioassays conducted in susceptible individuals, identifying the key events of the mode of action and the risk factors that can augment these key events can be critical in understanding risks to susceptible populations.

(4) Extrapolation to lower doses. An important issue to address in most EPA risk assessments is the estimation of risks at levels of environmental exposure (doses) that are lower than the levels at which adverse effects (responses) have been observed. Historically, EPA used an approach known as linear extrapolation for all potential carcinogens, which involves modeling risk in an approximately straight line extrapolation from a particular dose level (the point of departure) to the zero dose/zero response point. This approach differs from that used by EPA in assessing risks in the case of most noncancer effects, which typically involve nonlinear extrapolation. The Draft Final Guidelines generally reaffirm the use of a linear extrapolation approach for carcinogens when mode of action information is limited or indicates a linear dose-response relationship, such as in the case of mutagenic agents. The Draft Final Guidelines also discuss potential uses of nonlinear extrapolation when consistent with understanding of the mode of action, and recommend the development of a reference dose (or reference concentration) as established by EPA for effects other than cancer. This default approach is in keeping with the Agency's goal of harmonizing the assessment of risks from agents, whether carcinogens or not, that operate by a nonlinear mode of action.

(5) Susceptible populations and lifestages. The Draft Final Guidelines explicitly recognize that variability exists among people in their susceptibility to carcinogens and emphasize that this variability should be considered in risk assessment. Some subpopulations may experience increased susceptibility to carcinogens throughout their lives, such as people who have inherited a predisposition to certain cancer types or reduced capacity to repair genetic damage. Also, during certain lifestages the entire population may experience heightened susceptibility to carcinogens. In particular, the Guidelines note that childhood may be a lifestage of greater susceptibility for a number of reasons, such as susceptibility related to the rapid growth and development that occurs prenatally and after birth.

Supplemental Guidance on Early-Life Exposure

The discussion of consideration of childhood risks in the Draft Final Guidelines has been augmented by the development of the separate draft document entitled ''Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens.'' This document contains an analysis of studies and a possible approach for how quantitative scientific data could inform risk assessments when exposure to carcinogens occurring during childhood is considered. The draft document will be reviewed by EPA's Science Advisory Board following the public comment period. After SAB recommendations and public comments are incorporated into the document, the supplemental guidance will be issued separately from the final Cancer 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.

Request for Comment

EPA requests comments on today's Draft Final Guidelines and will consider all comments in completing final Guidelines. Comments on earlier drafts of the revised Guidelines already submitted to EPA need not be resubmitted. Public comments are also invited on the draft supplemental guidance on early-life exposure to carcinogens. Following the public

comment period, EPA's SAB will peer-review the supplemental guidance. A separate notice of the planned SAB meeting will also appear in the **Federal Register**.

Dated: February 25, 2003.

Paul Gilman,

Assistant Administrator for Research and Development.

[FR Doc. 03–4912 Filed 2–28–03; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE UNITED STATES

Economic Impact Policy

This notice is to inform the public that the Export-Import Bank of the United States has received an application to finance the export of $113 million worth of U.S. goods and services to a buyer in India. The equipment will enable the Indian buyer to produce 553,000 metric tons of Pure Terephthalic Acid (PTA) annually. According to the foreign buyer, the additional capacity of PTA is likely to be entirely consumed in the Indian market. However, depending on market conditions in India, some of the production could be exported to China, the leading market for the Indian buyer's other products. Interested parties may submit comments on this transaction by e-mail to *economic.impact@exim.gov* or by mail to 811 Vermont Ave., NW., Room 1238, Washington, DC 20571, within 14 days of the date this notice appears in the **Federal Register**.

Helene S. Walsh,

Director, Policy Oversight and Review.

[FR Doc. 03–4866 Filed 2–28–03; 8:45 am]

BILLING CODE 6690–01–M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection(s) Requirement Submitted to OMB for Emergency Review and Approval

February 21, 2003.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before April 2, 2003. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all comments to Kim A. Johnson, Office of Management and Budget, Room 10236 NEOB, Washington, DC 20503, (202) 395–7232 or via Internet at *Kim_A._Johnson@omb.eop.gov,* and Les Smith, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., Washington, DC 20554 or via Internet to *lesmith@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at (202) 418–0217 or via Internet at *lesmith@fcc.gov*.

SUPPLEMENTARY INFORMATION: *The Commission has requested emergency OMB review of this collection with an approval by February 20, 2003.*

OMB Control Number: 3060–0113.

Type of Review: Revision of a currently approved collection.

Title: Broadcast EEO Program Report, FCC Form 396.

Form Number: FCC 396.

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents: 2,000.

Estimated Time per Response: 1.5 hours.

Frequency of Response: Recordkeeping; Renewal reporting requirement.

Total Annual Burden: 3,000 hours.

Total Annual Cost: $100,000.

Needs and Uses: On November 7, 2002, the FCC adopted a Second Report and Order and Third NPRM (Second R&O), MM Docket No. 98–204, FCC 02–303, which established new EEO rules and forms to comply with the court's decision in *MD/DC/DE Broadcasters Association* v. *FCC.* The new rules reinstate the requirement that broadcast licensees file the FCC Form 396 at the time they file for renewal of license. The new EEO rules also ensure equal employment opportunity in broadcast and multi-channel video program distributor industries through outreach to the community in recruitment and prevention of employment discrimination. Among other things, the Second R&O affords broadcasters with five or more full-time employees maximum flexibility in designing EEO programs while ensuring broad dissemination of full-time employment opportunities. These broadcasters must file annually an EEO public file report detailing their outreach efforts. In addition, licensees must include a narrative statement demonstrating how the station achieved an inclusive outreach in the prior two years and report the status of any employment discrimination complaints.

OMB Control Number: 3060–0120.

Type of Review: Revision of a currently approved collection.

Title: Broadcast Equal Employment Opportunity Model Program Report, FCC Form 396–A.

Form Number: FCC 396–A.

Respondents: Business or other for-profit entity; Not-for-profit institutions.

Number of Respondents: 5,000.

Estimated Time per Response: 1 hour.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 5,000 hours.

Total Annual Cost: None.

Needs and Uses: On November 7, 2002, the FCC adopted a Second Report and Order and Third NPRM (Second R&O), MM Docket No. 98–204, FCC 02–303, which established new EEO rules and forms to comply with the court's decision in *MD/DC/DE Broadcasters Association* v. *FCC.* The new rules reinstate the requirement that broadcast licensees file the FCC Form 396–A at the time they file applications for construction permits, or assignments or transfers of license. The new EEO rules also ensure equal employment opportunity in broadcast and multi-channel video program distributor industries through outreach to the community in recruitment and prevention of employment discrimination. While FCC Form 396–A remains almost entirely the same as the form used under the rules adopted in 2000, the Second R&O also builds in flexibility for licensees to implement a program in compliance with the new