

submitted to the IRIS Submission Desk, or on-line, in accordance with the address and instructions provided at the end of this notice.

FOR FURTHER INFORMATION: For information on the IRIS program, contact Amy Mills, Program Director, National Center for Environmental Assessment (mail code 8601D), Office of Research and Development, U.S. Environmental Protection Agency, Washington, DC 20460, or call (202) 564-3204, or send electronic mail inquiries to mills.amy@epa.gov. For general questions about access to IRIS or the content of IRIS, please call the IRIS Hotline at (301) 345-2870 or send electronic mail inquiries to hotline.iris@epa.gov.

SUPPLEMENTARY INFORMATION:

Background

IRIS is an EPA data base containing Agency consensus scientific positions on potential adverse human health effects that might result from exposure to chemical substances found in the environment. IRIS currently provides information on health effects associated with more than 500 chemical substances.

The data base includes chemical-specific summaries of qualitative and quantitative health information in support of the first two steps of the risk assessment process, *i.e.*, hazard identification and dose-response evaluation. Combined with specific situational exposure assessment information, the information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

EPA's overall process for developing IRIS assessments consists of: (1) An annual **Federal Register** announcement of EPA's IRIS agenda and call for scientific information from the public on selected chemical substances; (2) a search of the current literature; (3) development of draft health assessments and IRIS summaries; (4) peer review within EPA; (5) peer review outside EPA; (6) EPA consensus review and management approval; (7) preparation of final IRIS summaries and supporting documents; and (8) entry of summaries and supporting documents into the IRIS data base.

The IRIS Annual Agenda

Each year, EPA develops a list of priority chemical substances and an annual agenda for the IRIS program. EPA uses four general criteria to set these priorities: (1) EPA statutory, regulatory, or program-specific implementation needs; (2) availability of

new scientific information or methodology that might significantly change the current IRIS information; (3) interest to other levels of government or the public; and (4) availability of other scientific assessment documents such that only a modest additional effort would be needed to complete the review and documentation for IRIS. The decision to assess any given chemical substance hinges on available Agency resources. Timing of EPA's risk assessment guidance, guidelines, and science policy decisions may also play a role in deciding when the Agency has the appropriate methods to assess a chemical substance.

On February 5, 2003, EPA stated (68 FR 5870) that it might publish a supplement to its fiscal year 2003 agenda by identifying additional priority chemical substances selected for assessment. Accordingly, today's notice supplements the priority list published in the **Federal Register** on February 5, 2003, (68 FR 5870) by providing a list of additional health assessments beginning in fiscal year 2003 and instructions for submitting scientific information to EPA pertinent to the development of health assessments for these chemical substances. The February 5, 2003, notice also stated that EPA planned to publish a solicitation later in the year for public nomination of chemical substances to consider for assessment beginning in fiscal year 2004. Consequently, today's notice provides instructions for nominating additional chemical substances for EPA's consideration.

EPA continues to build and update the IRIS data base by addressing the foremost user needs, as expressed by EPA and the public. EPA will also work toward updating all assessments in the data base where new scientific information is available to do so.

Stakeholder Workshop on Priority-Setting Criteria

As announced in the February 5, 2003, **Federal Register** notice (68 FR 5870), EPA sponsored a stakeholder workshop on March 4, 2003, concerning priority-setting criteria that are used or should be used to select chemical substances for an IRIS assessment. Versar, Inc., an EPA contractor, convened and facilitated this workshop to obtain input and suggestions from a spectrum of IRIS users on the appropriateness of EPA's current priority-setting criteria, and whether other criteria such as public health impact or economic impact should be added. In general, the panel members agreed that IRIS is an important international scientific resource with a

valuable core purpose of providing high-quality health assessments of chemical substances with potentially significant impacts on public health. While workshop panelists generally supported the current priority-setting criteria, they suggested that EPA evaluate whether public health concerns are sufficiently addressed by the current criterion for statutory, regulatory, and programmatic need. Panel members also discussed possible alternatives to the current priority-setting system. Some cautioned that the development of a more elaborate priority-setting system might make the process overly complex and burdensome to the Agency, leading to unnecessary delays.

In response to the panelists' suggestion, EPA reviewed previous chemical substance nominations to determine if public health concerns were implicitly covered by the statutory, regulatory, or programmatic needs driving the nominations. Public health impact is defined, for this purpose, as being associated with adverse human health effects and widespread exposure. EPA determined that most of the chemicals nominated in the annual priority-setting process have known or suspected toxicity and known or suspected widespread exposure. EPA concludes that public health concerns appear to be adequately subsumed in the current IRIS nomination process and that no specific additional public health criterion is needed at this time.

Many panel members also recommended that EPA focus its improvement efforts on making the IRIS priority setting process more transparent by including information concerning why each chemical substance was selected for an assessment. To that end, this notice adds transparency by listing supplemental fiscal year 2003 chemical substances with the corresponding rationale for each selection. With additional resources available to the IRIS program, EPA is also able to provide an open public chemical substance nomination process for 2004 to better respond to the broader IRIS user community. Additional information on the stakeholder workshop and EPA's position of how public health concerns are addressed in its current priority-setting criteria can be obtained by calling the IRIS Hotline (301) 345-2870, or by sending electronic mail inquiries to hotline.iris@epa.gov.

Submission of Scientific Information on Supplementary Assessments for Fiscal Year 2003

With the publication of this notice, EPA announces the start of assessments for the following chemical substances in