UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FILE

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OFFICE OF
THE ADMINISTRATOR

March 14, 1990

Honorable William K. Reilly
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Subject: Science Advisory Board's review of the Integrated Risk Information System

Dear Mr. Reilly:

The Environmental Health Committee of the Science Advisory Board (SAB) was given a presentation by EPA staff on the Integrated Risk Information System (IRIS) at its meeting on October 26, 1989. The presentation also included discussion of the activities of the Carcinogen Risk Assessment Verification Endeavor (CRAVE) and the RfD (Reference Dose) Review Group.

While it is our understanding that the IRIS was developed primarily for use within EPA, the Committee believes that the IRIS would be of great utility both within EPA and other organizations concerned with the potential health impacts of toxic chemicals in the environment. IRIS has the potential to provide a summary of toxicological data for a large number of chemicals in readily accessible form, either from an EPA on-line computer data bank, from access through existing routes such as the National Library of Medicine's TOXNET, or from regularly updated computer diskettes distributed to IRIS users. Many state and local regulatory agencies, as well as scientists working in the field of regulatory toxicology, would find IRIS to be a valuable reference source.

The IRIS files contain not only the toxicological data, but

also EPA's summary of these data, which may be in the form of the weight-of-evidence characterization for carcinogenicity, unit risk numbers for substances judged to have sufficient evidence for carcinogenicity in animals or humans, and reference dose numbers. This type of information may be widely used both within EPA and by other environmental regulatory agencies as the basis for regulatory decisions. It is therefore very important that the information in IRIS be carefully reviewed for its accuracy, timeliness, and completeness, and that appropriate caveats regarding the data and EPA's evaluation of the data be included in the IRIS files.

We recommend that SAB reviews of Agency documents on specific substances be referenced in the IRIS files for these substances. A short summary of the SAB evaluation of EPA conclusions, especially as to the weight-of-evidence characterization, unit risk, or reference dose, should also be included in the IRIS file, and a short summary of any subsequent communications from the Administrator back to the SAB in response to its evaluation.

We understand that Federal Register notices of proposed regulatory actions and final regulatory actions for chemicals in IRIS are now included in the regulatory summaries of IRIS files for those chemicals, a step forward which we commend. In the same vein, major EPA scientific reports such as health advisories, health assessment documents, criteria documents, and Risk Assessment Forum reports should also be cited in IRIS files, and we understand that this will occur in the future. Checks of the files for individual chemicals indicated that IRIS currently lacks citations to some key EPA reports on specific chemicals.

The current computer implementation of IRIS is somewhat cumbersome. For example, capabilities such as returning to earlier text in files or doing searches for specific words or phrases are not available in the current implementation. We understand that the computer implementation of IRIS will be upgraded, and we urge EPA to develop an implementation that is flexible and "user friendly" for the spectrum of anticipated users both inside and outside of EPA. EPA should also consider the need for, and

potential benefits from, developing more training materials and on-line help capabilities to assist users unfamiliar with IRIS to learn how to use the system. In any such efforts, EPA should remain cognizant that an increase in users should be expected, and the system designed accordingly.

The Agency needs an overall strategy on computerized lists of chemicals, one which takes into account the differing needs of various segments of the user community. While IRIS may be very helpful for those wishing to know about the toxicological data, other users may simply wish to know what regulatory actions EPA has taken on a specific chemical, or how to deal with an emergency response in the event of chemical spills. EPA either has or is developing other computerized lists of chemicals, but the planning and coordination among these efforts could be improved. EPA should consider what computerized chemical lists are needed and, more broadly, how modern computer and telecommunications technology can assist in the processes of risk assessment and risk management for the thousands of chemicals that are of interest to EPA. The Agency should then take steps to assure coordination, cross referencing, and standardization in access procedures for the various computerized lists of chemicals it is, and will be, developing.

The Environmental Health Committee is pleased to have had the opportunity to review IRIS and to offer its advice. We would appreciate your response to the major points we have raised:

1. Need for critical review of data for accuracy and completeness

2. Inclusion of SAB evaluations

3. Citation of major relevant EPA reports, including health advisories and other key documents

4. Implementation of improved electronic systems to allow more flexible handling of the data

5. Development of training materials and on-line help

6. Coordination, cross-referencing, and standardization of access to the various listings under development

We will be pleased to assist the Agency further as it proceeds with the development of IRIS and other computerized chemical lists.

Dr. Raymond Loehr, Chairman
Science Advisory Board
Executive Committee

Dr. Arthur Upton, Chairman
Environmental Health Committee