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

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SAB-EHC-86-018

Honorable Lee M. Thomas
Administrator
U.S. Environmental Protection
Agency
401 M Street SW
Washington, DC 20460

OFFICE OF
THE ADMINISTRATOR

Dear Mr. Thomas:

During recent meetings of the Enviromental Health Committee of EPA's Science Advisory Board, the members have discussed, both formally and informally, possible ways in which EPA and the Committee might enhance the efficiency with which we carry out our joint responsibilities in preparing and reviewing risk assessments, respectively. Some changes in the Committee's methods for planning scientific reviews need to be made in the near future because the volume of requests for reviews is growing rapidly.

The following issues represent the Committee's current concerns and viewpoints.

Multiple Risk Assessment Documents

Different EPA program offices frequently issue their own technical source document for the same substance.[1] The Committee understands that this practice arose because of different regulatory schedules and requirements. The Committee is concerned, however, that this practice may be taken as evidence of insufficient planning and coordination within the Agency. Issuing multiple source documents for a single substance, and seeking separate scientific reviews for each document, is not an efficient use of EPA or SAB resources, and contention arises when minor inconsistencies are noted by external parties.

[1] For more dicussion of this issue for a specific substance, see the Committee's report of April 26, 1985, on the Agency's draft Health Assessment Document for Dioxins. Several reports on dioxins were prepared within the Office of Research and Development (ORD) for different program offices. The Committee is aware of more than one document prepared by ORD and the Office of Toxic Substances for asbestos, butadiene and an addendum for methylene chloride. The Committee has also noted, during its recent reviews of Office of Drinking Water (ODW) Health Advisories, that Health Assessment Documents and Drinking Water Criteria Documents (both prepared by ORD) exist for the following substances: chlorobenzene, dichlorobenzene, epichlorohydrin, hexachlorobenzene, mercury, nickel, tetrachlorodibenzo-p-dioxin and toluene. Finally, ORD and ODW (or ODW contractors) developed Drinking Water Criteria Documents for the following compounds: arsenic, cadmium, carbon tetrachloride, chlorobenzene, chromium, methylene chloride, trichloroethylene, methyl chloroform, tetrachloroethylene and vinyidene chloride.

What is unclear is the degree to which multiple documents imply the existence of differing scientific conclusions. In addition, such documents are differently structured and do not clarify how they satisfy an Agency need not met by an existing document.

The Committee recommends that the Agency utilize a core document approach. By "core" document, the Committee means a critical evaluation of the available health and exposure data, such that the needs of all program offices would be met. The document could be supplemented by individual program offices. Several characteristics of this approach include: joint planning by EPA programs to identify their individual and collective technical assessment needs for future documents; and use of one core document as the technical basis for program specific regulatory activities. To the extent that individual program offices rely on media-specific data such as exposure information, these should be regarded as supplementary to the core document and should be carefully labelled and explained.

Integration of Data

Agency offices do not apply consistent decision rules in preparing assessment documents. Many of the documents submitted for SAB review, for example, address the hazard evaluation or dose-response functions, while others represent a risk characterization (including exposure data). The Committee recommends that the Agency prepare documents which integrate hazard data with exposure data (to the extent such data are available) in order that the sources of and implications for risk estimates are made clear.[2] Even a preliminary exposure assessment will clarify the way in which the Agency plans to use such data in risk assessment.[3] Hazard data also change, and the Agency has procedures in some areas which allow additions to a document, based on receipt of a new mechanism, bioassay or epidemiological information without rewriting the entire evaluation. Similarly, some offices have used a detailed cover memorandum to expand interpretation of scientific data in technical documents.[4]

While the desire of program offices to retain flexibility to meet evolving and sometimes rapid technical changes is reasonable, appropriate caveats can be placed in core documents to satisfy future, program-specific needs. The peer-reviewed, published monitoring and modelling information can be described and integrated with hazard data to estimate risks. These estimates need not be prepared in great detail for each environmental route of exposure. However, if a risk assessment serves as the technical basis of a regulatory decision, and if Agency decision makers desire a Science Advisory Board review, the Committee

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[2] See the SAB's Resolution on Exposure Assessment dated October 25, 1984.

[3] The Office of Air Quality Planning and Standards (OAQPS) has submitted memoranda to the Committee that summarize current exposure information on hazardous air pollutants. For the most part, this brief summary data has been adequate to enable Committee members to better understand the significance of health effects from individual substances. However, for an evaluation of a more extensive exposure analysis, see the Committee's October 1, 1985 report of its review of the Office of Toxic Substances' assessment of risks from formaldehyde.

[4] As examples, see the ODW memoranda entitled "Quantification of Toxicological Effects" that further interpret the information from ORD Health Assessment Documents for substances such as ethylene dichloride.

should evaluate as complete a risk assessment as is possible for the Agency to develop.

Scope of Reviews

Standard Agency practice for core documents should be to review the available literature on a substance in a comprehensive fashion. The Committee has been pleased with the critical and concise evaluation in some of the assessments submitted for review, but assessments that look at only a subset of the existing data for a substance can imply to the public that EPA has ignored or discarded data in conflict with a prior position. This practice, if not fully explained, can erode the Agency's scientific credibility. Where unacceptable data are found, then EPA should say so. If less comprehensive documents need to be prepared, their purpose should be explicitly stated, along with an explanation for the more limited focus.

Cutoff Dates for Literature Reviews

The Committee often has requested that Agency staff provide in the preface to a technical document, a date at which they believe the literature citations are complete.[5] The Committee's position is that EPA cannot always update the literature while simultaneously writing and reviewing a document. Therefore, studies appearing after a cut-off date may (but need not) be acknowledged, and the new data should be reviewed only at the discretion of Agency staff. A document with a cutoff date will be defensible against charges that it is incomplete, whereas the lack of a cutoff date may confuse the public, particularly when a long delay occurs between the literature review and final document publication.

Modern Terminology

The Agency's scientific documents will further benefit from the use of current terminology, particularly when referring to issues such as hazard and risk. For example, the term "unit risk estimate" found in some EPA documents more commonly is called a "potency" by the toxicological community.

Inconsistency of Nomenclature

Agency documents often carry different labels, depending on the program office issuing the document. For example, quite similar documents are labelled as health assessments, criteria documents or risk assessments. More precise and consistent titling would help communicate to the public more clearly the aims of such documents and provide the Committee with firmer guidelines for their review. Some inconsistency may be unavoidable because of statuatory language. For this and other reasons, internal EPA guidance on the preparation of documents is likely to enhance staff and public understanding.

Assignment of Priorities

During the past several years, the Environmental Health Committee has received multiple requests from the Agency for reviews of essentially the same scientific

[5] See, for example, the Committee's report of January 4, 1985 on ORD's Health Assessment Document for 1,2-dichloroethane ((ethylene dichloride).

data. Given its limited resources, the Committee needs further EPA assistance in assigning priorities to those draft documents for which review is desired. The Committee has less capability to make such management decisions. There are several criteria by which the Agency can establish a high priority for review, such as widespread potential health effects, legal requirements, a need of several program offices for the document, and important or unique scientific issues.

The above list of concerns and views is raised for your attention. It represents views shaped by the past several years of experience in reviewing the Agency's scientific documents but is not meant to be comprehensive or proscriptive. We recognize that the issue of improved planning and coordination of risk assessments is currently receiving a high priority by senior Agency managers. We hope this letter will be taken in the spirit of supporting this effort and of improving our own scientific review methods. As these issues are long-standing, we would now welcome a written response from Agency staff, which the SAB will review.

Sincerely yours,

Richard A. Griesemer
Chair, Environmental Health Committee

Norton Nelson
Chair, Executive Committee