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

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July 17, 1989

OFFICE OF
THE ADMINISTRATOR

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 THALLIUM health criteria document

Dear Mr. Reilly:

The Metals Subcommittee of the Science Advisory Board's Environmental Health Committee has completed its review of the Drinking Water Health Criteria Document for Thallium, dated May, 1988. The review was conducted December 8, 1988 at the One Washington Circle Hotel in Washington, D.C. Participants in the review are listed in Attachment 1. The Subcommittee addressed two issues:

> Is the use of the Stoltz et al (1986) study, with an uncertainty factor (UF) of 3000, an appropriate basis for setting a Drinking Water Equivalent Level (DWEL)?
>
> If not, should the UF be revised to derive a DWEL for thallium?

The DWEL proposed by the Office of Drinking Water (ODW) is based on the Stoltz study noted above, which reported no toxicity (but some changes in clinical chemistry--Ca, Na, SGOT, and LHD levels) at dosages of 0.2 mg/kg/day. This level was identified as the NOAEL (No Observed Adverse Effects Level). After inclusion of an uncertainty factor of 3000 (to account for the use of an animal study of less then life-time duration and for inadequate testing of certain endpoints), and the "standard" assumptions for body weight, consumption of drinking water, and routes of exposure, a DWEL of 0.002 mg/l was derived for thallium.

The Subcommittee believes that additional analysis of the data underlying the document is required in order to realize an acceptable DWEL proposal. As recognized by the ODW, the choice of a UF of 3000 is essentially arbitrary, with no articulated analytical or theoretical rationale other than "standard practice." At least part of the ambiguity results from EPA's continuing reliance on data from single dose levels, such as the NOAEL and

the Lowest Observed Adverse Effect Level (LOAEL) to calculate Reference Doses and associated standards. Several of the studies cited, however, especially those from which effects levels were derived, lend themselves to a more meaningful dose-response (effect) analysis. Dose-response analysis could possibly also extract data from otherwise unusable data. For example, a study cited in the document (Gibson and Becker, 1970) is dismissed because "The NOAEL for developmental toxicity could not be established due to the presence of effects at all levels treated..." With suitable analysis, this study could yield valuable data. The Subcommittee urges EPA to study further its approach to uncertainty factors and their use in developing DWELs and reference doses.

The thallium document itself is a fairly complete compilation of the pertinent literature. Like other documents of this type, however, it serves primarily as an annotated bibliography rather than a critical review. In most cases, it provides enough details about individual studies for a reviewer to make critical judgments. The absence of a critical stance within the document itself, however, often leads to confusion because studies of widely divergent quality are seemingly accorded equivalent weight. Individual chapter summaries reflect this approach--they tend to be condensed versions of the chapter itself rather than a coherent integration of findings and conclusions. The Subcommittee recommends that future documents adopt a more evaluative, analytic posture and clarify the relative weight/emphasis accorded to particular studies. A more useful document should result.

More detailed comments on specific editorial and technical issues have been forwarded to the program office.

The Subcommittee appreciates the opportunity to present our views on the thallium health criteria document. We look forward to the Agency's response to our report.

Enclosure

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ABSTRACT

This report presents the conclusions and recommendations of the U.S. Environmental Protection Agency's Science Advisory Board summarizing a review of the Drinking Water Health Criteria Document for Thallium. The Board's major conclusion is that the proposed Drinking Water Equivalent Level (DWEL) of 0.002 mg/l of thallium, based on the 1986 Stoltz et al study, is not supportable because of insufficient analysis of the available data. The Board also recommended that the Agency attempt to extend its application of dose-response analysis to extract more information from the available data.

Key Words: Thallium; DWEL; drinking water,

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