

June 14, 2010

Via E-Mail

Information Quality Guidelines Staff
Mail Code 2811R
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Request for Correction -- SAB Workgroup Review of Draft IRIS
Assessment for Inorganic Arsenic

Dear Sir or Madam:

This request for the correction of information (RfC) is submitted under the Information Quality Act (IQA)¹ and the implementing guidelines (Guidelines) issued, respectively, by the Office of Management and Budget (OMB)² and the United States Environmental Protection Agency (EPA),³ on behalf of the Organic Arsenical Products Task Force (OAPTF) and the Wood Preservative Science Council (WPSC).⁴ As discussed below, the OAPTF and WPSC seek the correction of information disseminated in a draft EPA document,⁵ “Toxicological Review of Inorganic Arsenic: In Support of the Summary Information on the Integrated Risk Information System (IRIS)” (draft Report), and in connection with the Science Advisory Board (SAB) Workgroup’s April 6-7, 2010, review of this document.

¹ Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, P.L. 106-554; 44 U.S.C. § 3516 (notes).

² 67 Fed. Reg. 8452 (Feb. 22, 2002).

³ EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-008 (Oct. 2002) (Guidelines).

⁴ The OAPTF consists of Drexel Chemical Co and Luxembourg-Pamol, Inc., registrants of herbicide products containing monosodium methanearsonate (MSMA).

⁵ EPA/635/R-10/001.

Background

On March 29, 2010, the OAPTF provided comments⁶ on the content of the draft Report in response to EPA's public comment request. Subsequently, in two separate letters submitted on April 20, 2010, to the EPA docket maintained in support of the Report (ID No. EPA-HQ-ORD-2010-0123), the OAPTF brought to EPA's attention fundamental deficiencies present in the scientific underpinnings of the draft Report and in its review by the SAB Workgroup, as follows:⁷

- One letter (April 20, 2010, Missing Literature Letter) provided an illustrative list of relevant materials from the scientific literature on inorganic arsenic that EPA had failed to include in the docket and had omitted to review in developing the draft Report (appended document numbers 59379 and 59401).
- The other letter (April 20, 2010, Science and Process Comment Letter) described process shortcomings in connection with the April 6-7, 2010, public SAB Workgroup meeting and review that have exacerbated the impacts of these omissions and other deficiencies in the science noted in that letter (appended document numbers 59336, 57316, 59332, and 59333).

Unless the draft Report is revisited and revised to address these weaknesses, the IQA objectives of objectivity and utility will be severely compromised.

EPA's IQA Guidelines -- the "Objectivity" and "Utility" Criteria

EPA's IQA Guidelines "contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information we disseminate" as well as specifically describing "new mechanisms to enable affected persons to seek and obtain corrections from EPA regarding disseminated information that they believe does not comply with EPA or OMB

⁶ See OAPTF Comments sent to Dr. Sue Shallal, Designated Federal Officer, SAB, Re: Toxicological Review of Inorganic Arsenic: In Support of the Summary Information of the Integrated Risk Information System" (Mar. 29, 2010) (appended document number 58435).

⁷ The extent to which this RfC may address issues similar to those raised with EPA through any such comments in no way affects EPA's responsibility to make a substantive response to the RfC, which proceeds under different and distinct statutory and regulatory authorities.

guidelines.”⁸ As such, the Guidelines explicitly contemplate and provide a pathway for the correction of information disseminated by EPA that falls short of the “basic standard of quality, including objectivity, utility, and integrity,” enunciated in its own Guidelines or those issued by OMB.⁹

Of the three criteria that go to the quality of information disseminated by EPA, “objectivity” and “utility” are jeopardized by the deficiencies the OAPTF and WPSC are seeking to address. Like OMB, EPA views the “objectivity” inquiry to be “whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.”¹⁰ The “utility” criterion refers to “the usefulness of the information to the intended users.”¹¹

EPA acknowledges that the “influential scientific, financial, or statistical information” it disseminates “should meet a higher standard of quality.”¹² Under the Guidelines, information is considered influential if “the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions.”¹³ Given the vast implications of the significantly higher cancer slope factor for inorganic arsenic in EPA’s draft Report, it is indisputable that such information, as well as the data on which the draft Report and its conclusions rest, is “influential scientific . . . information,” which under the EPA Guidelines, like those of OMB, is therefore subject to “a higher degree of quality (for example, transparency about data and methods).”¹⁴ Furthermore, as described below, because EPA failed to assess adequately not only a number of key recommendations in the 2007 SAB report but well-informed comments from many scientists outside of EPA, the information in its draft Report is not consistent with the best available and current science. As such, the draft Report also involves

⁸ EPA Guidelines at 3.

⁹ *Id.*

¹⁰ *Id.* at 15; OMB Guidelines § V.3, 67 Fed. Reg. at 8459.

¹¹ EPA Guidelines at 15; OMB Guidelines § V.2, 67 Fed. Reg. at 8459.

¹² EPA Guidelines at 19.

¹³ *Id.*

¹⁴ *Id.* at 20; OMB Guidelines §§ V.3(b)(ii) and V.9, 67 Fed. Reg. at 8460.

“controversial scientific . . . issues,” a specific class of “influential information” that “should adhere to a rigorous standard of quality.”¹⁵

To illuminate the means for ensuring the “objectivity” of “influential scientific risk assessment information,” the EPA Guidelines have adapted the quality principles in the Safe Drinking Water Act Amendments (SDWA) of 1996¹⁶ to provide as follows:

- (A) The substance of the information is accurate, reliable and unbiased. This involves the use of:
 - (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and
 - (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data).
- (B) The presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable.¹⁷

¹⁵ See EPA Guidelines at 20.

¹⁶ 42 U.S.C. § 300g-1(b)(3)(A) and (B). The OMB Guidelines, § V.3(b)(ii)(C), direct federal agencies to “adopt or adapt” the SDWA principles for these purposes. 67 Fed. Reg. at 8460.

¹⁷ EPA Guidelines at 22.

How the Draft Report Violates EPA IQA Guidelines

The draft Report and the database underlying it are in stark contrast to what the “objectivity” criterion requires, especially in light of the above-quoted SDWA quality principles. Additionally, disseminating the draft Report with its pervasive deficiencies and flaws contravenes the “utility” criterion. The draft Report and the data on which it is based fall far short of embodying “the best available science and supporting studies conducted in accordance with sound and objective scientific practices” and the other components of “objectivity.” The very nature of a long-anticipated and widely disseminated scientific document such as the draft Report makes its adherence to IQA criteria essential. The dissemination of so problematic a draft document is inappropriate and does its users a disservice; dissemination of a final Report without correcting these problems would be even worse.

Key among the shortcomings of the draft Report is EPA’s astonishing insistence to over-rely on study data from Taiwan that are over 50 years old and lacking in relevant exposure data. In other instances, evident throughout the draft Report, EPA failed to keep up with state-of-the-art research generated beyond 2007. The OAPTF provided a list¹⁸ of additional studies that EPA should have reviewed and reflected in the draft Report. Where available and relevant -- which the latter studies are -- such recent data must be considered to meet the “best available science and supporting studies” and the “best available methods” standards for objectivity under the SDWA. The science-related issues for which correction is requested include the following:

1. ***Post -2007 Scientific Literature.*** EPA must consider, and the draft Report must reflect, the scientific literature of at least 73 relevant publications that were published after 2007. Not only does this omission run counter to the “best available science” standard, but it fails to take into account research conducted with specific reference to questions raised by the SAB in 2007.¹⁹
2. ***1999-2007 Scientific Literature.*** EPA must consider, and the draft Report must reflect, all the relevant scientific literature that was published by

¹⁸ Appended to OAPTF’s April 20, 2010, Missing Literature Letter.

¹⁹ Indeed, the draft Report fails largely to address the substance of the 2007 SAB’s recommendations. As noted at page 5 of the April 20, 2010, Science and Process Comment Letter, a March 25, 2010, letter submitted by some of the 2007 SAB panel members stating concerns about the contents of the draft Report was treated as a technical correction, rather than as an impetus for further review by the current panel of the substantive issues flagged by the 2007 panel members.

2007, including 212 relevant publications that were published between January 1999 and December 2007.

3. ***Mode of Action (MOA).*** EPA must consider, and the draft Report must reflect, the relevance of all the literature on “mode of action” (MOA), rather than -- as the Workgroup did -- summarily adhering to the notion of “multiple MOAs.” Although the prior SAB had requested that a critical and complete analysis of existing MOA studies be performed, this was not done. Overlooked recent data, such as the ongoing science in the laboratory of Dr. Sam Cohen, should be taken into account; this work supports the conclusion that there is a known MOA for inorganic arsenic. Table 4.1 of the draft Report presents a list of MOAs with the number of publications supporting each MOA. The authors of the draft Report then calculate which MOA is discussed most frequently in the literature. Such a tool can be used only if the literature is covered in full, and not when publications are selectively chosen.
4. ***Meta-Analysis.*** EPA must conduct, and the draft Report must reflect, a meta-analysis to estimate the relative risk for low (less than 1.0) exposures to arsenic. Alternatively, EPA must review, and the draft Report should reflect, the ten other available recent meta-analyses that support this result. Such review should use the same criteria used for the review of the study in Taiwan, which is not the case in the draft Report, in which different criteria were used for the review of the study in Taiwan and studies in the USA.
5. ***Taiwan Data -- Reference Population and Exposure Estimates.*** In connection with its problematic reliance in the draft Report on the Taiwan data, EPA must revisit the appropriateness of selecting a reference population outside the southwest Taiwan study area. To date, EPA has not addressed the host of scientific issues raised about whether the reference population was comparable to the study area population in all respects other than arsenic exposure. Additionally, EPA must adequately address all aspects of Taiwanese population exposure estimates to assume the use of representative values; the over-emphasis on non-water aspects and water consumption amounts open the results to serious question.
6. ***Taiwan Data -- Sensitivity Analysis of Dose-Response Evaluation.*** EPA has failed to address the SAB panel recommendation concerning the need for a proper sensitivity analysis of the dose-response evaluation of the Taiwan data, specifically including simultaneous changes in several critical parameters.

7. **Sensitivity Analysis -- Other Issues.** The role of true threshold models in the sensitivity analysis must be addressed, as must be the margin of exposure analysis using a point-of-departure such as a benchmark dose.
8. **Selection of MOA.** EPA must address the appropriateness of a linear extrapolation, in light of the 2007 SAB's conclusion that evidence for all possible MOAs is linear and likely involves a threshold. It is very disturbing that, of all the many possible MOAs, EPA selected the only MOA that has been shown *not* to occur.

Conclusion -- Why Correcting the Report Is Essential

All the issues for correction listed above are very significant and must be addressed substantively before the draft Report, containing "influential scientific information," can be considered to have met IQA standards of objectivity and utility. Indeed, with its many failures to consider the state-of-the-art scientific literature, among other documented inadequacies, the draft Report falls far short of meeting the "utility" criterion in that it is scarcely robust enough to serve as a vehicle for information discussion by either the SAB or the interested public as they work toward development of a final Report. The content of any such Report will suffer incalculably if the errors in the draft remain uncorrected, and the value of the final Report in future regulatory actions involving arsenic in general and MSMA specifically will be so severely compromised as to be of questionable value.

Therefore, the OAPTF and WPSC respectfully submit that this RfC should be granted and the corrections implemented accordingly.

Sincerely,



Lynn L. Bergeson
Managing Director
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for
Organic Arsenical Products Task Force
Wood Preservative Science Council

Attachments

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