



PERCHLORATE STUDY GROUP

A coalition of aerospace, defense,
chemical and allied industries

March 25, 2004

Information Quality Guidelines Staff
Mail Code 28220T

U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C., 20460

Sent via email to quality.guidelines@epa.gov

Reference: Request for Correction #13679.

On behalf of the Perchlorate Study Group (PSG), I am following up on our Request for Correction dated December 3, 2003.¹ The U.S. Environmental Protection Agency (EPA) acknowledged receipt on December 23, 2003.² To date we have received no other written response from EPA, and no oral communication from the information quality guidelines staff or any other EPA personnel.

Critical information disseminated by EPA is not “capable of being substantially reproduced.” This “reproducibility” test applies to the information PSG asked EPA to disclose. EPA has a legal obligation to disclose sufficient information such that PSG, a highly “qualified member of the public,” is capable of substantially reproducing the Agency’s data and analytic results, and to do so in a timely manner. Transparency sufficient to permit the reproduction of data and results is the most fundamental principle embodied in both OMB’s and EPA’s information quality guidelines. Timely disclosure is not burdensome for EPA because PSG seeks only full disclosure of information needed to reproduce EPA’s data summaries and analytic results, and not an actual change or correction. Further, EPA information owners needed this information to conduct their original analysis and the Agency could not perform its required pre-dissemination review without it. Continued EPA delay is likely to deny PSG any reasonable opportunity to evaluate, prior to the effective conclusion of the ongoing National Academy of Sciences review, whether critical information disseminated by the Agency satisfies applicable information quality guidelines. Finally, it appears likely that the Academy committee charged with reviewing this information also cannot reproduce EPA’s data and analytic

¹ Letter from Michael Girard to U.S. Environmental Protection Agency Information Quality Guidelines Staff, December 3, 2003 (hereinafter “PSG December 3 Petition”). Online at <http://www.epa.gov/oei/qualityguidelines/afreqcorrectionsub/13679.pdf>.

² Letter from EPA Information Quality Guidelines Processing Staff to Michael Girard, December 23, 2003. Online at <http://www.epa.gov/oei/qualityguidelines/afreqcorrectionsub/13679Ack.pdf>.

results. That would render the committee unable to perform a key element of its EPA-sponsored assignment—“verification that the key studies underlying the health assessment are of the quality, reliability and relevance that are required to draw conclusions about the health implications of exposure to low levels of perchlorate in drinking water among sensitive subpopulations.”³

The PSG December 3 Petition asked EPA to disclose information critical for an independent review of certain portions of the Agency’s October 1, 2003, document titled “Disposition of Comments and Recommendations for Revision to “Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization” (External Review Draft, January 16, 2002)” (hereinafter, the “Disposition” document). This information is critical because EPA relies on it to support certain factual scientific statements, inferences and conclusions essential to the Agency’s proposed Reference Dose for perchlorate. The new data and analytic results contained in the Disposition document are not capable of being reproduced without this information.

EPA’s information quality guidelines state that the Agency will ensure a high degree of transparency when it disseminates influential original and supporting data:

EPA recognizes that influential scientific, financial, or statistical information should be subject to a higher degree of quality (for example, transparency about data and methods) than information that may not have a clear and substantial impact on important public policies or private sector decisions. A higher degree of transparency about data and methods will facilitate the reproducibility of such information by qualified third parties, to an acceptable degree of imprecision. For disseminated influential original and supporting data, EPA intends to ensure reproducibility according to commonly accepted scientific, financial, or statistical standards.⁴

For analytic results based on influential information, EPA has committed to meeting “a higher degree of transparency”:

It is important that analytic results for influential information have a higher degree of transparency regarding (1) the source of the data used, (2) the various assumptions employed, (3) the analytic methods applied, and (4) the statistical procedures employed. It is also important that the degree of

³ Letter from Paul Gilman, Assistant Administrator, EPA Office of Research and Development, to Bruce M. Alberts, President, National Academy of Sciences, March 19, 2003 (“Charge”) at 1 (hereinafter “National Academy Transmittal Letter”).

⁴ Environmental Protection Agency, “Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency,” (hereinafter “EPA Information Quality Guidelines”) at 30-31 (emphasis added). This language mimics that of the Office of Management and Budget, “Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication,” (hereinafter “OMB Information Quality Guidelines”), ¶V.3.b.ii.B at 8460: “[A]gency guidelines shall generally require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public. These transparency standards apply to agency analysis of data from a single study as well as to analyses that combine information from multiple studies.”

rigor with which each of these factors is presented and discussed be scaled as appropriate, and that all factors be presented and discussed.⁵

Transparency sufficient to permit the reproduction of results is the fundamental core of both OMB's and EPA's information quality guidelines. As OMB has stated:

The purpose of the reproducibility standard is to cultivate a consistent agency commitment to transparency about how analytic results are generated: the specific data used, the various assumptions employed, the specific analytic methods applied, and the statistical procedures employed. If sufficient transparency is achieved on each of these matters, then an analytic result should meet the "capable of being substantially reproduced" standard.⁶

With respect to original and supporting data, EPA is obligated to "include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties".⁷ The PSG is qualified to reproduce original and supporting data. However, PSG-affiliated scientists have been unable to do so.

With respect to analytic results derived from these original and supporting data, EPA is required to display "sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public."⁸ PSG is a qualified member of the public and we cannot reproduce EPA's analytic results from the information the Agency has disclosed. Because the results in the Disposition document are not "capable of being substantially reproduced," there is not "sufficient transparency."

The information PSG asked the Agency to disclose in our December 3 Petition is readily available to information owners⁹ in EPA's Office of Research and Development. EPA must have possessed this information to conduct its analysis and perform its required pre-dissemination review, so our request cannot be burdensome.

In its acknowledgement letter, EPA states that the Agency's "goal" is to respond within 90 calendar days. This default timeframe for response is stated in EPA's Information Quality Guidelines.¹⁰ EPA's guidelines also state, however, that the

⁵ Id.

⁶ OMB Information Quality Guidelines at 8456.

⁷ OMB Information Quality Guidelines (¶V.3.b.ii) at 8460.

⁸ OMB Information Quality Guidelines (¶V.3.b.ii.B) at 8460.

⁹ "Information owners" are the responsible persons designated by management in the applicable EPA Program Office, or those who have responsibility for the quality, objectivity, utility, and integrity of the information product or data disseminated by EPA." See EPA Information Quality Guidelines at 30.

¹⁰ EPA Information Quality Guidelines at 31.

Agency's actual timeframe for response depends on the "nature and timeliness of the information involved."¹¹

The Office of Management and Budget's government-wide information quality guidelines state that agencies "must apply these standards flexibly, and in a manner appropriate to the nature and timeliness of the information to be disseminated".¹² Hence, in any instance where EPA's default timetable is inappropriate given considerations such as the nature of the information at issue and the need for timeliness, the Agency must expedite its efforts.

EPA has set forth criteria governing the speed at which it would respond to requests for correction, and these criteria suggest that the Agency should be able to respond quickly.

Considerations relevant to the determination of appropriate corrective action include the nature and timeliness of the information involved and such factors as the significance of the error on the use of the information and the magnitude of the error.¹³

EPA's use of this information could hardly be more significant—it is the foundation of the Agency's Disposition document which it disseminated to the National Academy of Sciences.¹⁴ PSG's capacity to participate in an "open and rigorous"¹⁵ peer review effectively depends on its ability to reproduce EPA's work in time to provide timely public comments to the National Academies.

The National Research Council's Committee to Assess the Health Implications of Perchlorate Ingestion met publicly on October 27, 2003, at which time EPA staff presented the new information at issue. This occurred weeks prior to EPA's public

¹¹ EPA Information Quality Guidelines at 31-32.

¹² OMB Information Quality Guidelines at 8453.

¹³ EPA Information Quality Guidelines at 31-32 (emphasis added).

¹⁴ Although nominally titled "Disposition of Public Comments," the document contains extensive new material that could be inserted into EPA's 2002 draft health risk assessment when it is put "final." It is clear that this information was disseminated by EPA for a significant purpose.

¹⁵ John D. Graham, "Memorandum for the President's Management Council; Presidential Review of Agency Rulemaking by OIRA," September 20, 2001, ("Peer Review"). Online at http://www.whitehouse.gov/omb/inforeg/oira_review-process.html. See also Office of Management and Budget, "Proposed Bulletin on Peer Review and Information Quality," 68 Fed. Reg. 54023-54029 (hereinafter OMB Draft Peer Review Bulletin), at 54028: "The agency shall provide an opportunity for other interested agencies and persons to submit comments. The agency shall ensure that such comments are provided to the peer reviewers with ample time for consideration before the peer reviewers conclude their review and prepare their report."

disclosure of the Disposition document containing the new information. This put all stakeholders (including PSG) at a disadvantage. At the Committee's December 12, 2003, public meeting, EPA again discussed the new information in the Disposition document. PSG was again unable to assemble and provide informed comments for the Committee on this new information. More than one week prior to the December 2003 public meeting, PSG submitted its letter to EPA specifically requesting that the Agency disclose this critical information. In our letter, we asked EPA to make these essential disclosures in time for us to provide comments to the Committee prior to its third scheduled meeting on March 17-18, 2004.

To date EPA has not responded. Further delays on EPA's part would make it impossible for PSG (and other qualified members of the public) to substantially reproduce the Agency's new information, ascertain whether it satisfies applicable information quality standards, and thereby participate meaningfully and appropriately in the peer review process.¹⁶

The purpose of the NRC review is to resolve a number of scientific questions so that the federal government can expeditiously follow normal procedures set forth by the Safe Drinking Water Act and the Administrative Procedure Act to issue regulatory standards based on the best available, objective science, and other considerations as the law provides.

The ability of the NRC Committee to resolve scientific questions will be compromised if EPA does not promptly disclose, to both the Committee and the public, critical information necessary to reproduce the Agency's new analytic results. OMB's proposed government-wide policy on peer review states that:

The charge [to reviewers] should generally frame specific questions about information quality, assumptions, hypotheses, methods, analytic results, and conclusions in the agency's work product. It should ask reviewers to apply the standards of OMB's Information-Quality Guidelines and the agency's own information quality guidelines.¹⁷

This policy is reflected in the Charge to the NRC Committee, which contains the following paragraph in its preface related specifically to information quality concerns:

A cross-cutting issue is verification that the key studies underlying [EPA's 2002] Draft Health Assessment are of the quality, reliability and relevance that are required to draw conclusions about

¹⁶ There is no evidence from EPA's Disposition document suggesting that the Agency performed a pre-dissemination review as required by both OMB's and EPA's own information quality guidelines.

¹⁷ Office of Management and Budget, "Peer Review and Information Quality; Proposed Bulletin, § 3 ("Charge to Reviewers"), emphasis added (disseminated August 29, 2003).

the health implications of exposure to low levels of perchlorate in drinking water among sensitive subpopulations.¹⁸

The NRC Committee cannot fully perform this elemental peer review function if EPA does not disclose information sufficient to make the Agency's data and analytic results capable of being substantially reproduced.

PSG hereby renews its request, pursuant to applicable EPA procedures under its Information Quality Guidelines, that the Agency immediately disclose the information that we requested in our December 3 Petition.

Sincerely,



Mr. Michael Girard
Chairman
The Perchlorate Study Group

Cc. Dr. John D. Graham, Administrator, Office of Information and Regulatory Affairs
Dr. Kathie L. Olsen, Associate Director, Office of Science and Technology Policy
Dr. Richard Johnston, Jr., Chairman, Committee to Assess the Health Implications of Perchlorate Ingestion, National Research Council

¹⁸ National Academy Transmittal Letter ("Charge") at 1.