PSG
PERCHLORATE STUDY GROUP
A coalition of aerospace, defense, chemical and allied industries

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August 24, 2004

Information Quality Guidelines Staff
US EPA - Room M1200
1300 Pennsylvania Ave., NW
Washington, DC 20008

Request for Reconsideration (RFR) regarding Request for Correction (RFC) 13679

1. Contact name, organization, and contact information.

This Request for Reconsideration (RFR) is filed by the Perchlorate Study Group (PSG), an alliance of manufacturers and users of perchlorate established in 1993 to fund and perform scientific research to identify and estimate the human health effects of perchlorate exposure. PSG is an "affected person" under the language of OMB's Information Quality Guidelines.

Please address all communications to:

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The Perchlorate Study Group
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2. Why we disagree with EPA's decision and a specific recommendation for corrective action.

The Perchlorate Study Group (PSG) submitted a Request for Correction (RFC) dated December 3, 2003.[1] EPA acknowledged this RFC on December 22, 2003,[2] and assigned it RFC # 13679. According to EPA's Information Quality Guidelines, the Agency is to respond to requests within 90 days of receipt.[3] Having received neither an

[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/quality/informationguidelines/documents/13679.pdf.
[2] Letter from EPA Information Quality Guidelines Processing Staff to Michael Girard, December 23, 2003. Online at http://www.epa.gov/quality/informationguidelines/documents/13679Ack.pdf.
[3] Environmental Protection Agency, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA," EPA/260R-02-008, October 2002. Online at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

oral nor written response from EPA within that time period, we submitted a second letter on March 25, 2004[4] requesting both an explanation for and an end to EPA's delay. On March 31, 2004, Assistant Administrator Paul Gilman responded to PSG.[5] Dr. Gilman did not acknowledge PSG's March 25 letter, but committed the Agency to make a decision by a date certain:

> EPA is carefully evaluating the information you provided and is preparing a response to your request, but will require additional time to coordinate reviews of the response. We anticipate that a response providing the Agency's decision will be forwarded to you within an additional 60 days.

This extension of time expired on May 30, 2004. Seven more weeks have passed, and Dr. Gilman has now sent PSG another letter that offers essentially the same excuse:

> EPA is preparing a response to your request and will require additional time to coordinate reviews of the response. We anticipate that a response providing the Agency's decision will be forwarded to you within an additional 60 days.

Our original petition is now more than seven months old. Given the nature of PSG's original request and its time-sensitive nature, we request that EPA immediately disclose the original data we are seeking. The Agency's persistent delay is a de facto denial of our RFC, this letter constitutes a formal Request for Reconsideration (RFR) pursuant to the internal appeal procedures in EPA's Information Quality Guidelines.[6] According to these guidelines, our original petition and EPA's de facto denial should now be presented to an Executive Panel for internal resolution.[7]

Normally, this Executive Panel would be comprised of the Science Advisor/AA for the Office of Research and Development (ORD), Chief Information Officer/AA for OEI, and the Economics Advisor/AA for the Office of Policy, Economics and Innovation (OPEI).[8] In this case, however, EPA's Science Advisor/AA for the Office of Research

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[4] Letter from Michael Girard to U.S. Environmental Protection Agency Information Quality Guidelines Staff, March 25, 2004. Online at http://www.epa.gov/quality/informationguidelines/documents/13679-related.pdf.

[5] Letter from Assistant Administrator Paul Gilman to Michael Girard, March 31, 2004. Online at http://www.epa.gov/quality/informationguidelines/documents/13679-interim.pdf.

[6] Environmental Protection Agency, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA," EPA/260R-02-008, October 2002. Online at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

[7] To be clear, this letter is in an appeal of EPA's de facto denial of our December 2002 RFC. It raises no new issues. Therefore, there is no justification under EPA Guidelines for the Agency to treat it as a new petition and "restart the clock" for another 90 days.

[8] Ibid, at 35.

and Development is also the "information owner" responsible for the de facto denial of PSG's original RFC. Therefore, EPA's Guidelines require that Dr. Gilman be excluded from service on this panel and that another assistant administrator take his place.[9]

EPA's persistent delay has caused PSG irreparable harm. Had EPA made a timely disclosure of the original data we sought in our December 2003 petition, PSG would have been able to attempt to reproduce EPA's results in a timely fashion, and questions about the objectivity of these data and the integrity of the database might have been resolved. Timely disclosure would have permitted PSG to provide informed comment to the National Academies' ad hoc committee reviewing scientific issues concerning the potential risks of perchlorate ingestion.[10] EPA has made its analysis of these data the centerpiece of three presentations to the Committee, but the Agency's failure to disclose the raw data has made it impossible for us (and likely for the Committee itself) to independently assess either their objectivity or the integrity of the database. No more public meetings of the Committee are expected, and the panel appears to be well on its way toward finalizing its report on schedule.

Full disclosure of these data by EPA remains necessary to satisfy the requirement for transparency set forth in both EPA and OMB Information Quality Guidelines. However, full disclosure at this late date would no longer be a sufficient response precisely because the National Academies' ad hoc committee has almost concluded its review. Therefore, PSG requests that the Executive Panel formally withdraw the data addressed in sections 3(a)-(f) of our December 2003 petition, publicly announce that these data do not comply with applicable information quality standards because they are not capable of being reproduced by qualified independent parties, and promptly notify the National Academies' ad hoc committee of these actions.[11]

3. Data covered by sections 3(a)-(f) of PSG's December 2003 petition (RFC # 13679).

PSG's original petition identified specific animal data and related information related to EPA's October 2003 submission to the National Academies' ad hoc committee

[9] "When the subject of the RFR originated from a member office, that panel member would be replaced by an alternate AA or RA." Id. EPA's Guidelines generally exclude from service on Executive Panels Assistant Administrators from program offices, such as the Office of Solid Waste and Emergency Response. In addition, we strongly encourage the Agency to exclude any Regional Administrator whose region has issued or has under development a Record of Decision in which a perchlorate remediation standard could be applied.

[10] See http://www4.nas.edu/cp.nsf/Projects%20_by%20_PIN/BEST-K-03-05-A?OpenDocument.

[11] PSG also requested that EPA disclose the attachment to the "Marcus 2003" memorandum. See section 3(g) of our original petition. Subsequently, but without notice to PSG, EPA replaced the online version of the Marcus 2003 memorandum with one containing the attachment. PSG is not at this time contesting the substance of EPA's de facto response but notes that it was, quite clearly, procedurally defective.

and subsequently made public.[12] In section 4 of this document, EPA summarized these data and offered an interpretation of their significance for human health risk assessment. EPA concluded that these new data "strongly reinforce the argument that EPA made using the Argus (2001) data: that adverse effects of ammonium perchlorate are present at the lowest dose level tested."[13]

Ever since EPA delivered its first presentation of these conclusions to the National Academies' ad hoc committee, PSG has been unable to reproduce the Agency's results. The Agency has prevented any attempt to reproduce its results by failing to disclose the underlying data and supporting information needed to evaluate their objectivity and the integrity of the database. In addition to its own analysis, EPA has made available only the summary report of its hired pathologist.[14] In contrast, in January 2002 EPA simultaneously announced the release of both its 2002 draft health risk assessment and the original data.[15] PSG's reviews of these data[16] could not have been performed if the data had not been disclosed.

Full disclosure of scientific data is the cornerstone of EPA's Information Quality Guidelines. Through these Guidelines, EPA announced it was "affirming a new commitment to information quality, especially the transparency of information products."[17] Further, EPA made significant commitments to ensure that influential scientific information would, in fact, be reproducible by third parties such as PSG:

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[12] Environmental Protection Agency, "Disposition of Comments and Recommendations for Revision to 'Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization (External Review Draft, January 16, 2002)'," n.d. Online at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=72117.

[13] Ibid, at 4-35, 36.

[14] Consultants in Veterinary Pathology, "Morphometry Review Report; Protocol 1416-003. Hormone, Thyroid, and Neurohistological Effects of Oral (Drinking Water) Exposure to Ammonium Perchlorate in Pregnant and Lactating Rats and in Fetuses and Nursing Pups Exposed to Ammonium Perchlorate During Gestation or Via Maternal Milk. Task 1—Review of Selective Morphometric Data F1 Generation Day 22 Postpartum Rats, Including New Morphometric Data Obtained From Additional Step Sections." February 3, 2003; online at http://www.epa.gov/ncea/perchlorate/references/documents/cvp-report2003.pdf.

[15] *See* 67 Fed. Reg. 77 (January 2, 2002).

[16] See, e.g., Wahlsten, D. Summary and Re-Analysis of Data: Brain Morphometry Results from a Perchlorate Toxicity Study (Primedica 2001), February 10, 2002; online at (http://www.epa.gov/ncea/perchlorate/comments/documents/doc083.pdf; Wahlsten, D., Perchlorate Effects on Neonatal Brain Development (February 18, 2002); online at http://www.epa.gov/ncea/perchlorate/comments/documents/doc081.pdf; The Perchlorate Study Group. 2003. Summary of Expert Comments for the National Academy of Sciences (NAS) Committee to Assess the Health Implications of Perchlorate Ingestion. Material provided to committee on October 27, 2003. Referenced online at http://www4.nas.edu/webcr.nsf/MeetingDisplay1/BEST-K-03-05-A?OpenDocument&ExpandSection=1#_Section1.

[17] EPA Information Quality Guidelines at 14.

> 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. 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.[18]

We agree with EPA that a "higher degree of transparency about data and methods will facilitate the reproducibility of such information by qualified third parties." In our December 2003 Request for Correction, we asked EPA to abide by this commitment by disclosing the data that formed the basis for its analysis. More than seven months later, however, the Agency has failed to do so.

4. EPA's failure to ensure transparency in a timely manner has caused PSG irreparable harm.

PSG has participated actively, constructively and appropriately in the process established by the National Academies for the review of scientific information underlying EPA's 2001 draft health risk assessment for perchlorate. The Committee has generously held three public meetings during which we provided our analyses of the huge body of available scientific information. We also presented new data in response to specific questions raised by EPA, other stakeholders, and the ad hoc Committee. EPA also has presented information at each of these public meetings, but neither PSG nor any other stakeholder has been able to provide informed comment on the information presented by EPA because EPA has refused to make the data public.[19]

EPA's failure to disclose critical data, while at the same time arguing that these data "strongly reinforce" the Agency's previously stated positions, has caused PSG irreparable harm in the National Academies' review process. Through its inaction, EPA has prevented PSG from evaluating the data, attempting to reproduce the data, and from commenting on its evaluation. Like PSG, the Committee cannot be expected to be able to fully evaluate these data and EPA's analysis of them without having the capacity to reproduce both the data and EPA's analysis. Inasmuch as a review of the quality of these

[18] Ibid at 20-21.
[19] In contrast with EPA, PSG has made its data available to the Committee and will make these data public once manuscripts prepared based on them are published.

data appears to be an overarching element of its Charge,[20] it is unclear how the Committee could fulfill its obligation to perform such a review. This is precisely what the Information Quality Guidelines were designed to prevent.

5. Recommended corrective action.

Full disclosure of these data remains an obligation of EPA to ensure transparency. Therefore, PSG continues to seek full disclosure. We specifically ask EPA's Executive Panel to order the Office of Research to promptly and completely disclose the data and materials listed in sections 3(a)-(f) of our petition.

Full disclosure is not sufficient, however, because PSG's opportunity to review and comment on these data during the National Academies' review process has come and gone. We cannot participate retroactively.

Therefore, PSG asks the Executive Panel to formally withdraw the data addressed in sections 3(a)-(f) of our December 2003 petition, publicly announce that these data do not comply with applicable information quality standards because they are not capable of being reproduced by qualified independent parties, and promptly notify the National Academies' ad hoc committee of these actions.

Sincerely,

Michael Girard
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

[20] "A cross-cutting issue is 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." See Letter from Paul Gilman to Bruce M. Alberts, March 19, 2003 (enclosure titled "Charge").