PSG
PERCHLORATE STUDY GROUP

A coalition of aerospace, defense, chemical and allied industries

December 21, 2004

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

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

1. **Contact name, organization, and contact information.**

This letter is styled as a Request for Reconsideration 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 EPA's and OMB's Information Quality Guidelines.[1]

Please address all communications to:

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[1] Environmental Protection Agency, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-008, December 2002 (hereinafter "EPA Information Quality Guidelines"); Office of Management and Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication, 67 Reg. Reg. 8459 (hereinafter "OMB Information Quality Guidelines"). In section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106–554; H.R. 5658), Congress directed OMB to issue government-wide guidelines implementing information quality language set forth in the 1995 Paperwork Reduction Act amendments but heretofore not acted upon by OMB. OMB's guidelines directed all federal agencies to issue agency-specific implementing guidelines consistent with OMB's. Thus, the EPA guidelines are derivative from and, in case of conflict or ambiguity, superseded by OMB's guidelines, which are mandated by law.

2. History of PSG's communications with EPA.

The Perchlorate Study Group (PSG) submitted a Request for Correction dated December 3, 2003.[2] In our letter we asked EPA to disclose information within its possession that was critical for reproducing the Agency's latest analysis of perchlorate health risks. We noted that a timely reply was essential to enable PSG (and other members of the public) to participate effectively and provide informed comment to The National Academies' ad hoc committee reviewing scientific issues concerning the potential risks of perchlorate ingestion.[3]

EPA acknowledged this Request for Correction on December 22, 2003,[4] and assigned it RFC #13679. According to EPA's Information Quality Guidelines, the Agency's goal is to respond to requests within 90 days of receipt.[5] Having received neither an oral nor a written response from EPA within that time period, we submitted a second letter on March 25, 2004, requesting an immediate response from EPA given the time-critical nature of the information EPA had not disclosed.[6]

Assistant Administrator Paul Gilman responded to PSG on March 31, 2004, saying only that EPA needed another 60 days to craft and coordinate reviews of its response.[7] He did not acknowledge PSG's March 25 letter. This extended period expired on May 30, 2004. On July 16, 2004, a full six weeks after this self-imposed deadline, Dr. Gilman sent another interim response again stating that the Agency needed another 60 days.

On August 24, 2004—more than eight months after submitting our initial petition—PSG submitted a letter styled as a Request for Reconsideration.[8] It was and remains our view that EPA's dilatory conduct constituted a de facto denial of our Request for Correction. According to EPA procedures set forth in its Information Quality Guidelines, a Request for Reconsideration must be referred to an executive panel consisting of independent assistant administrators, specifically excluding Dr. Gilman and his successors, whether acting or confirmed.

Dr. Gilman responded on behalf of EPA in a letter dated September 15, 2004. This letter purports to be a response to the *PSG December 2003 Request for Correction*,

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[2] Letter from Michael Girard to U.S. Environmental Protection Agency Information Quality Guidelines Staff, December 3, 2003 (hereinafter "*PSG December 2003 Request for Correction*"). Online at http://www.epa.gov/quality/informationguidelines/documents/13679.pdf.

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

[4] 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.

[5] EPA Information Quality Guidelines at 31.

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

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

[8] Letter from Michael Girard to U.S. Environmental Protection Agency Information Quality Guidelines Staff, August 24, 2004 (hereinafter "*PSG August 2004 Request for Reconsideration*"); http://www.epa.gov/quality/informationguidelines/documents/13679-related2.pdf.

and concludes with language indicating that EPA "will not be treating" PSG's August 2004 letter as a Request for Reconsideration.

Why we disagree with EPA's decision.

EPA's response is puzzling if the Agency is genuinely committed to fulfilling its legal obligations under the Federal Data Quality Act. The Agency's letter invokes irrelevant facts and presents contorted logic that contradicts both the spirit and letter of the EPA Information Quality Guidelines, and of the OMB Information Quality Guidelines. By waiting more than nine months to deliver this inadequate response EPA also displays disregard for its own procedures and the Agency's stated commitments to information quality:

> EPA works every day to expand the public's right to know about and understand their environment by providing and facilitating access to a wealth of information about public health and local environmental issues and conditions. This enhances citizen understanding and involvement and provides people with tools to protect their families and their communities.[9]

EPA's behavior is so inconsistent with the Agency's stated procedures that the Agency's commitment to ensuring and enhancing information quality is in question. In the subsections that follow, we show why EPA's response to our petition fails the most elementary scrutiny.

a. EPA's basis for denying our petition is defective on its face.

EPA applies our petition to the wrong document; falsely asserts that a disclaimer on the wrong document (but not on the right document) exempts the right document from having to meet applicable information quality standards; and alleges that ongoing peer review exempts both documents.

i. EPA applies our petition to the wrong document.

PSG's petition sought from EPA the disclosure of information critical for reproducing certain original Agency data and analytical results related thereto which were disseminated by EPA. We listed four documents that EPA posted on its website on or about November 7, 2003. EPA submitted these documents in October 2003 to The National Academies' ad hoc committee reviewing perchlorate.[10] In section 4 of the *Disposition of Comments*, EPA summarized new brain morphometry data whose collection the Agency initiated and sponsored, and offered an interpretation of the significance of these data for human health risk assessment. EPA stated that these new

[9] EPA Information Quality Guidelines at 5.

[10] One of these four documents was the subject of the *PSG December 2003 Request for Correction*: Environmental Protection Agency, 2003. Disposition of Comments and Recommendations for Revision to "*Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization (External Review Draft, January 16, 2002)*," n.d.; http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=72117 (hereinafter "*2003 Disposition of Comments*").

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."[11]

Inexplicably, EPA has mistaken our Request for Correction with respect to the October *2003 Disposition of Comments* as if we were referring to the Agency's 2002 external review draft health risk assessment (*2002 ERD*) [12]:

> The U.S. Environmental Protection Agency (EPA) has reviewed your Request for Correction (RFC) … regarding certain information associated with the EPA's assessment of *Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization (External Review Draft, January 16, 2002).*

EPA's *2002 ERD* is quite obviously a different document than its *2003 Disposition of Comments*, and it is difficult to imagine how the Agency could have been confused on this point. This is especially perplexing because we neither mentioned nor cited the *2002 ERD* in our petition.

Any and all facts, claims or argument EPA might raise with respect to the Agency's *2002 ERD* are therefore irrelevant to PSG's Request for Correction. EPA's response is therefore wholly and completely unresponsive, and cannot stand as a credible reply prepared and delivered in good faith.

ii. EPA falsely asserts that its *2002 ERD* and its *2003 Disposition of Comments* documents were never "disseminated" apparently because of a boilerplate disclaimer, an ongoing peer review, or both.

In its response EPA notes that the cover of the Agency's *2002 ERD* (but not the *2003 Disposition of Comments*) contains a disclaimer stating that the document "has not been formally released by EPA and should not at this stage be construed to represent Agency policy." EPA also notes that both documents are the subject of an ongoing review by The National Academies. Apparently based on these two facts, but no other logical explanation, EPA asserts that neither document was "disseminated":

> EPA does not consider these materials to be disseminations under the agencies' [sic] Information Quality Guidelines.

This interpretation directly conflicts with the clear language of both EPA's and OMB's Information Quality Guidelines. Neither authority restricts the definition of "dissemination" to information that has been "formally released" by the Agency, nor do

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

[12] Environmental Protection Agency, 2002. Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization (NCEA-1-05-3), External Review Draft. Washington, D.C.: Office of Research and Development. January 16; http://cfpub2.epa.gov/ncea/cfm/recordisplay.cfm?deid=24002 (hereinafter "*2002 ERD*").

they exempt information subject to ongoing peer review. These considerations are not criteria for determining whether information has been disseminated.

EPA's Information Quality Guidelines apply to all information whose distribution is "initiated" or "sponsored" by EPA:

> For purposes of these Guidelines, EPA disseminates information to the public when EPA initiates or sponsors the distribution of information to the public.[13]

Further, information distributed by EPA "to formulate or support" an "Agency decision or position constitutes "dissemination":

> EPA initiates a distribution of information if EPA prepares the information and distributes it to support or represent EPA's viewpoint, or to formulate or support a regulation, guidance, or other Agency decision or position.[14]

This definition includes information prepared by outside parties if EPA distributes it "in a manner that reasonably suggests" Agency endorsement and information EPA proposes to use "to formulate or support" an "Agency decision or position":

> EPA initiates a distribution of information if EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it; if EPA indicates in its distribution that the information supports or represents EPA's viewpoint; or if EPA in its distribution proposes to use or uses the information to formulate or support a regulation, guidance, policy, or other Agency decision or position.[15]

Both the *2002 ERD* and EPA's *2003 Disposition of Comments* were authored, initiated, sponsored and distributed by EPA; contain information from outside parties presented in a manner that reasonably suggests EPA endorsement; and are identified by EPA as supporting or representing the Agency's viewpoint. Further, EPA has proposed to use the *2003 Disposition of Comments* as the literal text of a final risk assessment and Reference Dose for perchlorate. According to the plain meaning EPA's Information Quality Guidelines, EPA clearly has disseminated both documents and the Agency's claim that it "does not consider these materials to be disseminations" lacks foundation.

Moreover, nothing in EPA's guidelines restricts the definition of dissemination to information that has been "formally released" or exempts information undergoing peer review.[16] If it can be reasonably demonstrated these EPA distributed these documents "to

[13] EPA Information Quality Guidelines at 15 (emphasis added).
[14] Ibid (emphasis added).
[15] EPA Information Quality Guidelines at 16 (emphasis added). The OMB Information Quality Guidelines contain similar but not identical language at 8454.
[16] EPA's claim that the 2003 *Disposition of Comments* is undergoing peer review is itself contestable. When The National Academies' ad hoc committee reviewing the potential risks of perchlorate ingestion was established, the 2003 *Disposition of Comments* did not exist, EPA submitted this document to the Committee, and disseminated it to the public via its web site, to summarize and respond to comments it had received from the ERG-sponsored external peer review committee. See *2002 ERD* at 1-1. The 2003

support or represent EPA's viewpoint," no disclaimer—boilerplate or otherwise—is sufficient to exempt them.[17]

Section 8.5 of EPA's Information Quality Guidelines purports to allow EPA to delay responding to petitions challenging information contained in draft documents that are subject to public comment. Irrespective of whether this provision is consistent with OMB's government-wide guidelines,[18] it is irrelevant to the facts in this case. The public comment period for the *2002 ERD* has long since closed. Therefore, had PSG challenged some element in the *2002 ERD*, Section 8.5 could no longer apply. In fact, PSG's petition concerns information contained in EPA's *2003 Disposition of Comments* and Section 8.5 could not apply to that document because EPA did not seek public comment on it.

The only remaining question is whether the content of the *2003 Disposition of Comments*, or the manner in which EPA disseminated it, "reasonably suggests that the agency agrees with the information".[19] On this point both the information itself and the manner in which EPA disseminated it unmistakably demonstrate EPA endorsement. The *2003 Disposition of Comments* is disseminated freely on the Agency's website and was summarized orally by EPA staff at a public meeting held by The National Academies. On its inside cover, the document states:

> This document has been reviewed in accordance with U.S. Environmental Protection Agency policy and approved for publication.

No stronger statement of Agency endorsement exists.

iii. EPA did not include this disclaimer language in its *2003 Disposition of Comments* document.

EPA's claim that a boilerplate disclaimer exempts influential scientific information from information quality guidelines and standards has significant repercussions across a wide array of Agency activities. For example, EPA includes similar disclaimers in several editions of its cancer risk assessment guidelines, its 1998 ecological risk assessment guidelines, its 1992 exposure assessment guidelines, and its 1996 reproductive toxicity guidelines. EPA also has issued draft risk assessments with similar disclaimers for numerous other substances including dioxin, particulate matter and trichloroethylene. Using this reasoning, we are left to conclude that EPA has not disseminated these documents, either.

Disposition of Comments is but one of many documents, including numerous documents prepared by PSG, submitted to assist the Committee in fulfilling its Charge.

[17] Any such text would conflict with OMB's Information Quality Guidelines, which establish very broad government-wide definitions of "information" and "dissemination" that EPA cannot merely ignore and which do not include these new criteria. See OMB Information Quality Guidelines, Section V.5 and V.8.

[18] OMB delegated broad discretion to agencies in designing their error correction procedures. However, OMB also required these procedures to provide "timely correction" of error and be "appropriate to the nature and timeliness of the disseminated information." See OMB Information Quality Guidelines at 8459. Section 5 *supra* details why EPA's response has not complied with both the Agency's and OMB's Information Quality Guidelines for timeliness.

[19] OMB Information Quality Guidelines at 8452.

In any event, the effect of disclaimers is immaterial in this case. EPA's *2003 Disposition of Comments* includes no such disclaimer. Thus, if it were (counterfactually) assumed that disclaimers exempt information from all guidelines, requirements and standards flowing from the Federal Data Quality Law, it could not exempt EPA's *2003 Disposition of Comments.* This document lacks any such disclaimer, and in its place is language stating clearly that it was "approved for publication" by EPA. Clearly the *2003 Disposition of Comments* did represent EPA's views.[20]

b. EPA's response violates both the Agency's information quality guidelines and the government-wide guidelines issued by OMB.

According to the Agency's response, "EPA does not consider" the Agency's *2002 ERD* and *2003 Disposition of Comments* documents "disseminations under the agencies' [sic] Information Quality Guidelines." This position is wholly contradicted by EPA's Information Quality Guidelines:

> These Guidelines apply to "information" EPA disseminates to the public. "Information," for purposes of these Guidelines, generally includes any communication or representation of knowledge such as facts or data, in any medium or form. Preliminary information EPA disseminates to the public is also considered "information" for the purposes of the Guidelines.[21]

Having initiated the document, sponsored the collection of data that is the subject of the *PSG December 2003 Request for Correction*, and distributed this information "to formulate or support a regulation, guidance, or other Agency decision or position"[22]—in this case, deriving a Reference Dose for perchlorate—it is clear beyond all doubt that EPA disseminated this document. This is self-evident in EPA's response because the Agency fails to articulate any explanation, grounded in its own or the OMB Information Quality Guidelines, why it "does not consider these materials to be disseminations".

c. EPA's procedures violate both the Agency's and OMB's Information Quality Guidelines.

Government-wide guidelines issued by the Office of Management and Budget require agencies to incorporate into their agency-specific guidelines procedures that ensure a "timely" response:

> To facilitate public review, agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines.[23]

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[20] Id. (information prepared by either the agency or an outside party disseminated "in a manner that reasonably suggests that the agency agrees with the information" is covered information):
[21] EPA Information Quality Guidelines at 15 (emphasis added).
[22] Ibid (emphasis added).
[23] OMB Information Quality Guidelines at 8459.

EPA guidelines implement this requirement by stating that "EPA's goal is to respond to requests within 90 days of receipt."[24] However, EPA did not respond until 263 days after the date it acknowledged our petition.[25] A delay three times longer than the Agency's stated goal cannot be defended as timely, especially when combined with a decision merely dismissing the petition on unfounded procedural grounds.

EPA's response should be viewed as intentionally dilatory given the nature of the PSG petition. We did not seek a *correction* of information in the conventional sense, but rather the full public disclosure of *information necessary to reproduce the data and analytic results* in EPA's *2003 Disposition of Comments*. In its guidelines, EPA established a very high performance standard for pre-dissemination review, including adherence to (1) the EPA Quality System (section 4.1), (2) the EPA Peer Review Policy (section 4.2), (3) EPA's Action Development Process (section 4.3), (4) EPA's Integrated Error Correction Process (section 4.4), (6) EPA's Information Resources Manual (section 4.5), and (6) EPA's Risk Characterization Policy and Handbook (section 4.6). Indeed, EPA's stated commitment to transparency is noteworthy:

> 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.[26]

In this instance EPA conduct has been in direct conflict with EPA policy. The information we sought is information that EPA should have made public in October 2003. Moreover, *timely* disclosure of this information by EPA was essential for PSG to have a fair opportunity to reproduce and analyze the Agency's new analysis and present comments to The National Academies' ad hoc committee investigating the risks of perchlorate ingestion. Having labored for nine months to respond to our petition, EPA now claims that the *2003 Disposition of Comments*, as well as the presentation it delivered in public to The National Academies and posted on its website[27] summarizing this 364-page document also posted on the Agency's website,[28] was never disseminated.

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[24] EPA Information Quality Guidelines at 31.

[25] EPA acknowledged the *PSG December 2003 Request for Correction* 19 days after it was sent by express delivery service.

[26] EPA Information Quality Guidelines at 20-21.

[27] See http://www.epa.gov/ncea/presentations/perchlorate/index.html. EPA documents posted on the EPA website are covered by EPA's information quality guidelines: "'Information,' for purposes of these Guidelines, generally includes any communication or representation of knowledge such as facts or data, in any medium or form. Preliminary information EPA disseminates to the public is also considered

d. EPA's dilatory conduct denied PSG a fair opportunity to review the Agency's analysis.

By the time we sent the *PSG August 2004 Request for Reconsideration* on August 24, 2004, our opportunity to provide informed scientific comment on these new data to The National Academies had been lost. The final public meeting of the Committee was held in May 2004. As we indicated in August 2004 Request for Reconsideration, EPA's failure to respond constituted a de facto denial of our petition.

4. The substance of EPA's response is unresponsive.

In the *PSG December 2003 Request for Correction*, we sought public disclosure of very specific information critical for reproducing EPA's analysis, including raw data underlying the summary reports found in certain documents prepared by EPA and its contractors. Transparency is essential for PSG—or any other competent party—to ascertain whether the information disseminated by EPA satisfies applicable standards of integrity and objectivity. In its information quality guidelines OMB states the relationship between objectivity and reproducibility:

> If an agency is responsible for disseminating influential scientific … information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties."[29]

There is no question that information related to the potential human health risk posed by perchlorate constitutes "influential" scientific information. Further, EPA has disseminated both types of influential scientific information identified by OMB-- "original and supporting data" and "analytic results". OMB granted agencies substantial discretion concerning how they implemented its government-wide guidelines, but denied them discretion concerning their obligation to ensure that influential scientific information is reproducible:

> With regard to analytic results related thereto, agency guidelines shall generally require sufficient transparency about data and methods that a qualified member of the public could undertake an independent reanalysis.

In addition to its unfounded procedural denial of our petition, described and rebutted in Section 3 *infra*, EPA also includes a purportedly substantive response. EPA's substantive response is aptly described as unresponsive. With respect to most of the information PSG sought,[30] EPA's substantive response consists merely of the assertion

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'information' for the purposes of the Guidelines. Information generally includes material that EPA disseminates from a web page." See EPA Information Quality Guidelines at 15 (emphasis added).

[28] See http://cfpub2.epa.gov/ncea/cfm/recordisplay.cfm?deid=72117.

[29] OMB Information Quality Guidelines, Section V.3.b.ii.

[30] See *PSG December 2003 Request for Correction* at Sections 3(b)-(f). In its response, EPA says that on December 5, 2003, it uploaded the information we requested in Section 3(g). EPA's Information Quality Guidelines state on page 32, "Whether or not EPA determines that corrective action is appropriate, EPA provides notice of its decision to the requester." From December 5, 2003, until September 15, 2004,

that the Agency disclosed adequate information to reproduce its work. This is simply untrue.

a. Missing high resolution images in Consultants in Veterinary Pathology (2003) and criteria for assignment to data[31]

This reference is a report by EPA's consultant summarizing new data obtained at the direction of EPA staff. EPA relies on these new data in its *2003 Disposition of Comments* document. EPA did not, however, disclose the high resolution slides on which the summary report depends. PSG can reproduce the *analysis* of these summary data but cannot reproduce the summary data themselves without the high-resolution images. Whether the summary data are accurate and complete is a fundamental scientific issue because, as EPA knows, the morphometric data in the original "Effects Study" have been a matter of significant scientific controversy.

These data are essential to EPA's scientific claim that the new data support EPA's interpretation of the original "Effects Study" data. EPA apparently obtained these new data precisely because the original data were controversial, and did so in hopes that these new data would resolve the controversy. However, the measurements of EPA's pathologist cannot be reproduced without disclosure of the high-resolution images. As we indicated in our petition, neither an independent, external reviewer nor a member of The National Academies' panel can reproduce the results reported in the reference without disclosure of the slides.

As we noted in our petition, a second critical issue is that EPA's pathologist did not disclose the specific criteria he used to assign plate numbers to data. These plate numbers come from the atlas of the rat brain by Paxinos and Watson cited in the reference. An independent, external reviewer cannot evaluate the appropriateness of the pathologist's assignment without examining the high-resolution scanned images, *and* knowing what criteria he used to make the assignments. Hence, disclosure of the high-resolution images is necessary *but not sufficient* for this reference to be adequately transparent.

On a related matter, the laboratory method EPA uses to assess an effect—slicing brains along the coronal plane and taking simple linear measures—is at best dated, and unconventional and crude by comparison to modern methods. The literature for the past decade reveals that for brain regions varying substantially and naturally in thickness along the anterior to posterior plane (*e.g.*, the corpus callosum), measurements of area or volume in mid-sagittal sections are strongly preferred precisely to prevent artifacts of the type that occurred in the original Effects Study. It is therefore critical that if only coronal

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however, EPA neglected to provide notice despite sending PSG two "interim" responses. We learned on our own that EPA had uploaded information responsive to Section 3(g) and withdrew that element of our complaint in our first Request for Reconsideration. See PSG August 2004 Request for Reconsideration at footnote 11.

[31] See *PSG December 2003 Request for Correction*, Section 3(a). This reference is itself influential scientific information disseminated by EPA because it was "sponsored" by the Agency and is characterized by the Agency as representing or supporting its viewpoint.

sections are available, plate numbers must be carefully matched to anatomical landmarks and that this sectioning be consistent across animals. Otherwise, variations in the measures of the width of brain regions can occur simply due to slight variations in the plane of sectioning.[32]

EPA's response to our petition is unresponsive. It could be read to imply that the Agency does not now (and never did) possess copies of these images, and further, that the Agency relied exclusively on the summary report of its contractor despite ample knowledge that this report would be influential and could be highly controversial. Mere reliance on a consultant's report is inconsistent with the extensive pre-dissemination review procedures set forth in EPA's Information Quality Guidelines to ensure that influential information satisfies applicable information quality standards. Indeed, it is difficult to imagine how EPA could possibly have performed any pre-dissemination review without careful examination of these slides to reproduce the consultant's measurements. In our petition we asked EPA to disclose the high resolution images. If in the alternative EPA did not (and never did) possess copies of these images, then PSG asked the Agency to explain how it conducted an effective pre-dissemination review to ensure that the data reported by its consultant satisfied information quality standards applicable to influential scientific data.

EPA's response consists of shifting the burden of disclosing the slides to third parties and ignoring our request for information concerning the Agency's pre-dissemination review. EPA directs us to obtain copies of the high-resolution slides from Argus Laboratories. However, Argus Laboratories did not perform the laboratory analysis and cannot verify that the images in its possession are true and complete. It is EPA's obligation, not PSG's or Argus', to ensure the integrity and objectivity of influential data that EPA disseminates. The Federal Data Quality Act requires more of EPA than to provide a mere statement of belief in its contractor or to shift its responsibilities to third parties not covered by EPA's Information Quality Guidelines.

[32] Geller (2003), the reference EPA says is responsive to Section 3(c) of the *PSG December 2003 Request for Correction*, asserts on behalf of EPA that Agency guidelines for developmental neurotoxicity testing [OPPTS 870.6300] recommend coronal sections. The text of this guidance does not support this claim. The guidance states, "At a minimum, [morphometric analysis] would consist of a reliable estimate of the thickness of major layers at representative locations within the neocortex, hippocampus, and cerebellum. For guidance on such measurements see Rodier and Gramann." Rodier and Gramann, a citation from 1979, describes a study in which both coronal and mid-sagittal sections of adult mice brains were taken to determine which regions of the brain are affected when neuronal development is interrupted during critical gestational periods. Geller (2003) also asserts that EPA's decision to perform only coronal sections was made "by agreement by representatives of the [Defense Department], defense industry, EPA and the [National Institute for Environmental Health Sciences]" (emphasis added). PSG was not party to this agreement.

b. Critical details missing from the discussion of materials and methods in Consultants in Veterinary Pathology (2003)[33]

In our petition we noted that critical details needed to reproduce EPA's data and analytic results were missing from the report of EPA's consultant. We identified several specific questions that needed answers:

- What were the tissue storage conditions since the first Effects Study was performed?
- How was the tissue prepared for sectioning?
- What steps were taken to ensure that the degree of tissue compression during sectioning and shrinkage during processing was equivalent in the two series; or alternatively, what steps were taken to measure the extent of tissue compression and shrinkage *in each series of sections* to allow for arithmetic correction necessary to place the measures of the two series on the same scale?
- Who actually sliced the paraffin-embedded brains, what microtome was used, and with what kind of knife?

EPA's response is unresponsive. The Agency merely states that the methods used by its consultant "are available in the report and appendices." These documents lack information responsive to these questions.

c. Discrepancies in EPA's statistical analysis of the data in Consultants in Veterinary Pathology (2003)[34]

In its *2002 ERD* (which is not and never has been the subject of PSG's Request for Correction), EPA reported the results of a multivariate profile analysis that, as shown in its Figure 5-15, suggested a strong perchlorate dose effect as a possible inverted U-shaped function. In its *2003 Disposition of Comments* (the document that is the subject of PSG's Request for Correction), EPA also reports such a statistical analysis. However, in this latter document EPA does not provide graphical descriptions of the results of this analysis or sufficient details for the analysis to be capable of being reproduced. The absence of these details is highly irregular given the degree of prominence that EPA attached to this analysis (and its graphical summary) in the *2002 ERD*. As we indicated in our Request for Correction, this raises profound doubts about the presentational objectivity of EPA's report.

EPA's response provides new information that we are now examining to ascertain whether we can now reproduce the Agency's statistical analysis. We note that Geller (2003), the reference that EPA says contains the information we seek, appears to only summarize the Agency's analysis and report the Agency's inferences from it (based on

[33] See PSG December 2003 Request for Correction, Section 3(b).
[34] See PSG December 2003 Request for Correction, Section 3(c).

the limited statistical outputs of *F* and *p* values), but does not include significant information about how the analysis was performed, including how many different models were run. In addition, Geller (2003) relies explicitly on another reference—Garman (2003)—which is inherently not transparent, as indicated in Section 3(f) of our Request for Reconsideration. Pending the completion of our review and EPA's reconsideration of its response to Section 3(f) of our petition, this issue remains open.

d. Missing data in Consultants in Veterinary Pathology (2003)[35]

Our examination of Tables 1-4 in the report of EPA's consultant indicated that a great deal of data appeared to be missing. For example, there were only data for six out of 16 rats in Group I, CC Plate 15 (third column, Table 1). In Group II, there were only data for four out of 16 animals (last column, Table 2). In Table 4, none of the columns contain values for more than two out of 16 animals. Although statistical analyses were not performed with brain section levels with less than five data points, EPA should have explained the lack of data and justified the criteria used for statistical analysis especially given the large number of missing data. EPA's response is unresponsive. The Agency merely states that it is "unaware of any missing data."

Contrary to EPA's response, the reference does not adequately explain why these data are missing, nor does it explain EPA's basis for performing statistical tests on only those data which are reported. The reference does not explain the disposition of the 19 sections between the step sections that were mounted on slides and stained. In our petition we noted that critical sections may have been missed or their results not disclosed. EPA's response is silent with respect to this concern.

As we indicated in the *PSG December 2003Request for Correction*, this information is essential for interpreting reported measures of thickness of structures in the serial coronal sections and for establishing the correspondence between sections measured in the Argus 2001 report and EPA's new reference. Conventional practice requires that section numbers be assigned to each section sliced from a block of brain tissue. These sections numbers were not provided in the report of the original 2001 data, nor were they memorialized on the scanned images of sections that were measured, and they are not included in this reference. Section numbers must be disclosed so that independent, external reviewers can reproduce the results reported in the reference based on the high resolution scanned images. Transparency also requires that EPA state explicitly which of the sections measured and reported in Tables 1 through 4 correspond to scanned images of sections that were included in the Argus 2001 report. If section numbers cannot be disclosed because they were not recorded at the time they were collected, then this should be clearly stated and acknowledged as a material defect that makes the data incapable of being reproduced.

[35] See PSG December 2003 Request for Correction, Section 3(d).

e. Affirmative Showing of GLP compliance for Consultants in Veterinary Pathology (2003)[36]

PSG's petition noted that while the data reported by EPA's contractor were new, they came from tissues collected as part of an earlier study funded by PSG and performed by Argus Research Laboratories. At EPA's insistence, the original study funded by PSG was performed in compliance with EPA's Good Laboratory Practice (GLP) regulations set forth in 40 C.F.R. Parts 160 and 792. Adherence to GLP regulations provides assurance that the most stringent and demanding laboratory procedures have been followed. EPA's Information Quality Guidelines specifically mention GLP compliance as providing evidence of data quality:

> EPA takes many actions based on studies and supporting data provided by outside sources, including confidential or proprietary information that has not been peer reviewed. For example, industry can be required by regulation to submit data for pesticides under FIFRA or for chemicals under TSCA. The data are developed using test guidelines and Good Laboratory Practices (GLPs) in accordance with EPA regulations. While there is not a requirement to have studies peer reviewed, such studies are reviewed by Agency scientists to ensure that they were conducted according to the appropriate test guidelines and GLPs and that the data are valid.[37]

That is, Agency scientists conduct a two-part review to (i) ensure that GLP requirements were met and (ii) that the data developed are valid. Data do not require an additional peer review step if they satisfy this two-part test.[38]

As we indicated in the *PSG August 2004 Request for Reconsideration*, neither the report of EPA's consultant nor EPA's *2003 Disposition of Comments* includes any statement or evidence that these new data were obtained in accordance with GLP requirements. We specifically asked EPA to disclose this evidence. EPA's response does not do so.

f. Material information from Garman (2003) is not disclosed[39]

EPA relies on this reference for influential scientific information. In particular, it is EPA's scientific basis for concluding that "morphometric measurements from anterior corpus callosum and striatum taken at a brain depth identified as plate 17 (block level I) and from posterior corpus callosum taken at plate 31 (block level II) … were reasonably representative of the brain areas examined".[40] The representativeness of these samples is obviously an important scientific question. However, EPA did not disclose any material information about this reference, which is described only as a "personal communication"

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[36] See PSG December 2003 Request for Correction, Section 3(e).
[37] EPA Information Quality Guidelines at 24.
[38] EPA Information Quality Guidelines at 26, 50.
[39] See PSG December 2003 Request for Correction, Section 3(f). This reference is itself influential scientific information disseminated by EPA because it is derived from research "sponsored" by the Agency and is characterized by the Agency as representing or supporting its viewpoint.
[40] 2003 *Disposition of Comments* at 4-33 and 4-34.

between EPA staff and EPA's consultant. Independent, external reviewers do not have enough information from what EPA has disclosed to reproduce it.

EPA's response is therefore unresponsive. EPA's response simply ignores the very specific issue PSG raises as if we had never raised it.

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

In *PSG's August 2004 Request for Reconsideration* we made clear why we believe EPA's conduct has caused us 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, much of which we funded. We also presented new data that we also collected at our expense 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 covered by this RFC because EPA has refused to make the data public.[41]

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 ensured that the Agency, *and the Agency alone*, might be capable of reproducing its own work. Like PSG, the NAS 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 analytic results. Inasmuch as a review of the quality of such data appears to be an overarching element of its Charge, it is unclear how the Committee could fulfill its obligation to perform such a review. This is precisely what EPA, through its Information Quality Guidelines, promised would not happen.

EPA's response to the *PSG December 2003 Request for Correction* could not and does not ameliorate any of these harms. To the extent that EPA now denies that it ever disseminated its *2003 Disposition of Comments*—despite presenting its work in public session at The National Academies, representing that work as the "technical perspective" of EPA,[42] and posting it on the EPA website—then the Agency's response compounds the irreparable harm suffered by PSG by denying us any administrative recourse.

[41] PSG August 2004 Request for Reconsideration at 5.
[42] Farland WH, and Jarabek AM, "Perchlorate Risk Characterization: US EPA Technical Perspectives," http://www.epa.gov/ncea/presentations/perchlorate/perchlorate-presentation-nrc_files/v3_document.htm.

6. Corrective actions PSG seeks.

PSG continues to seek the same remedies and corrections we sought in Sections 3(a)-(f) of our December 2003 petition. In general, these remedies consist of full disclosure by EPA of critical information necessary to reproduce the work of the Agency and its consultants. We continue to believe that the Agency must fulfill its minimum legal obligations under the Federal Data Quality Act to ensure the transparency and reproducibility of its work.

EPA made significant commitments to ensure that influential scientific information would, in fact, be transparent reproducible by third parties such as PSG:

> 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.[43]

We agree with EPA's stated policy that a "higher degree of transparency about data and methods will facilitate the reproducibility of such information by qualified third parties." In the *PSG December 2003 Request for Correction*, we asked EPA to abide by this commitment by disclosing the data that formed the basis for its analysis. EPA's response, sent 269 days later, is clear and convincing evidence that the information owner in this case does not intend to adhere to Agency policy.

Further, PSG seeks a clear declaration from the Agency whether it now or ever did possess copies of the high-resolution slides identified in Section 3(a) of our petition and reiterated in Section 4(a) above. EPA's response is ambiguous and appears to be evasive. If the answer to this question is negative, then PSG seeks full, public disclosure of the pre-dissemination review EPA performed to ensure the integrity and objectivity of the data summaries reported by its contractor. Disclosure of EPA's pre-dissemination review is especially important given PSG's inability to reproduce the Agency's work based on the limited information EPA has thus far disclosed. As we stated in the *PSG December 2003 Request for Correction*, EPA may believe that its consultant's report fully and accurately characterizes the raw data, but the Agency's legal obligation under the Federal Data Quality Act goes well beyond a mere statement of belief in its contractor.

[43] EPA Information Quality Guidelines at 20-21.

In the *PSG August 2004 Request for Reconsideration*, we reasonably interpreted EPA's unresponsiveness as a de facto denial of our Request for Correction. We sought remedies in addition to full disclosure, and we repeat them here:

> Full disclosure is not sufficient … 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. If EPA's Office of Research and Development is convinced that these data satisfy the applicable substantive standards for influential scientific information, then it would have an opportunity to make that case at a later date subsequent to the full disclosure of the data sought in our original petition.[44]

Finally, PSG recently learned that EPA hired the Oak Ridge Institute for Science and Education (ORISE) to perform a peer review of exactly the same EPA data and analytic results that we have been unable to reproduce based on the limited information EPA has disclosed.[45] Precisely because we have been unable to reproduce EPA's work, we do not understand how any peer review panel could reasonably accomplish this task. Despite our extensive and continuing contributions to the body of science on perchlorate, we learned about this peer review only by accident. It is therefore not clear whether EPA intends this peer review to be conducted in secret, or openly so that all stakeholders can fairly participate. Contrary to the advice provided in the Peer Review Handbook, EPA has not announced this peer review in the Federal Register, nor has EPA "advertised via other avenues".[46] The public remains completely uninformed about the purpose of this peer review, the panelists who might have been selected, the contents of EPA's Charge to the reviewers, and the workshop procedures that will be followed.

As EPA's Peer Review Handbook makes clear, hiring a contractor to organize and perform peer review generally exempts it from the open meeting and balanced membership requirements of the Federal Advisory Committee Act (FACA).[47] The public interest is not well served by a peer review that evades these requirements and follows secretive procedures or relies on an unbalanced panel. Further, EPA has not asked PSG to provide any input into the development of the Charge as provided for in Section 3.2.4 of

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[44] PSG August 2004 Request for Reconsideration at 6. EPA states that it "will not be treating" this letter "as a request for reconsideration". See EPA Response at 2.

[45] See http://www.dasnr.okstate.edu/agco/ad02252004USEPA.html. EPA appears to have hired ORISE no later than February 2004 to perform this peer review at some future date —at the same time that The National Academies is reviewing the same scientific information.

[46] EPA Peer Review Handbook at 50: "Non-FACA meetings may be announced in the Federal Register (providing that it is clear in the notice that such meetings are not subject to FACA) as it provides the public with useful information and a point of contact concerning the peer review. In addition, non-FACA (as well as FACA) meetings should also be advertised via other avenues (e.g., the Web, local newspapers, and mailing lists)."

[47] EPA Peer Review Handbook, Section 2.8.

the Agency's Peer Review Handbook.[48] Therefore, to ensure that transparency and reproducibility are achieved, PSG formally requests that EPA's corrective action include an opportunity for PSG to fully participate in this peer review.

Sincerely,

Michael Girard
The Perchlorate Study Group

[48] Environmental Protection Agency, Peer Review Handbook (2d. Ed), EPA 100-B-00-001 (December 2001) at 54 (hereinafter "EPA Peer Review Handbook").