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VIA ELECTRONIC MAIL

Information Quality Guidelines Staff
United States Environmental Protection Agency
1300 Pennsylvania Ave., N.W.
Washington, DC 20004

Re: Request for Correction of Information Disseminated by EPA in Support of its Proposed National Ambient Air Quality Standard for Lead, 73 Fed. Reg. 29,184 (May 20, 2008), Docket ID No. EPA-HQ-OAR-2006-0735

Dear Sir or Madam:

On behalf of the Association of Battery Recyclers ("ABR" or "Petitioner"), this document is being submitted as a formal Request for Correction ("RFC") pursuant to the Information Quality Act (Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001). Petitioner objects to influential scientific and technical information being disseminated by EPA in association with its recent proposed rulemaking on the Lead National Ambient Air Quality Standard ("NAAQS"), 73 Fed. Reg. 29,184 (May 20, 2008) -- Lanphear, B.P., *et al.*, Low-level environmental lead exposure and children's intellectual function: an international pooled analysis, Environ. Health Perspect. 113: 894–899 (2005). EPA has failed to ensure that this information meets the information quality principles of objectivity -- substantive and presentational -- and utility.

ABR is a national trade association that has represented the lead recycling industry for more than twenty-five years. Members of the ABR include battery manufacturers, lead chemical manufacturers, lead fabricators, secondary lead smelters, and consultants and vendors to the lead recycling industry. The lead recycling industry members of ABR collectively represent virtually all of the lead recycling capacity currently available in the United States. On behalf of its members, ABR has participated throughout this rulemaking proceeding, but its ability to meaningfully participate has been compromised by EPA's failure to comply with its information quality guidelines. ABR Members may also be subject to increased regulation as a result of the proposed revisions to the lead NAAQS. Thus, ABR and its members are affected persons.

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I. The Information Quality Act.

The Office of Management and Budget ("OMB") has issued guidelines to meet the purposes of the Information Quality Act, providing "policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." 67 Fed. Reg. 8452, 8452 (Feb. 22, 2002). Quality is an encompassing term defined to include utility, objectivity and integrity. *Id.* at 8459. "'Utility' refers to the usefulness of the information to its intended users, including the public." *Id.* Objectivity includes two elements -- presentation and substance. *Id.*

Both elements of objectivity are intended to ensure that the information disseminated is accurate, reliable, and unbiased. Presentational objectivity ensures that the information is being presented in an accurate, clear, complete, and unbiased manner. OMB recognized the importance of providing the underlying data to meet this goal of objectivity:

> Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation. Also, the agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality protections) and, in a scientific, financial or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users.

Id. Substantive objectivity involves a focus on ensuring accurate, reliable and unbiased information: "In a scientific, financial, or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods." *Id.* Moreover, influential scientific, financial or statistical information "shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." *Id.* at 8460.

EPA has stated that it "is committed to providing public access to environmental information." EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA, EPA/260R-02-008, at 3 (Oct. 2002) (hereinafter referred to as "EPA Information Quality Guidelines"). These guidelines apply to, among other things, "information collected through contracts" and "information that is either voluntarily submitted to EPA in hopes of influencing a decision or that EPA obtains for use in developing a policy, regulatory, or other decision," including scientific information published in journal articles. *Id.* at 6-7. EPA is responsible for the quality of information generated by external parties when it endorses or adopts it. *Id.* at 8.

In addition, for purposes of EPA's guidelines, information disseminated in support of Economically Significant actions as defined in Executive Order 12866 (58 Fed. Reg. 51,735 (Oct. 4, 1993)) is considered "influential" by EPA. *Id.* at 19-20. Such information should meet a higher standard of quality, including transparency about data and methods. *Id.* Transparency about data and methods will facilitate the reproducibility of such information. *Id.* at 21. EPA's call for transparency is consistent with OMB's guidelines.

II. EPA's Failure to Comply with the Information Quality Act.

On May 20, 2008, EPA published a proposed rule for revising the NAAQS for lead at 73 Fed. Reg. 29,184. In support of its proposed rule, EPA relied on the following paper -- Lanphear, B.P., *et al.*, Low-level environmental lead exposure and children's intellectual function: an international pooled analysis, Environ. Health Perspect. 113: 894–899 (2005) (hereinafter referred to as "Lanphear (2005)"). The Lanphear (2005) paper is also relied on in EPA's Criteria Document, Staff Paper and Risk Assessments. EPA listed the study as supporting and related materials in the docket for the proposed rule (EPA-HQ-OAR-2006-0735-5302, available at www.regulations.gov). Several comments were submitted outlining the major deficiencies in Lanphear (2005), including comments submitted by ABR and the International Lead Zinc Research Organization Inc. ("ILZRO"). *See e.g.,* ABR Comments on Proposed Rule, Aug. 4, 2008 (EPA-HQ-OAR-2006-0735-5717.1); ILZRO Comments on Proposed Rule, Aug. 3, 2008 (EPA-HQ-OAR-2006-0735-5700.1); Gradient Corp. Comments on Advanced Notice of Proposed Rulemaking, on behalf of ABR, Mar. 19, 2008 (EPA-HQ-OAR-2006-0735-5114.1). Consistent with EPA's Information Quality Guidelines, ABR expects that EPA will address those comments in the final rulemaking and in its response to comments.

However, in addition to noting the deficiencies in the study, some of which EPA itself has conceded, the submitted comments also note EPA's failure to provide the underlying data in the Lanphear (2005) paper. Nonetheless, EPA continues to have the Lanphear paper listed in its docket and has not, to our knowledge, provided any additional information related to the underlying data that purports to support the findings of this paper. EPA's failure to provide this information and to provide an independent analysis of the underlying data violates the Information Quality Act. As of the filing of this RFC, EPA has not issued its final rule.

A. The Information Quality Act applies to Lanphear (2005).

As noted above, information subject to the Information Quality Act includes papers published in scientific journals. EPA Information Quality Guidelines at 7. Dissemination occurs when EPA relies on such studies in support of its actions. In this case, EPA relies on Lanphear (2005) in its Criteria Document, Staff Papers, and Risk Assessments and throughout its proposed rule to revise the lead NAAQS. *See, e.g.,* 73 Fed. Reg. at 29,199-29,203, 29,208-29,209, 29,225, 29,238-29,239. Multiple assumptions regarding the dose response for lead's impact upon the intelligence quotient ("IQ") of children are derived from the Lanphear (2005) analysis. EPA's reliance on the paper in support of its proposed rulemaking indicates it is endorsing it or is otherwise adopting it. Moreover, EPA partly funded the study.

In addition, the Lanphear (2005) paper is "influential" scientific information. EPA has defined the lead NAAQS proposal as an "economically significant regulatory action" within the meaning of Section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect on the economy of $100 million or more. 73 Fed. Reg. at 29,276. Moreover, the Lanphear (2005) paper has played a substantial role in EPA's policy making decision. As such, EPA must apply a higher degree of quality to Lanphear (2005). In particular, EPA must ensure the study's transparency and reproducibility.

B. EPA has failed to ensure the objectivity and utility of Lanphear (2005) and has failed to allow the public the opportunity to review the paper's objectivity and utility.

The objectivity principle involves ensuring accurate, reliable and unbiased information. 67 Fed. Reg. at 8459. Utility refers to the usefulness of the information to its intended users, including the public. *Id.* EPA has failed to ensure that Lanphear (2005) meets these objectives.

EPA (and the authors) to date has failed to provide crucial information regarding the underlying data and methods used in the analysis. The failure to provide such information has raised numerous questions as to the accuracy and reliability of the findings EPA has endorsed and adopted in the lead NAAQS proposed rule. The following are examples of possible errors that cannot be confirmed and, thus, have not been corrected due to the lack of information that has been provided by the authors of the study and EPA:

- Table 4 from the Lanphear (2005) paper purports to show the Mean Unadjusted and Adjusted Changes in Full Scale IQ Score associated with an Increase in Blood Lead Concentration (log scale), from the 5th to 95th percentile of the concurrent blood lead level at the time of IQ testing. The Table had errors in the third column titled "5th - 95th percentile of study population PbB (µg/dL)," which informed the IQ deficits provided in the last column of the table. EPA purported to provide a corrected table in January of 2007 -- "Correction to Errors Identified in Lanphear et al. 2005 Pooled Analysis Study and Implications for

Pilot Risk Assessment," Mem. from Zachary Pekar (EPA OAQPS) to Lead NAAQS Docket, Jan. 26, 2007 (EPA-HQ-OAR-2006-0735-5494).[1] Despite these changes, the other columns (IQ deficits and Blood lead-IQ slope) remained unchanged in the revised table. Based on the information provided, it is unclear whether the estimated IQ deficit or the blood lead-IQ slope values should also have been corrected. It is clear that the relationships previously reported no longer hold after these changes. This calls into question the reliability of the results relied on by EPA.

- Figure 3 in Lanphear (2005), which purports to show how well the log-linear concentration-response function fits the data in a plot of IQ versus concurrent blood lead level, includes incorrect confidence limits on the blood lead data groups. Confidence intervals on the mean are a function of sample size, and the nearly identical range of the confidence intervals shown in Figure 3 would require that each blood lead category have a very similar sample size, or that the standard deviation of IQ in each interval differ in such a way to perfectly offset the differences in sample size. However, the publication reports that there are a total of 1333 data points with a median concurrent blood lead level of 9.7 µg/dL. Based on the number of data points, it would appear that the confidence levels provided are in error or, at a minimum, suspect.

- EPA uses a dose-response curve based on concurrent blood lead data above and below a peak blood lead level of 7.5 µg/dL from Lanphear (2005). 73 Fed. Reg. at 29,201 (citing Criteria Document, section 6.2.13). The slope from Lanphear (2005) is an outlier as shown in EPA's summary of slopes found in several studies in Table 1 of the Proposed Rule. *Id.* at 29,203. The slope derived based on blood lead levels below 7.5 µg/DL is quite disparate and does not plot in proximity to either of the other two curves or the data symbols. As such, the slope estimates may be in error, again raising questions as to the accuracy and reliability of the slope EPA uses based on the Lanphear (2005) paper.

Under OMB guidelines, the disseminated information must be presented in an accurate, clear, complete, and unbiased manner to meet the objectivity test. 67 Fed. Reg. at 8459. These errors illustrate how the information in Lanphear (2005) is not presented in an accurate, clear or complete manner. OMB specifically recognizes the need to provide

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[1] In its memorandum providing the updated table, EPA noted that "[t]he degree to which errors in Table 4 of the Lanphear et al. 2005 study impact pilot risk results is not clear without rerunning the risk analysis for both the concurrent and lifetime average blood Pb metrics." Mem. from Zachary Pekar (EPA OAQPS) to Lead NAAQS Docket, Jan. 26, 2007 (EPA-HQ-OAR-2006-0735-5494).

additional information, including the supporting data, "so that the public can assess for itself whether there may be some reason to question the objectivity of the sources." *Id*.

Similarly, the substantive element of the objectivity criteria cannot be established. Along with failing to provide adequate information, the errors noted above, among others, illustrate the potential problems in the study's methodology, in particular, how the authors fit the data from the individual studies into the model used for the pooled analysis. Issues with transparency are further discussed in the next section.

Because of the defects in meeting the objectivity criteria, the Lanphear (2005) paper is of little utility without the underlying data. The Lanphear (2005) paper purports to support EPA's Criteria Document, Staff Paper and Risk Assessments. All of these documents are intended to inform the Administrator, as well as the public, of the potential risks posed by air related lead emissions. Similarly, the Notice of Proposed Rulemaking is intended to articulate and communicate to the public the scientific information that the Administrator considered and the reasoned basis for determining what standard to propose to set. However, EPA's failure to ensure that the scientific support meets the high standard of quality under the Information Quality Act calls into question the information relied on by the Administrator. Further, without the underlying data, the public cannot adequately assess the objectivity of the Lanphear (2005) paper.

C. The results of Lanphear (2005) cannot be reproduced without the underlying data.

The information sought herein also is essential for reproducing the results in Lanphear (2005). Because the paper was used to support an economically significant action, it is influential scientific information subject to a higher degree of quality. As noted above, this includes transparency of data and methods to facilitate the reproducibility of such information. Reproducibility means that the information is capable of being substantially reproduced. 67 Fed. Reg. at 8460. "With respect to analytic results, 'capable of being substantially reproduced' means that independent analysis of the original or supporting data using identical methods would generate similar analytical results." *Id.* While each of these is subject to some acceptable degree of imprecision or error, the degree of imprecision that is tolerated is reduced for information judged to have more important impacts. *Id.* Regardless of the level of imprecision that may be tolerable in this case, which involves a study that has significant impacts on EPA's decision, the Lanphear (2005) paper is not capable of being reproduced.

The Lanphear (2005) paper is a "pooled" analysis involving a review of data from seven international studies initiated before 1995 that involved sites in Boston,

Massachusetts; Cincinnati, Ohio; Cleveland, Ohio;[2] Mexico City, Mexico; Port Pirie, Australia; Rochester, New York; and Yugoslavia. The authors noted that the data for at least two of the studies had not previously been published elsewhere. The data in each of these studies may differ and pooling of the data may result in a loss of information.

> The reproducibility standard applicable to influential scientific, financial, or statistical information is intended to ensure that information disseminated by agencies is sufficiently transparent in terms of data and methods of analysis that it would be feasible for a replication to be conducted. The fact that the use of original and supporting data and analytic results have been deemed "defensible" by peer-review procedures does not necessarily imply that the results are transparent and replicable.[3]

67 Fed. Reg. at 8455. In order to attempt to reproduce the analytical results in Lanphear (2005), the underlying data and additional information as to the authors' methodology is necessary.

III. Recommendation for Corrective Action and Benefits to Petitioner.

Obtaining the underlying data would have enabled Petitioner (and the public) to investigate the errors noted above and possibly correct them. It would also have answered questions regarding the objectivity and utility of the information provided in

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[2] The author of the study on Cleveland, while providing the data, withdrew from authorship due to disagreements with the conclusions in Lanphear (2005). Ernhart, Claire B., Effects of Lead on IQ in Children, Environ. Health Perspect. 114: A85–A86 (2006).

[3] Although the journal in which Lanphear (2005) was published provides for peer review, it is insufficient to support a finding of objectivity in this case. OMB guidance notes that "the need for rigorous peer review is greater when the information contains precedent-setting methods or models, presents conclusions that are likely to change prevailing practices, *or is likely to affect policy decisions that have a significant impact*." 70 Fed. Reg. 2664, 2668 (Jan. 14, 2005) (emphasis added). As EPA has found, the lead NAAQS proposed rule will have a significant impact on the economy. Given the errors noted above, it is self-evident that the peer review process involved in this case was inadequate to ensure the objectivity of the paper under the Information Quality Act. Moreover, since the underlying data has not been adequately provided, the appropriate peer review is not likely to have occurred.

Lanphear (2005). For these reasons, ABR recommends as corrective action that EPA provide the following to comply with the Information Quality Act:

1. Copies of the original data sets submitted by each investigator contributing to the pooled analysis, including the data submitted by the investigators of the Boston, Cincinnati, Cleveland, Port Pirie, Rochester, Mexico City and Yugoslavia prospective child development studies.

2. Details defining the multi-step process employed by Lanphear (2005) in which the data from individual studies was first fitted to simple unadjusted models and then combined into a linear model adjusted for the seven study sites. In particular, details of the methods used for "adjustment for study site" are requested as well as all methods used in the generation of the single linear model subsequently generated and subjected to analysis using a restricted cubic spline function.

3. All data pertaining to the derivation of the single linear model referred to in paragraph 2. above, inclusive of identifiers for individual data points, their associated blood lead measures and all confounder data associated with each data point (whether or not it was used in the final analysis).

4. All calculations pertaining to the "final model" developed in the pooled analysis, inclusive of details defining the seven separate adjusted models developed for each of the cohorts, and the impact of omitting individual data sets upon overall model characteristics and descriptive parameters.

Numerous questions arise regarding the Lanphear (2005) paper, including specific questions regarding the choice of models fitted to the pooled analysis data set; reservations regarding the assumed (supralinear) slope of the blood lead: IQ relationship at blood lead levels less than 10 µg/dL; and possible artifacts that might be imparted by residual confounding. Such issues are amenable to further analysis, and the data utilized in the pooled analysis can be subjected to further evaluation that advances our understanding of the impact of lead upon IQ at low blood lead levels. Being able to review the underlying data would both allow the public, such as ABR to determine the objectivity of the Lanphear (2005) paper, and allow additional analysis, which would assist EPA and the public in understanding the potential impacts of air-related exposures to lead.

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We appreciate your attention to this matter. Please let us know if you require any supplemental information or have any questions. We look forward to your response in accordance with EPA's Information Quality Guidelines.

Sincerely yours,

/s/ Robert N. Steinwurtzel

Robert N. Steinwurtzel

cc: Molly A. O'Neill, Assistant Administrator for Environmental Information and Chief Information Officer, EPA
EPA Air and Radiation Docket, Docket ID No. EPA–HQ– OAR–2006–0735

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