UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 27 2011

OFFICE OF
AIR AND RADIATION

Mr. Robert Steinwurtzel
Bingham McCutchen, LLP
2020 K Street NW
Washington, D.C. 20006-1806

Dear Mr. Steinwurtzel:

This letter is in response to your July 7, 2010 correspondence, on behalf of the Association of Battery Recyclers (ABR). In this correspondence, you request that the U.S. Environmental Protection Agency (EPA) respond to your October 14, 2008, Request for Correction (RFC) 09001, pursuant to the EPA Information Quality Guidelines (IQG).[1] In this RFC, ABR challenges the objectivity and utility of a scientific document that was part of the evidence relied upon by EPA in support of the proposed and final rulemaking on the National Ambient Air Quality Standard (NAAQS) for lead (73 FR 29184, 73 FR 66964).

EPA has consistently followed its EPA IQG procedures for responding to the ABR RFC. EPA provided a response[2] to this RFC on March 8, 2009. In this response, EPA conveyed its decision to delay consideration of the ABR RFC until the conclusion of the legal challenge to the National Ambient Air Quality Standard (NAAQS) for lead in the D.C. Circuit court and gave ABR the option to submit a new RFC at the conclusion of the litigation if the association believed that its information quality concerns had not been addressed. EPA is treating your July 7, 2010 correspondence as a new request to respond to the information quality concerns raised in the October 14, 2008 correspondence.

The March 8, 2009 RFC response is consistent with other EPA RFC decisions regarding information which may be related to pending litigation. On March 18, 2009 ABR submitted another letter regarding the Agency's decision to defer consideration of the ABR RFC, and raising issues under the Freedom of Information Act (FOIA) as well. On May 1, 2010, EPA responded to this letter,[3] noting that the EPA IQG are not intended to contravene any other legal requirements that may apply to particular agency determinations or other actions.[4] In addition, you have filed a separate request under FOIA and EPA's regulations promulgated at 40 CFR 30.36(d) seeking certain records and data. As you are aware, that request is being processed

[1] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA, 2002. (67 FR 63657)
[2] http://epa.gov/quality/informationguidelines/documents/09001-response.pdf
[3] http://epa.gov/quality/informationguidelines/documents/09001-rel3.pdf
[4] EPA IQG, page 4

separately and we have requested the research data for the Lanphear *et al* (2005) study from Cincinnati Children's Medical Health Center (CCHMC). We anticipate being able to provide you with a copy of the data, pending resolution of any remaining issues under FOIA (such as fees or confidentiality), in the near future.

Your October 14, 2008, request focuses on the Lanphear *et al.* (2005)[5] study, which EPA listed as supporting and related materials in the docket of the proposed rule. EPA finds that the issues you raise in this RFC are similar to the concerns you raised during the open public comment period for the 2008 Proposed Rule on the National Ambient Air Quality Standards for Lead. These information quality concerns were addressed in the *Responses to Significant Comments on the 2008 Proposed Rule on the National Ambient Air Quality Standards for Lead*[6] (referred to as the "Response to Comments" document). For your convenience, your RFC information quality concerns and the EPA responses found in the Response to Comments document can be found in the enclosed document.

Members of ABR filed a court challenge to EPA's use of the Lanphear *et al.* (2005) study in the most recent review of the NAAQS for lead. The U.S. Court of Appeals for the D.C. Circuit[7] denied the petition. The court stated "Consequently, petitioners have failed to identify errors in the Lanphear study that would make EPA's reliance on it arbitrary and capricious, and EPA thus appropriately considered the Lanphear study and was not required to obtain and make public the data underlying the Lanphear study."[8] The court also stated, "Similarly unavailing is petitioners' contention that EPA did not respond adequately to comments concerning errors in the Lanphear study."[9]

Also, as part of the last review of the NAAQS for lead, the Agency conducted a thorough and robust review of the publication by Lanphear *et al.* (2005) in the context of the review of the air quality criteria (described in the Air Quality Criteria Document or AQCD[10]). EPA further considered this peer-reviewed publication in the conduct of the risk assessment, described in the Risk Assessment Report[11] and summarized in the Staff Paper[12] and in the notice of proposed rulemaking.[13] EPA's consideration and interpretation of the data, methods and conclusions described in this publication for purposes of reviewing and revising the lead NAAQS received

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[5] Lanphear, B.L., Hornung, R., Khoury, J., Yolton, K., Baghurst, P., Bellinger, D.C., Canfield, R.L., Dietrich, K.N., Bornschein, R., Greene, T. Rothenberg, S.J., Needleman, H.L., Schnaas, L., Wasserman, G., Graziano, J., Roberts, R. (2005) Low-level environmental lead exposure and children's intellectual function: An international pooled analysis. Environ Health Persp 113(7): 894-899.

[6] Responses to Significant Comments on the 2008 Proposed Rule on the National Ambient Air Quality Standards for Lead, EPA. 2008 (73 RF 29184) - http://www.epa.gov/ttnnaaqs/standards/pb/data/20081015_responsetocomments.pdf

[7] *Coalition of Battery Recyclers Association v. EPA*, 604 F.3d 613 (D.C. Cir. 2010) , available at http://pacer.cadc.uscourts.gov/common/opinions/201005/09-1011-1244831.pdf

[8] *Id.*at 624.

[9] *Id.*

[10] *Air Quality Criteria for Lead.* EPA/600/R-5/144aF. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment-RTP Division. Research Triangle Park, NC. October 2006.

[11] Available at http://www.epa.gov/ttnnaaqs/standards/pb/s_pb_cr_td.html

[12] Available at http://www.epa.gov/ttnnaaqs/standards/pb/s_pb_cr_sp.html

[13] 73 FR 29184, available at http://www.epa.gov/ttnnaaqs/standards/pb/s_pb_cr_fr.html

extensive external peer review by the Clean Air Scientific Advisory Committee (CASAC) as well as review by the public. For example, CASAC performed seven separate reviews as part of this NAAQS review (variously involving the AQCD, risk assessment, Staff Paper, and proposed rulemaking notices) and, in several cases, explicitly recommended this study to the Agency for consideration as part of the lead NAAQS rulemaking.[14] As a result of these internal and external reviews of this publication, including comments from the public, EPA identified and addressed three errors in the study publication, as described on pages 24-25 of the Response to Comments document. EPA believes these thorough internal and external reviews are consistent with the robustness checks recommended in the EPA IQG. Further, as noted in the Response to Comments document and described in the AQCD, separate analysis of the Lanphear *et al.* (2005) dataset was conducted by Rothenberg and Rothenberg (2005), yielding the same effects estimates for the loglinear model as those reported by Lanphear *et al.* (2005).

Although EPA did not have or review the underlying data for the Lanphear *et al.* (2005) study, the internal and external reviews described above confirm that the quality, objectivity and utility of the Lanphear *et al.* publication are appropriate for their intended use.

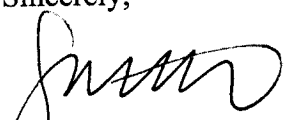
In summary, EPA believes the Agency's use of the Lanphear *et al.* (2005) study was consistent with EPA's IQG, and that the decision to defer consideration of the ABR RFC pending a ruling from the court was appropriate. The U.S. Court of Appeals for the D.C. Circuit confirmed that EPA adequately responded to petitioners' information quality concerns about the Lanphear *et al.* study. The court also confirmed that the use of the Lanphear *et al.* study was appropriate for its intended use.

If you are dissatisfied with the Agency's response to your information quality concerns, you may submit a Request for Reconsideration (RFR). EPA requests that any such RFR be submitted within 90 days of the date of EPA's response. If you choose to submit a RFR, please send a written request to the EPA Information Quality Guidelines Processing Staff via mail (Information Quality Guidelines Processing Staff, Mail Code 2811R, U.S. EPA, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460); electronic mail (quality@epa.gov); or fax [(202) 565-2441]. If you submit a RFR, please reference the request number assigned to the original Request for Correction (RFC 09001). Additional information about how to submit a RFR is listed on the EPA Information Quality Guidelines website at www.epa.gov/quality/informationguidelines.

[14] For example, see the September 27, 2007 letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee, to Administrator Stephen L. Johnson (Re: Clean Air Scientific Advisory Committee's (CASAC) Review of the 2nd Draft Lead Human Exposure and Health Risk Assessments) and the January 22, 2008 letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee, to Administrator Stephen L. Johnson (Re: Clean Air Scientific Advisory Committee's (CASAC) Review of the Advance Notice of Proposed Rulemaking (ANPR) for the NAAQS for lead).

I appreciate the opportunity to be of service and trust the information provided is helpful.

Sincerely,



Gina McCarthy
Assistant Administrator

Enclosure

cc: Malcolm D. Jackson
Acting Assistant Administrator and Chief Information Officer
Office of Environmental Information
U.S. EPA

Enclosure: EPA Responses to Statements in the Association of Battery Recyclers RFC

Below are the statements that the Association of Battery Recyclers (see ABR RFC dated October 14, 2008[15] for full description of requested changes) would like to see corrected, the comment found in the Response to Comments (RTC)[16], RTC response and where applicable the Circuit Court decision[17]. The statements below are quotations from the cited documents, with page references in parentheses at the end. As reflected in the RTC response and the quoted language from the Circuit Court decision, EPA's overall approach for the use of scientific information to support the lead NAAQS rulemaking, including its use of the Lanphear paper, is consistent with the EPA IQG.

1. **ABR RFC:** 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. (RFC, page 4-5)

   RTC Comment: One industry commenter stated that the Lanphear et al. (2005) paper contains errors and cannot be relied upon (ABR pp. 10-11). For example, comments from ABR note an error regarding which EPA published a technical memo (Jan 26, 2007), describe a potential 2nd error in Table 4 of the paper that they note they cited in March 2008 comments to EPA, which they state has not been resolved, and also describe what they claim is a potential 3rd error regarding Figure 3 of the paper. (RTC, page 24)

   RTC Response: EPA agrees with the commenter that two errors have been identified with regard to Table 4 in the Lanphear et al. (2005) publication. However, EPA notes the February 21, 2007 email from the R. Hornung, one of study authors, that is in the docket for this rulemaking, provides a corrected version of this table that addresses both of these issues. In addition, EPA identified typographical errors in two numbers associated with confidence

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[15] http://epa.gov/quality/informationguidelines/documents/09001.pdf

[16] Responses to Significant Comments on the 2008 Proposed Rule on the National Ambient Air Quality Standards for Lead, EPA. 2008 (73 RF 29184) - http://www.epa.gov/ttnnaaqs/standards/pb/data/20081015_responsetocomments.pdf

[17] *Coalition of Battery Recyclers Association v. EPA*, 604 F.3d 613 (D.C. Cir. 2010), available at http://pacer.cadc.uscourts.gov/common/opinions/201005/09-1011-1244831.pdf

intervals reported at the top of the 1st column on p. 897 of the publication, In reporting this information in the CD, EPA corrected these errors (CD, p. 6-70). Further, none of the errors identified by EPA affect aspects of the study on which EPA has relied in this review. (RTC, page 24-25)

Circuit Court Decision: Similarly unavailing is petitioners' contention that EPA did not respond adequately to comments concerning errors in the Lanphear study. EPA responded to petitioners' comments by noting that errors in Table 4 and two typographical errors in the Lanphear study had been corrected and explaining that these corrected errors did not affect the portions of the study on which EPA had relied. (*Coalition of Battery Recyclers Association v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010))

2. **ABR RFC:** 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. (RFC, page 5)

RTC Response (see RTC comment above): EPA considers the commenters statements about Figure 3 to be without sound basis. Figure 3 illustrates the log-linear model for concurrent blood Pb level and IQ, along with the mean IQ and 95% confidence intervals on the mean for 5 subgroups of the full dataset. The commenters state that the confidence intervals shown in this figure are a function of sample size and they suggest that based on their interpretation of information in the paper for the sample size of the group with peak blood Pb levels below 10 μg/dL, the <5 μg/dL concurrent blood Pb level group is much smaller than the 5-10 μg/dL concurrent blood Pb, and accordingly the confidence interval bars should be much different in size. As the commenters state, the confidence intervals are a function of sample size, which is likely to differ notably among the study groups (although the authors do not report these sample sizes), however they are not simply a direct function of sample size. The standard deviation also affects the width of the confidence interval, and may vary in the different blood Pb categories. Thus, there is no basis to conclude that the confidence intervals displayed in Figure 3 are incorrect, although EPA's conclusions drawn regarding this study did not depend upon this figure. Additionally, in considering the Lanphear et al. (2005) publication, EPA notes the analysis by Rothenberg and Rothenberg (2005) of the same dataset. In the latter publication, the authors state that the data set "was analyzed with the original model specifications, including logtransformed BPb, using multiple regression analyses" and they obtained the same effect estimates for the loglinear model as those reported by Lanphear et al. (2005). These findings add to EPA's confidence in our consideration of the Lanphear et al. (2005) publication. (RTC, page 25)

Circuit Court Decision: EPA also explained in response to petitioners' questioning of Figure 3 of the Lanphear study how petitioners had misinterpreted the statistical methods involved in the figure and that EPA's conclusions from the Lanphear study did not depend on the figure. *See id.* at 24-25. EPA further observed that its confidence in the Lanphear study had been reaffirmed by the "Rothenberg" study, which had re-analyzed the Lanphear data and confirmed the nonlinear relationship between IQ and blood lead levels shown in Figure 3 of the Lanphear study. [3] (604 F.3d at 623-624)

3. **ABR RFC:** 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. (RFC, page 5)

   RTC Comment: A few commenters (e.g., ILZRO, ABR, BCI) cautioned against relying on Lanphear et al. (2005), particularly the slope estimate from the subgroup analysis which included children whose maximal blood Pb levels were below 7.5 μg/dL. They state that the slope from this analysis, which is the high end of first set of "steeper" slopes identified in the proposal, is an "outlier". That is, the commenter stated that the linear slope for the relationship of IQ with blood Pb levels from the Lanphear et al. (2005) analysis of children whose maximal blood Pb levels did not exceed 7.5 ug/dL should not be considered in identifying an estimate for the concentration-response relationship between blood Pb and IQ. The commenter notes that the sample size for this analysis included only 103 children, with majority representation (~67%) from the Rochester cohort and minority representation from the Boston and Yugoslavia studies. (RTC, page 20)

   RTC Response: While EPA recognizes that the slope from the analysis of children with peak blood Pb levels below 7.5 ug/dL is notably higher than slopes from other analyses involving children with somewhat similar blood Pb levels, EPA disagrees with the commenters' view regarding the analysis supporting this slope (see response to previous comment). Further, in identifying a C-R slope for use with the air-related IQ loss evidence-based framework, EPA has relied on consideration of the four slopes from four different analyses from four different studies of children with blood Pb levels closest to those in the U.S. today, as described in section II.C.3.b of the preamble. The analysis from Lanphear et al. (2005) of children with peak blood Pb levels below 7.5 ug/dL is included among these four analyses. Given the general similarity of the blood Pb levels in these four analyses, EPA concludes that it is not appropriate to single one slope out, but rather has given equal weight to the full group. As described in section II.C.3.b of the preamble, the median from these

[3] *See* S.J. Rothenberg & J.C. Rothenberg, Testing the Dose-Response Specification in Epidemiology: Public Health and Policy Consequences for Lead, 113 Envtl. Health Persp. 1190 (2005).

slopes (1.75 IQ points loss per 1 μg/dL blood Pb) is used to avoid undue influence from any one study. (RTC, page 20)[18]

4. **ABR RFC:** The results of Lanphear (2005) cannot be reproduced without the underlying data. (RFC, page 6)

   EPA IQG: Original and supporting data may not be subject to the high and specific degree of transparency provided for analytic results; however, EPA should apply, to the extent practicable, relevant Agency policies and procedures to achieve reproducibility, given ethical, feasibility, and confidentiality constraints. (EPA IQG, page 21)

   RTC Comment: One commenter (ABR) stated, and another (BCI) agreed, that EPA cannot rely upon the Lanphear et al. (2005) study in promulgating the final NAAQS standard because the underlying data have not been reviewed by EPA or made publicly available. In support of this argument, ABR cites a number of cases which stand for the proposition that under the APA an agency must disclose the technical studies and data on which the proposed rule relies. (RTC, page 71)

   RTC Response: EPA notes that revisions to the NAAQS are promulgated under section 307(d) of the Act, and the APA rulemaking provisions generally do not apply to such rulemakings. See CAA section 307(d)(1). When this precise question was raised in a challenge to the 1997 PM NAAQS, the U.S. Court of Appeals for the D.C. Circuit looked to the specific language of CAA 307(d) and concluded that the "Clean Air Act imposes no … obligation [to obtain and publicize data underlying published studies on which the Agency relies]; it merely directs EPA to include in any notice of proposed rulemaking 'data, information, and documents … on which the proposed rule relies.'" *American Trucking Associations, Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002). The court found that since EPA was relying on the published studies, not the underlying data, it was unnecessary to docket the underlying data. The court explicitly endorsed EPA's view that imposing a requirement on EPA to obtain data for published studies would be impractical, unnecessary, and would make plainly relevant scientific information unavailable to EPA for use in standard-setting.

   EPA continues to believe, for the reasons stated in the notice of the final rulemaking for the PM NAAQS in 1997 (62 FR 38652, 38689), that it would unnecessarily and improperly limit EPA's scientific review to interpret the CAA as requiring that data underlying studies be included in the docket, even where (as here) EPA has never been in possession of, or reviewed, the raw data underlying a study. As was the case for the PM NAAQS reviewed in *American Trucking*, EPA has placed in the docket all data, information, and documents on which it relied in promulgating this rule. EPA placed in the docket the Lanphear et al (2005) publication, as well as documentation of correction of two errors with regard to Table 4 of that publication. These errors were identified as a result of EPA's examination of the published study in the course of the risk assessment, and were corrected

[18] EPA notes that while the litigants chose not to raise the specific question of whether the Lanphear study should be disregarded as an outlier in their challenge to the standards, they did challenge EPA's selection of which studies were most relevant and the court rejected that challenge as well. See 624 F.3d at 619-621.

by the study authors. EPA recognized at that time that the errors did not affect the results of the risk assessment (Pekar, 2007). In addition, EPA identified typographical errors in two numbers associated with confidence intervals reported at the top of the 1st column on p. 897 of the publication. In reporting this information in the CD, EPA corrected these errors (CD, p. 6-70). Further, as EPA notes in response to comment (7) in section II.A.2.c.iv above, none of the errors identified by EPA affect aspects of this study on which EPA has relied in this review. ABR has alleged in its comments that there are additional, uncorrected mathematical errors in Figure 3 of the Lanphear et al. (2005) study. As discussed elsewhere in this Response to Comments (section II.A.2.c.iv), EPA has no reason to believe that Figure 3 of this published, peer reviewed study contains the errors suggested by the commenter, and further notes that conclusions drawn regarding this study did not depend on this figure. Furthermore, even assuming the items identified by ABR are errors, EPA does not believe they would rise to the level of fraud, abuse or scientific misconduct warranting review of the raw data. EPA notes that this study was generally consistent with a large body of other evidence demonstrating associations between exposure to Pb and neurocognitive decrement in children. EPA does not consider ABR's comments to provide a basis for doubting the overall, fundamental validity of the study's conclusions. The public had adequate opportunity to comment on the strengths and weaknesses of each study, including Lanphear et al. (2005). EPA does not consider its reliance on this study, its lack of review of the underlying data, and the lack of docketing of the underlying data, to be an error, either procedural or substantive. (RTC, pages 71-72)

Circuit Court Decision: Petitioners contend the Lanphear study contained such errors that EPA acted arbitrarily and capriciously in relying on results from the study without first obtaining and making public the underlying data for the study. However, in *American Trucking*, 283 F.3d 355, 350 U.S. App. D.C. 254, this court rejected the notion that EPA had improperly failed to obtain and make public data underlying studies on which it had relied during a NAAQS rulemaking, holding that "[t]he Clean Air Act imposes no such obligation" and that "requiring agencies to obtain and publicize the data underlying all studies on which they rely would be impractical and unnecessary." *Id.* at 372 (quotation marks omitted).

Petitioners attempt to distinguish their request on the ground that in *American Trucking* the court was addressing requests for data underlying several studies, while they request only that EPA obtain and make public the data underlying the Lanphear study. This distinction finds no support in the reasoning of *American Trucking*. Rather than distinguishing between an agency's burden in obtaining data from one versus many studies, the court distinguished EPA's reliance on a study's results from its reliance on the raw data underlying such results, noting that raw data often is unavailable due to proprietary interests of a study's scientific investigators or confidentiality agreements with study participants. *See id.* Petitioners do not contend EPA possessed the underlying data but failed to include it in the rulemaking record. *Cf. Am. Radio Relay League, Inc. v. FCC, 524 F.3d 227, 237-38 (D.C. Cir. 2008).* (604 F.3d at 622-623)