

Robert N. Steinwurtzel
Direct Phone: 202.373.6030
Direct Fax: 202.373.6001
robert.steinwurtzel@bingham.com

March 18, 2009

VIA ELECTRONIC MAIL

Elizabeth Craig
Acting Assistant Administrator
Office of Air and Radiation
United States Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 6101A
Washington, DC 20460
craig.beth@epa.gov

Information Quality Guidelines Processing Staff
Mail Code 2811R
United States Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460
quality@epa.gov

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 - **Request Number 09001**

Dear Ms. Craig:

On October 14, 2008, we submitted, on behalf of the Association of Battery Recyclers (“ABR” or “Petitioner”), 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). The RFC requested that EPA provide data, an explanation of methodology, and calculations related to information being disseminated by EPA in association with EPA’s rulemaking revising the lead National Ambient Air Quality Standard (“NAAQS”) -- 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)”). On November 17, 2008, we submitted a supplement to the RFC. The supplement noted that EPA made a determination on February 14, 2008 that it was required to

Boston
Hartford
Hong Kong
London
Los Angeles
New York
Orange County
San Francisco
Santa Monica
Silicon Valley
Tokyo
Washington

Bingham McCutchen LLP
2020 K Street NW
Washington, DC
20006-1806

T 202.373.6000
F 202.373.6001
bingham.com

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Information Quality Guidelines Staff
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obtain the requested information pursuant to a Freedom of Information Act (“FOIA”) request.

On March 6, 2009, you sent a letter stating that EPA “is deferring consideration” of ABR’s RFC due to pending litigation related to the revised lead NAAQS. Notwithstanding that litigation, EPA has an ongoing obligation to comply with its Information Quality Act guidelines and has a statutory obligation to provide the requested information under FOIA. Because the pending litigation does not alleviate EPA from these obligations, EPA’s continued delay in considering and responding to ABR’s RFC is without legal justification.

I. BACKGROUND

A. EPA’s Dissemination of Lanphear (2005).

EPA initiated its review of the lead NAAQS in 2004 with a call for information. 69 Fed. Reg. 64,926 (Nov. 9, 2004). Pursuant to Section 108 of the Clean Air Act, EPA released its final air quality criteria document for lead (“AQCD”), based on the updated information, in September of 2006. 71 Fed. Reg. 57,508 (Sept. 29, 2006). The AQCD relies on Lanphear (2005), which was partly funded by a grant from EPA. *See* EPA National Center for Environmental Research, *Center for the Study of Prevalent Neurotoxicants in Children*, available at http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770 (last visited Mar. 16, 2009). EPA risk assessments and the November 2007 final Staff Paper for lead NAAQS similarly relied on Lanphear (2005). Public comments outlined major deficiencies and errors in Lanphear (2005). *See, e.g.*, ABR Comments Lead Human Exposure and Health Risk Assessments for Selected Case Studies (Draft Report), dated Aug. 29, 2007 (EPA-HQ-OAR-2006-0735-4773.1).

In August of 2007, a FOIA request was submitted to EPA seeking the underlying data used in the Lanphear (2005) study pursuant to 2 C.F.R. § 215.36 and 40 C.F.R. § 30.36. EPA initially denied this request on September 2007, and an administrative appeal was sought. On December 17, 2007, EPA issued an Advanced Notice of Proposed Rulemaking (“ANPR”) for the lead NAAQS, which again relied on Lanphear (2005). 72 Fed. Reg. 71,488 (Dec. 17, 2007). In light of EPA’s reliance on Lanphear (2005) in its ANPR, EPA reversed its earlier denial of the FOIA request and agreed, on February 14, 2008, that 40 C.F.R. § 30.36(d) applied to Lanphear (2005) and agreed to process the FOIA request. Public comments on the ANPR again outlined the problems with Lanphear (2005). *See, e.g.*, ABR Comments on ANPR, Jan. 16, 2008 (EPA-HQ-OAR-

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2006-0735-4845.1); Gradient Corp. Comments on ANPR, on behalf of ABR, Mar. 19, 2008 (EPA-HQ-OAR-2006-0735-5114).

Despite the fact that EPA agreed it had an obligation to obtain the Lanphear (2005) data and the comments raised by the public, EPA issued a proposed rule to revise the lead NAAQS, which again relied on Lanphear (2005), still without providing the underlying data to the public. 73 Fed. Reg. 29,184 (May 20, 2008). Public comments on the proposed rule (as throughout the rulemaking proceeding) outlined major deficiencies in Lanphear (2005) and noted the need for the public to review the underlying data. See ABR Comments on Proposed Rule, Aug. 4, 2008, at 2, 10-12, 16-18 (EPA-HQ-OAR-2006-0735-5717.1). See also Comments of International Lead Zinc Research Organization Inc. on Proposed Rule, Aug. 3, 2008 (EPA-HQ-OAR-2006-0735-5700.1). The final lead NAAQS rule was published at 73 Fed. Reg. 66,964 (Nov. 12, 2008). In the final rule, EPA continues to cite to and rely on Lanphear (2005) without providing the requested underlying data.

On January 12, 2009, three petitions for review were filed in the U.S. Court of Appeals for the District of Columbia, challenging various aspects of the final lead NAAQS rule.¹ See *Missouri Coalition for the Environment Foundation, et al. v. EPA*, No. 09-1009 (D.C. Cir. filed Jan. 12, 2009); *Coalition of Battery Recyclers Association v. EPA*, No. 09-1011 (D.C. Cir. filed Jan. 12, 2009); *Doe Run Resources Corp. v. EPA*, No. 09-1012 (D.C. Cir. filed Jan. 12, 2009). On February 12, 2009, EPA requested that the petitions for review be consolidated and the case be held in abeyance for six months, pending its review of an administrative petition for reconsideration submitted by Petitioners in Case No. 09-1009, *Missouri Coalition for the Environment Foundation, et al.*, on the threshold for source-oriented monitoring in the lead NAAQS rule.²

¹ The March 6, 2009 letter erroneously states that “ABR is a petitioner challenging this rule.” Although several members of ABR are participating in the lead NAAQS litigation, ABR is not a petitioner, and is not involved in the challenge to the lead NAAQS rule.

² Case Nos. 09-1011 and 09-1012 already have been consolidated. Petitioner Coalition of Battery Recyclers Association partially opposed the motion, requesting that the issues unrelated to the petition for reconsideration not be held in abeyance.

B. ABR's Request for Correction.

On October 14, 2008, ABR submitted an RFC, which outlined how EPA's dissemination of Lanphear (2005) did not comply with the guidelines issued pursuant to the Information Quality Act. In particular, EPA's dissemination of the information did not comply with the objectivity and integrity components of the guidelines. In addition, the results of Lanphear (2005) are not transparent or reproducible without the underlying data. As such, ABR recommended 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.

On November 17, 2008, ABR submitted a supplement in support of its RFC, which pointed out that EPA -- prior to issuing the proposed lead NAAQS rule -- had agreed to obtain the underlying data from Lanphear (2005) pursuant to a 2007 FOIA request. EPA's FOIA response constituted an admission that

Lanphear (2005) was used by EPA and was an important part of the lead NAAQS rulemaking. It also recognized EPA's obligation under FOIA to obtain and disclose the information. Such disclosure, if complied with, would have occurred months prior to the issuance of the proposed rule.

On January 8, 2009, EPA sent a letter, indicating it needed more time to respond to the RFC. The January 8, 2009 letter noted that the "draft response is currently undergoing an internal review" and that a response was expected within 90 days of the letter. On March 6, 2009, however, EPA sent a letter indicating it was "deferring consideration of [ABR's] request," because, noting the challenge filed to the lead NAAQS rule in the D.C. Circuit, issues raised in the request "may be related to the on-going litigation." The letter states that, "if at the conclusion of the litigation your data quality concerns have not been addressed, you may resubmit this request."

II. THE LITIGATION DOES NOT RELIEVE EPA'S OBLIGATIONS UNDER THE INFORMATION QUALITY ACT AND FOIA.

A. EPA Has an Obligation to Ensure the Information It Disseminates Meets the Information Quality Act's Goals of Objectivity and Utility.

The Information Quality Act (Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001) required the Office of Management and Budget ("OMB") to issue guidelines that "provide 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." OMB did so in 2002. 67 Fed. Reg. 8452 (Feb. 22, 2002). EPA issued its guidance also in 2002, stating 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"). Under the Information Quality Act guidance, providing the underlying data to the public is key to meet the goal of objectivity. 67 Fed. Reg. at 8459. "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. See also EPA Information Quality Guidelines, at 19-21.

To date, EPA has failed to ensure that Lanphear (2005) meets the Information Quality Act's objectives. As outlined in ABR's RFC, the failure to provide the underlying data and the requested information related to the methods used in the analysis raised numerous questions as to the accuracy and reliability of the findings EPA has disseminated. Further, the continued failure of EPA to provide the underlying data used in Lanphear (2005) fails to ensure that the information disseminated by EPA is transparent. The information sought by the request for correction is essential for reproducing the results in Lanphear (2005). EPA, therefore, has an ongoing duty to ensure that the information meets its data quality guidelines.

EPA's obligations under the Information Quality Act and its duty to address RFCs submitted by the public are separate from the challenge to the lead NAAQS rule. The Information Quality Act provides an *administrative process* to address the quality of information disseminated by EPA. The OMB's guidelines require federal agencies to "[e]stablish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the OMB or agency guidelines." EPA Information Quality Guidelines at 9. Courts also have found: "[t]he language of the IQA reflects Congress's intent that any challenges to the quality of information disseminated by federal agencies should take place in administrative proceedings before federal agencies and not in the courts."³ *Salt Institute v. Thompson*, 345 F. Supp. 2d 589, 601 (E.D. Va. 2004), *aff'd*, 440 F.3d 156 (4th Cir. 2006). Nothing prevents EPA from completing its administrative process while the challenge to the lead NAAQS rule is pending.⁴

Moreover, ABR's RFC relates to, not just the reliance of EPA on Lanphear (2005) in the final lead NAAQS rule, but to EPA's continuing dissemination of Lanphear (2005) without ensuring its objectivity and utility as required under the Information Quality Act. EPA's docket for the lead NAAQS

³ Indeed, there is a question as to whether petitioners in Court have a separate claim under the Information Quality Act. *See, e.g., Salt Institute v. Leavitt*, 440 F.3d 156 (4th Cir. 2006) (finding plaintiffs lacked standing to raise Information Quality Act challenge where Information Quality Act did not provide plaintiffs with any legal right to access information or to its correctness).

⁴ The Clean Air Act contemplates that additional administrative proceedings may be ongoing during judicial review of a challenged agency action. 42 U.S.C. § 7607(b).

rule, the AQCD, the Staff Paper, and EPA's risk assessments, as well as the proposed and final rules, all include references to and discussion of Lanphear (2005). This information continues to be posted on EPA's website.⁵ In addition, the use of Lanphear (2005) extends beyond the lead NAAQS rule,⁶ and may continue to be used in subsequent regulatory actions without correction. For example, EPA has indicated an intention to issue an ANPR regarding its review of the national emission standards for hazardous air pollutants for secondary lead smelters in 2009 under Section 112(f) of the Clean Air Act. This review will include an assessment of risks, which also may seek to rely on Lanphear (2005) or EPA's lead NAAQS AQCD similar to prior EPA risk assessments related to lead exposures. EPA's obligations under the Information Quality Act, therefore, cannot be avoided because of the pending litigation.

B. EPA Has an Obligation to Provide the Underlying Lanphear (2005) Data Under the Freedom of Information Act.

FOIA requires agencies to provide information upon request for records, subject to limited exceptions. 5 U.S.C. § 552(a)(3). Materials released by an agency upon request must also be made available to the public when the agency determines the materials "have become or are likely to become the subject of

⁵ "Information generally includes material that EPA disseminates from a web page." EPA Information Quality Guidelines, at 15.

⁶ For example, EPA relied on the Lanphear (2005) paper in assessing risks associated with lead paint, specifically referencing the lead NAAQS AQCD. *See* EPA, Draft Hazard Assessment For CASAC Consultation Meeting, Feb. 5, 2007, at 3 (Dec. 20, 2006) ("The studies most relevant to the OPPT LRRP risk assessment that are identified in the AQCD are Canfield, et al., 2003 and Lanphear et al., 2005. . . . Descriptions of these 2 studies, taken from Sections 6.2.3.1.9 and 6.2.3.1.11 of the AQCD, are presented below."), *available at* <http://www.epa.gov/lead/pubs/hazard.pdf>. *See also* EPA, An Approach for Estimating Changes in Children's IQ from Lead Dust Generated during Renovation, Repair, and Painting in Residences and Child-Occupied Facilities, Draft For CASAC Review on July 9-10, 2007 (June 8, 2007), *available at* http://www.epa.gov/lead/pubs/casac_draft_approach_july2007.pdf. EPA notes that it "no longer updates this information, but it may be useful as a reference or resource." EPA, *Renovation, Repair, and Painting Program Clean Air Scientific Advisory Committee Consultation Materials*, <http://www.epa.gov/lead/pubs/casac.htm>.

subsequent requests for substantially the same records.”⁷ *Id.* § 552(a)(2)(D). On February 14, 2008, EPA found it had a duty under its FOIA regulations to obtain and provide the underlying data for the Lanphear (2005) paper. (See Exhibit B to ABR Supplement to Request for Correction).

EPA’s regulations require that EPA obtain and provide the underlying data for Lanphear (2005). EPA regulations provide:

[I]n response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the EPA shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA.

40 C.F.R. § 30.36(d)(1). *See also* 2 C.F.R. § 215.36(d)(1). Under EPA’s regulations, “used by the Federal Government in developing an agency action that has the force and effect of law” is defined as “when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.” 40 C.F.R. § 30.36(d)(2)(iii). Because EPA relied on Lanphear (2005) in the ANPR for the lead NAAQS rule, EPA found that it had an obligation to obtain and provide the underlying data pursuant to 40 C.F.R. § 30.36. EPA continues to have an obligation to obtain the data under the pending FOIA request.

Since EPA was required to obtain the information, and has had ample opportunity to do so, it should also make the information available to the public under 5 U.S.C. § 552(a)(2)(D). Given the requests from the public for the underlying data during the lead NAAQS rulemaking, there is ample evidence that future requests for the information would be made. EPA’s obligations under FOIA are unrelated to the pending litigation challenging the lead NAAQS rule.

⁷ A complainant may request a United States District Court to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. 5 U.S.C. § 552(a)(4)(B). The court may also award attorney fees and litigation costs. *Id.* § 552(a)(4)(E).

C. ABR is Prejudiced by EPA's Undue Delay in Responding to its Request for Correction.

As outlined above, ABR has been seeking for several years to have EPA thoroughly review Lanphear (2005) and provide the public with an opportunity to review that data. Despite its obligations under the Information Quality Act, EPA continues to avoid addressing the issue. Now, EPA again seeks to delay resolution of ABR's concerns regarding the objectivity, accuracy, and transparency of Lanphear (2005).

OMB's guidelines expressly require that agencies "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." 67 Fed. Reg. at 8459 (emphasis added). Agencies are required "to specify appropriate time periods for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made." *Id.* EPA's Information Quality Act guidance provides that EPA will seek to respond to requests for correction within 90 days. EPA Information Quality Guidelines, at 35. After almost 90 days from the date of ABR's RFC, EPA requested an additional 90 days on January 8, 2009, noting only that the response was undergoing internal review.⁸ EPA, however, has now indicated that it will not respond at all to ABR's RFC.

Instead EPA states ABR can resubmit its RFC after the litigation is resolved.⁹ No where in EPA's Information Quality Guidelines does it indicate that EPA believes pending litigation is sufficient reason to delay its obligations under the Information Quality Act. EPA Information Quality Guidelines, at 31-33. Challenges to EPA regulations typically take months just to be briefed. The Court then takes several months, at least, to issue its decision, which is then subject to a petition for rehearing or a petition for a writ of certiorari from the Supreme Court. Thus, it is likely to take a year or more for the lead NAAQS litigation to come to resolution. In fact, a review of the Court's docket reveals

⁸ Given that EPA agreed in February of 2008, almost a year earlier, to obtain the requested information, it is unclear why EPA needed to delay its response.

⁹ As noted above, ABR is not a petitioner in the pending litigation challenging EPA's lead NAAQS rule.

that EPA has asked that the litigation be held in abeyance for six months pending EPA's administrative proceeding on a petition for reconsideration filed by Petitioners Missouri Coalition on the Environment Foundation, *et al.*¹⁰ This delay in addressing ABR's concerns regarding Lanphear (2005) is unwarranted, even assuming, as EPA asserts in the March 6, 2009 Letter, that "the issues raised in [ABR's] RFC *may be* related to the on-going litigation."¹¹ (Emphasis added).

More important, the information disseminated by EPA will continue to be in the public realm without correction. Lanphear (2005) was relied on by EPA as early as December 2005 in its first external draft of the AQCD,¹² and has been cited elsewhere by EPA despite known errors.¹³ Thus, EPA continues to give the

¹⁰ It cannot be assumed that the six months will be the only delay if the Court grants EPA's motion. EPA may not conclude its reconsideration proceedings within that time, and, even if it does, a briefing schedule must then be issued.

¹¹ EPA appears to be unfairly prejudicing industry. EPA has opposed Petitioner Coalition for Battery Recyclers Association request to only hold the limited issue that is the subject of reconsideration in abeyance, even though the one issue raised by the Missouri Coalition Petitioners on reconsideration before the agency is unrelated to the issues raised by the Coalition to the D.C. Circuit. Here, on the other hand, EPA has taken the opposite position, apparently finding that it cannot proceed on a separate administrative process while such litigation is pending. Moreover, even if the petitioners prevail on their challenges to the lead NAAQS rule, the Court would only remand the decision back to EPA for further consideration consistent with its decision. The Court is not likely to require EPA to obtain and post such data, and ABR would have to resubmit its RFC.

¹² Although EPA has posted corrections to a table found in the Lanphear (2005) paper with its Technical Documents for the 2008 revision to the lead NAAQS (*available at* http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_cr_td.html), it is not easily linked to the AQCD and other EPA documents that rely on the study, and the corrections do not address the additional errors in the paper and the questions raised by the corrections themselves.

¹³ Moreover, EPA provides links to the study elsewhere on its webpage. These links do not include any reference even to the correction that was made by EPA. *See* EPA National Center for Environmental Research, *Center for the Study of Prevalent Neurotoxicants in Children*, *available at* <http://cfpub.epa.gov/ncer/abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/1770> (last visited Mar. 16, 2009); EPA Children's Environmental Health Centers, *Cincinnati Children's Environmental Health*

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public misinformation, against the intention of Congress in passing the Information Quality Act.

III. EPA'S DELAYING TACTICS ARE CONTRARY TO THE
ADMINISTRATION'S RENEWED FOCUS ON TRANSPARENCY.

EPA's decision to defer its response in this case is particularly troubling given this Administration's statements regarding a renewed commitment to transparency. Among President Obama's first acts as President was to issue several memoranda to federal agency heads expressing a commitment to openness in government. *See* Presidential Memorandum for the Heads of Executive Departments and Agencies, regarding Freedom of Information Act, Jan. 21, 2009, 74 Fed. Reg. 4683 (Jan. 26, 2009); Presidential Memorandum for the Heads of Executive Departments and Agencies, regarding Transparency and Open Government, Jan. 21, 2009, 74 Fed. Reg. 4685 (Jan. 26, 2009). *See also* Presidential Memorandum for the Heads of Executive Departments and Agencies, regarding Scientific Integrity, Mar. 9, 2009, 74 Fed. Reg. 10,671 (Mar. 11, 2009). President Obama stated: "The presumption of disclosure also means that agencies should take affirmative steps to make information public. They should not wait for specific requests from the public. . . . Disclosure should be timely." 74 Fed. Reg. at 4863. As noted above, the public comments on the lead NAAQS rule made clear that the public was interested in the underlying data of the Lanphear (2005) paper. Because EPA already acknowledged its obligation to obtain the data and it has failed to do so for over one year, it should do so and make the information available to the public in an expeditious manner.

Administrator Jackson echoed this commitment to openness. In a memorandum to employees, Administrator Jackson stated: "EPA's actions must be transparent. . . . I will uphold the values of scientific integrity, rule of law and transparency every day." EPA, Mem. to EPA Employees, Jan. 23, 2009, <http://www.epa.gov/administrator/memotoemployees.html> (last visited Mar. 13, 2009). She has also stated that she "will ensure EPA's efforts to address the environmental crises of today are rooted in three fundamental values: science-based policies and programs, adherence to the rule of law, and *overwhelming*

(Footnote continued from Previous Page.)

Center Publications, http://es.epa.gov/ncer/childrenscnters/cincinnati_pubs.html (last visited Mar. 16, 2009).

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transparency.” EPA, Administrator Lisa Jackson, <http://www.epa.gov/administrator/> (last visited Mar. 16, 2009) (emphasis added). Based on EPA’s renewed commitment to transparency, EPA should respond to ABR’s RFC expeditiously consistent with its Information Quality Act Guidelines.

* * *

ABR requests that EPA provide a response to its RFC by April 8, 2009 (90 days from EPA’s January 8, 2009 letter indicating it would provide such response) consistent with its Information Quality Act guidelines. We appreciate your attention to this matter.

Sincerely yours,

/s/ Robert N. Steinwurtzel

Robert N. Steinwurtzel

cc: EPA Air and Radiation Docket, Docket ID No. EPA-HQ-OAR-2006-0735
a-and-r-Docket@epa.gov

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