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November 17, 2008

VIA ELECTRONIC MAIL

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

Re: Supplement to 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 Sir or Madam:

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 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) (hereinafter referred to as "Lanphear (2005)"). The information requested is necessary to ensure that the Lanphear (2005) paper meets the required level of quality under the Information Quality Act and under EPA's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency. This letter is intended to supplement the RFC with additional information we have received.

It has come to our attention that EPA should have requested (and obtained) the underlying data for the Lanphear (2005) paper several months prior to the issuance of its proposed rule on the lead NAAQS. In September of 2007, EPA denied a Freedom of Information Act ("FOIA") request "for data (as well as data collection forms, any necessary software programs, and data dictionaries)" for the Lanphear (2005) paper. (See Exhibit A). In denying the request, EPA indicated that it did not locate any documents responsive to the request. EPA also found that it was not required to obtain the data under 2 C.F.R. § 215.36(d)(1), which provides:

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In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that was used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency 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. . . .¹

At the time of the request, Lanphear (2005) was cited by EPA in a draft report entitled Lead Human Exposure and Health Risk Assessment for Selected Case Studies. EPA's denial was based on its claim that the "final version of this report *will not have the force and effect of law when it is issued.*" (Exhibit A) (emphasis added). EPA so found because the draft report would only "provide relevant information" to the Administrator in his review of the lead NAAQS. (*Id.*).

EPA's denial of the FOIA request was appealed, and EPA subsequently granted the appeal on February 14, 2008. (Exhibit B). EPA noted that, under its 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." (Exhibit B at 2). EPA found that, in light of the fact that EPA had issued an Advanced Notice of Proposed Rulemaking that cited Lanphear (2005) and a proposed rule was required by May 2008, the request satisfies the requirements of 40 C.F.R. § 30.36. At that time, almost three months prior to issuing the proposed rule, EPA agreed to proceed with processing the request.

This finding is relevant to ABR's RTC. It confirms that the study was "used" by EPA and was an important part of EPA's rulemaking.² It also provides further evidence that EPA's own regulations confirm the importance of providing such information to the public, and EPA's duty to do so. More important, it indicates that EPA not only would have had access to the data but could have had the data prior to May of 2008 when it published the proposed rule at issue here. Since EPA agreed to request the data in February of 2008, EPA would have had more than enough time to obtain and present the data to the public with the proposed rule. EPA also could have done so after several members of the public, including ABR, pointed out errors in the study and requested such

¹ This is a regulation issued by the Office of Management and Budget. The Exhibit erroneously references 2 C.F.R. § 215.37. EPA's version of this regulation is at 40 C.F.R. § 30.36.

² It also confirms that the data was collected through a grant by EPA, which also makes it subject to EPA's guidelines.

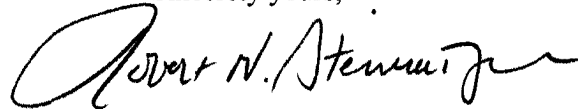
data during the public comment period. Moreover, EPA had more than sufficient time to conduct additional analysis to ensure the paper's potential errors identified by EPA and the public had properly been corrected prior to issuing the final rule. The final rule was published at 73 Fed. Reg. 66,964 (Nov. 12, 2008) and continues to cite to and rely on Lanphear (2005).

In its Response to Comments on the proposed rule, EPA continued to deny the public's requests to review the data, claiming that the Clean Air Act does not require it to obtain such data and that it saw no "fraud" warranting review of the data. (EPA-HQ-OAR-2006-0735-5984 at 71-72). EPA relied on a statement it made in an unrelated Federal Register notice dated well before the Information Quality Act was issued. EPA is required to ensure that information it disseminates meets the objectivity and utility requirements of the Information Quality Act and its guidelines. In particular, the public's comments exemplified why the transparency and reproducibility requirements could not be met without analysis of the underlying data.

Since EPA was required to obtain the data pursuant to the FOIA request, any claim that it need not obtain such data now is unfounded. For the reasons outlined in ABR's RFC, EPA should also make the data available to the public to comply with the Information Quality Act.

We appreciate your attention to this matter.

Sincerely yours,



Robert N. Steinwurtzel

Attachment

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



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

FEB 14 2008

OFFICE OF
GENERAL COUNSEL

Amy K. Pohl
Jones Day
500 Grant Street, Suite 3100
Pittsburgh, PA 15219-2502

Re: Freedom of Information Act Appeal HQ-RJN-01843-07 (HQ-APP-00009-08)

Dear Ms. Pohl:

I am responding to your October 18, 2007 Freedom of Information Act ("FOIA") appeal. You appealed the September 21, 2007 decision of Kelly Rimer for Stephen D. Page, Director, Office of Air Quality Planning and Standards, Office of Air and Radiation ("decision") of the U.S. Environmental Protection Agency ("EPA" or "Agency"), to deny the request you submitted to EPA on August 9, 2007. Your request sought the data underlying the July 2005 federally funded study, "Low Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis," reported in Environmental Health Perspectives ("Study"). The decision stated that your request was denied because (1) the Agency does not have the underlying data, and (2) because the draft report, "Lead Human Exposure and Health Risk Assessment for Selected Case Studies" ("Report"), which cites the Study, does not have the "force and effect of law" as required by 40 C.F.R. § 30.36. The decision also indicates that the Report in final form would not satisfy the "force and effect of law" requirement.

I have carefully considered your request, EPA's decision, and your appeal. For the reasons set forth below, I have determined that your appeal should be, and is granted in part and denied in part.

You assert in your appeal that EPA has not conducted a proper search for records responsive to your request. After receiving your appeal, I have confirmed that the Agency conducted a reasonable search for records responsive to your request, and am confident that the Agency does not have the requested data.

You also assert that Office of Management and Budget's ("OMB's") regulation at 2 C.F.R. § 215.36 requires the EPA to obtain a copy of the data and release the data under FOIA.¹ The Agency's regulation at 40 C.F.R. § 30.36(d)(1) states that "in response to a Freedom of Information Act (FOIA) request for research data relating to published

¹ EPA's version of the OMB regulation is found at 40 C.F.R. § 30.36.

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." "Used by the Federal Government in developing an agency action that has the force and effect of law" is defined in the regulation 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."

The original determination was correct that use of the Study in the Report does not obligate EPA to obtain the data underlying the study pursuant to 40 C.F.R. § 30.36(d)(1). However, since the time of that determination EPA has issued an Advance Notice for Proposed Rulemaking ("ANPR") for the lead National Ambient Air Quality Standards (NAAQS) revision (Federal Register publication December 12, 2007) which cited the Study in presenting and soliciting comment on evidence and risk-based considerations and regulatory options for the Administrator's review of the lead NAAQS. Furthermore, by court order, the Agency must, *inter alia*, issue its Proposed Rule for the lead NAAQS revision by May 1, 2008. In light of all of these facts and circumstances, I have determined that your request satisfies the requirement of 40 C.F.R. §30.36 and therefore, your appeal is granted on this ground.

In accordance with EPA's regulations, EPA will proceed to process your request in accordance with 40 C.F.R. § 30.36(d)(1), contact the grant recipient, and will request an estimate of fees for responding to your request. Per your original request, EPA will contact you with an estimate of fees before proceeding further.

This letter constitutes EPA's final determination on your appeal. In accordance with 5 U.S.C. § 552(a)(4)(B), you have the right to seek judicial review of this determination by instituting an action in the district court of the United States in the district in which you reside, or have your principal place of business, or in which the Agency records are situated, or in the District of Columbia.

Should you have any questions concerning this matter, please call Sara E. McGraw, at (202) 564-2565.

Sincerely,



Kevin M. Miller
Assistant General Counsel
General Law Office

cc: HQ FOI Office



EPA_Office_of_Air_Quality_P
lanning_and_Standards@epa
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To akpohl@jonesday.com

cc

bcc

Sent by:
Russell.Sherry@epamail.epa.
gov

Subject Your Freedom of Information Request - RIN-01843-07

09/21/2007 12:48 PM

Amy K. Pohl
Jones Day
500 Grant Street, Suite 3100
Pittsburgh, Pennsylvania 15219

Re: Freedom of Information Act Request RIN-01843-07

Dear Ms. Pohl:

This is in response to your Freedom of Information Act (FOIA) request of August 9, 2007, pursuant to 5 U.S.C. § 552 et seq. and 2 C.F.R. § 215.37 for data (as well as data collection forms, any necessary software programs, and data dictionaries) for the study reported in "Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis," Environmental Health Perspectives, (vol. 113, no. 7, July 2005) ("the Study").

Employees within EPA's Office of Air Quality Planning and Standards conducted a search that was reasonably calculated to uncover records in the Agency's possession and control that were responsive to your request, and have not located any documents responsive to your request.

Although Dr. Zachary Pekar did issue a correction notice regarding this study, EPA identified that error without having reviewed the data underlying the Study. Likewise, although EPA received, and made publicly available, a corrected table for the Study, EPA did not receive data underlying the study along with the correction table.

You also requested that EPA make the data available under 2 C.F.R. § 215.37. This regulation provides that, in certain circumstances, a Federal agency shall request research data from a researcher in response to a FOIA request. However, this provision only applies where published research findings produced under an award "was used by the Federal Government in developing an agency action that has the force and effect of law." 2 C.F.R. § 215.37(d)(1); see also § 215.37(d)(2)(iii) (defining "used by the Federal Government in developing an agency action that has the force and effect of law").

As of the date of your request, EPA had cited the Study in support of its draft report, released July 30, 2007, Lead Human Exposure and Health Risk Assessment for Selected Case Studies (as well as an earlier draft report on a pilot version of the lead risk assessment, released December 15, 2006). This draft report does not have the force and effect of law. Indeed, the final version of this report will not have the force and effect of law when it is issued. Rather, it will represent an effort by agency staff to provide relevant

information to the Administrator for his use in determining whether it is appropriate to retain or revise the National Ambient Air Quality Standards (NAAQS) for lead. See 42 U.S.C. § 7409 (requirements for establishing and reviewing NAAQS); §7601(a)(1) (prohibiting Administrator from delegating the authority to promulgate or revise NAAQS). Accordingly, EPA is not required to obtain data underlying the Study pursuant to 2 C.F.R. § 215.37 and has not done so.

You may appeal this response to the National Freedom of Information Officer U.S. EPA, Records, FOIA and Privacy Branch 1200 Pennsylvania Avenue, NW (2822T) Washington, DC 20460, Fax: (202) 566-2147, E-mail: hq.foia@epa.gov. The appeal must be made in writing and it must be submitted no later than 30 calendar days from the date of this letter. The Agency will not consider appeals received after the 30 calendar day limit. The appeal letter should include the RIN number listed above. For quickest possible handling, the appeal letter and its envelope should be marked "Freedom of Information Act Appeal."

Sincerely,

Kelly Rimer (for)

Stephen D. Page
Director
Office of Air Quality Planning

(Note: This mailbox does not accept reply messages.)