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November 17, 2009

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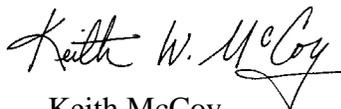
Re: Request for Reconsideration of RFC #09002 - Oxides of Nitrogen

Dear Sir or Madam:

On behalf of the National Association of Manufacturers (NAM), I am submitting the attached Request for Reconsideration (RFR) pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (the Information Quality Act or IQA),¹ and the guidelines implementing the IQA issued by the United States Office of Management and Budget (OMB)² and the United States Environmental Protection Agency (EPA).³ By way of background, the NAM is the nation's largest industrial trade association representing small, medium and large manufacturers in all 50 states.

As detailed below, the NAM appeals EPA's August 19, 2009 response to the NAM's Request for Correction related to the final Integrated Science Assessment for Oxides of Nitrogen. The NAM believes that EPA's response is facially deficient and requests that EPA address the eight specific corrections outlined in the RFC filed on June 2, 2009. If you have any questions related to the NAM's appeal, please contact me or Bryan Brendle at (202) 637-3176 or at bbrendle@nam.org. Thank you for your consideration.

Sincerely,



Keith McCoy

November 17, 2009

Via E-Mail [to quality@epa.gov]

Information Quality Guidelines Staff (Mail Code 2811R)
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Ariel Rios Building
Washington, D.C. 20460

Re: IQA Request for Reconsideration of RFC #09002; ISA -- Oxides of Nitrogen

Dear Sir or Madam:

This Request for Reconsideration (RFR) is submitted by the National Association of Manufacturers (NAM), pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (the Information Quality Act or IQA),¹ and the guidelines implementing the IQA issued by the United States Office of Management and Budget (OMB)² and the United States Environmental Protection Agency (EPA).³ NAM is the nation's largest industrial trade association representing small, medium, and large manufacturers in all 50 states.

This RFR is an appeal of EPA's August 19, 2009, response⁴ to NAM's June 2, 2009, Request for Correction (RFC) concerning the final Integrated Science Assessment for Oxides of Nitrogen.⁵ In that RFC, NAM

¹ 44 U.S.C. § 3516 (notes).

² OMB, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452 (Feb. 22, 2002), available at <http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf>.

³ EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-008 (Oct. 2002) (EPA Guidelines), available at http://www.epa.gov/QUALITY/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

⁴ Letter from Lek Kadeli, Acting Assistant Administrator, Office of Research and Development, to Mr. Keith McCoy, NAM (Aug. 19, 2009) (attached to this letter as Appendix 1).

⁵ Letter and attachment from Mr. Keith McCoy, NAM, to EPA Information Quality Guidelines Staff, Re: Request for Correction; Integrated Science Assessment -- Oxides of Nitrogen (June 2, 2009), EPA RFC #09002 (NAM RFC) (attached to this letter as Appendix 2).

requested that EPA make eight specific corrections in the Final ISA,⁶ as well as conforming corrections to the final Risk and Exposure Assessment for the Primary NO₂ National Ambient Air Quality Standard (NAAQS),⁷ and to any EPA proposals or other documents based on the specified deficient information. In its August 19, 2009, response, EPA stated that it would treat the NAM RFC as a comment on the Notice of Proposed Rulemaking for the Primary NAAQS for NO₂ that EPA issued on July 15, 2009.⁸

As explained below, this response by EPA is deficient on its face, because the administrative process for consideration of the proposed rule affords no meaningful opportunity for EPA to correct the underlying scientific errors that were the subject of the RFC. EPA is treating the inaccurate and deficient scientific information in the Final ISA and Final REA as accurate and complete for purposes of formulating an appropriate policy response, and there is no indication that either of these documents will be subject to further revision or scientific peer review as part of the rulemaking process. This is especially unfortunate because EPA is materially relying on information in these documents that was inserted by EPA staff as the documents were being prepared in final, and which were never the subject of any meaningful comment process or external scientific review. This failure by EPA to utilize properly the peer review process mandated by Congress, and to allow the public to participate fully and meaningfully in that process, is not just a clear violation of EPA's IQA guidelines. These procedural irregularities also violate the Clean Air Act (CAA) and the Federal Advisory Committee Act (FACA).

I. RATIONALE FOR EPA RESPONSE

In its response to the RFC filed by NAM, EPA declines to respond to the request based on the premise that the NAAQS criteria documents are “information supporting a proposed rule,” and that the information deficiencies identified by NAM can therefore be addressed by treating the RFC “like a comment to the rulemaking.” This response is inadequate in this instance for several reasons.

First, the NAAQS criteria documents are not just “information supporting a proposed rule.” Issuance of these documents is a separate EPA action required by the CAA. For each pollutant listed as a substance that “may be reasonably anticipated to endanger public health or welfare,”⁹ EPA is required to develop air quality criteria for that substance that “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities.”¹⁰ When these mandatory scientific criteria are inadequate to meet EPA Information Quality Guidelines, the resulting problem is greater than a question concerning the adequacy of the “information supporting a proposed rule.” When the comment opportunities that EPA has established for development and review of its air quality criteria documents are inadequate or even illusory, this is a serious procedural problem that cannot be resolved by providing comment opportunities concerning a separate administrative action. Moreover, the CAA explicitly requires that the evidence and rationale set forth in EPA air

⁶ EPA, Integrated Science Assessment for Oxides of Nitrogen -- Health Criteria, EPA/600/R-08/071 (July 2008) (Final ISA), *available at* http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=475020.

⁷ EPA, Risk and Exposure Assessment to Support the Review of the NO₂ Primary National Ambient Air Quality Standard, EPA-452/R-08-008a (Nov. 2008) (Final REA), *available at* http://www.epa.gov/ttn/naaqs/standards/nox/data/20081121_NO2_REA_final.pdf.

⁸ EPA, Proposed Rule, Primary National Ambient Air Quality Standard for Nitrogen Dioxide, 74 Fed. Reg. 34404 (July 15, 2009).

⁹ CAA § 108(a)(1), 42 U.S.C. § 7408(a)(1).

¹⁰ CAA § 108(a)(2), 42 U.S.C. § 7408(a)(2).

quality criteria documents be reviewed fully by an advisory committee composed by independent scientists,¹¹ and FACA requires that interested persons be afforded an opportunity to participate in this process.¹²

Second, the proposed rule issued by EPA is implicitly predicated on the reliability of the scientific assessments in the Final ISA and Final REA. There is no indication in the proposed rule that EPA intends as part of the rulemaking on a proposed Primary NAAQS standard for NO₂ to correct any inaccuracies or deficiencies in these documents, or otherwise to revisit the reliability of the scientific information they contain. Although the NPRM nominally states that “EPA invites general, specific, and/or technical comments on all issues involved with this proposal,”¹³ the discussion in the proposed rule makes it clear that the EPA Administrator is accepting the criteria documents as authoritative and is focusing instead on the policy choices to be made in reliance on this scientific information. Indeed, EPA stated during the inter-agency review process mandated by Executive Order 12866 that it would not be “productive” to have further discussions about the EPA evaluations of particular studies in the criteria documents.¹⁴

Third, the information errors and deficiencies that NAM has identified in its RFC cannot be corrected simply by addressing them in an EPA response to comments. The most serious problems involve a lack of transparency about EPA methods and a failure to utilize properly the scientific peer review process the CAA mandates. In the Final ISA and the proposed rule that now relies on it, EPA has made substantial and critical use of an unpublished “meta-analysis” that used methodology that has not been properly tested against the established scientific principles that apply to this type of assessment.¹⁵ Moreover, in the Final REA, EPA materially relied on a purported association between short-term NO₂ exposure and asthma from a particular study that was not properly reviewed in the Final ISA when it selected a lower bound for potential short-term NO₂ standards.¹⁶ These are serious violations of IQA principles that cannot be properly rectified by a post-hoc EPA response to comments prepared in the current rulemaking.

NAM recognizes that the process of criteria development for NO₂ and the periodic review of the NAAQS for NO₂ have both been expedited by EPA in order to conform to the terms of a consent decree entered in U.S. District Court.¹⁷ NAM further recognizes that this schedule has been a challenging one due in part to the desire of EPA staff to explore the potential basis for, and to develop a satisfactory methodology for expressing and enforcing, a new short-term Primary Standard for NO₂. Nonetheless, the time and resource constraints associated with this process cannot justify blatant disregard for EPA’s own Information Quality Guidelines.

¹¹ CAA § 109(d)(2), 42 U.S.C. § 7409(d)(2).

¹² FACA § 10(a)(3), 5 U.S.C. App. (FACA) § 10(a)(3).

¹³ 74 Fed. Reg. at 34407.

¹⁴ See E-mail from L. Wegman, EPA, to D. Mancini and M. Schwab, OMB, Docket No. EPA-HQ-OAR-2006-0922-0126 (June 17, 2009) (“I don’t think it is productive to have further discussions of the specific epi studies. I believe we’ve been clear about the scientific bases for our proposed levels as described in the revised level section of the proposal...”).

¹⁵ NAM RFC at 5-7.

¹⁶ NAM RFC at 7-8.

¹⁷ Consent Decree (Nov. 19, 2007), as amended by Stipulation to Amend Consent Decree (Dec. 4, 2008), *Center for Biological Diversity v. Johnson*, No. 05-1814 (D.D.C.).

Although NAM acknowledges that it did not submit its own comments concerning the Final ISA or the Final REA, NAM's June 2, 2009, RFC was based in substantial part on comments on the ISA and REA previously submitted by NAM association member American Petroleum Institute (API) and by various member companies of API on October 31, 2007, May 5, 2008, May 30, 2008, September 28, 2008, October 22, 2008, and December 1, 2008. Thus, if EPA intended to suggest by the statement that "NAM did not submit comments on the ISA or REA" in its August 19, 2009, response to the RFC that NAM and its members did not fully utilize the available opportunities to comment on these criteria documents, such an inference is unwarranted. If EPA had afforded timely opportunities to comment on all aspects of the Final ISA and Final REA, and if EPA had properly addressed the concerns raised by API and its members, it would not have been necessary for NAM to submit its June 2, 2009, RFC. Moreover, as explained above, NAM does not believe that the information quality problems it has identified for the Final ISA and the Final REA can be properly addressed and resolved through EPA's decision to construe the RFC as a comment in the subsequent rulemaking on revision of the NO₂ NAAQS.

II. SUBSTANTIAL USE BY EPA OF DEFICIENT SCIENTIFIC INFORMATION

A. EPA's Unpublished "Meta-Analysis"

As explained in the NAM RFC, EPA staff added to the Final ISA a table purporting to be a "meta-analysis" of a diverse group of existing studies that considered the relation between NO₂ exposure and changes in airway responsiveness in asthmatics.¹⁸ The process by which EPA prepared, adopted, and utilized this meta-analysis does not satisfy the EPA Guidelines concerning "transparency about data and methods." The meta-analysis in question was prepared by EPA staff, but it was never published, presented to CASAC, or subjected to any other type of peer review process.

EPA staff has subsequently explained that the EPA "meta-analysis" involved modification of a prior paper by Folinsbee,¹⁹ and that EPA staff "swapped out one study in the meta-analysis for another to make the methodologies of the studies more consistent."²⁰ This additional explanation merely serves to illustrate why EPA should have fully disclosed the methodology it used and subjected that methodology to proper peer review. EPA has itself acknowledged the methodological limitations and problems with the use of "meta-studies" elsewhere in the Final ISA. EPA states that the validity of such analyses can be limited by "between-study heterogeneity and obvious publication bias,"²¹ and "the heterogeneity of risk estimates seen in meta-analysis may also reflect the variation in analytical approaches across studies."²²

The choices EPA made in preparing its "meta-analysis" have never been properly scrutinized. EPA has provided no explanation or justification of the criteria it used to include or exclude particular studies. There is no indication that EPA conducted any sensitivity analysis or used any of the established tests for heterogeneity. EPA also has not explained its selection of a test for statistical significance that considers only the frequency of response, but does not consider the magnitude of response or the causal relationship to NO₂ exposure.

¹⁸ Final ISA at 3-16.

¹⁹ Folinsbee, L.J. (1992). Does nitrogen dioxide exposure increase airways responsiveness? *Toxicol. Ind. Health* 8:273-283.

²⁰ "Key EPA Official Rebuts Industry Claims of NO₂ Study Secrecy, Impact," *Inside EPA* (Aug. 7, 2009).

²¹ Final ISA at 3-23.

²² Final ISA at 3-49.

During the interagency review process mandated by Executive Order 12866, EPA received some additional comments questioning the scientific legitimacy of the EPA “meta-analysis.” The Interagency Working Comments included in the EPA docket state:

EPA partially relies on this study to support 100ppb as a health relevant threshold, yet this meta-analysis has many weaknesses in regards to establishing causality that should be mentioned. First, the strength of the association is unknown, second the dose-response relationship appears to be violated, and there is a lack of consistency with other studies at this exposure level.²³

The severe scientific deficiencies of the EPA meta-analysis are further illustrated by contrasting it with a new meta-analysis by Goodman, *et al.*,²⁴ that includes a wider range of studies and also considers how the observed effects vary based on the magnitude of exposure. This new study has been both peer reviewed and accepted for publication in a reputable scientific journal, and it concludes that “NO₂ is not associated with clinically relevant effects on AHR at exposures up to 0.6 ppm.”²⁵

Although the EPA meta-analysis was inserted into the Final ISA without prior comment or review by CASAC, the EPA Administrator has placed considerable reliance on this information as a key basis for the proposal to establish a short-term standard for NO₂ at or below 100 ppb.²⁶ Thus, it is clear that the failure of EPA to satisfy Information Quality Act requirements during the development of the criteria documents has now had a material effect on the policy choices under consideration in the rulemaking.

B. Reliance in Final REA on Study Not Critically Reviewed in Final ISA

Delfino, *et al.* (2002)²⁷ is primarily an assessment of the effects of particulate air pollution, and it was barely mentioned during preparation of the Final ISA. References to this study appear only in two tables in the Final ISA²⁸ and in one table in the accompanying comprehensive ISA Annexes.²⁹ In contrast to many other epidemiologic studies, there is no narrative discussion of this study in the Final ISA, nor is there any indication that EPA scientists did any critical analysis of the study while preparing the Final ISA.

²³ Summary of Interagency Working Comments on Draft Rule under EO 12866, Docket No. EPA-HQ-OAR-2006-0922-0127 (posted July 7, 2009) at 4.

²⁴ Goodman, J.E., Chandalia, J.K., Thakali, S., and Seeley, M. (2009), Meta-analysis of Nitrogen Dioxide Exposure and Airway Hyper-responsiveness in Asthmatics, *Crit. Rev. in Toxicology* 39(9):719-742.

²⁵ Goodman, *et al.* at 740.

²⁶ 74 Fed. Reg. at 34433-34, 34435, 34437.

²⁷ Delfino, R.J., Zeiger, R.S., Seltzer, J.M., Street, D.H., McLaren, C.E. (2002). Association of asthma symptoms with peak particulate air pollution and effect modification by anti-inflammatory medication use. *Environ. Health Perspect.* 110:A607-A617.

²⁸ Final ISA at 5-8 and 5-17.

²⁹ EPA, Integrated Science Assessment for Oxides of Nitrogen -- Health Criteria, Annexes, EPA/600/R-08/072 (July 2008) at 6-22, available at http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=475024.

Although critical review of the Delfino, *et al.* (2002) study would establish that this study does not support an association between either short-term or long-term NO₂ exposure and asthma symptoms, EPA based a very important policy determination in the Final REA on the purported existence of such an association. Based on additional ambient air exposure data obtained by EPA from the investigators in the Delfino, *et al.* (2002) study, EPA concluded that the maximum short-term NO₂ concentrations to which the subjects were exposed were relatively low (50 ppb at the 98th percentile and 53 ppb at the 99th percentile).³⁰ Based on this information and the incorrect premise that the Delfino, *et al.* (2002) study provides “evidence for associations between short-term ambient NO₂ concentrations and respiratory morbidity,” the Final REA concludes “that it is appropriate to base the lower end of the range of alternative standard levels on this study.”³¹

Just as the EPA Administrator used EPA’s poorly documented and rationalized last minute “meta-analysis” to support the need for a short-term NO₂ standard at or below 100 ppb, the EPA Administrator also has used the incorrect conclusions by EPA concerning Delfino, *et al.* (2002) in the Final REA to establish the lower end of the range for a potential short-term standard.³² Indeed, it appears that the critical quantitative parameters used by EPA to establish the range for a potential short-term standard are based primarily on EPA interpretations of scientific data that were never subjected to proper peer review.

C. Other Errors Concerning Particular Studies

Though the impact of the other errors described in the NAM RFC is not as egregious as the EPA Administrator’s reliance on the EPA “meta-analysis” and on the incorrect interpretation by EPA of Delfino, *et al.* (2002) in the Final REA, other specific errors identified by NAM in the RFC are also reflected in the EPA rationale set forth in the proposed rule. For example, conclusions in the Final ISA that are based in part on EPA’s inconsistent interpretation of the Krewski, *et al.* (2000) study³³ are referenced in the discussion of effects on mortality in the proposed rule.³⁴ Similarly, EPA’s inconsistent interpretation of Schildcrout, *et al.* (2006)³⁵ in the Final ISA is also reflected in the proposed rule.³⁶

III. CONCLUSION

NAM appreciates the opportunity to submit this appeal of EPA’s response to its June 2, 2009, RFC (RFC # 09002). EPA’s response to NAM’s RFC does not address the severe IQA problems that were

³⁰ Final REA at 53.

³¹ Final REA at 54.

³² 74 Fed. Reg at 34431, 34435, 34437.

³³ Krewski, D., Burnett, R.T., Goldberg, M.S., Hoover, K., Siemiatycki, J., Jerrett, M., Abrahamowicz, M., White, W.H. (2000). Reanalysis of the Harvard Six Cities study and the American Cancer Society study of particulate air pollution and mortality: a special report of the Institute’s Particle Epidemiology Reanalysis Project. Cambridge, MA: Health Effects Institute, available at <http://pubs.healtheffects.org/view.php?id=6>.

³⁴ 74 Fed. Reg at 34416.

³⁵ Schildcrout, J.S., Sheppard, L., Lumley, T., Slaughter, J.C., Koenig, J.Q., Shapiro, G.G. (2006). Ambient air pollution and asthma exacerbations in children: an eight-city analysis. *Am. J. Epidemiol.* 164:505-517.

³⁶ 74 Fed. Reg. at 34414.

enumerated in that document, and EPA's decision to treat the RFC as a comment concerning the subsequent proposed rule will not provide any meaningful relief. Accordingly, NAM reiterates its request that EPA take the specific actions to correct the IQA deficiencies enumerated in its RFC. If you have any questions concerning this RFR, please contact me or Bryan Brendle at (202) 637-3176.

Respectfully submitted,

Keith McCoy
Vice President, Energy and Resources Policy

Attachments