Information Quality and Credibility in Risk Assessment: Section 307(d) Rulemakings Under the Clean Air Act

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The credibility of a human health risk assessment depends, in the first instance, on what it actually says. The facts need to be accurate, the analysis needs to be rigorous, and the conclusions need to flow rationally from the underlying facts and analysis. The credibility of a risk assessment may also depend, however, on what it does not say. If the risk assessment omits certain facts that might otherwise alter the analysis or interpretation of the scientific data on which the risk assessment is based, confidence in the risk assessment can be diminished when the omitted facts are disclosed or discovered. Information quality as a principle in risk assessment helps to ensure that any information omitted from a risk assessment does not reduce confidence in the conclusions of the risk assessment. This Article examines the link between information quality and credibility with reference to a recent "residual risk" assessment completed by the U.S. Environmental Protection Agency (EPA) for the ferroalloy source category under §112(f) of the Clean Air Act (CAA).[1] This Article concludes that the most credible risk assessments are risk assessments that comply with EPA's guidelines for ensuring the quality, objectivity, utility, and integrity of information developed pursuant to the Information Quality Act (IQA).[2] The Article also concludes that EPA's failure to comply with IQA requirements should be subject to judicial review under §307(d) of the CAA.

I. Technical Background

On November 23, 2011, EPA issued a proposed rule for promulgation of national emission standards for hazardous pollutants (NESHAPs) emitted from ferroalloy production facilities.[3] In the proposal, EPA concludes that the residual risks presented by emissions from ferroalloy production facilities are unacceptable. EPA's residual risk determination is based primarily on concerns about manganese (Mn) air emissions from those facilities. As explained by EPA in the preamble to the Ferroalloy NESHAP, "chronic noncancer risks associated with manganese emissions are the primary determinant of unacceptable risks . . . ."[4] Neither estimated cancer risks, nor risks associated with other hazardous air pollutants (HAPs) emitted by the ferroalloy facilities, significantly influenced (if at all) EPA's determination. In the case of cancer risk, for example, EPA determined that "the estimated maximum individual cancer risks would, by themselves, not generally lead us to a determination that risks are unacceptable," and, to the contrary, fall in a range that "in the past EPA has weighed . . . heavily in a determination of acceptable risk."[5] Similarly, in the case of other HAP emissions, EPA determined that "while our screening for potential acute and multi-pathway impacts of concern from the 2 sources in the category did identify some potential concerns for a few HAPs, these screening results did not weigh heavily in our proposed determination that risks are unacceptable."[6]

The determination that Mn emissions present an unacceptable risk is based on application of the inhalation reference concentration (RfC) for Mn developed in 1993 as reported on EPA's Integrated Risk Information System (IRIS).[7] An RfC is a "safe" level of inhalation exposure—

1. 42 U.S.C. §§7401-7671q, ELR Stat. CAA §§101-618.
2. Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. No. 106-554; H.R. 5658).
3. *See* 76 Fed. Reg. 72508 (Nov. 23, 2011) (referring to docket EPA-HQ-OAR-2010-0895) [hereinafter Ferroalloy NESHAP].
4. *Id.* at 72530.
5. *Id.*
6. *Id.*
7. *Id.* ("Given that the chronic noncancer risks associated with manganese emissions are the primary determinant of unacceptable risks, we provide here a brief discussion of the EPA's RfC associated with the inhalation of manganese and our confidence in the principal studies supporting the de-

i.e., an "estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime."[8] EPA applies RfCs in its residual risk assessments to calculate a hazard index (HI), which is a measure of the degree to which inhalation exposures at and around industrial facilities exceed (or not) the relevant RfC.[9] The Mn RfC was set in 1993 at a level of 0.05 micrograms Mn per cubic meter of air ("µg Mn/m^3"). Applying this value in its residual risk assessment, EPA states:

> The proposed determination that risks are unacceptable for this source category is primarily based on the fact that the maximum chronic noncancer HI values (90 based on actual emissions, 200 based on allowable, both dominated by manganese emissions) are higher than 1 (an HI exposure level of 1 is generally considered to be without appreciable risk of adverse health effects).[10]

EPA's residual risk assessment provides an excellent illustration of the link between information quality and credibility in risk assessment. Because EPA is a highly competent and expert government agency, its credibility is substantial, and the residual risk assessment, *when reviewed from the perspective of the facts it presents*, does nothing to diminish its overall credibility. The content of the risk assessment appears to be comprehensive in scope, balanced in presentation, and well-reasoned and, therefore, entirely credible. But conclusions that seem entirely credible based on one set of facts may not appear as credible *based on a different set of facts*. This Article explains why, with reference to (1) EPA's obligations under the governing statutory framework for the adoption of NESHAPs, and (2) a substantial body of scientific information relating to Mn that EPA opted to ignore for unspecified reasons in its residual risk assessment.

II. The Governing Statutory Framework

The Ferroalloy NESHAP must be adopted in accordance with the rulemaking requirements of §307(d) of the CAA.[11] Among other things, CAA §307(d)(9) requires that EPA observe all procedures required by law. One such procedure is compliance with the IQA and the associated IQA guidelines EPA developed for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by EPA.[12] EPA's IQA guidelines require that, in the case of "influential" risk assessment information, EPA "ensure, to the extent practicable and consistent with Agency statutes and existing legislative regulations, the objectivity of such information disseminated by the Agency by applying" the following "quality principles":

- The substance of the information is accurate, reliable and unbiased.[13]
- The presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable.[14]

Application of EPA's quality principles requires, in turn, use of:

- [T]he best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies[15]; and
- [D]ata collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data).[16]

The Ferroalloy NESHAP is "influential" because (a) it was signed by the Administrator and therefore demands "the ongoing involvement of the Administrator's office,"[17] and (b) it is an economically significant action under Executive Order No. 12866.[18]

EPA's IQA guidelines encourage any person who believes information disseminated by EPA does not meet the IQA guideline requirements to seek "correction" of the information.[19] A person may petition EPA for an appropriate correction,[20] but such a petition is not necessary in all circumstances, as explained by the Agency's IQA guidelines:

> [W]hen EPA issues a notice of proposed rulemaking supported by studies and other information described in the proposal or included in the rulemaking docket, it disseminates this information within the meaning of the Guidelines. The public may then raise issues in comments regarding the information. If a group or an individual raises a question regarding information supporting a proposed rule, EPA generally expects to treat it procedurally

velopment of that RfC for context."). The Mn RfC can be found at http://www.epa.gov/IRIS.

8. *See* Draft Residual Risk Assessment for the Ferroalloy Source Category, *available at* http://www.regulation.gov docket EPA-HQ-OAR-0895-0046, at 12 [hereinafter Residual Risk Assessment].
9. *Id.* at 23.
10. 76 Fed. Reg. at 72530.
11. 42 U.S.C. §7607(d)(1)(C); CAA §307(d)(1)(C).
12. *See* 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) [hereinafter IQA Guidelines].
13. *Id.* at 22.
14. *Id.*
15. *Id.*
16. *Id.*
17. *Id.* at 20.
18. *Id.*; *see also* 76 Fed. Reg. at 72543.
19. IQA Guidelines, *supra* note 12, at 30.
20. *Id.*

> like a comment to the rulemaking, addressing it in the response to comments rather than through a separate response mechanism."[21]

EPA's IQA guidelines also state: "EPA believes that the thorough consideration provided by the public comment process serves the purposes of the Guidelines, provides an opportunity for correction of any information that does not comply with the Guidelines, and does not duplicate or interfere with the orderly conduct of the action."[22]

In the case of any rule adopted under CAA §307(d), EPA action cannot be arbitrary or capricious and must be in accordance with law.[23] In addition, the failure by EPA to follow a procedure required by law is grounds to invalidate the rule whenever the failure to do so is "arbitrary and capricious" and the error is sufficiently "serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made."[24]

III. The Residual Risk Assessment and EPA's IQA Guidelines

EPA's IQA guidelines impose a clear procedural and substantive obligation upon EPA to ensure the quality, objectivity, utility, and integrity of all information disseminated by EPA. This obligation requires, in turn, that EPA rely on the best available science. The IRIS Mn RfC established in 1993 and on which the Ferroalloy NESHAP is based does not meet these information quality obligations.

As EPA itself has plainly recognized, a substantial body of scientific information is available concerning inhaled Mn. On April 25, 2008, EPA released the results of a scientific "literature search" for Mn in anticipation of commencing a new review of the IRIS Mn RfC during 2008.[25] EPA's literature search identified a total of 539 scientific references, of which 201 were identified "as potential key references with the remaining 338 serving as supporting references."[26] All of those studies were published *after* EPA developed the Mn RfC. And because the literature search was completed nearly four years ago, the number of available scientific studies has no doubt grown even larger since that time.

The various technical documents that support EPA's proposed Ferroalloy NESHAP nowhere acknowledge, much less assess, the substantial body of science for Mn published subsequent to adoption of the Mn RfC in 1993. EPA's complete silence on this issue is a bit surprising, given that EPA has been urged repeatedly over the past several years to consider the many scientific developments for Mn.[27] Had EPA undertaken even the most superficial of reviews, EPA likely would have discovered at least three fundamental reasons why continued reliance on the 1993 Mn RfC is unwarranted. These reasons include: (1) the process used to derive the 1993 Mn RfC; (2) the establishment of Mn reference concentrations by other respected regulatory authorities that are different from and higher than the 1993 Mn RfC; and (3) EPA-mandated research (now complete) designed to reduce uncertainty in Mn risk assessments. Each of these reasons is addressed separately below.

IV. The Process EPA Used to Derive the 1993 Mn RfC

EPA developed the IRIS Mn RfC as part of a fuel additive waiver application under §211(f) of the CAA and released it in November 1993.[28] In contrast to EPA's current practices when developing IRIS reference values, EPA derived the Mn RfC without providing any opportunity for public comment.[29] When confronted with a claim that derivation and application of the Mn RfC in the waiver proceeding without any opportunity for public comment violated due process, EPA opted to seek public comment to allow "further dialogue" with interested parties "on issues related to the health effects of manganese" and to "determine whether it is appropriate to make any adjustments to or revisions of the RfC for inhaled manganese."[30] Accordingly, EPA initiated a 60-day period for public comment on the new Mn RfC.[31]

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21. *Id.* at 32.
22. *Id.*
23. 42 U.S.C. §7607(d)(9); CAA §307(d)(9).
24. *Id.*
25. *See* 73 Fed. Reg. 22366 (Apr. 25, 2008) (notice identifying Mn as one of "20 assessments that may start in 2008"); *see also* 72 Fed. Reg. 72715 (Dec. 21, 2007) (listing Mn on the IRIS 2008 agenda and noting, "based on the results of literature searches and as EPA resources allow, assessments will be started for those chemicals with data that may support development of one or more toxicity values").
26. Justin G. Teeguarden & Jessica D. Sanford, *Proposed Key Literature for the Toxicological Review of Manganese in Support of Summary Information on the Integrated Risk Information System (IRIS)*, Battelle (Jan. 31, 2008) (on file with author).
27. Industry has repeatedly urged EPA to initiate a new IRIS review for the Mn RfC. In January 2007, for example, the American Iron and Steel Institute, the Steel Manufacturers Association, and the Specialty Steel Industry of North America formally nominated Mn for IRIS review in response to EPA's request for such nominations. The Manganese Interest Group (MIG) made a second nomination in December 2010. In that nomination, the MIG specifically referred to the then-forthcoming Ferroalloy NESHAP as a reason to reassess the Mn RfC. The MIG has also referred specifically to the requirements of the IQA as yet another reason why the IRIS Mn RfC should be reconsidered. Finally, in April 2011, the MIG urged EPA to reassess the IRIS Mn RfC as part of President Barack Obama's initiative to improve regulations pursuant to Executive Order No. 13563.
28. *See* 58 Fed. Reg. 64761, 64763 (Dec. 9, 1993) ("During the course of the remand of Ethyl's waiver application, the EPA Office of Research and Development (ORD) was reviewing the available data concerning the health effects associated with inhalation of manganese as part of a separate process to establish a reference concentration (RfC) for inhaled manganese."). For a more detailed description of EPA's derivation of the Mn RfC, see Kevin L. Fast, *Treating Uncertainty as Risk: The Next Step in the Evolution of Environmental Regulation*, 26 ELR 10627 (Dec. 1996).
29. 58 Fed. Reg. at 64763 ("there had been no opportunity for public comment concerning the use of the new manganese inhalation RfC in assessing any risks which might be posed by granting Ethyl's application"). *Compare* Memorandum from Lisa Jackson re: New Process for Development of Integrated Risk Information System Health Assessments (May 21, 2009) (referring to a 105-day period for external peer review and public review and comment), *available at* http://www.epa.gov/iris/process.htm.
30. 58 Fed. Reg. at 64763-64.
31. *Id.* at 64765.

In 1994, EPA completed review of extensive public comment on the 1993 IRIS Mn RfC value and its derivation.[32] Based on its review, EPA identified various "leading candidate estimates for an alternative Mn RfC" ranging from 0.09 to 0.2 µg Mn/m^3.[33] EPA derived each of the "leading candidate" alternatives using various benchmark dose (BMD) statistical approaches (as opposed to the approach used in derivation of the 1993 Mn RfC). EPA ultimately opted, however, not to change the IRIS Mn RfC because, in the Agency's view at that time, "there is no significant difference between the verified RfC of 0.05 µg/m^3 and the alternative estimates of 0.09 to 0.2 µg/m^3."[34]

Whatever merit, if any, may have existed in the Agency's conclusions in 1994, EPA's preferred approach at present for derivation of IRIS reference values is use of BMD statistical analysis. In fact, EPA's residual risk assessment for the Ferroalloy NESHAP states this preference in no uncertain terms.[35] As noted, the range of "best candidate" alternative RfC values for Mn identified by EPA in 1994 are all based on use of BMD statistical approaches.

V. Mn RfCs Established by Other Regulatory Authorities

Since 1993, a range of other respected health authorities have established inhalation reference concentrations for Mn different from (and higher than) EPA's existing IRIS Mn RfC. These values include:

- The World Health Organizations (WHO) air guideline for manganese of 0.15 µg Mn/m^3 developed in 2001[36];
- California's Office of Environmental Health Hazard Assessment (OEHHA) chronic Mn reference exposure level (REL) of 0.09 µg Mn/m^3 established in 2008[37];
- Health Canada's Mn RfC range of 0.05-0.14 µg Mn/m^3 established in 2010 based on $PM_{3.5}$ (versus EPA's existing IRIS Mn RfC, which is based on PM_{5-6}) and different potential exposure metrics and health endpoints[38];
- The Ontario Ministry of Environment's 24-hour ambient air quality criterion for Mn of 0.10 µg Mn/m^3 established in 2011[39];
- The Agency for Toxic Substances Disease Registry (ATSDR) proposed minimal risk level (MRL) of 0.3 µg Mn/m^3 (to replace the ATSDR's Mn MRL value of 0.04 µg/m^3 established in 2000).[40]

Notably, each of these health authorities used EPA's preferred BMD approach for derivation of their reference values for Mn (as opposed to the approach used by EPA to derive the existing IRIS Mn RfC). That a range of reference values for Mn has been adopted (or proposed) that is higher (and in some cases significantly higher) than the existing IRIS Mn RfC established in 1993 provides direct and very credible evidence that the existing IRIS Mn RfC may not be consistent with the best available science now in existence.

VI. EPA-Mandated Mn Research and Human Physiologically Based Pharmacokinetic Models for Mn

Mn is both essential to good health at low doses and potentially toxic at high doses. Mn is a natural component of many food groups, and it has long been recognized that animals have elaborate homeostatic mechanisms that regulate how ingested Mn is handled by the body—namely, how it is absorbed, distributed, metabolized, and eliminated. The existence of these well-known homeostatic mechanisms has led regulatory authorities to conclude that the body is able to handle substantial variations in dietary Mn without adverse consequence.[41]

What was not known with precision in the past is whether these same homeostatic mechanisms regulate how the body handles inhaled Mn. This uncertainty prompted concerns that the long-term inhalation of even very low levels of Mn in ambient air might present a risk to public health because of the possibility that inhaled Mn might accumulate over time in various sensitive target tissues. Illustrating this concern, EPA stated in 1994, when it opted to retain the existing IRIS Mn RfC:

> Unlike ingested Mn, inhaled Mn is transported directly from the respiratory system to the vicinity of the brain before its first pass by the liver. Depending on the form of Mn inhaled, its conversion to other oxidation states (e.g., oxidation of Mn^{2+} to Mn^{3+} or reduction of Mn^{4+} to Mn^{3+}), and its ability to enter the brain (through a protein transport mechanism or otherwise), *it is quite possible that*

32. *See* 59 Fed. Reg. 42227, 42239-45, and 42249-50 (Aug. 17, 1994).
33. *Id.* at 42245.
34. *Id.* at 42250.
35. *See* Residual Risk Assessment, *supra* note 8, at 39 ("A POD is determined by (in order of preference): (1) a statistical estimation using the benchmark dose (BMD) approach; (2) use of the dose or concentration at which the toxic response was not significantly elevated (no observed adverse affect level—NOAEL); or (3) use of the lowest observed adverse effect level—LOAEL."); *see also* Residual Risk Report to Congress, EPA-453/R-99-001, at 52 (Mar. 1999) [hereinafter Residual Risk Report].
36. *See* http://www.euro.who.int/_data/assets/pdf_file/0003/123078/AQG2nd Ed_6_8Manganese.pdf.
37. *See* http://oehha.ca.gov/air/toxic_contaminants/rels101008.html.
38. *See* http://www.hc-sc.gc.ca/ewh-semt/pubs/air/manganese-eng.php.
39. *See* http://www.ebr.gov.on.ca/ERS-WEB-External/displaynoticecontent.do?noticeId=MTA2MTc3&statusId=MTU5MjM4.
40. *See* http://www.atsdr.cdc.gov/toxprofiles/tp151.html.
41. IRIS, Manganese CASRN 7439-96-5, *available at* http://www.epa.gov/iris ("When ingested, Mn is considered to be among the least toxic of the trace elements. In the normal adult, between 3 and 10% of dietary Mn is absorbed. Total body stores normally are controlled by a complex homeostatic mechanism regulating absorption and excretion.").

> *a significant fraction of even small amounts of inhaled Mn would be able to reach target sites in the [central nervous system]*. Thus, the apparently greater toxicity of inhaled versus ingested Mn may reflect important pharmacokinetic differences of Mn that enters the body by different routes. *A more definitive understanding of these issues will require more empirical information*.[42]

Since EPA made the statement quoted above, a substantial body of new information has been developed to provide the "more definitive understanding" sought by EPA concerning the pharmacokinetics of inhaled Mn. Pursuant to its authority under §211(a) of the CAA,[43] EPA required a series of studies it deemed necessary to address various uncertainties EPA had identified when assessing the risks of using an Mn-based fuel additive in gasoline. As EPA explained at the time, "[t]o more accurately define an RfC for manganese . . . additional research will have to be conducted."[44] These studies, conducted under close EPA supervision, provide a wealth of new data that have been used to develop human physiologically based pharmacokinetic (PBPK) models for inhaled Mn.

PBPK models consist of a series of mathematical representations of biological tissues and physiological processes in the body that simulates the absorption, distribution, metabolism, and excretion of chemicals that enter the body. PBPK models are designed to estimate an internal dose to target tissues that results from a particular level of exposure, i.e., an administered dose. The choice of an internal dose metric (sometimes called the biologically effective dose) replaces the administered dose in the derivation of the quantitative dose-response relationship, with the intent of reducing the uncertainty inherent in risk assessments based on an applied dose, i.e., exposure level. This reduction in uncertainty and the improved scientific basis for the dose-response value are the main advantages of PBPK models. PBPK models also can simulate an internal dose from exposure conditions of interest where no data are available, i.e., they can extrapolate to conditions beyond those of the data set used to develop the model.[45]

The human PBPK models for Mn, which have been validated using measured radioactive tracer data derived from direct human testing, are described in the following two peer-reviewed scientific papers:

- Jeffry Schroeter et al., *Analysis of Manganese Tracer Kinetics and Target Tissue Dosimetry in Monkeys and Humans With Multi-Route Physiologically Based Pharmacokinetic Models*, 120(2) Toxicological Sci. 481-98 (2011).
- Miyoung Yoon et al., *Physiologically Based Pharmacokinetic Modeling of Fetal and Neonatal Manganese Exposure in Humans: Describing Manganese Homeostatis During Development*, 122(2) Toxicological Sci. 297-316 (2011).

These validated human PBPK models provide an important new empirical tool for reevaluating the biological plausibility of the 1,000-fold uncertainty factor used by EPA to derive the 1993 Mn RfC.[46] The human PBPK models demonstrate that Mn accumulation in target tissues (and the potential for toxicity that such accumulation *might begin* to entail) does not occur when the level of Mn in air is low. This is the case even for those brain tissues thought to be most sensitive, as well as for those groups in the population thought to be potentially sensitive (such as neonates), and without regard to the form of Mn that is inhaled. Accumulation in target tissues begins to occur only when animals are exposed to levels of Mn above an identifiable dose-dependent transition point.

The identification of dose-dependent transition points for the accumulation of inhaled Mn in brain and other body tissue provides a new scientific basis for rethinking application of traditional uncertainty factors when developing limit values for airborne Mn. Once uncertainty factors are applied to produce an air standard below the dose-dependent transition point, the application of additional uncertainty factors is not necessary and does not produce any additional "safety" against potential adverse effects.[47]

The human Mn PBPK models are already being accepted and applied by the scientific community. In June 2011, for example, the Ontario Ministry of Environment (MOE) acknowledged, "these models have provided a better understanding of the kinetic processes that control tissue Mn levels over a wide range of exposure concentrations through both inhalation and oral exposure."[48] Although the Ontario MOE did not have direct access to the validated human Mn PBPK models, the Ontario MOE opted to apply the "results" of PBPK modeling reported to it in public comments "as a means of providing weight-of-evidence for the newly derived Ontario air standard."[49] Applying this weight-of-evidence approach, the Ontario MOE concluded:

42. 59 Fed. Reg. at 42240 (emphasis added).
43. 42 U.S.C. §7545(a).
44. 59 Fed. Reg. at 42255.
45. *See generally* Approaches for the Application of Physiologically Based Pharmacokinetic (PBPK) Models and Supporting Data in Risk Assessment, EPA/600/R-05/043F (2006).
46. "Biological plausibility" is one of several key concepts that govern the assessment of scientific data in the RfC development process. As explained by EPA, "[t]he culmination of the hazard identification phase of any risk assessment involves integrating a diverse data collection into a cohesive, *biologically plausible* toxicity 'picture'; that is, to develop the weight of evidence that the chemical poses a hazard to humans" at some particular level of exposure. *See* Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry, EPA/600/8-90/066F, at 2-44 (Oct. 1994) (emphasis added) [hereinafter RfC Guidance]. This means, according to EPA, that there must be a "[b]iologically plausible relationship between metabolism data, the postulated mechanism of action, and the effect of concern." *Id.*
47. William Slikker Jr. et al., *Dose-Dependent Transitions in Mechanisms of Toxicity*, Toxicology & Applied Pharmacology 203-25 (2004); William Slikker Jr. et al., *Dose-Dependent Transitions in Mechanisms of Toxicity: Case Studies* Toxicology & Applied Pharmacology 226-94 (2004).
48. *See* Ontario Air Standards for Manganese and Manganese Compounds, Ontario Ministry of the Environment 93 (June 2011).
49. *Id.* at 95.

> Modeled data suggest that Mn begins to accumulate within the globus pallidus at approximately 10 μg/m^3. Adjustment from simulated to continuous human exposure and the application of uncertainty factors that the Ministry would still consider necessary in order to protect the entire population, including inter-individual variability, vulnerability of the developing nervous system, extrapolation from subchronic to chronic exposure (models are based on parameters derived from subchronic 13-week inhalation exposures) would lead to the derivation of a value consistent with one that has been derived from the epidemiological dataset.[50]

Recall that the Ontario MOE adopted an Mn ambient air standard (0.1 μg/m^3) two times greater than the existing IRIS Mn RfC.

Notably, the human Mn PBPK models are also cited by researchers for the purpose of interpreting the results of an EPA-sponsored study conducted in Marietta, Ohio, where one of the two facilities in the ferroalloy source category is located. The purpose of the study was to determine if ambient Mn levels in Marietta, Ohio, are adversely impacting public health. In one peer-reviewed paper for the study, the researchers state:

> A recent study in Mn-exposed welders showed that current exposure to Mn-containing welding fumes (Mn-air: GM, 27.7 μg/m^3; range 1.3-729 μg/m^3) did not change the plasma-Mn concentration when Mn-air remained below 10 μg/m^3 (Hoet et al. 2011). Recently developed pharmacokinetic models in non-human primates and humans indicate that inhalation exposure to respirable $MnSO_4$ particulate at levels below 10 μg/m^3 is not expected to lead to Mn^{2+} accumulation in the globus pallidus (Anderson et al., 2010; Schroeter et al., 2011). Since increased concentrations of plasma-Mn are not expected for Mn-air exposure below 10 μg/m^3, the likelihood of Mn accumulation in the brain and the biological[ ] plausibility of subsequent neurological disruption does not seem very high. Associations between Mn-air and adverse CNS effects are thus unlikely to occur in Marietta participants, as there is no reason to believe that their chronic Mn exposure conditions would entail increased plasma Mn levels.[51]

In a second peer-reviewed paper describing different results from the EPA-sponsored research, the researchers state:

> Recent PBPK-model results (Anderson et al., 2010; Schroeter et al., 2011) and a toxicokinetic study in welders (Hoet et al., 2011) indicate that homeostatic processes are likely to cope well with exposure to respirable Mn in concentrations below 10-20 μg/m^3. Furthermore, the PBPK model did not show any increase in accumulation of Mn in brain regions (basal ganglia) with high affinity for Mn when chronic exposures to respirable Mn particulate remain below 10 μg/m^3. The similarity in MnB between the Marietta and Mount Vernon participants suggests that Mn-Air in Marietta has been too low in recent years to overwhelm the homeostatic regulatory mechanisms of Mn which would result in increased Mn accumulation in the brain. In line with this is the lack of clear-cut differences in neurotoxic effects between Mn-exposed and comparison participants in the current study and the lack of significant associations in the exposed group between neurological endpoints (UPDRS, motor efficiency) and indices of Mn exposure (CEI, MnB).[52]

If natural homeostatic mechanisms can handle exposure to respirable Mn up to 10 to 20 μg Mn/m^3, those same homeostatic mechanisms ought to be readily able to handle exposure at or near the existing IRIS Mn RfC value of 0.05 μg Mn/m^3.

Finally, the scientific importance of the human Mn PBPK models was also recently highlighted as part of the Toxicology Excellence for Risk Assessment (TERA)/International Toxicity Estimates for Risk (ITER) peer review process. The purpose of the ITER database is to provide risk assessors and managers with the latest human health risk values from organizations around the world. ITER includes chronic human health risk data from ATSDR, Health Canada, the International Agency for Research on Cancer, the National Institute of Public Health and the Environment (RIVM)—The Netherlands, U.S. EPA, and independent parties whose risk values have undergone peer review. Because the peer-reviewed literature contains many more risk values that may be of value to risk practitioners, TERA developed a process to include these peer-reviewed, "literature-based" values on the ITER database. In order to be considered for inclusion in ITER, literature-based values must meet the following criteria:

- A manuscript that includes derivation of a risk assessment value has been published in a peer-reviewed journal;
- The assessment follows an identified, commonly used methodology . . . ; and
- The manuscript's acknowledgment clearly states the source of funding for the work, or the authors provide this source of funding at the review meeting for full disclosure to the panel on ITER.

The Article reviewed in the TERA/ITER peer review process was Lisa A. Bailey et al., *Proposal for a Revised Reference Concentration (RfC) for Manganese Based on Recent Epidemiological Studies*," 55 Reg. Toxicology & Pharmacology 330-39 (2009). That Article proposes a Mn RfC in the range 2-7 μg Mn/m^3. Following the standard TERA/ITER peer review process, the proposed RfC range was

50. *Id.*
51. Yangho Kim et al., *Motor Function in Adults of an Ohio Community With Environmental Manganese Exposure*, 32 Neurotoxicology 606, 611 (2011). Interestingly, EPA refers specifically to this study in the Ferroalloy NESHAP. *See* 76 Fed. Reg. at 72515, n.7.
52. Rosemarie M. Bowler et al., *Anxiety Affecting Parkinsonian Outcome and Motor Efficiency in Adults of an Ohio Community With Environmental Airborne Manganese Exposure*, 215 Int'l J. Hygiene & Envtl. Health 393-405 (Apr. 2012).

added to the ITER database. As reflected in the TERA/ITER meeting report, moreover, the reviewers relied upon the human Mn PBPK models for much of the technical justification for the proposed Mn RfC range.[53] As the peer reviewers ultimately noted, "[t]his proposed range of values is fairly different from values already loaded on ITER, but it uses the most recent epidemiology studies and PBPK models" and therefore "is likely to be valuable to the risk assessment community as well."[54]

VII. Discussion

As the foregoing material makes abundantly clear, even a cursory review of the science for Mn developed since 1993 provides ample evidence to support the view that a comprehensive assessment of the best available science for Mn could (and likely would) result in a different (and likely higher) Mn RfC. EPA's own scientific analyses (now apparently forgotten) support such an inference, as do more contemporary scientific analyses completed by other respected regulatory authorities and independent scientific bodies.

More than 200 years ago, John Adams said, "[f]acts are stubborn things, and whatever may be our wishes, our inclinations, or the dictates of our passions, they cannot alter the state of facts or evidence."[55] Ultimately, information quality is about facts—namely, identifying and marshalling the best available facts to ensure dissemination of information that is both accurate and credible.[56] Credibility, on the other hand, is about the power of facts. Omitting immaterial facts has little impact on credibility because immaterial facts have little in the way of power. Omitting material facts, on the other hand, can devastate credibility because the power of a material fact can be substantial. For human health risk assessment, the essential part (which is also the part requiring careful judgment) is deciding which facts are material and which facts are immaterial.

EPA's failure to identify and marshal the best available science for the Ferroalloy NESHAP consistent with the requirements of its IQA guidelines directly undercuts the credibility of the residual risk assessment on which it is based. Even a modest change to the IRIS Mn RfC could substantially alter EPA's residual risk assessment for the ferroalloy industry. As reported in the residual risk assessment, 27,990 people have a hazard index greater than 1.0, but less than 10. This means, in turn, that exposures for this group of individuals fall in the range of 0.05 to 0.5 µg Mn/m^3.[57] Only 10 individuals have an HI at 10 or higher (meaning exposures are greater than 0.5 µg Mn/m^3) and the maximum HI is 90 (meaning that the highest modeled exposure is 4.5 µg Mn/m^3).[58]

Although neither EPA's residual risk assessment nor docket EPA-HQ-OAR-2010-0895 at the www.regulations.gov website include the modeling data on which EPA's exposure analysis depends, the residual risk assessment reports mean monitored Mn exposure data in Table 3.2-3 for three elementary schools located close to the Eramet plant in Marietta, Ohio, i.e., between 0.5 to 2.5 kilometers from the plant. As EPA notes, all three locations have mean-measured Mn levels greater than 0.05 µg Mn/m^3.[59] However, only two of the schools have mean-measured Mn levels in excess of 0.09 µg Mn/m^3 (the low end of EPA's "leading candidate" alternative RfCs), and none of the schools have mean-measured Mn levels in excess of 0.2 µg Mn/m^3 (the high end of EPA's leading candidate alternative RfCs). It necessarily follows, of course, that none of the locations (and, indeed, no individual within 50 kilometers of the plant) would be exposed in excess of 5 µg Mn/m^3 if that value were chosen as the Mn RfC (as the ITER database suggests might be possible). Moreover, assuming, as seems reasonable, that a comparison of EPA's modeled Mn exposures to different RfC levels would show a similar result, the number of individuals potentially at risk would change substantially depending on the level of the Mn RfC applied in the analysis.

Nor is the Agency in a position to argue, as it did in 1994, that no significant difference exists between the IRIS Mn RfC it used in its residual risk assessment and the "leading candidate" alternatives identified in 1994. To the contrary, the alternatives differ by up to a factor of four, and as noted, are all based on EPA's currently preferred BMD statistical approach for developing such values. The various hazard indices that EPA has identified in its residual risk assessment would necessarily change as the concentration in air deemed to be without appreciable risk changes. To suggest otherwise would be nonsensical.

Had EPA adhered to its IQA guidelines for its residual risk assessment in the Ferroalloy NESHAP, none of these issues would have arisen because EPA would have evaluated the best available science *before making any conclusions* about the residual risks associated with ferroalloy production. Although the merits (or lack thereof) of the IQA have been the subject of considerable debate,[60] the IQA and the

53. *See* Report of the ITER Review Meeting on Literature Risk Values for Manganese Oxide 13-18 (June 29, 2011) [hereinafter ITER Review Meeting Report).
54. *Id.* at 18.
55. John Adams, Argument in Defense of the [British] Soldiers in the Boston Massacre Trials (1770), *reprinted in* John Bartlett, Familiar Quotations 337 (16th ed. 1992).
56. IQA Guidelines, *supra* note 12, at 13 ("it is our responsibility to ensure that the information is accurate and credible").
57. 76 Fed. Reg. at 72530.
58. *Id.*
59. Residual Risk Assessment, *supra* note 8, at 31. The measured manganese data are in the PM_{10} size fraction. *See* http://www.epa.gov/schoolair/pdfs/MariettaTechReport.pdf. EPA does not explain why it is appropriate to compare PM_{10} values directly against the Mn RfC, which is in the PM_{5-6} size fraction. The portion of the PM_{10} measurements that fall in a PM_{5-6} size fraction would likely be less than the values shown in Table 3.2-3.
60. *See, e.g.*, Sidney A. Shapiro et al., *Ossifying Ossification: Why the Information Quality Act Should Not Provide for Judicial Review*, Center for Progressive Reform (Feb. 2006); Kellen Ressemeyer, *The Information Quality Act: The Little Statute That Could (Or Couldn't) Applying the Safe Drinking Water Act Amendments of 1996 to the Federal Communication Commission*, 59:1 Fed. Comm. L.J. (Dec. 2006): Sidney A. Shapiro, *The Information Quality Act and Environmental Protection: The Perils of Reform by Appropriations Rider*, 28 Wm. & Mary Envtl.L. & Pol'y Rev. 339 (2004); Charles N. Herrick, *Objectivity Versus Narrative Coherence: Science, Environmental Policy, and the U.S. Data Quality Act*, 7 Envtl. Sci. & Pol'y 419-33 (2004); Wendy E.

IQA guidelines EPA developed to implement its directives impose, for good or bad, clear procedural requirements that tee up quite nicely potential judicial review of application of the IQA in §307(d) rulemakings under the CAA. At present, no court has yet sanctioned judicial review of IQA "correction" claims.[61] But no court has yet addressed application of an IQA-related claim in a §307(d) rulemaking under the CAA.

Unlike IQA-related legal challenges that have been asserted pursuant to the judicial review provisions of the Administrative Procedures Act, §307(d) of the CAA specifically requires EPA to adhere to all "procedure required by law" when conducting rulemaking under that provision and reserves to the exclusive jurisdiction of the U.S. courts of appeal all challenges to "procedural determinations made by the Administrator under this subsection."[62] And despite the fact that the bar has been set fairly high for achieving successful outcomes in any such procedural challenges,[63] the fact remains that a bar exists against which to measure EPA's IQA-related actions. Absent a decision by EPA, either to defer the Ferroalloy NESHAP pending a review of all available science for Mn or to correct the information that it has disseminated in that rulemaking, a clear opportunity exists to establish an important new precedent concerning the role of the IQA in CAA §307(d) rulemakings.[64]

VIII. Conclusion

Ensuring the quality, objectivity, utility, and integrity of information disseminated by EPA is a laudable goal. EPA's IQA guidelines provide a very effective means for achieving that goal, but only if EPA adheres in all cases to the guidelines' directives. As explained in this Article, EPA's actions with respect to the Ferroalloy NESHAP fall far short of adherence with the Agency's IQA guidelines and, as a result, the scientific foundation on which EPA's proposal is based is highly suspect and lacks credibility. The Ferroalloy NESHAP very effectively illustrates the link between information quality and credibility and potentially sets the stage for further judicial consideration of the role of the IQA in EPA rulemaking.

One final observation is warranted. EPA has identified "environmental justice" as one of its top "priorities."[65] Among the Agency's objectives for environmental justice is to ensure that "everyone enjoys the same degree of protection from environmental and health hazards."[66] In order to achieve this objective, EPA has acknowledged the necessity of bringing "the best science to decision-making around environmental justice issues."[67] EPA also has recognized that it must use "the best available science" to "ensure that all parts of society have access to accurate information sufficient to effectively participate in managing human health and environmental risks."[68]

EPA's failure to assess the substantial body of science concerning Mn amassed since 1993 as part of the Ferroalloy NESHAP is not consistent with the Agency's environmental justice objectives. In fact, EPA's failure to assess the best available science may directly undercut those objectives. Research sponsored by EPA clearly demonstrates that residents who live near the Eramet plant in Marietta, Ohio, are anxious that emissions from the plant present risks to human health.[69] Those anxieties are based, at least in part, on EPA's outdated IRIS Mn RfC and the fact that ambient manganese concentrations exceed the IRIS Mn RfC near various schools and other locations in and around Marietta, Ohio.[70] Continued reliance on the outdated IRIS Mn RfC reinforces those anxieties, even though the latest science ultimately may confirm that such anxieties are completely baseless. EPA does not serve its environmental justice objectives by unnecessarily (and inappropriately) disseminating to the local population outdated information that may be inaccurate. To the contrary, reinforcing anxieties that ultimately may be baseless promotes a form of environmental injustice. For this reason as well, scrupulous adherence to the Agency's IQA guidelines provides a very effective tool for promoting EPA's environmental justice objectives.

Wagner, *The "Bad Science" Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, 66 L. & Contemp. Probs. 63 (2003); James W. Conrad, *The Information Quality Act—Antiregulatory Costs of Mythic Proportions?*, 12 Kan. J.L. & Pub. Pol'y 521 (2003).

61. *See, e.g.*, Prime Time International Co. v. Vilsack, 599 F.3d 678 (D.C. Cir. 2010) (IQA Guidelines do not apply to information disseminated in an adjudication); Americans for Safe Access v. Department of Health & Human Services, No. 07-17388 (9th Cir. 2010) (unpublished opinion) (response to IQA correction petition is not final agency action); Salt Institute v. Leavitt, 440 F.3d 156 (4th Cir. 2006) ("By its terms, this statute creates no legal rights in third parties."); Family Farm Alliance v. Salazar, 749 F. Supp. 2d 1083 (2010) (IQA correction claims dismissed in action arising under the Administrative Procedure Act).
62. 42 U.S.C. §7607(d)(8).
63. To succeed in any procedural challenge, a petitioner must be able to demonstrate that: (1) the failure to adhere to a procedure required by law is arbitrary and capricious; (2) an objection to the procedural determination was made during the period for public comment on the proposed rule; and (3) the procedural error was so serious and of such central relevance that there is a substantial likelihood that the rule would have been significantly changed had the error not been made. *See id.* §7606(d)(9)(D).
64. On May 7, 2012, EPA published a *Federal Register* notice listing manganese as one of several substances that will undergo "priority" review under EPA's IRIS program. According to the notice, the review will commence in fiscal year 2013. *See* 77 Fed. Reg. 26751 (May 7, 2012). Although EPA does not identify the reasons why it chose manganese, one possible (and probably likely) reason is strong opposition to the Ferroalloy NESHAP by the targeted sources in that source category. *See generally* http://www.regulation.gov (docket EPA-HQ-OAR-0895-0046).
65. U.S. EPA, Plan EJ 2014 (Sept. 2011), *available at* http://www.epa.gov/environmentaljustice/.
66. *Id.*
67. *Id.* at 21.
68. *Id.* at 2.
69. *See* Bowler et al., *supra* note 52. ("At this stage it is not yet possible to discern whether increased generalized anxiety in Marietta residents . . . is related to the perception that the overall air pollution at Marietta might represent a health hazard.").
70. *See* U.S. EPA, SAT Initiative: The Ohio Valley Education Center (Marietta, Ohio), Warren Elementary School (Marietta, Ohio), and Neale Elementary School (Vienna, West Va.) (Oct. 26, 2010), *available at* http://www.epa.gov/schoolair/pdfs/MariettaTechReport.pdf.