



August 1, 2011

Via E-Mail

Information Quality Guidelines Staff
Mail Code 2811R
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Request for Correction -- Draft IRIS Assessment for Halogenated
Platinum Salts

Dear Sir or Madam:

This request for the correction of information (Request for Correction) is submitted under the Information Quality Act (IQA)¹ and the implementing guidelines (Guidelines) issued, respectively, by the Office of Management and Budget (OMB)² and the U.S. Environmental Protection Agency (EPA),³ on behalf of the International Platinum Group Metals Association (IPA). As discussed below, the IPA seeks the correction of information disseminated in a draft EPA document, the “Toxicological Review of Halogenated Platinum Salts and Platinum Compounds: In

¹ Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, P.L. 106-554; 44 U.S.C. § 3516 (notes).

² 67 Fed. Reg. 8452 (Feb. 22, 2002).

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).

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Support of Summary Information on the Integrated Risk Information System (IRIS)” (draft IRIS Report).⁴

Information for Correction

On February 5, 2009, EPA announced in the *Federal Register* that the draft IRIS Report was available for public review. The draft IRIS Report proposes a revised reference concentration (RfC) of 1 pg/m³ for halogenated platinum salts (1 trillionth of a gram/m³), some 8,000 times below any RfC previously established under the IRIS program. This concentration also is 2 million times below the current U.S. and European Union (EU) occupational exposure level (OEL) of 2 µg/m³ time weighted average (TWA). This dramatically reduced limit is based exclusively on a single study that has been rejected as a basis for setting a threshold for occupational exposures to emissions from halogenated platinum salts by its lead author and by the relevant EU committee. Accordingly, the IPA believes that EPA’s exclusive reliance on the single and inappropriate study, as well as the proposed RfC derived based on that study, constitutes erroneous information, the dissemination of which -- even in “external review draft” form -- contravenes the IQA.⁵

⁴ EPA, Toxicological Review of Halogenated Platinum Salts and Platinum Compounds: In Support of Summary Information on the Integrated Risk Information System (IRIS), EPA/635/R-08/018 (Jan. 27, 2009). The title page of the document denotes it as an “External Review Draft,” with the information it contains “distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines” and as such, “not . . . formally disseminated by EPA.” Notwithstanding this standard disclaimer, we believe -- as noted elsewhere in this Request for Correction -- that a failure to correct promptly the errors it contains will significantly compromise the content and conclusions in the eventual final report.

⁵ It should be noted that EPA opted belatedly to include halogenated platinum salts to a risk assessment that, according to all of its public statements and notices over the previous few years, was to have focused only on elemental platinum. Halogenated platinum salts present an entirely different exposure scenario. Releases of elemental platinum to the ambient air may be associated with fuel-borne emissions from automotive catalytic converters due to the use of platinum as a fuel additive. There are no data that indicate that such automotive exhaust catalyst emissions pose any risk of ambient exposures to halogenated platinum salts (Footnote continued on the next page . . .)

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In the draft IRIS Report, EPA acknowledges that its derivation of the 1 pg/m³ RfC for halogenated platinum salts is based solely on data collected by Dr. Rolf Merget as part of an epidemiologic study of 275 workers involved in manufacturing automotive catalysts in Germany in 1989-1994.⁶ Reliance upon a single study is a significant scientific deficiency in itself, according to the World Health Organization (WHO): “It is generally recommended that risk assessors not look at only a single test result, although that study might be fully valid.”⁷ Furthermore, in this case, the single study relied upon by EPA is not at all fully valid for the purpose to which EPA put it. Although the medical observations that Dr. Merget made as part of this study were extensive and robust, there was only very limited area sampling of ambient concentrations, and still less personal exposure monitoring, which was conducted for only five of those 275 workers, during a single week in 1993. The very limited sampling data, although known to EPA, was not provided to external peer reviewers. Because of data deficiencies, Dr. Merget himself stated, in his published report of the study, that “a valid cut-off value for occupational hygiene cannot be defined by this study.”⁸ Dr.

or compounds. Exposures to halogenated platinum salts and compound, by contrast, are confined to the workplace, where these salts and compounds are used in the manufacture of emission control equipment for the automobile industry. These occupational exposures are well-controlled. This clear distinction between emissions, and emissions control, scenarios for halogenated platinum salts and compounds, on the one hand, and for elemental platinum on the other is not reflected in the draft IRIS Report, however. Nonetheless, EPA inexplicably expanded the draft IRIS Report to encompass halogenated platinum salts, purportedly because ambient exposures have not been sufficiently characterized to rule out their possible presence. This error underscores the necessity of taking prompt action in response to this Request for Correction.

⁶ Merget, R; Kulzer, R; Dierkes-Globisch, A; *et al.* (2000). Exposure-effect relationship of platinum salt allergy in a catalyst production plant: conclusions from a 5-year prospective cohort study. *J. Allergy Clin. Immunol.* 105: 364-370.

⁷ WHO, ILO and UNEP Harmonization Project -- Draft 2011 -- Guidance for Immunotoxicity Risk Assessment for Chemicals, Section 6.3.3. This draft document is marked “DRAFT FOR PUBLIC REVIEW: DO NOT CITE OR QUOTE” and is cited here for the very limited purpose of supporting this Request for Correction.

⁸ Merget *et al.* (2000), *supra* note 6.



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Merget repeated this warning in another contemporaneous publication: “Available information does not permit the definition of an exposure limit for Pt salts”⁹ and more recently confirmed this conclusion, stating once again that, in the context of sensitization induction, “no valid threshold of airborne platinum can be derived from the available data.”¹⁰ These three statements -- two in published scientific literature -- by the author of the single study relied upon by EPA must undermine the reliability and credibility of the EPA conclusion.

The EU’s Scientific Committee on Occupational Exposure Limits (SCOEL), consistent with Dr. Merget’s own position, stated in the minutes of its June 2010 meeting that it would not rely on the Merget data for standard-setting purposes, but instead would await data relevant to occupational exposures to platinum salts. According to the SCOEL minutes:

The limitations of the Merget study used by DECOS in recommending 5 ng/m³ as TWA to chloroplatinates were pointed out. It is already recognised by the authors of this good health surveillance study, that its design was not intended to supply a NOAEL.

.....

It was interpreted that the study by Merget *et al.* does not allow using the value of 5 ng/m³ to prevent from sensitisation; old (higher) exposures could have contributed to the sensitisation cases. Therefore, it was concluded that research is needed on the sensitising potency of platinum salts and SCOEL would need to see the results of the study announced to progress in this file.

⁹ Merget, R (2000). Occupational platinum salt allergy. Diagnosis, prognosis, prevention and therapy. In: Zereini, F; Alt, F; eds. Anthropogenic platinum-group element emissions: their impact on man and environment. New York, NY: Springer Verlag, pp. 257-265.

¹⁰ Merget letter to International Platinum Group Metals Association (2009).



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In the mean time, the recommendation will be published with no value, but with all the information gathered.¹¹

Unlike SCOEL, however, EPA is opting to rely on data that are simply wrong for the purpose and that contravene the IQA and its implementing guidance.

EPA's IQA Guidelines -- the "Objectivity" and "Utility" Criteria

EPA's IQA Guidelines "contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information [it] disseminate[s]" as well as specifically describing "new mechanisms to enable affected persons to seek and obtain corrections from EPA regarding disseminated information that they believe does not comply with EPA or OMB guidelines."¹² Accordingly, the Guidelines expressly set out a pathway for seeking correction of information disseminated by EPA that falls short of the "basic standard of quality, including objectivity, utility, and integrity," enunciated in its own Guidelines or those issued by OMB.¹³

Both the "objectivity" and "utility" criteria are implicated by EPA's reliance on the Merget *et al.* study as a basis for its proposed RfC. As does OMB, EPA considers the "objectivity" inquiry for IQA purposes to be "whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased."¹⁴ The "utility" criterion refers to "the usefulness of the information to the intended users."¹⁵

¹¹ European Commission, 77th Meeting of the Scientific Committee on Occupational Exposure Limits (June 28-29, 2010) § 6.2.

¹² EPA Guidelines at 3.

¹³ *Id.*

¹⁴ *Id.* at 15; OMB Guidelines § V.3, 67 Fed. Reg. at 8459.

¹⁵ EPA Guidelines at 15; OMB Guidelines § V.2, 67 Fed. Reg. at 8459.



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Like OMB, EPA recognizes that the “influential scientific, financial, or statistical information” it disseminates “should meet a higher standard of quality.”¹⁶ Under the EPA Guidelines, information is considered influential if “the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact (*i.e.*, potential change or effect) on important public policies or private sector decisions.”¹⁷ Certainly an RfC for halogenated platinum salts which is 8,000 times below any RfC previously established under the IRIS program and also 2 million times below current U.S. and EU OELs for these substances is “influential scientific . . . information,” as are the data on which the proposed RfC purports to be based. It thus must reflect “a higher degree of quality (for example, transparency about data and methods).”¹⁸ Additionally, because the key -- and only -- database on which the proposed RfC relies is a study deemed inapplicable for this purpose by both the lead investigator and by SCOEL, the information at issue is inconsistent with the best available and current science. Accordingly, the draft IRIS Report also involves “controversial scientific . . . issues,” a specific class of “influential information” that “should adhere to a rigorous standard of quality.”¹⁹

For giving content to the concept of ensuring the “objectivity” of “influential scientific risk assessment information,” EPA, in developing the Guidelines, adapted the quality principles in the Safe Drinking Water Act Amendments (SDWA) of 1996²⁰ as follows:

- (A) The substance of the information is accurate, reliable and unbiased. This involves the use of:

¹⁶ EPA Guidelines at 19.

¹⁷ *Id.*

¹⁸ *Id.* at 20; OMB Guidelines §§ V.3(b)(ii) and V.9, 67 Fed. Reg. at 8460.

¹⁹ *See* EPA Guidelines at 20.

²⁰ 42 U.S.C. §§ 300g-1(b)(3)(A) and (B). The OMB Guidelines, § V.3(b)(ii)(C), direct federal agencies to “adopt or adapt” the SDWA principles for these purposes. 67 Fed. Reg. at 8460.



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- (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and
 - (ii) data 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).
- (B) The presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable.²¹

How the Proposed RfC Violates EPA IQA Guidelines and Why the Erroneous Information It Contains Must Be Corrected Immediately

As noted above, rather than grounded in “the best available science and supporting studies,” the RfC for halogenated platinum salts proposed in the draft IRIS Report rests on the data from a single study that is inappropriate for the purpose. The proposed RfC and its asserted scientific foundation fall far short of what the SDWA quality principles call for to satisfy the “objectivity” criteria. The purported derivation of the proposed RfC from these data cannot reasonably be described as “objective” within the meaning of the IQA. They do not even appear “objective” as the term is ordinarily understood. The highly dubious nature of the scientific underpinning of the proposed RfC by its very nature also compromises the utility of the draft IRIS Report going forward.

While EPA may assert that the current version is “only a draft,” it has been widely circulated -- and apparently unchanged -- for some two-and-a-half years. Any disclaimer that it lacks influence due to its draft nature loses real-world meaning every day, week, month, or year that

²¹ EPA Guidelines at 22.



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it is available and circulating uncorrected. EPA also may assert this Request for Correction is coterminous with comments the IPA already has submitted. Neither the RfC nor the draft IRIS Report, however, is a regulation, and EPA is not subject to a rulemaking timetable or to procedural obligations to consider or respond to comments, as is the case with rulemaking. EPA can shape, and limit, the opportunities for public participation, and it can leave the proposed RfC -- as in fact it has done -- in draft form for an indefinite period, despite the shaky foundation on which these influential pieces of information rest. In any event, to the extent to which this Request for Correction raises issues similar to those that the IPA has sought to bring to EPA's attention through comments, this circumstance does not alter EPA's responsibility to provide a substantive response to the Request, which proceeds on different statutory and regulatory grounds.

Conclusion

For the reasons set out above, the IPA respectfully submits that this Request for Correction should be granted. As such, the proposed RfC of 1 pg/m³ for halogenated platinum salts should be withdrawn and EPA should revisit the issue of a revised RfC only when supporting data are available that (1) are responsive to the exposure scenario for halogenated platinum salts; and (2) meet the relevant IQA criteria for "influential scientific risk assessment information."

Sincerely,

A handwritten signature in blue ink, appearing to read 'Gabriele Randlshofer'.

Gabriele Randlshofer
Managing Director