

25 June 2021

For the kind attention of Illinois EPA

Re: Proposed amendments to 35 III. Admin. Code 620: Groundwater Quality

Substance: Molybdenum

The International Molybdenum Association (IMOA) has very recently become aware of the ongoing Illinois EPA (IEPA) ground water standards proposals for molybdenum, and wishes to participate in the stakeholder group, contributing data and dialogue, and likewise this submission during the public commenting period.

Beyond the minimal information indicated in the on-line Excel sheet tab 'Class 1 GQS' on the IEPA website, we have not been able to identify any scientific support documentation specific to molybdenum that clearly articulates the convincing scientific support for the proposed standard. If we are not mistaken, US EPA's IRIS is the primary data source. In this respect, we would like to share the following concerns with you for your consideration:

- US EPA's IRIS for molybdenum has not been updated for the last 29 years, since it was written in 1992, based on scant data available at that time.
- IMOA has commissioned many environmental and human health studies between 2007-2020, where the initial driver for those studies was compliance with the EU REACH Regulation that required detailed hazard and risk assessment of substances, based on robust data from studies conducted in accordance with internationally accepted protocols. These studies are available free-of-charge to regulatory authorities, and indeed those already available by 2014 are accredited to the OECD Mutual Acceptance of Data scheme. The 2014 OECD SIAP for highly soluble molybdenum salts is accessible via: https://hpvchemicals.oecd.org/UI/SIDS_Details.aspx?id=5c88d62f-4401-4cad-b521-521a4bd710f3 The OECD-generated profile (called the Screening Information Dataset [SIDS] Initial Assessment Profile [SIAP]) contains brief summaries of SIDS endpoints as well as the major conclusions of the hazard assessment. The USA was one of the OECD country reviewers prior to the accreditation being awarded, which amongst other things is an endorsement of the quality of the dataset, having passed peer-review by multiple OECD-member countries.
- The key study in US EPA's IRIS for the molybdenum reference dose is the Koval'skiy study (1961)¹, which for many years now is widely recognised by the regulatory community as unsuitable for regulatory purposes. And recently a summary of the significant shortcomings and uncertainties of that study are now publicly documented in the May 2020 <u>US ATSDR</u>

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Page | 1

¹ Koval'skiy VV, Yarovaya GA, Shmavonyan DM. 1961. Changes of purine metabolism in man and animals under conditions of molybdenum biogeochemical provinces. Zh Obshch Biol 22(3):179-191.



<u>Toxicological Profile for Molybdenum</u>. Likewise the NAS Institute of Medicine 2001² publication concluded the Koval'skiy study is unreliable science, and this is also reflected by US ATSDR in its publication.

Page | 2

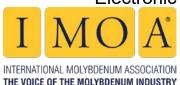
- For regulatory compliance purposes, between 2011-2017 three higher-tier human health studies using laboratory animals, each an OECD guideline-compliant GLP study, were commissioned using the highly soluble salt sodium molybdate, all conducted by USA-based laboratories: 90-day repeated dose toxicity, prenatal developmental toxicity, and 2-generation reproduction toxicity studies. The US ATSDR Tox Profile for Molybdenum critically assesses and takes account of each of those studies, and ultimately selected the 90-day repeated dose toxicity study as the key study and basis for its intermediate oral MRL derivation. The derived intermediate oral MRL screening value is 0.06 mg/kg-d. The ATSDR Toxicological Profile and the MRL underwent an Inter-Agency peer review that included representatives from the US EPA Office of Water. ATSDR also explicitly notes that screening values can be as much as 100-fold below levels shown to be non-toxic in laboratory animal studies³, and consequently even screening level MRL's are not an appropriate basis for state groundwater quality standards.
- The US EPA IRIS database for metals in many cases has not been updated for decades. Whilst we completely understand that resourcing constraints mean that other higher priority substances receive attention and updating, it does also mean that the US EPA IRIS database cannot be the 'go to' database it once was, because enhanced global chemicals management legislation circa 2007 onwards has resulted in the availability of high-quality robust datasets that are not in the US EPA IRIS database, meaning that the underlying scientific rigor of outdated US EPA IRIS evaluations certainly warrants review. The North American Metals Council dialogued with the US EPA IRIS offices in 2018/2019 about this highly relevant disconnect. In 2020 IRIS introduced a second tab 'Other EPA Information' which links to the US EPA Chemistry Dashboard where newer data can be sourced. Another useful source is the publicly accessible EU REACH database.

In relation to the data shown on the Excel sheet and methodological information made available online by IEPA we note that:

• The HTTAC methodology bases the water standard on an assumed 15 kg body weight & drinking water consumption of 0.78L/day for a 0-6 year old child. This is nearly twice as conservative as the usual approach of using the values for an adult. We are concerned as to the suitability of the adopted approach for standard-setting for a whole population, not least on the basis that molybdenum is a recognised bio-essential trace nutrient for humans, (animals & plants), and we are unable to discern whether the essentiality of molybdenum was factored in to your proposed value of just 0.019 mg Mo/L. We note this is the same value IEPA is proposing for silver (Ag), whereas the toxicity of the two substances differs significantly and Ag is not an essential trace element.

² NAS. 2001. Molybdenum. In: Dietary reference intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc. Washington, DC: National Academies Press, 420-439.

³ US ATSDR Toxicological Profile for Molybdenum, Appendix A, page A-1



A further concern is whether the economic considerations relating to the proposed value of 0.019 mg Mo/L have been adequately addressed in terms of the ability for the impacted facilities to actually achieve such a highly challenging mandatory standard? That in turn feeds back into the concern to transparently demonstrate the compelling scientific support for the proposed standard.

The IEPA Excel file also has a 'Class II GQS' tab, proposing 0.05 mg Mo/L, which does not appear to provide further insights into how the value was derived and for which purpose (e.g. forage or nonforage). More detail would be appreciated for the sake of transparency and enhanced understanding.

In light of the above rationale and multiple concerns, IMOA will welcome further dialogue with Illinois EPA, particularly in relation to the proposed groundwater standard value of 0.019 mg Mo/L. We are available and keen to engage in discussion about these matters, and to provide the available molybdate datasets and information sources for your review and consideration with a view to appropriate revision of the current molybdenum proposals.

With kind regards.

Sandra Carey

Sandra Carey HSE Executive

Response Email: sandracarey@imoa.info

Page | 3

From: Sandra Carey
To: Brown, Don

Subject: [External] Urgent - IMOA submission re 35 III.Code 620 and access to today"s hearing please

Date: Wednesday, March 9, 2022 11:52:43 AM

Attachments: Molybdenum - Submission relating to 35 III. Code 620 Groundwater Quality.msq

Importance: High

Hello Don

Via a colleague at the American Chemistry Council I have obtained your contact details as apparently the right person to contact about the fact that here at the International Molybdenum Association we submitted comments on 25 June 2021 (attached), and I cannot see them listed anywhere online as having been received, and neither did we receive any Email receipt acknowledgement requested in our submission.

So we are very concerned that you may not have captured our comments about molybdenum, which we submitted on a timely basis to Illinois EPA for your careful consideration.

Could you please provide me with a telephone number where I may call you, and please can you investigate and confirm that our submission was duly received last year and is being considered.

Also, I understand there is a hearing precisely today. If it is online, could you please send me the link to join.

Many thanks. Sandra

Sandra Carey

HSE Executive



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