15 September 2022

RE: R22-18 - IMOA Pre-filing Testimony for the third hearing in relation to proposed amendments to Groundwater Quality 35 ILL.ADM.CODE 620

With reference to the R22-18 proposed amendments to groundwater quality 35 ILL.ADM.CODE 620, and in follow-up to the in-person hearing on 21 June 2022 at which the undersigned gave testimony on behalf of the International Molybdenum Association (IMOA), this communication respectfully requests a deferment on any ruling about molybdenum until such time as this substance can be assessed on current best available science instead of the US IRIS database entry for molybdenum which is vastly out-of-date and thereby a wholly unsuitable and misleading scientific basis for assessment.

This deferment proposal is underpinned and substantiated as follows:

- At the June 2022 hearing it was publicly acknowledged by IEPA that the contents of the 1992 US IRIS database for molybdenum are 30 years out-of-date (transcript pages 59, 61, 61, 90). Despite this, US IRIS was nevertheless the 'Tier One' data-source used for the IEPA assessment of molybdenum and current proposal of a groundwater quality standard of 19 µg Mo/litre.

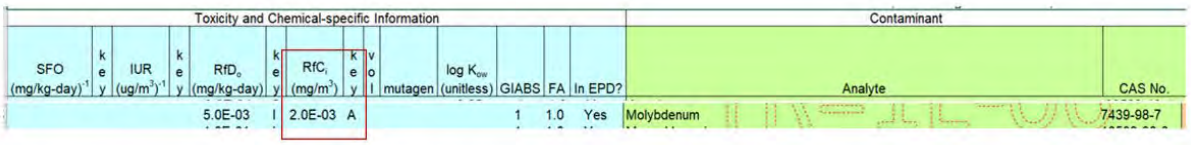
- It was further acknowledged that IEPA is aware about the existence of the 2020 US ATSDR Toxicological Profile for Molybdenum, containing significantly more recent scientific data already assessed by that US Government agency, but IEPA had not used it in their assessment because US ATSDR is a 'Tier Three' data-source (transcript page 38).

- It was also stated at the hearing that despite US ATSDR being a 'Tier Three' data-source, IEPA had opted to use the recent US ATSDR Toxicological Profiles of various PFAS substances as the basis for the current IEPA groundwater proposals for those substances. Below is the US ATSDR Profile extract showing Intermediate Oral values for PFOA and PFOS but no available chronic values:

Table 1-2. Overview of Minimal Risk Levels Derived for Perfluoroalkyls

	Inhalation MRLs			Oral MRLs		
Compound	Acute	Intermediate	Chronic	Acute	Intermediate	Chronic
PFOA	X[a]	X	X	X	$3x10^{-5}$ mg/kg/day (Table 1-3)	X
PFOS	X	X	X	X	$2x10^{-5}$ mg/kg/day (Table 1-4)	X
PFHxS	X	X	X	X	[illegible]	X

- By contrast, IEPA commented it looks to US EPA Regional Screening Levels (RSLs) for molybdenum. The current RSL data for molybdenum was last updated in November 2020 (after the May 2020 release of the US ATSDR Toxicological Profile for Molybdenum). This is reflected in the Reference Concentration (RfC) of 2.0E-03 (i.e. 0.002 mg Mo/m3) which is precisely the MRL Chronic (molybdenum trioxide) inhalation exposure value in the 2020 Profile. The RfD value of 5.0E-03 however has not yet been updated. The US ATSDR 2020 Profile provides an Intermediate MRL for Oral exposure, of 0.06 mg Mo/kg/day, and similar to PFOA/PFOS there is no available Chronic value.



Toxicity and Chemical-specific Information														Contaminant	
SFO (mg/kg-day)$^{-1}$	key	IUR (ug/m^3)$^{-1}$	key	RfD_o (mg/kg-day)	key	RfC_i (mg/m^3)	key	vol	mutagen	log K_{ow} (unitless)	GIABS	FA	In EPD?	Analyte	CAS No.
				5.0E-03	I	2.0E-03	A				1	1.0	Yes	Molybdenum	7439-98-7

- It therefore appears an inconsistent application of data-sourcing rules that Intermediate values are transparently a usable basis for some substances but this has not been applied to molybdenum, despite a precedent already existing to use Intermediate Oral values based on recent US Government Agency assessments, as in the PFOA/PFOS examples given above.

- A fundamentally important assessment differentiator between the relevance and reliability of the IRIS and US ATSDR datasets is as follows:
    - After assessing all available data, the 2020 US ATSDR toxicological assessment selects the OECD test protocol-compliant 90-day repeated dose toxicity study (Murray 2014a) as its point of departure for Oral MRL calculation, and amply documents the multiple shortcomings of the 60-year old Koval'skiy 1960 study, (which uses imprecise colorimetric methods and other outdated tools), but which is the basis for the (three decades) outdated IRIS assessment.

- Further weight-of-evidence for using the Murray 2014a (instead of Koval'skiy in US IRIS) for molybdenum assessments can be also found in the earlier Hays et al 2016 publication, 'Biomonitoring equivalents for molybdenum', where two of the four co-authors are from the Health Canada regulatory authority:

2.4. BE derivation approach

The BEs were derived for the EAR, RDA and UL from IOM, RfD from EPA, TDI from RIVM, UL from EC SCF, and the lowest NOAEL identified for Mo in the OECD SIDS assessment profile from a 90-day toxicity study (Murray et al., 2014a), herein referred to as the OECD SIDS NOAEL (Table 1). The OECD SIDS NOAEL was included for BE derivation because the OECD SIDS assessment profile includes newer OECD test guideline compliant studies, which were not available at the time of the EPA, IOM, EC SCF or RIVM evaluations of Mo. Additionally, these studies have higher reliability than the studies used in above mentioned exposure guidance values because they were conducted according OECD test guidelines and good laboratory practices. The BEs associated with the IOM EAR,

- Many molybdenum studies assessed by US ATSDR in its 2020 Profile, including Murray 2014a, are contained within the current *OECD Mutually Accepted Dataset* for highly soluble molybdenum salts (also known as the OECD SIDS assessment profile). Our understanding is that this signifies the dataset is required (i.e. binding obligation) to be the starting point for developing or revising legislation on molybdenum for OECD-member countries. USA is an OECD-member country, and indeed the USA was one of six countries (Australia, Canada, Japan, Netherlands, USA, UK and the OECD COCAM Secretariat) that scrutinized the molybdenum dataset prior to it being awarded Mutual Acceptance of Data (MAD) status by the OECD in 2014. The OECD-endorsed dataset is downloadable at: https://hpvchemicals.oecd.org/UI/SIDS_Details.aspx?id=5c88d62f-4401-4cad-b521-521a4bd710f3

- An example of adherence to the OECD MAD process in practice can be found by Health Canada, in their November 2016 'Science Approach Document to Biomonitoring' that contains a specific section on Molybdenum, and the following specific commentary about why Health Canada rejected using the chronic Reference Dose (RfD) of 0.005 mg Mg/kg bw/day for oral exposure derived by (US) IRIS (1992):

caused by molybdenum (Health Council of the Netherlands 2013). As well, the OECD SIDS assessment report (OECD 2013) concluded that the available human data was of insufficient quality and reliability to use quantitatively in a risk assessment. Therefore, the chronic Reference Dose (RfD) of 0.005 mg Mo/kg bw/day for oral exposure derived by IRIS (1992) based on human serum uric acid levels and gout-like symptom reported in a cross-sectional epidemiological study was not considered as a suitable exposure guidance value for deriving biomonitoring guidance values in this assessment. The details of the approaches used in the derivation of whole blood and urine BEs are described in Hays et al. (2016).

When considering all of the above, it is also valuable to recognise that unlike the other nine proposed man-made organic substances for regulation in R22-18, molybdenum is a naturally-occurring inorganic substance that is an *essential trace element for life*: for animals including humans, plants and bacteria.

It is surely in the interests of all parties that best available science is used to most accurately assess the toxicology of substances. This has transparently not happened for molybdenum in the current R22-18 proposal because, as set out above, the IEPA has used the vastly outdated US IRIS database as its data-source for assessment instead of the much more recent best available science already in the public domain in the US ATSDR 2020 Toxicological Profile for Molybdenum.

The International Molybdenum Association therefore respectfully proposes that any ruling on molybdenum be deferred until such time as IEPA are able to assess the substance on currently best available science, instead of the (three decades) outdated US IRIS database.

Your sincerely

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References:

Hays et al, 2106: Biomonitoring equivalents for molybdenum. Regulatory Toxicology & Pharmacology, Vol 77, p 223-229. https://www.sciencedirect.com/science/article/abs/pii/S0273230016300460?via%3Dihub

Health Canada, November 2016: Science Approach Document – Biomonitoring-based Approach 2 for (… molybdenum -containing substances) https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=D335D89F-1

Koval'skiy et al, 1961. Changes of purine metabolism in man and animals under conditions of molybdenum biogeochemical provinces. Zh. Obshch.Bio.22, 179-191 (Russian trans.)

Murray et al, 2014a. 90-day subchronic toxicity study of sodium molybdate dihydrate in rats. Regul. Toxicol. Pharmacol. 70(3), 579-588 https://www.sciencedirect.com/science/article/pii/S0273230013001487

US ATSDR 2020, Toxicological Profile for Molybdenum. Open Access: www.atsdr.cdc.gov/ToxProfiles/tp212.pdf

US EPA 1992, Integrated Risk Information System (IRIS). Online. National Centre for Environmental Assessment, Washington DC. https://iris.epa.gov/ChemicalLanding/&substance_nmbr=425