THE VOICE OF THE MOLYBDENUM INDUSTRY

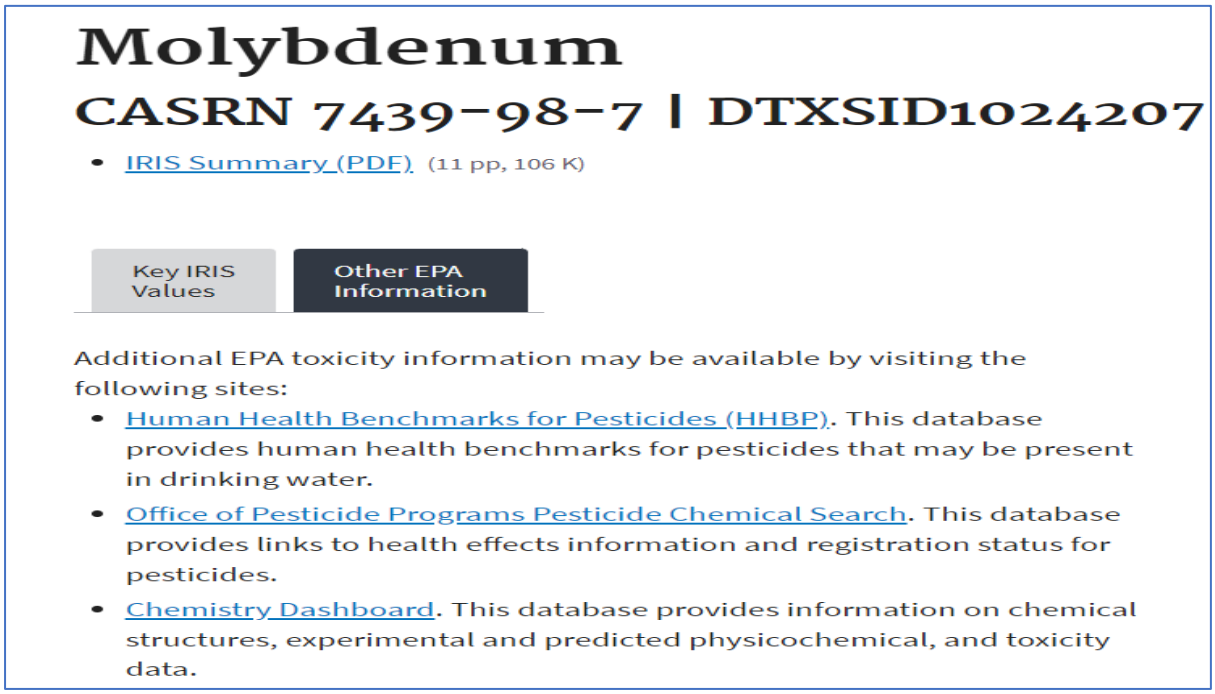
22 November 2022

RE: R22-18 - IMOA Responses to questions raised in relation to proposed amendments to Groundwater Quality 35 ILL.ADM.CODE 620

IMOA received four questions in Section VI of the pre-filed questions from the Illinois Environmental Protection Agency, dated 27 October 2022, to which we respond as indicated below:

1) **Does US EPA utilize the IRIS database toxicity value when calculating health-based screening levels through RSL?**

The current US IRIS database entry for molybdenum is vastly out-of-date, as it was generated in 1992, based on a 1961 study (Kovalskiy), and has not been updated since then, so it does not take into account any molybdenum science developments over the last 30 years. The North American Metals Council (NAMC) and IMOA formally raised this issue of concern with US EPA in 2018/2019 about excessively out-of-date IRIS datasets for several metals, because it means that toxicity assessments are not based on best available science when IRIS is the assessment basis. NAMC and IMOA requested that the IRIS database at least include pointers towards more recent science in recognition of IRIS dataset antiquity. In recognition and response, US EPA (ORD/ORD CPHEA) began introducing a new tab 'Other EPA Information' for each IRIS entry that links to the US EPA Chemistry Dashboard, which in turns points a data-enquirer to sources of more recent scientific data. See screenshot below (taken on 21 Nov 2022):



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The afore-mentioned EPA/NAMC/IMOA dialogue, on 5 November 2019, is formally reflected in EPA IRIS on-line documentation available at: https://iris.epa.gov/Events/#stakeholderMeetings – the EPA IRIS Minutes are also attached to this document for your ease of reference.

2) **Are toxicity values for the proposed PFAS constituents available from US EPA's Tier 1 or Tier 2 sources (IRIS and PPRTV)?**

The International Molybdenum Association is understandably focused on molybdenum substances. In our earlier pre-filing testimony of 15 September 2022, we made the point that it was stated at the 21 June 2022 hearing in Springfield 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, using the US ATSDR *Intermediate Oral* MRL value. We make the parallel that US ATSDR has also derived an Intermediate Oral MRL value for molybdenum, of 0.06 mg Mo/kg/day. It therefore appears an inconsistent application of data-sourcing rules that Intermediate MRL values are transparently a usable basis for some substances (PFOA/PFOS) but the same approach is not being equally applied for molybdenum.

3) **Is an inhalation toxicity value (inhalation reference concentration (RfC) available from the US EPA's Tier 1 or Tier 2 sources?**

In November 2020 US EPA added an inhalation toxicity value to their Regional Screening Level tables for Molybdenum. The RfC value of 2.0E-03 (i.e. 0.002 mg Mo/m3) adopted in the US EPA RSL is precisely the MRL Chronic (molybdenum trioxide) inhalation exposure value in the US ATSDR 2020 Toxicological Profile for Molybdenum. The Molybdenum 1992 IRIS (Tier 1) dataset *pre-dates* the existence of the study (NTP TR 462, 1997) which is the basis for the US ATSDR 2020 inhalation reference concentration.

4) **Does US EPA consider the IRIS RfD to be an acceptable toxicity value for calculating health-based screening levels?**

IMOA cannot answer on behalf of US EPA. But we would refer you to our response to question one, in which US EPA's action of introducing an additional 'Other EPA information' tab to the US IRIS database is a clear acknowledgement of the outdatedness of the IRIS dataset for molybdenum (and other substances). It is our understanding from discussions with US EPA Office of Water over the last couple of years that in recognition of the availability of significant new molybdenum science, as largely reflected in the US ATSDR 2020 Toxicological Profile for Molybdenum, an update of the US EPA Health Advisory for Molybdenum was being drafted, but has not been finalized due to US EPA re-focusing staff workload priorities on other substances, including PFOA, PFOS and other PFAS.

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Many molybdenum studies assessed by US ATSDR in its 2020 Toxicological Profile for Molybdenum, including Murray 2014a which provides the No Observable Adverse Effect Level basis for their Intermediate Oral MRL of 0.06 mg/kg/day (as compared to the IRIS RfD of 0.005 mg/kg/day), 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

For the reasons given above, and those in our previous written submission of 15 September 2022, it is an inescapable conclusion that the 1992 IRIS dataset for molybdenum using Kovalskiy 1961 as its key study, can in no way be considered either recent or best available science, and is therefore unequivocally an outdated, unsuitable basis for a scientifically-sound toxicity assessment of molybdenum. (The US ATSDR 2020 Toxicological Profile for Molybdenum amply documents the multiple shortcomings of the 60-year old Kovalskiy study).

A much more comprehensive and recent dataset by the US government agency ATSDR *is* available for use, but seemingly Illinois EPA data hierarchy rules place that ATSDR molybdenum dataset and its Intermediate Oral MRL out of scope as Tier 3 data, even though ATSDR Intermediate Oral MRLs *are* being used by IEPA for other PFAS substances.

IMOA therefore respectfully requests a deferment on any ruling about molybdenum until such time as this substance can be assessed by IEPA on current best available science instead of the three decades outdated US IRIS dataset (and 60-year outdated 'key study') for molybdenum.

Your sincerely

Sandra Carey

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Enc. US EPA ORD Summary of Action Items document, 5 November 2019 meeting, available on-line at: https://iris.epa.gov/Events/#stakeholderMeetings

References:

Kovalskiy et al. (1961). The change in purine metabolism of humans and animals under the conditions of molybdenum geochemical provinces. Zhurnal obshchey biologii - Journal of General Biology Vol. 22, No. 3, 1961, pp. 179-191.

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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

NTP (1997) National Toxicology Program. Toxicology and Carcinogenesis Studies of Molybdenum Trioxide (CAS No. 1313-27-5) in F344/N Rats and B6C3F1 Mice (Inhalation Studies). Natl. Toxicol. Program Tech Rep Ser 1997; 462: 1-269.

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

US EPA IRIS, ORD/ORD CPHEA meeting, 5 November 2019:
https://iris.epa.gov/Events/#stakeholderMeetings

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Summary of Meeting Action Items

Event Title: North American Metals Council (NAMC) Request for IRIS Website Updates (follow-up)
Date: November 5th, 2019
Time: 4:00 PM – 4:30 PM
Keyword: IRIS, Molybdenum

Attendees:

Sandra Carey – International Molybdenum Association (IMOA)
Kathleen Roberts – B&C Consortia Management, LLC
Ligia Duarte Botelho – B&C Consortia Management, LLC
Jennifer Orme-Zavaleta – US EPA, ORD
David Dunlap – US EPA, ORD
Mary Ross – US EPA, ORD OSAPE
Kris Thayer – US EPA, ORD CPHEA
Andrew Kraft – US EPA, ORD CPHEA
Dahnish Shams – US EPA, ORD CPHEA
Vicki Soto – US EPA, ORD CPHEA
Madison McGovern – US EPA, ORD CPHEA

Summary of Meeting Activities:

- This meeting was scheduled as a follow-up to the May 16th, 2019 meeting with NAMC regarding information presented on the IRIS website.
    - NAMC requested that EPA more prominently display the publication dates of values presented within the IRIS Database. Additionally, NAMC inquired on the ability to provide a reference to more recent toxicity information in other publications. These suggestions were made verbally and in a November 1, 2019 letter from NAMC (see attachments).
- International Molybdenum Association (IMOA) presented concerns over regulatory use of the current IRIS toxicity value for molybdenum published in 1992. More recent toxicity information for molybdenum developed in partnership with organizations in the U.S. and Europe have been presented and used in other regulatory settings in those jurisdictions.
- EPA explained the ORD process for nominating a chemical for a new or updated IRIS assessments is driven by National Program priorities.
    - IMOA stated they had engagement with OW since 2011 regarding health advisory updates and they intended to send molybdenum data to OCSPP during the current data call-in ending 1 December 2019, for reevaluation under TSCA.
- EPA presented slides (see attachments) to review updates made to the IRIS website since May 2019, including increasing the font size of the “Last Updated” text. The font size is now in line with the surrounding text on the website. Additionally, EPA has begun to rollout a new tab called “Other EPA Information” that presents other Agency resources that may provide relevant toxicological information (e.g., Chemistry Dashboard).

- EPA noted that the Molybdenum landing page has not yet been updated with the "Other EPA Information" tab, but will be with an estimated completion date of no later than March 2020.
- IMOA requested links to the US ATSDR Toxicological Profile for Molybdenum, and the OECD[1] MAD (Mutually Accepted Dataset) for highly soluble molybdenum salts[2].
    - EPA responded that since this information is not EPA data, it would not be directly linked, although may be available on the Chemistry Dashboard which the tab does link to.
      EPA noted information identified in the Chemistry Dashboard have not been verified by EPA. As stated in the Chemistry Dashboard disclaimer "This resource is a compilation of information sourced from many sites, databases and sources including U.S. Federal and state sources and international bodies that saves the user time by providing information in one location. The data are not reviewed by USEPA – the user must apply judgment in use of the information."
- IMOA requested IRIS assessment dates be more prominent, to alert users to consider the likelihood of newer information being available than is currently contained in IRIS, suggesting bolding or change in font color.

Action Items:

- EPA has begun to explore the possibility of applying color change to the latest update date. However, we do not expect to have clarity on this until 2020 Q2 as it entails exploration of potential violations of EPA web guidance and Section 508 of the Rehabilitation Act. (29 U.S.C. § 794d). In addition, addressing this topic is part of ongoing plans to assess IRIS database re-development. EPA has begun to implement using bold font for the update dates, but this change has not yet been applied to all chemicals. It has been applied to the molybdenum assessment page (https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=425).

[1] Organisation of Economic Cooperation & Development (OECD) Existing Chemicals Database
[2] OECD Mutually Accepted Dataset for Highly Soluble Molybdenum Salts