ELECTRIFYING THE FUTURE

Development of Colorado's Water Quality Standard for Molybdenum

December 6, 2022

Climax Molybdenum
A Freeport-McMoRan Company

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Overview

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- Introductions and background
- Hearing schedule
- Stakeholder survey results
- Reference dose: modifying factor and update on CRL study
- Relative source contribution
- Update on treatment plant construction
- Next steps

Background

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- Colorado's water quality standard for molybdenum to protect water supply use = 210 ug/L
  - Commission derived a reference-dose like value from 1990 Fungwe grad student study
    - EPA's IRIS is based on flawed Koval'sky et al. (1961), which ATSDR did not consider suitable for derivation of an MRL
  - Commission adopted standard while recognizing need to update standard in the future based on new scientific developments
- New and evolving science supports revision of the molybdenum standard
  - Fungwe no longer a sound basis for CO water quality standard
  - Climax petitioned for a rulemaking to revise this standard using this new and evolving science

Hearing schedule

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- Molybdenum rulemaking had been scheduled for June 2023
  - Commission adopted Division's proposed extension of the molybdenum temporary modification based on June 2023 hearing date
- Division has since proposed delaying the molybdenum hearing along with the June 2023 Arkansas and Rio Grande basins hearing
  - Division has said that June 2024 is most workable, but they are working with parties and seeking input about other concerns and impacts
- Commission has preliminarily agreed to delay the molybdenum hearing
  - If hearing is after December 2023, a temporary modification extension will be necessary and justified

Stakeholder Survey Results

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- Reference dose and CRL study
- Development of the relative source contribution
- Interest in toxicologist call discussion
- Concentrations of molybdenum and downstream impacts
  - Water quality monitoring data publicly available at ClimaxMoinCO.com

Reference Dose (RfD)

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- Reference dose is based on three input factors: no observed adverse effect level (NOAEL), uncertainty factors (UF) for inter- and intra-species uncertainty, optional modifying factor (MF)
- ATSDR calculated its *minimal risk level* (MRL) using these factors
  - NOAEL= 17 mg Mo/kg/day
  - UF = 100
  - **MF = 3**
  - MRL = 0.06 mg Mo/kg/day

Equation 1-1: $\text{DWS/MCLG, µg/l} = \frac{\text{RfD} \times 70 \times 1000\ \text{µg/mg} \times \text{RSC}}{2 \times \text{UF}}$

where:

RfD[2]	=	verified reference dose for non-carcinogens, mg/kg-day
70	=	weight of an average adult, kg
2	=	daily drinking water consumption, liters/day
RSC[3]	=	relative source contribution (0.2 is default value)
UF	=	Uncertainty Factor (1.0 for most chemicals, 10 for certain Group C chemicals)

Concerns with the Modifying Factor

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- Current Colorado water quality standard, based on Fungwe, uses a total UF of 30 and does not use a modifying factor

- **ATSDR's decision to apply MF=3 lacks scientific basis and was not applied in a transparent, peer-reviewed process**
- Because of concerns related to *developmental effects*, ATSDR applied MF=3 to the more stringent *kidney effects* NOAEL instead of the developmental effects NOAEL
  - Concerns based on marginal copper diets from Fungwe
  - MF=3 was not included in the draft profile, and was not subject to peer review or public comment
  - A MF had never been used in a risk assessment for any essential element

CRL Study and Next Steps

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- Recent study conducted at CRL to determine whether the Fungwe study results can be replicated
  - Results discussed at Aug. 2022 meeting
  - Fungwe study is not reproducible and not reliable
  - **CRL study further confirms that modifying factor is not warranted**

- Final report is 931 pages
  - Article to be published in peer-reviewed journal in 2023

- Organizing call with toxicologists to discuss CRL study and RfD

No Need for a Subchronic to Chronic Toxicity Uncertainty Factor (UF)

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- "An uncertainty factor for sub-chronic to chronic exposure is not needed as the NOAEL is derived from a 2-generation study where animals are exposed throughout the sensitive life stage." --EPA Comments on the Water Supply WQS Proposal, Enclosure 2, p. 6 (Oct. 27, 2017)
- The NOAEL for-systemic toxicity is 17 mg Mo/kg bw/day in the 2-generation reproductive toxicity study of molybdenum (the same as the NOAEL in the 90-day study used as the critical study by ATSDR).
- To the best of my knowledge, no essential element has received a 10-fold UF for subchronic to chronic exposure by the NAS Institute of Medicine, ATSDR, or EPA.

Risk Assessment of Essential Elements

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- EPA scientists in the Office of Water have cautioned against treating essential elements as toxic chemicals and using excessive uncertainty factors
- "Establishing an RfD for essential nutrients presents a challenge because the assumptions that are made when defining exposure limits for toxic substances may yield an RfD value that would pose a nutritional risk for some segments of the population."
- "The approach used in determining the RfD value for zinc was the application of the half-logarithmic uncertainty factor (UF) of 3.... The selection of this UF was based on the use of a minimal LOAEL (or maximal NOAEL) from a study of moderate duration …"

-- Cantilli R, Abernathy CO, and Donohue JM (1994) Derivation of the Reference Dose for Zinc, Risk Assessment of Essential Elements, Eds., Mertz W, Abernathy CO, Olin S

Relative Source Contribution (RSC)

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- Relative source contribution is an input factor to account for exposure from drinking water versus diet
  - Default is 0.2 (allowing 20% of exposure through drinking water), but different RSC should be used when information is available
- While ATSDR looked at information that may be relevant to the RSC, ATSDR did not establish RSC

$$\text{Equation 1-1: DWS/MCLG, } \mu g/l = \frac{\text{RfD} \times 70 \times 1000\ \mu g/mg \times \text{RSC}}{2 \times \text{UF}}$$

where:

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Calculation of the Relative Source Contribution

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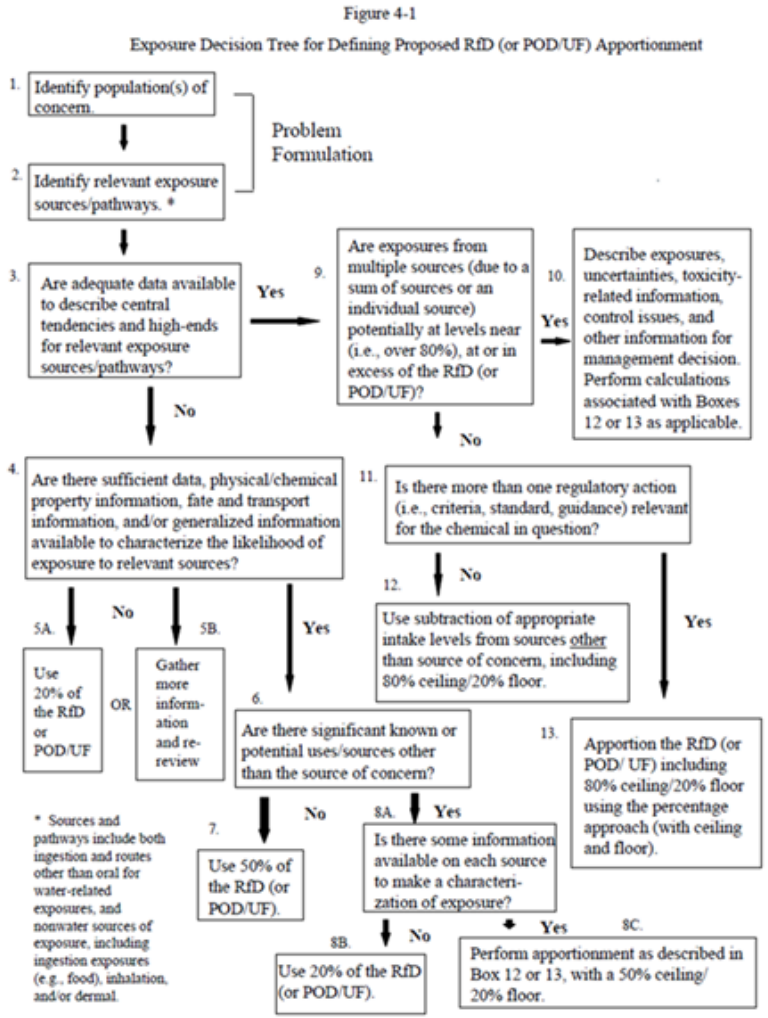
- EPA calculated RSC of 0.8 in 2017
  - Based on Exposure Decision Tree from 2000 methodology for human health criteria
  - Appropriate because dietary intake for molybdenum is low

- Dr. Murray has been analyzing the Exposure Decision Tree in light of current information
  - RSC of 0.8 remains appropriate
  - Early draft will be shared with stakeholders in 2023



Policy 96-2 Equation: Two Scenarios

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Scenario 1 (ATSDR without MF, with RSC 0.8):

$$\text{DWS/MCLG, µg/L} = \frac{0.17 \times 80 \times 1000\ \mu g/mg \times 0.8}{2.4 \times 1} = 4{,}350\ \mu g/L\ \text{(chronic)}$$

Where:

- 0.17 = Calculated RfD (without MF), in mg/kg/day
- 80 = weight of an average adult in kg
- 2.4 = daily drinking water consumption in liters/day
- 0.8 = RSC

Scenario 2 (ATSDR with RSC 0.8):

$$\text{DWS/MCLG, µg/L} = \frac{0.06 \times 80 \times 1000\ \mu g/mg \times 0.8}{2.4 \times 1} = 1{,}600\ \mu g/L\ \text{(chronic)}$$

Where:

- 0.06 = Calculated RfD (with MF=3), in mg/kg/day
- 80 = weight of an average adult in kg
- 2.4 = daily drinking water consumption in liters/day
- 0.8 = RSC

Update on Treatment Plant Construction

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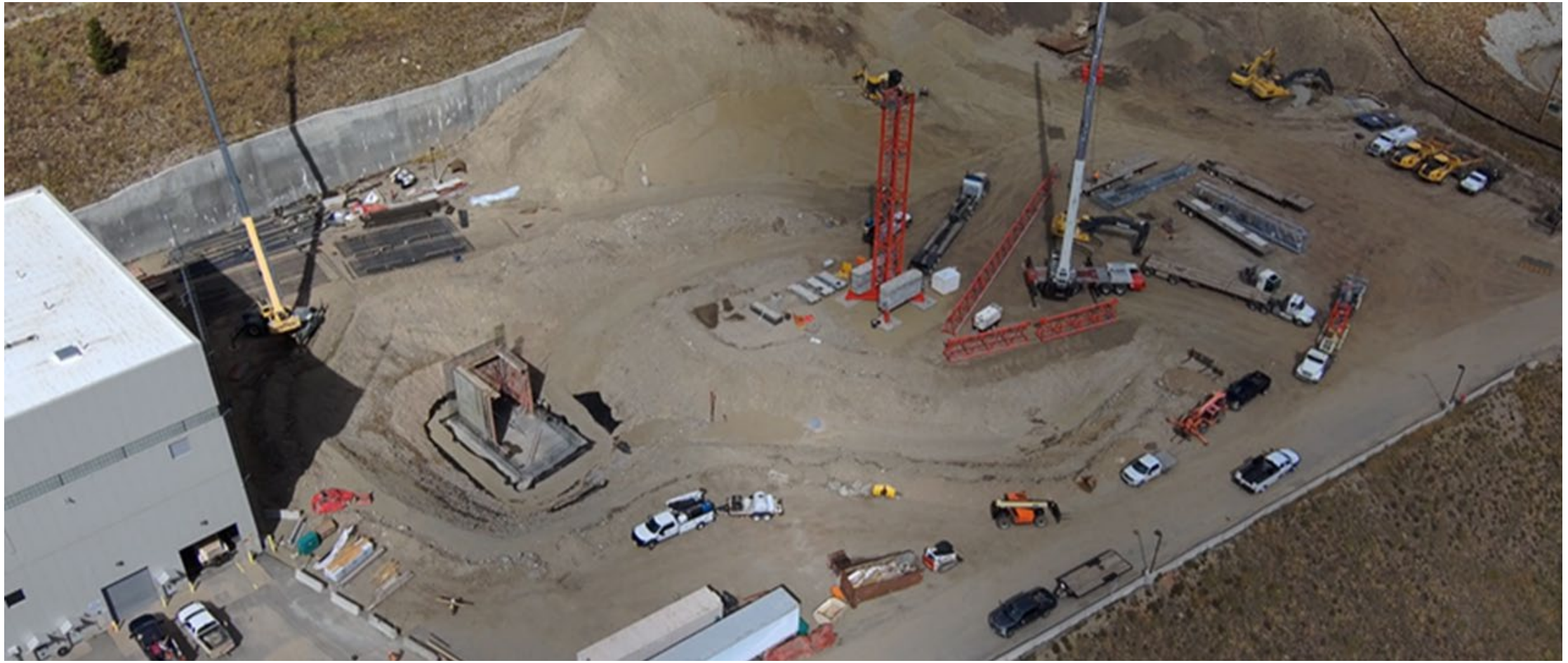

Update on Treatment Plant Construction

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- Construction is progressing as scheduled

Next Steps

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- Climax will distribute a survey to collect feedback on information presented to date
  - Survey to be sent in the week following meeting, likely 3 weeks for responses
- Schedule call(s) with toxicologists to discuss CRL study
- Additional stakeholder meetings to be scheduled for 2023
  - Dr. Murray will continue compiling the RSC information
  - RSC information will be shared with stakeholders sufficiently in advance of the hearing