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RESPONSIBLY. RELIABLY. RELENTLESSLY.

Development of Colorado's Water Quality Standard for Molybdenum

January 11, 2022

 **Climax Molybdenum**
A Freeport-McMoRan Company

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- Introductions
- Background review
 - History of water supply standard
 - Progress since Temp Mod
- Calculation of a water supply standard under WQCC Policy 96-2
- Treatment alternatives
- Need for prompt hearing
- Process and next steps

History of Water Supply Standard

- | | |
|-------------|--|
| 2007 | Water Quality Control Commission (WQCC) adopts standard of 35 µg/L in ground water (Reg. 41) based on 1961 Armenian study |
| 2010 | WQCC adopts standard of 210 µg/L in surface water (Reg. 31) based on 1990 graduate student study (Fungwe) |
| 2012 | WQCC revises ground water standard in Reg. 41 to 210 µg/L for consistency with Reg. 31 |
| | WQCC adopts 210 µg/L standard for all Colorado River Basin water supply segments |
| 2014 | WQCC also adopts a “current conditions” temporary modification for Blue River Segment 14 to allow more time to resolve uncertainty about the current standard, including the science |
| 2017 | WQCC continues a rulemaking hearing to consider revision of the standard to allow for ATSDR review |
| 2018 | WQCC continues rulemaking and extends temp. mod. |
| 2019 | WQCC continues rulemaking again and extends temp. mod. to 6/30/23 |

- Significant Advances in Science
 - Publication of 3 state-of-the-art molybdenum studies
 - Independent review, including the ATSDR, of the improved science
 - ATSDR profile published in May 2020
- Climax continues to maintain current conditions
- Climax continues to monitor water quality
 - Worked with local stakeholders to identify locations to sample moly concentrations
 - Data made available to the public on ClimaxMOinCO.com

- Climax analyzed more than 30 water treatment alternatives
- Climax reviewed local produce to understand potential dietary exposure to moly
- Climax continues robust outreach to stakeholders since the 2017 hearing continuation
 - Annual written updates to the WQCD and stakeholders 2019-2021
 - Update to the WQCC and stakeholders at the 2018 and 2019 Temporary Modification hearings
 - Briefing to stakeholders on molybdenum science in September 2019
 - Presentations and engagement with stakeholders at a variety of forums

- Addresses WQCC methodology and rationale for establishing human health-based water quality criteria for Colorado surface and ground waters
- Provides equations for calculating chronic human health criteria and standards
 - EPA's National Primary Drinking Water Regulations equation for calculation of maximum contaminant level goals (MCLGs)
 - MCLGs are the concentrations of a contaminant in water at which no known or anticipated adverse effects on the health of persons occur, and which allows an adequate margin of safety

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

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)

➤ **RfD = Reference Dose**

- Verified reference dose in mg/kg-day
- Derived from values such as NOAELs, applying uncertainty and/or modifying factors as appropriate

➤ **RSC = Relative Source Contribution**

- Accounts for amount of intake through diet vs. drinking water
- Default is 0.2, but 0.5 or 0.8 can be used

➤ **Body weight and drinking water intake**

- Weight of an average adult
- Daily drinking water intake

Input Factor Issue 1: ATSDR Use of Modifying Factor

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

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ATSDR Toxicological Profile for Molybdenum

- No-observed-adverse-effect-level (NOAEL) of 17 mg/kg-day
 - Based on Murray et al. (2014) which ATSDR deemed a high-quality study
- Uncertainty and modifying factors (UF and MF) = 300
 - UF = 100 (10 intraspecies, 10 interspecies)
 - MF = 3 (not included in Draft Profile)
- Still considered Fungwe et al. (1990) despite numerous concerns with that study
- For purposes of a prompt hearing and to build consensus Climax will accept ATSDR UFs
- However, MF = 3 is not necessary

Source	NOAEL, mg/kg/day	UF Inter-species	UF Intra-species	Modifying Factor	Calculated RfD
ATSDR MRL	17	10	10	3	0.06
Climax	17	10	10	1	0.17

Why the MF of 3 is Unnecessary

Presentation by F. Jay Murray, Ph.D. | Murray & Associates

- ATSDR applied a MF of 3 “to address concern that reproductive/developmental alterations may be sensitive outcomes in populations with marginal copper intakes.”
- But, the MF of 3 was applied to the NOAEL of 17 mg Mo/kg/day for mild kidney effects
- ATSDR’s MRL already provides and embeds an uncertainty factor of 2.4 for developmental and reproductive alterations.
- By applying the additional MF of 3 to the POD of 17 mg Mo/kg/day, the MRL is considerably more than 300-fold below the NOAEL for developmental and reproductive alterations

New Supplemental Developmental Toxicity Study: Design and Maternal Toxicity

- In 2019, IMOA commissioned a supplemental toxicity study (OECD TG 414 guideline complaint GLP) at CRL to extend the dose range
- Dose levels: 0, 80, or 120 mg Mo/kg/day (diet) on GD 6-21
- Included postnatal recovery groups at 0 and 120 mg Mo/kg/day
- Moderate and marked maternal toxicity at 80 and 120 mg Mo/kg/day, respectively.
- Far exceed the 20% decrease in maternal weight gain considered excessive by experts

New Supplemental Developmental Toxicity Study: Evaluation of Offspring

- Reduction in fetal body weight proportionate to maternal effects
- Postnatal evaluations confirmed no adverse effect on pup growth to weaning.
- No adverse effect on the incidence of external, visceral or skeletal malformations or variations.
- Slight differences in ossification status at 120 mg Mo/kg/day were confirmed as transient by skeletal exams of pups at PND 21 and were consistent with the fetal weight alterations

Change in Mean Fetal and Corrected Maternal Body Weight Relative to Controls on GD 21

Dose, Mg Mo/kg/day	Change in mean fetal body wt relative to controls, %	Change in corrected maternal body weight relative to controls, %
3	+0.5	0
10	0.0	0
20	0.0	0
40	+0.5	0
80	-11	-12
120	-22	-24

Benchmark Dose (BMD) Evaluation of the Alterations in Fetal Body Weight

- IMOA commissioned a benchmark dose (BMD) analysis by Bruce Allen
- Combined the results of the Murray et al. (2014) and Hoberman (2021) studies
- BMD approach is considered superior to the NOAEL approach by many regulatory agencies
- ATSDR considered BMD approach for its oral MRL
- Allen evaluated BMD05 and BMDL05 for fetal body weight, the most sensitive alteration, using several approaches
- EPA scientists have confirmed the validity of this approach

Allen's Benchmark Dose (BMD) Results

Modeling Approach	BMR Definition	BMD05, mg Mo/kg/day	BMDL05, mg Mo/kg/day
Continuous	5% relative decrease	57	47
Continuous	0.5 std. dev. Decrease	47	37
Nested Dichotomous	5% extra risk of small fetus	56	45

Implications of the New Developmental Toxicity Study and the BMD Analysis

- There is as much as a 3.4-fold difference between the BMD and the POD of 17 mg Mo/kg/day for mild kidney effects
- ATSDR has already applied and embedded an uncertainty factor of 3 for developmental/reproductive alterations
- For an essential element, the ATSDR MRL represents a dose level that is approximately 1000-fold less than the BMD05 for developmental alterations
- In conclusion, the results of the new developmental toxicity study (Hoberman 2021) and the BMD analysis very strongly indicate that there is no need to apply a MF of 3 to the POD for mild kidney effects of 17 mg Mo/kg/day

New Developmental Toxicity Study with a “Marginal” Copper Diet

- Supplemental study, sponsored by Climax, is designed to evaluate whether Fungwe’s results can be replicated
- Address comments from WQCD about Cu-Mo interaction
- Study was started in December 2021 at Charles River Laboratory (Horsham, PA)
- Female rats are receiving a semi-synthetic diet (AIN-93G) containing approximately 6.3 ppm copper (alleged concentration in Fungwe’s diet)

Issue

Applied MF of 3

- Never publicly noticed, appeared for the first time in the final Profile
- Not supported by the current science
- Results in double-counting
- Unprecedented for an essential element

Proposed resolution

Remove MF of 3

- Calculate the reference dose (RfD) accepting ATSDR uncertainty factor of 100 (10x10), and no modifying factor
- IMO and BMD studies support removal of MF
- Avoids concerns that MF was added without following proper process

- **RfD = 0.17 mg/kg-day**
 - Uses ATSDR recommended NOAEL of 17 mg/kg/day
 - Applies ATSDR's recommended UFs of 100 (10 for intraspecies, 10 for interspecies)
 - Does not apply an MF

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

where:

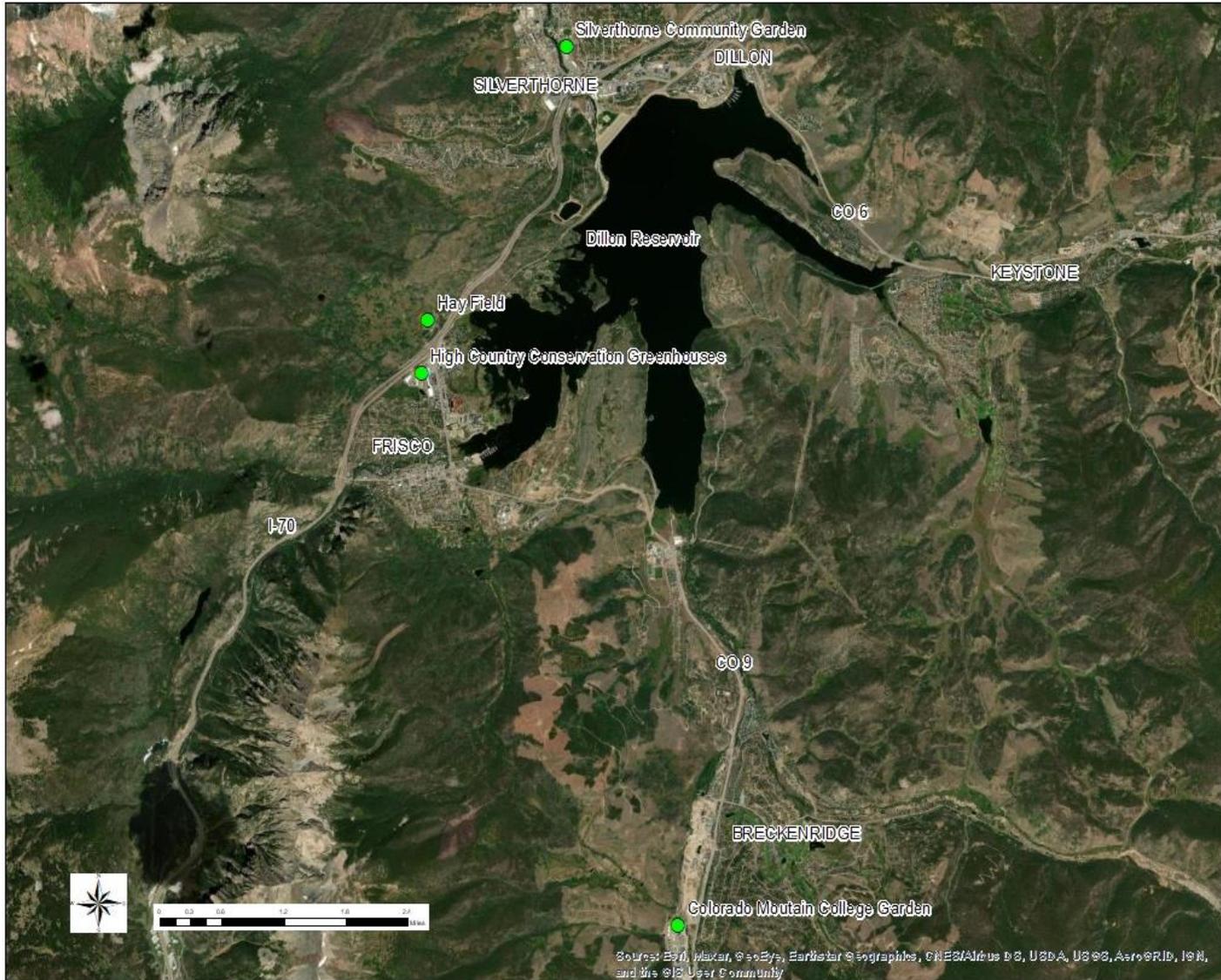
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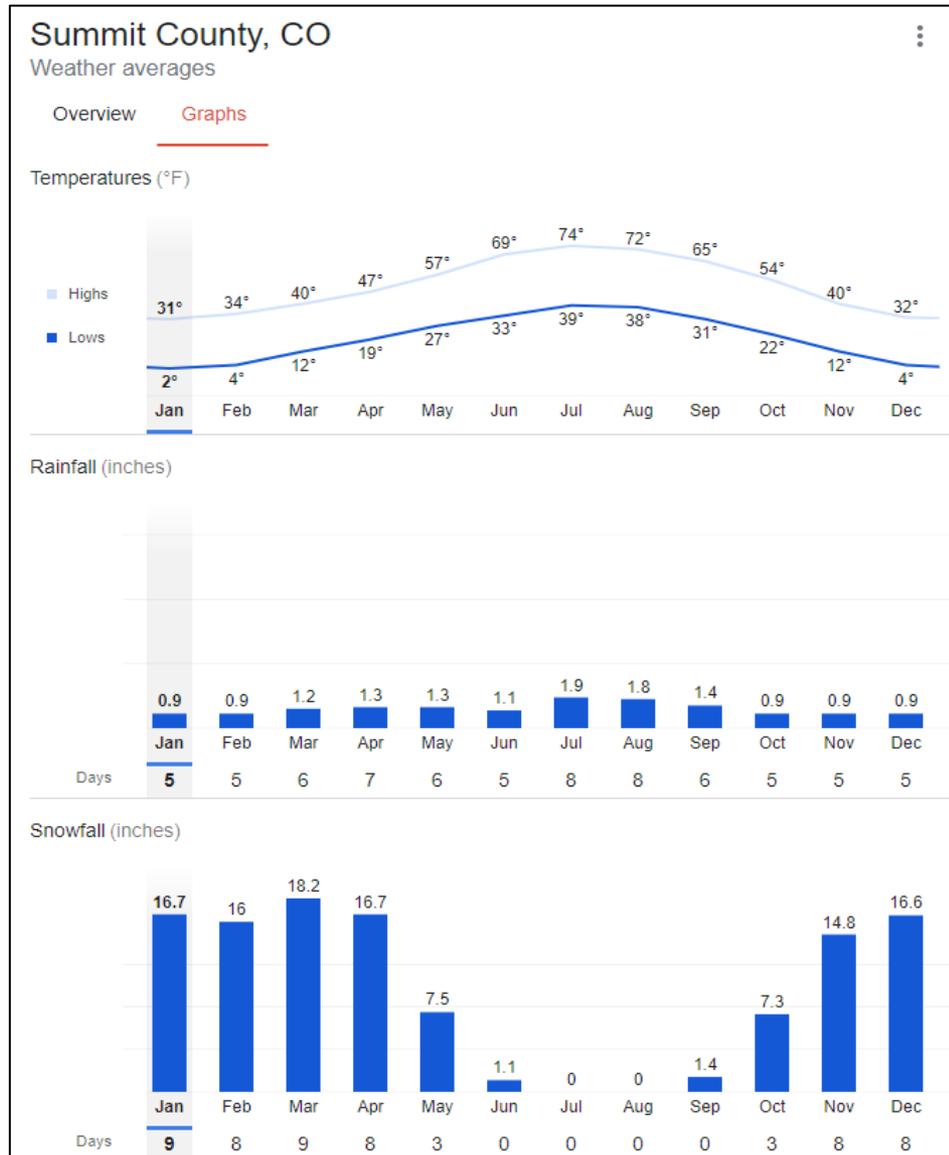
- RSC is fraction of acceptable Mo exposure allocated to drinking water as opposed to diet
 - EPA uses range of 0.2 – 0.8 RSC
 - Because dietary exposure to Mo is generally very low, in 2017 EPA recommended RSC of 0.8 (80% of exposure to Mo in drinking water)
- WQCD questioned whether dietary exposure to Mo could be higher in Summit County
 - Climax pursued a produce study

Relative Source Contribution from Diet (RSC)

- In 2021, Climax completed a produce study for Summit County to determine if Summit County residents are getting Mo in their diet from locally grown produce
- Items examined
 - Commercially Grown Produce
 - Local Green Houses
 - Farmers Markets
 - Climate

Produce Study





Conclusions from the produce study

- Found no local commercial growing of produce
- Local farmers markets sell other goods and produce from the Front Range or Grand Junction area
- The local green houses grow a limited amount of produce that does not utilize native soil
- Region does not have appropriate climate to support produce

➤ **RSC = 0.8**

- Uses national data on low dietary exposure to Mo
- Protective of Summit County residents in addition to residents statewide
- Not necessary to have a site-specific RSC applied for Summit County

- **Body weight = 80 kg; Drinking water intake = 2.4 L**
 - EPA values (updated in 2015) should apply as the Policy 96-2 factors are out of date and based on outdated science
 - Consistent with recent WQCC determinations in April 2020 Regulations 41, 42, and 31 rulemaking hearing
 - Consistent with WQCD position in December 2021 Policy 96-2 Administrative Action Hearing

- **RfD = 0.17 mg/kg/day**
 - Applies ATSDR's chosen NOAEL, and ATSDR's UFs
 - Removes MF based on unnecessary application and updated science
- **RSC = 0.8**
 - Applies EPA's recommended RSC from 2017, as further confirmed by the Produce Study
- **Body weight = 80 kg; Drinking water intake = 2.4 L**
 - Based on updated science, and approved by WQCC and WQCD

Policy 96-2 Equation with Updated Inputs: Two Scenarios

$$1: \text{ DWS/MCLG, } \mu\text{g/L} = \frac{0.17 \times 80 \times 1000 \mu\text{g/L} \times 0.8}{2.4 \times 1} = 4350 \mu\text{g/L (chronic)}$$

Where:

0.17 = Calculated RfD, in mg/kg/day

80 = weight of an average adult in kg

2.4 = daily drinking water consumption in liters/day

0.8 = RSC

$$2: \text{ DWS/MCLG, } \mu\text{g/L} = \frac{0.06 \times 80 \times 1000 \mu\text{g/L} \times 0.8}{2.4 \times 1} = 1600 \mu\text{g/L (chronic)}$$

Where:

0.06 = Calculated RfD, in mg/kg/day

80 = weight of an average adult in kg

2.4 = daily drinking water consumption in liters/day

0.8 = RSC

Treatment Alternatives

	Alternative 1	Alternative 1A	Alternative 2	Alternative 3
Description	Full Flow MRWTP with sand filters	Full Flow MRWTP without sand filters	MRWTP 75% of full flow	MRWTP 50% of full flow
CAPEX estimate <i>(Q3 2021 Dollars)</i>	\$112,000,000- \$118,000,000	\$81,000,000- \$87,000,000	\$91,000,000- \$97,000,000	\$69,000,000- \$75,000,000
OPEX estimate <i>(Q3 2021 Dollars)</i>	\$3,688,000	\$3,318,000	\$3,242,000	\$2,724,000
Flow at capacity, gpm	14,000	14,000	10,500	7,000
Molybdenum effluent criteria with low exceedance risk	210 ug/l	1,000 ug/l	4,330 ug/l	7,660 ug/l
Duration to implement <i>(2020 Estimate)</i>	3 yrs	2.5 yrs	3 yrs	3 yrs
Treatment Plant Still Needed after closure	Yes	Under Investigation	No	No

- Colorado's Mo standard is based on outdated science
- Resolution of the Mo standard is a high priority and needed to provide regulatory certainty
 - Dec 2019: WQCC said, "When the ATSDR toxicological profile becomes available, a hearing to consider a revised molybdenum standard will be scheduled expeditiously."
 - Climax has been working for 7+ years to resolve the uncertainty about the molybdenum standard
 - Ready to use the best information available to replace outdated science
 - Climax altered its mine plan to maintain "current condition" through resequencing of ore mining phases
 - Need resolution of the moly standard to develop the mine plan, including water treatment if necessary
- Advantages to prompt resolution:
 - Job creation, tax revenue, and generally further the ability of Climax to make impactful social investments in surrounding communities
 - Further responsible development of molybdenum resources to support global sustainable development including energy efficiency, low carbon power generation, environmental protection, resource conservation, and quality of life

- Proposal is ripe:
 - Adequate data and other information is available
 - Climax will continue to engage in stakeholder discussions, including this meeting
 - Fits within the legal framework
 - Need to resolve promptly
- Only two issues need to be resolved:
 - Does applying a 100 UF to calculate the RfD sufficiently account for uncertainty, without an additional MF?
 - Is an RSC of 0.8 supported?

- When?
 - Climax in discussions with WQCD and WQCC about schedule
 - Climax petition WQCC in late January to ask WQCC to set a hearing date
- Stakeholder discussions to try to arrive at consensus
 - January 11, 2022, 1:30–3:00 pm (this meeting)
 - Follow-up meeting TBD Spring 2022 (likely via Teams)
 - More discussions to be scheduled depending on stakeholder interest and time