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# Development of Colorado's Water Quality Standard for Molybdenum

January 11, 2022

 **Climax Molybdenum**  
A Freeport-McMoRan Company

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**FREEPORT**  
FOREMOST IN COPPER

- 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

- |             |  |
|-------------|--|
| <b>2007</b> | Water Quality Control Commission (WQCC) adopts standard of 35 µg/L in ground water (Reg. 41) based on 1961 Armenian study  |
| <b>2010</b> | WQCC adopts standard of 210 µg/L in surface water (Reg. 31) based on 1990 graduate student study (Fungwe)  |
| <b>2012</b> | 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   |
| <b>2014</b> | 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 |
| <b>2017</b> | WQCC continues a rulemaking hearing to consider revision of the standard to allow for ATSDR review   |
| <b>2018</b> | WQCC continues rulemaking and extends temp. mod.   |
| <b>2019</b> | 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](http://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 <sup>2</sup>	=	verified reference dose for non-carcinogens, mg/kg-day
70	=	weight of an average adult, kg
2	=	daily drinking water consumption, liters/day
RSC <sup>3</sup>	=	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

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- 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

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- 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

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- 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

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- 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

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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

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- 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

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- 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

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### 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

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### 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:

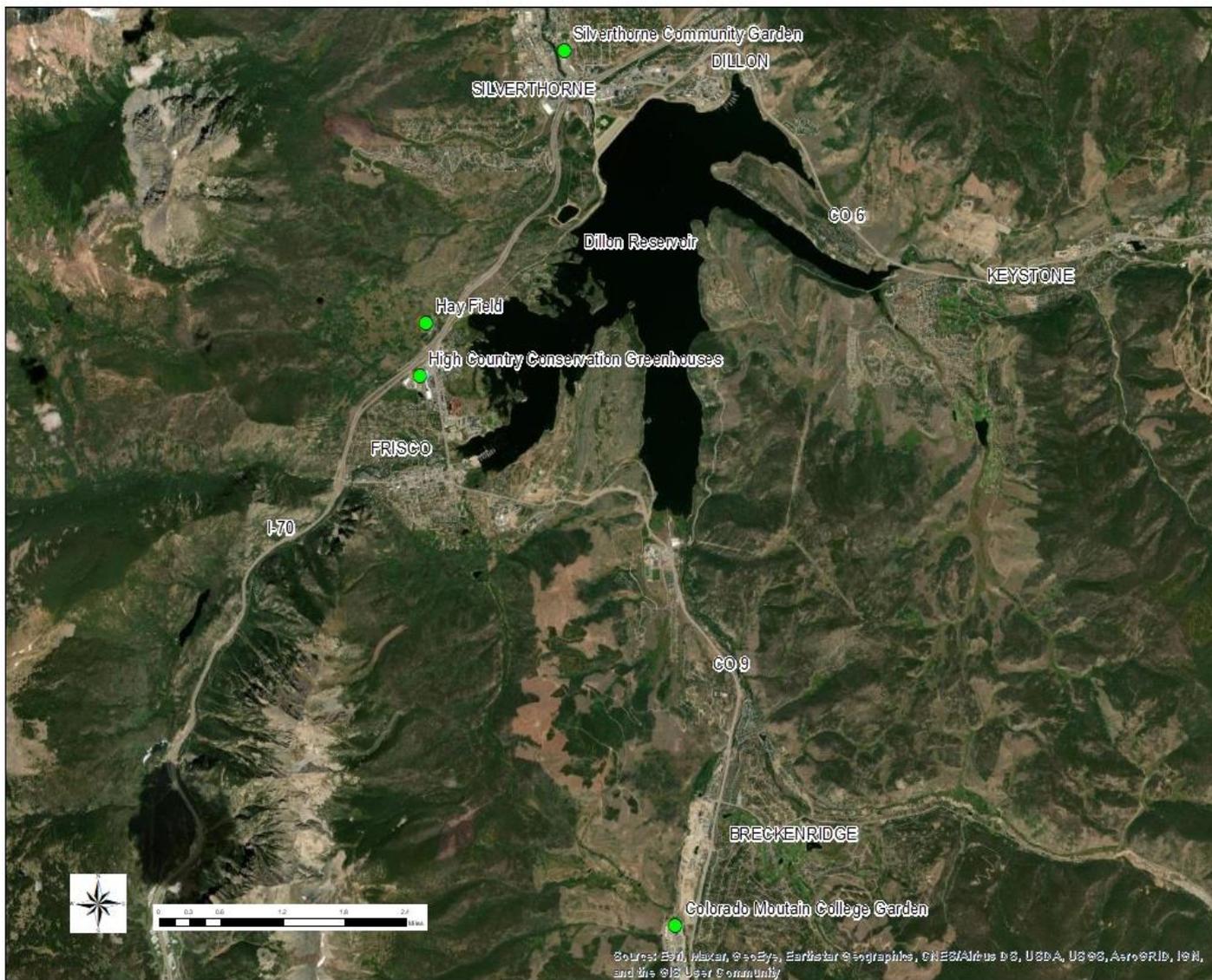
RfD <sup>2</sup>	=	verified reference dose for non-carcinogens, mg/kg-day
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RSC <sup>3</sup>	=	relative source contribution (0.2 is default value)
UF	=	Uncertainty Factor (1.0 for most chemicals, 10 for certain Group C chemicals)

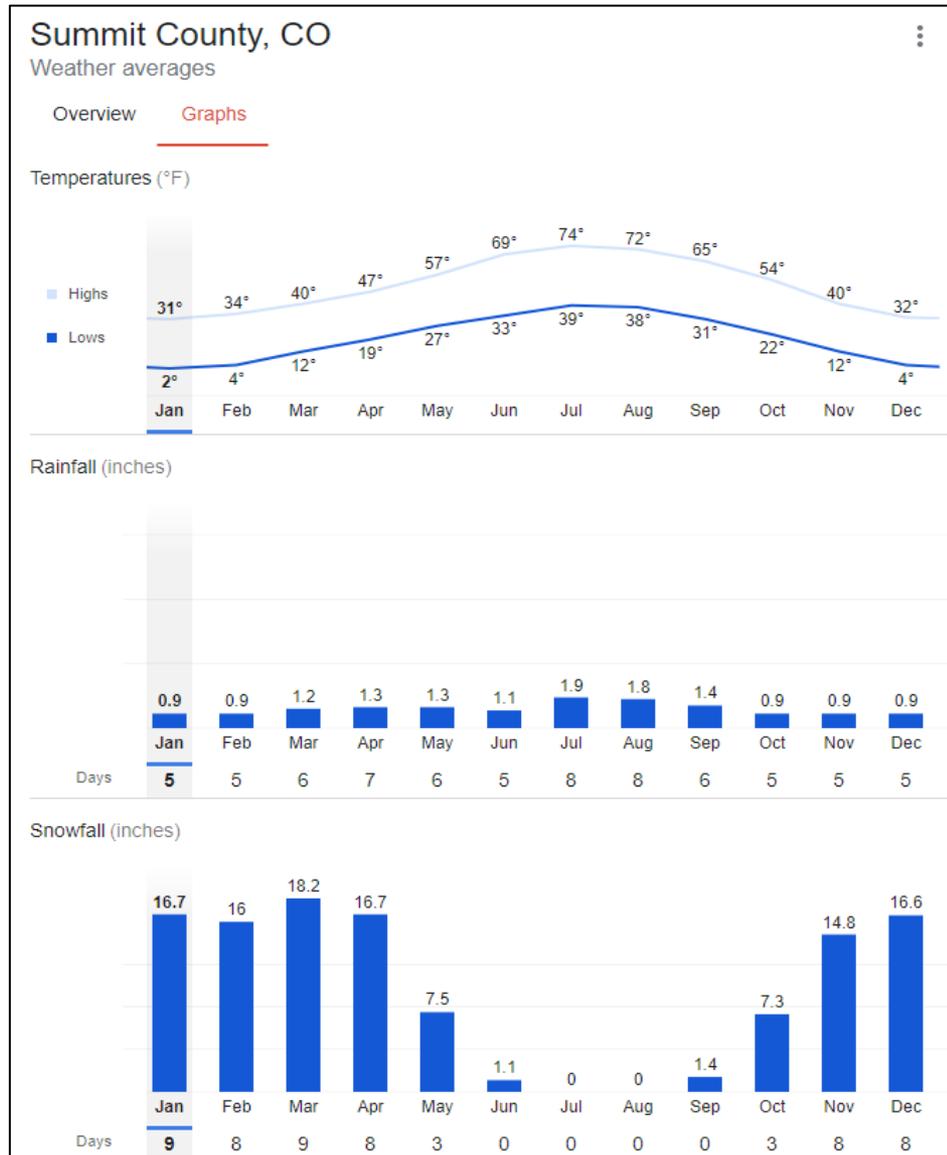
- RSC is fraction of acceptable Mo exposure allocated to drinking water as opposed to diet
  - EPA uses range of 0.2 – 0.8 RSC
  - Because dietary exposure to Mo is generally very low, in 2017 EPA recommended RSC of 0.8 (80% of exposure to Mo in drinking water)
- WQCD questioned whether dietary exposure 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

	<b>Alternative 1</b>	<b>Alternative 1A</b>	<b>Alternative 2</b>	<b>Alternative 3</b>
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