



Pennsylvania Senate Environmental Resources & Energy Committee Hearing

September 9, 2020

PADEP Proposed Rulemaking: "Water Quality
Standards for Manganese and
Implementation"

Statement of Dr. Lisa A. Bailey

Overview of Analysis and Conclusions

- At the request of the Pennsylvania Coal Alliance (PCA), Gradient reviewed the derivation of the Pennsylvania Department of Environmental Protection (PADEP) Proposed Manganese (Mn) Ambient Water Quality Criterion (0.3 mg/L) and whether the criterion is necessary to protect human health
 - The proposed standard of **0.3 mg/L is overly conservative** and not consistent with the current state of the science for Mn and human health effects.
 - The current **1 mg/L Mn water quality standard is protective** for human consumption.
- It is a **highly unlikely scenario that people would use untreated surface water as their main drinking water source**
 - Pennsylvania's public drinking water systems must supply drinking water that meets the Secondary Maximum Contaminant Level (MCL) of 0.05 mg/L Mn (odor and staining).
 - Application of the criterion at the point of intake is health protective, including for other potential surface water uses (swimming and fishing).

Background on Manganese Essentiality and Health Effects

- Mn is an essential nutrient needed for normal functioning of the human body (bones and brain development).
- At high occupational exposure concentrations (*via* inhalation), Mn can lead to adverse neurological effects.
- No current human studies are available that provide evidence for an oral Mn dose that leads to adverse health effects.
- United States Environmental Protection Agency (US EPA) Integrated Risk Information System (IRIS) Mn Toxicity Assessment (1995, updated 2002):
 - Mn oral reference dose (RfD) based on upper tolerable dietary intake for Mn (considered safe), and not on adverse health effects.
 - US EPA also recommends a modifying factor (MF) of 3 be applied to the RfD (non-food pathways, including drinking water).

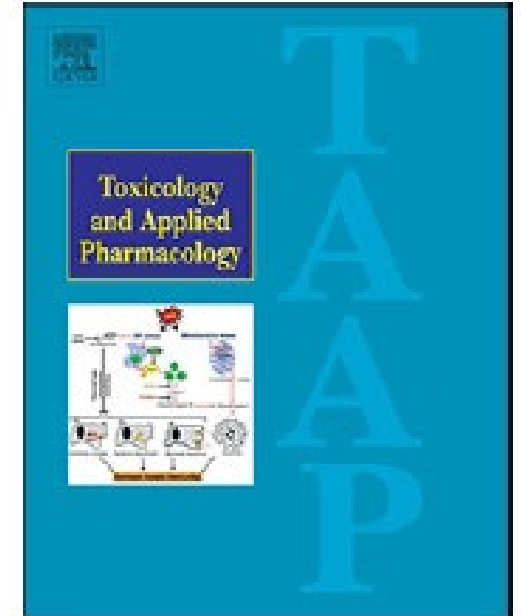


US EPA's Basis for Applying a Modifying Factor of 3 to the Manganese Reference Dose in 2002

- US EPA's Mn Toxicity Assessment (2002) indicates:
 1. Some studies suggested possible adverse health effects following a lifetime consumption of 2 mg/L Mn in drinking water;
 2. Concern for possible increased uptake of Mn from water vs. food, particularly in infants.
- However, there was no conclusive evidence in 2002 to support either concern:
 - US EPA noted that the human drinking water studies had many limitations, and none were of sufficient quality to derive a Mn oral RfD.
 - US EPA described a key study that reported no difference in bioavailability in uptake of Mn from food and water.
 - US EPA provided no evidence for increased uptake in fasted individuals.

Current Science for Manganese Provides Evidence that a Modifying Factor of 3 is No Longer Necessary

- Several Physiologically Based Pharmacokinetic (PBPK) models for Mn have been developed since 2002.
- Recent application of these PBPK models by Song *et al.* (2018) and Yoon *et al.* (2019) provide evidence that:
 1. Mn is not more bioavailable in drinking water compared to food;
 2. Mn is not more readily absorbed in formula-fed infants compared to breastfed infants, or compared to children and adults; and
 3. Mn drinking water concentration of 1 mg/L does not alter Mn brain concentrations beyond normal levels for all age groups evaluated (adults, teens, children, toddlers, infants).

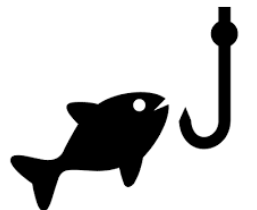


Recent Manganese Community Drinking Water Studies Have Many Limitations

- PADEP rationale document discusses several recent community studies that reported possible associations between Mn in drinking water and intellectual impairment in children.
- However, these studies have many limitations that make it impossible to attribute the reported effects to Mn (ATSDR, 2012; Health Canada, 2019).
 - Cross-sectional study design (one point in time, not over an exposure period).
 - Studies included limited (or sometimes no) individual exposure evaluations.
 - Potential for other factors to influence outcome (other contaminants, caregiver IQ, home environment).

Conclusions

- Based on the most current and scientifically robust information available, a MF of 3 is not needed for human health risk evaluation of Mn in drinking water; therefore, the proposed **0.3 mg/L criterion is not necessary to protect human health.**
- Removal of the MF of 3 from the proposed Mn water quality criterion results in **the current 1 mg/L criterion that is protective for human consumption.**
- Mn surface water concentrations 40-fold higher than 1 mg/L are **health-protective for swimming and fish ingestion.**
 - 40 mg/L Mn in surface water is much higher than what is typical in the US, and much higher than what would be expected in surface water bodies upstream of a surface potable water supply withdrawal.
 - Federal requirements limit Mn concentrations in treated discharge from coal mining operations to a monthly average of 2 mg/L.



Thank you! Questions?