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Independent Regulatory
Review Commission

Testimony of Dr. Lisa Bailey:

PADEP Environmental Quality Board meeting on September 8, 2020

Regarding the Proposed Rulemaking for the "Water Quality Criterion for Manganese and Implementation" (PADEP July 25, 2020 Bulletin)

- Hello – and thank you for the opportunity to provide testimony today on Pennsylvania DEP's Proposed Rulemaking for the water quality criterion for manganese. My name is Dr. Lisa Bailey. I am a principal scientist employed by Gradient, an environmental consulting firm in Boston, Massachusetts. I have more than 20 years experience in the field of human health risk assessment and toxicology, and have extensive experience evaluating potential human health risks from exposure to manganese in air, water, and soil.
- At the request of the Pennsylvania Coal Alliance, I and my Gradient colleagues have reviewed the derivation of the Pennsylvania DEP proposed water quality criterion for manganese of 0.3 mg/L, and whether that criterion is necessary to protect human health.
- **Based on our analysis, we conclude that the proposed criterion is overly conservative and is not consistent with the current state of the science for manganese and human health effects. As I will describe further, the current 1 mg/L manganese water quality criterion is protective for human consumption.**
- In addition, it is very important to keep in mind that it is highly unlikely that someone would use untreated surface water as their main source of drinking water. The drinking water that most PA citizens consume will be after the water is treated to meet the manganese secondary maximum contaminant drinking water level of 0.05 mg/L (which is based on odor and staining and not on adverse health effects, and is well below the 0.3 mg/L proposed surface water criterion).
- **Therefore, not only is the proposed criterion overly protective regardless of where in the surface water body it is applied, the proposed criterion is based on a hypothetical scenario that will almost never occur, providing support that application of the criterion at the point of intake is health protective. In fact, our analysis found that application of the criterion at the point of intake is also health protective for more typical surface water uses, such as swimming and fishing.**
- It is important to keep in mind that manganese is an essential nutrient needed for normal functioning of the human body. However, at high exposure concentrations, mostly observed from high occupational exposures *via* inhalation, manganese can cause adverse neurological effects. As for oral exposures, there are no studies currently available that provide reliable evidence of an oral manganese dose in humans that leads to adverse effects.
- Therefore, unlike other substances for which EPA has derived oral reference doses based on studies of adverse health effects, the manganese reference dose derived by EPA in 1995 and last reviewed in 2002 is not based on a study of adverse health effects, but instead is based on an upper tolerable dietary intake level of manganese that is considered safe. The Pennsylvania DEP proposed manganese water quality criterion relies on this reference dose, and on a modifying factor of three applied to that reference dose that is also recommended by EPA for evaluating risk from non-food exposure pathways, including drinking water.
- The main reasons EPA describes as supporting the need for application of the modifying factor are: 1) some studies suggested possible adverse health effects in humans following a lifetime consumption of 2 mg/L Mn in water, and 2) there was concern for possible increased uptake of manganese from water compared to food, particularly in infants.
- However, our review of the studies available at that time indicates that there was no conclusive evidence to support either of these concerns.

- In fact, EPA described a number of limitations in the human drinking water studies and noted that none of the human studies were of sufficient quality to use to derive an oral manganese reference dose.
- EPA also described a key study that found no significant differences in the bioavailability of Mn from food and water. Although EPA discussed possible increased uptake of Mn in fasted individuals as an additional basis for the MF of 3, there are no published studies that provide support for this concern.
- Since EPA's last review of its evaluation for manganese in 2002, more data have become available that provide support for removal of the modifying factor of three. In particular, recent application of a physiologically-based pharmacokinetic (PBPK) model for Mn published in two studies by Song *et al.* (2018) and Yoon *et al.* (2019) provides further evidence that:
 1. Manganese is not more bioavailable in drinking water compared to food;
 2. Manganese is not more readily absorbed in formula-fed infants compared to breastfed infants, or compared to children and adults; and
 3. Manganese drinking water concentrations of 1 mg/L did not alter Mn brain concentrations beyond normal levels for all age groups evaluated.
- Therefore, we conclude, based on the most current scientific information available, that a MF of 3 is not needed for risk evaluation of manganese in drinking water.
- Removal of the modifying factor of three from Pennsylvania DEP's proposed Mn water quality criterion results in the current 1 mg/L criterion that is protective for human consumption.

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[on behalf of the Pennsylvania Coal Alliance]