



North American Metals Council

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September 23, 2020

Via Docket Submission

Kristina Thayer, Ph.D.
U.S. Environmental Protection Agency
Office of Research and Development
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Re: Integrated Risk Information System Assessment Plan for Oral
Exposure to Vanadium and Compounds; Docket Number EPA-
HQ-ORD-2020-0183

Dear Dr. Thayer:

The North American Metals Council (NAMC)¹ is pleased to submit this letter regarding the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) assessment plan for oral exposures to vanadium and compounds. We applaud EPA's efforts to develop an assessment plan for vanadium and its compounds. NAMC expresses, here, however, concerns related to process considerations and unique hazard assessment issues presented by metals.

NAMC urges the IRIS Program to consider carefully the comments submitted by the Vanadium Producers & Reclaimers Association (VPRA),² an NAMC member. NAMC endorses those comments and incorporates them by reference here. As VPRA points out, the IRIS review of vanadium and its compounds is unique, because it is not confined to a single chemical species of vanadium such as elemental vanadium. The IRIS Program includes the

¹ NAMC is an unincorporated, not-for-profit organization serving as a collective voice for North American metals producers and users. NAMC is a leader for the metals industry on science- and policy-based issues affecting metals.

² VPRA, its members, and consultants are respected industry experts on vanadium chemistry and toxicology.



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entire class of inorganic vanadium compounds. This diverse and complex scope includes four possible oxidation states (+2, +3, +4, +5), 23 species, and nine charges that include both anions and cations (Kelsall *et al.*, 1993). The IRIS assessment plan EPA outlined identifies more than 140 primary studies and more than 1,000 studies as relevant supplemental information. This complexity, which is characteristic of metals in contrast to organic compounds, necessitates a particularly careful and deliberate hazard assessment process, and requires that distinctions be drawn among the various forms of vanadium where appropriate to ensure scientific integrity.

With that in mind, NAMC is concerned from a process standpoint on the time line that EPA is following as it begins this IRIS review. The *Federal Register* announcement for the first public meeting on the IRIS assessment plan for Oral Exposure to Vanadium and Compounds (Scoping and Problem Formulation Materials) (July 2020) was not published until July 24, 2020, which gave the public less than one month to prepare. The IRIS Program, however, convened the public stakeholder meeting on August 19, 2020, despite VPRA's timely request for a postponement. NAMC urges EPA to be more mindful of the stakeholder community's desire to engage meaningfully and to proceed administratively more aware of the need for time and advanced notice to facilitate public participation.

NAMC is also concerned that EPA initiated this review before an oral drinking water study has been completed by the National Toxicology Program (NTP) at EPA Office of Water's request. The dose-response assessment phase of the IRIS review for vanadium and compounds, however, was initiated by the EPA Office of Water, which is the same entity requesting the toxicity studies that remain underway at NTP on vanadyl sulfate (+4) and sodium metavanadate (+5). NTP has indicated its intent to publish the data by the end of the year; therefore, beginning an IRIS assessment without NTP's key data may prove to be premature and consequently, not robust.

Given the concerns outlined above, NAMC urges EPA to facilitate public engagement and consider stakeholders' desire to provide robust comment on the unique issues associated with the assessment of vanadium and its compounds in all future IRIS assessments. The insufficiency of time and inadequate notice provided to stakeholders to submit a meaningful review and provide input do not align with the most basic requirements of the Administrative Procedure Act and due process.



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Thank you for the opportunity to submit these comments.

Sincerely,

William J. Adams, Ph.D.
NAMC Chair