November 15, 2018

Via Docket Submission

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460–0001


Dear Sir or Madam:

The North American Metals Council (NAMC)\(^1\) and the National Mining Association (NMA)\(^2\) are pleased to submit these comments in response to the U.S. Environmental Protection Agency’s (EPA) notice of availability of its document, “A Working

\(^1\) 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.

\(^2\) NMA is a national trade association whose members produce most of the nation’s coal, metals, and industrial and agricultural minerals; are the manufacturers of mining and mineral processing machinery, equipment, and supplies; and are the engineering and consulting firms, financial institutions, and other firms serving the mining industry.
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Approach for Identifying Potential Candidate Chemicals for Prioritization” (Working Approach Document) and to request an opportunity to meet with EPA regarding prioritization approaches specific for metals and metal substances under the Toxic Substances Control Act (TSCA).


While NAMC and NMA appreciate that EPA acknowledged its intent to follow the Framework for Metals Risk Assessment (Metals Framework) as part of its response to comments, we believe it would be appropriate to include a reference to the Metals Framework as part of EPA’s Working Approach Document, as well as an express statement that EPA acknowledges its statutory requirement to follow the Metals Framework for prioritization and risk evaluation for metals and metals compounds.

Given that much of the Working Approach Document focuses on assessment approaches for organic substances, it is important for EPA to clarify that such approaches are not applicable to metals and metal substances. In Section 7, as part of its discussion on binning the TSCA Inventory, EPA outlines five components that would be used to calculate a score but does not highlight considerations needed to calculate scores for these components for metals. Application of these components for metals will require a different approach than it would for organic chemicals. For example, Section 7.3, “Human Hazard-to-Exposure Ratio Component,” does not address naturally occurring substances, nor does it consider whether the substance is essential for maintaining proper health of humans, animals, plants, and microorganisms. These two factors are critical for metals and metal substances. Likewise, Section 7.7, “Persistence and Bioaccumulation Component,” does not include a discussion on bioavailability, which is a critical factor for metals risk assessment.

NAMC and NMA recognize the scientific complexities associated with metals risk assessment issues, and as such, do not anticipate that EPA should revise its Working Approach Document to incorporate fully the Metals Framework. We do, however, respectfully request that EPA include a citation or reference to the Metals Framework in the Working Approach Document for the administrative record so stakeholders are aware of the alternative approaches necessary for metals and metal substances. We would also recommend referencing the Organization for Economic Cooperation and Development’s (OECD) December 19, 2016, document, “Guidance on the Incorporation of Bioavailability Concepts for Assessing the
Chemical Ecological Risk and/or Environmental Threshold Values of Metals and Inorganic Metal Compounds.\footnote{Available at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2016)66&doclanguage=en.}

If EPA has made a determination as to how it intends to apply the Metals Framework for purposes of metal risk prioritization, it should issue its proposed approach for public input as soon as practicably possible.

**Metals on the TSCA Work Plan Do Not Meet the Factors for Identifying Candidate Chemicals under the Near Term Approach**

NAMC and NMA believe that the metals and metal substances currently listed on the 2014 TSCA Work Plan do not meet two of the three factors selected by EPA to identify candidate chemicals in the near term.

In its Working Approach Document, EPA states that three factors will be considered in selecting potential chemicals for prioritization in the near term: (1) whether prioritization of the chemical is dictated by overarching EPA and other federal priorities; (2) the quantity and quality of information available for the chemical; and (3) the expected workload involved in EPA’s evaluation of the chemical. While NAMC and NMA acknowledge that the metals listed on the TSCA Work Plan have extensive data sets and, thus, could satisfy factor (2), we do not believe they meet the other two factors listed. NAMC and NMA are not aware of any specific interests or needs from EPA or other federal agencies for the metal substances listed on the TSCA Work Plan. Concerning workload issues, as already noted, the metal substances on the TSCA Work Plan will need to be assessed using the Metals Framework, which may not be well known or understood among current EPA staff and would add to the near-term resource constraints given the statutory deadlines for risk evaluations under TSCA.
For these reasons, NAMC and NMA respectfully recommend that the metal substances currently on the TSCA Work Plan not be included in the upcoming prioritization process.

**Request for Scientific Workshop**

NAMC and NMA believe EPA would benefit greatly from a technical workshop with metals experts to enable EPA risk assessment staff to engage in a scientific dialogue on the Metals Framework, the availability of new tools specific for assessing metals and metal substances, and the application of these concepts in a risk prioritization/screening approach. We hope EPA agrees, and we would welcome an opportunity to meet with EPA to discuss the merits of this suggestion. We hope to schedule such a meeting before the end of 2018.

Thank you for the opportunity to submit these comments.

Sincerely,

Kathleen M. Roberts  
NAMC Executive Director

Tawny A. Bridgeford  
NMA Deputy General Counsel & Vice President, Regulatory Affairs