North American Metals Council
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National Mining Association

October 31, 2024

Via Electronic Docket
Via E-Mail

Ms. Sarah K. Soliman
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Re: Comments on the Pre-Prioritization and Consideration of Existing Chemical Substances for Future Prioritization Under the Toxic Substances Control Act (TSCA) (EPA-HQ-OPPT-2023–0606)

Dear Ms. Soliman:

The North American Metals Council (NAMC) and the National Mining Association (NMA) submit these comments in response to the U.S. Environmental Protection Agency's (EPA) notice regarding the pre-prioritization and consideration of existing chemical substances for future prioritization under the Toxic Substances Control Act (TSCA).[1] Specifically, NAMC and NMA have a direct interest in EPA's inclusion of the following four metals on the updated candidate list: antimony and antimony compounds, arsenic and arsenic compounds, cobalt and cobalt compounds, and lead and lead compounds. For the reasons provided below, we strongly urge EPA to not include these metals or metal compounds in the next round of prioritization. Instead, NAMC and NMA invite EPA to engage in a formal dialogue with the metals industry on important scientific updates related to assessing metals and metal compounds, and the application of these concepts in a risk prioritization/screening approach.

NAMC is a non-profit organization serving as a collective voice for North American metals producers and users. Members include trade associations and individual companies. NAMC has been a leading voice for the metals industry on science- and policy-based issues affecting metals. The organization has worked closely with the U.S. federal and international agencies to address risk assessment issues unique to metals at various stages of their lifecycle -- sourcing, production, engineering, use, recycling, and recovery.

[1] 89 Fed. Reg. 68894 (Aug. 28, 2024).

NMA represents America's mining industry, which supplies the essential materials necessary for nearly every sector of our economy -- from technology and healthcare to energy, transportation, infrastructure, and national security. NMA is the only national trade organization that serves as the voice of the U.S. mining industry and the hundreds of thousands of American workers it employs before Congress, the federal agencies, the judiciary, and the media, advocating for public policies that will help America fully and responsibly utilize its vast natural resources.

1. EPA Must Consult the *Framework for Metals Risk Assessment* throughout the TSCA Prioritization Process

When initiating prioritization on any metal or metal compound and throughout the prioritization process, EPA must consult and use its own *Framework for Metals Risk Assessment* (*Metals Framework*).[2] Metals exhibit unique characteristics that make it inappropriate and unreasonable to evaluate and prioritize metals and metal compounds using the general hazard evaluation principles applied to organic (carbon-based) chemicals. Metals are not the same as organic chemicals and do not conform to the general risk principles for organic chemicals. Risk factors for a metal depend on -- among other things -- the specific metal, the form of the metal and/or metal compound, the bioavailability of the metal to particular organisms, whether it is an essential element, and the organism's ability to regulate and/or store the metal. Certain traits used to screen, assess, or prioritize organic compounds, such as bioaccumulation and persistence, are not appropriate for assessing the hazard of metals.

Importantly, EPA recognized in the *Metals Framework* that: "metals present unique risk assessment issues, and [the] need to develop a framework document that puts forth key scientific principles for metals risk assessments to help ensure consistency in metals assessments across EPA programs and regional offices."[3] EPA's *Metals Framework* further explains:

> The purpose of this document is to present key guiding principles based on the unique attributes of metals (as differentiated from

[2] EPA, *Framework for Metals Risk Assessment* (Mar. 2007), available at https://www.epa.gov/sites/default/files/2013-09/documents/metals-risk-assessment-final.pdf.

[3] EPA, Office of Science Advisor, Fact Sheet on Framework for Metals Risk Assessment (Mar. 8, 2007), available at https://archive.epa.gov/raf/web/html/factsheet.html.

> organic and organometallic compounds) and to describe how these metals-specific attributes and principles may then be applied in the context of existing EPA risk assessment guidance and practices. While organic compounds, for example, undergo bioaccumulation, there are unique properties, issues, and processes within these principles that assessors need to consider when evaluating metal compounds. Furthermore, the latest scientific data on bioaccumulation do not currently support the use of bioconcentration factors and bioaccumulation factors when applied as generic threshold criteria for the hazard potential of metals.[4]

The unique characteristics of metals and how they should be addressed in a risk assessment framework are often ignored in discussions of chemical management systems, leading to consequences that sometimes are irrational and commercially crippling, even though unintended. That is why TSCA now requires EPA to use the *Metals Framework* in identifying priorities for risk evaluation for metals and metal compounds.[5]

2. Prioritizing Metals for the Next Round of Risk Evaluations Does Not Meet EPA Prioritization Criteria

NAMC and NMA believe that the metals and metal compounds 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 "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization"[6] (Working Approach Document), EPA states that three

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4 *Metals Framework* at xiv.

5 TSCA § 6(b)(2)(E), 15 USC § 2605(b)(2)(E) ("In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.").

6 EPA, "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization" (Sept. 2018), available at https://www.epa.gov/sites/default/files/2018-09/documents/preprioritization_white_paper_9272018.pdf. *See also* EPA, Assessing and

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 appreciate that EPA acknowledged its intent to follow the *Metals Framework* as part of its response to comments on the Working Approach Document, EPA did not include a reference to the *Metals Framework* as part of EPA's Working Approach Document. EPA also did not expressly state that it acknowledges its statutory requirement to follow the *Metals Framework* for prioritization and risk evaluation for metals and metal compounds. Yet, EPA acknowledges in its final rule, "Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act":

> In the context of prioritization, EPA interprets the Metals Framework provision in TSCA to require EPA to take into account the special attributes and behaviors of metals and metal compounds as described in the Framework document. For example, the document's Key Principles discuss the differences between inorganic metals and organic and organometallic compounds, and their attributes, properties, issues, and processes associated with metals and metal compounds.[7]

EPA staff, during its September 30 and October 1, 2024, webinars, "Prioritization of Chemical Substances Under TSCA," did not reveal whether EPA, in fact, used this important document in applying the Working Approach Document and selecting the updated candidate list for prioritization. Given that much of the Working Approach Document focuses on assessment approaches for organic substances, it is important for EPA to acknowledge publicly that such approaches are not applicable and were not applied to metals and metal compounds during the

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Managing Chemicals under TSCA, Identifying Existing Chemicals for Prioritization under TSCA, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/identifying-existing-chemicals-prioritization-under.

7 82 Fed. Reg. 33753, 33756 (July 20, 2017).

prioritization process.[8] This is the first time EPA has selected metals for the candidate list. Accordingly, NAMC and NMA request more transparency from EPA on how it has used the *Metals Framework* in selecting the following four metals and metal compounds: antimony, arsenic, cobalt, and lead.

Turning to the factors EPA considers in selecting chemical substances for prioritization in the near term, NAMC and NMA acknowledge that some metals listed on the 2014 TSCA Work Plan have extensive data sets and, thus, could satisfy factor (2). Other metals, such as cobalt, are currently undergoing a multi-year and multi-million-dollar research program to fill critical scientific data gaps and, therefore, do not satisfy this factor.

Regardless, we do not believe metals meet the other two factors listed based on the information provided by EPA. First, NAMC and NMA are not aware of any specific interests or needs from EPA or other federal agencies for the metals and metal compounds listed on the TSCA Work Plan. EPA did not provide any information in its September 30 and October 1, 2024, webinars announcing the updated candidate list related to this factor and the selection of the four metals and metal compounds. Accordingly, we are not able to comment further on the validity of any identified EPA or other federal priorities.

Second, NAMC and NMA are concerned that the unique characteristics of metals will complicate EPA's ability to complete the prioritization and risk evaluation process without first completing necessary training on recently peer-reviewed science. EPA indicates that workload is an important factor in the overall consideration of chemical substances selected for

[8] NAMC previously explained in comments concerns related to Section 7 of the Working Approach Document and the discussion on binning the TSCA Inventory. EPA outlined five components that would be used to calculate a score but did not highlight considerations needed to calculate scores for these components for metals. Application of these components for metals requires a different approach than that of 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 compounds. Likewise, Section 7.7, "Persistence and Bioaccumulation Component," does not include a discussion on bioavailability, which is a critical factor for metals risk assessment.

prioritization. As discussed below, the metals and metal compounds 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. Indeed, officials from EPA's Office of Research and Development, Office of Water, and Office of Chemical Safety and Pollution Prevention have recognized that resources are needed to update the *Metals Framework* in a manner that reflects recent and ongoing scientific contributions in metals risk assessment research.

Importantly, two papers were recently published in peer-reviewed literature recommending specific updates to the *Metals Framework*.[9] The metals stakeholder community has been urging EPA to commit to this update as a strategic priority to inform properly the very tasks the TSCA program envisions with the current pre-prioritization listing for several metals. To date, EPA has not opened any informal or formal dialogues to explore these scientific developments and how they may be accepted as amendments to the *Metals Framework*.

The TSCA Work Plan 2014 Update states that "Some chemicals identified as 'high' through this scoring system may not necessarily be practical candidates for assessment under TSCA when other information is factored into the process. For example, the risks presented by certain chemicals may already be addressed by significant regulation under other statutes."[10] Such is the case for the four metals and metal compounds that EPA has identified as candidates for future prioritization for risk evaluation. We believe subjecting highly regulated metals and metal compounds to a TSCA risk assessment on a priority basis would consume EPA resources that should instead be spent on assessing other chemicals with little, if any, existing assessments and no or almost no regulation.

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9 Boreiko, C. 2024. Modelling of Local and Systemic Exposure to Metals and Metalloids After Inhalation Exposure: Recommended Update to the U.S. EPA Metals Framework. IEAM, 20(4): 951; Adams. W. J. and Garman, E. R. Recommended updates to the USEPA Framework for metals risk assessment: aquatic ecosystems, IEAM, (4):924.

10 EPA, "TSCA Work Plan for Chemical Assessments: 2014 Update" (Oct. 2014) at 2-3, available at https://www.epa.gov/sites/default/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.

3. Persistent, Bioaccumulative, and Toxic (PBT) As a Prioritization Factor Is Not Appropriate for Metals and Metal Compounds

EPA's 2014 TSCA Work Plan indicates that EPA uses a PBT approach to selecting chemicals for inclusion on its TSCA Work Plan. EPA staff, during its September 30 and October 1, 2024, webinars, stated that "[p]ersistence and bioaccumulation scores of three" and "[k]nown human carcinogens, and high acute or chronic toxicity" are particular characteristics that EPA is using to prioritize chemical substances from the 2014 TSCA Work Plan into the risk evaluation pipeline.[11]

PBT screening and criteria established for organic substances are not appropriate for assessing the potential hazards of metals and metal compounds. As EPA has explicitly acknowledged: "While organic compounds, for example, undergo bioaccumulation to some extent, there are unique properties, issues, and processes within these principles that assessors need to consider when evaluating metal compounds. Furthermore, the latest scientific data on bioaccumulation do not currently support the use of bioconcentration factors and bioaccumulation factors when applied as generic threshold criteria for the hazard potential of metals."[12] This same statement also appears in the *Metals Framework*.[13]

While we point out that EPA should recognize that PBT cannot be applied to inorganic substances such as metals and metal compounds, we also note that the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulations, for example, specifically recognize that PBT criteria do not apply to metals. The European Chemicals Agency (ECHA) *Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB assessment* states, "This Annex shall apply to all organic

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11 EPA, Materials from September 30/October 1, 2024 Webinar on Next Round of Chemicals Being Considered for Prioritization under TSCA (*see* Slides from the Webinars), available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/materials-september-30october-1-2024-webinar-next-round.

12 EPA, Office of Science Advisor, Fact Sheet on Framework for Metals Risk Assessment (Mar. 8, 2007), available at https://archive.epa.gov/raf/web/html/factsheet.html.

13 *Metals Framework* at xiv.

substances, including organo-metals. Annex XIII to the REACH Regulation is generally applicable to any substance containing an organic moiety. Based on the common definition of an organic substance in chemistry, PBT and vPvB criteria are not applicable to inorganic substances"[14]

Regarding persistence, we point out that all metals and elements on the periodic table are conserved[15] and hence, persistent. The form and availability of the metal can change (thereby affecting its potential bioavailability and toxicity), however, depending on the environmental conditions. Thus, a criterion set for organic chemicals' persistence automatically captures all metals, including those that are essential (iron, copper, zinc, molybdenum). As a result, applying criteria designed for organics to metals results in misleading assessments of potential hazards. A more discriminating approach is needed.

In relation to toxicity, metals are generally not readily soluble. Toxicity test results are typically based on soluble metal salts and frequently overestimate the bioavailability and the potential for toxicity of many metals and metal compounds, especially when the metals are present in massive forms or as insoluble metal sulfides and oxides.

Section 6(b)(2)(E) of amended TSCA directs EPA to use the *Metals Framework* to implement the prioritization and risk evaluation provisions of the statute.[16] Congress was very clear in its legislative mandate -- stating that EPA "shall use" the *Metals Framework* in identifying priorities for risk evaluation and for conducting risk evaluations on metals and metal compounds. Congress was clear that the *Metals Framework* is a relevant source of information for risk evaluation of metals, including information on the relevant prioritization screening criteria for metals. As discussed above, EPA developed the *Metals Framework* because it recognized that

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[14] European Chemicals Agency, *Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB assessment, version 4.0* (Dec. 2023) at 17, available at https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f?t=1498475968629.

[15] Law of Conservation of Mass is a relation stating that in a chemical reaction, the mass of the products equals the mass of the reactants. *See* https://www.thoughtco.com/definition-of-conservation-of-mass-law-604412.

[16] TSCA § 6(b)(2)(E), 15 U.S.C. § 2605(b)(2)(E).

metals have unique attributes that are different from organic and organometallic substances. The development process occurred over five years and included the creation of a Metals Action Plan (MAP), peer-review activities, public workshops, development of issue papers, engagement by other federal agencies, review by EPA's Science Advisory Board, and extensive peer consultation.

The *Metals Framework* includes approaches and guidance for characterizing potential hazards, including consideration that some metals are essential; in addition, this includes the assessment of exposure potential, including consideration of naturally occurring metals and metal compounds. These hazard and exposure characterizations are among the screening criteria included in TSCA Section 6(b)(1)(A). Indeed, EPA itself recognizes that persistence and bioaccumulation are relevant in the prioritization process, and the *Metals Framework* explains why metals and metal compounds must be treated differently from organic chemicals as far as these two characteristics are concerned. If metals are not properly characterized as articulated in the *Metals Framework*, their prioritization screening outcomes will be adversely impacted. NAMC and NMA believe that Congress recognized this potential, which is why it specifically required EPA to rely on the *Metals Framework*.

4. Conclusion

For these reasons, NAMC and NMA respectfully recommend that the metals and metal compounds currently on the TSCA Work Plan not be included in the upcoming prioritization process. Metals are irreplaceable components of modern technology to which no comparable alternatives exist, serve as the backbone of advanced energy technologies and critical infrastructure, are essential to defense and our national security, and contribute to protecting health and saving lives through medical devices. The United States must accelerate domestic minerals production to meet the Administration's goals for the nation's economy, national security, and energy future. Before proceeding with the prioritization of any metals or metal compounds, NAMC and NMA strongly 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 compounds, 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 recommendation in **early 2025**.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Bill Adams at adamsw10546@gmail.com or Tawny Bridgeford at tbridgeford@nma.org.

Respectfully submitted,

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