December 14, 2023

Submitted via https://www.regulations.gov

Michal Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Pennsylvania Ave. NW
Washington, DC 20004

RE: Proposed Rule, Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 88 Fed. Reg. 74,292 (Oct. 30, 2023), Docket No. EPA-HQ-OPPT-2023-0496.

Assistant Administrator Freedhoff:

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 of proposed rulemaking entitled "Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act" (TSCA).[1] EPA proposes to amend the procedural framework rule for conducting risk evaluations under TSCA Section 6. EPA's risk evaluations determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use.

Statement of Interest

NAMC is an unincorporated, not-for-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

[1] 88 Fed. Reg. 74,292 (Oct. 30, 2023).

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 and various stages of their lifecycle – sourcing, production, engineering, use, recycling, and recovery.

The 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. The 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.

NAMC and NMA filed joint comments on EPA's proposed risk evaluation rule in 2017.[2] Our members have a direct interest in this rulemaking given that several metals and metal compounds are listed on EPA's 2014 TSCA Work Plan.[3] EPA's changes to the risk evaluation framework will set a precedent for how metals and metal compounds are assessed in the future.

NAMC and NMA Comments

A TSCA Section 6 risk evaluation is the foundation for risk determinations and subsequent risk management actions. We are concerned that EPA's proposed revisions to the procedural framework for conducting risk evaluations would codify policy choices that would impede the risk evaluation and eventual risk management process. The proposed revisions and policy pivot from a condition of use to a whole chemical unreasonable risk determination, results in unreasonable risk determinations for most, if not all, chemical substances. Ultimately, this policy decision results in overly stringent risk management actions, as seen with the initial risk management rulemakings, especially since the unreasonable risk determinations are not based on the best available science.

---

[2] *See* Joint Comments by NAMC and NMA, *available at* https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0654-0058 (last visited Dec. 14, 2023).

[3] EPA, TSCA Work Plan for Chemical Assessments: 2014 Update (Oct. 2024), *available at* https://www.epa.gov/sites/default/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf (last visited Dec. 14, 2023). Metals and metal compounds of interest include antimony and antimony compounds, arsenic and arsenic compounds, cadmium and cadmium compounds, chromium and chromium compounds, cobalt and cobalt compounds, lead and lead compounds, molybdenum and molybdenum compounds, and nickel and nickel compounds.

We believe EPA's proposal would slow and complicate risk evaluations and impede meeting EPA's statutory deadlines due to the whole chemical approach; would fail to provide adequate notice to the regulated community of what uses are in the scope of a risk evaluation that could be regulated in a subsequent risk management action without appropriate public comment; and would not satisfy TSCA's statutory obligations for using the best available science and weight of the scientific evidence. Moreover, the proposed revisions would displace the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA) as the primary workplace regulators for chemical exposures, resulting in conflicting or duplicative regulatory requirements for workplaces.

We offer the following specific comments on this proposed rule.

I. We Support the Continued Use of the Framework for Metals Risk Assessment

EPA asserts that it "will use applicable EPA guidance when conducting risk evaluations, as appropriate and where it represents the best available science."[4] EPA further states that it will "evaluate chemical substances that are metals or metal compounds in accordance with 15 U.S.C. 2605(b)(2)(E)."[5] Congress clearly mandated that EPA evaluate metals using the approaches and guidance identified in the March 2007 Framework for Metals Risk Assessment[6] (Framework document), or a successor document. This Framework document was developed because EPA recognized that metals have unique attributes that are different from organic and organometallic substances. The Framework document includes approaches and guidance for characterizing potential hazards of metals (including consideration that some metals are essential) and for assessing the exposure potential of metals (including consideration of naturally occurring metals and metal substances). The Framework document also describes how these metal-specific attributes and principles may then be applied in the context of existing EPA risk assessment guidance and practices.

Since no successor document is available yet, EPA must continue to evaluate metals and metal compounds based on the Framework document. The

---

[4] 88 Fed. Reg. at 74,321.

[5] 15 U.S.C. 2605(b)(2)(E) states "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, Framework for Metals Risk Assessment, EPA 120/R-07/001 (March 2007) *available at* https://www.epa.gov/risk/framework-metals-risk-assessment (last visited Dec. 14, 2023).

regulatory language as it currently stands is clear regarding the congressional mandate to use the Framework document during the risk evaluation processes for metals and metal compounds. Therefore, NMA and NAMC strongly support EPA's continued mandatory use of the Framework document.

II. We Oppose Certain Revisions to the Risk Evaluation Procedural Framework

a. Occupational Exposure Assumptions

EPA states that it will no longer assume the use of personal protective equipment (PPE) in an occupational setting when making unreasonable risk determinations. Only where EPA has "reasonably available information that substantiates use and effectiveness of PPE (e.g., information demonstrating that performance of a condition of use is impossible in the absence of PPE)," will the agency "take that information into account in the risk determination."[7] In that circumstance, EPA would take "[t]he exposure reduction information (e.g., use of PPE) from the risk evaluation's exposure assessment" and "consider [] and incorporat[e] [it] in a future risk management action."[8] On the other hand, the agency would not consider "assumed" uses of PPE by workers as part of the unreasonable risk determination.[9] Notably, EPA would instead only focus on worker exposure "due to absence or ineffective use of [PPE]."[10]

EPA asserts that workers may be highly exposed to substances because they may not be covered by OSHA standards. According to EPA, "data on violations of PPE use suggest that assumptions that PPE is always provided to workers, worn properly, and effective at eliminating exposures are not justified."[11] At the same time, EPA states it "is not suggesting that there is widespread non-compliance with applicable OSHA standards."[12] Yet, EPA suggests that OSHA's limits are outdated and not effective, finding that OSHA exposure limits were "largely adopted in the 1970s and have not been updated since they were established."[13] However, just this year, OSHA

---

7 88 Fed. Reg. at 74,305.
8 *Id.*
9 *Id.*
10 *Id.*
11 *Id.* at 74,294.
12 *Id.* at 74,304.
13 *Id*.

published a guidance document detailing PPE requirements for employers to comply with safety and health standards.[14]

NMA and NAMC strongly disagree with EPA's assumptions regarding PPE use and their policy to disregard the use of PPE (or consider it to be ineffective) in occupational exposure scenarios embedded in a chemical substance's risk evaluation. We also strongly disagree with EPA's proposal to only consider uses of PPE in risk determinations when the performance of a condition of use is impossible in the absence of PPE. EPA's proposed approach unfairly and arbitrarily disregards the multitude of occupational hygiene programs designed to protect workers from the risks of chemical exposures and to enhance occupational safety overall. Our concerns also extend beyond EPA's treatment of OSHA's regulatory authority and safety programs and standards.

With respect to the mining industry, MSHA has primary regulatory authority on the health and safety of miners.[15] For example, MSHA has extensive safety and health standards for surface metal and nonmetal mines (30 C.F.R. Part 56[16]), safety and health standards for underground metal and nonmetal mines (30 C.F.R. Part 57[17]), health standards for metal and nonmetal mines (30 C.F.R. Part 58[18]), mandatory health standards for underground coal mines (30 C.F.R. Part 70[19]), mandatory health standards for surface coal mines and surface work areas of underground coal mines (30 C.F.R. Part 71[20]), and health standards for coal mines (30 C.F.R. Part 72[21]).

---

[14] OSHA Personal Protective Equipment 2023 Guidance Document, *available at* https://www.osha.gov/sites/default/files/publications/osha3151.pdf (last visited Dec. 14, 2023).

[15] MSHA's mission statement clearly states that it "works to prevent death, illness, and injury from mining and promote safe and healthful workplaces for U.S. miners." *See* MSHA, "Mission," *available at* https://www.msha.gov/about/mission (last visited Dec. 14, 2023).

[16] 30 C.F.R. Part 56 Subpart N- Personal Protection; 30 C.F.R. Part 56 Subpart Q- Safety Programs.

[17] 30 C.F.R. Part 57 Subpart N- Personal Protection; 30 C.F.R. Part 57 Subpart Q- Safety Programs.

[18] 30 C.F.R. Part 58 Subpart E- Miscellaneous.

[19] 30 C.F.R. Part 70 Subpart B- Dust Standards; 30 C.F.R. Part 70 Subpart C- Sampling Procedures.

[20] 30 C.F.R. Part 71 Subpart B- Dust Standards; 30 C.F.R. Part 71 Subpart C- Sampling Procedures; 30 C.F.R. Part 71 Subpart D- Respirable Dust Control Plans; 30 C.F.R. Part 71 Subpart H- Airborne Contaminants.

[21] 30 C.F.R. 72.700- Respiratory Equipment; Respirable Dust; 30 C.F.R. 72.701- Respiratory Equipment; Gas, Dusts, Fumes, or Mists; 30 C.F.R. 72.710- Selection, Fit, Use, and Maintenance or Approved Respirators; 30 C.F.R. 72.800- Single, Full-Shift Measurement of Respirable Coal Mine Dust.

Notably, MSHA directly addresses chemical safety and miners' use of PPE in its December 2020 handbook.[22] The handbook has an extensive chemical contaminants index describing applicable exposure limits, detailing PPE recommendations for that particular contaminant, and sampling methodology for over 100 contaminants.[23] Apart from posing a risk to worker health and safety, noncompliance with PPE and other safety violations can result in heavy monetary penalties, further dissuading noncompliance.[24] While EPA has completely ignored this important federal safety program, we expect the agency would treat MSHA similarly to OSHA in a future TSCA risk evaluation of chemical substances, such as metals. We therefore urge EPA to thoroughly analyze MSHA's regulations and to better understand the risk reduction and prevention measures that would properly inform occupational exposure scenarios and ultimately aspects of a reasonable risk determination.

In sum, we disagree with EPA's assumptions that the use of PPE is ineffective, that employers do not comply with requirements for the use of PPE, and that the use of PPE can be considered only in risk management decisions where a condition of use could not occur without the use of PPE. These assumptions should be rejected. We also disagree with EPA's view that federal occupational health and safety programs and standards are ineffective and not directly relevant to EPA's work under TSCA. EPA's proposal to dismiss such programs and standards rather than factoring them into the TSCA risk evaluation process is unlawful. We strongly urge EPA to consider other federal safety programs in the risk evaluation process rather than postponing any such consideration (if it is to occur at all) until the subsequent risk management process. We also recommend that EPA should use its authority under Section 9 of TSCA to defer risk management to the appropriate federal agencies, such as OSHA and MSHA.[25]

---

[22] *See* U.S. Department of Labor, MSHA Handbook Series: Health Inspection Procedures Handbook, PH20-V-4 (Dec. 2020), Chapter 9, *available at* https://arlweb.msha.gov/READROOM/HANDBOOK/PH20-V-4.pdf (last visited Dec. 14, 2023). *See also* U.S. Department of Labor, Mine Safety and Health Administration, Educational Field and Small Mine Services, "Personal Protection", *available at* https://arlweb.msha.gov/epd/efsms/toolbox/personal-protection.pdf (last visited Dec. 14, 2023).

[23] *Id.*, Attachment- Contaminant Index, *available at* https://arlweb.msha.gov/READROOM/HANDBOOK/PH20-V-4.pdf (last visited Dec. 14, 2023).

[24] 30 C.F.R. Part 100 (Criteria and Procedures for Proposed Assessment of Civil Penalties) and 30 C.F.R. Part 104 (Pattern of Violations).

[25] 15 U.S.C. § 2608.

b. Scoping

EPA states that it has the discretion not to provide an opportunity for public comment if it revises a final scoping document or final risk evaluation after the publication of that final document.[26] While changes from a final scoping document to the draft risk evaluation will be afforded public comment (as part of the regular comment period on the draft risk evaluation), no such public comment is given if changes from the draft to the final risk evaluation are only identified and discussed in the final risk evaluation. NMA and NAMC disagree with this proposed approach and urge EPA to allow public comment not only when changes are made to a final scoping document but also when changes are made to a draft risk evaluation.

c. Spills and Leaks

EPA asserts that it would expect to consider spills or leaks of a chemical as a condition of use "if known or reasonably foreseen to occur during a condition of use."[27] NMA and NAMC are concerned that EPA has provided no discernable standard. We believe this will lead to a lack of consistency and arbitrary results during a chemical risk evaluation, making it harder for chemical users to discern when spills or leaks will be considered for a particular "condition of use."

d. Aggregate Exposure and Cumulative Risk

EPA is suggesting in this proposal that TSCA authorizes EPA to take action on a "category of chemical substances" [28] the same way that it would take action on a single chemical substance.[29] EPA plans to use this for both aggregate exposure and cumulative risk assessment when evaluating risk. NMA and NAMC are concerned that EPA lacks a discernable standard when grouping chemicals.

e. Definitions of "Best Available Science" and "Weight of Scientific Evidence"

We are concerned that if EPA's proposal to eliminate the definitions for "best available science" and "weight of scientific evidence" is promulgated as final,

---

26 88 Fed. Reg. at 74,311-74,312

27 *Id.* at 74,298.

28 EPA explains that "categories of chemical substances" are defined as: "[a] group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment…" 15 U.S.C. § 2625(c)(2)(A).

29 88 Fed. Reg. at 74,305.

it will allow EPA to lower the scientific rigor of its risk evaluations performed under TSCA Section 6. Lack of rigor can be abused to be either over- or under-protective. It will also provide EPA with latitude in identifying and incorporating previously peer-reviewed information into its draft risk evaluations without justifying the use of such information when conflicting peer-reviewed information exists.

EPA's stated rationale for its proposal to eliminate the definitions for "best available science" and "weight of scientific evidence" is that these definitions inhibit "the Agency's flexibility to quickly adapt to and implement changing science."[30] EPA did not, however, provide examples of how these definitions inhibited its flexibility with adapting to changing science on the first ten final risk evaluations and other activities it has undertaken in support of its risk evaluations. Our concern is that EPA codified the definitions for these terms, yet now seeks to eliminate those definitions apparently, because EPA repeatedly failed to meet the requirements it established. It may be that revising regulatory definitions to accommodate flexibility while incorporating scientific changes is a valid and defensible reason for a proposed update, but we do not see evidence of this need. Rather, it is our view that EPA has frequently failed to meet the definitions it established, suggesting that EPA simply seeks to lower the standard and paper over issues related to lapses in scientific integrity.

Additionally, EPA stated that it will:

> rely on established Agency guidance documents to guide the required application of [weight of scientific evidence (WOSE)] in TSCA risk evaluations. At this time, EPA will primarily look to four documents for implementing WOSE in TSCA risk evaluations: 2016 Weight of Evidence in Ecological Assessment [citation omitted], Guidelines for Carcinogen Risk Assessment [citation omitted], 2011 Endocrine Disruptor Screening Program Weight-of-Evidence: Evaluating Results of EDSP Tier 1 Screening to Identify the Need for Tier 2 Testing [citation omitted], and 2022 ORD Staff Handbook for Developing IRIS Assessments [citation omitted].[31]

Our concern with the above approach is that the documents EPA cites are focused primarily on hazard and dose-response and do not provide metrics for informing the weight of scientific evidence for other evidence streams (*e.g.*, exposure). We recognize that EPA issued the 2021 Draft Systematic

---

30 88 Fed. Reg. at 74,295.

31 *Id.* at 74,311.

Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances (the 2021 Draft SR Protocol).[32] We note, however, that EPA has not issued this document in final. We further note that the TSCA Science Advisory Committee on Chemicals (SACC) concluded that the approaches in the 2021 Draft SR Protocol for integrating evidence in exposure and hazard "presents a complicated and potentially inefficient method for integrating data within the various disciplines." [33] We also note that EPA's use of the 2021 Draft SR Protocol would not satisfy its codified definitions of "best available science" and "weight of scientific evidence," yet with the elimination of these terms, EPA will have free reign to adjust the benchmark for how it determines scientific information meets the description of these terms under TSCA Sections 26(h) and 26(i), in the absence of codified definitions. EPA must be held to an objectively high scientific standard and not simply what EPA concludes is the "best available science" in any action or based on the preferences of any administration.

Conclusion

NMA and NAMC support EPA's proposed regulatory language at Section 702.37(a)(6), requiring EPA to continue using the 2007 Framework for Metals Risk Assessment when conducting risk evaluations of metals and metal compounds. Conversely, we strongly disagree with EPA's proposed occupational exposure assumptions, believe there is a need for greater clarity regarding the proposed treatment of spills and leaks and aggregate exposure/cumulative risk, and oppose eliminating the definitions for "best available science" and "weight of scientific evidence." Finally, we recommend that EPA provide greater opportunity for public comment on when changes are made to a final scoping document or a draft risk evaluation. NMA and NAMC strongly urge EPA not to codify the above-mentioned proposed changes.

---

[32] EPA, Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0 (Dec. 2021), *available at* https://www.epa.gov/system/files/documents/2021-12/draft-systematic-review-protocol-supporting-tsca-risk-evaluations-for-chemical-substances_0.pdf. (last visited Dec. 14, 2023).

[33] Science Advisory Committee on Chemicals, Meeting Minutes and Final Report No 2022-2, "Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0" held on April 19-21, 2022, at 17, *available at* https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0414-0044 (last visited Dec. 14, 2023).

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.

Sincerely,

Chairman
North American Metals Council

General Counsel and Senior Vice President, Regulatory Affairs
National Mining Association