



North American Metals Council
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March 20, 2017

Via Docket Submission

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Input on Proposed Procedures for Prioritization of Chemicals for
Risk Evaluation under Amended TSCA; Docket Number EPA–
HQ–OPPT-2016-0636

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) proposed process under amended Toxic Substances Control Act (TSCA) Section 6 for prioritizing chemicals for risk evaluation (82 Fed. Reg. 4825 (Jan. 17, 2017)).

EPA Cannot Ignore Congressional Mandate to Use Metals Framework Document

EPA suggests that Section 6(b)(2)(E) of amended TSCA, which directs EPA to use the March 2007 Framework for Metals Risk Assessment (Framework document) to implement the prioritization and risk evaluation provisions of the statute, will not be directly

¹ NAMC is an unincorporated, not-for-profit organization serving as a collective voice for the North American metals producers and users. NAMC has been a leading voice for the metals industry on science- and policy-based issues affecting metals. Our organization has worked closely with the U.S. federal and international agencies to address risk assessment issues that are unique to metals and various stages of their lifecycle -- sourcing, production, engineering, use, recycling, and recovery.

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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relevant during the prioritization process.³ But Congress was very clear in its legislative mandate -- stating that EPA “shall use” the Framework document in identifying priorities for risk evaluation and for conducting risk evaluations on metals and metal compounds.⁴ EPA does not have the discretion to conclude that the Framework document is not relevant for prioritization.

Moreover, NAMC and NMA strongly disagree with EPA’s contention that much of the Framework document is not applicable for the proposed prioritization process.⁵ While NAMC and NMA recognize that during prioritization, EPA will not be performing a full risk assessment, EPA states it “expects to evaluate all relevant sources of information while conducting the **screening review**”⁶ (emphasis added) and pre-prioritization considerations are intended to serve as a guide for the agency, “based on EPA’s current understanding of important considerations regarding potential **chemical risk**”⁷ (emphasis added).

Congress was clear that the Framework is a relevant source of information for risk evaluation of metals, including information on the relevant screening criteria for metals. TSCA Section 6(b)(1) requires EPA to establish a “risk-based screening process...” for prioritization. Since by law, prioritization is a risk screening, EPA must use the Framework document in its prioritization of metals and metal substances. As a reminder, the Framework document was developed because EPA recognized that 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 the EPA Science

³ 82 Fed. Reg. at 4827.

⁴ TSCA § 6(b)(2)(E), 15 U.S.C. § 2605(b)(2)(E).

⁵ 82 Fed. Reg. at 4827.

⁶ *Id.* at 4832.

⁷ *Id.* at 4830-4831.



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Advisory Board (SAB), and extensive peer consultation.⁸ The Framework document includes approaches and guidance for characterizing potential hazards, including consideration that some metals are essential; and assessing 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,⁹ and the Framework document 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 Framework document, their prioritization screening outcomes will be adversely impacted. NAMC believes that Congress recognized this potential, which is why it specifically required EPA to rely on the Framework document.

To properly reflect Congressional intent, the proposed regulatory text must be changed as follows:

Metals or metal compounds. In identifying priorities and screening criteria for chemical substances that are metals or metal compounds, EPA will, ~~as appropriate, refer to relevant considerations from the use,~~ among other sources, the Framework for Metals Assessment of the Office of the Science Advisor, Risk Assessment Forum, dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.¹⁰

⁸ EPA, Framework for Metals Risk Assessment, available at <https://www.epa.gov/risk/framework-metals-risk-assessment>.

⁹ 82 Fed. Reg. at 4826.

¹⁰ *Id.* at 4834-4835 (proposed 40 C.F.R. § 702.1(e)).



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Among the other sources that NAMC and NMA anticipate EPA will use in metal prioritization is 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."¹¹

Furthermore, the criteria included in 40 C.F.R. § 702.5 must be modified to ensure metals are properly screened.¹² The proposed regulatory text under 40 C.F.R. § 702.5(c)(1) should state that in evaluating persistence, bioaccumulation, and toxicity in the case of metals and metal compounds, EPA will apply the principles and factors set forth in the Framework document. Likewise, the regulatory text should indicate that a screening evaluation of metals used in children's products (40 C.F.R. § 705(c)(2)) and in consumer products (40 C.F.R. § 705(c)(3)) will take into account the bioavailability of the metal in those products. Finally, because metals are naturally occurring and many are essential to life, they will be detected in human or ecological biomonitoring programs. Accordingly, 40 C.F.R. § 702.5(c)(4) should not be a relevant consideration when evaluating metals as potential candidates for prioritization, and the text of 40 C.F.R. § 702.5 should make this clear.

Proposed 40 C.F.R. § 702.7(c)(7) Should Be Deleted

Proposed 40 C.F.R. § 702.7(c) sets forth screening criteria to be applied to candidates for High-Priority Substance designation. Six of these criteria reflect the legislative mandate in Section 6(b)(1)(A) of amended TSCA. But EPA proposes to add a seventh criterion, *viz.*, "[a]ny other risk-based criteria relevant to the designation of the chemical substance's priority, in EPA's discretion."¹³ NAMC and NMA strongly disagree with EPA's proposal to add this entirely discretionary criterion that is without grounding in the statute. If Congress intended to provide EPA full discretion to determine prioritization criteria, it would not have specified the six factors in the legislative text.

¹¹ Available online at [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2016\)66&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2016)66&doclanguage=en).

¹² 82 Fed. Reg. at 4835 (proposed 40 C.F.R. § 702.5).

¹³ *Id.* at 4836 (proposed 40 C.F.R. § 702.7(c)(7)).



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EPA Must Be Flexible in Assessing Conditions of Use

One of the weaknesses of the original TSCA was the lack of a specific approach for assessing existing chemicals. In response, Congress included a legislative requirement for EPA to prioritize chemicals for risk evaluation -- with some being designated as high-priority substances and some being designated as low-priority substances. As outlined in EPA's proposed prioritization process, however, essentially all chemicals will be identified as high-priority candidates based on the Agency's view that a chemical should be deemed a potential high-priority substance if there is a hazard and exposure under **any** condition of use, no matter how limited that condition of use may be.¹⁴ NAMC and NMA do not believe this was Congress' intent. If Congress had envisioned that all chemicals would be prioritized as high priority, why would it have mandated the prioritization process in the first place?

NAMC and NMA do not believe that Congress intended that every possible use of a chemical must be assessed. Instead, it anticipated that EPA would apply a cost effective and timely approach that would focus EPA efforts, particularly given the stringent timelines imposed by the legislative text. NAMC and NMA support the positions and reasoning outlined by the American Chemistry Council (ACC) regarding conditions of use. Indeed, for metal substances, we believe the current interpretation that EPA must assess each and every condition of use will result in a collapse of the process. EPA must consider a more pragmatic approach.

Furthermore, EPA should fully incorporate existing engineering controls and other workplace exposure reduction practices as part of a chemical's condition of use. Those practices are known circumstance under which a chemical is used and, therefore, should be reflected in the EPA evaluation.

EPA Should Provide Additional Details on Pre-Prioritization Process

EPA correctly states that the law does not direct or limit how EPA should select a chemical substance on which to initiate prioritization. The law did, however, direct EPA to prepare a risk-based screening process by rulemaking within one year of enactment. NAMC and NMA believe that part of that process should be clear information as to how a chemical is selected for prioritization. As currently proposed in 40 C.F.R. § 702.5, it is unclear to NAMC

¹⁴ See *id.* at 4835 (proposed 40 C.F.R. § 702.5(a)).



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and NMA how a chemical will be chosen for pre-prioritization review. Nor do we understand how EPA will gather the information under the pre-prioritization step to determine if the chemical can proceed to prioritization. For the public to know what chemicals are being considered for pre-prioritization, EPA will need to issue notification, and must allow for public review and comment. The EPA notice should indicate how the chemicals in question were evaluated, including how potential substitutes or alternative chemicals were evaluated.

NAMC and NMA urge EPA to provide greater clarity on the pre-prioritization process.

EPA Should Provide Clear Communications on High-Priority Designations

NAMC and NMA agree with the EPA statement that a high-priority designation is not an affirmation of risk and that priority designations “will need to be carefully communicated to the public.”¹⁵ EPA must be prepared to address this issue clearly, concisely, and comprehensively as it is likely that some groups will be quick to use the high priority chemical list as a “do not use” list.

Relevant Exposure Should be Factor in High Priority Designation

EPA should revise the regulatory text under proposed Section 702.7(b) to indicate that in selecting chemical candidates for high priority designation, EPA will consider those substances with the greatest hazard and *relevant* exposure potential.¹⁶ Many chemicals, including metal substances, may present a serious hazard (*e.g.*, carcinogenicity) through one route of exposure (*e.g.*, inhalation) but not another (*e.g.*, ingestion or dermal contact). The final rulemaking should clearly acknowledge that the relevance of the exposure route presenting the hazard will be considered before designating a chemical as high priority.

¹⁵ *Id.* at 4832, 4833.

¹⁶ *Id.* at 4835 (proposed 40 C.F.R. § 702.7(b))



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Thank you for the opportunity to submit these comments

Sincerely,

A handwritten signature in black ink, reading "Kathleen M. Roberts". The signature is written in a cursive style with a large, stylized "K" and "R".

Kathleen M. Roberts
NAMC Executive Director

A handwritten signature in black ink, reading "Tawny A. Bridgeford". The signature is written in a cursive style with a large, stylized "T" and "B".

Tawny A. Bridgeford
NMA Deputy General Counsel