



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 Chemical Risk Evaluation under  
Amended TSCA; Docket Number EPA-HQ-OPPT-2016-0654

Dear Sir or Madam:

The North American Metals Council (NAMC)<sup>1</sup> and the National Mining Association (NMA)<sup>2</sup> 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 conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use (82 Fed. Reg. 7562 (Jan. 19, 2017)).

While we appreciate EPA's hard work in developing the proposal, we are disappointed with the lack of specificity in the proposed risk evaluation process. Instead of providing meaningful insight as to how EPA will conduct risk evaluations under amended TSCA, EPA indicates generically that it will continue to use the same guidance and policies as in the past. There seems to be no consideration of revised or new approaches needed to assess new

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<sup>1</sup> 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.

<sup>2</sup> 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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technologies or consideration of better options for assessing current chemistries. Congress explicitly called on EPA to issue a rule on the risk evaluation process within one year of implementation. Had Congress felt that the past approaches and policies were adequate, it would not have directed EPA to promulgate such a rule. Given the critical importance of risk evaluation within the larger context of TSCA, it is imperative that all parties fully understand the process under which a chemical of interest will be assessed; that is not achieved with this proposal.

### **EPA Must Rely on Metals Risk Framework for Metals Risk Assessment**

Under Part II.B.6 - Background, Statutory Requirements for Risk Evaluation, Metals and Metal Compounds, the *Federal Register* notice states:

When evaluating metals or metal compounds, EPA must “use” the March 2007 Framework for Metals Risk Assessment of the Office of the Science Advisor (Ref. 8) or a successor document that addresses metals risk assessment and is peer-reviewed by the Science Advisory Board.<sup>3</sup>

It is unclear why EPA opted to put the word “use” in quotation marks in the notice. It seems to imply that EPA can rely on other options for evaluating metals and metal compounds, or otherwise invite an element of uncertainty or ambiguity that the law clearly does not reflect. Congress was uniquely clear in its mandate to EPA that risk evaluations of metals must rely on the approaches and guidance identified in the Framework for Metals Risk Assessment (Framework document), or a successor document. Given there is no successor document available, EPA must evaluate metals and metal compounds based on the March 2007 Framework document.

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 Advisory Board (SAB), and extensive peer

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<sup>3</sup> 82 Fed. Reg. at 7564-7565.



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consultation.<sup>4</sup> The resulting Framework document includes approaches and guidance for characterizing potential hazards of metals (including consideration that some metals are essential); and for assessing exposure potential of metals (including consideration of naturally occurring metals and metals substances). The Framework document also describes how these metals-specific attributes and principles may then be applied in the context of existing EPA risk assessment guidance and practices. As stated in the Framework document:

The Framework for Metals Risk Assessment is a science-based document that addresses the special attributes and behaviors of metals and metal compounds to be considered when assessing their human health and ecological risks. The document describes basic principles to be considered in assessing risks posed by metals and is intended to foster consistency in how these principles are applied across the Agency's programs and regions when conducting these assessments.<sup>5</sup>

As required by Congress, NAMC and NMA expect that for metals and metal compounds, EPA will apply the principles, approaches, and guidance contained in the Framework document in each step of the proposed risk evaluation process -- scoping, hazard assessment, exposure assessment, risk characterization, and risk determination. In addition, among 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."<sup>6</sup>

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<sup>4</sup> EPA, Framework for Metals Risk Assessment, available at <https://www.epa.gov/risk/framework-metals-risk-assessment>.

<sup>5</sup> *Id.* at xiv.

<sup>6</sup> 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).



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### **EPA Must Be More Pragmatic in Assessing Conditions of Use**

Metals and metal compounds are used extensively throughout today's society, including in agriculture, medicine, housing, infrastructure, transportation, telecommunications, and energy supply. EPA's interpretation that it must assess every condition of use in the risk evaluation of a chemical or category of chemical substances is impractical and unnecessary. NAMC and NMA do not believe Congress intended that every possible use of a chemical must be assessed. Instead, they anticipated that EPA would adopt a cost effective and timely approach that focuses assessment efforts on the most significant potential risks, particularly given the stringent timelines imposed by the legislative text. For example, if EPA is evaluating potential carcinogenic risks of a chemical that is carcinogenic only via inhalation, there is no need to assess conditions of use that involve only dermal exposure. NAMC and NMA support the positions and reasoning outlined by the American Chemistry Council (ACC) regarding conditions of use. Indeed, particularly for metal substances, we believe the current interpretation that EPA must assess each and every condition of use will result in 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.

### **NAMC and NMA Support Proposed Additional Elements for the Scoping Document**

NAMC and NMA support the proposed inclusion of information on models, screening methods, and policies expected to be relied on during the risk evaluation within the scoping document.<sup>7</sup> We also support the proposal to include an analysis plan with details on associated uncertainties and default assumptions.<sup>8</sup> This information will be helpful for stakeholders to understand how the chemical in question will be assessed.

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<sup>7</sup> 82 Fed. Reg. at 7578 (proposed 40 C.F.R. § 702.39(c)(3)).

<sup>8</sup> *Id.* at 7578 (proposed 40 C.F.R. § 702.39(c)(5)).



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### **More Details Needed on the Proposed Risk Evaluation Process, Definitions**

The proposed risk evaluation process does not provide clarity or transparency to stakeholders on how risk assessments will be conducted under amended TSCA. Instead, EPA references National Academy of Science (NAS) reports, existing policies, and current guidance documents. If Congress were satisfied with the current process, it would not have mandated a process rulemaking, with public review and comment. EPA needs to provide stakeholders with more information as to when and how default assumptions and uncertainty factors will be applied, what sources of information will be relied on, and what criteria will be used to assess data strengths and limitations. Referring to “accepted science policies” does not provide clarity.

NAMC and NMA are particularly disappointed that EPA declined to define key terms, including “best available science,” “weight-of-the-evidence,” and “sufficiency of information.” We disagree with EPA’s view that defining these terms will be “unnecessary and ultimately problematic.”<sup>9</sup> These terms and how they will be applied by EPA are the cornerstones for risk evaluation under TSCA. These definitions will also be important in implementation approaches for Sections 4 and 5.

NAMC and NMA oppose the proposed definition of “[p]otentially exposed or susceptible subpopulation,” as it is too broad and open-ended, particularly regarding the proposed inclusion of “acquired characteristics.”<sup>10</sup>

### **EPA Should Codify Interagency Collaboration**

While NAMC and NMA appreciate EPA’s stated commitment to ensure that interagency collaboration occurs, we believe it would be prudent to codify the process in the regulation.<sup>11</sup> Engagement with other agencies as part of the risk evaluation process will be an important activity and should not be left to chance. EPA should have a specific process laid out so stakeholders are aware when and how interagency communications and collaboration will take place. We do not see this limiting or complicating ongoing collaboration efforts.

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<sup>9</sup> *Id.* at 7572.

<sup>10</sup> *Id.* at 7576 (proposed 40 C.F.R. § 702.33).

<sup>11</sup> *Id.* at 7568.



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### **Manufacturer Request for Risk Evaluation on Metals and Metal Compounds**

The proposed regulatory text states that a manufacturer's request for a risk evaluation must include information on the chemical substance's persistence and bioaccumulation.<sup>12</sup> As is clearly laid out in the Framework document, metals and metal compounds should not be assessed by these criteria. The regulatory text should include a footnote or other provision that if the manufacturer request for a risk evaluation involves a metal or metal compound, information on persistence and bioaccumulation is not required. Instead, the manufacturer request should provide information on persistence of bioavailable forms of the metals or metal compounds.

### **Language in Certification Statement Is Excessive and Unnecessary**

NAMC and NMA believe that the last sentence in the proposed certification statement is excessive and unnecessary. As proposed, the certification statement would be:

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and the information contained therein, to the best of my knowledge is, true, accurate, and complete and I have not withheld any relevant information. I am aware there are significant penalties for submitting incomplete, false and/or misleading information, including the possibility of fine and imprisonment for knowing violations.<sup>13</sup>

Given the first sentence already references "under penalty of law," the second sentence, which is overly aggressive in tone, is simply not needed.

### **Timeframe for Public Comment on Draft Risk Evaluations**

NAMC and NMA believe the proposed no less than 30-day comment period for a draft risk evaluation is insufficient as it could result in a 30-day review period, which is far too

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<sup>12</sup> *Id.* at 7576 (proposed 40 C.F.R. § 702.37(b)(3)(ii)).

<sup>13</sup> *Id.* at 7576, 7577 (proposed 40 C.F.R. § 702.37(b)(5)).



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short.<sup>14</sup> Given the consequences of pending legal challenges impacted by the risk evaluation comments:

All comments that could be raised on the matters addressed and issues presented in the draft risk evaluation must be presented during this comment period. Any issues not raised at this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.<sup>15</sup>

EPA should provide for no less than a 60-day comment period on draft risk evaluations.

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Thank you for the opportunity to submit these comments.

Sincerely,

Kathleen M. Roberts  
NAMC Executive Director

Tawny A. Bridgeford  
NMA Deputy General Counsel

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<sup>14</sup> *Id.* at 7580 (proposed 40 C.F.R. § 702.45(a)).

<sup>15</sup> *Id.* at 7580 (proposed 40 C.F.R. § 702.45(a)(2)).