



North American Metals Council  
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January 25, 2018

Via Docket Submission

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

Re: Approaches for Identifying Potential Candidates for Prioritization  
for Risk Evaluation under Amended TSCA; Docket Number EPA-  
HQ-OPPT-2017-0586

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) request for comment on possible approaches for identifying potential candidate chemical substances for EPA's prioritization process under the Toxic Substances Control Act (TSCA) (82 Fed. Reg. 51415 (Nov. 6, 2017)), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. NAMC and NMA are pleased that EPA is soliciting public input on the pre-prioritization process referenced in the EPA January 17, 2017, proposal. NAMC and NMA had specifically identified pre-prioritization an issue of concern in its comments. We appreciate EPA hosting the December 11, 2017, workshop to review possible approaches and tools for identifying candidate chemicals for prioritization and for providing the opportunity to provide these written comments.

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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 is a leader for the metals industry on science- and policy-based issues affecting metals.

<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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### **EPA Should Adopt Understandable, Publicly Available Pre-Prioritization Process**

In the opening remarks at the workshop, EPA staff indicated that a potential outcome of its review of options and stakeholder input could be that no specific process is adopted. NAMC and NMA believe such an outcome would be ill-advised. To achieve full transparency on the critical processes under Section 6, stakeholders need to understand how a chemical could be selected for prioritization. They also need to understand how EPA will gather the information under the pre-prioritization step to determine if the chemical can proceed to prioritization. NAMC and NMA urge EPA to identify and adopt a transparent and coherent process or processes so all stakeholders are fully informed as to how TSCA risk evaluation can and will occur.

### **Discussion Document Approaches Do Not Address Inherent Metal Attributes**

In its “Discussion Document, Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization” (Discussion Document) and at the December 11, 2017, workshop, EPA reviewed six options:

1. The TSCA Work Plan as a Tool
2. Canada’s Chemicals Management Plan (CMP)
3. Utilizing Safer Chemicals Ingredients List
4. Functional Category Approach, Based on Use and Exposure Potential
5. Functional Category Approach, Based on Chemical Structure and Function
6. Integration of Traditional and New Approaches

NAMC and NMA are disappointed that none of the approaches reviewed takes into account the inherent differences between metal substances and organic substances. Indeed, the Discussion Document approaches include screening factors for persistence and bioaccumulation and, as stated by NAMC and NMA in past submissions, the screening approaches used to assess persistence and bioaccumulation for organic chemical substances are not appropriate for metals and metal substances. Rather, metals need to be screened and



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assessed based on bioavailability. With this in mind, whatever pre-prioritization approach is adopted by EPA, it must reference and incorporate the principles included in the March 2007 Framework for Metals Risk Assessment (Framework document).<sup>3</sup> Indeed, Section 6(b)(2)(E) of amended TSCA specifically directs EPA to use the Framework to identify priorities for risk evaluation for metals and metal compounds.<sup>4</sup> In addition, NAMC and NMA urge EPA to reference 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>5</sup> and the recently released book entitled, "Risk Management of Complex Inorganic Substances" published by Academic Press.

Additionally, if the pre-prioritization process EPA decides to adopt includes a screening factor for chemicals found in biomonitoring programs, it should also highlight that metals are naturally occurring and many are essential to life. As such, they will and should be detected in human or ecological biomonitoring programs, but such detection is not considered adverse. Accordingly, biomonitoring should not be a relevant consideration or screening factor when evaluating metals as potential candidates for prioritization.

On a separate but related note, NAMC and NMA also are concerned that the processes outlined in the Discussion Document do not seem equipped to screen properly Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCB Substances). Given the number of UVCBs on the TSCA Inventory, this exclusion could be problematic and should be addressed.

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<sup>3</sup> EPA, Framework for Metals Risk Assessment, available at <https://www.epa.gov/risk/framework-metals-risk-assessment>.

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

<sup>5</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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### **Possible Approaches Lack Detail on Chemical Selection, Determination of Data Robustness**

None of the proposed approaches fully explains how an individual chemical within the process would be selected. For example, if EPA uses the TSCA Work Plan as the approach for pre-prioritization, how will the next five or six chemicals be selected from the remaining chemicals on the list? Would they be selected randomly, and if so, by what randomization mechanism? Would staff choose them based on expertise with those chemicals or use patterns?

Likewise, none of the approaches provides details as to how a chemical would be assessed for data robustness. We understand that EPA does not wish to select a data-poor chemical in pre-prioritization because once the prioritization timeline starts, there is no exit ramp. EPA noted that a data-poor chemical going into the prioritization process would likely lead to a high priority designation based on lack of data. A high priority chemical automatically goes into the risk evaluation and without data, risk decisions would be based on default judgments, uncertainty factors, and assumptions, which could, in EPA's judgment, result in litigation. NAMC and NMA understand and support EPA's position but are concerned that the approaches listed in the Discussion Document do not specifically articulate how EPA will make the determination of data adequacy for a candidate chemical. If a possible approach for identifying potential candidate chemicals includes screening of ten hazard and/or exposure factors and a candidate chemical has data or can be assessed on five factors, is that considered robust enough? EPA needs to provide additional clarity in this area.

### **Pre-Prioritization Should Focus on Active Chemicals**

NAMC and NMA fully agree with EPA's position that pre-prioritization efforts should focus first on those chemicals listed as "active" on the TSCA Inventory. This allows EPA resources to be properly allocated to those chemicals that are likely in commercial distribution. NAMC and NMA note that inactive chemicals that are later notified as active will be subject to prioritization review as EPA determines necessary under TSCA Section 8(b)(5)(B)(IV).

### **Pre-Prioritization Should Focus on Chemicals Not Already Assessed**

NAMC and NMA note that one of the perceived failures of old TSCA was the lack of risk evaluation on existing chemicals. To address this issue, EPA should adopt a pre-



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prioritization approach that assesses whether a candidate chemical has already been reviewed. If, for example, a chemical has been evaluated under the old TSCA new chemicals review, it should receive a lower priority rating than a chemical that has not undergone new chemical assessment. NAMC and NMA are not suggesting that all chemicals assessed under the old TSCA process be given a final designation of low priority. Rather, NAMC and NMA believe that chemicals that have not undergone any assessment be among the first candidates to undergo prioritization. In addition to Section 5 reviews, EPA should also consider whether the candidate chemical has been evaluated under other regulatory or scientific programs, including the European Union Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program. Again, NAMC and NMA are not suggesting that these chemicals should be given a final designation of low priority, but NAMC and NMA recommend that EPA expend its limited time and resources in assessing chemicals that have not yet been evaluated. Re-evaluating chemicals that have already undergone a regulatory assessment under another program is unlikely to result in further protections to public health or the environment. Likewise, having an excessively large universe of chemicals to select from for pre-prioritization is not helpful. As it begins the pre-prioritization process, we believe EPA would be well-served to find opportunities to develop a manageable list of candidate chemicals, such as focusing on chemicals not yet assessed by other programs. The list can later be supplemented as EPA gains experience in the process.

### **Low Priority Designations**

NAMC and NMA strongly disagree with the EPA interpretation that amended TSCA requires the identification of only 20 chemicals as low priority. The legislation requires designation of *at least 20 within the first 3.5 years*, but that number cannot and should not be viewed as the final threshold number. We appreciate the EPA position in the Discussion Document that EPA is committed to exceeding 20 low priority chemical designations and suggest that EPA refrain from further indication that the legislation only anticipates 20 low priority designations in total.

### **TSCA Work Plan Chemical Approach**

The adopted pre-prioritization process cannot be predisposed to identifying high priority chemicals independent from chemical-specific data. The available data on the chemical should be the basis for a high or low priority determination; not the process. EPA has already stated that the current TSCA Work Plan approach is more aligned with designating chemicals as



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high priority. If EPA proceeds with adopting a version of the TSCA Work Plan approach, it will need to refine that approach so that low priority designations can occur.

Toward that end, NAMC and NMA support the suggestion during the December 11, 2017, workshop to re-review those chemical substances that were considered in the 2012 Work Plan review but were excluded because their hazard and/or exposure scores were low, as those chemicals may be candidates for a low priority designation.

### **Canada CMP Approach**

NAMC and NMA do not support the adoption of the Canada CMP approach for pre-prioritization. The CMP prioritization process did not include discriminatory functions for metals and the screening mechanism set up for organics did not work well for metals. Instead, an advisory expert group had to be formed to assist with interpreting the CMP regulations for metals and other inorganics.

### **Functional Approaches**

NAMC and NMA applaud EPA's interest in offering other approaches for pre-prioritization, including those that focus on functional categories. NAMC and NMA are concerned, however, that if data-poor chemicals are excluded from pre-prioritization screening within a functional category, but all the other chemicals are screened and potentially receive high priority designations, the data-poor chemical could gain a commercial advantage within that function simply because it was not screened. NAMC and NMA are also concerned that a number of factors to be assessed under the functional category approaches, such as number of workers or volume of chemical used per function, are reporting elements under the Chemical Data Reporting (CDR) rule that we are well aware often have severely conflated values due to duplicative reporting among CDR submitters.

### **Integration of Traditional and New Approaches**

NAMC and NMA believe that the final EPA approach will need to integrate older approaches with new scientific screening methods. We note, for example, support for re-evaluating the chemicals excluded from the 2012 TSCA Work Plan Chemicals list using newer screening methodologies, as we believe that will help identify some of those chemicals as low priority designations.



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NAMC and NMA do not support the suggestion made during the December 11, 2017, workshop that some of these approaches should be used to identify chemical alternatives within a category. While consideration of alternatives may be necessary within a risk evaluation process, that should not be occurring at the pre-prioritization step.

Thank you for the opportunity to submit these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Kathleen M. Roberts". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Kathleen M. Roberts  
NAMC Executive Director

A handwritten signature in black ink, appearing to read "Tawny A. Bridgeford". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Tawny A. Bridgeford  
NMA Deputy General Counsel