



North American Metals Council
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August 24, 2016

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 TSCA Section 6 Risk-Based Screening Process; Docket
Number EPA-HQ-OPPT-2016-0399

Dear Sir or Madam:

The North American Metals Council (NAMC) is pleased to submit these comments in response to the U.S. Environmental Protection Agency's (EPA) request for comment on the anticipated proposed rulemaking under Toxic Substances Control Act (TSCA) Section 6(b)(1)(A), under which EPA must establish a risk-based prioritization procedure.

The Prioritization Process Must Reflect EPA's Framework for Metals Risk Assessment

EPA recognizes that metals present unique risk assessment issues, and sees 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. (*EPA Fact Sheet on Framework for Metals Risk Assessment.*)

As mandated in TSCA Section 6(b)(2)(E), EPA shall use the [Framework for Metals Risk Assessment \(Metals Framework\)](#) in identifying priorities for risk evaluation for metals and metal compounds.¹ The prioritization process must reflect that metals exhibit unique characteristics that make it inappropriate to evaluate and prioritize metal substances using the general hazard evaluation principles applied to organic chemicals. The prioritization process should include consideration of key risk factors for metals that include -- among other things -- the specific metal, the form of the metal and/or metal compound, the bioavailability of the metal

¹ NAMC notes that metals and metal compounds are also specifically excluded from the expedited action under Section 6(h).



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to particular organisms, and the organism's ability to regulate and/or store the metal. As detailed in the Metals Framework, certain traits used to screen, assess, or prioritize organic compounds, such as bioaccumulation and persistence, are not appropriate for assessing the hazard of metals and should not be used as prioritization criteria.

**The Presence of Metals in Consumer Products
Should Not Be Presumed to Present a Health Risk**

NAMC urges EPA to consider relevant exposure routes when considering consumer uses in its prioritization process. In particular, NAMC cautions EPA that metals that might be used in consumer and children's products are not accessible via a pathway (*e.g.*, inhalation) that could potentially present a health risk (*e.g.*, lung cancer). It would be inappropriate for EPA to identify metals as high-priority chemicals under Section 6 merely because of their presence in consumer products when those metals are not accessible for biological impacts through a relevant route of exposure.

NAMC notes that many metals have been classified as "generally recognized as safe" by the U.S. Food and Drug Administration (FDA) and are used in food, vitamins, and cosmetic products, which should also be considered in the EPA prioritization process.

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Thank you for the opportunity to submit these comments. NAMC looks forward to reviewing the proposed rulemaking and engaging in further public review and comment.

Sincerely,

Kathleen M. Roberts
Executive Director