



North American Metals Council

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May 18, 2020

Via Docket Submission

U.S. Environmental Protection Agency  
Office of the Science Advisor  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Re: Strengthening Transparency in Regulatory Science; Docket  
Number EPA-HQ-OA-2018-0259

Dear Sir or Madam:

The North American Metals Council (NAMC)<sup>1</sup> is pleased to submit these comments in response to the U.S. Environmental Protection Agency's (EPA) supplemental notice of proposed rulemaking (SNPRM) to strengthen the transparency of EPA regulatory science (85 Fed. Reg. 15396 (Mar. 18, 2020)). We applaud EPA's efforts in addressing this important issue and support the goal of ensuring that the bases for EPA's regulatory decisions are transparent, while protecting confidential business information (CBI) and information critical for national security.

At the same time, we believe that "pivotal regulatory science" and "pivotal science underlying influential scientific information" should be based on the best available science -- as is called for in many of the programmatic environmental statutes that EPA administers, such as Section 26(h) of the Toxic Substances Control Act, 15 U.S.C. Section 2625(h). NAMC has observed instances in the scientific reference review process where EPA considered statements from published papers as factual, even though the statements were not supported by the data presented in the studies. It is, therefore, critical in the implementation of EPA's programmatic environmental statutes that EPA staff determine that the findings provided in all references on which EPA relies are aligned with and fully supported by the facts and data

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<sup>1</sup> NAMC is an unincorporated, not-for-profit organization serving as a collective voice for North American metals producers and users. NAMC is a leader for the metals industry on science- and policy-based issues affecting metals.



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presented in the scientific references. In addition, EPA should consider whether there is new knowledge that may either validate or supersede earlier findings that are relevant to the issue being addressed. EPA decisions should be evidence-based and fully transparent, including disclosure of areas of uncertainty and potential confounding of the data.

### **The SNPRM Appropriately Expands the Scope of the Rule to Cover All Scientific Data and Models Underlying Pivotal Science and Pivotal Regulatory Science, Not Just Dose-Response Models and Dose-Response Data**

NAMC supports the SNPRM proposal to set a foundation of transparency expectations along with specific policies and approaches that would apply to all agency programs when “pivotal regulatory science” and “pivotal science” are being used to justify “significant regulatory decisions” or “influential scientific information.” In particular, NAMC supports EPA’s expansion of the scope of the rule beyond dose-response data and dose-response models, since the rationale for transparency also applies to other scientific data and models that underlie “pivotal regulatory science” or “pivotal science.”

### **EPA Must Explicitly Address the Appropriateness of Using Linear, No-Threshold Dose-Response Assumptions in 40 C.F.R. Section 30.6**

EPA stated in the advance notice of proposed rulemaking (ANPRM) that one goal of this rulemaking is “to increase transparency of the assumptions underlying dose response models.”<sup>2</sup> At that time, EPA explicitly acknowledged the “growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects.”<sup>3</sup> EPA further explained that “[t]he use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions.” In comments on the ANPRM, NAMC supported EPA’s consideration of non-linear dose-response approaches to risk assessment in appropriate cases, including use in threshold models for metals. As NAMC explained, many metals are essential nutrients that result in non-linear dose-response toxicity

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<sup>2</sup> 83 Fed. Reg. 18,768, 18,770 (Apr. 30, 2018).

<sup>3</sup> *Id.*



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relationships. Yet, EPA often fails to consider appropriately or flat-out disregards non-linear dose-response approaches in assessing metals and metal compounds.

NAMC is disappointed that EPA has not carried over this approach into the SNPRM as originally proposed either in the regulatory text or the preamble. While EPA's proposed 40 C.F.R. Section 30.6 directs the agency to "evaluate the appropriateness of using default assumptions on a case-by-case basis," it does not specifically highlight the need to critically evaluate "assumptions of a linear, no-threshold dose response."<sup>4</sup> EPA rationalizes removing the language specific to "assumptions of a linear, no-threshold dose response" to eliminate any implication that the regulation is specific to those assumptions. NAMC believes that the agency can include a specific reference to "assumptions of a linear, no-threshold dose response" without implying that the agency should not evaluate other default assumptions. EPA can simply tweak the language in proposed 40 C.F.R. Section 30.6 to say: "EPA shall evaluate the appropriateness of using default assumptions on a case-by-case basis, including assumptions of a linear, no-threshold dose response and other default assumptions as appropriate."<sup>5</sup>

In the alternative, EPA must include in the preamble to the final rule a discussion specific to 40 C.F.R. Section 30.6 on the importance of considering non-linear dose or concentration-health effect response functions in assessing potential health risks associated with exposure to certain substances. EPA can simply carry over the discussion highlighted above from the ANPRM. The public needs to understand clearly why EPA selects particular models to evaluate dose-response effects of exposure to different substances and what uncertainty factors are included for the model chosen in regulatory decision-making for those substances. Public access to information on model selection and uncertainty factors is as important as transparency of underlying data. If the final rule fails to include this discussion, the agency has lost an important opportunity to guide regulators and the public on evaluating these underlying default models, particularly when they involve metals risk assessments.

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<sup>4</sup> 85 Fed. Reg. 15,400, 15,406 (Mar. 18, 2020) (to be codified at 40 C.F.R. Section 30.6).

<sup>5</sup> In the proposed 40 C.F.R. § 30.6, EPA lists certain "high quality studies" that "EPA shall give explicit consideration to." EPA's list does not foreclose the agency from considering other "high-quality studies" as indicated by the phrase "including but not limited to." EPA can use similar language in this instance as well.



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### **The Scope of the Transparency Rule Needs Clarification**

The SNPRM states that that rule “would apply to data and models evaluated at the time a significant regulatory action or influential scientific information is developed, regardless of when the data and models were generated.”<sup>6</sup> This situation raises two questions in our minds.

First, NAMC interprets “at the time [a rule] ... is developed” to mean that EPA will apply the transparency rule to the proposed rulemaking stage, if not sooner. That is, we interpret the rule to mean that data and models underlying any pivotal regulatory science or pivotal science that EPA might use in promulgating a significant regulatory decision or making influential scientific information final will be made available for analysis and comment in connection with the notice of proposed rulemaking. If NAMC’s interpretation is correct, we encourage EPA to clarify this point in the final rule. If it is not correct, we urge EPA to revise the rule to make clear that the proposed 40 C.F.R. Section 30.5 applies at the proposed rule stage as well as to the final agency action.

As noted in NAMC’s comments on the ANPRM, the proposed rulemaking stage is when public stakeholders will need to weigh in on potential concerns related to the scientific basis for EPA’s proposal and when efforts at independent validation of the relevant data might occur. Deferring public access to the “pivotal regulatory science” or “pivotal science” until the final rulemaking is issued is inappropriate, as it will be too late for active public engagement. NAMC is also concerned that the statement could be interpreted as excluding subsequent reanalysis of the data used to develop a rule during the period between the proposed rule and the final rule. Therefore, NAMC requests that EPA include language explicitly addressing data reanalysis in its final rule. As currently proposed, EPA has not specified how or when the public will be able to engage in the reanalysis of data or independent validation. Obtaining and reanalyzing data that are made public through this rule could take more time than has traditionally been provided to submit comments on a proposed rule. EPA must account for this step in the public comment process to allow meaningful engagement.

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<sup>6</sup> 85 Fed. Reg. 15,403 (Mar. 18, 2020).



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Second is the question of whether the rule will apply only to data and models that are developed in the future or also to existing data sets and models. Given the rule's goal of enhancing transparency in science, we believe that existing data and models should be covered if they underlie "pivotal regulatory science" in a rulemaking or "pivotal science" in the development of influential scientific information. In this regard, we note that while existing data and models would be covered by the rule under this approach, the proposed 40 C.F.R. Section 30.9 gives the Administrator discretion to grant a case-by-case exemption on impracticability grounds if the data or model at issue was completed or updated before the effective date of the final rule.

### **The Transparency Rule Should Apply to the IRIS Program**

NAMC urges EPA to apply the transparency rule to EPA's Integrated Risk Information System (IRIS) program and to clearly state as much when it promulgates the final rule. The IRIS program, which has functioned since 1985 as a science and risk assessment authority in the Office of Research and Development (ORD), identifies and characterizes the health hazards of chemicals. While the IRIS program was not established by statute, the work conducted by EPA under this program directly informs significant regulatory actions and decisions. As EPA acknowledges, IRIS assessments "[a]re the preferred source of toxicity information used by EPA" and are used in "set[ting] national standards and clean[ing] up hazardous sites."<sup>7</sup> That being the case, we presume that IRIS assessments and the toxicity values derived in those assessments would be considered "influential scientific information" within the meaning of proposed 40 C.F.R. Section 30.2, since EPA "reasonably can determine [that IRIS assessments and toxicity values] will have ... a clear and substantial impact on important public policies or private sector decisions." Yet, despite recent agency efforts,<sup>8</sup> the lack of full transparency in the IRIS program's development of toxicity values, as well as the inability to independently reproduce some of those values, continues to present obstacles to ensuring sound

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<sup>7</sup> EPA, *Basic Information about the Integrated Risk Information System*, available at <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system>.

<sup>8</sup> See National Academy of Sciences, "Progress toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation," National Academies Press (2018), available at <https://www.nap.edu/catalog/25086/progress-toward-transforming-the-integrated-risk-information-system-iris-program>.



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scientific decisions. Applying the principles of the transparency rule to IRIS assessments and allowing the public early access to the data and methods used by the agency is essential to safeguarding transparency in significant regulatory actions that rely upon IRIS toxicity values. Accordingly, EPA should make clear that the final transparency rule applies to data and models underlying pivotal science in IRIS assessments.

### **Tiered Approach for Regulatory Decisions Is Suitable**

NAMC commends EPA's efforts to apply science transparency to EPA decisions, while still acknowledging that, inevitably, there will be occasions in which EPA may have to rely on CBI and/or Personally Identifiable Information (PII). NAMC supports the SNPRM's modified regulatory text that provides greater scope to consider studies in which underlying data can be reasonably available through tiered access so that CBI, proprietary data, or PII remains protected while still allowing sufficient opportunity for independent validation.

Although NAMC generally supports the tiered approach as highlighted above, members are concerned that the overall language on tiered access is vague. NAMC believes that clarification on who would have access to CBI and PII would be helpful, accompanied by clarification on how the tiered access would work.

### **Exemption Proposal Is Apt**

NAMC supports the SNPRM modified scope on provisions for exemptions that the Administrator is authorized to grant on a case-by-case basis. NAMC commends EPA for providing clearer parameters as to when exemptions would be considered and the factors the Administrator would consider in determining whether to grant an exemption to the proposed public availability requirements for using data and models. NAMC agrees with EPA's proposal to consider technological barriers and the age of data and models in determining the feasibility of making underlying data and models publicly available.



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Thank you for the opportunity to submit these comments.

Sincerely,

William J. Adams, Ph.D.  
NAMC Chair