October 31, 2005

VIA E-Mail: Miller.tom@epa.gov

Mr. Tom Miller
Designated Federal Officer
EPA Science Advisory Board
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Comments on SAB Draft Report (9/15/05) on EPA's Draft Framework for Inorganic Metals Risk Assessment

Dear Mr. Miller:

The North American Metals Council ("NAMC") appreciates the opportunity to provide comments on the September 15, 2005, Draft Report prepared by the Science Advisory Board ("SAB") on EPA's Draft Framework for Inorganic Metals Risk Assessment. The SAB's Draft Report will be considered at the SAB teleconference on November 7, 2005, see 70 Fed. Reg. 60338 (October 17, 2005). NAMC is an unincorporated group of 30 metals-producing and-using associations and companies that focuses on science and policy-based issues that affect metals in a generic way. Its members include representatives of a broad cross-section of metals industries that have a strong interest in the scientific issues that are presented in the draft Framework.

NAMC has been actively involved in the issues that are the subject of the ongoing SAB review and submitted written and oral comments to the SAB panel during its deliberations. Our comments consist of the points made directly below in the text of this letter, briefly addressing specific points raised by the SAB Draft Report, as follows:

SAB Draft Report

Executive Summary: *Use of the term "Bioaccumulation" versus "Accumulation" to Describe Metals Concentrations…..* "The SAB believes it important to recognize that some metals do bioaccumulate in the tissues of humans and that this bioaccumulation is related to their toxicity."

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NAMC Comment:

The statement above does not clearly distinguish bioaccumulation and toxicity as separate concepts for assessment; nor does it reflect the fact that bioaccumulation/accumulation can occur in some organs without concomitant effects. If this point is retained, the emphasis should be changed from "bioaccumulation is related to toxicity" to "*toxicity is related to bioaccumulation*."

NAMC recommends the following clarifications:

- The above statement should be changed to read: "*The SAB believes it important to recognize that some metals do bioaccumulate in the tissues of humans and that toxicity may occur when effects thresholds at the site of action are exceeded*."

NAMC further notes that the SAB Draft Report as well as the EPA Draft Framework do not point out the absence of scientifically reviewed approaches for measuring or assessing the significance of bioaccumulation in humans. In the absence of such approaches, the use of bioaccumulation in humans to prioritize the need for further assessment or regulation of metals and other substances in commerce is problematic.

NAMC recommends the following change in the same section of the report:

- To the new sentence above we recommend adding: "*Scientifically recognized approaches for measuring or assessing the significance of bioaccumulation in humans have not been developed to date*." It would now read in its entirety, "The SAB believes it important to recognize that some metals do bioaccumulate in the tissues of humans and that toxicity may occur when effects thresholds at the site of action are exceeded. Scientifically recognized approaches for measuring or assessing the significance of bioaccumulation in humans have not been developed to date."

- Similar changes to the discussion in section 5, page 8 should also be included.

SAB Draft Report

Executive Summary: Definition of the term "Bioaccumulation." The Draft Report proposes to define this term (with the italicized portion as a proposed addition) as: "The net accumulation of a metal in a tissue of interest or the whole organism that results from exposure to all environmental sources, including air, water, solid phases (i.e., soil, sediment) and diet, *and that represents a net mass balance between uptake and elimination of the metal*."

NAMC Comment:

The phrase "net mass balance between uptake and elimination of the metal" is potentially confusing. The intent of the proposed definition appears to be focused on an increase in the steady-state body burden of a metal as a result of uptake exceeding elimination of the metal. The phrase "net mass balance" conveys equilibrium rather than an increase. NAMC recommends that the SAB revise this definition to express more clearly what is intended -- or delete it.

SAB Draft Report

Section 5, page 5 now reads: "The discussion of simultaneously extracted metals – acid volatile sulfides (SEM-AVS) does not adequately address the limitations of the approach (e.g., bioavailability from oxidized sediments). Similarly, discussions of the biotic ligand model (BLM) do not adequately describe its limitations or the early stage of BLM development. Finally, other approaches such as the National Oceanic and Atmospheric Administration's (NOAA) empirically-derived effects range median (ERM) and effects range low (ERL) approach (Long & Morgan, 1990; 1991) should be included in the discussions."

NAMC Comment:

NAMC agrees that the Framework should address limitations of the SEM-AVS approach, especially its application to oxidized sediments. At the same time, it is important to note that extensive research has been supported by the metals industry on copper, zinc and nickel the past three years to address this issue with more than 200 chronic sediment toxicity tests being performed. This work is making its way into the peer reviewed literature. The intent has been to develop a basis for assessing bioavailability of metals in oxidized sediments as well as anaerobic sediments where sulfide chemistry dominates.

NAMC has serious reservations about recommending the approach of Long and Morgan as an overarching recommendation to EPA. The methodology of Long and Morgan is not metals-specific, does not consider bioavailability and cannot ascribe effects to a given substance. We believe the Agency should be encouraged to develop metal-specific methods for sediment assessment. Approaches such as that of Long and Morgan may have utility as an interim approach for national assessments, but their significant limitations should be noted.

NAMC recommends the following change to the above sentence:

- "The discussion of simultaneously extracted metals – acid volatile sulfides (SEM-AVS) does not adequately address the limitations of the approach (e.g., bioavailability from oxidized sediments). Similarly, discussions of the biotic ligand model (BLM) do not adequately describe its limitations or the early stage of BLM development. Finally, *other approaches based on empirically-derived effects thresholds, with their strengths and limitations, should be included* in the discussions."

SAB Draft Report

Section 6.3.14.1, page 72, now reads: "The BLM is in the relatively early stages of development and also has inherent limits. For example, the BLM: 1) has no dietary component; 2) has no chronic component; and 3) has no cross-species comparisons among differing mechanisms for binding and effects-level metal concentrations."

NAMC Comment:

To assist with the accuracy of the SAB review, NAMC points out that chronic BLMs have been developed and published for zinc and copper for algae (*Selenastrum* sp.), fathead minnows and *Daphnia magna*. The model is nearing completion for the same species for nickel and is under development for cadmium, silver, aluminum and cobalt. Since the development of this approach in the early 1990s the BLM has advanced significantly and characterizing it as in early development is not entirely accurate. It is true that a dietary component has not been built into the approach, but cross-species comparisons with differing mechanisms have been done and continue to be done. Further, chronic BLMs exist as noted above. (Literature citations for the above referenced chronic BLMs can be provided.) We recommend that the statement in section 6.3.14.1 be revised to reflect these points.

SAB Draft Report

Section 6.3.14.1, page 73 now reads: "For risk assessments of a broader nature, e.g., at the national level, clearly the only viable approach to be implemented may be through the assessment of bulk sediment numbers."

NAMC Comment

It is recommended that the above recommendation be modified to reflect the developing state of the science. National risk assessments have recently been completed in Europe for zinc, copper and nickel. These are the most comprehensive assessments for metals to date and, to a large degree, they have not relied upon the use of bulk sediment numbers. Rather, specific approaches have been used for oxidized and non-oxidized sediments where bioavailability has been

considered; bulk numbers are used only as a first tier screening level assessment. We point out that bulk sediment assessment is one way of performing national assessments.

Thank you for the opportunity to submit comments on the SAB Draft Report on EPA's Draft Framework, which NAMC believes will place EPA's assessment of metal-related hazards and risks on sound scientific footing.

Sincerely,

William J. Adams, Ph.D.
Chairman, NAMC