North American Metals Council

September 13, 2010

Via E-mail

Fran Kammerer, Esquire
Staff Counsel
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

Re: Pre-regulatory Draft of the Green Chemistry Hazard Traits, Endpoints and Other Relevant Data

Dear Ms. Kammerer:

The North American Metals Council (NAMC)[1] appreciates the opportunity to submit these comments on the August 10, 2010, pre-regulatory draft of the Green Chemistry Hazard Traits, Endpoints and Other Relevant Data. As discussed below, the proposed hazard traits of persistence, bioaccumulation, and biopersistence cannot be applied to metals and metal substances. In addition, careful consideration is needed to evaluate toxicity studies using metals and metal substances. As such, the Office of Environmental Health Hazard Assessment (OEHHA) will need to consider alternative approaches applicable for assessing metals in the finalized Green Chemistry regulations.

Why "P" and "B" Criteria Are Not Appropriate for Metal Substances

OEHHA's attempt to specify certain hazard traits and environmental endpoints that will be applied to all chemical substances is misguided because certain factors cannot be applied to metals. Persistence ("P") and bioaccumulation ("B") criteria were developed for organic chemicals and are inappropriate to evaluate the hazards of metals. Assessments of metal substances using traditional "P" or "B" criteria have significant limitations, as outlined below.

[1] NAMC is an unincorporated not-for-profit group of metals-producing and metals-using associations and companies that focuses on science and policy issues that affect metals in a generic way.

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- ***Persistence***: Persistence is problematic for metals because all metals and other elements on the periodic table are conserved[2] and hence, persistent -- although the form and availability of the metal can change (thereby affecting its potential bioavailability and toxicity) depending on the environmental conditions. Indeed, one of the basic principles of the U.S. Environmental Protection Agency's (EPA) *Framework for Metals Risk Assessment* (*Framework*) is that the "environmental chemistry of metals strongly influences their fate and effects on human and ecological receptors."[3] The nature of these changes and the environmental conditions under which they occur are different for each metal element and must be considered on a metal-by-metal basis. Thus, setting a persistence criterion such as a half life for degradation of 70 percent in 28 days in water automatically captures all metals, including those that are essential (iron, copper, zinc, etc.), even though the metals may be present in a form that cannot exert toxicity. Applying to metals persistence criteria designed for organics can, therefore, result in misleading assessments of potential hazard. A more discriminating approach is needed. This issue becomes particularly significant when such criteria are used to identify contaminants of concern and to introduce restrictions on commerce or requirements for transportation and labeling.

- ***Bioaccumulation***: Unlike organic substances, the bioaccumulation potential of metals cannot be estimated using octanol-water partition coefficients (Kow). For metals, bioconcentration and bioaccumulation factors (BCF and BAF) are inversely related to the concentration of the metal in the surrounding environmental medium and are not reliable predictors of chronic toxicity, food chain accumulation, or hazard. The

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[2] Law of Conservation of Mass is a relation stating that in a chemical reaction, the mass of the products equals the mass of the reactants. *See* http://chemistry.about.com/od/chemistryglossary/a/conservmassdef.htm.

[3] U.S. EPA, *Framework for Metals Risk Assessment*. EPA 120/R-07/001, Office of the Science Advisor, Risk Assessment Forum, Washington, DC 20460 (Mar. 2007) at 1-1, available at http://www.epa.gov/raf/metalsframework/pdfs/metals-risk-assessment-final.pdf.

> inverse relationship between exposure concentration and BCF means that organisms from the cleanest environments (*i.e.*, background) have the largest BCF or BAF values, even though they are least at risk of toxic insult. This inverse relationship does not exist for organic substances. Thus, it is counterintuitive to use BCF/BAF and log Kow -- which were originally derived for hazard evaluation of organic substances[4] -- to evaluate hazard and risk for metals.

Based on the foregoing, it is clear that persistence and bioaccumulation are inappropriate to assess the hazard potential and potency of metal substances. OEHHA should, therefore, reconsider the application of these proposed hazard traits to metal substances.

Biopersistence and Metals

As OEHHA works to prepare in final its regulatory proposal, it must recognize that some metals are essential for maintaining proper health of humans, animals, plants, and microorganisms. Many organisms appear to regulate metal accumulation to some extent, especially in the case of essential metals. Any program, including California's Green Chemistry Program, should avoid setting hazard traits or exposure restrictions that may fall below the concentration levels needed to maintain health.

Toxicity Studies on Metals May Overestimate Toxicological Hazard Traits

Toxicity tests frequently are conducted using soluble forms of metals, particularly when oral exposures are at issue. But metals generally are not readily soluble. Thus, toxicity test results based on soluble metal salts may overestimate the bioavailability and the potential for toxicity of many metal substances, especially for the massive (and, therefore, less soluble) particles and insoluble sulfide and metal oxide forms. Further, many organisms appear to regulate metal accumulation to some extent, especially in the case of essential metals. This is not the case for organic chemicals. OEHHA needs to evaluate carefully how metals should be assessed with the current proposed toxicological hazard traits.

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[4] McGeer, J.C., K.V. Brix, D.K. DeForest, S.I. Brigham, J.M. Skeaff, W.J. Adams and A. Green. 2003. Bioconcentration Factor for the Hazard Identification of Metals in the Aquatic Environment: A Flawed Criterion? *Environ. Tox. Chem*. 22(5): 1017-1037.

EPA and EU REACH Regulations Acknowledge PBT Cannot Be Applied to Metals

In March 2007, EPA published its *Framework*, which acknowledged that inorganic metals and metal compounds present unique issues for risk assessors. As noted in the *Framework*:

> The purpose of this document is to present key guiding principles based on the unique attributes of metals (as differentiated from organic and organometallic compounds) and to describe how these metals-specific attributes and principles may then be applied in the context of existing EPA risk assessment guidance and practices. While organic compounds, for example, undergo bioaccumulation, there are unique properties, issues, and processes within these principles that assessors need to consider when evaluating metal compounds. Furthermore, the latest scientific data on bioaccumulation do not currently support the use of bioconcentration factors and bioaccumulation factors when applied as generic threshold criteria for the hazard potential of metals.[5]

As EPA notes elsewhere in the *Framework*, this last point applies specifically to the question of whether a substance should be classified as a persistent, bioaccumulative, toxic (PBT) chemical for purposes of human and ecological risk assessments.[6]

Similarly, the REACH regulations state specifically that PBT criteria do not apply to metals.[7] Thus, the text in Annex XIII, which outlines the criteria for identification of PBT

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[5] *Framework*, Executive Summary at xiv.

[6] *See id*. at 1-11.

[7] Commission of the European Communities. 2001. Amended Proposal for a Decision of the European Parliament and of the Council Establishing the List of Priority Substances in the Field of Water Policy, Paragraph 20 (Jan. 16, 2001); Official Journal of the European Union, ANNEX XIII - Criteria For The Identification Of Persistent, Bioaccumulative And Toxic Substances, And Very Persistent And Very Bioaccumulative Substances.

substances, specifically notes that "this annex shall not apply to inorganic substances," which includes metals, although it does apply to organo-metals.

Because EPA and the European Parliament do not apply expressly the persistence and bioaccumulation factors to metals, OEHHA should not do so either. Accordingly, we urge OEHHA to reconsider the application of these hazard traits to metals.

Alternative Approach for Assessing Metal Substances

OEHHA should consider valuable guidance documents on metals classification already developed and used by the metals and mining industry globally. The EPA *Framework* mentioned above provides key considerations on how metals should be assessed. In addition, there are several European documents generally recognized as standard best practices, "Metals Environmental Risk Assessment Guidance" (ICMM 2007)[8] and "Health Risk Assessment Guidance" (sponsored by the ICMM and Eurometaux).[9]

OEHHA should also consider relying upon a book developed as a consensus opinion from a 2003 Society of Environmental Toxicology and Chemistry (SETAC) workshop.[10] Scientists at the workshop agreed that individual criteria, like PBT, are limited in their ability to assess hazard or to prioritize metal substances in terms of hazard and risk. The PBT criteria are not linked or integrated, and they attempt to identify or predict effects (hazard) using bioaccumulation and persistence as modifiers of toxicity, without fully incorporating other important fate characteristics, which for metals include speciation, complexation, precipitation, dissolution, transformation, and sedimentation.

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8 International Council on Mining & Metals, Metals Environmental Risk Assessment Guidance, available at http://www.icmm.com/page/1185/metals-environmental-risk-assessment-guidance-merag.

9 International Council on Mining & Metals, Health Risk Assessment Guidance for Metals, available at http://www.icmm.com/page/1213/health-risk-assessment-guidance-for-metals-herag.

10 Adams, W.J., and P.M. Chapman, 2005. Assessing the Hazard of Metals and Inorganic Metal Substances in Aquatic and Terrestrial Systems: Summary of a SETAC Pellston Workshop. Pensacola (FL). SETAC Press, Pensacola, FL, USA.

The SETAC workshop opinion suggested that -- for both metals and organics -- a more comprehensive approach be taken, an approach under which a generic hazard ranking would be developed using a "unit world" model. The aim is to incorporate partitioning, transport, reactivity, bioavailability, and route of exposure information to generate a single and transparent metric of hazard. It is essentially a "critical load" approach in which an estimate is made of the rate at which a chemical must be introduced into a common defined environment to achieve a concentration in a target compartment (such as water or soil) that is deemed to be of concern from toxicity or regulatory objective viewpoints. An LC_{50} or no-effect level could be used. More hazardous substances will have lower critical emission rates. A group of metals and organics can thus be ranked for a common metric of hazard using this critical load approach. Following the workshop, efforts have been ongoing to develop and validate a Unit World Model.[11] This model is now available for use (http://unitworldmodel.net/).

Conclusion

Because several of the proposed hazard traits in the draft were expressly developed for organic chemicals and are inappropriate to evaluate the hazards of metals, NAMC urges OEHHA to consider using an exposure concept of transformation relative to the potential release of forms of metals that are bioavailable.

Thank you for this opportunity to comment on the pre-regulatory draft. NAMC members would be happy to meet with OEHHA staff to address any questions or discuss the scientific issues in more detail.

Sincerely,

Kathleen M. Roberts
NAMC Executive Director

[11] Farley, K. 2010. Validation of the Unit World Model. Presentation at the ICMM Technical Working Group Meeting, Raleigh-Durham, January 7, 2010. Manuscript I Preparation, Manhattan College, New York.