North American Metals Council

WRITTEN STATEMENT OF
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ON

"PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT): STRENGTHS AND WEAKNESSES"

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Introduction

As Chairman of the North American Metals Council (NAMC), I appreciate the opportunity to submit this testimony for the Subcommittee's consideration. 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. On behalf of NAMC members, I am pleased to provide these comments on the use of PBT -- or persistence, bioaccumulation, and toxicity -- for assessing the hazard of chemical substances, including metals and metal compounds.

My background is as a scientist with a Ph.D. in Environmental Science with 14 years work experience in the organic chemical industry and 15 years experience in the metals industry. I have published several papers specifically addressing PBT issues and edited a book on the subject. Over the years, I have developed approximately 100 technical papers in the environmental science field. Additionally, I served on the U.S. Environmental Protection Agency (USEPA or EPA) Science Advisory Board for 10 years. I currently work for Rio Tinto, a global mining company.

As Chairman of NAMC, I am particularly proud of NAMC's cooperative role with EPA in the development of the *Framework for Metals Risk Assessment* (*Framework*).[1] The *Framework* was published in 2007 and outlines key principles on how metals should be considered in health and ecological risk assessments. As recognized by EPA in the *Framework*, inorganic metals and metal compounds present unique issues for risk assessors and generally should not be assessed using models developed for organic substances. It is with this perspective that I offer the following comments.

What Are PBT Criteria and How Are They Used?

PBT criteria are measures of chemical substance properties that have been used since the early 1970s to assess the hazard and key environmental fate attributes of chemicals as a means to identify substances that have the potential to harm the environment. In the U.S., the development of hazard and risk assessment methodologies for chemical substances began in the late 1960s and early 1970s to formalize an approach for selecting product substitutions (for example in the soap and detergent industry and eventually in the pesticide and industrial chemical industry). Hazard (or "toxicity") is defined as a measure of the inherent (intrinsic) capacity of a substance to cause an adverse response in a living organism. Risk is

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

defined/described as the integration of hazard and exposure information and is thus not an intrinsic attribute of a substance (*e.g.*, the extent of risk will vary depending on the extent of exposure).

In the context of PBT approaches, "T" or toxicity has been used primarily, but not exclusively, to assess the hazard of substances to aquatic organisms. "B" typically refers to bioaccumulation in fish or other aquatic species; there are no universal metrics of B for humans. "P" refers to persistence and is generally measured as a half-life for degradation in the environment. This can include biological (biodegradation) as well as chemical (*e.g.*, hydrolysis, photolysis) processes. In the 1990s, there was increasing recognition that organic chemicals such as polychlorinated biphenyls (PCBs) and dichlorodiphenyltrichloroethane (DDT) that present properties of P, B, and T are of particular concern for their potential effect on the environment.

There have been several primary uses of PBT information:

- prioritization of substances for further testing;
- environmental hazard classification of substances and use in safety data sheets;
- ranking and/or selection of priority substances;
- selection of contaminated sites for further evaluation; and
- selection of substances for water, soil, and sediment quality guidelines or criteria.

There is considerable literature on the environmental assessment of organic substances focusing on Persistence (P), Bioaccumulation (B), and Toxicity (T).[2,3,4,5] These factors are used in

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[2] Adams, W.J., B. Conard, G. Ethier, K.V. Brix, P.R. Paquin, and D.M. DiToro. 2000. The challenges of hazard identification and classification of insoluble metals and metal substances for the aquatic environment. *Hum. Ecol. Risk Assess.* 6(1): 1019-1038.

[3] Kleka. G, Boethling B, Franklin J, Grady L, Graham D, Howard PH, Kannan K, Larson RJ, Mackay D, Muir D, van de Meent D. 2000. *Evaluation of Persistence and Long-Range Transport of Organic Chemicals in the Environment.* SETAC Press, Pensacola, FL, USA.

Europe, Canada,[6] the U.S.,[7] and elsewhere by national and international agencies (*e.g.*, the Stockholm Convention on Persistent Organic Pollutants[8]). In the U.S., PBT criteria have been used to identify substances of concern for waste minimization, emissions reporting, and for the identification of substances for stricter regulations (air, water, solid waste). In Canada, a PBT-type approach is one avenue used for categorizing substances on the Domestic Substances List (DSL) to determine if a screening assessment is required. Most recently, the use of PBT has been applied in Europe as part of the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) legislation, wherein PBT criteria are used as part of an overall approach for identifying substances that may require Authorization for continued use.

For reasons that I will explain in more detail below, it is very important to recognize that there is acknowledgement in the REACH regulations that these PBT criteria do not apply to metals.[9] The text in Annex XIII, which outlines the criteria for identification of PBT substances, specifically notes that "this annex shall not apply to inorganic substances," which includes metals, although it does apply to organo-metals.

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4 Scheringer M. 2002. Persistence and Spatial Range of Environmental Chemicals: New Ethical and Scientific Concepts for Risk Assessment. Wiley & Sons Inc. Hoboken, NJ, USA.

5 Lipnick RL, Hermens JLM, Jones KC, Muir DCG (eds). 2000. American Chemical Society Symposium Series No.772 *Persistent, Bioaccumulative, and Toxic Chemicals: Volume I*. American Chemical Society, Washington, DC, USA.

6 Government of Canada. 1999. *Canadian Environmental Protection Act (CEPA)*. Government of Canada, Ottawa, ON, Canada.

7 EPA. New Chemicals PBT Policy at http://www.epa.gov/fedrgstr/EPA-TOX/1999/November/Day-04/t28888.htm.

8 Stockholm Convention on Persistent Organic Pollutants at http://chm.pops.int/Convention/tabid/54/language/en-US/Default.aspx.

9 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.

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Recognized Limitations of PBT Applications

The scientific underpinnings of the use of PBT lie in the fact that these measures are believed to represent inherent or intrinsic properties of the chemical. As such, these properties are independent of environmental changes in temperature, pressure, fish species, etc., or other factors, especially exposure concentration. This turns out to be only partially true, as it is known that biodegradation studies used to measure P are subject to changes in temperature as this affects the rates of biodegradation by microorganisms. B is also affected by temperature and length of the exposure, and the potential for metabolic breakdown (metabolism) which can differ between species.

To overcome these difficulties, standard test methods have been established such that the measures reflect pseudo-intrinsic values. For both P and B, the test results obtained for most organic substances using these methods are independent of test concentration making the measures relevant to real world systems where concentrations often vary. Toxicity, however, is directly related to exposure concentration and duration (*e.g.*, acute versus chronic exposures) and therefore test conditions are standardized to allow for repeatable measures of toxicity to standard species.

In the U.S., PBT was proposed for use by the USEPA in 1997 for selection of substances for waste minimization, identified as a Waste Minimization Prioritization Tool. PBT criteria were used to score chemical substances. In 1999, EPA's Office of Solid Waste developed a list of substances using the PBT tool. At that time, NAMC provided comments on the limitations of the tool for application to inorganic substances, including metals. In 2007, EPA's *Framework* clearly identified the limitations of applying P and B for metals assessment.[10]

Strengths and Weaknesses of the Use of PBT Approaches and Standard Criteria

Strengths -- The main advantage of the use of PBT is its simplicity. It requires only three measures that are easily determined and apply to many classes of organic compounds. The test procedures are standardized and utilized globally. Data bases now exist where the PBT values can be identified and used as needed. The development of the High Production Volume (HPV) program under the Organization for Economic Cooperation and Development (OECD) and by USEPA has generated additional PBT data, and the REACH regulation in Europe should provide yet additional information. All of these efforts lend themselves to making a vast amount of data available for assessing hazard and environmental fate of chemical substances using a PBT approach. The approach has the advantage and reputation of identifying problematic substances that are recognized internationally in the Stockholm Convention on Persistent Organic

[10] *Framework* at Section 5.2.5.4.

Pollutants. It is important to note that the PBTs addressed under the Stockholm Convention are limited to organic substances that also have the ability for global environmental transport (*e.g.*, dioxins, furans, PCBs, organochlorine pesticides such as DDT, dieldrin, chlordane, etc.). It is important to recognize that not all organic PBTs have the potential for global transport.

Weaknesses -- The simplicity of the approach is also a drawback to its broad application. The PBT screening criteria assess only hazard and key environmental fate properties, not risk. A substance may pose PBT concerns, but not present risk if exposure is controlled or is minimal. To assess risk, a PBT approach must additionally consider volume of production and release to the environment. PBT assessment provides information on the properties of the substance, but not the probability or likelihood of effects. Other disadvantages include the following:

- PBT does not consider pathways and magnitude of entry to the environment.

- Octanol-water partition coefficients (Kow) have been used as surrogates for measures of B. These measures do not consider the potential for metabolism and are not applicable to some classes of compounds, including metals, silicates, and other inorganic substances.

- Measures of persistence typically focus on biodegradation and not other environmental loss mechanisms that can include hydrolysis, photolysis, complexation, burial in sediments, and remineralization.

In addition, the approach does not consider the benefits of a given chemical substance.

Why PBT Criteria Are Not Appropriate for Metal Substances

Specifically for metal substances, there are several disadvantages and reasons why PBT criteria have limitations to their use, which are outlined below. That is why NAMC supports an alternative approach to PBT assessment for evaluating metals and metal compounds, which is explained later in this testimony.

- Persistence: Persistence is problematic for metals because all metals and elements on the periodic table are conserved[11] and hence, persistent. The form and availability of the metal can change depending on the

[11] 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.

environmental conditions. They are also different for each metal element and this must be considered. Thus, setting a criterion such as a half life for degradation of 70% in 28 days in water automatically captures all metals, including those that are essential (iron, copper, zinc, etc). As a result, applying criteria designed for organics to metals can be misleading. A more discriminating approach is needed. This issue becomes significant if PBT criteria are used to identify contaminants of concern and to introduce restrictions on commerce, transportation, and labeling.

- Bioaccumulation: Unlike organic substances, bioaccumulation potential of metals cannot be estimated using octanol–water partition coefficients (Kow). Bioconcentration and bioaccumulation factors (BCFs and BAFs) are inversely related to exposure concentration and are not reliable predictors of chronic toxicity, food chain accumulation, or hazard. The inverse relationship between exposure concentration and BCF results in organisms from the cleanest environments (*i.e.*, background) having the largest BCF or BAF values. This result is counterintuitive to the use of BCF and log Kow as originally derived for organic substances.[12]

- Toxicity: Metals are generally not readily soluble. Toxicity test results based on soluble salts may overestimate the bioavailability and the potential for toxicity for many substances, especially for the massive metals and insoluble sulfide and metal oxide forms. Further, many organisms appear to regulate metal accumulation to some extent, especially for essential metals.

Alternative Approach for Assessing Metal Substances

In 2003, I chaired a workshop which was sponsored by the Society of Environmental Toxicology and Chemistry (SETAC), a professional society that supports practices for protection, enhancement, and management of sustainable environmental quality and ecosystem integrity. At the workshop, PBT issues were discussed at length and reported out in a book.[13] Consensus was

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12 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.

13 Adams WJ, Chapman PM. 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.

reached at the workshop that individual criteria, like PBT, are limited in their ability to assess hazard or to prioritize metal substances. The 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.

It was suggested that a more comprehensive approach be taken for both metals and organics in which a generic hazard ranking be sought using a "unit world" model. The aim is to incorporate partitioning, transport, reactivity, bioavailability, and exposure route information to give a single and transparent metric of hazard. It is essentially a "critical loading" 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 fish) that is deemed to be of concern from toxicity or regulatory objective viewpoints. An LC50 or no-effect level could be used. 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 loading approach. Following the workshop, efforts have been on-going to develop and validate a Unit World Model.[14] This model is now available for use (www.unitworldmodel.net).

Conclusion

Any attempt to universally and uncritically apply PBT criteria to all chemical substances -- for example, to create lists of chemicals of concern -- would be scientifically inappropriate and would result in misleading if not erroneous outcomes. Similarly, since PBT information, by itself, cannot determine risk, such criteria should not be used in isolation as a basis for requiring regulatory action. If, regardless of these cautions, an attempt is made to base regulatory actions on PBT information for some substances, it is important to understand that persistence and bioaccumulation factors cannot be applied to metal materials because P and B criteria were developed for organic chemicals and are ill-suited to evaluate the hazards of metals. Instead, consideration must be given to an exposure concept of transformation relative to the potential release of forms of metals that are bioavailable.

Thank you for this opportunity.

[14] 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.