North American Metals Council

June 27, 2006

The Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Re: Report of the Commission for Environmental Cooperation, *Toxic Chemicals and Children's Health in North America*

Dear Administrator Johnson:

On May 17, 2006, the Commission for Environmental Cooperation ("CEC"), an organization funded jointly by the U.S., Canadian, and Mexican Governments, issued its final report entitled *Toxic Chemicals and Children's Health in North America (2006)* ("CEC Report"). Two years ago, when the CEC released the draft version of this report, representatives of the North American Metals Council ("NAMC") and several of its members met with officials from EPA's Office of International Affairs to share scientific concerns about the draft report. These concerns included the unsupported and erroneous attribution of adverse health effects to a variety of metals, based almost entirely on the Environmental Defense "Scorecard," which itself has been criticized for lack of scientific rigor and peer review.

Further concerns stemmed from the draft report's use of pollutant release and transfer register ("PRTR") data to imply relative rankings of risk to children, an inappropriate and misleading exercise, given that PRTR data plainly do not reflect actual risk. The latter is a point that EPA always emphasizes in the Agency's annual public release of Toxics Release Inventory ("TRI") data.

NAMC subsequently submitted comments to the CEC that laid out these points in writing. Several NAMC members, including the American Zinc Association, the Nickel Institute, the Copper Development Association, and the International Cadmium Association, also filed comments providing specific examples of inaccuracies relating to each of those metals. We

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are aware that the U.S. and Canadian Governments also submitted comments to CEC raising many of these same points.

We are disappointed that the final CEC Report largely ignored these carefully documented concerns and suggestions for improvements in the analysis and scientific foundation of the document. Because of its inaccuracies and scientific failings, the Report does not provide the kind of objective, accurate information that can serve as an appropriate basis for identifying significant risks to children.

We attach for your reference an Annex of examples of shortcomings of the report with regard to several metals. This list is provided for purposes of illustration and is by no means an exhaustive catalogue of problems with the Report.

Please let me know if it would be helpful to meet or if we should take any follow-up action.

Sincerely,

Jane C. Luxton

Jane C. Luxton
Counsel to
North American Metals Council

Att.

cc: Jerry Clifford, Office of International Affairs

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Annex to Letter to Stephen L. Johnson (June 27, 2006)

Examples of Problems and Inaccuracies
in the Commission for Environmental Cooperation Report
"Toxic Chemicals and Children's Health in North America (2006)"

Zinc

- The list of "suspected neurotoxicants" includes "zinc and its compounds," reportedly on the basis of the Environmental Defense Scorecard. (CEC Report at 21.) However, as the comments of the U.S. Government and American Zinc Association to the CEC on its draft report made clear, the Environmental Defense Scorecard lists only two low-volume zinc compounds, not "zinc and its compounds." [1]
- Comments filed by the U.S. and Canadian Governments and the American Zinc Association on the draft report (June 2004) stressed the public health importance of the report's identifying the dangers of zinc (and copper) deficiency, particularly in pregnant mothers and young children.[2] The CEC Report includes a passing comment that it is "of note that some of these compounds (certain forms of copper and zinc) are essential trace nutrients at lower levels of exposures; moreover, over-exposure to these substances is quite unusual." (CEC Report at 27.) However, the Report fails to include any discussion of the public health importance of addressing deficiency of these essential elements and instead classifies them as among the "five chemicals suspected to be developmental and reproductive toxicants released or transferred in the largest quantities" in 2002 (Report at 26).

Nickel

- The CEC Report identifies nickel and nickel compounds as "recognized developmental and reproductive toxicants" based solely on the Environmental Defense Scorecard characterization. This is inconsistent with the CEC's own stated criterion for determining whether chemicals are "recognized developmental and reproductive toxicants" – *i.e.*, they are listed as such under California's Proposition 65 program.[3] The only nickel species listed as a developmental or reproductive toxicant under Proposition 65 is nickel carbonyl, which would rapidly break down if emitted into ambient air, so that there is no risk of exposure to children or anyone else outside a small number of work environments.

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[1] Comments of the U.S. Government at 3; comments of the American Zinc Association ("AZA") at 1-2.
[2] *See, e.g.*, Comments of the Canadian Government on the draft report at 10 ("language should be inserted in the report to ensure the appropriate public health message remains, which is that pregnant mothers and young children must have sufficient levels of copper [and] zinc in their diets to avoid nutritional deficiencies."); comments of Dr. Barbara Levine of Rockefeller University (on behalf of AZA) at 4 ("in the interests of good science and good health, the Draft needs to be totally redone to highlight that the larger threat to children's health is zinc deficiency, not exposure to zinc.")
[3] *See* Report at 21; *id.*, Note to Tables 3-6 and 3-7 ("A chemical is included as a developmental or reproductive toxicant if it is listed as a recognized developmental or reproductive toxicant on the California Proposition 65 list.").

- The CEC Report also relies solely on Scorecard to identify nickel and nickel compounds as "suspected neurotoxicants." The basis for this characterization in Scorecard is a reference to Table 1 of a paper by R.G. Feldman entitled "Role of the Neurologist in Hazard Identification and Risk Assessment." *Environmental Health Perspectives*. 104 (Supplement 2):227-237. 1996. But the only symptom with which nickel is associated in Table 1 of the Feldman paper is "Headache." The Table does not list nickel as being associated with "Ataxia," or "Cognitive impairment," or "Peripheral neuropathy," or "Tremors." We do not know why nickel was identified as a possible cause of headache in this paper. But, even if there is some basis for that association, it hardly seems sufficient to designate nickel as a neurotoxicant, and neither Environmental Defense nor the CEC Report offers any reasons for this conclusion.

- The foregoing is symptomatic of a more general failing. The CEC Report relies on the Environmental Defense Scorecard listings even though Environmental Defense (1) has no governmental or other mandate to identify developmental toxicants and neurotoxicants; (2) possesses no special expertise in making such scientific determinations; and (3) does not purport to apply any specified criteria in classifying chemicals as developmental toxicants or neurotoxicants. As the U.S. Government pointed out in its Comments on the draft report two years ago: "The final lists [of chemicals] used in the report should be based on scientifically sound, peer reviewed data pursuant to clearly defined and transparent criteria." Scorecard does not meet that test because, among other things, it "do[es] not define what criteria were used to categorize 'suspected neurotoxicants' or 'recognized or suspected developmental toxicants.'" *Id.* The CEC is not justified in relying on Environmental Defense's arbitrary and subjective determinations of developmental toxicity and neurotoxicity to develop chemical lists in the Report.

- The CEC Report implies that nickel is carcinogenic when ingested in drinking water. *See* Report at 23 (referring to nickel as one of the "top ten water carcinogen releases"). In fact, however, neither nickel metal nor nickel compounds have been identified as oral carcinogens. To the contrary, under California's Proposition 65 program, nickel and nickel compounds are identified as presenting no significant risk of cancer by the route of ingestion. 22 CCR § 12707(b)(5). Similarly, based upon the negative results of a two-year oral carcinogenicity study of nickel sulfate hexahydrate in rats completed in July 2005 (which confirmed the negative results of all prior oral carcinogenicity studies of nickel compounds), the European Union Risk Assessment for Nickel and Nickel Compounds limits the carcinogenic classification to the inhalation route of exposure. The World Health Organization's recent decision to raise the Guideline Value for nickel in drinking water to 70 µg/l also reflects the view that nickel is not carcinogenic via the route of ingestion. Only the CEC Children's Health Report implies the contrary – though it provides no basis whatsoever for doing so.

- The values used to develop the Toxic Equivalency Potentials ("TEPs") for nickel and its compounds cannot be discerned in the CEC Report itself. Nor are they readily apparent in the Environmental Defense Scorecard from which the CEC claims to have taken the TEP values. How did the CEC and Environmental Defense derive non-cancer TEPs of 3,200 for nickel in air and 26 for nickel in water when, as shown above, they do not even provide an understandable basis for characterizing nickel as a "recognized developmental

- toxicant" or a "suspected neurotoxicant" in air or water? What toxic potency values were used to derive TEP values for those endpoints and what justification was there for selecting them? If this can be determined from the CEC Report, the means for doing so is not apparent. The same is true for the cancer TEP value of 2.8 that the Report uses for nickel and its compounds in air. If the CEC wants to rank chemical releases to air and water when normalized for toxicity, there should be a good deal more transparency and scientific support than is provided in the Report.

Molybdenum

- The CEC Report claims that molybdenum trioxide is a 'suspected neurotoxicant,' including it in Appendix B to the Report (at 56) but without a literature reference or any supporting documentation. It appears that, like other substances on the CEC Report's lists, molybdenum trioxide is included because of its classification as a neurotoxicant in the Environmental Defense Scorecard. No basis is provided for this listing in Scorecard other than the simple conclusory statement that molybdenum trioxide is "more hazardous than most chemicals in 1 out of 8 ranking systems."[4]

- Statements that molybdenum has harmful neurological effects usually derive from 1960s-era Russian epidemiological studies on exposure of industrial workers to dusts. It has long been disputed whether the effects are due to molybdenum and whether the work has any relevance to the general population. The recent research literature provides evidence that molybdenum is not a neurotoxin.[5]

- A deficiency of the enzyme sulfite oxidase causes neurological impairment in human infants. Molybdenum is an essential component of this enzyme. Therefore, molybdenum is, in fact, essential for neurological health.

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[4] *See*, http://www.scorecard.org/chemical-profiles/summary.tcl?edf_substance_id=1313%2d27%2d5#hazards.

[5] *See, e.g.*, David A, Lobner D., Eur J Orthod., 2004, 26(4),421-6. *In vitro cytotoxicity of orthodontic archwires in cortical cell cultures* (alloys containing molybdenum were found NOT to be neurotoxic and molybdenum was NOT among the metals common to those alloys which were neurotoxic); Mofid MM, Thompson RC, Pardo CA, Manson PN, Vander Kolk CA., Plast Reconstr Surg. 1997,100(1), 14-20; discussion 21-2: *Biocompatibility of fixation materials in the brain.*