North American Metals Council
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North American Metals Council (NAMC)
Statement on Metals and Endocrine Disruption
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Within the ongoing scientific dialogue regarding endocrine disruptor chemicals, metals may be of particular interest, given their ubiquity in the environment. As explained below, while there are data showing potential hazards of some metals to terrestrial and aquatic organisms, caution is needed before general conclusions can be drawn related to metals and endocrine disruption.

Background on Endocrine Disruptor Chemicals

In recent years, concerns regarding the ability of chemical substances to disrupt the normal function of the endocrine system in humans and wildlife have been growing among the public and international regulatory community. Significant research has been devoted and is underway to understanding chemical exposure and endocrine disruption.

As established by the World Health Organization (WHO) and accepted globally by regulatory authorities, an endocrine disruptor is a substance or mixture that alters the function of the endocrine system and consequently causes adverse health effects in an organism or its offspring.[1] While a substance may demonstrate biological activity in an endocrine pathway, it is not considered to be an endocrine disruptor unless an endocrine disruptive mode of action is determined to result in adverse health effects. To ensure both aspects of the definition are taken into account, the U.S. Environmental Protection Agency (EPA) developed a two-tiered approach for its Endocrine Disruptor Screening Program (EDSP) that first identifies endocrine active substances and then further investigates the substances that may adversely affect the endocrine system to develop a quantitative relationship between the dose and the adverse effect.

Evaluation of Metals for Endocrine Disruption

Testing for potential impacts to the endocrine system is uniquely different than traditional toxicity testing. The Organization for Economic Cooperation and Development (OECD) has recommended specific testing strategies for the evaluation of the endocrine system.[2]

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1 *See* WHO, Children's Environmental Health, *State of the Science of Endocrine Disrupting Chemicals -- 2012*, available at http://www.who.int/ceh/publications/endocrine/en/.

2 *See* OECD, Guidance Document on Standardized Test Guidelines for Evaluating Chemicals for Endocrine Disruption (OECD TG 150), available at

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Most of the toxicity studies on metals were not conducted under these specific strategies, so it is not possible to correlate the findings to specific endocrine effects.[3] In addition, to elicit a toxic effect, many studies were performed at very high concentrations of the subject metal that are not representative of what are found in the environment. Consequently, it cannot be concluded that the effects seen in these high-concentration studies are reflective of real-world conditions.

While testing approaches and additional data on endocrine disruption are evolving, it is important to recognize that the EDSP has not included metals in any of its screening lists.[4] Likewise, the European Commission (EC) compiled a priority list of substances for further evaluation of their role in endocrine disruption and categorized the suspected substances based on the strength of evidence available.[5] Although the list contains several metals, including lead, cadmium, mercury, and aluminum, the EC classified all of the metals as Category 3C, which indicates that there was no scientific basis to support inclusion on the list.[6] The Endocrine Disruption Exchange (TEDX)[7] developed the TEDX list which includes several

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http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono%282012%2922&doclanguage=en.

3 Iavicoli I, Fontana L, Bergamaschi A. 2009. The Effects of Metals as Endocrine Disruptors. *J. Toxicol. Environ. Health B Cit. Rev.* 12(3):206–223; Dyer CA. 2007. Heavy Metals as Endocrine-Disrupting Chemicals. In: Gore AC, ed. *Endocrine-Disrupting Chemicals: From Basic Research to Clinical Practice*, New Jersey: Humana Press, pp. 111-133.

4 74 Fed. Reg. 17579 (Apr. 15, 2009); 78 Fed. Reg. 35922 (June 14, 2013).

5 *See* EC, Environment, *Endocrine Disruptors Strategy*, available at http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm.

6 *See* EC, Environment, *Annex 10, List of 564 Substances with their Selection Criteria*, available at http://ec.europa.eu/environment/archives/docum/pdf/bkh_annex_10.pdf.

7 *See* The Endocrine Disruption Exchange, *List of Potential Endocrine Disruptors*, available at https://endocrinedisruption.org/interactive-tools/tedx-list-of-potential-endocrine-disruptors/search-the-tedx-list.

metals such as aluminum, cadmium, chromium, iron, lead, and manganese. As noted by the Endocrine Policy Forum (EPF), however, the TEDX list does not adhere to the globally accepted WHO definition of an endocrine disruptor.[8]

Conclusion

Many metals are essential for maintaining the proper health of humans, animals, plants, and microorganisms. As data evolve on metals and potential endocrine activity, careful consideration must be given to how findings are characterized. Any classification or categorization of metals as endocrine disruptors must be based on established and widely-accepted criteria and should reflect effects from metal concentrations that are environmentally relevant.

[8] *See* Endocrine Science, *"Lists of EDCs": Understanding Major Limitations of Many Chemical Lists -- TEDX List, SIN List, Danish EPA List, and REACH SVHC List*, available at https://www.endocrinescience.org/lists-edcs-understanding-major-limitations-many-chemical-lists-tedx-list-sin-list-danish-epa-list-reach-svhc-list/.