Comments On Pre-Prioritization And Consideration Of Cobalt And Cobalt Compounds Under The Toxic Substances Control Act (TSCA)
Submitted by Cobalt Institute

October 31, 2024

Ms. Sarah K. Soliman
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460- 0001

EPA Docket ID: **EPA-HQ-OPPT-2023-0606**

Dear Ms. Soliman:

The Cobalt Institute appreciates the opportunity to submit comments on EPA's inclusion of cobalt and cobalt compounds on its list of 27 chemicals under consideration for pre-prioritization under the Toxic Substances Control Act. We urge the agency to not proceed at this point with the pre-prioritization of cobalt and cobalt compounds, until further consideration is given to the critical points below. This document is submitted alongside, and in support, of the North American Metals Council (NAMC)'s and National Mining Association (NMA)'s comments.

The Cobalt Institute (CI) is the leading global organization representing cobalt producers and the downstream user community in the cobalt value chain. We promote the responsible and sustainable production and use of cobalt in all its forms and applications, including significant uses that support the global energy transition, contribute to U.S. supply chains in critical manufacturing sectors and ensure U.S. national security.

1. *The Role Of EPA's Metals Risk Assessment Framework*

EPA should consult and follow its own Framework for Metals Risk Assessment under the prioritization process for TSCA.

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As EPA's own Office of Research and Development (ORD) and key program offices have highlighted with respect to the science underlying metals regulatory decision making, metals and metal compounds have inherently unique properties that require a different approach to chemicals management as compared to traditional organic substances. Historically, the EPA has taken into consideration the need for this unique approach and importantly has published its own *Framework on Metals Risk Assessment*[1] in 2007 to guide agency decisions.

- Cobalt and certain cobalt-containing substances are biologically essential for maintaining the good health of humans, other animals, plants and microorganisms. As such, a unique approach to chemicals management is needed for these substances.

- The use of persistence and bioaccumulative as properties to prioritize metals is not appropriate. As stated in EPA's Fact Sheet on Framework for Metals Rish Assessment[2], "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".

- CI echoes statements previously made by NAMC, "The unique characteristics of metals and how they should be addressed in a risk assessment framework are often ignored in discussions of chemical management systems, leading to consequences that sometimes are irrational and commercially crippling even though unintended. Persistent, bioaccumulative and toxic (PBT) as a prioritization factor is not appropriate for metals".

- CI also raises concerns regarding the EPA's Framework for Metals Risk Assessment not being applied in the pre-prioritization process. As previously raised by NAMC, section 6(b)(2)(E) of amended TSCA directs EPA to use the March 2007 Framework for Metals Risk Assessment to implement the prioritization and risk evaluation provisions of the statute. Congress' legislative mandate was clear in stating that EPA "shall use" the Framework document in identifying priorities for risk evaluation and for conducting risk evaluations on metals and metal compounds.

[1] EPA, Framework for Metals Risk Assessment (March 2007), available at https://www.epa.gov/sites/default/files/2013-09/documents/metals-risk-assessment-final.pdf.
[2] EPA, Office of Science Advisor, Fact Sheet on Framework for Metals Risk Assessment (March 8, 2007), available at https://archive.epa.gov/raf/web/html/factsheet.html.

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There have been on-going efforts for collaboration and capacity building between the EPA and the metals industry regarding the chemicals management of metals and metal compounds. CI urges continued and sustained efforts toward ultimately updating the Framework for Metals Risk Assessment and incorporating the most recently emerging health and environmental science developments since its publication in 2007 (see recent publications by Adams and Garman 2023; Boreiko 2024[3]).

2. *The Cobalt Institute's Scientific Research Agenda*

EPA should take into consideration the large strategic testing program for cobalt and cobalt compounds that will inform on several critical scientific data gaps.

- In 2023, Cobalt Institute was given official authorization to conduct new scientific studies to inform decision making on hazard identification and risk assessment of cobalt and cobalt compounds, regarding aquatic ecotoxicity, carcinogenicity, genotoxicity, reproductive toxicity and repeated-dose toxicity (inhalation)[4].

- This multi-million dollar and multiple-year program of studies will answer key scientific questions that have been raised by the US EPA and other global regulatory agencies (i.e. US EPA – IRIS, US EPA – Safe Drinking Water Act, US EPA – Clean Water Act, EU ECHA under REACH). As one example, the data from the combined oral chronic and carcinogenicity study are of key relevance to both the IRIS and Safe Drinking Water processes.

- These studies are required in order to approach hazard identification with the appropriate scientific rigor, generate a robust risk assessment and apply a suitable risk management approach.

- CI is concerned that significant scientific and technical efforts will not be properly taken into account if cobalt is pre-prioritized under TSCA at this point in time.

3. *The Role of Emerging Assessments and Prioritization Criteria*

[3] Adams. W. J. and Garman, E. R. 2023. Recommended updates to the USEPA Framework for metals risk assessment: aquatic ecosystems, IEAM, (4):924;
Boreiko, C. 2024. Modelling of Local and Systemic Exposure to Metals and Metalloids After Inhalation Exposure: Recommended Update to the U.S. EPA Metals Framework. IEAM, 20(4): 951.
[4] Combined oral chronic and carcinogenicity study (data required by January 2030); extended one-generation reproductive toxicity study (EOGRTS), in vivo transgenic rodent (TGR) assay and in vivo COMET assay, 90-day repeated-dose inhalation studies (data required by January 2028).

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EPA should take into consideration that existing assessments for cobalt and cobalt compounds are not finalized and certain prioritization criteria are not applicable to metals.

- In the webinar presentation given by EPA in September / October 2024, the sole reference to cobalt and cobalt compounds states that there are *existing* assessments for these substances under IRIS and ATSDR (and potentially CCL5). This is not accurate.
    - The IRIS assessment of cobalt and cobalt compounds began in November 2022 with the release of the problem formulation materials, IRIS assessment plan and systematic review protocol. Currently, cobalt remains at Step 1 in the IRIS program, with the draft IRIS assessment not yet released for public consultation and external peer-review.
    - The status of the ATSDR tox profile for cobalt remains still in progress as of October 31, 2024.
    - Cobalt remained on the final chemicals contaminant list 5 (CCL5) and has not been prioritized for a regulatory determination.

- In addition, in relation to the list of chemical substances being considered from the 2014 TSCA Work Plan, EPA has indicated that it seeks chemical substances with these characteristics: persistence and bioaccumulation scores of three; and known human carcinogens, and high acute or chronic toxicity.
    - The CI has particular concerns (listed in point 1 of this response) regarding the inappropriate prioritization of metals using the properties of persistence and bioaccumulation.
    - Cobalt is not a known human carcinogen. Workplace epidemiology studies have not demonstrated a conclusive link between cobalt exposure and cancer. Cobalt metal and five cobalt salts are classified under UN GHS for carcinogenicity as Category 1B ('presumed human carcinogens') based on animal studies. These substances were also evaluated under IARC in March 2022 and given a Group 2A classification ('probably carcinogenic to humans').

- The CI is also concerned that regulatory efforts are emerging for cobalt, and there is potential that significant scientific and technical conclusions associated with IRIS will not be considered should the prioritization of cobalt and cobalt compounds begin in the near term.

We thank the agency in advance for consideration of the concerns outlined above and welcome any additional requests or clarifications from EPA regarding this submission as well as our ongoing

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research and current collaboration with the agency. For further information or clarification, please contact Dr Vanessa Viegas at the Cobalt Institute (vviegas@cobaltinstitute.org).

With best regards,
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