



**American Water Works
Association**

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Government Affairs Office
1300 Eye Street NW
Suite 701W
Washington, DC 20005-3314
T 202.628.8303
F 202.628.2846

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EPA Docket Center (ORD Docket)
Mail Code: 28221T
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460 Washington, DC

FOR ELECTRONIC DELIVERY

RE: Draft IRIS Toxicological Review of Hexavalent Chromium, Docket No. EPA-HQ-ORD-2014-0313

Dear Sir or Madam,

The American Water Works Association (AWWA) appreciates the opportunity to comment on the “IRIS Toxicological Review of Hexavalent Chromium.” This is a very important document for the U.S. Environmental Protection Agency’s (EPA’s) Safe Drinking Water Act (SDWA) program. AWWA has a specific interest in the toxicity of hexavalent chromium (Cr(VI)) when ingested orally. Water systems are charged with providing the communities they serve with safe and reliable drinking water service. In June 2020 EPA agreed in a settlement with Waterkeeper Alliance, LLC v EPA that was accepted by the U.S. District Court for the Southern District of New York, to consider proposing a primary drinking water standard based on the final IRIS Cr(VI) toxicological review.¹ The care with which EPA undertakes its work, including its preparation of this toxicological review must reflect the consequences of the analysis when it is applied by risk managers.

Observations on EPA Cancer Guidelines and Available Data

In reviewing the draft toxicological review, AWWA arrived at the following observations:

1. It is not clear that the draft analysis comports with established and current EPA policy guidance. EPA’s Cancer Guidelines including supplemental memoranda direct agency staff to apply the agency’s mode of action framework to determine the mutagenic mode of action for the chemical being analyzed through a weight-of-evidence evaluation. EPA did summarize a substantial body of data but ended that evaluation without demonstrating a mutagenic mode of action. Section 3.2.3.4 and Figure 3-16 do not present a basis to assert mutagenic toxicity when cytotoxicity could, and other researchers and regulatory agencies suggest is, the critical mode of action.

¹ Waterkeeper Alliance, LLC v EPA. 19 Civ. 899 (LJL) June 15, 2022.

AWWA comments to EPA in 2010 conveyed the concern that EPA was reviewing the toxicity of Cr(VI) with the *“implicit and critical assumption that mutagenicity / genotoxicity is the **primary mode of action** at dose of environmental concern.”* [emphasis added]² The current draft toxicological review continues to be constructed with this implicit assumption without a clear demonstration of the available evidence that this assumption is valid.

2. The data quality visualizations available through EPA’s Health Assessment Workspace Collaborative (HAWC) referenced by the draft toxicological review illustrate EPA’s reliance on studies that almost ubiquitously are “low-confidence” with respect to carcinogenicity via oral exposure.”³ The visualizations also succinctly summarize EPA’s assessment of the studies underpinning its characterization. HAWC visualizations with regard to Cr (VI) mechanistic studies were either not prepared or are not available to the public.⁴
3. The review appears to systematically dismiss data collected and funded by “industry” as though the source of funding inherently made the data suspect. If federal agency analyses are to work under the construct that data is suspect based on who paid for the data, then the data that supports all of the major federal chemical approval programs are flawed. “Industry” funded data currently underpins pharmaceutical approval by the Food and Drug Administration, pesticide registration by EPA, and new chemical registration by EPA.

In 2010 AWWA recommended that EPA consider research organized through ToxStrategies.⁵ Now in 2022, the breadth of work undertaken through this collaborative research program is even more substantial.⁶ This work has been received by peer-review journals, professional conference organizers, and relevant experts as being of high quality. Yet, it does not appear that the draft toxicological review seriously contemplates considering the import of this research portfolio.

Comparison with Health Canada Cr(VI) Toxicological Review

Comparison with analysis by Health Canada suggests that EPA’s draft toxicological review is either flawed or overly conservative. The Health Canada analysis took advantage of the same research used to support EPA’s draft toxicological review, yet Health Canada’s analysis results in a maximum acceptable concentration (MAC) of 50 µg/L, a value more than at 1,400 times higher than the value generated by the draft EPA analysis.⁷

² AWWA, Comment letter regarding “Draft Toxicological Review of Hexavalent Chromium: In Support of Summary Information on the Integrated Risk Information System (IRIS) (Docket ID. No. EPA-HQ-ORD-2010-0540). (November 18, 2010).

³ EPA. Health Assessment Workspace Collaborative, Cr(VI) (2017)(Draft).

⁴ EPA. Health Assessment Workspace Collaborative, Cr(VI) (mechanistic) (2018) at

<https://hawc.epa.gov/assessment/100500006/>.

⁵ AWWA, Comment letter regarding “Draft Toxicological Review of Hexavalent Chromium: In Support of Summary Information on the Integrated Risk Information System (IRIS) (Docket ID. No. EPA-HQ-ORD-2010-0540). (November 18, 2010).

⁶ Toxstrategies. <https://toxstrategies.com/publication-topic/hexavalent-chromium/>. (Available 12/12/2022).

⁷ Health Canada, Chromium in Drinking Water, March 2016. Available at <https://www.canada.ca/en/health-canada/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-guideline-technical-document-chromium-profile.html> on April 9, 2019.

Importance of Cr(VI) Occurrence in Drinking Water

We know that Cr(VI) is present in drinking water at nanogram and microgram per liter concentrations. The draft toxicological review touches on Cr(VI) occurrence but does not adequately convey the importance of recognized occurrence to subsequent analysis. In the third cycle of the Unregulated Contaminant Monitoring Rule (UCMR3), 4,919 water systems participating in a nationally representative sample tested finished water for Cr(VI).⁸ Ninety percent (n = 4,401) public water systems (PWSs) observed Cr(VI) at detectable levels (i.e., greater than 0.03 µg/L). Cr(VI) is present in both groundwaters and surface water; it is present in source waters used by systems of all sizes, but is a particularly relevant as a contaminant for small, groundwater systems. In most instances Cr(VI) occurrence is a product of the minerals water comes in contact with, not contamination from anthropogenic sources. Assuming EPA follows usual practice in calculating occurrence, the draft toxicological review EPA has provided for public review, would infer that that roughly 90% of the public water systems in the United States have Cr(VI) levels above the level of health concern (i.e., a drinking water health advisory level). A thorough review by the SAB is critical and particularly so given the potential implications for communities across the United States.

Reducing concentrations of Cr(VI) in potable water is challenging and expensive; communities treating to remove Cr(VI) should be those where there is a meaningful opportunity to protect human health. When PWSs must reduce Cr(VI) in source water, options are limited to (1) abandoning and removing sources (e.g., water wells), (2) treating with ion exchange, (3) reduction, oxidation, coagulation, filtration treatment, or (4) membrane treatment.⁹ Abandonment/removal of available water sources is becoming less of an option as population migration and climate change increasingly tax available water supplies and development of new supplies is challenging (e.g., new wells in declining aquifers, inability to obtain permit approvals for surface water impoundments, cost of desalination, and public acceptance / policy challenges associated with potable reuse). Ion exchange and membrane treatment are very expensive treatment options with difficult to dispose waste streams.¹⁰ As there is rarely attributable anthropogenic sources of Cr(VI) contamination the cost of new water supplies and water treatment are paid for through water rates.¹¹

EPA is not considering Cr(VI) in ongoing drinking water standard formulation. EPA has a statutory duty to consider the management of co-occurring contaminants in setting primary standards.¹² Currently there is limited research available for EPA to utilize were it to add managing risk associated with Cr(VI) to its rulemaking analyses, raising the prospect of mistakes in risk management decision-making.

⁸ [UCMR3 Fact Sheet: Searching for Emerging Contaminants in Drinking Water \(pdf\)](#) (May 2012, EPA 815-F-12-002)

⁹ California Waterboard, Division of Drinking Water. Request for External Scientific Peer Review of the Scientific Basis of Proposed Hexavalent Chromium Maximum Contaminant Level Best Available Technologies. August 10, 2021.

¹⁰ Chad J. Seidel, Issam N. Najm, Nicole K. Blute, Christopher J. Corwin, XueyiNg Wu. National and California treatment costs to comply with potential hexavalent chromium MCLs. AWWA Journal. (June 2013, <https://doi.org/10.5942/jawwa.2013.105.0080>)

¹¹ John A. Izbicki, Michael Wright, Whitney A. Seymour, R. Blaine McCleskey, Miranda S. Fram, Kenneth Belitz, Bradley K. Esser. Cr(VI) occurrence and geochemistry in water from public-supply wells in California. Applied Geochemistry. <https://doi.org/10.1016/j.apgeochem.2015.08.007>

¹² 42 U.S. Code § 300g-1(b)(3)(C)

Critical Question: Is this Toxicological Review Fit-to-Purpose?

The SAB review needs to answer the critical question of whether this toxicological review is fit for purpose. The SAB faces an unenviable task, reviewing over a few months more than 1,100 pages of analysis prepared by a team of almost 50 contributors over almost a decade. Moreover, EPA is asking for discrete answers to a list of 30 carefully prescribed questions. AWWA asks that the SAB answer two more important questions that underpin virtually every other charge question. Please provide (1) a prioritized list of critical errors and analytical gaps or shortfalls and (2) a prioritized list of corrective measures EPA should take so that the final toxicological review is fit for purpose.

AWWA is particularly concerned that the final toxicological review meets the needs of EPA's Office of Water. As currently drafted, the toxicological review implies a health concern for a concentration of Cr(VI) in water that is almost 3,000 times lower than the current total chromium maximum contaminant level and does so largely based on a single pair of animal studies where the lowest doses tested were nearly 300,000 times higher than the alleged level of concern in humans exposed via drinking water ingestion. AWWA has previously commented to EPA that a fit-for-purpose analysis was necessary.^{13,14} The current draft does not demonstrate that EPA has given serious consideration to AWWA's prior request.

AWWA greatly appreciates the work of the SAB. While you are uncompensated volunteer experts, you serve as the only external peer review of this toxicological review, which will substantively inform EPA's final document. The SAB's work comes at a time when this document has not likely received adequate internal review. Currently EPA's limited staffing and resources for toxicological analysis are focused on other agency priorities, including statutory duties to revise processes under the Toxic Substances Control Act (TSCA), preparing analyses of the risk of a suite of per- and polyfluoroalkyl substances (PFAS), and supporting other administration priorities and rulemakings. Across all of these program areas EPA is also plagued by the loss of senior scientists with years of practical experience in risk characterization. While there is not a record of internal agency review, only four federal agencies provided any comments on the draft toxicological review. Consequently, the SAB review may be the only focused, federal government-sponsored review this draft document receives.

¹³ AWWA. Comment letter regarding « Availability of the Systematic Review Protocol for the Hexavalent Chromium (Cr(VI)) Integrated Risk Information System (IRIS) Assessment, Docket ID No. EPA-HQ-ORD-2014-0313 » (April 29, 2019).

¹⁴ AWWA. Comment letter regarding "Assessment Materials for Hexavalent Chromium and Inorganic Arsenic Docket ID: EPA-HQ-ORD-2014-0313" (June 25, 2014).

AWWA appreciates the opportunity to offer comment on EPA's draft toxicology review, and we look forward to opportunities to engage as the analysis of the toxicology of Cr(VI) is brought to completion. If you have any questions regarding this correspondence or if AWWA can be of assistance in some other way, please contact Steve Via at svia@awwa.org or 202-326-6130.

Best regards,

ON BEHALF OF THE AMERICAN WATER WORKS ASSOCIATION



G. Tracy Mehan, III

Executive Director for Government Affairs

cc: John Morris, Hexavalent Chromium Review Panel Chair
Radhika Fox, EPA/OW
Wayne Cascio, EPA/ORD/CPHEA
Jennifer McLain, EPA/OW/OGWDW
Betsy Behl, EPA/OW/OST
Hanna Holsinger, EPA/OW/OGWDW
Suhair Shallal, EPA/SAB
Catherine Gibbons, EPA/ORD/CPHEA
Alan Sasso, EPA/ORD/CPHEA

Who is AWWA?

The American Water Works Association (AWWA) is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes more than 4,500 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. Our 50,000-plus total membership represents the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. AWWA unites the diverse water community to advance public health, safety, the economy, and the environment.