June 30, 2025

Via U.S. Mail and Email

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From:

Aluminum Association
American Chemistry Council (ACC)
American Foundry Society (AFS)
California Alliance of Small Business Associations
California Chamber of Commerce (CalChamber)
California Metals Coalition (CMC)
California Manufacturers and Technology Association (CMTA)
Independent Lubricant Manufacturers Association (ILMA)
Industrial Environmental Association (IEA)
Industrial Fasteners Institute (IFI)
Los Angeles Business Federation (LA BizFed)
Metal Finishing Association of California (MFA)
Metal Treating Institute (MTI)
National Association for Surface Finishing (NASF)
National Tooling and Machining Association (NTMA)
National Federation of Independent Business (NFIB)
Precision Metalforming Association (PMA)
Recycled Materials Association--West Coast Chapter (ReMA)

Re: Petition for Review of the Toxic Air Contaminant Human Health Assessment for Hexavalent Chromium Pursuant to Health and Safety Code Section 39662(e)

Dear Chief Scheele and Chief Holmes-Gen:

On behalf of the coalition of organizations identified above, we are writing to formally petition the California Air Resources Control Board (CARB) to review the inhalation unit risk factor (IUR) underlying CARB's toxic air contaminant determination for inhaled hexavalent chromium (Cr(VI)) under the Toxic Air Contaminant Identification and Control Act. California developed its current health assessment and IUR in 1985 and designated Cr(VI) as a TAC nearly 40 years ago. Since that time, significant new scientific evidence has emerged that warrants an update to the cancer potency and IUR estimated in the 1986 TAC determination.

I. INTRODUCTION

A fundamental principle of California's comprehensive air toxics programs is that human health risk assessments must be based on the best available scientific evidence and periodically updated to reflect advancements in scientific understanding. This important public policy is enshrined in statute in both the Toxic Air Contaminant Identification and Control Act[1] (TAC Act) and the Air Toxics Hot Spots Information and Assessment Act[2] (Hot Spots Act).

California identified Cr(VI) as a toxic air contaminant (TAC) and developed the inhalation unit risk factor (IUR) for Cr(VI) nearly 40 years ago, based on a human health risk assessment developed in 1985 by the Department of Health Services (DHS). At that time, relevant scientific evidence was extremely limited and, as a result, DHS primarily based the Cr(VI) human health assessment on just one study of workers at a chromate production plant in Painesville, Ohio (Mancuso (1975)[3]). While DHS determined that Mancuso (1975) was the best available science in 1985, it acknowledged that the study has significant limitations. For example, Mancuso (1975) only studied workers employed before 1940, a time when environmental controls to reduce workplace exposure to air contaminants were uncommon and workplace exposures were much higher than they are today. Cr(VI) monitoring data was not available, and DHS did not control for exposures to other substances, such as tobacco smoke, that likely contributed to cancer incidence in the study population, because data for these other exposures was also not available. DHS had to rely on indirect estimates and numerous assumptions to fill gaps in the sparse available data, and it used a crude model that did not consider competing causes of death.[4]

Since 1985, significant new scientific evidence has been published, and risk assessment methodology has advanced well beyond the rudimentary tools and policies available at that time. These developments include:

1. Updated analyses of the Painesville cohort evaluated in Mancuso (1975) that reduce some of the uncertainties in the 1975 study (Mancuso (1997)[5]);

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[1] Health & Saf. Code, § 39650, *et seq.*
[2] Health & Saf. Code, § 44300, *et seq.*
[3] Mancuso (1975). *Consideration of chromium as in industrial carcinogen.* In International Conference of Heavy Metals in the Environment; v. III, health; October. Toronto, ON, Canada: Institute for Environmental Studies, 343–356.
[4] DHS, Health Assessment for Chromium (Sept. 1985), pp. 2-3, *available at* https://ww2.arb.ca.gov/sites/default/files/classic/toxics/id/summary/hexchromepartb.pdf
[5] Mancuso (1977). *Chromium as an industrial carcinogen: Part I.* Am. J. Ind. Med. 31: 129-139.

2. Evaluations of a large cohort of workers at a chromate production facility in Baltimore, Maryland that include relatively precise exposure information and control for the effects of smoking (Gibb *et al.* (2020[6], 2015[7], 2000[8]));
3. A pooled analysis of 14 case-controlled studies from Europe and Canada evaluating exposure response relationships for Cr(VI) and lung cancer that controlled for smoking and included analyses for both men and women (Behrens *et al.* (2023)[9]);
4. An updated assessment by USEPA's Integrated Risk Information System (IRIS) that employed systematic review principles and methods to select the Baltimore cohort data as the foundation for inhalation risk assessment (U.S. EPA, 2024).[10]
5. New research involving male and female workers exposed to Cr(VI) in an aircraft manufacturing plant in Burbank, California (Lipworth *et al.* (2025)[11]); and
6. A new pooled analysis that combines data from the Painesville, Baltimore, and Burbank cohorts to develop a statistically robust lung cancer assessment (Allen *et al.* (2025)[12]).

The larger worker populations, better exposure data, and newer methodologies of the later studies allow CARB and the Office of Environmental Health Hazard Assessment (OEHHA) to develop a Cr(IV) IUR that is less reliant on estimates and assumptions and provides a more accurate assessment of human health risk. In 2011, based on a fraction of the new data available today, OEHHA concluded that Mancuso (1975) no longer provides the best basis to assess inhalation cancer risk.[13] The United States Environmental Protection Agency (EPA) recently reached the same conclusion and, in August 2024, it updated the IRIS Toxicological Review of Hexavalent Chromium based on the availability of "significant new epidemiologic and

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[6] Gibb *et al.* (2020). *The effect of age on the relative risk of lung cancer mortality in a cohort of chromium production workers.* Am. J. Ind. Med. 63: 774-778.
[7] Gibb *et al.* (2015). *Extended follow up of a cohort of chromium production workers.* Am. J. Ind. Med. 58: 905-913.
[8] Gibb *et al.* (2000). *Lung cancer among workers in chromium chemical production.* Am. J. Ind. Med. 38: 115-126.
[9] Behrens *et al.* (2023). *Occupational exposure to nickel and hexavalent chromium and the risk of lung cancer in a pooled analysis of case-control studies.* Int. J. Cancer. 152(4): 645-660.
[10] EPA, *Systematic Review Protocol for the Hexavalent Chromium IRIS Assessment (Preliminary Assessment Materials), Supplemental Information – Appendix A*, p. 1-1 (2024), *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549549; EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546.
[11] Lipworth *et al.* (2025). *Lung cancer mortality among aircraft manufacturing workers with long-term, low-level, hexavalent chromium exposure.* J. Occup. & Environ. Hyg. 22(3):214-227.
[12] Allen *et al.* (2025). *Lung cancer risk assessment associated with exposure to hexavalent chromium: Results of pooled analysis of three cohorts.* J. Occup. & Environ. Hyg. (May 28, 2025).
[13] OEHHA, Public Health Goals for Chemicals in Drinking Water, Hexavalent Chromium (CR VI) (July 2011), pp. 61-62, 84, 94-95, *available at* https://oehha.ca.gov/media/downloads/water/chemicals/phg/cr6phg072911.pdf.

experimental animal toxicity information for Cr(VI)" since EPA's 1998 IRIS assessment for Cr(VI).[14] OEHHA's conclusion nearly 15 years ago that Mancuso (1975) is no longer the best available science, and EPA's recent decision to update its 1998 IRIS assessment for the same reason, indisputably demonstrate the need for California to review and update the cancer potency and IUR estimated in the 1986 TAC determination.[15]

Continued reliance on an outdated and inaccurate Cr(VI) IUR undermines CARB's air toxics program and California public policy by increasing the risk of harm to disproportionately impacted communities. Limited state, local, and private resources provide the greatest public benefits when they are directed to regulation and control of air contaminants that are demonstrated to pose the greatest risks to human health based on the best available science. The 40-year old Cr(VI) IUR continues to drive regulatory decisionmaking despite the fact that scientific evidence developed after the 1985 IUR was derived demonstrates that it substantially overstates the health risk of inhaled Cr(VI). This calls into question the efficacy of all regulatory decisions and actions based on the IUR. It causes the public to be misinformed, agencies to ineffectively prioritize and misallocate limited resources, and regulated businesses to incur compliance costs for measures that do not improve public health. To ensure that regulatory and compliance actions maximize public health benefits, CARB must undertake a review and evaluation of the best science currently available and, as warranted by the scientific evidence, update the IUR estimated in the TAC determination.

II. BACKGROUND

a. CALIFORNIA'S AIR TOXICS PROGRAM

Reducing the public's health risk from exposure to airborne toxic chemicals is one of California's most fundamental air quality goals. Several laws, including the TAC Act and the Hot Spots Act, form the basis for CARB to identify and control TACs from a multitude of sources, to inform the public of significant risks from exposures to TACs, and provide pathways to reduce those risks.[16]

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[14] EPA, *Systematic Review Protocol for the Hexavalent Chromium IRIS Assessment (Preliminary Assessment Materials), Supplemental Information – Appendix A*, p. 1-1 (2024), *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549549; EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546.

[15] Petitioners do not assert that the new scientific evidence warrants changes to CARB's health effects determination or threshold determination.

[16] In addition to programs under the TAC Act and the Hot Spots Act, California's air toxics program includes the Children's Environmental Health Protection Program, the Community Air Protection Program, and local air district regulations. (CARB website, *Air Toxics Program*, available at https://ww2.arb.ca.gov/our-work/programs/air-toxics-program/about.)

CARB, OEHHA, and the state's 35 local air districts each play important roles in advancing these objectives.

Under the TAC Act, CARB identifies TACs and manages potential health risks.[17] CARB relies on health assessments prepared by OEHHA to determine whether regulatory action is necessary to reduce risks posed by potential TACs, to prioritize potential TACs for evaluation and potential regulation, to develop airborne toxic control measures (ATCM), and to ensure that ATCMs are cost-effective and appropriately balance public health protection and economic growth.[18]

The Hot Spots Act compliments the TAC Act. It is designed to provide information to state and local agencies and to the public on the extent of airborne emissions from stationary sources and the potential public health impacts of those emissions. Its purpose is to collect emissions data, to identify facilities having localized impacts, to ascertain health risks, to notify nearby residents of significant risks, and to mitigate those risks.[19] It creates a process to identify sources of TACs and to provide exposure information necessary for CARB to prioritize and develop regulations for TACs.[20]

Local air pollution control districts implement aspects of the Hot Spots Act and enforce regulations designed to reduce TAC emissions from businesses and industries in the state. Regulated facilities are required to report the types and quantities of certain TACs their facilities routinely release into the air.[21] CARB compiles this data into publicly available emissions inventories, which are updated every four years.[22]

Local air districts use the CARB inventories and OEHHA's TAC health assessments to prioritize facilities for regulatory review. High risk facilities are required to prepare health risk assessments utilizing health reference values, including but not limited to IURs for cancer causing substances, prepared by OEHHA.[23] Based on the results of these risk assessments, facilities may be required to notify surrounding populations of potential health risks associated with exposure to TACs

[17] Health & Saf. Code, § 39650.
[18] Health & Saf. Code, §§ 39665-39669; CARB, AB 1807-Toxics Air Contaminant Identification and Control, *available at* https://ww2.arb.ca.gov/resources/documents/ab-1807-toxics-air-contaminant-identification-and-control; CARB, Health Risk Assessment, *available at* https://ww2.arb.ca.gov/resources/documents/health-risk-assessment.
[19] Health & Saf. Code, § 44301.
[20] Health & Saf. Code, §§ 44301, 44364.
[21] Health & Saf. Code, § 44322.
[22] Health & Saf. Code, §§ 44340-44346.
[23] Health & Saf. Code, §§ 44344, 44344.6, 44360-44366; OEHHA, *Air Toxics Hot Spots Program Guidance Manual for the Preparation of Health Risk Assessments (2015)*, Appendix L (OEHHA/ARB Approved Health Values for Use in Hot Spot Facility Risk Assessments), *available at* https://oehha.ca.gov/air/crnr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0).

emitted by the facility or invest in airborne toxic risk reduction measures (ATRRMs), or both.[24] CARB is required to consider facility emissions reports and risk assessments to identify, establish priorities for, and control TACs.[25]

i. Health Risk Assessments Must be Based on the Best Available Scientific Evidence.

California public policy favors evidence-based decision-making and scientific integrity.[26] In the TAC Act, the Legislature explicitly found and declared that "the identification and regulation of toxic air contaminants should utilize the best available scientific evidence gathered from the public, private industry, the scientific community, and federal, state, and local agencies."[27] The Act requires OEHHA to base its health assessments on "all available scientific data," including relevant data provided by state, federal, and international health agencies, private industry, academic researchers, and public health and environmental organizations.[28] OEHHA must also use "current principles, practices, and methods used by public health professionals who are experienced practitioners in the fields of epidemiology, human health effects assessment, risk assessment, and toxicity," when evaluating the health effects of a substance.[29]

The relevant data that OEHHA must consider in connection with a health assessment under the TAC Act includes the current emissions reports and risk assessments required by the Hot Spots Act. Facilities must update their emission inventories every four years taking into consideration "improvements in measurement techniques and advancing knowledge concerning the types and

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[24] Health & Saf. Code, §§ 44390-44394.
[25] Health & Saf. Code, § 44364.
[26] CARB website, *About*, available at https://ww2.arb.ca.gov/about ("Reducing air pollution and protecting public health guide CARB's actions. Our role is to: … Research the causes and effects of air pollution problems – and potential solutions – using the best available science and technology."); *see also* CalEPA website, *About Us*, available at https://calepa.ca.gov/about/ ("Our departments are at the forefront of environmental science, using the most recent research to shape the state's environmental laws."); see also The White House, *Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking*, January 27, 2021, available at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/ ("It is the policy of my Administration to make evidence-based decisions guided by the best available science and data. Scientific and technological information, data, and evidence are central to the development and iterative improvement of sound policies, and to the delivery of equitable programs, across every area of government.").
[27] Health & Saf. Code, § 39650(d).
[28] Health & Saf. Code, § 39660, subd. (b).
[29] Health & Saf. Code, § 39660, subd. (b).

toxicity of hazardous materials released or potentially released."[30] The Legislature explicitly required CARB to consider this regularly-updated scientific data when regulating TACs.[31]

To ensure OEHHA's TAC health assessments are based on sound scientific knowledge, methods, and practices, the TAC Act requires independent public and scientific review of OEHHA's TAC health assessments and the related reports that CARB and OEHHA jointly prepare.[32] The Scientific Review Panel on Toxic Air Contaminants (SRP) has the responsibility to perform this independent review and to advise CARB in its evaluation of the health effects of substances that may be designated as TACs.[33]

ii. Health Assessments Must be Reevaluated and Updated When Warranted by New Scientific Evidence

To ensure health assessments continue to be based on the best available scientific evidence, periodic review of the scientific data and methods underlying existing health assessments and related regulations is required by both the TAC Act and the Hot Spots Act.[34] The Hot Spots Act requires consideration of new scientific data by imposing a requirement to collect and update emissions data every four years and to use that current data to prioritize and prepare updated risk assessments for regulated sources, and by requiring CARB to consider these data and risk assessments when regulating TACs.[35] In addition, the TAC Act provides a mechanism for CARB to reevaluate the scientific basis for a TAC identification in response to a petition alerting CARB to the existence of new scientific evidence.[36]

The Act allows any person to petition CARB to review a prior TAC determination based on new scientific evidence. In response, CARB, in coordination with OEHHA and the SRP, should review its prior TAC health assessment to consider "additional scientific evidence regarding the health effects of a substance which was not available at the time the original determination was made and any other evidence which would justify a revised determination."[37] The petition process is outlined below.

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[30] Health & Saf. Code, § 44344.
[31] Health & Saf. Code, § 44364.
[32] Health & Saf. Code, §§ 39650(d), 39660(b), 39661(c).
[33] Health & Saf. Code, §§ 39660(c), 39661, 39670.
[34] See Health & Saf. Code, §§ 39650(d), 39660(b), 39662(d), (e), 44344, 44344.6, 44360.
[35] Health & Saf. Code, §§ 44344, 44344.6, 44360,44364.
[36] Health & Saf. Code, §§ 39650(d), 39660(b), 39662(d), (e).
[37] Health & Saf. Code, § 39662, subd. (e).

iii. SRP Guidance Set Out Procedures for Petition Review

In anticipation of requests to consider new scientific information that may be relevant to a TAC health assessment, CARB and the SRP developed procedures and criteria to guide evaluation of and decisions on petitions to review a TAC health assessment (SRP Guidance). The SRP Guidance provides that CARB and OEHHA will first screen the petition "to determine whether the material contains the necessary elements to warrant the SRP's attention." The petition must "describe specifically what in the original risk assessment will be qualitatively and/or quantitatively changed," including whether and how the new evidence, if accepted, would "change the determination of the health effects of the compound," "change the threshold determination adopted by the Board and contained in the regulation," or "change the potency which was the basis of the original risk assessment."[38] The petition must also "describe the importance of the new evidence as it relates to the science (e.g. evidence, data, calculations, assumptions, and procedures) used to establish the original risk assessment," and "demonstrate that the new evidence is peer reviewed, either in the form of acceptance for publication by an academically or scientifically reputable journal, or documented acceptance by a recognized group of scientific experts (such as the International Agency for Research on Cancer, National Cancer Institute, National Toxicology Program, Environmental Protection Agency, or National Academy of Sciences)."[39]

If OEHHA finds that there is a need for further review of the original health assessment, it transmits the finding to the CARB Chair. Otherwise, the CARB Chair will ask the SRP to review the petition and OEHHA's evaluation, and to advise CARB on whether the new information warrants a review of the original TAC health assessment. The SRP's evaluation process includes consultation with OEHHA and other appropriate agencies and individuals, and discussion at a public SRP meeting. The SRP will advise the CARB Chair of its conclusion and recommendation, after which CARB may accept the petition and reevaluate the health effects of the substance in coordination with OEHHA and the SRP.[40]

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[38] Petitioners do not assert that the new evidence would change the determination of the health effects of the compound or the threshold determination adopted by the Board and contained in the regulation. Therefore, this petition focuses on how the new evidence changes the potency that was the basis of the original risk assessment.

[39] CARB, SRP, *Process for Evaluation and Response to Submittals for New Scientific Information as Evidence for Review of Toxic Air Contaminant Risk Assessments* (Dec. 12, 1989), available at https://ww2.arb.ca.gov/sites/default/files/classic/srp/document/statementofneed_1989_.pdf.

[40] CARB, SRP, *Process for Evaluation and Response to Submittals for New Scientific Information as Evidence for Review of Toxic Air Contaminant Risk Assessments* (Dec. 12, 1989), p. 2, available at https://ww2.arb.ca.gov/sites/default/files/classic/srp/document/statementofneed_1989_.pdf; see Health & Saf. Code, §§ 39660-39662.

b. CALIFORNIA'S Cr(VI) HEALTH ASSESSMENT AND TAC DETERMINATION

In 1986, CARB identified Cr(VI) as a TAC that has the potential to cause cancer based on an evaluation of health effects developed in 1985 by DHS, OEHHA's predecessor agency.[41] DHS established the current inhalation unit risk factor (IUR) for Cr(VI) at 1.5E-1 as the lifetime increased risk per microgram of Cr(VI) per cubic meter of exposure $(\mu g/m^3)^{-1}$, which is the 95 percent upper confidence limit on the estimated increased cancer risk from a lifetime of exposure at 1 $\mu g/m^3$. DHS used that value to calculate an inhalation cancer slope factor of 5.1E+02 milligrams per kilogram per day $(mg/kg\text{-}day)^{-1}$.[42] Based on the limited scientific evidence available at that time, CARB was unable to identify an exposure level below which there would be no risk of carcinogenic effects.[43]

DHS's 1985 Health Assessment was based primarily on a single epidemiology study evaluating exposures to workers at a Painesville, Ohio chromate production plant (Mancuso (1975)). The Mancuso cohort exposures exceed environmental exposures by approximately one million times current background levels in ambient air and the action level established by the South Coast Air Quality Management District (SCAQMD) for ambient Cr(VI), which makes the linear extrapolation highly uncertain.[44] Mancuso (1975) is also based on a single exposure monitoring event conducted in 1949, up to 18 years after exposures began for the study population (1931-37); it lacks direct measurements for Cr(VI), which requires estimates of the Cr(VI) fraction of total chromium; it does not include exposure estimates after 1949 even though the plant continued to operate until 1972, resulting in highly uncertain exposure estimates for long-term workers; and it does not control for confounding factors such as smoking status and exposure to other carcinogenic substances.[45]

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[41] CARB, Staff Report: Initial Statement of Reasons for Proposed Rulemaking, pp. 5-11, *available at* https://ww2.arb.ca.gov/sites/default/files/classic/toxics/id/summary/hex.pdf; DHS, Health Assessment for Chromium (Sept. 1985), *available at* https://ww2.arb.ca.gov/sites/default/files/classic/toxics/id/summary/hexchromepartb.pdf.

[41] OEHHA, Technical Support Document for Cancer Potency Values, Appendix B (May 2009).

[42] OEHHA, Technical Support Document for Cancer Potency Values, Appendix B (May 2009), pp. B-201 to B-207.

[43] Cal. Code Regs., tit. 17, § 93000; see also CARB, Staff Report: Initial Statement of Reasons for Proposed Rulemaking, *available at* https://ww2.arb.ca.gov/sites/default/files/classic/toxics/id/summary/hex.pdf.)

[44] See, e.g., SCAQMD, Updated Air Monitoring Plan for Paramount [referencing an ambient concentration of 1 ng/m^3 as the basis for reducing the size of the Paramount monitoring network "to focus on other areas that have higher potential for air toxics exposure"], *available at* http://www.aqmd.gov/docs/default-source/compliance/Paramount/updated-monitoring-plan.pdf?sfvrsn=8.

[45] See DHS, Health Assessment for Chromium (Sept. 1985), pp. 3, 95-97, *available at* https://ww2.arb.ca.gov/sites/default/files/classic/toxics/id/summary/hexchromepartb.pdf; OEHHA, Public Health Goals for Chemicals in Drinking Water, Hexavalent Chromium (CR VI) (July 2011), p. 94, *available at* https://oehha.ca.gov/media/downloads/water/chemicals/phg/cr6phg072911.pdf.

In 1985, DHS considered Mancuso (1975) to be the best science available at the time to derive dose-response curves for Cr(VI).[46] DHS noted uncertainty in the results due to "extrapolating from high occupational exposure levels to low ambient levels, the reliance on imprecise historical exposure levels as the basis for estimating potency, the lack of data differentiating between chromium oxidation states and compound specificity, and the lack of control for potential confounding factors (e.g., cigarette smoking)."[47] DHS acknowledged that it made several assumptions in its 1985 Health Assessment, including deriving results from application of the linear non-threshold model to the Mancuso data, and recognized the "limitations in the epidemiological data which create uncertainty in the risk assessment."[48]

c. CURRENT STATE OF THE SCIENCE RELEVANT TO THE Cr(VI) IUR

i. OEHHA Identified Substantial New Quantitative Risk Assessment Data for Inhaled Cr(VI) in 2011 That Were Not Available to DHS in 1985

Since 1985, significant additional scientific evidence has been published regarding the health effects of inhaled Cr(VI). In 2011, OEHHA described the new scientific information that was available at that time in its Public Health Goal (PHG) for Cr(VI) in drinking water.[49] It found that two studies were particularly relevant. The first study is Mancuso (1997), which included follow-up data on the same cohort as the Mancuso (1975) study, and also reported airborne Cr(VI) exposure measurements. The second study is Gibb *et al.* (2000), which examined mortality rates from lung cancer, prostate cancer, and all cancers combined among 2,357 male chromate production workers at a Baltimore, Maryland chromate production facility who were first employed between 1950 and 1974.[50]

OEHHA found that Gibb *et al.* (2000) had several major strengths that "make it a better candidate for potency estimation than the 1975 Mancuso study that has been the basis of previous risk quantifications (U.S. EPA, 1998; California Air Resources Board, 1985)." These include "relatively precise exposure information, a relatively large number of cancer deaths, and

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[46] DHS, Health Assessment for Chromium (Sept. 1985), p. 2, *available at* https://ww2.arb.ca.gov/sites/default/files/classic/toxics/id/summary/hexchromepartb.pdf.
[47] DHS, Health Assessment for Chromium (Sept. 1985), p. 3, *available at* https://ww2.arb.ca.gov/sites/default/files/classic/toxics/id/summary/hexchromepartb.pdf.
[48] DHS, Health Assessment for Chromium (Sept. 1985), p. 3, *available at* https://ww2.arb.ca.gov/sites/default/files/classic/toxics/id/summary/hexchromepartb.pdf.
[49] OEHHA, Public Health Goals for Chemicals in Drinking Water, Hexavalent Chromium (CR VI) (July 2011), pp. 61-62, 84, *available at* https://oehha.ca.gov/media/downloads/water/chemicals/phg/cr6phg072911.pdf.
[50] OEHHA, Public Health Goals for Chemicals in Drinking Water, Hexavalent Chromium (CR VI) (July 2011), p. 94, *available at* https://oehha.ca.gov/media/downloads/water/chemicals/phg/cr6phg072911.pdf.

control of smoking in some analyses."[51] Gibb *et al.* (2000) included all lengths of employment (instead of a 90-day minimum, and excluded workers first employed before 1950 because of less complete exposure information prior to that date. The analyses controlled for the potentially confounding effects of age, calendar year, gender, and race. It compared the cohort's mortality information for the period from 1950 through 1992 to the United States and the State of Maryland's general population cancer rates. The investigators found a statistically significant increased rate of mortality from lung cancer compared to standardized rates for the State of Maryland.[52]

OEHHA noted that Gibb *et al.* (2000) "was well conducted," and that the data "provided superior exposure measurements, which were generally much lower."[53] OEHHA also found that Gibb *et al.* (2000) is superior to Mancuso (1997) in several ways: "Some of the most important are the concurrent measurements of exposure, 7-fold larger cohort, 5-fold large[r] number of person years, and 2-fold larger number of cancer deaths. Most importantly, Gibb *et al*. (2000) provided data on expected cancer cases by calendar year, whereas Mancuso (1975, 1997) did not give information allowing assured reconstruction of expected cancer deaths in that regard." OEHHA noted a potential bias in Mancuso (1997), stating that the annually increasing background rate of lung cancer over the course of the study "is likely to bias risk slopes upwards with the referent population in the modeling."

For these reasons, OEHHA found that Gibb *et al.* (2000) provided a better basis for assessing cancer inhalation risk than the 1975 Mancuso study. It declined to use the Mancuso (1997) data, concluding that Mancuso (1997), like Mancuso (1975) is too uncertain and, "especially because it does not have a referent population, Mancuso (1997) is subject to too much bias to be useful by the present approaches."[54]

ii. U.S. Environmental Protection Agency's 2024 Integrated Risk Information System (IRIS) Assessment for Cr(VI)

On August 1, 2024, the U.S. Environmental Protection Agency (EPA) updated its 1998 IRIS assessment for Cr(VI) based on "[s]ignificant new epidemiologic and experimental animal toxicity

[51] OEHHA, Public Health Goals for Chemicals in Drinking Water, Hexavalent Chromium (CR VI) (July 2011), p. 61, *available at* https://oehha.ca.gov/media/downloads/water/chemicals/phg/cr6phg072911.pdf.
[52] OEHHA, Public Health Goals for Chemicals in Drinking Water, Hexavalent Chromium (CR VI) (July 2011), p. 61, *available at* https://oehha.ca.gov/media/downloads/water/chemicals/phg/cr6phg072911.pdf.
[53] OEHHA, Public Health Goals for Chemicals in Drinking Water, Hexavalent Chromium (CR VI) (July 2011), pp. 94-95, *available at* https://oehha.ca.gov/media/downloads/water/chemicals/phg/cr6phg072911.pdf.
[54] OEHHA, Public Health Goals for Chemicals in Drinking Water, Hexavalent Chromium (CR VI) (July 2011), p. 94, *available at* https://oehha.ca.gov/media/downloads/water/chemicals/phg/cr6phg072911.pdf.

information for Cr(VI) [that] has become available, including updates of occupational cohort studies."[55] The total lifetime exposure IUR for Cr(VI) for human lung cancer risk estimated in the updated "IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]" (2024 IRIS Assessment) is 1.8×10^{-2} (per µg Cr(VI)/m^3), which is the upper 95 percent confidence limit (95% CI) and includes age-dependent adjustment factors (ADAFs). The 95% CI value, not including ADAFs,[56] is 1.1×10^{-2} (per µg Cr(VI)/m^3).[57]

Because evidence of carcinogenicity of inhaled Cr(VI) is well established, EPA focused on identifying additional appropriate studies to update the quantitative exposure-response analysis and the derivation of the IUR. EPA notes that "[m]ore recent epidemiologic studies have been identified in the peer-reviewed literature which include higher quality exposure data, longer follow-up times, larger sample sizes, and more sophisticated analyses than were available in 1998."[58] To identify the best available science, EPA conducted a comprehensive systematic review of hundreds of studies on cancer and multiple noncancer health effects of inhalation and oral exposure to Cr(VI) to identify studies that might improve the quantitative dose-response analysis for human lung cancer.[59]

EPA initially identified 64 human lung cancer studies based on title and abstract screening. It conducted a full-text screening of these 64 studies for exposure-response data that may be informative for derivation of a revised IUR. It excluded studies that were not epidemiological analyses examining quantitative measures of chromium exposure in relation to lung cancer incidence or mortality risk. It also excluded studies if Cr(VI) measurements in air, or convertible equivalents such as CrO_3, were not presented, or if group-level exposure assignments were based on job title and not chromium measurements. EPA then restricted the remaining list to studies with the most recent cohort follow up data, and excluded studies that did not conduct exposure-response analyses using estimated airborne concentrations of speciated Cr(VI)

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[55] EPA, *Systematic Review Protocol for the Hexavalent Chromium IRIS Assessment (Preliminary Assessment Materials), Supplemental Information – Appendix A*, p. 1-1 (2024), *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549549.

[56] EPA's use of the 95% CI is consistent with OEHHA's risk assessment methodology for inhalation cancer potency factors. (See OEHHA, Air Toxics Hot Spots Program Guidance Manual (Feb. 2015), pp. 7-1 through 7-2, *available at* https://oehha.ca.gov/media/downloads/crnr/2015guidancemanual.pdf.)

[57] EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024) (EPA (2024)), p. 4-69 to 4-72, *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546.

[58] EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), p. 4-56, *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546; see EPA, *Systematic Review Protocol for the Hexavalent Chromium IRIS Assessment (Preliminary Assessment Materials), Supplemental Information – Appendix A* (2024), *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549549.

[59] EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)] – Supplemental Information* (Aug. 2024), *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549547.

compounds from which a slope and its standard error could be obtained. EPA evaluated the remaining studies for risk of bias and sensitivity, including consideration of exposure assessment, outcome ascertainment, population selection, confounding, selective reporting, sensitivity, and data analysis. Applying these criteria, EPA identified four occupational cohort studies classified as "high" or "medium" confidence to be considered for the derivation of the IUR for Cr(IV). Three of these studies involved the chromate production facility in Baltimore, Maryland (Gibb *et al.* (2020, 2015, 2000)), which EPA classified as high confidence. The fourth study involved the chromate production facility in Painesville, Ohio (Proctor *et al.* (2016)[60]), which EPA classified as medium confidence.[61]

Ultimately, EPA based its updated IUR on the Baltimore cohort studies by Gibb et al. (2020, 2015, 2000). EPA selected the Baltimore cohort (Gibb *et al.* (2020, 2015, 2000)) over the Painesville cohort (Proctor *et al.* (2016)) as the basis for deriving the IUR because the Baltimore cohort was (1) larger than the Painesville cohort, (2) had longer follow-up time, (3) had more deaths from lung cancer, (4) had no deaths from mesothelioma, despite having 66,651 additional years of person-time at risk than in the Painesville cohort, suggesting lower potential for confounding by asbestos exposure, (5) had more than an order of magnitude lower average exposures which can be more relevant to estimating effects at lower exposures and requires less extrapolation, (6) had more air samples to estimate exposures, and (7) had more complete data on smoking.[62] EPA applied the Cox proportional hazards model[63] to the Baltimore data set and controlled for smoking to develop the updated IUR.[64]

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60 Proctor *et al.* (2016). Inhalation cancer risk assessment of hexavalent chromium based on updated mortality for Painesville chromate production workers. J. Expo. Sci. Environ. Epidemiol. 26(2):224-31.

61 EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), p. 4-56 to 4-59, *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546.

62 EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), p. 4-61 to 4-63, *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546.

63 "The Cox proportional hazards model (Cox, 1972) is one of the most commonly used statistical models for the epidemiologic analysis of survival and mortality in cohort studies with extensive follow-up, including studies of the Baltimore, MD cohort (Gibb et al. (2020, 2015, 2000)). The Cox proportional hazards model assumes that a function of covariates (e.g., exposures) result in hazard functions that are a constant proportion of the baseline hazard function in unexposed individuals over some timescale, typically calendar time or age (e.g., the background age-specific rates of lung cancer in the population). One of the strengths of this model is that knowledge of the baseline hazard function is not necessary, and no particular shape is assumed for the baseline hazard; rather, it is estimated nonparametrically." (EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), p. 4-64, *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546, *citing* Cox (1972). *Regression models and life-tables*. J. of the Royal Stat. Socy. Series B (Methodological). 34(2): 187–220.)

64 EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), p. 4-69 to 4-72, *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546.

EPA's 2024 IRIS Assessment underwent independent external scientific peer review managed by EPA's Science Advisory Board (SAB).[65] The SAB agreed that EPA appropriately synthesized the available data for the IUR to describe its strengths and limitations, noting that "[t]he search parameters are defined, and the process used to narrow the choice to one cohort was logical, rational, and carefully explained in detail," and "the strengths and limitations of the top two choices (i.e., Baltimore, Maryland and Painesville, Ohio) for deriving the IUR are carefully and robustly delineated." It also agreed that the available data supports EPA's conclusions in the draft IRIS Assessment, noting that "the dose-related decisions are transparent and scientifically justified, including study selection for dose-response analyses, point of departure (POD) estimates, modeling choices and assumptions, dosimetric adjustments, derivation of candidate values, and confidence in the calculated values." The SAB stated that the IUR and ADAF would need to be amended if, upon additional evaluation, the evidence is sufficient to support a nonlinear approach.[66]

The SAB observed that, in the Gibb *et al.* studies, a large proportion of the cohort members were smokers, and that smokers accounted for 98% of lung cancer deaths that occurred in the study. Because this percentage is high, the SAB expressed concern that it could lead to speculation about the role of Cr(VI) and whether there could be an interaction between Cr(VI) and smoking. At SAB's suggestion, EPA included a discussion of the recent Behrens *et al.* (2023) study.[67]

Behrens *et al.* (2023) provides a pooled analysis of 14 case-controlled studies from Europe and Canada evaluating exposure-response relationships for Cr(VI) and nickel in relation to lung cancer risk (the SYNERGY study). This study includes 16,901 cases of lung cancer and 20,965 controls. A measurement-based job-exposure matrix (JEM) estimated job-year-region specific exposure levels to Cr(VI) and nickel, which were linked to the subjects' occupational histories. The average exposure in this study among controls is 40 $\mu g/m^3$-years among men and 26 $\mu g/m^3$-years among women, which is much lower than the exposures in the Painesville and Baltimore cohorts. The study controlled for smoking in pack-years and found exposure-response associations for never, former, and current smokers. The analysis was stratified for men and women, although the analysis of women was limited by the small sample size among those exposed. Among men, dose-response results appear to be consistent with results from the

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[65] SAB Review of EPA's draft IRIS Toxicological Review of Hexavalent Chromium (2023), p. 36, https://sab.epa.gov/ords/sab/f?p=114:0:5666222636833:APPLICATION_PROCESS=REPORT_DOC:::REPORT_ID:1121.

[66] SAB Review of EPA's draft IRIS Toxicological Review of Hexavalent Chromium (2023), pp. 36-37, https://sab.epa.gov/ords/sab/f?p=114:0:5666222636833:APPLICATION_PROCESS=REPORT_DOC:::REPORT_ID:1121.

[67] EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), p. 4-76, *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546; SAB Review of EPA's draft IRIS Toxicological Review of Hexavalent Chromium (2023), pp. 36-37, https://sab.epa.gov/ords/sab/f?p=114:0:5666222636833:APPLICATION_PROCESS=REPORT_DOC:::REPORT_ID:1121.

Baltimore and Painesville chromate production cohort studies, and the authors reported linear associations for Cr(VI) cumulative exposures and lung cancer risk. Among women, the findings were somewhat less consistent and not significant. The authors concluded that increased duration and cumulative exposure to Cr(VI) was associated with increased odds of lung cancer. EPA concluded that Behrens *et al.* (2023) further strengthened EPA's adjustment for smoking to note the possibility of an interaction.[68]

iii. New Peer-Reviewed Studies Provide Additional Significant New Scientific Evidence on Health Risks From Inhalation of Cr(VI) at Low Exposure Levels

Since EPA issued its updated Cr(VI) IRIS assessment in August 2024, two additional peer-reviewed studies have been published, Lipworth *et al.* (2025), and Allen *et al.* (2025), that add to the currently available scientific evidence on health risks posed by inhalation of Cr(VI).

a. Lipworth *et al.* (2025)

Lipworth *et al.* (2025) presents new research involving Cr(VI)-exposed painters, platers, and aircraft assembly workers, with one to 37 years of exposure, from a Lockheed Martin Aircraft Manufacturing plant in Burbank, California. It reconstructs individual-level exposures using a job-exposure matrix (JEM) and examines mortality among 3,723 Cr(VI)-exposed aircraft manufacturing workers, including 440 women, with long-term low-level Cr(VI) exposures, and long-term follow-up. The study evaluated cumulative exposures by worker from 1960 to 1998. A retrospective cohort mortality study was also conducted to calculate standardized mortality ratios (SMRs) by population demographics and exposure, and to conduct internally-referenced dose-response analysis. Smoking prevalence within the cohort, especially for women, was higher than the general population.

The workers in this cohort had mean and median cumulative exposures of 16 $\mu g/m^3$-yrs and 2.9 $\mu g/m^3$-yrs, respectively. Lipworth *et al.* (2025) found that, at the comparatively lower exposures observed in the Burbank cohort, there is no discernable relationship between increasing exposure to Cr(VI) and increasing lung cancer risk. Based on 1,758 observed deaths, mortality from cancer overall, smoking-related cancers, and lung cancer were significantly elevated, and lung cancer mortality was more highly elevated among women. The study analyses did not reveal a dose-response relationship between cumulative Cr(VI) exposure and lung cancer

[68] SAB Review of EPA's draft IRIS Toxicological Review of Hexavalent Chromium (2023), pp. 36-37, https://sab.epa.gov/ords/sab/f?p=114:0:5666222636833:APPLICATION_PROCESS=REPORT_DOC:::REPORT_ID:1121. The authors of the SYNERGY study acknowledged that the study has limitations, particularly regarding the exposure assessment, that may result in differential bias that could have unpredictable effects on reported associations.

mortality, suggesting that elevated cancer risks in this cohort are primarily smoking-related. The authors noted that, possibly as a consequence of the elevated smoking-related risks, any increased risk associated with Cr(VI) exposure was not observable. Nevertheless, the study provides significant new data in the low exposure range and among women, which will be useful for quantitative risk assessment.

b. Allen *et al.* (2025)

The exposure and lung cancer incidence data from the Burbank cohort were also combined with that of the Painesville and Baltimore cohorts in a quantitative cancer risk assessment that uses all of the available individual-level cohort study data. In the recent Allen *et al.* (2025) study, worker-specific exposure and lung cancer occurrence data was pooled across the full range of exposure from the three cohorts[69] for dose-response analysis to generate a more statistically robust lung cancer assessment than can be developed using any single study. The study noted that use of the pooled cohort broadens the range for dose-response analysis due to the comparatively low level exposures to Cr(VI) in the Burbank cohort.

The primary analysis focused only on male workers from all three cohorts with at least one year of exposure. Allen *et al.* (2025) found that the best dose-response function was a Michaelis-Menten equation.[70] The IUR from the primary model was 0.01 (95% CI: 0.006-0.01) per $\mu g/m^3$. Sensitivity analyses were then conducted to assess the impact of including the female workers from the Burbank cohort and workers with less than one year of exposure. Best estimates of the three IURs from secondary analyses, which removed the respirator use adjustment factors, included females from the aerospace cohort, and added workers with less than one year of exposure from the chromate production cohorts, were relatively consistent with the primary analyses, ranging from 0.008 to 0.03 per $\mu g/m^3$.

While inclusion of women and short-term workers increased the IUR, the authors concluded that this observation should be considered cautiously for several reasons. The Burbank women represent a relatively small fraction of the total cohort (440 vs. 3732 total primary pooled cohort) and contributed only 24 lung cancer deaths. Women had only low level cumulative

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[69] The studies by Gibb *et al.* (2020, 2015, 2000) of the Baltimore cohort yield consistent findings. As the Gibb *et al.* (2000) individual data are publicly available, and the data from the 2015 and 2020 publications are not, the 2000 data are used in the Allen *et al.* (2025) pooled cohort study.

[70] Michaelis-Menten kinetics is a model of enzyme kinetics that describes the relationship between enzyme and substrate concentrations and the rate of an enzyme-catalyzed reaction. The Michaelis-Menten equation describes the relationship between substrate and enzyme concentrations and the rates of enzyme-catalyzed reactions. (Cornish-Bowden (2016). *The origins of enzyme kinetics.* FEBS Letters 587(17): 2725-2730.)

exposure, which raises the potential for violation of the positivity assumption.[71] And the available smoking data, in terms of prevalence and pack-years, indicate that the Burbank women had relatively high smoking prevalence and pack years. As smoking is a strong risk factor for lung cancer, the finding that women are at higher risk than men warrants further investigation.

III. NEW SCIENTIFIC EVIDENCE REQUIRES A CHANGE IN THE 1985 DHS Cr(VI) CANCER POTENCY AND UNIT RISK FACTORS

The SRP Guidance criteria for screening of new scientific evidence, which are set forth in Section II.A. of the SRP Guidance, clearly demonstrates the need the SRP to formally evaluate the new evidence and provide a recommendation to CARB.

SRP Guidance Criteria II.A.1.: What in the original risk assessment will be quantitatively and/or qualitatively changed?[72]

The 1985 DHS health assessment for Cr(VI), on which CARB's 1986 TAC determination for Cr(VI) is based, must be quantitatively changed based on the new peer-reviewed scientific evidence discussed above. While this new data does not change DHS's 1985 determination that Cr(VI) poses an inhalation cancer risk, or CARB's finding in the 1986 TAC determination that there is no measurable threshold for increased cancer risk related to inhalation of Cr(VI), it does change the potency that was the basis of the 1985 health assessment, and the magnitude of the change is significant.

SRP Guidance Criteria II.A.2.: The importance of the new evidence as it relates to the science used to establish the original risk assessment.

When DHS conducted the original Cr(VI) health assessment 40 years ago, the Mancuso (1975) study provided the best available scientific data on Cr(VI) inhalation exposure and respiratory cancer risk. But DHS had to make numerous assumptions to develop a risk assessment based on

[71] Positivity violations occur when certain subgroups in a sample rarely or never receive an exposure of interest. The resulting sparsity in the data may increase bias with or without an increase in variance and can threaten valid inference. (Peterson *et al.* (2012). *Diagnosing and responding to violations in the positivity assumption.* Stat Methods Med Res. 21(1):31–54.)

[72] The SRP Guidance requires submittals of new scientific evidence to address whether and how the new evidence changes (1) the determination of the health effects of a compound, (2) the threshold determination adopted by CARB and contained in the regulation, and (3) the potency that was the basis of the original risk assessment. (CARB, SRP, *Process for Evaluation and Response to Submittals for New Scientific Information as Evidence for Review of Toxic Air Contaminant Risk Assessments* (Dec. 12, 1989).) As noted above, petitioners do not assert that the new evidence warrants a change in either of the first two elements. Therefore, this petition focuses on how the new evidence changes the potency that was the basis of the original risk assessment.

the data from the Mancuso (1975) study, and it acknowledged these assumptions would impact the accuracy of the risk assessment because of the study's data limitations and related uncertainties. The more recent peer-reviewed studies discussed above substantially reduce the uncertainties inherent in the Mancuso data, enabling OEHHA to rely on more refined and statistically robust scientific data, instead of assumptions, to derive a more accurate cancer potency value. The importance of the new evidence is discussed in greater detail below.

DHS's 40-year-old IUR has never been updated to account for advances in scientific evidence and methods of quantitative risk assessment which OEHHA currently uses for newly assessed carcinogens. Although current scientific evidence demonstrates that the 1985 IUR is considerably higher than necessary to protect human health, until it is revised through the statutorily prescribed process, OEHHA, CARB, and local air districts must continue using it in their regulatory decision-making and resource allocation decisions.[73] An updated IUR is needed for state and local regulators to update air toxics risk assessments and corresponding risk management actions to reflect the higher quality scientific evidence now available. These actions will ensure more effective investments of limited public and private sector resources to maximize public health protection.

SRP Guidance Criteria II.A.3.: The new evidence is demonstrated to be peer reviewed by either (i) publication by a scientifically reputable journal, or (ii) documented acceptance by a recognized group of scientific experts (e.g., EPA).

Section II.c.iii., above, demonstrates that the substantial new scientific evidence is peer reviewed and published by academically or scientifically reputable journals. In addition, for the new scientific evidence available as of August 2024, section II.c.ii. of this petition establishes that the scientific experts at EPA have accepted the new data. This acceptance is documented in EPA's updated IRIS assessment that EPA based on the new Baltimore cohort data following a systematic review of principles and methods.[74]

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[73] See OEHHA, Technical Support Document for Cancer Potency Values, Appendix A (May 2009), *available at* https://oehha.ca.gov/media/downloads/crnr/appendixa.pdf (listing the 1985 Cr(VI) IUR in an appendix to its air toxics risk assessment guidance, which is updated periodically to incorporate new cancer potency factors and inhalation unit risk values for other substances).

[74] EPA, *Systematic Review Protocol for the Hexavalent Chromium IRIS Assessment (Preliminary Assessment Materials), Supplemental Information – Appendix A*, p. 1-1 (2024), *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549549; EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546.

a. NEW PEER-REVIEWED SCIENTIFIC EVIDENCE IS MORE ROBUST, AND LESS UNCERTAIN, THAN THE LIMITED EVIDENCE AVAILABLE TO DHS IN 1985

The Mancuso (1975) study is no longer the best scientific evidence available regarding the health effects of inhaled Cr(VI). The Mancuso data set reaches back to the 1930s, a time period where exposures were not measured, exposure controls were essentially non-existent, and exposures to other sources of Cr(VI) and other carcinogenic substances in and out of the workplace, such as cigarette smoke, abounded. DHS had no choice but to rely heavily on assumptions and uncertainty factors to overcome limitations in the data.[75]

Since 1985, there have been considerable advances in the quantity and quality of data available from animal carcinogenesis bioassays, epidemiological studies, and newer mechanistic studies of carcinogenesis and related phenomena, which are summarized in section II.c., above.[76] As required in SRP Guidance Criteria II.A.3., and as discussed above, the new evidence is peer-reviewed and, for the scientific evidence available as of August 2024, accepted by the EPA, one of the authoritative bodies indicated in the SRP Guidance. Several recent studies have helped to fill gaps in the scientific literature, including the evaluation of more representative occupational and environmental exposure data from the Burbank cohort in Lipworth *et al.* (2025), and the pooled analysis of the Painesville, Baltimore, and Burbank cohort data in Allen *et al.* (2025). This more comprehensive and higher quality epidemiological data allows for more refined modeling approaches, including application of both linear and non-linear models, which better predict dose-response in the low exposure range.

While OEHHA has taken note of some scientific advances since 1985, the Cr(VI) IUR continues to rely on the outdated Mancuso (1975) study. In 1995, OEHHA acknowledged a study then underway at Johns Hopkins University "evaluating a much larger worker population with better exposure data" that "may help to resolve some of the differences and uncertainties in the [Cr(VI) inhalation] unit risk values."[77] That study was published more than 20 years ago (Gibb *et al.* (2000)) and, based on the availability of that study, OEHHA determined in 2011 that the

[75] DHS, Health Assessment for Chromium (Sept. 1985), pp. 3, 95-97, *available at* https://ww2.arb.ca.gov/sites/default/files/classic/toxics/id/summary/hexchromepartb.pdf.
[76] OEHHA, Technical Support Document for Cancer Potency Values (May 2009), p. 93-95, *available at* https://oehha.ca.gov/media/downloads/crnr/tsdcancerpotency.pdf.
[77] OEHHA. 1995. Appendix B. Comparison of Cal/EPA and US EPA Toxicity Values. California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, *available at* https://oehha.ca.gov/media/downloads/risk-assessment/report/appbraac.pdf

Mancuso (1975) study is no longer the best available science for quantifying cancer risk from inhalation of Cr(VI).[78]

Outside of California, there has also been an ongoing effort by regulatory agencies in the U.S. and abroad to update older risk assessment documents that relied on Mancuso (1975), including, most recently, EPA in August 2024.[79] These regulatory agencies have all cited the recent and more representative data from the Baltimore cohort studies (Gibb *et al.* (2020, 2015, 2000)) to establish inhalation cancer potency estimates for Cr(VI). EPA, OSHA, the National Institute for Occupational Safety and Health (NIOSH), and the Texas Commission on Environmental Quality (TCEQ, 2014) have each developed quantitative measures of inhalation risk from the updated Baltimore cohort data.[80,81] Additionally, the European Commission Scientific Committee on Occupational Exposure Limits (SCOEL) has used Gibb *et al.* (2000) to recommend a Cr(VI) occupational exposure limit for European Union member states.[82] The values derived by EPA, NIOSH, TCEQ, and SCOEL are markedly different than the value derived from DHS's 40-year-old health assessment, which is still being used by CARB, OEHHA, and local air quality management districts.

EPA's recent update to its Cr(VI) IRIS assessment, based on the evaluation and acceptance of the newer peer-reviewed scientific data by EPA's scientific experts, provides persuasive evidence of the need for California to update it's 1985 Cr(VI) IUR.[83] As noted above, to develop the 2024 IRIS

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[78] OEHHA, Public Health Goals for Chemicals in Drinking Water, Hexavalent Chromium (CR VI) (July 2011), pp. 61-62, 84, 94-95, *available at* https://oehha.ca.gov/media/downloads/water/chemicals/phg/cr6phg072911.pdf.
[79] EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546; EPA, *Systematic Review Protocol for the Hexavalent Chromium IRIS Assessment (Preliminary Assessment Materials), Supplemental Information – Appendix A*, p. 1-1 (2024), *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549549.
[80] EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546; OSHA, Occupational Exposure to Hexavalent Chromium; Final Rule (29 CFR Parts 1910, 1915 (Feb. 28, 2006), available at https://www.govinfo.gov/content/pkg/FR-2006-02-28/pdf/06-1589.pdf; NIOSH, *Criteria for a Recommended Standard. Occupational Exposure to Hexavalent Chromium,* DHHS (NIOSH) Publication No. 2013-128, available at https://www.cdc.gov/niosh/docs/2013-128/pdfs/2013_128.pdf; TCEQ, Hexavalent Chromium (Particulate Compounds), Development Support Document (Aug. 4, 2014), available at https://www.tceq.texas.gov/downloads/toxicology/dsd/final/hexavalent_chromium.pdf.
[81] NIOSH, OSHA and TCEQ had access to the individual-level Gibb *et al.* (2020) worker exposure data, which eliminated the modeling issues encountered by OEHHA in the 2011 PHG evaluation.
[82] SCOEL REC 386 (2017) available at SCOEL/REC/386 Chromium VI compounds - Publications Office of the EU (europa.eu).
[83] See CARB, SRP, *Process for Evaluation and Response to Submittals for New Scientific Information as Evidence for Review of Toxic Air Contaminant Risk Assessments* (Dec. 12, 1989) [stating that SRP's screening criteria requires the

Assessment, EPA relied on later versions of the Baltimore cohort study (Gibb *et al.* (2020, 2015)) that addressed limitations in the Gibb *et al.* (2000) study, including the lack of accounting for time since first exposure and the lack of individual work histories.[84] The updated data includes individual work history exposure data, which enabled EPA to assess 5-year and 15-year lag periods, resolving both uncertainties OEHHA encountered when it attempted to model the Gibb *et al.* (2000) study data based on the publications alone (without the underlying data).[85]

Since EPA published its 2024 IRIS Assessment last August, two additional peer-reviewed studies have been published in the Journal of Occupational and Environmental Hygiene that add substantially to the weight of evidence supporting an update of the 1985 DHS health assessment used to establish the existing California IUR – Lipworth *et al.* (2025) and Allen *et al.* (2025). The Burbank cohort evaluated in Lipworth *et al.* (2025) is much larger than those of Baltimore or Painesville, and it includes women. Importantly, this research also evaluates airborne exposures that were far lower than in the Painesville and Baltimore cohorts. These levels are more representative of current occupational and environmental exposures, and Lipworth *et al.* (2025) showed that there is no discernable relationship between increasing exposure to Cr(VI) and increasing lung cancer risk at these low exposure levels. The pooled analysis performed in the Allen *et al.* (2025) study expands exposure conditions to those more typical of modern industries, rather than being exclusively reliant on data from the historical chromate production industry. The use of the pooled cohort broadens the range for dose-response analysis due to the comparatively low-level exposures to Cr(VI) in the Burbank cohort. The pooled IUR estimate also allows for inclusion of a broader dose-response range and reduced uncertainty by way of a larger population, additional years of follow-up, and incorporation of broader geographical and cohort characteristics that are more relevant to the general population.

Table 1 compares the 1985 DHS California IUR estimate to other values developed from more recent risk assessments using more robust and relevant data sets. This information indicates that the existing California value overpredicts cancer risk from inhalation of Cr(VI) by more than an order of magnitude. Specifically, the current OEHHA IUR of 0.15 per $\mu g/m^3$ is 9 to 37 times higher than all other comparable Cr(VI) IURs developed from the newer datasets.

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new peer-reviewed scientific evidence to be either published in a reputable journal or accepted by a recognized group of scientific experts, which expressly includes scientific experts at EPA].

[84] OEHHA, Public Health Goals for Chemicals in Drinking Water, Hexavalent Chromium (CR VI) (July 2011), pp. 94-95, *available at* https://oehha.ca.gov/media/downloads/water/chemicals/phg/cr6phg072911.pdf.

[85] See EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), pp. 4-59 to 4-63, *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546.

Table 1. Comparison of IUR values from the 1985 CDHS evaluation with published values developed in other studies of newer, more refined and statistically robust data

Risk Assessment Publication	No. of Workers	Cr(VI) Exp Data	Concurrent Exp Data	Account for Smoking	IUR at Maximum Likelihood Estimate (MLE)	IUR 95% Upper Confidence Limit[1]
CDHS, 1985	332	No	No	No	0.009	**0.15**
Haney *et al.* (2014)[86] (Based on Gibb *et al.* (2000) and Crump *et al.* (2003)[87]) Basis of TECQ IUR	1518	Yes	Yes	Yes	0.0023 (weighted combined best estimate)	0.004 (Gibb *et al.* (2000)) 0.0036 (Crump *et al.* (2003))
Proctor *et al.* (2016)[88] (Painesville)	714	Yes	Yes	Yes	0.0083	0.017
EPA (2024) based on Gibb *et al.* (2020) (Baltimore)	2357	Yes	Yes	Yes	0.0080	0.011
Allen *et al.* (2025) (Primary cohort of workers from Baltimore, Painesville, and Burbank)	3283	Yes	Yes	Yes	0.0096	0.013
Primary + short term workers (Allen *et al.* (2025))	5,032	Yes	Yes	Yes	0.011	0.014
Primary +Burbank females (Allen *et al.* (2025))	3723	Yes	Yes	Yes	0.026	0.034

[86] Haney *et al.* (2014). *Development of an inhalation unit risk factor for hexavalent chromium*. Regul. Toxicol. Pharmacol. 68(2):201-11.
[87] Crump *et al.* (2003). *Dose-response and risk assessment of airborne hexavalent chromium and lung cancer mortality.* Risk Anal. 23(6): 1147-63.
[88] Proctor *et al.* (2016). *Inhalation cancer risk assessment of hexavalent chromium based on updated mortality for Painesville chromate production workers*. J. Expo. Sci. Environ. Epidemiol. 26(2):224-31.

As Table 1 shows, the IUR values at the maximum likelihood estimate (MLE) are remarkably consistent, including the value derived by DHS in 1985. However, at the 95% upper confidence limit, the DHS IUR stands out as a substantial outlier relative to all the other estimates due to the high uncertainty and very limited statistical power of the Mancuso (1975) study. Use of this study as the basis of the DHS (1985) health assessment resulted in very wide confidence intervals relative to risk assessments based on the more refined data sets.

EPA's new IUR uses much more current, comprehensive, and reliable data to derive the upper 95% confidence interval (CI).[89] The availability of the more robust Baltimore cohort study, and EPA's selection of that study over the Painesville cohort for purposes of quantitative risk assessment by itself warrants a change in the existing California IUR. The rigor and sophistication of these newer data enabled EPA to apply the Cox proportional hazards model to the Baltimore data set, and control for smoking in quantifying cancer risk. This new scientific data resulted in EPA deriving an IUR of 1.1×10^{-2} (per µg Cr(VI)/m^3), which is more than an order of magnitude lower than OEHHA's current value of 1.5×10^{-1} (per µg Cr(VI)/m^3).[90]

The EPA 2024 IRIS Assessment, coupled with the additional evidence from Lipworth *et al.* (2025) and Allen *et al.* (2025), demonstrate that the 1985 DHS assessment substantially overpredicts cancer risk from inhalation of Cr(VI). The accumulated evidence requires a change to the cancer potency that was developed in the 1985 DHS health assessment to inform more accurate risk assessments and more targeted and effective risk management actions.

b. ADVANCEMENTS IN RISK ASESSMENT METHODOLOGY AND PRACTICE SINCE 1985 HAVE IMPROVED THE ACCURACY AND RELIABILITY OF RISK ASSESSMENTS

Advancements in health risk assessment methodology and practice since 1985 have improved the accuracy of human health risk assessments, and the science of risk assessment continues to develop rapidly. OEHHA acknowledges that there have been a number of advances in cancer risk assessment methodology since the 1980s. These include OEHHA's 2009 Technical Support

[89] EPA's 1998 IRIS IUR, which is 1.2×10^{-2} (per µg Cr(VI)/m^3), is the maximum likelihood estimate (MLE), and was developed from the Mancuso (1975) study, rather than the upper 95% CI. In 1998, EPA did not report an upper 95% CI, which OEHHA typically uses as the basis of its IURs to ensure they do not underestimate risk. Importantly, the new EPA value is the upper 95% CI IUR, consistent with the approach taken by OEHHA. (See EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), pp. 4-64 to 4-74, *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546.)

[90] EPA, *IRIS Toxicological Review of Hexavalent Chromium [Cr(VI)]* (Aug. 2024), pp. 4-69 to 4-70, *available at* https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549546

Document for Cancer Potency Factors,[91] EPA's 2005 Guidelines for Carcinogen Risk Assessment,[92] EPA's 2012 Benchmark Dose Technical Guidance,[93] EPA's Review of the Reference Dose and Reference Concentration Processes,[94] and EPA's Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens.[95]

EPA's 2024 IRIS Assessment for Cr(VI) provides a helpful reference. For example, EPA used benchmark dose modeling methodology, which is generally considered a preferred method for deriving a point of departure for risk assessment.[96] When DHS conducted its health assessment in 1985, benchmark dose modeling was not commonly used for this derivation. Recent advancements in risk assessment methodology also include systematic review and risk of bias analyses of all available studies that could be used for derivation of unit risk values and overall confidence classification. EPA conducted such a systematic review for its 2024 IRIS Assessment, which led to its selection of four studies that it determined provided date suitable for quantitative risk assessment, including the most recent studies of the Baltimore and Painesville cohorts. Notably, EPA did not select any of the Mancuso studies, which it screened out during the systematic review process for exposure-response data of Cr(VI) and lung cancer.[97]

c. AN UPDATED IUR IS NEEDED TO ACCURATELY ASSESS HUMAN HEALTH RISK AND DIRECT RESOURCES TO BEST PROTECT PUBLIC HEALTH

The decision to update health reference values used in air toxics regulatory programs should not be limited only to those instances where new scientific information indicates that the substance may pose a higher risk than previously determined. An accurate IUR, whether it is higher or lower than the current IUR, is needed for CARB and local air districts to accurately evaluate the potential for increased cancer risk from inhalation of Cr(VI) in the vicinity of stationary sources

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[91] OEHHA, *Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures* (May 2009), available at https://oehha.ca.gov/air/crnr/technical-support-document-cancer-potency-factors-2009.

[92] EPA, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005), https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

[93] EPA, Benchmark Dose Technical Guidance (Jun. 2012), *available at* https://www.epa.gov/sites/default/files/2015-01/documents/benchmark_dose_guidance.pdf.

[94] EPA, Review of the Reference Dose and Reference Concentration Processes (Dec. 2002), *available at* https://hero.epa.gov/hero/index.cfm?action=search.view&reference_id=88824.

[95] EPA, Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (Mar. 2005), *available at* https://hero.epa.gov/hero/index.cfm?action=search.view&reference_id=88823.

[96] EPA, IRIS Toxicological Review of Hexavalent Chromium (Final Report, 2024), pp. 4-63 to 4-72, *available at* https://iris.epa.gov/document/&deid=361833.

[97] EPA, IRIS Toxicological Review of Hexavalent Chromium (Final Report, 2024), pp. 1-1, 1-13 to 2-3, *available at* https://iris.epa.gov/document/&deid=361833; see also EPA, *Final Systematic Review Protocol for the Hexavalent Chromium IRIS Assessment* (Aug. 2024), *available at* https://iris.epa.gov/document/&deid=343950.

and in ambient air. It may be tempting to conclude that no public harm could result from using an IUR that is lower than necessary to protect human health, but that is a false premise with negative societal consequences.

Based on the outdated 1985 IUR, Cr(VI) continues to be a significant risk driver throughout the state. The range of annual mean concentrations and estimated risks from Cr(VI) exposure reported by CARB between 2015 and 2022 at certain California sites are presented below in Table 2.[98] Calculated risks range from 10 to 35 per million, which exceed de minimis risk levels established by several air districts.

Table 2. Range of mean concentrations and estimated risks of Cr(VI) at California locations between 2015 and 2022 (source: CARB [a])

Location (years)	CrVI [b]	
	Mean Concentration Range (ng/m^3)	Estimated Risk Range (per million)
Riverside, CA (2015-2022)	0.032 – 0.083	13 – 34
Simi Valley, CA (2015-2022)	0.025 – 0.063	10 – 26
Roseville, CA (2015-2022)	0.025 – 0.035	11 – 14
San Francisco, CA (2015-2022)	0.043 – 0.083	18 – 35

[a.] California Air Resources Board (CARB). Monitoring Sites with Ambient Toxics Summaries, Hexavalent Chromium https://www.arb.ca.gov/adam/toxics/sitelists/cr6sites.html

[b.] Means and risks only shown for years with data in all 12 months. The annual mean is calculated by averaging the monthly means of all measurements taken at the site. Estimated risks represent the risk that one person in a population of one million may have of developing cancer from exposure to the annual mean concentration over 70 years, based on a IUR of 0.15 µg/m^3 for hexavalent chromium.

Because the 1985 Cr(VI) IUR is outdated, the estimated risks are unreliable and, as indicated by EPA's 2024 IRIS Assessment, the newer scientific evidence on which it is based, and the subsequently published Lipworth *et al.* (2025) and Allen *et al.* (2025) studies, significantly overstated. Continued reliance on outdated and overstated risk estimates in regulatory programs can produce or perpetuate unintended and counter-productive outcomes.

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[98] The available data for the selected locations generally do not include annual mean concentrations of Cr(VI) from 2018, 2020, and 2021.

Consider the following example from the South Coast Air Quality Management District (SCAQMD). SCAQMD issued a 2021 update to their Multiple Air Toxics Exposure Study (MATES V),[99] which reported ambient concentrations of a wide range of air toxics at several locations in Southern California based on data collected in 2018 and 2019 (SCAQMD 2021). The average Cr(VI) concentrations at the 10 Southern California monitoring locations presented in MATES V are extremely low, ranging from 0.0264 nanograms per cubic meter of air (ng/m^3) to 0.0607 ng/m^3, and have decreased significantly since 1998 (MATES II). However, based on the 1985 IUR, cancer risks are still reported to exceed 20 per million in MATES V.

The concentrations of Cr(VI) in the South Coast Air Basin and the corresponding cancer risks are shown in Figure 1, below.

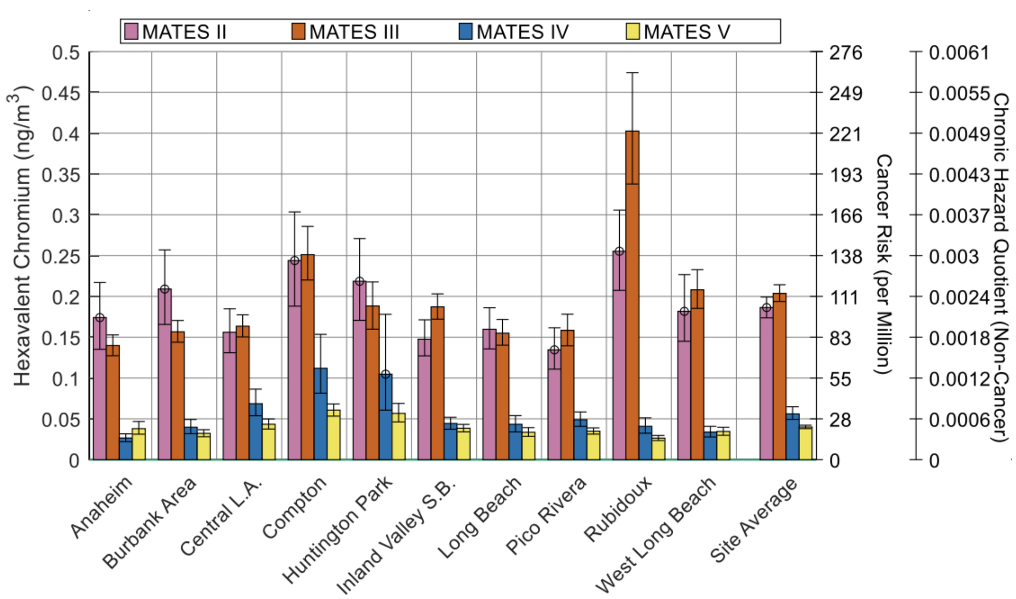

Figure 1. Average Concentrations of Hexavalent Chromium as TSP Reported in MATES V. Error bars denote the 95% confidence interval. [MATES II (1998-1999), MATES III (2004-2006), MATES IV (2012-2013), MATES V (2018-2019)]

[99] South Coast Air Quality Management District (SCAQMD). 2021. Multiple Air Toxics Exposure Study in the South Coast AQMD, MATES V. Appendix IV. August.

At these levels, virtually any emissions of Cr(VI) from a stationary source are likely to trigger the requirements of SCAQMD's Rule 1402,[100] including but not limited to public notification and facility-specific risk reduction audits and plans. The latter often requires substantial capital investments in emissions control equipment and ongoing operations and maintenance costs. Where this process is driven by health reference values based on outdated science, as is the case for Cr(VI), there is a higher probability that both regulatory and facility resources will be misdirected toward actions that do not yield meaningful public health benefits. These resources will not be available to mitigate exposures to other, potentially higher risk substances (there are hundreds of substances subject to regulation pursuant to federal, state, and local air toxics regulatory programs[101]) or to address cumulative risks in overburdened communities. These outcomes also present risk communication challenges for the regulatory agency, the regulated facility, and the surrounding community because perceptions of involuntary risk from exposure to facility emissions often cause unnecessary alarm and tension between facility operators, local regulatory and elected officials, and the surrounding community. Furthermore, escalating operating costs, regulatory, and political pressures on affected businesses can lead to lost economic productivity in the form of facility curtailments and closures, and lost jobs and tax revenues in the communities in which they operate. CARB and OEHHA should carefully consider these broader public health and public policy impacts when evaluating this petition.

IV. CONCLUSION

Pursuant to Health and Safety Code section 39662(e), Petitioners request that CARB grant this petition, direct the SRP to provide a formal evaluation and recommendation to CARB, and direct OEHHA to reevaluate and update the Cr(VI) IUR based on the significant new scientific evidence that was not available when California developed its current health assessment and IUR nearly 40 years ago. This includes EPA's 2024 IRIS Assessment, the scientific evidence on which it is based, and the subsequently published Lipworth *et al.* (2025) and Allen *et al.* (2025) studies, which demonstrate convincingly that the 1985 IUR for Cr(VI) is outdated and that its application significantly overstates estimated public health risk from Cr(VI) concentrations in ambient air. The new scientific evidence clearly establishes that a quantitative change to California's Cr(VI) cancer potency and IUR is warranted.

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[100] SCAQMD, Rule 1402, available at https://www.aqmd.gov/docs/default-source/rule-book/reg-xiv/rule-1402.pdf?sfvrsn=4.

[101] For example, CARB has identified over 200 substances and groups of substances as TACs. (CARB website, CARB Identified Toxic Air Contaminants*, available at* https://ww2.arb.ca.gov/resources/documents/carb-identified-toxic-air-contaminants.)

CARB's continued reliance on the outdated IUR for Cr(VI) is inconsistent with the letter and spirit of the TAC Act, the Hot Spots Act, and California air quality policy. It causes decision-making by CARB, local air districts, and the regulated community to favor actions that, while imposing a substantial cost to regulated entities and the public at large, do not meaningfully improve public health protection. Unless and until the current IUR is reconsidered in light of current scientific evidence, its use in California will continue to result in deleterious real-world impacts.

Thank you for your time and consideration.

Sincerely,

James Simonelli, Executive Director
California Metals Coalition

cc: Via Email Only
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