Public Health Goal Science Policy White Paper

January 2022

I. Executive Summary

California's drinking water systems, like our electricity and transportation systems, were designed based on population and usage patterns, climactic conditions, statutory requirements, and societal expectations that have changed dramatically over the past several decades. Today, the Human Right to Water Act (**HRTWA**)[1] challenges public water systems to deliver water that is simultaneously clean, safe, accessible and affordable for all customers, regardless of prevailing conditions and system limitations. We are committed to working cooperatively with the state to achieve HRTWA objectives on a statewide basis.

Recent statewide assessments demonstrate that a business-as-usual approach to drinking water management has become a barrier to achieving HRTWA objectives. Conventional strategies need to evolve to address competing demands on finite resources and to reverse current trends that compromise health benefits, drinking water accessibility and affordability. This effort is especially important in the drinking water standard-setting context because many standards for emerging contaminants can divert water system budgets from actions necessary to treat for known health threats and maintain reliable service. They also often require rate increases that disproportionately impact low-income households and cause previously self-sufficient systems to become dependent on state funding. State agencies can no longer afford to wait until the end of the standard-setting process to consider the impact of new drinking water standards on HRTWA objectives. Rather, achieving the multiple objectives of the HRTWA must begin at the front end of the process – with the development of Public Health Goals (**PHG**).

The California Safe Drinking Water Act (**CSDWA**) establishes PHGs as the single most influential factor in determining new Maximum Contaminant Levels (**MCL**). Recent developments in health risk assessment methods and published research on emerging contaminants like **1,4-dioxane** present opportunities for the Office of Environmental Health Hazard Assessment (**OEHHA**) to conduct cutting edge assessments that more accurately characterize health risk and will support development of MCLs by the State Water Resources Control Board (**SWRCB**) that achieve all the objectives of the HRTWA.

[1] AB 685 (Eng., 2012), Water Code §106.3.

Moving forward, we recommend that OEHHA incorporate the best available health effects science and risk assessment methods into future PHG risk assessments to:

- Continue to improve the accuracy of health risk estimates;
- Support sound risk management decisions, including targeted investment of water utility and state resources for public health protection and increased water supply resilience; and
- Minimize negative impacts on public health and welfare that result from significant increases in the cost of water.

Developing a PHG for 1,4-dioxane presents a good opportunity to apply the most current science and scientific methods to support a future MCL that advances state efforts to achieve HRTWA objectives.

II. A business-as-usual approach will not achieve Human Right to Water Act Objectives.

Success in achieving the objectives of the HRTWA will depend on new strategies that take data-driven approaches to drinking water management rather than business-as-usual approaches that create conflict, scarcity and competition for limited resources. The SWRCB's first drinking water "needs assessment"[2] demonstrates that the business-as-usual approach has created a multi-billion-dollar funding gap for hundreds of at-risk and failing water systems. Continuing in that same vein will inevitably compromise the ability of water providers to fully utilize available water resources, including local groundwater and recycled water, to support system and supply resilience.

OEHHA's scientific assessments impose real world obligations on water systems and ratepayers.

OEHHA's scientific evaluations are used to support drinking water Notification Levels (NL) and Response Levels (RL), adopted by the SWRCB, and PHGs adopted by OEHHA, both of which place obligations on public water systems independent of MCLs. In practice, and as a result of recent legislation (AB 756, C. Garcia, 2019), NLs and RLs are increasingly and inappropriately treated as *de facto* enforceable standards. For example, the SWRCB Division of Drinking Water has refused to approve operating

[2] 2021 Drinking Water Needs Assessment; Informing the 2021-22 Safe & Affordable Drinking Water Fund Expenditure Plan; State Water Resources Control Board; April 2021: https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/needs/2021_needs_assessment.pdf[3] The California Public Utilities Commission prohibits investor-owned utilities from recovering costs for PFAS treatment, since there is no enforceable MCL.

permits for some new water treatment systems that do not include treatment for PFOA and PFOS, even though it has yet to adopt MCLs for these contaminants, and despite the fact that water systems are incapable of recovering their treatment costs in the absence of an enforceable standard.[3]

Health and Safety Code §116470(b) also requires public water systems with more than 10,000 service connections that detect contaminants at levels above their corresponding PHGs to disclose those exceedances in Consumer Confidence Reports, and to hold public hearings on those Reports.[4] These disclosures are often misconstrued as indications that consumers are being exposed above "safe" levels, causing unnecessary alarm and undermining public trust in the drinking water supply.[5] Low-income consumers are most directly harmed by mistrusting the safety of tap water and turning to more expensive and less regulated alternatives such as bottled water.[6] Water systems make every effort to avoid these outcomes, including through closure of wells with concentrations above PHGs, which can compromise water supply resilience, and pre-emptive installation of treatment systems, which increases water rates and exacerbates existing water affordability problems. Similar actions have been taken in response to exceedances of NLs.

Finally, laboratory sample analysis at the very low levels established for many PHGs are at the very limit of what is technologically possible. Setting PHGs at low parts per billion or parts per trillion implies that such measurements are routinely achievable and widely accessible. In practice, such extremely sensitive test methods are not widely available for many contaminants, either because they have not been developed or because they are difficult to perform and relatively few laboratories are certified to use them. These limitations result in much more expensive sample analysis which may be cost prohibitive for smaller water systems.

The most effective approach to mitigating these counterproductive outcomes is for OEHHA to use the best available science and scientific methods to develop risk assessments and PHGs that are as accurate and representative of actual health risk as possible.

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[3] The California Public Utilities Commission prohibits investor-owned utilities from recovering costs for PFAS treatment, since there is no enforceable MCL.

[4] https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/CCR.html accessed 8/31/21.

[5] Sydney Evans, David Andrews, Ph.D., Tasha Stoiber, PhD., and Olga Naidenko, Ph.D., "PFAS Contamination of Drinking Water Far More Prevalent Than Previously Reported," https://www.ewg.org/research/national-pfas-testing/

[6] Leila Family, PhD, MPH, Guili Zheng, PhD, MPH, Maritza Cabezas, DDS, MPH, Jennifer Cloud, MPH, Shelly Hsu, MPH, Elizabeth Rubin, MPH, Lisa V. Smith, MS, DrPH, Tony Kuo, MD, MSHS, "Reasons why low-income people in urban areas do not drink tap water." https://doi.org/10.1016/j.adaj.2018.12.005

PHGs have a direct impact on the ability of water systems to achieve HRTWA objectives.

To achieve the objectives of the HRTWA, and the public health protection purpose of the CSDWA, health risk assessment practice must incorporate the most current health effects science and risk assessment methods. The CSDWA establishes PHGs as the cornerstone of MCLs for drinking water contaminants.[7] Since protection of public health is a high priority, the PHG understandably has a greater influence on where the MCL is set than any other factor considered by the SWRCB.

PHGs that rely on default assumptions, or individual studies instead of weight-of-evidence analysis, or that do not employ best available scientific methods, may not accurately predict human health risk, and may drive MCLs that trigger more detrimental health trade-offs.

For contaminants like 1,4-dioxane that require specialized and energy-intensive treatment systems, imposition of unnecessary compliance obligations will trigger potential health trade-offs, especially for smaller water systems, because they will have a disproportionate impact on the budgets of the affected water systems and the households they serve. Water systems that are not eligible for, or are unsuccessful in securing, financial support from the state will be forced into compliance scenarios that may not provide meaningful additional health benefits, but will increase burdens on socioeconomically disadvantaged populations, increase the risk of water supply disruptions and diminish the ability of water agencies to implement long term plans for water supply resilience.

Alternatively, risk assessments that utilize the best available science and scientific methods will produce more finely tuned PHGs that can support health protective MCLs without placing unnecessary new constraints on drinking water access or affordability.

The relationship between expensive regulations and negative health outcomes is well documented.

Published research demonstrates that a regulation which reduces household income will result in reduced spending on healthcare, food and other goods and services that are foundational to good health.[8] It is equally well established that extremely stringent

[7] Health and Safety Code §116365(a) requires the SWRCB to set the MCL as close to the PHG as is technologically and economically feasible, "placing primary emphasis on the protection of public health."

[8] *See e.g.*, James A. Auerbach & Barbara Kivimae Krimgold, Income, SOCIOECONOMIC STATUS, AND HEALTH (2001) at p. 139; Susan L. Ettner, *New evidence on the relationship between income and health*, 15 Journal of Health Economics

drinking water standards can substantially increase compliance burdens for water systems and water rates for the public. However, the incremental public health benefits from such established standards are not well documented and may be small compared to negative public health trade-offs from increasing the cost of water. And, these negative outcomes will not be evenly distributed on a statewide basis or within individual system service areas. Rather, they will be concentrated in socioeconomically disadvantaged subpopulations that do not have the capacity to absorb additional costs. These dynamics can diminish or negate the intended health benefits of drinking water regulations and ratepayer affordability initiatives.

Faced with these challenges, the state can no longer afford to wait until the end of the MCL development process to consider the impact of a new standard on public health and safety, access to reliable water supplies and water affordability. Rather, the effort to achieve the multiple objectives of the HRTWA must begin at the front end of the standard setting process – with development of the PHG.

III. OEHHA's work on PHGs must incorporate the best available science and the most current practices and methods in risk assessment.

A safe, no-effect level of exposure can be determined for substances with threshold effects.

The current science on understanding chemical toxicity continues to evolve. Practices once considered leading-edge are being replaced by new methods and data that allow for a more in-depth understanding of how chemicals interact with human biological systems. This section describes current methods and techniques being used by authoritative bodies in their evaluations of drinking water contaminants, including:

- Evaluating potential threshold modes of action for carcinogens;
- Using Physiologically Based Pharmacokinetic (**PBPK**) and other biological models; and
- Incorporating systematic review and weight-of-evidence (**WOE**) into the evaluation and review of available data.

Scientific advances in these areas are contributing to improved predictive estimates of cancer risk.

67, 82 (1996); Robert W. Hahn et al., Do Federal Regulations Reduce Mortality?, AEI-Brookings Joint Center For Regulatory Studies (2000) at p. 4.; Randall Lutter & John F. Morrall III, *Health-Health Analysis: A New Way to Evaluate Health and Safety Regulation*, 8 Journal of Risk and Uncertainty 43, 44 (1994).

Most assessments of cancer risks are derived from animal studies conducted at the highest non-lethal exposures possible, and the lowest exposures are often much higher than anticipated human exposures. It can be challenging to estimate risk to humans from datasets generated from animal studies. To do that, assessors model tumor responses at exposures below those used in the animal studies. In general, two basic approaches are used: (1) linear low-dose extrapolation, and (2) a non-linear/threshold approach.

The linear approach predicts risk by extrapolating from the lowest dose tested in the animal study through the origin of the dose-response curve. In this model, risk to humans is proportional to dose or exposure. This linear approach is generally used to estimate risks from substances such as mutagens[9], and where the available data are insufficient to support a more predictive approach. This risk model assumes any dose or exposure represents a finite risk.

The threshold approach estimates low-dose risk by identifying an exposure below which adverse effects, including cancer, are unlikely[10]. This threshold can be derived from an understanding of the mode of action (MOA) of biochemical events, such as adverse effects that exceed inherent repair processes, or processes that eliminate the substance before tissue concentrations become harmful. If the anticipated exposure is less than the threshold exposure, the risk of adverse health effects, including cancer, is *de minimis*. If the exposure is above the threshold, risk is proportional to dose.

With the rapid advancement of tools available to determine the basis for tumor development, risk assessments are increasingly based on an understanding of the underlying biology and recognition that many biological processes involved in chemical carcinogenesis have thresholds due to the natural adaptive and repair capabilities of the body. The threshold approach generally makes greater use of information about the underlying biology than the linear approach and applies this information to assess risk.

Authoritative bodies have recognized threshold effects for carcinogens.

[9] US EPA. "Guidelines for Carcinogen Risk Assessment [EPA Report]. (EPA/630/P-03/001F)." Washington, DC, 2005. https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

[10] Clewell RA, Thompson CM, Clewell HJ. Dose-dependence of chemical carcinogenicity: Biological mechanisms for thresholds and implications for risk assessment. *Chem Biol Interact*. 2019;301:112-127. doi:https://doi.org/10.1016/j.cbi.2019.01.025

Current science is calling into question some long-held assumptions about linear dose-response relationships for carcinogens[11]. Linear models were originally developed from radiation studies where a nonzero risk was assumed for any exposure to radiation, no matter how small. This approach was adapted to assess risk from exposure to chemical carcinogens, and current practices for cancer risk assessment often use a linear approach as the default for deriving cancer slope factors. However, the linear approach was established when scientific understanding of chemical carcinogenesis was in its infancy.

By 2005, USEPA had already indicated in its Guidance for Carcinogen Risk Assessment that the default approach should be used only when critical data are absent[12]. Much more has been learned about cancer biology since then, and it has become evident that in many cases critical biochemical events must occur before the subsequent development of tumors. It is now understood that even for mutagenic and/or genotoxic chemicals, intrinsic molecular and cellular processes precede tumor formation, often with clear dose-dependent thresholds.[13] As a result, the potential for threshold mechanisms should be evaluated before employing the default linear approach.

A number of regulatory assessments have utilized non-linear (i.e., threshold) dose-response curves, and regulatory agencies and other authoritative bodies have increasingly used threshold approaches for evaluating chemical carcinogens. Several examples of these approaches are summarized below:

- **Chloroform** – Perhaps the oldest and best-known example of the use of biological understanding and weight-of-evidence to inform a non-linear threshold is USEPA's 2001 risk assessment for chloroform. That assessment concluded that the liver and kidney tumors observed in animal studies were a consequence of sustained cell toxicity (cytotoxicity) leading to an increase in cell repair and replacement and spontaneous errors in DNA replication. Because cytotoxicity always preceded the development of tumors, US EPA concluded this was a threshold response and exposures below the cytotoxicity threshold did not present significant risk.[14]

[11] Golden R, Bus J, Calabrese E. An examination of the linear no-threshold hypothesis of cancer risk assessment: Introduction to a series of reviews documenting the lack of biological plausibility of LNT. *Chem Biol Interact*. 2019;301:2-5. doi:10.1016/j.cbi.2019.01.038

[12] US EPA. *Guidelines for Carcinogen Risk Assessment [EPA Report]. (EPA/630/P-03/001F).* Washington, DC; 2005. https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

[13] Kobets T, Williams GM. Review of the evidence for thresholds for DNA-Reactive and epigenetic experimental chemical carcinogens. *Chem Biol Interact*. 2019;301:88-111. doi:https://doi.org/10.1016/j.cbi.2018.11.011

[14] US EPA. *Toxicological Review of Chloroform (CAS No. 67-66-3) In Support of Summary Information on the Integrated Risk Infomation System (IRIS) EPA/635/R-01/001*. Washington, DC; 2001. https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0025tr.pdf.

- **Hexavalent Chromium** - Current evidence demonstrates that CrVI causes tumors in the lung and GI tract by a threshold MOA resulting from chronic inflammation leading to cytotoxicity, cell proliferation and spontaneous mutations. Risk assessments conducted by the World Health Organization (2019)[15] and Health Canada (2018)[16] concluded that the weight of evidence supports this non-linear threshold MOA. Both concluded that exposures below those that caused inflammation and cytotoxicity were protective of both cancer and non-cancer effects.

- **Cadmium -** The European Commission Scientific Committee on Occupational Exposure Limits (**SCOEL**) determined in 2017 that the mechanisms by which Cd causes cancer in humans is through both genotoxic and non-genotoxic pathways that are best described by a threshold model. SCOEL determined that although there is some evidence of mutagenicity, it is secondary to adverse outcome pathways that have dose-dependent thresholds.[17]

- **Nickel -** SCOEL determined in 2011 that the MOA for Ni is threshold chronic toxicity and inflammation resulting in cell proliferation, spontaneous mutations and tumor development.[18] The resulting occupational exposure limits set by SCOEL were derived based on protection against inflammatory effects in the lung, which would also protect against carcinogenic effects.

- **Formaldehyde** – SCOEL issued a comprehensive evaluation of the formaldehyde data in 2016, concluding that tumors in the nasal mucosa of rodents are the result of chronic cell proliferation processes.[19] The Biologically Based Dose Response (BBDR) model developed for formaldehyde was one of the first models considered by USEPA in a risk assessment.

- **Titanium Dioxide** – The European Union Committee for Risk Assessment (RAC) has determined that the MOA for TiO_2 involves accumulation of respirable particles in the lung, which can induce chronic inflammation, cytotoxicity, cell

[15] WHO. *Chromium in Drinking-Water Draft Background Document for Development of WHO Guidelines for Drinking-Water Quality*.; 2019. https://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/draft-chromium-190924.pdf.
[16] Health Canada. *Guidelines for Canadian Drinking Water Quality: Guideline Technical Document – Chromium*. Ottawa; 2018. https://www.canada.ca/en/health-canada/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-guideline-technical-document-chromium.html.
[17] Opinion from the Scientific Committee on Occupational Exposure Limits (SCOEL) 336, Cadmium and its inorganic compounds. European Commission. Adopted 8 February 2017.
[18] Recommendation from the Scientific Committee on Occupational Exposure Limits for nickel and inorganic nickel compounds (SCOEL/Sum/85). European Commission. June 2011.
[19] Recommendation from the Scientific Committee on Occupational Exposure Limits for Formaldehyde (SCOEL/REC/125). European Commission. Adopted 30 June 2016.

proliferation and mutations.[20] RAC concluded that the MOA is consistent with a practical threshold, and that lung tumors only develop when exposure levels overload the capacity of the lungs to clear the particles.

- **Pesticides** – To date, US EPA has established threshold MOAs for 27 pesticide active ingredients (AI)[21]. Examples include folpet, acifluorfen, amitrole, captan, cyproconazole, lactofen, and pyroxasulfone.

Methods for identifying and applying mode of action as a basis for quantifying health risk should be integrated into OEHHA's risk assessment practice.

The MOA provides a framework for organizing and evaluating the information from the systematic review and WOE approach to characterize the biological sequence of events from exposure to the eventual adverse effect. USEPA, in their 2005 Cancer Risk Assessment Guidelines, has defined the MOA for the development of cancer as "a sequence of Key Events and processes, starting with interaction of an agent with a cell, proceeding through operational and anatomical changes, and resulting in cancer formation."

The use of the MOA framework fosters a deeper understanding of the biological basis for an adverse effect, which reduces uncertainty in the risk assessment. Numerous regulatory agencies including USEPA, Health Canada and EFSA encourage the use of an MOA framework and have incorporated it into guidance documents and chemical toxicity assessments.

PBPK models have been developed for many chemicals that use biological information to predict human health effects with much greater precision than extrapolation from high dose animal studies using default assumptions.

As discussed in USEPA's 2005 Guidelines for Carcinogen Risk Assessment, the use of biologically based information to support dose-response assessment is the preferred approach. The National Academy of Sciences report "Toxicity Testing in the 21st Century: A Vision and a Strategy" also highlights the importance of biological models to define chemical dose-response and more accurately predict human health risk[22].

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[20] RAC. *Committee for Risk Assessment RAC Opinion Proposing Harmonised Classification and Labelling at EU Level of Titanium Dioxide*. Helsinki, Finland; 2017. https://echa.europa.eu/documents/10162/682fac9f-5b01-86d3-2f70-3d40277a53c2.

[21] http://npic.orst.edu/chemicals_evaluated.pdf

[22] Krewski, Daniel, Daniel Acosta, Melvin Andersen, Henry Anderson, John C. Bailar, Kim Boekelheide, Robert Brent, et al. "Toxicity Testing in the 21st Century: A Vision and a Strategy." *Journal of Toxicology and Environmental Health - Part B: Critical Reviews*, 2010. https://doi.org/10.1080/10937404.2010.483176.

Physiologically based pharmacokinetic (**PBPK**) models and biologically based dose-response (**BBDR**) models are being used with increasing frequency in chemical risk assessments. Advances in PBPK and BBDR modeling, and the increasing availability of supporting data, have resulted in the development of increasingly accurate models. PBPK and BBDR models have been developed to evaluate health effects by regulatory agencies worldwide. Modeling allows for the holistic evaluation of chemicals based on knowledge of the underlying biology of the specific chemical.

Systematic review methods and weight-of-evidence enable the risk assessor to objectively evaluate the suitability and consistency of published studies for quantitative risk assessment.

Systematic review methods provide a framework to formulate the objective of the review, develop search criteria, and define the criteria used to evaluate the retrieved information. Application of well-defined evaluation criteria enable the risk assessor to select studies and results on the basis of information quality and relevance, rather than on the basis of the most conservative findings among all identified studies. USEPA[23] and the European Food Safety Authority (**EFSA**)[24] have incorporated systematic review into their risk assessment guidelines.

While the application of the systemic review process enhances the effectiveness and quality of literature reviews, WOE approaches allow the synthesis of actionable conclusions for use in the risk assessment process. USEPA has recognized that both are necessary and has developed guidance for incorporating WOE into the risk assessment process. EFSA has developed similar guidelines.

IV. The need for application of the best available science in drinking water health risk assessments has never been greater.

The SWRCB has found that the average cost of water has increased by 45% between 2007 and 2015[25], and that "cost increases for any single need, such as water, can force families to make difficult and risky tradeoffs which could harm their health and

[23] US EPA. *APPLICATION OF SYSTEMATIC REVIEW IN TSCA RISK EVALUATIONS*. Washington, DC; 2018. doi:EPA 740-P1-8001

[24] EFSA. Application of systematic review methodology to food and feed safety assessments to support decision making. *EFSA J*. 2010;8(6):1637. doi:10.2903/j.efsa.2010.1637

[25] State Water Resources Control Board, Options for Implementation of a Statewide Low-Income Water Rate Assistance Program, February 2020, page 4.[26] State Water Resources Control Board, Options for Implementation of a Statewide Low-Income Water Rate Assistance Program, February 2020, page 4.

welfare."[26] The SWRCB also found that: "If water is unaffordable, low-income households will likely either consume less water than is healthy and/or consume less of other vital goods and services to pay for the water they need.[27]

In 2020, concerns about the impact of the COVID-19 pandemic on drinking water service prompted the SWRCB and the California Public Utilities Commission to jointly evaluate the extent of consumer debt and water system revenue losses due to non-payment of water bills. A SWRCB survey of water systems in November 2020[28] indicated that approximately 1.6 million California water customers have accumulated $1 billion in debt, more than $600 million of which is due to non-payment of water bills. That same survey also identified nearly 300 water systems at "high or extreme risk of failing."

More recently, the SWRCB completed the statewide drinking water "needs assessment" required by the 2018 Budget Act and SB 200 (Monning, 2019).[29] That report, released on April 9, 2021, identified:

- 345 water systems that fail to meet the goals of the Human Right to Water Act;
- 617 public water systems, 611 state small water systems and approximately 80,000 domestic wells that are at-risk of exceeding water quality standards, going dry, becoming unaffordable or otherwise becoming impaired;
- A total cost of approximately $10.25 billion to implement interim and long-term solutions for failing and at-risk systems and sources over the next 5 years;
- A funding and financing gap of $4.7 billion in existing SWRCB-administered drinking water programs and another $3 billion in costs that are not eligible for grant funding under existing programs.

In announcing the release of the needs assessment report, Water Board Chair Joaquin Esquivel stated that the at-risk systems are "not failing now, but they're one pump failure, one drought, *one new maximum contaminant level,* one crisis, an economic

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[26] State Water Resources Control Board, Options for Implementation of a Statewide Low-Income Water Rate Assistance Program, February 2020, page 4.

[27] Id. at page 10.

[28] https://www.waterboards.ca.gov/drinking_water/programs/documents/ddwem/covid_financial_survey_board_ppt_20210119.pdf[29] 2021 Drinking Water Needs Assessment; Informing the 2021-22 Safe & Affordable Drinking Water Fund Expenditure Plan; State Water Resources Control Board; April 2021: https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/needs/2021_needs_assessment.pdf

[29] 2021 Drinking Water Needs Assessment; Informing the 2021-22 Safe & Affordable Drinking Water Fund Expenditure Plan; State Water Resources Control Board; April 2021: https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/needs/2021_needs_assessment.pdf

downturn, from no longer serving clean, safe, affordable water."[30] Chair Esquivel's comment underscores the fact that the needs assessment is a snapshot in time that, among other limitations, does not include estimates of compliance requirements resulting from adoption of future MCLs. These factors, combined with the current drought and state policies such as the 2020 California Water Resilience Portfolio[31] that promote greater reliance on local water resources, place many more communities at greater risk of future water supply disruptions and sharper increases in the cost of water. MCLs that are lower than necessary to protect public health will only add to this burden.

Water systems must prioritize spending to achieve the Human Right to Water.

Just as the state must prioritize limited funding and staff resources to address Human Right to Water Act challenges which impact the most vulnerable communities, water systems must prioritize expenditure of ratepayer revenues to maximize protection of public health, minimize disruptions in water service which compromise public access to water, and minimize the imposition of additional costs on water customers that will undermine drinking water affordability. OEHHA identified these challenges in its January 2021 report to the SWRCB on Achieving the Human Right to Water in California. OEHHA's report states that "Many low-income households depend on water systems struggling with issues such as aging infrastructure, unreliable supplies, and a cost structure that pushes water rates to unaffordable levels."[32] It also acknowledged that the Human Right to Water cannot be achieved by making progress toward one goal at the expense of the others.[33] A system that serves water below applicable affordability thresholds, but routinely violates drinking water standards, is not achieving the goals of the HRTWA. At the same time, a system that provides water below all applicable MCLs at a cost that exceeds affordability thresholds also does not achieve the goals of the HRTWA. All state agencies are required to consider the policies of the HRTWA when revising, adopting, or establishing policies and regulations, when those policies or regulations are pertinent to drinking water.[34]

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30 https://login.politicopro.com/?redirect=https%3A%2F%2Fsubscriber.politicopro.com%2Farticle%2F2021%2F04%2F09%2Fcalifornia-estimates-6b-needed-to-fix-failing-drinking-water-systems-9426077%3Fsource%3Demail

31 https://waterresilience.ca.gov/wp-content/uploads/2020/07/Final_California-Water-Resilience-Portfolio-2020_ADA3_v2_ay11-opt.pdf

32 Achieving the Human Right to Water in California: An Assessment of the State's Community Water Systems; Office of Environmental Health Hazard Assessment, January 2021, page 8: https://oehha.ca.gov/media/downloads/water/report/hrtwachievinghrtw2021f.pdf

33 Id., page 15: "A system's deficiencies in any given component (i.e., water quality, water accessibility and water affordability) should not be outweighed or downplayed by more favorable performance in the other components."[34] Water Code § 106.3, subdivision (b).

34 Water Code § 106.3, subdivision (b).

PHGs that more accurately predict human health risk will support MCLs that protect public health while minimizing additional water accessibility and affordability burdens. The need for fine-tuned PHG risk assessments has never been greater and is necessary to achieve the goals of the HRTWA.

V. 1,4-Dioxane is an unconventional contaminant that requires a more refined risk assessment.

1,4-Dioxane occurrence in drinking water sources.

1,4-dioxane was historically used as a stabilizer for chlorinated solvents. Today, it is used primarily as a chemical intermediate. According to the California Department of Toxic Substances Control, it is also commonly generated during production of consumer products such as shampoo, body wash, dish detergent, and laundry detergent.[35] Most of the 1,4-dioxane in these products mixes with wastewater after product use.[36] It may also be released into soil and groundwater when these products are disposed into septic systems and landfills. Because 1,4-dioxane is water soluble and can migrate through soils, these historic and current sources have resulted in 1,4-dioxane detections in groundwater and drinking water supplies. And, because wastewater treatment plants do not effectively remove 1,4-dioxane (see below),[37] California water conservation policies promoting reuse of treated wastewater for ground water recharge[38] create an additional pathway for 1,4-dioxane occurrence in drinking water at low levels.

US EPA's Unregulated Contaminant Monitoring Rule 3 (**UCMR-3**) sampling results show widespread occurrence of 1,4-dioxane at low levels in Public Water Systems (**PWS**) sampled nationwide.[39] The frequency of detections was highest in California, with PWS in Los Angeles and Orange Counties having relatively higher 1,4-dioxane concentrations compared to other parts of the state.

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[35] California Department of Toxic Substances Control (DTSC), 2019. Safer Consumer Products Work Plan Implementation, 1,4-Dioxane in Personal Care and Cleaning Products, page 2.
[36] Id., page 3.
[37] Id., page 8: "The presence of 1,4-dioxane in surface water and the effluents of wastewater treatment plants has been documented in several studies (Abe, 1999; Kawata et al., 2003; Simonich et al., 2013; Sun et al., 2016). Stepien et al. (2014) showed that treatment of domestic wastewater did not reduce concentrations of 1,4-dioxane at several plants."
[38] State Water Resources Control Board, Water Quality Control Policy for Recycled Water, December 11, 2018: https://www.waterboards.ca.gov/board_decisions/adopted_orders/resolutions/2018/121118_7_final_amendment_oal.pdf.
[39] Adamson et al., 2017. 1,4-Dioxane drinking water occurrence data from the third unregulated contaminant monitoring rule; Science of the Total Environment.

The weight of the health effects evidence supports a threshold for cancer risk.

USEPA evaluated the potential human health risk of 1,4-dioxane in 2013 - nearly a decade ago - and designated it as "likely to be carcinogenic to humans."[40] Since then, new information has been published to clarify the carcinogenic mode of action. This new information indicates that carcinogenic effects occur only above a threshold level of exposure. This information adds to the weight of evidence supporting a cytotoxic MOA for 1,4-dioxane that involves the following key events: 1) sustained high exposure levels that 2) saturate both cell defense mechanisms and the ability of cells to metabolize and excrete 1,4-dioxane, followed by 3) cell damage, 4) repair and rapid reproduction of cells, 5) incorporation of genetic errors leading to 6) formation of tumors. Importantly, the key events described in this MOA are not observed at exposures below the metabolic saturation threshold described in key event 2. The weight of the evidence does not justify use of the default linear approach.

This cytotoxic MOA is consistent with the findings of other public health regulatory bodies, including the World Health Organization, and the European Union Chemical Bureau.[41] In March of this year, Health Canada adopted a national drinking water standard for 1,4-dioxane of 50 ppb based on a threshold MOA.[42] Health Canada's action, along with the most recent scientific publications, demonstrate that USEPA's (2013) assumption of a linear dose-response is at odds with its own findings on genotoxicity and is incompatible with the current understanding of human cancer risk from exposure to 1,4-dioxane in drinking water.

In March of 2020, the USEPA announced that it would delay making a determination to regulate 1,4-dioxane in drinking water because it had not established that regulation would present a "meaningful opportunity for public health risk reduction."[43] In fact, US EPA determined that based on available occurrence information "less than two additional baseline cancer cases per year [are] attributable to 1,4-dioxane in drinking water" on a nationwide basis.[44]

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[40] U.S. EPA. 2013. Toxicological Review of 1,4-Dioxane (with inhalation update) (CAS No. 123-91-1) in Support of Summary Information on the Integrated Risk Information System (IRIS) [EPA Report]. Washington, D.C. EPA-551 635/R-11/003-F.

[41] WHO, 2005. 1,4-Dioxane in drinking water. (WHO/SDE/WSH/05.08/120). Geneva, Switzerland; ECJRC, 2002. European Union risk assessment report: 1,4-dioxane. (EUR 19833 EN). Luxembourg: Office for Official Publications of the European Communities.

[42] Health Canada; Guidelines for Canadian Drinking Water Quality, Guideline Technical Document – 1,4-Dioxane; March 2021: https://www.canada.ca/en/health-canada/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-guideline-1-4-dioxane.html

[43] U.S. Federal Register Vol. 85., No. 47, March 20. Environmental Protection Agency. Announcement of Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List. EPA-HQ-OW-2019-0583; FRL-10005-88-OW.

[44] *Ibid.*

1,4-Dioxane presents unique and complex treatment challenges.

Available research indicates 1,4-dioxane is difficult and expensive to remove from drinking water, especially at low levels. Due to its historical use as a solvent stabilizer, 1,4-dioxane may be detected in ground water along with other chlorinated solvents. The combination of multiple contaminants with varying chemical characteristics, as well as the unique properties of 1,4-dioxane, complicate treatment strategies.[45] In addition, its widespread presence in consumer products and expansive reuse of treated wastewater for irrigation and groundwater recharge means low levels of 1,4-dioxane continue to be introduced into groundwater aquifers. Conventional treatment methods used for other common contaminants (*e.g.*, air stripping; granular activated carbon) are not efficient or reliable for 1,4-dioxane. To achieve levels approaching 1 ppb (the state's current notification level), water purveyors would need to install new treatment systems specifically designed to remove 1,4-dioxane. The best available technologies for treatment of this chemical are capital and energy intensive, resulting in high treatment costs relative to other contaminants, and can generate by-products that are more toxic than 1,4-dioxane itself. These conclusions are supported by published literature and full-scale treatment systems operated by the Los Angeles Department of Water and Power.[46]

OEHHA's approach to the PHG will weigh heavily on how a future MCL affects at-risk water systems and disadvantaged populations.

The best available science and the weight of the evidence indicate that a PHG for 1,4-Dioxane based on the above-described threshold MOA will result in an MCL that is protective of public health. A PHG established using the default linear approach may result an MCL that forces trade-offs which adversely impact human health, will impose unnecessary new cost burdens on water systems and ratepayers, restrict access to drinking water sources and exacerbate drinking water affordability problems, without

[45] For *in-situ* remediation, biodegradation of 1,4-DX has proven challenging and applicable only under limited conditions. *Ex-situ* biological treatment methods such as propane-based bioreactors show promise but are often not applicable to co-contaminants and additional evaluation of performance is required before they become widely accepted. According to the SWRCB (see footnote 12), chlorination has been demonstrated to remove 1,4-DX, but the resulting by-products are more toxic than the 1,4-DX itself. Advanced ex-situ treatment methods are currently in use and under further development, including advanced oxidation processes involving peroxide and ultraviolet light or ozone.

[46] See for example LADWP project involving ultraviolet advanced oxidation process treatment to remove VOCs and 1,4-dioxane in the San Fernando Groundwater Basin: http://bondaccountability.resources.ca.gov/Project.aspx?ProjectPK=30580&PropositionPK=48. Estimated project cost is $283,238,991.00.

achieving the intended public health and safety objectives. These outcomes would be contrary to the goals of the CSDWA and the HRTWA.

VI. Conclusions and Recommendations

We recognize that some challenges to achieving the goals of the Human Right to Water Act are beyond the ability of the state to control. Regulation of emerging contaminants is a notable exception, and an area of opportunity to improve public health outcomes in a manner consistent with the HRTWA. OEHHA and the SWRCB exercise considerable discretion in their interpretation and implementation of the CDSWA.

Moving forward, we recommend that OEHHA incorporate the best available health effects science and risk assessment methods into future PHG risk assessments to:

- Continue to improve the accuracy of health risk estimates;
- Support sound risk management decisions, including targeted investment of water utility and state resources for public health protection and increased water supply resilience; and
- Minimize negative impacts on public health and welfare that result from significant increases in the cost of water.

In the immediate future, OEHHA's effort to develop a PHG for 1,4-dioxane presents a timely opportunity to evaluate a threshold model consistent with the best available science and the most current scientific methods. The CSDWA requires that the PHG be set at the safe dose response threshold "if adequate scientific evidence demonstrates that a safe dose response threshold for a contaminant exists."[47] It would also be consistent with OEHHA's strategic plan, which seeks to "Advance the science for the evaluation of risks posed to the public health and environment, and provide risk assessment leadership for the State of California."[48]

[47] Health and Safety Code section 116365 (c)(1)(D)
[48] OEHHA Strategic Plan: 2018 Update, Goal 2, page 14.