January 4, 2019

Lauren Zeise, Ph. D.
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Office of Environmental Health Hazard Assessment
Post Office Box 4010
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**RE**: Proposed Public Health Goals for Trihalomethanes in Drinking Water

Dear Director Zeise:

The Association of California Water Agencies, the California Water Association, the California Municipal Utilities Association, the Southern California Water Coalition, and the California – Nevada Section of the American Water Works Association appreciate your receipt of our coalition letter dated November 15, 2018 and the extension of the public comment period regarding the release of the draft technical support document (TSD) for the proposed Public Health Goals (PHGs) for trihalomethanes (THMs) by the Office of Environmental Health Hazard Assessment (OEHHA). This release is of tremendous interest to the drinking water community in California. The effective treatment and distribution of water for safe use is one of the greatest advancements of the last century and is an essential public health protection. Drinking water disinfection is the first and most important line of defense in this process - it protects water users from pathogens in organic matter that can cause disease and death.

As our industry has indicated in discussions with OEHHA staff dating back to 2010, the establishment of individual PHGs for each of the four regulated THM constituents would be a major departure from the current risk management approach in California involving regulation of total THMs. OEHHA's proposed PHGs place too much emphasis on reducing incremental cancer risks from exposure to THMs that other authoritative bodies have established are minor in comparison to the health risks posed by inadequate drinking water disinfection. To the extent they result in new drinking water standards that force changes to effective drinking water disinfection practices, the proposed PHGs could have unintended consequences for public health.

The Draft PHGs for Individual THMs are a Significant Departure from the Established Approach to Addressing THMs

Currently, California regulates THMs under the Maximum Contaminant Level (MCL) for total THMs (TTHM) of 0.08 mg/L (80 µg/L). The California Department of Public Health established the MCL as the sum of the concentrations of chloroform, bromoform, bromodichloromethane (BDCM), and dibromochloromethane (DBCM) in 2006. In 2010, OEHHA proposed a single PHG for TTHM based on its risk assessment of "the mean concentrations of each of the four chemicals in California drinking water" but never finalized the PHG. In the current proposal, OEHHA has replaced the single PHG with separate PHGs for each of the four THMs.

Health and Safety Code (H&SC) §Section 116365(c)(1) states: "The Office of Environmental Health Hazard Assessment shall prepare and publish an assessment of the risks to public health posed by each contaminant ***for which the state board proposes a primary drinking water standard***.". We emphasize the close linkage of PHGs with MCLs to maintain that OEHHA should not operate in a vacuum when publishing a PHG for any contaminant but should consider the full public health context from readily available sources such as ones we identify below.[1] It is highly significant that there are no existing state or federal MCLs for any of the four individual THMs.

Under OEHHA's proposal, water utilities would be required to report exceedances of substances for which no regulatory standard exists. As OEHHA knows, published PHGs impose specific obligations on public water systems, including periodic public disclosures where water contains concentrations of contaminants above corresponding PHGs.[2] Therefore, while they may not be enforceable regulatory standards, PHGs that reach beyond the authority of the statute are inappropriate and can cause confusion and concern about drinking water safety and confound the intent of the Health and Safety Code provisions that seek to provide effective public right-to-know.

For these reasons, and those we discuss below, OEHHA should return to its earlier focus on a single goal for TTHMs and should not propose separate PHGs for the individual THMs.

[1] See also H&SC §116365(e)(2): "On or before January 1, 1998, the Office of Environmental Health Hazard Assessment shall publish a public health goal for at least 25 drinking water contaminants for which a primary drinking water standard has been adopted by the state board. The office shall publish a public health goal for 25 additional drinking water contaminants by January 1, 1999, and for all remaining drinking water contaminants ***for which a primary drinking water standard has been adopted by the state board*** by no later than December 31, 2001." (emphasis added)

[2] H&SC §116470(b) et. seq.; these requirements apply to systems serving 10,000 or more connections.

OEHHA Must Evaluate the Public Health Benefits of Chlorination Relative to the Public Health Risks of THMs

Almost all community water systems in California use some type of chlorine-based disinfection method—either alone or in combination with other chlorine and non-chlorine disinfectants. In the most recent American Water Works Association water survey more than 90 percent of respondents rely on a chlorine-based disinfectant.[3] Free chlorine and chloramines are not only used for primary disinfection but are two of a list of five specifically ***allowed*** disinfectants under existing federal regulations. In addition to controlling disease-causing organisms, chlorination offers additional benefits, including:

- Eliminating slime bacteria, molds and algae that commonly grow in water supply reservoirs;
- Controlling and reducing microorganism-containing biofilms;
- Removing chemical compounds that hinder disinfection; and
- Reducing disagreeable tastes and odors.

Perhaps most importantly, only chlorine-based chemicals provide residual disinfection capacity in the distribution system to control and reduce microbial re-growth. OEHHA needs to recognize that surface water systems are ***required as a matter of federal regulation*** to ensure a disinfectant residual is present throughout the distribution system.

THMs are present in drinking water as a result of chlorination of organic matter present in raw water supplies. It is therefore critical, in assessing the risks associated with the ingestion of THMs in drinking water, to also consider the substantial benefits to public health associated with disinfection by chlorination. The use of chlorine for disinfection has virtually eliminated waterborne microbial diseases because of its ability to kill or inactivate essentially all enteric pathogenic microorganisms, including viruses and bacteria from the human intestinal tract. Chlorine is the most accessible and easily controlled disinfectant and is approved for use in all public water systems in California (and may be required in some, as noted above). It is a strong oxidant for which a residual can be maintained in the distribution system to prevent bacterial regrowth. Numerous public health organizations, including the World Health Organization (WHO), have consistently described the profound historical and continuing public health benefits that chlorination provides and strongly caution that:

> [I]n attempting to control DBP [disinfection byproduct] concentrations, it is of paramount importance that the efficiency of disinfection is not compromised and

[3] AWWA. 2017 Water Utility Disinfection Survey Report. AWWA: Denver, Colorado (2018).

> that a suitable residual level of disinfectant is maintained throughout the distribution system.[4]

In establishing a public health goal, Health and Safety Code section 116365(c)(1) directs OEHHA to estimate the level of the contaminant in drinking water "that is not anticipated to cause or contribute to adverse health effects, or that does not pose any significant risk to health." As part of this assessment, OEHHA is required to take into account several factors including "[s]ynergistic effects resulting from exposure to, or interaction between, the contaminant and one or more other substances or contaminants."[5] While the authorizing language does not define "synergistic effects," this term has a common definition in the public health literature that considers the combined biological effect of exposure to two or more substances.[6] A plain reading of this language suggests that OEHHA's assessment must include an evaluation of the effects that may result from the creation of THMs as well as the effects that may result from efforts to reduce THM concentrations in drinking water. The importance of this more comprehensive evaluation is underscored in a separate 2011 WHO report, cited in OEHHA's Technical Support Document, which states that "the risks to health from these by-products are extremely small in comparison to the risks associated with inadequate disinfection."[7]

The THMs are unlike other drinking water contaminants for which OEHHA has developed PHGs. The presence of these substances in drinking water is incidental to the beneficial use of chlorination to remove potentially fatal concentrations of organic matter in the source water and the distribution system. As the WHO and other entities charged with protection of public health have indicated, the public health benefits of drinking water disinfection are indispensable and far greater than the public health risks associated with incremental exposures to DBPs. As a result, it is inappropriate and potentially harmful to public health to consider the public health impacts of the THMs without also considering whether further efforts to reduce THM exposures would sacrifice the more important public health benefits. Since the statute requires the State Water Resources Control Board (SWRCB) to set the enforceable MCL "as close as feasible to the corresponding public health goal" this evaluation should not be left to a subsequent decision

[4] WHO. 2017. Guidelines for Drinking-water Quality. Fourth Edition Incorporating the First Addendum, at p. 173. WHO: Geneva, Switzerland.

[5] H&SC §116365(c)(1)(C).

[6] See for example The National Library of Medicine, Division of Specialized Information Systems (IUPAC Glossary of Terms Used in Toxicology, 2nd Edition), which defines synergism as "pharmacological or toxicological interaction in which the combined biological effect of exposure to two or more substances is greater than expected on the basis of the simple summation of the effects of each of the individual substances."

[7] First Public Review Draft, Trihalomethanes in Drinking Water: Chloroform, Bromoform, Bromodichloromethane, Dibromochloromethane, Office of Environmental Health Hazard Assessment, October, 2018, page 2.

which would presume only public health benefits with the proposed PHGs.[8] Moreover, it be inappropriate for staff in the SWRCB's Division of Drinking Water to make that evaluation because they do not possess the necessary breadth or depth of expertise in epidemiology, risk assessment, and toxicology.

This is an unusual instance where actions taken to reduce exposure to a chemical contaminant could significantly *increase* overall health risks from drinking water consumption. To avoid this outcome, OEHHA must exercise its statutory discretion and scientific expertise to evaluate this potential risk tradeoff and ensure that any proposed PHG will not inadvertently create a bigger public health problem than it seeks to solve.

A Variety of Factors Affect THM Levels in Drinking Water

The formation of trihalomethanes is a complex process that occurs when chlorine reacts with organic matter present in the water. The process is a function of naturally occurring organic precursor concentrations, chlorine dose, contact time, water pH and temperature, and bromide ion concentration.

THM levels are generally higher in chlorinated water originating from surface water compared with groundwater, because of the higher amount of organic matter present in surface water. The extent of formation of THMs such as chloroform also varies with different water treatment processes.

The most effective approaches for reduction of THMs in drinking water involve reducing the amount of organic compounds prior to disinfection followed by removal of THMs formed in the disinfection process. Initial removal of organic precursors can improve the efficiency of the disinfection process while minimizing the formation of chlorinated organic by-products.

Alternative disinfectants to chlorine include chloramines, ozone and ultraviolet (UV) irradiation. Although these systems may have some applicability for drinking water disinfection, they do not achieve the breadth of efficacy, disinfectant residual, ease of use in both low and high-technology environments, widespread availability, cost-effectiveness, broad flexibility and reliability for chlorination.

[8] Health and Safety Code §116365(b)(3) also requires the SWRCB to consider "technological and economic feasibility of compliance with the proposed primary drinking water standard." However, the statute does not authorize the SWRCB to expand the scope or otherwise re-evaluate PHGs adopted by OEHHA.

- Chloramines are a much weaker disinfectant than chlorine and are not recommended as primary disinfectants, especially where virus or parasite cyst contamination may be present (NAS, 1987).

- Ozone is an excellent disinfectant and does not form THMs; however, it must be used in combination with a secondary disinfectant to maintain a residual disinfection capacity in the distribution system. Ozonation by-products include bromate, acids, and aldehydes, and chlorination of ozonated drinking water will result in increased levels of chloral hydrate as a result of the chlorination of acetaldehyde. Chloral hydrate may subsequently degrade to chloroform depending on pH, temperature, and maturity (e.g., age) of the water (LeBel and Benoit, 2000).

- UV disinfection is a physical process that uses photochemical energy to effectively prevent cellular proteins and nucleic acids (i.e., DNA and RNA) from replicating. As a result, the microorganism cannot infect its host. UV irradiation under typical disinfection doses does not form significant levels of DBPs, nor does it affect the formation of THMs in the subsequent chlorination or chloramination processes (Reid Crowther & Partners Ltd., 2000). However, as with ozone, UV disinfection does not induce any disinfectant residual in the water, and therefore requires a secondary chemical disinfectant to maintain an adequate residual in the distribution system.

- Any change made to the treatment process, particularly when changing the disinfectant, must be accompanied by close monitoring of lead levels in the distributed water. A change of disinfectant has been found to affect the levels of lead at the tap. For example, in Washington, DC, switching from chlorine to chloramines decreased the oxidation-reduction potential of the distributed water and destabilized the lead dioxide scales, which resulted in increased lead leaching (Schock and Giani, 2004; Lytle and Schock, 2005). In this case, a change from chlorine to chloramines resulted in significantly increased levels of lead in the distributed drinking water.

Each water system poses unique disinfection challenges based on system design and source water chemistry. Even if a given system can overcome these individual challenges, there is no effective way to remove organic matter that is introduced as the finished water flows through the distribution system. Similarly, while granular activated carbon filtration or other methods can remove THMs after they are formed, some systems may have no available method to remove THMs formed after the water enters the distribution system. This reality underscores the critical importance of using a secondary chemical disinfectant to maintain an adequate residual disinfection capacity in the distribution system.

Comments on Derivation of Proposed PHGs

In developing the proposed PHGs for THMs, OEHHA has ignored the conclusions reached by various authoritative bodies, including the U.S. Environmental Protection Agency (USEPA), International Agency for Research on Cancer (IARC), WHO, and Health Canada. OEHHA based each of its four proposed PHGs on cancer evidence in laboratory animals exposed by oral gavage – despite the fact that studies evaluating dietary and drinking water exposures failed to find carcinogenic effects. OEHHA also has overestimated daily water consumption rates, reporting values approximately four times higher than indicated by available data, even after adjusting for life-stage variability and age-sensitivity. Taken together, these anomalies significantly overstate the risks associated with exposure to the four THMs that have led to the proposed PHGs that are not supported by the scientific evidence.

- Chloroform is a Threshold Carcinogen

  Contrary to OEHHA's analysis, USEPA, WHO, and Health Canada have concluded that cancer risk from chloroform is defined by a non-genotoxic, or threshold, mechanism. Their independent conclusions are based on substantial evidence that cancers observed in laboratory animals ***only*** result from sustained exposure to levels of chloroform that overwhelm the animal's natural defense mechanisms. Consistent with this conclusion, USEPA has adopted a maximum contaminant level goal (MCLG) – analogous to the PHG – of 70 parts per billion (ppb) for chloroform, which is more stringent than corresponding values developed by Health Canada (80 ppb) and the WHO (300 ppb). Despite the weight of the evidence and expert opinion supporting the threshold mechanism for chloroform, and the safety factors included in USEPA's MCLG calculation to protect all populations, including potentially sensitive subpopulations, OEHHA's proposed PHG is still 175 times lower (more stringent) than USEPA's MCLG.

- Bromoform in Not Carcinogenic

  While bromoform is listed as a carcinogen under Proposition 65 and by the USEPA, more recent assessments by IARC (1999) and Health Canada (2006) have concluded that the substance is unlikely to be carcinogenic. IARC designated bromoform as "not classifiable" as to its carcinogenicity (Group 3) while Health Canada considers it "possibly carcinogenic to humans" (Group IIID). In its most recent review, Health Canada concluded there was insufficient information available to support a drinking water guideline for bromoform. The WHO adopted the IARC Group 3 designation, establishing a drinking water guideline of 100 ppb.

- Bromodichloromethane Cancer Risk is Overstated

The WHO concluded in 2008 that its drinking water guideline value of 60 ppb for bromodichloromethane (BDCM) protects against any potential cancer risk from this substance, based on conflicting results from two cancer studies conducted by the National Toxicology Program (NTP, 2016). A panel of experts convened by Health Canada in 2008 concluded that the combined data from the two NTP studies do not support the default non-threshold cancer model employed by OEHHA in its draft Technical Support Document (TSD). Based on this analysis, the panel concluded that retention of Health Canada's previous guideline of 16 ppb is "unlikely to be necessary."

- Dibromochloromethane is Not Carcinogenic

OEHHA delisted dibromochloromethane (DBCM) from Proposition 65 in 1999, following the decision by IARC that it was "not classifiable" (Group 3) as to its carcinogenicity. Based on the IARC decision, the WHO set its DBCM guideline value at 100 ppb. Health Canada concluded in 2003 that the there was insufficient information to calculate a drinking water value. In 1992, US EPA classified DBCM as a "possible human carcinogen" (Group C), based on inadequate human data, limited evidence for carcinogenicity in animals, and consideration of structural similarity to other THMs which are known animal carcinogens. In the 1998, USEPA set an MCLG for DBCM at 60 ppb – 600 times higher than OEHHA's proposed PHG for the substance.

- OEHHA Significantly Overstates Drinking Water Consumption Rate

In addition to our concerns about OEHHA's proposal to consider all four THMs as genotoxic carcinogens and to use default assumptions to calculate the potential cancer risks, we are troubled by OEHHA's overestimate of water consumption rates used to generate the public health goal. As part of its PHG derivation, OEHHA uses a susceptibility-weighted daily water intake of 0.180 to 0.185 equivalent liters per kilogram body weight per day ($L_{eq}$/kg-day). This lifetime consumption rate is much higher than the weighted intake for any of the four life stages identified by OEHHA. For example, it appears to assume that an individual will consume 12.6 liters of water – 3.3 gallons - or more on a daily basis for the entirety of their time as a 70-kg adult. This rate is more than four times the total daily consumption rate of 3 $L_{eq}$/day assumed in the 2010 draft PHG and much higher than the average consumption rate recommended by authoritative bodies.[9] Using the average of the susceptibility weighted DWIs (equal to 0.045 $L_{eq}$/kg-day), on the other hand, generates a total adult consumption rate of 3.15 $L_{eq}$/day which is far more realistic.

The Best Available Science Does Not Support the Proposed PHGs

The health effects science for the four THMs at issue in OEHHA's Technical Support Document has not changed appreciably since California adopted the USEPA MCL for total THMs in 2006. Moreover, even if the identified THMs are evaluated in isolation, there is no compelling scientific justification for use of default assumptions which significantly overstate the potential cancer risk from exposure to individual THMs and result in PHG values that are far more stringent than necessary to protect public health.

Recommended Approach

Given the scientific reasons outlined in the preceding section, the statutory reasons cited on page 2, and the overriding public health benefits associated with primary and secondary drinking water disinfection – which should be quantified and compared to the incremental health benefits of the proposed PHGs - OEHHA should abandon the proposed approach of calculating individual PHGs for all four THMs. Instead, OEHHA should focus its review only on those substances that available evidence indicates are at least potential human carcinogens. This necessary narrowing of focus supports development of a single PHG for total THMs over individual values, which would also eliminate confusion, uncertainty and complexity in the MCL review process and for water systems that might otherwise be required to comply with multiple MCLs for individual THMs.

Finally, OEHHA should address the deficiencies in its derivation of cancer slope factors and exposure potential noted above, such that its revised proposal reflects a more realistic estimate of human health risk from exposure to THMs that is protective of all populations.

We appreciate OEHHA's consideration of our comments. If you have any questions regarding this coalition's comment letter, please feel free to reach out to any of the signatories below.

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[9] For example, The National Academies of Sciences, Engineering, and Medicine determined that an adequate daily intake *of all fluids*, including water, is about 15.5 cups (3.7 liters) a day for men and about 11.5 cups (2.7 liters) a day for women. https://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/water/art-20044256

Sincerely,

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