

May 1, 2020

Submitted via the Comments Submission Portal: <a href="https://oehha.ca.gov/comments">https://oehha.ca.gov/comments</a>

David Ting, Ph.D., Branch Chief Pesticide and Environmental Toxicology Branch Office of Environmental Health Hazard Assessment California Environmental Protection Agency P.O. Box 4010, MS-12B Sacramento, California 95812 Attention: PHG Program

RE: First Public Review Draft; Haloacetic Acids in Drinking Water; Monochloroacetic Acid, Dichloroacetic Acid, Trichloroacetic Acid, Monobromoacetic Acid, Dibromoacetic Acid; January 2020.

Dear Dr. Ting:

The American Chemistry Council¹ (ACC) Chlorine Chemistry Division² appreciates this opportunity to provide comments on the Office of Environmental Health Hazard Assessment's (OEHHA) first public review draft Technical Support Document (TSD) proposing individual Public Health Goals (PHGs) for five haloacetic acids (HAAs) in drinking water.³ Our comments are focused on three of the five HAAs with PHGs that are based on cancer endpoints: dichloroacetic acid (DCA), trichloroacetic acid (TCA), and dibromoacetic acid (DBA). Although the draft TSD also includes non-cancer based individual PHGs for monchloroacetic acid (MCA) and monobromoacetic acid (MBA), they are not specifically discussed in these comments.



<sup>&</sup>lt;sup>1</sup> The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®; common sense advocacy designed to address major public policy issues; and health and environmental research and product testing. The business of chemistry is a \$553 billion enterprise and a key element of the nation's economy. It is among the largest exporters in the nation, accounting for ten percent of all U.S. goods exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

<sup>&</sup>lt;sup>2</sup> The Chlorine Chemistry Division represents the major producers and users of chlorine in North America and works to promote and protect the sustainability of chlorine chemistry processes, products, and applications.

<sup>&</sup>lt;sup>3</sup> https://oehha.ca.gov/media/downloads/crnr/haaphg013120.pdf.

### **Overview**

As described in these comments, we are concerned that the draft PHGs could have profound negative impacts on the ability of regulated California drinking water utilities to maintain effective, affordable, and reliable drinking water disinfection. This outcome would be at odds with the established public health benefits of chlorine-based disinfection and current efforts by the State Water Resources Control Board (SWRCB) to reassure the public that the widespread use of these technologies by drinking water providers is effective against the virus that causes COVID-19.

As was the case in OEHHA's TSD for Trihalomethanes (THMs),<sup>4</sup> for the most part, the TSD for HAAs continues to approach the evaluation of lifetime theoretical cancer risks from exposure to HAAs in isolation. That is, as if they are independent of the acute health risks of waterborne diseases from exposure to pathogenic bacteria, viruses, protozoan parasites, and other microorganisms. We recognize that PHGs are not themselves regulatory standards, yet state law requires that enforceable Maximum Contaminant Levels (MCLs) be set as "close as feasible" to the corresponding PHG, placing primary emphasis on protection of public health. The draft cancer-based PHGs threaten the efficacy of chlorine-based disinfection because they propose HAA concentrations that cannot be readily and affordably achieved by public water systems that rely on those technologies.

As these comments will discuss, although a shift to alternative disinfection technologies may reduce concentrations and subsequent exposure and risk of HAAs in the centralized disinfection process, it will not protect against microbiological contaminants (e.g., *Legionella* bacteria) that may be present in the distribution system in the absence of an adequate disinfectant residual. Therefore, any future MCLs, or a single, group MCL for HAAs, set at levels approaching the draft cancer-based PHGs are likely to present a greater threat to public health than continuing to regulate total HAAs at or near the current group MCL of  $60 \,\mu\text{g/L}$  (parts per billion or ppb).

The HAA TSD should not force the SWRCB to make a "Hobson's choice." That is, either pursue much lower regulatory limits for individual HAAs to achieve small increments in cancer risk reduction at the expense of secondary disinfection, or leave the existing HAA MCL largely intact to protect public health from greater risks associated with exposure to microbiological contaminants.



 $<sup>^4</sup>$  https://oehha.ca.gov/water/crnr/announcement-publication-public-health-goals-and-technical-support-document.

<sup>&</sup>lt;sup>5</sup> https://www.merriam-webster.com/dictionary/Hobson%27s%20choice.

## Chlorination Is Critical to Public Health and the Safety of the California Drinking Water Supply

Millions of lives have been saved and countless illnesses avoided since the inception of continuous chlorine use in conjunction with filtration in water treatment over 110 years ago. The majority of U.S. community water systems still rely on chlorine or chlorine-based treatment or disinfection processes to protect their consumers. Free chlorine is typically added to drinking water as elemental chlorine (chlorine gas), sodium hypochlorite solution (bleach), or dry calcium hypochlorite. Other chlorine-based disinfectants used in drinking water include chloramine (specifically monochloramine, produced by mixing chlorine and ammonia) and chlorine dioxide.

Virtually all public water systems use a chlorine-based disinfection method, either for centralized (primary) disinfection or as a supplement to other technologies to prevent recontamination (secondary disinfection) of treated ("finished") water as it moves through the distribution system from the water treatment facility to the tap. More importantly, only free chlorine and chlorine-based chemicals<sup>8</sup> provide *residual* disinfection capacity in the distribution system to control and reduce microbial regrowth, including *Legionella* bacteria in building water systems, which is the cause of Legionnaires' disease.<sup>9</sup>

A wide variety of organic and inorganic disinfection byproducts (DBPs), including HAAs, can be formed unintentionally at low levels when chlorine and other disinfectants and oxidants react with organic matter in raw (natural or reclaimed) sources of drinking water. As the World Health Organization (WHO) continues to strongly caution:

The most common and widespread health risk associated with drinkingwater is microbial contamination.

In attempting to control DBP concentrations, it is of paramount importance that the efficiency of disinfection is not compromised and that a suitable



<sup>&</sup>lt;sup>6</sup> See review by McGuire, M.J. 2013. The Chlorine Revolution: Water Disinfection and the Fight to Save Lives. AWWA: Denver, Colorado.

<sup>&</sup>lt;sup>7</sup> See American Chemistry Council (ACC). 2018. Drinking Water Chlorination: A Review of U.S. Disinfection Practices and Issues, <a href="https://chlorine.americanchemistry.com/Chlorine-Benefits/Safe-Water/Disinfection-Practices.pdf">https://chlorine.americanchemistry.com/Chlorine-Benefits/Safe-Water/Disinfection-Practices.pdf</a>.

<sup>&</sup>lt;sup>8</sup> Chloramine, and to a much lesser extent, chlorine dioxide, are also used to provide residual disinfection in drinking water distribution systems (see ACC, 2018).

<sup>&</sup>lt;sup>9</sup> See ACC. 2020. *Legionella* Management in Building Water Systems: The Role of Chlorine Products, <a href="https://www.chlorine.org/wp-content/uploads/2020/03/Legionella">https://www.chlorine.org/wp-content/uploads/2020/03/Legionella</a> in Building Water Systems WEB March 2020.pdf.

residual level of disinfectant is maintained throughout the distribution system.  $^{10}$ 

We appreciate that the HAA TSD recognizes findings from the WHO and the International Agency for Research on Cancer (IARC) regarding the essentiality of drinking water disinfection, from centralized treatment facilities to individual taps, relative to incremental reductions in DBP concentrations. These definitive statements call for a quantitative analysis of the potential public health risks that may result from further efforts to reduce DBP concentrations in drinking water—particularly those associated with individual MCLs that are an order of magnitude lower than the current group MCL for HAAs. Yet such analysis does not exist in this draft TSD; as it did in the TSD for THMs, OEHHA is deferring this analysis to the SWRCB.

We remain convinced that a <u>quantitative</u> risk-balancing analysis is beyond the scope of the SWRCB's statutory authority in setting MCLs, and likely beyond its technical capacity. For these reasons, we would not expect the SWRCB to undertake such analysis as part of the MCL development process for any individual DBP or group of DBPs.

Also, the threat of microbial recontamination and waterborne disease outbreaks continue to increase due to (1) deficiencies in distribution systems, including microbial growth, leaks, water pressure loss, and pipe breaks, as aging drinking water infrastructure is operated beyond its design life; <sup>11</sup> and (2) investments in distribution system repair and maintenance are deferred in response to new regulatory obligations. <sup>12</sup> These challenges will likely increase in the future as a result of the novel coronavirus pandemic.

# Individual HAA Levels Can Vary Based on Source Water Characteristics, Disinfection Method, and Other Factors

HAA concentrations in treated water depend on several factors, including organic matter concentration, pH, temperature, and the season of withdrawal of the source water, which chlorine-based chemicals are applied, contact time, and the presence of other chemicals that may influence the disinfection reactions. HAA levels are generally higher in chlorinated water originating from surface water sources compared with groundwater because of the higher amount of organic matter present in surface water. Several pre- and post-disinfection techniques are widely recommended to maximize potable water safety and quality while minimizing any potential DBP risks. Such DBP control strategies can generally be divided into three categories: (1) removal of DBP precursors, (2) optimization of

 $<sup>^{12}</sup>$  See 2017 Infrastructure Report Card – Drinking Water.  $\underline{\text{https://www.infrastructurereportcard.org/catitem/drinking-water/}}$ .



<sup>&</sup>lt;sup>10</sup> WHO. 2017. Guidelines for Drinking-water Quality, 4th Edition Incorporating the First Addendum. WHO Press: Geneva, Switzerland. At pp. 29 and 173.

<sup>&</sup>lt;sup>11</sup> CDC. 2017. Surveillance for waterborne disease outbreaks associated with drinking water—United States, 2013–2014. MMWR Surveillance Summaries 66(44):1216–1221.

treatment and disinfection practices to minimize DBP formation, and (3) removal of DBPs after formation. <sup>13,14</sup> However, alternative pre-treatment measures have no impact on organic matter subsequently introduced in the distribution system. Moreover, care must be taken to avoid the production of other unregulated and less well-studied DBPs. <sup>15</sup>

# Alternatives to Chlorine-Based Primary Disinfection Methods Do Not Ensure Safer Drinking Water

Some centralized drinking water treatment facilities in California employ alternatives to free chlorine for primary disinfection, including chloramine, chlorine dioxide (ClO<sub>2</sub>), ozone, and ultraviolet (UV) irradiation. These alternatives can reduce HAA concentrations, but do not ensure safe drinking water at customer taps without secondary disinfection using free chlorine or chloramine. Nor do they achieve the scalability, reliability, efficacy, cost-effectiveness, and ease of use of chlorine in primary disinfection in low- to high-technology systems.

Although the use of chloramine does not form significant levels of HAAs compared to free chlorine, it is a much weaker disinfectant and is rarely used as a primary disinfectant. Chloramine reduces chlorinated DBP formation, but also produces different DBPs, including nitrogenous-DBPs.<sup>16</sup>

Ozone is an established and effective disinfectant and does not form HAAs, but ozonation must be used in combination with a secondary disinfectant to maintain a residual disinfection capacity in the distribution system. <sup>17</sup> Similarly, as UV disinfection does not provide any disinfectant residual in the water, its use also requires a secondary chemical disinfectant to protect against recontamination in the distribution system.

All disinfection technologies are associated with unique benefits, limitations, and costs. No single disinfection method is right for all circumstances, but, again, only free chlorine and chloramine provide lasting residual disinfection in the distribution system. Drinking water utility managers must consider these factors and design a disinfection approach according to each system's characteristics, resources, current and anticipated regulatory frameworks and standards, as well as source water quality.



 $<sup>^{13}</sup>$  National Toxicology Program (NTP). 2018. Report on Carcinogens Monograph on Haloacetic Acids Found as Water Disinfection By-Products.

<sup>14</sup> WHO. 2017.

<sup>&</sup>lt;sup>15</sup> Water Research Foundation (WRF). 2019. Disinfection Byproducts, <a href="https://www.waterrf.org/sites/default/files/file/2019-09/4949-DisinfectionByproducts.pdf">https://www.waterrf.org/sites/default/files/file/2019-09/4949-DisinfectionByproducts.pdf</a>.

<sup>&</sup>lt;sup>16</sup> U.S. Environmental Protection Agency (USEPA). 2009. Water Systems, Disinfection Byproducts, and the Use of Monochloramine, <a href="https://www.epa.gov/sites/production/files/2015-09/documents/how\_do\_the\_kinds\_and\_concentrations\_of\_disinfection\_byproducts\_formed.pdf">https://www.epa.gov/sites/production/files/2015-09/documents/how\_do\_the\_kinds\_and\_concentrations\_of\_disinfection\_byproducts\_formed.pdf</a>.

<sup>&</sup>lt;sup>17</sup> USEPA. 2009. Basic Information about Drinking Water Disinfection, <a href="https://www.epa.gov/sites/production/files/2015-09/documents/q4.pdf">https://www.epa.gov/sites/production/files/2015-09/documents/q4.pdf</a>.

## The Draft PHGs Do Not Assess the Public Health Risks of Major Reductions in HAA Concentrations

Currently, California regulates HAAs under the MCL for total HAAs of 60 ppb as the sum of the concentrations of MCA, DCA, TCA, MBA, and DBA. In the draft HAA TSD, OEHHA has replaced the single group PHG with separate PHGs for each of the five regulated HAAs. OEHHA's individual draft cancer-based PHGs are a dramatic departure from the current California MCL for total HAAs. In particular, the draft PHG for DBA is 2000-times more stringent than the current EPA and CA total HAA MCL. OEHHA's decision to develop individual PHGs for the five HAAs, rather than a total value, appears to chart a course for the SWRCB to develop individual MCLs. If the SWRCB decides instead to specify a group MCL for total HAAs, it would need to demonstrate how a single standard would meet the statutory requirement to be "as close as feasible" to the five individual HAA PHGs. These draft individual PHGs, if used as the basis for individual MCLs, have the potential to drive enforceable regulatory limits below levels that can be readily and affordably met by thousands of public water systems in California that rely on free chlorine or other chlorine-based disinfection technologies to supply safe, potable water.

Controlling acute public health threats presented by microbiological contamination of drinking water from pathogenic bacteria (e.g., *Legionella*), viruses (e.g., hepatitis A), and parasites (e.g., *Cryptosporidium*) through primary disinfection and maintenance of an adequate disinfectant residual is the highest public health priority for drinking water treatment. According to a 2019 report by the National Academies of Sciences, Engineering and Medicine (NASEM), "Legionnaires disease (a pneumonia caused by the *Legionella* bacterium) afflicts and kills more people in the US than any other reportable waterborne disease." That same report also emphasizes that "Public water systems that maintain a disinfectant residual and manage hydraulics to prevent stagnation are helping to reduce *Legionella* exposure from the distribution system." In this regard, the U.S. Centers for Disease Control and Prevention (CDC) emphasizes the importance of residual disinfection in building water systems. In particular, the need to "Ensure disinfectant levels are detectable where water enters the building and at points of use." This issue is likely to be a challenge for reopening office buildings, restaurants, and other facilities that have been shut down during the COVID-19 pandemic.<sup>20</sup>

The well documented public health consequences of waterborne disease outbreak risk in the absence of adequate drinking water disinfection necessitate a more balanced approach to HAA risk assessment than is currently reflected in the draft TSD. As noted above, OEHHA acknowledges the important health benefits of disinfection relative to the small incremental lifetime cancer risk from exposure to HAAs by reference to key WHO and IARC



<sup>&</sup>lt;sup>18</sup> National Academies of Science, Engineering, and Medicine (NASEM). 2019. Management of Legionella in Water Systems. National Academies Press: Washington, DC., at pp. 1 and 7.

<sup>19</sup> https://www.cdc.gov/legionella/wmp/monitor-water.html.

<sup>&</sup>lt;sup>20</sup> https://www.cdc.gov/coronavirus/2019-ncov/php/building-water-system.html.

findings, but then proceeds to focus on cancer risks for three of the five HAAs, setting the California EPA's drinking water program on a course that could compromise or eliminate the use of chlorine-based disinfectants. This outcome would be at odds with the established public health benefits of chlorine-based disinfection and recent statements by the SWRCB that widespread use of chlorine-based disinfection eliminates health risks that may result from the presence of the virus that causes COVID-19 in drinking water supplies.<sup>21</sup>

As it did in the final TSD for THMs, OEHHA states in the draft TSD for HAAs that the SWRCB bears the responsibility for comparing risks from exposure to DBPs to risks from exposure to microorganisms in water. In this instance, OEHHA acknowledges that this "risk-benefit analysis" should be quantitative, not qualitative, yet there is no indication in this document, in state law, or in past SWRCB practice that the SWRCB is required to conduct such analysis. We remain concerned that the SWRCB lacks the necessary scientific expertise to perform a quantitative risk assessment that involves balancing of health risks and benefits of drinking water chlorination. Moreover, in the absence of a quantitative risk-benefit analysis, important decisions about whether to develop a single total MCL or individual MCLs for HAAs—and subsequently where to set the MCL(s)—could be a qualitative and speculative exercise with unknown ramifications for public health protection.

## Comments on Health Risk Assessment and PHG Calculation

The draft TSD proposes that three of the five HAAs—DCA, TCA, and DBA—present a risk of liver cancer to humans, based on animal studies. The estimated risk from these three HAAs adds to the estimates of liver cancer risk presented by other DBPs, namely chloroform, bromodichloromethane (BDCM), and dibromochloromethane (DBCM), as presented in OEHHA's PHGs for Trihalomethanes (see Table 1). Although mean concentrations of these six substances in finished drinking water are one to two orders of magnitude (10–100 times) higher than their PHG, or proposed PHG, there is a lack of consistent evidence of an increased incidence of liver cancer in the multiple epidemiology studies that have been conducted. There is no consistent finding in these studies of increased liver cancer resulting from exposure to DBPs in drinking water.

Although CCD recognizes that (1) the PHGs are based on a theoretical construct designed to over-estimate potential risks, and (2) it is not appropriate to combine risk estimates for

<sup>&</sup>lt;sup>22</sup> While the rate of new liver cancer cases has gradually increased from 6.9 per 100,000 in 2000 to a high of 10.3 per 100,000 in California in 2014, concentrations of DBPs, including HAAs, have been reduced. <a href="https://gis.cdc.gov/Cancer/USCS/DataViz.html">https://gis.cdc.gov/Cancer/USCS/DataViz.html</a>.



https://www.waterboards.ca.gov/publications forms/publications/factsheets/docs/covid-19/covid19 drinking water factsheet english.pdf.

Table 1. Estimate of Liver Cancer Risk from Exposure to Haloacetic Acids and Trihalomethanes

DBP	Mean Conc. (ppb) <sup>1</sup>	CSF <sup>2</sup> (mg/kg-day)	Estimated Risk (× 10-6)
DCA	4.2	0.041	21
TCA	3.6	0.071	36
DBA	2.3	0.23	76
Chloroform	8.8	0.13	146
BDCM	6.2	0.087	103
DBCM	7.5	0.044	75
Combined	_		457

<sup>&</sup>lt;sup>1</sup> Source: OEHHA

multiple substances without evidence of a common mode of action,<sup>23</sup> the PHGs developed by OEHHA for six of the nine regulated DBPs to which individuals can be routinely exposed do not appear consistent with the available epidemiological evidence. Moreover, because OEHHA assumes a genotoxic mechanism for all six substances, assuming additivity of the cancer risks seems appropriate in this case.

In light of the significant disparity between OEHHA's estimates of cancer risk presented by DBPs and the epidemiological evidence, OEHHA should consider the proposed PHGs for DCA, TCA, and DBA in the larger context of the long history of chlorine disinfection in the state, declining concentrations of HAAs and other DBPs in finished drinking water, and the overall trends in liver cancer incidence. In this regard, the WHO noted, "Trihalomethanes and haloacetic acids are the most common DBPs and occur at among the highest concentrations in drinking-water. Under many circumstances, they can serve as a suitable measure that will reflect the concentration of a wide range of related chlorinated DBPs." 24

## **Specific Comments on the Draft PHGs**

OEHHA's is basing its draft PHGs for DCA, TCA, and DBA on cancer data from mouse studies that are limited, inconsistent, and not supported by the available genotoxicity data. The evidence for each HAA is discussed below.

## **OEHHA Overstates the Potential Cancer Risk from DCA Exposure**

The Draft PHG for DCA is based on reports of liver tumors in studies conducted in male mice. The evidence in female mice is less consistent, however, and studies in rats suggest lower sensitivity than in mice. Moreover, the mice in the key study selected by OEHHA for



<sup>&</sup>lt;sup>2</sup> CSF = cancer slope factor; the CSF for DBA and chloroform is for liver cancer only.

<sup>&</sup>lt;sup>23</sup> USEPA. 1999. Guidance for identifying pesticide chemicals and other substances that have a common mechanism of toxicity. Office of Pesticide Programs (January 26, 1999). https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-pesticide-chemicals-and-other.

<sup>&</sup>lt;sup>24</sup> WHO. 2017, at 65.

the DCA risk assessment (DeAngelo et al., 1999)<sup>25</sup> exhibited a high rate of spontaneous liver tumors and significant mortality and body weight decreases at the two highest doses.<sup>26</sup> As a result, it does not appear that this study is appropriate for deriving a cancer slope factor (CSF). The OEHHA analysis, in fact, notes limitations for all of the cancer studies considered as candidates for deriving the proposed PHG. Given these limitations, it is not clear why OEHHA did not derive the geometric mean of the CSFs for the most relevant studies (i.e., 0.027 per mg/kg per day)—rather than selecting the highest CSF among the male mouse studies.<sup>27</sup>

Moreover, although DCA appears to be weakly genotoxic, and only at higher doses, OEHHA assumes that the liver tumors result from a genotoxic mechanism. As noted by USEPA, there is little basis for judging whether genotoxic effects—including alterations in the genetic messages for various proto-oncogenes—are important in the carcinogenic response, and if so, whether the dose-response curve for genotoxic effects is linear or nonlinear.<sup>28</sup> USEPA notes, moreover, that:

The importance of these issues regarding the mechanism and shape of the dose-response curves for genotoxicity and carcinogenicity are highlighted by comparing the concentrations of DCA in water that are carcinogenic in animals (0.05 to 5 grams per liter) with those that are commonly observed in chlorinated drinking water (10 to 100 micrograms per liter) . . . Thus, concentration values are about 4-5 orders of magnitude lower in drinking water than were used in experimental studies in animals. This difference is further magnified by the lower water intake per unit body weight of humans (approximately 0.03 L/kg-day) compared to rodents (about 0.1-0.2 L/kg-day).<sup>29</sup>

## TCA Is Not a Genotoxic Carcinogen

As the Draft PHG indicates, while there is consistent evidence of liver tumors in male mice exposed to TCA, the evidence for tumors is less consistent in female mice and tumors have not been reported in rat studies. As with DCA, the key study selected by OEHHA (DeAngelo



<sup>&</sup>lt;sup>25</sup> DeAngelo, AB, George, MH, and House, DE. 1999. Hepatocarcinogenicity in the male B6C3F1 mouse following a lifetime exposure to dichloroacetic acid in the drinking water: dose-response determination and modes of action. *I Toxicol Environ Health A* 58(8):485–507.

<sup>&</sup>lt;sup>26</sup> Draft PHG, at 113.

<sup>&</sup>lt;sup>27</sup> This is consistent with the approach used for chloroform in the final PHG for Trihalomethanes.

<sup>&</sup>lt;sup>28</sup> USEPA. 2003. Toxicological Review of Dichloroacetic Acid (CAS No. 79-43-6). In support of support information on the Integrated Risk Information System (IRIS). EPA 635/R-03/007 Washington, DC (August 2003).

<sup>&</sup>lt;sup>29</sup> Id., at 71.

et al.,  $2008)^{30}$  reported a high incidence of tumors in the control group which diminishes the significance of the findings in the dose groups. Although OEHHA considered and rejected two other studies with male mice, it is not clear why they did not include the study by Pereira  $(1996)^{31}$  which reported liver tumors in female mice exposed to TCA for up to 576 days (82 weeks). Benchmark dose (BMD) modeling of the results of the Pereira study produces a 95% lower confidence limit on the BMD for a 10% response (BMDL<sub>10</sub>) of 4.67 mg/kg per day compared to a BMDL<sub>10</sub> of 1.50 mg/kg per day for the study by DeAngelo et al. (1999).

Peroxisome proliferation has also been demonstrated in a number of short- and long-term TCA exposure studies in both rats and mice. In light of the very limited evidence for the genotoxicity of TCA, it is likely that the mouse liver tumors result from a non-genotoxic mechanism defined by an exposure threshold below which the cancer risk would be zero.

## The PHG for DBA Should Not Be Based on Carcinogenicity

The cancer evidence for DBA is limited to a National Toxicology Program (NTP) study reporting liver tumors in male and female mice and an increase in lung tumors in male mice. <sup>33</sup> Liver and lung tumors were not observed in rats in the NTP study. <sup>34</sup> The control groups for both the male and female mice exhibited a high rate of spontaneous liver tumors, however, and the incidence of lung tumors was increased in the control group of the male mice. In addition, the lung tumors did not show a clear dose-response in the male mice. Tumors were significantly increased at a mid-dose of 500 mg/L (ppb), but not at the highest dose of 1000 mg/L (ppb).

Given the limited cancer data available for DBA, and the conflicting results reported in mice and rats, the mouse cancer data should not be used as the basis for the PHG. Moreover, any estimate of cancer risk should not include the lung tumors in male mice as a result of the high spontaneous incidence in the control animals and the lack of a clear dose-response in the male mice.



<sup>&</sup>lt;sup>30</sup> DeAngelo AB, Daniel FB, Wong DM, and George MH. 2008. The induction of hepatocellular neoplasia by trichloroacetic acid administered in the drinking water of the male B6C3F1 mouse. *J Toxicol Environ Health A* 71(16):1056–1068.

<sup>&</sup>lt;sup>31</sup> Pereira, MA. 1996. Carcinogenic activity of dichloroacetic acid and trichloroacetic acid in the liver of female B6C3F1 mice. *Fundam Appl Toxicol* 31(2):192–199.

<sup>&</sup>lt;sup>32</sup> USEPA. 2011. Toxicological Review of Trichloroacetic Acid (CAS No. 76-03-9). In support of summary information on the Integrated Risk Information System (IRIS). EPA/635/R-09/003F. September 2011.

<sup>&</sup>lt;sup>33</sup> NTP. 2007. Toxicology and Carcinogenesis Studies of Dibromoacetic Acid (CAS No. 631-64-1) in F344/N Rats and B6C3F1 Mice (Drinking Water Studies). Research Triangle Park, NC.

 $<sup>^{34}</sup>$  Increases in malignant mesothelioma in male rats and mononuclear cell leukemia in female rats were reported at the highest dose.

### **OEHHA Should Provide Public Comments to Peer Reviewers**

The public comments on the first public review draft of the THM TSD were submitted well ahead of the external scientific peer review reports on that document, yet there is no indication in the peer review reports that the reviewers considered those comments. OEHHA's passive approach to notifying peer reviewers about the availability of public comments, rather than specifically including those comments in the materials submitted to the peer reviewers, tends to produce peer reviews that focus only on the studies and the OEHHA analysis provided in the TSD. This approach appears inconsistent with the applicable peer review statute, which requires OEHHA to submit "the scientific portions of the proposed rule, along with a statement of the scientific findings, conclusions and assumptions on which the scientific portions of the proposed rule are based and the supporting scientific data, studies, **and other appropriate materials**, to the external scientific peer review entity for its evaluation" (emphasis added). The public comments constitute "other appropriate materials" because they provide important supplemental information that either was not included or not properly analyzed in OEHHA's TSD.

The peer review process is not transparent. Stakeholders have no visibility into how OEHHA develops charge questions or how it coordinates with the University of California to identify or select peer reviewers. The timeframe for peer review reports is unclear, and OEHHA does not post peer review reports for public inspection as they are submitted. Subsequent public review draft TSDs typically provide no indication of how OEHHA addressed peer reviewer comments in its proposed changes. OEHHA should correct these procedural deficiencies in future PHG peer reviews, starting with this one.

### Conclusion

The draft TSD for HAAs should be revised to address potential risks to public health that may result from MCLs designed to pursue incremental reductions in theoretical, lifetime-based cancer risks from exposures to DBPs. In keeping with the findings of authoritative public health agencies, further reductions in DBPs must not come at the expense of chlorine-based drinking water disinfection technologies that eliminate viruses and bacteria (e.g., *Legionella*), both at centralized treatment facilities and in the distribution system. Notably, these are the very same technologies that the SWRCB is citing as evidence that drinking water supplies are not contaminated by the novel coronavirus.

We appreciate OEHHA's consideration of our comments. If you have any questions or would like to discuss these comments, please contact me at <a href="mailto:judith.nordgren@americanchemistry.com">judith.nordgren@americanchemistry.com</a>.



<sup>35</sup> Health and Safety Code §57004(d)(1).

Respectfully,

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