January 16, 2013

Submitted Via Email

Mr. Michael Baes
Pesticide and Environmental Toxicology Branch
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
1515 Clay Street, 16th Floor
Oakland, CA 94612
Attention: PHG Project
Email: michael.baes@oehha.ca.gov

Re: Public Comments Concerning the Revised Public Health Goal for Perchlorate as Proposed by the Office of Environmental Health Hazard Assessment on December 7, 2012

Dear Mr. Baes:

The Southern California Water Committee (SCWC) writes to comment on the proposed revised public health goal (PHG) of 1 part per billion (ppb) for perchlorate in drinking water in California released for public comment by the Office of Environmental Health Hazard Assessment (OEHHA) on December 7, 2012. As an organization comprised of water agencies and professionals in the field of water resources management, SCWC recognizes the importance of protecting water consumers from the public health and environmental risks posed by drinking water contaminants. We also recognize that those risks must be carefully evaluated in light of the many competing demands on the limited resources available to water purveyors to ensure a safe and reliable supply of drinking water.

SCWC previously submitted detailed comments regarding OEHHA's January 7, 2011, proposal to lower the perchlorate PHG from the current 6 ppb to 1 ppb. We remain concerned that the extensive body of scientific literature on perchlorate does not support OEHHA's proposed 1 ppb PHG and that the PHG, if ultimately adopted as a maximum contaminant level (MCL) by the California Department of Public Health (CDPH), will interfere with the ability of our members to deliver safe, clean, affordable and accessible water to their customers[1].

<u>Lack of scientific evidence in support of a lower PHG for perchlorate</u>

In 2005, the National Academy of Sciences National Research Council (NRC) completed a thorough review of the scientific literature on perchlorate. In their analysis, the NRC calculated a no observable

[1] SB 685 (Eng, 2012) requires that these factors must be considered by agencies engaged in drinking water policy and regulatory decision-making.

effect level (NOEL) for perchlorate at a drinking water equivalent of 245 ppb based primarily upon a human study conducted by Greer et al (2002)[1], a study which also serves as the basis for OEHHA's existing and proposed revised perchlorate PHG. The NRC concluded that perchlorate's primary mode of action in the body at levels in excess of the NOEL is to inhibit iodine uptake in the thyroid gland--a non-adverse biochemical phenomena that precedes any adverse effects. The NRC, and every other authoritative body that has evaluated the perchlorate health effects literature, agrees iodine uptake inhibition (IUI) is a non-adverse effect. According to the NRC, "using a non-adverse effect that is upstream of adverse effects is a conservative, health protective approach to perchlorate risk assessment." In fact, the NRC found that the onset of IUI is several steps removed from adverse effects such as hypothyroidism or developmental deficits, and that perchlorate exposure must be sustained at a high level over an extended period of time (greater than 180ppb for 14 days) to overcome the biological mechanisms that compensate for iodine deficiency to preserve normal thyroid function. We are not aware of any credible human-related studies in the published literature demonstrating that adverse effects occur, or even may occur, from exposure to perchlorate in drinking water at levels below the NOEL, and certainly not at levels below the existing maximum contaminant level (MCL) and current PHG for perchlorate of 6 ppb.

To further ensure protection of all sensitive subpopulations, the NRC divided the NOEL by a safety factor of 10, resulting in a reference dose[2] equivalent to a drinking water level of 24.5 ppb. US EPA subsequently adopted the NRC reference dose, and the Agency for Toxic Substances and Disease Registry (ATDSR) and US EPA's Office of the Inspector General (OIG) have both issued reports supporting the NRC findings. The OIG concluded in 2010 that EPA's reference dose "is conservative and protective of public health, and further reducing perchlorate exposure below the [reference dose] does not effectively lower risk." Furthermore, numerous additional studies have been published on perchlorate since the 2005 NRC Report and there remains no basis for concluding that exposure to low levels of perchlorate typically found in drinking water sources has any measurable health effect, let alone an adverse health effect on any sensitive human subpopulation.

OEHHA's current PHG for perchlorate, established in 2004 at 6 ppb disregards the unprecedented level of protection inherent in the NRC NOEL and reference dose. OEHHA's PHG treats IUI as if it were an adverse effect through aggressive application of multiple safety factors designed to protect against even the most remote possibility that perchlorate exposure in drinking water alone could lead to incremental IUI or to downstream adverse effects. OEHHA's risk assessment starts with a dose level that is approximately half of the NRC NOEL, using benchmark dose methodology that was considered, but ultimately rejected by NRC. OEHHA applied a 10-fold uncertainty factor to this lower "point of departure", to protect sensitive subpopulations, but also added redundant protection for pregnant women (identified by both NRC and OEHHA as the most sensitive population) through application of population-specific body weight and water consumption estimates. In addition, OEHHA included a relative source contribution (RSC) adjustment to account for perchlorate exposures from food, which ignores the lack of control for dietary exposures among subjects in the Greer study. Taken together, these adjustments yielded a PHG over forty times lower than the NOEL and four times lower than the

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[1] Greer MA, Goodman G, Pleus RC, Greer SE. Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans.Environ Health Perspect. 2002;110:927–937

[2] A reference dose is the estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of adverse effects during a lifetime.

NRC reference dose. We remain at a loss to understand how such extreme compounding of safety factors can be justified, especially when the result is a PHG that is many times below a well-established human no effect level.

Bearing this history in mind, and given our understanding of the studies published since the NRC report was issued in 2005, OEHHA's current proposal to lower the perchlorate PHG to 1 ppb defies any rational explanation. The proposed change is based on OEHHA's assertion in the January, 2011 revised draft PHG that the infant, not the pregnant woman, is the most sensitive population. To arrive at this conclusion, OEHHA relies on inferences from epidemiological/ecological exposure studies on rats and rabbits, including two studies authored by the same OEHHA scientist who prepared the revised PHG proposal (Dr. Craig Steinmaus), to suggest that low level perchlorate exposures may induce thyroid hormone changes in human infants. Dr Steinmaus' dual role raises obvious conflict of interest issues. There is no scientific evidence demonstrating the deleterious effect on infants of low doses (less than 10ppb) of Perchlorate in drinking water. In addition, we note that some of this work (in particular, Steinmaus, 2007) has been discredited by a more recent publication, Bruce et al (2012) [3], which is not even cited in the revised draft PHG. Moreover, recent statements by US EPA's Science Advisory Board Perchlorate Panel establish that the epidemiological studies in question cannot support OEHHA's inferences. Despite these developments, OEHHA still proposes to use different body weight, water consumption and relative source contribution factors specific to infants. These additional adjustments, which suffer from the same shortcomings identified above relative to the current PHG, produce a lower proposed PHG of 1ppb.

We also note that perchlorate is characterized as a "goitrogen" because it may interfere with normal thyroid function at high doses over an extended duration. Other goitrogens commonly found in sources of drinking water and foods include nitrate and thiocyanate. While less potent than perchlorate, nitrate and thiocyanate are ubiquitous, and occur at much higher levels in water and food than does perchlorate. According to US EPA's Office of the Inspector General, exposures to nitrate and thiocyanate, along with iodine deficiency, are the overwhelming contributors to iodine uptake inhibition. OIG further states that perchlorate's total contribution to IUI is less than 1%. These findings have yet to be disproved by any meaningful scientific analysis. They support the conclusion that OEHHA's continued narrow focus on perchlorate is neither scientifically justified nor necessary to protect public health.

Finally, we challenge OEHHA to identify any incremental health benefits that would result from lowering the current 6 ppb PHG to 1 ppb. Absent defensible evidence of such benefits, OEHHA has no scientific basis for pursing its current course of action.

<u>Consequences of a lower PHG for perchlorate</u>

Pursuant to California Health and Safety Code Section 116365, the drinking water standard (MCL) for a regulated contaminant must be set by CDPH at a level that is as close as economically and technologically feasible to the PHG. In 2007, the MCL for perchlorate was set at 6 ppb, the same level at

[3] The National Health and Nutrition Examination Survey data evaluated in Steinmaus, 2007 has been supplanted by a more complete data set which evaluates eight different measures of thyroid function. Bruce et. al, 2012 analyzes this more complete data set and concludes that the association between perchlorate exposure and thyroid hormone levels observed in Steinmaus, 2007 does not exist.

which the initial PHG was adopted. If OEHHA revises the PHG downward to 1 ppb, CDPH will be under significant pressure to reset the MCL at or near 1 ppb. We are concerned that such action could have serious implications with regard to the provision of safe, clean, affordable and accessible water supply. The choice by OEHHA to exercise extreme precaution in its approach to PHG risk assessments, even when not supported by the weight of scientific evidence, limits CDPH discretion in setting drinking water standards which in turn demands tradeoffs in other areas critical to water system management. These tradeoffs are far from cost free and ought to be acknowledged by both OEHHA when setting the PHG and by CDPH when setting the MCL.

Residuals management concerns

The primary state-approved treatment method for perchlorate is anion exchange technology. This technology produces a brine waste that is considered hazardous waste in California. If the MCL is lowered from 6 ppb to 1 ppb, substantial additional waste will be generated from increased treatment, consuming limited hazardous waste disposal capacity and requiring more frequent shipment of hazardous waste from drinking water treatment facilities to permitted hazardous waste management facilities. Such operations will increase energy consumption, greenhouse gas emissions and localized criteria pollutants and toxic air contaminants. Some shipments will occur through areas of high population density, increasing the risk of accidents that may result in immediate public health, safety and environmental impacts.

California's experience with the gasoline additive MTBE is a textbook example of the consequences of failure to consider multi-media human health and environmental impacts associated with a single-media regulatory action. Neither OEHHA nor CDPH are statutorily required to consider multi-media environmental impacts in establishing or revising drinking water standards, despite the increasing potential for such impacts as compliance levels are ratcheted down.

Precautionary drinking water standards must be balanced against other critical water system demands.

In order to provide safe, clean, affordable and accessible drinking water supplies, water purveyors must balance competing demands on public water systems. These include replacing aging water supply infrastructure, watershed restoration and protection, escalating energy costs, expanding information technology needs, water conservation requirements, stormwater and wastewater management, system security preparedness and compliance with drinking water standards. In recent years the increasing cost and complexity of compliance with new drinking water standards has begun to skew this process to the detriment of other priorities. The potential consequences of this trend are illustrated in the following examples.

Water use reduction mandates: SBX7 7 (Steinberg, 2009) requires a 20% reduction in statewide per capita water use by 2020. SBX2 1 (2009) requires State Water Project contractors to reduce their reliance on the Sacramento-San Joaquin Delta, which provides water supply to two-thirds of the state's population, through increased conservation, recycling and other strategies designed to optimize use of alternative supplies. These mandates will necessitate greater reliance on groundwater sources, especially in Southern California. Residual perchlorate contamination in Southern California groundwater sources coupled with more precautionary drinking water standards will require more aggressive treatment at much greater expense to water rate payers. The Bay Delta Conservation Plan being developed pursuant to SBX7 1 (Simitian, 2009) is expected to include

new State Water Project conveyance systems that by-pass the Delta and will have to be financed through water rate increases. The full costs of this system are still a matter of debate, but are expected to amount to billions of dollars. These costs will be in addition to costs water purveyors will have to incur to develop alternative water supplies to compensate for forced water use reductions. In addition, the Delta Stewardship Council's draft Delta Plan (November 2012) has a policy for demonstrating consistency with the Delta Plan Regarding Reduced Reliance on the Delta and Improved Regional Self-Reliance (WR P1), reference Appendix P.

Aging infrastructure demands: California's water supply infrastructure is aging and in need of unprecedented maintenance, replacement and upgrades. The water supply infrastructure problem is the subject of a recent publication by the American Water Works Association, entitled "Buried No Longer: Confronting America's Water Infrastructure Challenge." In that publication, the challenge is described in the following terms:

> Much of our drinking water infrastructure, the more than one million miles of pipes beneath our streets, is nearing the end of its useful life and approaching the age in which it needs to be replaced. Moreover, our shifting population brings significant growth…requiring larger pipe networks to provide water service.
>
> Restoring existing water systems as they reach the end of their useful lives and expanding them to serve a growing population will cost at least $1 trillion over the next 25 years, if we are to maintain current levels of water services. Delaying the investment can result in degrading water service, increasing water service disruptions, and increasing expenditures for emergency repairs.

If aging infrastructure issues and expanded service needs are not adequately addressed in the near term, the public is at risk not only from significant disruptions in water supply, but also from adverse health outcomes associated with potentially increased exposure to biological contaminants and pathogens.

Small water system compliance: A significant portion of drinking water in California is groundwater supplied by small water systems and private wells. CDPH readily acknowledges that some of these small systems are unable to comply with the state's arsenic MCL. A recent report from UC Davis describes the challenges facing rural communities in the Central Coast and Southern San Joaquin Valley which depend on groundwater sources that consistently exceed the existing nitrate MCL. A permanent solution to these problems may involve consolidation of small, isolated systems into larger regional systems with a rate base sufficient to finance necessary infrastructure upgrades and treatment systems or require creative technical and financial solutions at a significant cost to drinking water rate payers.

Compliance with more precautionary drinking water standards for perchlorate will likely divert millions, if not billions, of dollars of ratepayer funds from these statewide water system needs. The balance between more precautionary drinking water standards and other drinking water system demands should be carefully evaluated, especially where the benefits of more stringent drinking water standards cannot be quantified.

Conclusion

California has reached a critical juncture in water supply management and regulation where state government must give greater consideration to balancing competing demands on increasingly constrained water resources. Failure to do so will inevitably compromise some goals to achieve others without regard to actual public health, environmental or water supply outcomes. We therefore call upon OEHHA to reconsider whether its current proposal to lower the perchlorate PHG is actually necessary to address real, quantifiable and scientifically validated risks to public health. To move ahead with the current proposal could be counter-productive and potentially lead to a net increase in public health and environmental risk.

Thank you for considering our comments.

Sincerely,

Richard Atwater
Executive Director

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