



January 22, 2013

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

RE: Proposed Revised Public Health Goal for Perchlorate in Drinking Water

Dear Mr. Baes:

The undersigned agricultural organizations are writing to comment on the proposed revised public health goal (PHG) of 1 part per billion (ppb) for perchlorate in drinking water in California released by the Office of Environmental Health Hazard Assessment (OEHHA) on December 7, 2012. Our members produce a majority of the fruits, vegetables, dairy products and other agricultural commodities that contribute significantly to the economic vitality of California and to American public health. We are concerned that OEHHA's proposal to revise the PHG for perchlorate from 6 ppb to 1 ppb is not scientifically defensible and will not provide any additional public health benefits. We remain concerned that resetting the PHG at the proposed level could result in severe collateral damage to the agricultural interests in this state as described below and that the public health implications of higher costs and lower confidence in the safety of California fresh fruits, vegetables and dairy products is a risk that far outweighs the benefits of a lower PHG for perchlorate..

The New Proposed PHG Is Not Founded in Good Science

As we stated in our comments on OEHHA's January, 2011 draft PHG document, we remain convinced that the weight of the scientific evidence does not support the approach taken by OEHHA in its proposal to lower the PHG from 6ppb to 1 ppb.

Safe Dose-Response Threshold Issues

The point of departure for OEHHA's revised PHG is based on iodine uptake inhibition (IUI) and remains unchanged from the original PHG. This estimate is derived from Greer et al, 2002, which was also relied upon by the National Academy of Sciences (NAS) to establish a No Observed Effect Level (NOEL) for perchlorate, equivalent to a drinking water concentration of 245 ppb. The NAS reported its NOEL in a 2005 review of the scientific literature on perchlorate. The NAS specifically recognized IUI as a non-adverse effect, and identified the Greer NOEL as a threshold dose below which there can be no progression to adverse effects. The NAS further concluded that "using a non-adverse effect that is upstream of adverse effects is a conservative, health protective approach to perchlorate risk assessment." The NAS took its analysis one step further by also calculating a reference dose (equivalent to a drinking water concentration of 24.5 ppb) for perchlorate by adding a safety factor of 10 to the NOEL to ensure protection of the most sensitive subpopulation, which it identified as the pregnant woman and her fetus.

Other authoritative bodies have since endorsed the NAS reference dose, including the Agency for Toxic Substances and Disease Registry (ATSDR, 2008) and EPA's Office of the Inspector General (OIG, 2010). According to OIG "further reducing perchlorate exposure below the [reference dose] does not effectively lower risk."

While we appreciate OEHHA's desire to err on the side of public health protection, it remains unclear why OEHHA feels compelled to deviate so dramatically from an authoritative reference dose based on a universally recognized non-adverse effect. As a practical matter, OEHHA cannot identify any public health benefits from reducing perchlorate exposures below the NAS reference dose. The science policy judgments that inform the PHG calculation seem more founded in results-oriented thinking than in objective evaluation of the best available science. OEHHA's current proposal to recalculate the PHG using new adjustments for infant body weight, water consumption and food exposure are further evidence of the same approach.

Infants as the Most Sensitive Subpopulation

OEHHA cites minor fluctuations in thyroid hormone and thyroid stimulating hormone (TSH) measures from certain epidemiology studies in the revised draft PHG as the basis for its decision to shift focus to protection of infants. Yet OEHHA fails to provide any evidence that would explain how perchlorate at levels below the threshold for IUI established in Greer can trigger impaired thyroid function or even alter thyroid hormone levels. One would think that this kind of analysis would be necessary to justify a course of action that effectively rejects decades of scientific research and a universally accepted mechanism of action.

Interpretation of Epidemiology Studies

The primary study cited as the basis for the revised PHG proposal and for selection of the infant as the most sensitive subgroup, Steinmaus 2010, measured thyroid hormone levels in newborns in the first 48 hours after birth. The study found an association between maternal exposure to perchlorate in drinking water and thyroid stimulating hormone (TSH) levels in infants. There are a number of problems with OEHHA's reliance on Steinmaus 2010 and related epidemiology studies.

First, a conflict of interest situation is presented because the primary author of the revised PHG document, Craig Steinmaus, is also the author of the primary study, Steinmaus (2010). As an academic, Dr. Steinmaus would be expected to defend his own published scientific work. As a regulator, Dr. Steinmaus would be expected to follow the laws and regulations to develop a

sound risk assessment. These two expectations can easily come into conflict where Dr. Steinmaus must analyze his own work in addition to the work of other scientists to determine which work to rely upon—and which work to discount—in developing the risk assessment. One cannot reasonably expect a neutral, fair and impartial evaluation of the science under these circumstances. In the PHG document, the author of the PHG evaluates his own scientific work and reinterprets other studies in a manner that supports his conclusions, regardless of the findings of the original authors. In the PHG document, Steinmaus devotes extensive discussion to validating the conclusions reached in his own study and re-analyzes data from other epidemiology studies (e.g. Kelsh and Li) to support his theory that relatively low levels of maternal exposure to perchlorate can cause subtle changes in thyroid hormones in newborns which may result in adverse developmental effects. These studies are reinterpreted in a manner that produces conclusions opposite to those reported by the original authors. Nonetheless, the PHG document cites to Kelsh and Li for conclusions that those authors did not reach—the conclusions stated are the conclusions of OEHHA and not the original authors. It is not generally accepted in the scientific community to cite to a study for conclusion that the authors of that study did not reach.

Second, as acknowledged by OEHHA, there are problems with evaluating thyroid hormone levels in the first 24-48 hours after birth as these levels naturally surge in newborns shortly after birth. For this reason, it is not possible to use data collected in the first 24-48 hours after birth to claim a cause and effect relationship between perchlorate levels in drinking water and neonatal thyroid function. It is our understanding that endocrinologists advise against use of data collected in this window for purposes of evaluating thyroid function. See La Franchi (2010).

Third, the use of epidemiology studies as the basis for calculating a health-based exposure level for perchlorate has recently been criticized by US EPA's Scientific Advisory Board Perchlorate Panel (SAB Panel). According to the SAB Panel's November, 2012 draft report, "[I]mprovements concerning study design, exposure assessment, sample size and statistical modeling have led to inconsistent results." Further, the SAB Panel concluded that epidemiology studies (especially the ecological studies relied upon by OEHHA) cannot be used to establish a causal relationship between perchlorate exposure and thyroid dysfunction. The draft report concludes that the current body of epidemiologic evidence cannot provide validation of a safe level of perchlorate in drinking water, nor be used to calculate a drinking water maximum contaminant level goal (and by extension, a PHG). The SAB's findings regarding the utility of perchlorate epidemiology studies effectively invalidate OEHHA's interpretation that some of these studies support identification of the infant as the most sensitive subpopulation. Absent some other justification for this finding, OEHHA cannot support its proposed changes to the PHG calculation for infants that result in a 1 ppb PHG.

Finally, some of the analysis supporting the revised PHG, such as OEHHA's reanalysis of published work by Kelsh and Li, does not appear to be peer reviewed in the scientific literature, despite the fact that OEHHA's own standards for scientific integrity mandate reliance on peer reviewed scientific findings. Moreover, since OEHHA's reanalyses are used to support conclusions contrary to those of the study's authors, and much of the detail of this work is not presented in the PHG document, it should not be used to inform the PHG – the scientific foundation for an enforceable drinking water standard – unless it is validated through independent scientific peer review in the published literature.

Questionable Reliance on the “Algebraic” Approach to Calculating the PHG

The SAB Panel was also critical of the “algebraic” approach traditionally used by US EPA in calculating the MCLG. The formula relies upon default assumptions for body weight, water consumption and contributions to perchlorate exposure from food, to calculate the MCLG. OEHHA used this standard algebraic approach in calculating the PHG.

The SAB Panel recommended instead that EPA employ scientific modeling techniques—in particular Physiologically Based Pharmacokinetic (PBPK) modeling -- in which actual experimental data is used in a model designed to simulate animal or human response to perchlorate exposures. The objective of such modeling techniques is to determine with much greater precision the levels of exposure at which actual adverse effects can be expected, such as impacts on thyroid hormone levels and downstream developmental effects in fetuses and young children.

In light of the SAB Panel's analysis, it is reasonable to conclude that OEHHA's reliance on the standard algebraic formula, rather than modeling, and OEHHA's application of this formula to a non-adverse endpoint (IUI), is not a scientifically defensible basis for establishing a PHG.

Use of Infant-Specific Body Weight and Drinking Water Intake Factors

OEHHA's original PHG calculation used body weight (BW) and drinking water intake rate (DWI) factors specific to a pregnant woman. OEHHA now proposes to replace these factors with a new set of values specific to infants. Neither approach is scientifically defensible. In fact, the use of population-specific BW/DWI factors in lieu of US EPA's standard practice of using a 70 kilogram default BW and 2 liter per day default DWI rate ignores the 10-fold uncertainty factor (UF) incorporated into the PHG calculation to protect all sensitive populations. In other words, the use of population-specific BW/DWI factors on top of the 10-fold UF amounts to double counting and produces an artificially low and scientifically unjustified PHG.

Furthermore the use of population-specific BW/DWI discounting factors in the perchlorate PHG calculation represents a significant policy change that is likely to be applied to future PHGs for other chemicals. Such policy changes should not be buried in this PHG document or other PHG documents. Rather, OEHHA should initiate a separate process, subject to public comment and external scientific peer review, indicating its intent to apply the proposed policy change to future PHGs. That process should include a proactive effort to solicit commentary from all stakeholders that may be impacted by the proposed shift in methods for developing PHGs for all compounds.

Reliance on Discredited Studies

A newly-published analysis of data released in 2011 by the US Centers for Disease Control (CDC) National Health and Nutrition Examination Survey (NHANES) invalidates the association between low level perchlorate exposure and decreased thyroid function reported in Blount, 2006 and Steinmaus, 2007, both of which are used by OEHHA to support the revised PHG proposal.

OEHHA used Blount (2006) and Steinmaus (2007) to support their conclusion that iodine-deficient women are especially vulnerable to low level perchlorate exposure and that interaction with nitrate and/or thiocyanate can increase the effects of perchlorate. However, at the time the Blount and Steinmaus papers were published, the NHANES dataset only reported two measures of thyroid function. In 2011, CDC released additional data for six other thyroid health endpoints for the same 2001-2002 NHANES dataset analyzed by Blount and Steinmaus. Contrary to OEHHA's prior conclusions, an analysis of this expanded NHANES dataset by Bruce et al (2012) reported no association between perchlorate exposure and thyroid function.

The findings reported in Bruce (2012) undermine the weight of evidence arguments offered by OEHHA in support of its latest proposal. This study was available in the published literature well in advance of OEHHA's release of its revised draft perchlorate PHG proposal, yet OEHHA fails to address or even cite this work in the revised draft document. This oversight is further evidence that the PHG should be subject to further independent scientific peer review before it is finalized.

Implications of a More Stringent PHG on Food Supply and Agricultural Operations in California

The PHG document states that “food is the primary source of perchlorate for the general population”. As we have noted in previous comments on OEHHA’s proposal to revise the current PHG, it is therefore highly likely that OEHHA’s hyper-conservative risk analysis for perchlorate in drinking water will have severe ramifications on the markets for implicated agricultural commodities, such as fresh fruits and vegetables and dairy products known to contain small amounts of perchlorate.

We remain concerned that activist organizations will assert, and the media will report, that consumption of these foods creates a substantial risk of adverse health effects based on a reset of the PHG at a level lower than the concentration of perchlorate in implicated fresh foods. In 2003 the Environmental Working Group published “Suspect Salads,” a document designed to alarm the public with respect to food and water as part of their campaign to regulate the cleanup of perchlorate. EWG’s use of fear mongering is largely a self serving ploy to produce frightening media stories, generate membership and raise funds. The resulting food scares confuse consumers and discourage consumption of nutritious food important to the diets of children and adults alike. Generating concerns about the health implications of California fruits and vegetables not only harms the general public but hurts our state economically as both domestic and international buyers seek alternatives to California products when they are called into question by alarmists.

The California agricultural producers of fresh fruits, nuts, vegetables, dairy and other products that will be harmed by eroding consumer and buyer confidence that may be realized due to an unnecessarily low PHG and a correspondingly low MCL for perchlorate will have the added burden of significantly higher costs for water in key production areas as limitations on available water supplies for blending force water providers into costly treatment programs. Water prices are already disproportionately higher for California agricultural operations than for their counterparts in other states. Driving water prices higher still, particularly where there is no credible scientific justification for doing so, will exacerbate the competitive disadvantage California producers already face in national and international markets.

In short, while this proposed action may be principally viewed as a water quality issue, there are significant negative collateral effects associated with a lower PHG and MCL. Consumers will be scared away from healthy fresh fruits and vegetables just as public health experts are urging Americans to eat more fresh produce due to its benefits in fighting obesity, diabetes and other diseases. Furthermore, a major segment of California’s economy – our farmers and the many associated businesses reliant on them – will be harmed as demand for their nutritious products falls under the onslaught of an unjustified food scare. This collateral damage cannot be justified scientifically.

If you have questions about these comments please contact Hank Giclas, senior vice president, Western Growers at (949) 885 2205 or hgiclas@wga.com. Thank you for consideration of our comments.

Sincerely,

Western Growers Association
California Farm Bureau Federation
Imperial Valley Vegetable Growers Association
Western Agricultural Processors Association
Grower-Shipper Association of Central California
Grower-Shipper Association of Santa Barbara and San Luis Obispo Counties

California Citrus Mutual
California Grape & Tree Fruit League
Ventura County Agricultural Association
Western United Dairymen