

February 23, 2005 Addendum to:

POSITION PAPER OF THE PERCHLORATE STUDY GROUP CONCERNING REVISION OF THE PERCHLORATE PUBLIC HEALTH GOAL TO ADOPT SCIENTIFIC FINDINGS OF THE NATIONAL ACADEMY OF SCIENCES

Given: (1) the adoption by the United States Environmental Protection Agency (US EPA) of the reference dose (RfD) derived by a committee formed under the auspices of the National Research Council (NRC), the operating unit of the National Academy of Sciences, in US EPA's Integrated Risk Information System (IRIS) on Friday February 18, 2005, and (2) the US EPA conclusion that the Drinking Water Equivalent (DWEL) to that RfD is 24.5 ppb, the Perchlorate Study Group (as designated in its Position Paper referenced above¹) asks the California Office of Environmental Health Hazard Assessment (OEHHA) to publish a significant upward modification of its preliminary Public Health Goal (PHG) of 6 ppb.

As presented in our initial Position Paper, in accordance with the latest science and the requirements of California law, the PHG should be set at a number no lower than the No Observed Effect Level (NOEL) less perhaps a scientifically justified amount to account for exposure through food, or about 236 ppb. California Health and Safety Code Section 116365 (c) (1) (D) requires that "if a safe dose response threshold for a contaminant exists, then the public health goal should be set at that threshold." The NOEL is the level in which the NRC found no observable non-adverse effects in humans—or, in other words, the lower bound of the statutory safe dose response threshold.

Nevertheless, should OEHHA follow a course not in accordance with the plain reading of the applicable California statute, the US EPA's adoption of the reference dose recommended by the NRC committee (which US EPA converts to a DWEL of 24.5 ppb) requires OEHHA, at the very least, to adjust its PHG to that DWEL. Given the unprecedented and highly conservative use of a NOEL as the point of the departure (where not even biologically insignificant effects are observable) divided by an arbitrary safety factor of 10, the US EPA specifically concludes that no further adjustments (for weight and consumption patterns) are required for sensitive sub-populations. Because of these substantial and redundant layers of safety, no further adjustment is appropriate for relative source contribution (RSC) as well. **Any such additional modification for RSC, though unnecessary to protect all populations at the highly conservative DWEL of**

¹ Participating in this position paper are the member companies of the Perchlorate Study Group, with the exception of Lockheed Martin Corporation.

24.5, nonetheless would still result in a PHG significantly higher than 6 ppb. Finally, given the use of a NOEL as the point of departure preferred by NRC and accepted by US EPA, the Benchmark Dose approach used by OEHHA is fundamentally inconsistent for several reasons, as outlined below.

The following facts and statements in quotes from the US EPA IRIS database and its press release that are most relevant to California's deliberations as to the justification for an upward adjustment in its 6 ppb PHG for perchlorate are as follows:

- **US EPA has now established a reference dose, based upon the recommendation of the report of the NRC committee, which US EPA concludes equates to a DWEL almost 25 times higher than the DWEL of 1 ppb US EPA proposed in 2002.** US EPA has specifically stated that the NRC committee derived its recommended RfD from a NOEL, a much lower point than all previous precedent which begins the analysis at the level at which there is no observed adverse effect-NOAEL (or at the lowest observed adverse effect-LOAEL). "The use of a NOEL differs from the traditional approach to deriving an RfD, which bases the critical effect on an adverse outcome...An interspecies uncertainty factor of 10 is applied to protect the most sensitive populations, the fetuses of pregnant women who might have hypothyroidism or iodide deficiency." "Because the NOEL is for a non-adverse effect, this is considered to be a more conservative and health protective approach than traditional hazard assessments." Essentially, the 10-fold adjustment is an added safety factor protecting sensitive populations from even experiencing biological effects that are not adverse (e.g. iodine uptake inhibition).

Therefore we conclude that, if OEHHA interprets the RfD itself as the safe dose response threshold, which factors in a 10-fold level of uncertainty to the NOEL, its PHG will be extremely protective compared to other PHGs, even without making a further adjustment downward for RSC.

- **US EPA notes that the NRC committee considered and rejected the California Benchmark Dose approach.** The NRC committee reviewed several proposed reference doses based on Benchmark Dose (BMD) methods, including the BMD performed by OEHHA and which provides the basis for its March 2004 Public Health Goal. The NRC committee concluded, however, that there was no scientific basis for preferring any one of them to the others and therefore decided not to use BMD methods. In conforming to the NRC committee's recommended analytical approach, US EPA emphasizes that the NRC committee decided against use of the BMD approach because it requires the use of "different models, approaches, parameters, response levels, and input data, making the comparison of results difficult." US EPA further noted that the NRC committee concluded that "although BMD modeling can be an improvement over the use of the NOAEL or LOAEL as the point of departure, there appeared to be no consensus on the criteria for choosing one BMD approach over another. Moreover, the NRC committee notes

that its RfD “is based on a non-adverse effect that precedes the adverse effect in the continuum of possible effects of perchlorate exposure.” It is unprecedented to use a nonadverse effect as the basis for deriving the RfD, and contrary to US EPA procedures for OEHHA to apply BMD methods to a non-adverse effect.

Therefore, we conclude that the NRC committee did not use a BMD approach because it found no way to justify any of the several models proposed, including the model proposed by California’s OEHHA. OEHHA cannot simultaneously claim that its PHG is consistent with the NRC committee report while retaining the BMD approach that the NRC committee specifically reviewed but found wanting. While a BMD approach may be appropriate when based upon an adverse effect, it is apparent that the committee was uncomfortable with OEHHA’s attempt to bootstrap the BMD approach to a non-adverse effect.

- **The US EPA has a high degree of confidence that its RfD is highly protective.** According to US EPA, “The overall confidence in this RfD is high because it is based on a no-effect level for a well-characterized biochemical precursor effect (iodide uptake inhibition), accompanied by a 10-fold uncertainty factor for susceptible populations. The RfD should protect the health of even the most sensitive populations, because a dose that does not inhibit thyroid iodide uptake will not affect thyroid function, even in subjects with an abnormal thyroid gland or very low iodide uptake.”

Therefore we conclude that OEHHA’s presently adopted PHG of 6 ppb is significantly out of line with the NRC committee’s approach, which US EPA has now adopted, as well as the US EPA’s statement that the DWEL for its reference dose is 24.5 ppb.

- **US EPA says that the default factors used to convert the RfD into drinking water concentrations already include a margin of safety for sensitive sub-populations.** The DWEL calculated by US EPA “is the concentration of a contaminant in drinking water that will have no adverse effect with a margin of safety.” No additional adjustments are needed to ensure protection for pregnant women, infants or children.

Therefore we conclude that use of standard default factors to calculate a DWEL, as was done by US EPA is appropriate and protective of all populations.

Conclusions:

1. US EPA has now endorsed 24.5 ppb as the lower bound of the national cleanup level for sites at which perchlorate is a constituent of concern (COC). This cleanup level is applied to groundwater used as drinking water, which further

implies US EPA acceptance of 24.5 ppb as a safe and appropriate drinking water level. The Agency is now developing guidance for site-specific risk assessment, and few sites will have perchlorate at levels high enough to make it a COC. Where levels are high enough to make perchlorate a COC, US EPA site remediation guidance requires that the 24.5 ppb DWEL be applied only if there is uncontrolled exposure to the sensitive subpopulation of concern (i.e., pregnant women who have untreated hypothyroidism due to iodine deficiency). There appear to be no such sub-populations in California. If no such exposure exists, 24.5 ppb will be unjustifiably stringent under US EPA guidance on site-specific risk assessment especially given that the RfD was derived from a NOEL.

2. No further adjustments to the 24.5 ppb DWEL based on alternative body weight, drinking water consumption rates, or relative source contribution are justifiable. US EPA believes that the default conversion factors, in addition to the 10-fold uncertainty factor, are adequately protective for all populations. For the same reasons, we believe that the adjustments for relative source contribution are redundant and unnecessary. However, even if one were to adjust for relative source contribution the resulting value would be significantly higher than the preliminary California PHG of 6 ppb.
3. US EPA now agrees that iodide uptake inhibition is not an adverse effect. The NOEL for this nonadverse effect converts to 245 ppb. US EPA further acknowledges that the NOEL is much more conservative than the points of departure traditionally used by US EPA and OEHHA, the NOAEL or the LOAEL. Moreover the RfD and corresponding 24.5 DWEL are rendered even more conservative by also building in an unprecedented 10-fold safety factor.
4. The 24.5 ppb DWEL will also be the basis for EPA's consideration of whether or not to set a drinking water standard (Maximum Contaminant Level or MCL) for perchlorate. Given the RfD's high degree of protection and the fact that environmental exposures are, for the most part, substantially below 24.5 ppb, US EPA may well decide that perchlorate does not warrant regulation under the Safe Drinking Water Act and thus decline to set a federal MCL.
5. The NRC committee concluded that OEHHA's Benchmark Dose (BMD) approach is inappropriate in this case for the reasons noted above. Because the choice of modeling approach is inextricably tied to the resulting RfD, US EPA has deferred to the NRC committee's judgment on this matter. Continued reliance on the BMD puts OEHHA at odds with both the NRC committee and US EPA. OEHHA cannot simultaneously claim that its PHG is consistent with the NRC committee, US EPA or both, while retaining the BMD approach that the NRC committee specifically reviewed but rejected.