PSG

PERCHLORATE STUDY GROUP

A coalition of aerospace, defense, chemical and allied industries

April 6, 2010

Joan E. Denton, Ph.D.
Office of Environmental Health Hazard Assessment
California EPA
1001 "I" Street
Sacramento, CA 95812

Re: Review of Perchlorate PHG
Health & Safety Code §116365(e)(1)

Dear Dr. Denton:

On behalf of the Perchlorate Study Group, this letter is provided to serve as a follow up to our conversations with your office on September 2 and November 30 of last year. We appreciate the time and attention OEHHA has given to the issue of perchlorate as well as to our questions and comments. I hope you find this information useful, and I look forward to a continued productive dialogue with you and your team.

As you know, OEHHA's Public Health Goal (PHG) of 6 ppb for perchlorate, established in 2004, was based on consistent scientific evidence, including evidence on the mechanism of action and potential adverse effects of perchlorate in humans, going back more than 60 years. Numerous new studies published since 2004 have not changed our fundamental understanding of the toxicology and pharmacology of perchlorate; in fact, subsequent reviews of the available epidemiological, clinical and laboratory evidence have concluded there is no evidence of adverse health effects below this level. Based on the collective scientific literature published to date, OEHHA's initial PHG was conservative, health protective, and based on a solid and consistent foundation of scientific information.

It is well-established that the mechanism of action of perchlorate is inhibition of iodide uptake into the thyroid gland. It is also well-known that the anions nitrate and thiocyanate, ubiquitous in food and water, inhibit iodide uptake into the thyroid by the same mechanism. Even after adjustment for potency differentials, perchlorate accounts for less than 1% of the inhibition of iodide uptake in the thyroid resulting from environmental exposure to nitrate, thiocyanate and perchlorate.

The PHG was developed taking into consideration the no observable effect level, or NOEL, reported by Greer *et al.* (2002). This dose caused ***no*** measurable inhibition of iodide uptake in human subjects. The Greer study is not the only clinical study of perchlorate, but it is the study that reported the lowest dose corresponding to no inhibition of iodide uptake. No studies published since 2004 have suggested that this approach is inappropriate or flawed.

In the actual development of the PHG for drinking water, a statistical method called a benchmark dose analysis was used. As a result, the analysis started with a dose level of ***half*** the NOEL reported by Greer. A "safety factor" of 10 was then applied to account for inter-individual differences and sensitive subpopulations. It was assumed that 60% of perchlorate exposure was from drinking water. A conservative body weight to water intake ratio was used (OEHHA, 2004). Thus, these assumptions resulted in a PHG that is more conservative than the drinking water limit of 15 ppb proposed by the U.S. EPA based on the Reference Dose (RfD) of 0.7ug/kg/day.

There is general agreement that the inhibition of iodide uptake does not in itself represent an adverse health effect of perchlorate (OEHHA, 2004; NAS, 2005; ATSDR, 2008), and that changes in serum thyroid hormone levels within the normal range cannot be interpreted as reflecting an adverse effect of exposure on thyroid function. It has been speculated that pregnant women and their developing fetuses may be more sensitive to potential adverse effects on the thyroid of environmental perchlorate exposure; however, there is no credible evidence from any of the numerous epidemiologic studies using a variety of designs that environmental exposure to perchlorate has any adverse effect on thyroid function, whether measured as changes in thyroid hormone levels, or among newborns, as the diagnosis of primary congenital hypothyroidism.

In 2005, the NAS conducted an exhaustive assessment of the perchlorate science. OEHHA commented that NAS "did not provide 'new scientific evidence' to suggest that perchlorate 'presents a materially different risk to public health than was previously determined.'"

More recently, ATSDR reviewed all studies conducted up to 2008, and concurred with the NAS review. ATSDR stated that its "decision was made after a careful evaluation of the NAS report and of studies that have been published after the NAS (2005) report. The results from newer studies do not change the bottom-line recommendation." No newer studies have provided data altering our understanding of perchlorate.

In summary, OEHHA's 6 ppb PHG for perchlorate is both conservative and fully protective of human health. This is demonstrated by the robust and well-understood database of scientific research available at the time the PHG was set, as well as OEHHA's very cautious and conservative approach, which placed particular focus on the most sensitive populations. Further, since the PHG was set, no new studies have brought information to bear which would call the protectiveness of the PHG into question.

If you have any questions or wish to discuss this matter, please contact me at (301) 548-2164.

Very truly yours,

Amy C. Jones, Ph.D.

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