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November 20, 2017

Samuel Hernandez
U.S. EPA, Office of Ground Water and Drinking Water
Standards and Risk Management Division, (Mail Code 4607M), 1200
Pennsylvania Avenue NW
Washington, DC 20460;

RE: Comments on EPA's Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water at Docket No. EPA-HQ-OW-2016-0438

Dear Mr. Hernandez:

The Environmental Working Group, a nonprofit research and advocacy organization based in Washington, DC, submits comments on the Environmental Protection Agency's draft report Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal (MCLG) for Perchlorate in Drinking Water.

Perchlorate exposure is of utmost concern for children's health because as of 2005-2010, the latest period for which data are available, more than half of all pregnancies in the U.S. were recorded for women with iodine intake below the WHO recommendation of 250 micrograms per day.¹ The EPA draft proposal represents a true step forward for protecting the health of American children from this toxic chemical that contaminates food and drinking water. EWG also wholeheartedly supports the detailed comments submitted by the Environmental Defense Fund and Natural Resources Defense Council.

In this letter, EWG highlights three main messages:

- The approaches for perchlorate MCLG derivation outlined in the draft report are scientifically sound and should be adopted for the final agency decision.
- The EPA should use a minimum tenfold safety factor when establishing a reference dose for perchlorate to account for human variability in thyroid vulnerability, and the prevalence of other goitrogens in water and food.
- The EPA's analysis conclusively demonstrates that the existing Reference Dose (RfD) of 0.7 ug/kg-day is not protective of public health and needs to be lowered.

Details and rationale for EWG's recommendations are provided below.



1. EWG supports the modeling and approaches outlined in the draft report.

EWG commends the Agency's modeling of perchlorate effects on the maternal thyroid gland in women with low iodine intake during pregnancy. EWG finds that the EPA has thoroughly reviewed the literature for both perchlorate effects on thyroid homeostasis, and synthesized a sizable body of literature linking thyroid perturbations during pregnancy and early life with altered brain development and motor control in young children. In our assessment, the EPA's method is rigorous, transparent, and appropriately evaluates perchlorate risks for the most vulnerable population and time periods, specifically with the additional focus on women with hypothyroxinemia during the first trimester of pregnancy.

2. EPA must use appropriate safety factors when determining acceptable perchlorate exposure.

While EPA's modeling is high quality and appropriately based on studies of perchlorate's effects on human pregnancies, important uncertainties remain. EWG is concerned that the draft EPA model may not capture the full variability of maternal response to thyroid perturbation, and does not account for women with pre-existing thyroid disease who may be more affected by perchlorate exposure.

EWG also notes that perchlorate intake does not occur in isolation. During pregnancy, women and the developing fetus are also exposed to other chemicals harmful to the thyroid. The EPA model did not explicitly account for the effects of concurrent exposures to certain goitrogens, such as thiocyanate and nitrate.

The EPA draft proposal has also neglected to consider chlorate, another goitrogen commonly detected in food and drinking water. Chlorate forms when drinking water is disinfected with hypochlorite bleach. Like perchlorate, chlorate is also formed when bleach degrades due to inadequate management conditions. If bleach is then used to disinfect food handling equipment and produce, both perchlorate and chlorate could contaminate food simultaneously, increasing the risk of harm to the thyroid. The European Food Safety Authority's 2015 assessment of chlorate bases its assessment of chronic exposure on the risk of iodine uptake inhibition, the same toxicity pathway that is affected by perchlorate.²

EWG urges the EPA to employ a minimum tenfold safety factor in the development of its reference dose for perchlorate to account for the outstanding uncertainties and to protect against the significant, lasting effects perchlorate exposure can have on children's brain and motor development.



3. Existing Reference Dose of 0.7 ug/kg-day is not protective of public health and needs to be lowered.

The reference dose for perchlorate exposure currently in effect was established by the EPA in 2005 and was based on a No Observed Effect Level (NOEL) reported in a study of thyroid function for healthy adult volunteers. The latest research conclusively demonstrates that data from non-pregnant adults, even with the use of additional uncertainty factors, does not adequately predict risks of thyroid hormone disruption during the sensitive life stages of gestation and childhood. Thus, the Agency's proposal to model effects of perchlorate exposures during pregnancy represents a true advance for children's health protection.

The EPA's draft released for comment in September 2017 presented two methods to evaluate adverse effects of perchlorate exposure. Both methods produced similar outcomes, demonstrating the overall robustness of the EPA proposal.

The EPA's first method assessed the impact of perchlorate on the circulating levels of free thyroxine, a thyroid hormone also called free T4 (fT4), in mothers with low dietary iodine. It identified four health endpoints that can be quantitatively correlated with maternal fT4 levels in pregnant women with low iodine intake. EWG recommends that EPA base its reference dose on the most sensitive outcomes associated with perchlorate exposure, a change in the infant Psychomotor Development Index. Exposure to 1.7 micrograms of perchlorate per kilogram of bodyweight per day during week 12 of pregnancy is expected to cause a one-point decrease in the Psychomotor Development Index in childhood. The reference dose and the future MCLG for perchlorate must protect against this type and degree of change in psychomotor development.

The EPA used a second method to determine the amount of perchlorate exposure that would shift additional American pregnancies towards the condition of hypothyroxinemia. The EPA defined the hypothyroxinemia cutpoint as the lower 10th percentile level of fT4 in a population with median iodine intake. The EPA's analysis points out that hypothyroxinemia during pregnancy is associated with poorer neurodevelopment in infants, including lower non-verbal intelligence, slower reaction times, non-verbal cognitive delays, as well as profound outcomes with life-long consequences such as schizophrenia, attention deficit hyperactivity disorder and autism.

The EPA draft report calculated that a dose of 0.3 - 0.4 ug/kg of perchlorate per day will cause a 1 percent increase in the number of pregnant women with clinically defined hypothyroxinemia, and a dose of 2.1 - 2.2 ug/kg per day will cause a 5 percent increase. The analysis jointly developed by the Environmental Defense Fund and Natural Resources Defense Council indicates this would impact 4,000 and 20,000 U.S. pregnancies, respectively.



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The modeling EPA presented clearly indicates that the current reference dose for perchlorate is not protective of public health and must be lowered. Using any of the points of departure identified above, and applying a minimum tenfold safety factor will protect many thousands of pregnancies in the United States today and the health of American children.

In conclusion, EWG finds that the EPA scientists have successfully addressed the central question raised by EPA's Science Advisory Board in 2013 and the agency's peer review panel, regarding the relationship between perchlorate exposure in the first trimester of pregnancy and a child's neurodevelopmental outcomes when the mother has insufficient iodine intake.

Submitted on behalf of the Environmental Working Group,

Sonya Lunder, MPH, Senior Analyst

Olga Naidenko, Ph.D., Senior Science Advisor

References:

¹ KL Caldwell, et al. Iodine status in pregnant women in the National Children's Study and in U.S. women (15-44 years), National Health and Nutrition Examination Survey 2005-2010. *Thyroid*, 2013. 23(8):927-37.

² EFSA. 2015. Scientific Opinion: Risks for public health related to the presence of chlorate in food. European Food Safety Authority. *EFSA Journal* 13(6):4135.