

# Children's Health Protection Advisory Committee

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November 3, 2008

Stephen L. Johnson, Administrator  
United States Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

RE: Preliminary Regulatory Determination on Perchlorate; Docket  
ID No. EPA-HQ-OW-2008-0068

Dear Administrator Johnson:

The Children's Health Protection Advisory Committee (CHPAC) has been closely monitoring the Agency's approach towards perchlorate as a drinking water contaminant. Our March 2006 letter to you recommended that the Agency develop a federal Maximum Contaminant Level (MCL) for perchlorate. This recommendation was based upon the ability of perchlorate to disrupt thyroid hormone synthesis, lowering circulating levels of thyroid hormone, and the critical importance of thyroid hormone to brain development. Our concern over perchlorate has focused on in utero and postnatal development, particularly for neonates whose exposures can be considerably greater than adults, and who lack stores of thyroid hormone. The life-long consequences of impaired brain development are sufficient to merit setting a protective MCL for perchlorate. Further, setting an MCL would mandate testing of public water supplies, and allow discovery of hot spots of contamination.

We are writing to you again on perchlorate because in the Preliminary Regulatory Determination on Perchlorate dated Oct 10, 2008, EPA decided against setting an MCL. This decision was based upon the establishment of a flawed benchmark, a Health Risk Limit (HRL) of 15 ug/L. This benchmark is clearly too high for infants as the Agency's own calculations show that an HRL of 15 ug/L would allow daily exposures to infants that are 2-5 times higher than the Reference Dose (RfD) (Federal Register, Vol 73, No.198, October 10, 2008, 60262-60282). The RfD is meant to be applied to everyone, yet in the case of perchlorate it is applied to adults but not infants. This decision does not recognize the science which supports the exquisite sensitivity of the developing brain to even small drops in thyroid hormone levels and the fact that

neonates have much diminished stores of thyroid hormone relative to adults. The Agency must ensure that this life stage is adequately protected.

The Agency justifies the high MRL by a pharmacokinetic model that simulates iodine uptake inhibition in the human fetus and newborn based upon experimental data in rat pups. While the model has been validated in adult humans and rat pups, it has not been validated in infants and children. As we described in the CHPAC 2006 letter, use of the rat data to project pharmacokinetics to human newborns is uncertain given the well known differences in the rate of development of clearance mechanisms between rodents and humans. The modeling performed by the Agency does not remove the clear concern for elevated neonatal exposure to perchlorate, well in excess of the RfD. This also represents an unorthodox use of pharmacokinetic modeling in regulatory risk assessment because once an RfD is established, it is inappropriate to use additional modeling to justify exceeding the RfD.

We note that the RfD itself is uncertain and is not necessarily a health protective benchmark. It is based upon a limited clinical study of short duration and small sample size not representative of the variability in the human population (Greer, et al., 2002). When a larger epidemiologic study was conducted by CDC, significant correlations were found between increasing perchlorate exposure and decreasing thyroid hormone levels in the subpopulation of women with low iodide intake, which the CDC NHANES data show constitutes 31% of all women (Blount, et al 2006). The exposure levels associated with anti-thyroid effects in these women were below the perchlorate RfD. These findings cast doubt on the protectiveness of the RfD, and make it especially important that no group exceed this health benchmark.

A number of states have recently established perchlorate drinking water standards or goals that are more appropriate than USEPA's HRL published in the Oct 10<sup>th</sup> FR notice. The New Jersey MCL is 5 ug/L, the California Public Health Goal is 6 ug/L and the Massachusetts MCL is 2 ug/L. These drinking water values were intended to keep perchlorate exposures below the RfD for all groups including young children. Approximately 4% of public water supplies serving 17 million Americans would be in exceedance of an HRL between 2 and 6 ug/L. This is 15 million more at risk individuals than currently estimated by the Agency. Thus, the proposed HRL of 15 ug/L has the potential to leave large numbers of infants inadequately protected against perchlorate.

The other concern is that, as noted earlier, without a federal MCL, detections of high level contamination (e.g., 1300 ug/L of perchlorate in a public water supply in Boxborough MA) will go undetected leading to high localized exposures. This high level of contamination would not have been detected without a state initiated testing program (MADEP, 2005). Given the unpredictable nature of these extreme concentrations, national monitoring is clearly needed. The 2001 Unregulated Contaminant Monitoring Regulation (UCMR) for perchlorate focused upon larger public water supplies and is not indicative of the numbers of people exposed or extent of exceedances possible from localized hot spots due to contamination of water from blasting, fireworks or industrial/military releases.

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The Safe Drinking Water Act (SDWA) requires the Administrator to establish an MCL when three conditions are met. The CHPAC feels strongly that all three conditions are met in the case of perchlorate. The first condition, that the contaminant has an adverse effect on the health of persons, is met for perchlorate. Perchlorate interferes with thyroid function and can lower circulating thyroid hormone levels in humans; lowered thyroid hormone levels and consequent impacts on the developing brain have been demonstrated in perchlorate-dosed animals. The developing fetus and infants are vulnerable to perchlorate due to the exquisite sensitivity of brain development to thyroid hormone levels, and the fact that newborns have no stores of this hormone. The second condition, that the contaminant occurs in public water supplies with a frequency and level of public health concern, is also met for perchlorate. The UCMR data show that millions of Americans are exposed to perchlorate in public supplies at concentrations greater than 6 ug/L, the highest of the three recently set state drinking water targets for perchlorate. The only way the second condition is not met is if an inappropriately high health benchmark is set. The CHPAC strongly feels that this is the case with USEPA's HRL of 15 ug/L as this would cause large numbers of infants to receive daily doses of perchlorate that are well above the Agency's RfD. The third condition of the SDWA, that the Agency has a meaningful opportunity for health risk reduction, is also met for perchlorate. The setting of an MCL will trigger requirements for testing to determine whether there are exceedances, and fortunately, sensitive test methods and effective treatment systems are readily available. Therefore, the Administrator has the opportunity to intervene to protect the health of millions of pregnant women and their fetuses, and lactating women and infants across the country who would otherwise be exposed to unsafe levels of perchlorate.

In summary, the CHPAC believes that all three conditions for setting an MCL are met and that the Agency must set an MCL for perchlorate. We request further communication with you and your staff regarding the Preliminary Regulatory Determination on Perchlorate. This is a critical and timely issue given the concerns over endocrine disruption by thyroid-active agents of various types and their potential to interact with other neurotoxicants to impair early life brain development. While many of these other neurotoxicants (heavy metals, pesticides, PCBs) have been aggressively targeted by USEPA, the lack of regulation of perchlorate is an obvious oversight that can readily be addressed.

Thank you for your attention to this matter.

Sincerely,



Melanie A. Marty, Ph.D., Chair  
Children's Health Protection Advisory Committee

Cc: Benjamin Grumbles, Assistant Administrator, OW  
Cynthia Dougherty, Director, OGWDW  
Eric Burneson, Chief, Targeting and Analysis Branch, OGWDW

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References:

Blount BC, Pirkle JL, Osterloh JD, Valentin-Blasini L, Caldwell KL. 2006. Urinary perchlorate and thyroid hormone levels in adolescent and adult men and women living in the United States. *Environ Health Perspect* 114:1865-1871.

Greer MA, Goodman G, Pleus RC, Greer SE (2002) Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans. *Environ Health Perspect* 110:927-937.

MADEP, 2006 Perchlorate Monitoring Results - Confirmed Above 1.0 ppb (Available at <http://www.mass.gov/dep/water/drinking/percinfo.htm>)