



September 20, 2012

Mr. Thomas Carpenter
Environmental Protection Agency
Designated Federal Officer (DFO)
Submitted via email to: carpenter.thomas@epa.gov

Re: Availability of the Science Advisory Board (SAB) Perchlorate Advisory Panel's Draft Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate.

Dear Mr. Carpenter:

The U.S. Environmental Protection Agency (EPA) Scientific Advisory Board's (SAB) Perchlorate Advisory Panel (Panel) has been charged with the important task of reviewing the available scientific information in order to provide guidance to the EPA Administrator on the development of a maximum contaminant level goal (MCLG) for perchlorate. In response to this charge, the Panel held a meeting on July 17 – 18, 2012 to discuss the EPA's Whitepaper titled: *"Life Stage Considerations and Interpretation of Recent Epidemiological Evidence to Develop A Maximum Contaminant Level Goal for Perchlorate"* and how best to consider the life stage information, the epidemiologic and biomonitoring data and the physiologically-based pharmacokinetic (PBPK) analyses for perchlorate. During the meeting, the American Chemistry Council¹ (ACC) presented oral comments which focused on the lack of scientific justification presented by the EPA's Whitepaper for developing an MCLG for perchlorate in drinking water. We also submitted more detailed comments for consideration by the Panel that noted several decades of scientific data in animals and humans which indicates that perchlorate does not pose an adverse effect at current exposure levels.

In early September 2012, the Panel released their draft *"Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate"*² (draft Advice); the Panel will conduct a teleconference on September 25, 2012 to discuss the draft Advice. ACC supports a thorough review of perchlorate and the use of the best available scientific information and methodologies to support regulatory actions. However, while the Panel's draft Advice offers some salient points for using physiologically-based pharmacokinetic/pharmacodynamic modeling based upon mode of action rather than the default algebraic

¹ ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$674 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

² Draft (9/5/2012) Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate. [http://yosemite.epa.gov/sab/SABPRODUCT.NSF/81e39f4c09954fcb85256ead006be86e/C42440409E599EBD85257A7100074906/\\$File/PAP+Report+090512.pdf](http://yosemite.epa.gov/sab/SABPRODUCT.NSF/81e39f4c09954fcb85256ead006be86e/C42440409E599EBD85257A7100074906/$File/PAP+Report+090512.pdf).



approach, the Panel's Advice does not provide adequate justification for an association of perchlorate with adverse effects.

In the draft Advice, the Panel states that *“the post-NRC epidemiology data are insufficient to guide causal inference with regard to the association between perchlorate exposure and thyroid dysfunction in pregnant women, neonates or the general population”* and *“Although no data exist on the long-term adverse neurodevelopmental effects of perchlorate per se, the data on the adverse effects of thyroid hormone perturbations (a down-stream effect from iodide uptake inhibition) on the developing brain justify the need for a life stage approach.”* It is unclear why the Panel has made an inferential determination that current perchlorate exposure levels will inevitably lead to adverse effects without providing additional scientific justification regarding the level of iodine uptake inhibition needed to cause thyroid hormone changes and what levels of perchlorate exposure leads to these changes. The Panel also states in its draft Advice that it recommends *“that hypothyroxinemia or subclinical hypothyroidism is more appropriate to consider in evaluating the potential adverse health effects for pregnant women, fetuses and infants than hypothyroidism.”* However, the weight of evidence linking perchlorate to hypothyroxinemia is limited and the scientific evidence illustrating a correlation between perchlorate and changes in thyroid hormones is inconsistent. While Blount et al. (2006)³ found a perchlorate-related increase in TSH and decrease in T4 in women Pearce et al. (2011⁴, 2010⁵) did not find an association between urinary perchlorate and thyroid hormone perturbations in first trimester pregnant women.

ACC strongly encourages the Panel to revise its draft Advice to: (1) clearly state that there is limited evidence of an association to current perchlorate exposure levels and adverse effects, (2) provide a discussion regarding the level of iodine uptake inhibition needed to cause thyroid hormone changes and what levels of perchlorate exposure leads to these changes, (3) provide a discussion on the thyroid hormone level changes needed to result in adverse effects and what levels of perchlorate are needed to cause these changes, and (4) provide additional justification for using hypothyroxinemia as the sensitive endpoint for determining adverse effects associated with perchlorate exposure. If you have any questions or require additional information please feel free to contact me by phone at 202-249-6707 or via email at Kimberly_Wise@americanchemistry.com.

Respectfully,

Kimberly Wise, Ph.D.
Senior Director
Chemical Products & Technology Division
American Chemistry Council

³ Blount, B.C., J.L. Pirkle, J.D. Osterloh, L. Valentin-Blasini, and K.L. Caldwell. 2006. Urinary perchlorate and thyroid hormone levels in adolescent and adult men and women living in the United States. *Environ Health Perspect.* 114(12):1865-1871.

⁴ Pearce, E.N., C.A. Spencer, J.H. Mestman, R.H. Lee, L.M. Bergoglio, P. Mereshian, X. He, A.M. Leung, and L.E. Braverman. 2011. Effect of environmental perchlorate on thyroid function in pregnant women from Cordoba, Argentina, and Los Angeles, California. *Endocrine Practice : Official Journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists.* 17(3): 412-417.

⁵ Pearce, E.N., J.H. Lazarus, P.P.A. Smyth, X. He, D. Dall'Amico, A.B. Parkes, R. Burns, D.F. Smith, A. Maina, J.P. Bestwick, M. Jooman, A. M. Leung, and L.E. Braverman. 2010. Perchlorate and thiocyanate exposure and thyroid function in first-trimester pregnant women. *The Journal of Clinical Endocrinology and Metabolism.* 95(7): 3207-3215.

