November 29, 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 Revised Draft Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate.

Dear Mr. Carpenter:

The American Chemistry Council[1] (ACC) appreciates this opportunity to provide comments on the U.S. Environmental Protection Agency (EPA) Scientific Advisory Board's (SAB) Perchlorate Advisory Panel (Panel) revised draft Advisory Report dated November 9, 2012. ACC previously provided comments on the Panel's first draft Advisory Report in September. Our comments strongly encouraged the Panel to revise its draft Advisory Report to: (1) clearly state that there is limited evidence of an association between 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.

ACC commends the Panel for revising the Advisory Report to include additional information on the available scientific data related to perchlorate, iodine uptake and potential adverse impacts. We also strongly support the Panel's recommendation that any derived maximum contaminant level goal (MCLG) for perchlorate utilize physiologically-based pharmacokinetic/pharmacodynamics (PBPK/PD) modeling based upon mode of action information rather than the default MCLG approach using the RfD and specific chemical exposure parameters. However, as the Panel has noted in its revised draft Advisory Report *"no data exist in humans directly examining the relation between perchlorate exposure, its thyroidal impact, and the developing brain,… no data exist on the long-term adverse neurodevelopmental effects of perchlorate…and the available epidemiological data published since the*

[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 $760 billion enterprise and a key element of the nation's economy. It is the largest exporting sector in the U.S., accounting for 12 percent of 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] EPA's Office of Inspector General Scientific Analysis of Perchlorate, April 19, 2010. Report

NRC 2005 report 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."

Considering that the regulation of perchlorate must present a meaningful opportunity for health risk reduction for persons served by public water systems, the Panel should also recommend that EPA, after completing the PBPK analyses, reevaluate whether or not the scientific findings support the necessity of regulation. As has been suggested by others, including EPA's Office of Inspector General, regulation of perchlorate will likely be less effective at reducing risk than approaches that include correcting moderate and mild iodide deficiency in populations of concern[2].

If you have any questions or require additional information regarding these comments 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

[2] EPA's Office of Inspector General Scientific Analysis of Perchlorate, April 19, 2010. Report No. 10-P-0101 http://www.epa.gov/oig/reports/2010/20100419-10-P-0101.pdf