UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
SOLID WASTE AND
EMERGENCY RESPONSE

Melanie A. Marty, Ph.D., Chair
Children's Health Protection Advisory Committee
California Environmental Protection Agency
Office of Environmental Health Hazard Assessment
1515 Clay St. 16th Floor
Oakland, California 94612

Dear Dr. Marty:

Thank you for your letter of March 8, 2006, to Administrator Johnson conveying the Children's Health Protection Advisory Committee's recommendations to the Agency for the risk management of perchlorate; specifically, recommendations relating to the Agency's development of a Superfund preliminary remediation goal (PRG) and a Safe Drinking Water Act (SDWA) maximum contaminant level (MCL) and interim health advisory.

As you know, in January 2005 the National Academy of Sciences National Research Council issued its report, "*Health Implications of Perchlorate Ingestion*," which provided state-of-the-science advice on perchlorate toxicity. The National Research Council recommended that EPA base its perchlorate reference dose (RfD) on a level at which we expect no statistically or biologically significant increase in an observable nonadverse effect—an approach that is more protective than EPA's traditional approach of basing RfDs on adverse health effects. The National Research Council specifically considered the risks to the most susceptible individuals in recommending an RfD, and in this instance identified the fetuses of pregnant women who have hypothyroidism or iodide deficiency as the subpopulation most sensitive to the effects of perchlorate exposure. To protect this subpopulation, the National Research Council recommended that the RfD be derived by taking the dose at which no observable effect, non-adverse or adverse, is anticipated in healthy adults, and reducing it further by an order of magnitude. After reviewing these findings, EPA based its RfD of 0.0007 mg/kg-day on the National Research Council's recommendations.

In January 2006, EPA's Office of Solid Waste and Emergency Response (OSWER) issued its Assessment Guidance for Perchlorate, which recommended a PRG of 24.5 micrograms/liter (or parts per billion). The PRG is based on the perchlorate RfD and appropriate exposure assumptions. It is important to remember that PRGs are not final cleanup levels, but are merely the starting point for site-specific goals. Our regulations require that PRGs be further evaluated, and modified as necessary, as information becomes available during the remedial

investigation/feasibility study, prior to establishing final remediation goals or clean-up levels. OSWER's recommended PRG was established to ensure that the most sensitive subgroup is protected against a nonadverse effect—a health-protective approach that is informed by the conclusions of the National Research Council. Because the fetus is most sensitive to the effects of perchlorate exposure, the pregnant woman is an appropriate focus when assessing exposure to perchlorate. The exposure assumptions that EPA used to develop its PRG are consistent with those of pregnant women, as well as being the standard exposure assumptions that the Agency uses to calculate PRGs generally. (See *Risk Assessment Guidance for Superfund (RAGS): Volume I. Part B, Development of Risk-based Preliminary Remediation Goals, Interim,* EPA/540/R-92/003, Dec. 1991.) EPA continues to examine the perchlorate science to ensure that our policies are appropriately health-protective, and has been consulting with other federal researchers to provide information on intake, distribution and excretion of perchlorate in humans at various life stages.

With regard to the Committee's recommendation that the PRG take into account an appropriate relative source contribution factor, OSWER's guidance is clear that exposure to non-water sources of perchlorate at Superfund sites should be considered based on site-specific data. EPA recognizes that perchlorate has been detected in samples of some foods. Although additional data collection efforts are underway, EPA has determined that current data are too limited to characterize exposure to perchlorate on a national scale. Until such data are available, the approach outlined in OSWER's guidance is currently the most scientifically defensible approach to considering non-water exposure to perchlorate at Superfund sites.

The Committee also recommended that EPA develop an MCL for perchlorate, and, in the interim, that EPA issue a drinking water health advisory for perchlorate. EPA's Office of Water (OW) has an established process for determining whether or not a chemical should be regulated in drinking water and an MCL established. Using criteria specified in the SDWA, this regulatory process determines: (1) if the contaminant may have an adverse health effect; (2) if the contaminant occurs in public water systems with a frequency and at levels of public health concern; and, (3) if regulation presents a meaningful opportunity for health risk reductions for persons served by public water systems. Perchlorate and other contaminants on EPA's second Candidate Contaminant List are currently being evaluated as part of this regulatory determination process.

As part of this process, OW is analyzing the nationally representative occurrence data for perchlorate that was collected as part of the Unregulated Contaminant Monitoring Rule (UCMR) sampling conducted at public water systems. As the Agency continues to review health effects in light of perchlorate occurrence and other information, including data on the relative source contribution, the Agency may take one or more affirmative steps as provided for in SDWA, such as issuing a health advisory, if needed, or issuing a preliminary regulatory determination.

EPA will continue to evaluate new scientific information on perchlorate as it becomes available, to ensure the protection of children's health. Thank you again for your contribution to this important effort.

Sincerely,

Susan Parker Bodine
Assistant Administrator

cc: Benjamin Grumbles, OW
George Gray, ORD