U.S. Environmental Protection Agency
Office of Inspector General

10-P-0101
April 19, 2010

At a Glance

Catalyst for Improving the Environment

Why We Did This Review

Stakeholders often dispute the scientific support for a particular U.S. Environmental Protection Agency (EPA) decision or program action. We believe there is a particular need for impartial reviews of EPA's regulatory toxicology. Therefore, as a prototype for this work, we conducted an independent, scientific review of the risk assessment process and procedures used by EPA to develop and derive the perchlorate reference dose (RfD).

Background

On February 18, 2005, EPA issued a perchlorate RfD that corresponds to a drinking water equivalent level of 24.5 parts per billion. A regulatory determination is pending on whether to issue a National Primary Drinking Water Regulation.

For further information, contact our Office of Congressional, Public Affairs and Management at (202) 566-2391.

To view the full report, click on the following links:

www.epa.gov/oig/reports/2010/20100419-10-P-0101.pdf

www.epa.gov/oig/reports/2010/20100419-10-P-0101 appD.pdf

www.epa.gov/oig/reports/2010/20100419-10-P-0101 appE.pdf

Office of Inspector General Scientific Analysis of Perchlorate

What We Found

EPA should conduct a cumulative risk assessment to reduce the uncertainty in characterizing the public health risk posed by perchlorate. A cumulative risk assessment is the current state-of-the-art technique for evaluating the public health risk from multiple stressors. Over the last two decades, EPA has received numerous recommendations to improve environmental risk assessments. In 1997, EPA Administrator Carol Browner issued guidance directing EPA to embrace the cumulative risk assessment approach on all future major risk assessments. Although directed to improve the environmental risk assessment process, EPA continues to rely on the outdated single chemical risk assessment approach, originally developed in 1954, to characterize the risk posed by perchlorate. The single chemical risk assessment approach fails to address known sources of scientific uncertainty, which lowers the confidence in the perchlorate RfD.

Against established EPA risk assessment procedures, EPA derived the perchlorate RfD from a nonadverse biological effect instead of an adverse effect. The perchlorate RfD protects against all human biological effects from exposure, which is a stricter public health criterion than limiting environmental exposure to protect against adverse effects in humans. This shift in risk management constitutes a significant change in environmental policy.

Based on our scientific analysis, perchlorate is only one of several chemicals that stress the thyroid's ability to uptake iodide. The other sodium iodide symporter (NIS) stressors include thiocyanate, nitrate, and the lack of iodide. All four of these NIS stressors meet EPA's risk assessment guidance for conducting a cumulative risk assessment using the dose-addition method. Our analysis implemented a cumulative risk assessment that found the following: 1) the risk from each of the four NIS stressors is not equal; 2) EPA's perchlorate RfD is conservative and protective of human health, and further reducing the perchlorate exposure below the RfD does not effectively lower risk; 3) increasing maternal total iodide intake to healthy levels will reduce the frequency and severity of permanent mental deficits in children; and 4) correcting moderate and mild iodide deficiency occurring in about 29 percent of the U.S. pregnant and nursing population is the most effective approach for reducing risk.