December 20, 2012

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Administrator Jackson:

Following your February 11, 2011, decision, we are extremely concerned by how EPA is moving forward with issuing a National Primary Drinking Water Regulation for perchlorate under the Safe Drinking Water Act (SDWA), as well as with issuing a maximum contaminant level goal (MCLG) for perchlorate. We hope you will correct several of the more problematic developments.

As you are no doubt aware, perchlorate is the first contaminant to proceed through the rulemaking process established under the 1996 SDWA amendments (Section 1412 of SDWA). Congress enacted these specific changes in order to improve EPA’s regulatory quality and focus. Specifically, Congress insisted that EPA target Agency regulatory efforts and resources on the nation’s highest demonstrated risks to public water systems. Most significantly, the 1996 SDWA amendments required that regulations be science-based and that the science underpinning these regulations be the best available, objective, relevant, and valid. However, we are extremely concerned that the Agency is transmogrifying these legal obligations by proceeding in a way that corrupts SDWA requirements.

The scientific review to support this perchlorate regulation should have included nearly 60 years of relevant information. However, the Science Advisory Board (SAB) was charged with only reviewing data generated since the National Research Council’s 2005 perchlorate report. While we recognize that there are statutory deadlines in SDWA section 1412(b)(1)(E) that necessitate the Agency move forward on the regulation in a timely manner, this limited scope does a disservice to the public and to the regulatory process.

It is deeply troubling to us that despite the direction to you in SDWA section1412(b)(3) to use “the best available, peer reviewed science and supporting studies conducted in accordance with sound and objective scientific practices,” as well as President Obama’s January 2011, EO 13563 on Improving Regulation and Regulatory Review, and your own direction to the Agency in a May 9, 2009 memo on Scientific Integrity; that numerous organizations have pointed out that the
Agency’s charge failed to include a review of all relevant and significant available epidemiological data and did not use a weight of the evidence approach. Moreover, SAB panelists remarked at the lack of transparency in the models used to establish the Agency’s conclusions as well as the sparse data provided by the Agency to support the SABs deliberations.

Particularly noteworthy to us is that EPA’s charge to SAB pays limited attention to the 2005 work of the National Research Council (NRC) on this very subject, which, as you know, was conducted at the Agency’s request. This seems all the more curious since the Agency’s charge to the SAB plainly admits “studies directly demonstrating the adverse effects of perchlorate in humans are not available” and, instead, suggests “potential effects can be inferred.” Placing these two facts side-by-side, and considering that previous exposure assessments the Agency conducted included consideration of all available epidemiological data, it is fair to question whether EPA is selectively using, or cherry-picking, the science or following a process that considers all high quality studies, regardless of their conclusions.

As you know, the EPA’s Integrated Risk Information System (IRIS) assessments and associated use of science in regulatory decisions have been the subject of criticism from many in the scientific community. In several cases, the Agency has taken actions not supported by the weight of the available scientific evidence, only to have the analyses and conclusions rejected by independent scientific review.

In this context, why has EPA continued to move forward with a rulemaking on perchlorate when so doing further validates the criticisms leveled at the Agency regarding scientific integrity and manipulation of the regulatory process? In prior responses to Congress on this matter thus far — and in the documents generated as part of the rulemaking — the Agency has done little to establish a defensible scientific or policy rationale for the direction it is taking on perchlorate. Ultimately, this expensive effort seems to leave the Agency vulnerable to legal challenges based upon rushed, indefensible conclusions and ignoring mandated requirements.

On top of the concern that the foundational science behind this regulation is incomplete, the Agency appears to be taking the precedent of regulating based upon No Observed Effect Level (NOEL) as opposed to a No Observed Adverse Effect Level (NOAEL). As we understand it, the use of NOEL in setting a reference dose is not the norm in standard risk assessment practices. Furthermore, by doing this, the Agency is deciding to pursue a regulatory ethos based upon the presence of any human effects, including those that might be positive. Using a NOEL seems inappropriate in this context and contrary to Agency policy, which, as presented on your Agency’s website, claims its purpose is to “ensure all Americans are protected from significant risks to human health and the environment where they live, learn, and work.” Finally, it is a bit perplexing that EPA would need to lower the 2005 NRC-developed reference dose (RfD) for perchlorate, which the NRC clearly stated is protective of all sensitive subpopulations.

As someone who has been following the issue of perchlorate exposure, particularly in drinking water, for many years, please explicate the Agency’s thinking on its actions and decisions in this regulatory process by providing written answers to the following questions:
Concerns about EPA’s following its own good science guidelines concerning the establishment of an MCLG

The May 2012 white paper, “Life Stage Considerations and Interpretation of Recent Epidemiological Evidence to Develop a Maximum Contaminant Level Goal for Perchlorate” explains how EPA used 10 different “sensitive life stages” to derive the range of the MCLG from 2-18mg/L.

1. Does EPA typically use sensitive life stage segments when deriving an MCLG?
2. Are 10 stages typical for an MCLG determination?
3. What past MCLGs have been determined using this method and what was the MCL that was ultimately set for each?
4. Is EPA planning to use this method on all regulated chemicals?

Adverse health effect that presents a meaningful opportunity for public health risk reduction

The National Academies of Science and the Agency for Toxic Substances and Disease Registry (ATSDR) have noted that although it is “anticipated” that people exposed to excessive amounts of perchlorate for a long time may develop a decreased production of thyroid hormones, this effect has never actually been observed. “Life Stage Considerations and Interpretation of Recent Epidemiological Evidence to Develop a Maximum Contaminant Level Goal for Perchlorate” states that “studies directly demonstrating the adverse effects of perchlorate in humans are not available” and, instead, “potential effects can be inferred.” The SAB perchlorate panel found that “the epidemiological studies provided to the panel are inadequate for quantitatively estimating [the] reduction in adverse health effects realized in regulating perchlorate in drinking water”.

1. Has an adverse effect from exposure to environmental levels of perchlorate ever been documented in scientific literature?
2. Since EPA has determined that it is not seeking to establish a precise safe level of perchlorate in drinking water – through NOAEL – and is instead pursuing an arbitrary use of NOEL, please identify both the actual adverse effect that regulating perchlorate will fix as well as any actual effect that EPA expects to prevent with these regulations?
3. Does EPA typically infer potential effects rather than using directly demonstrated effects?
4. For what chemicals has EPA inferred potential effects when determining an MCLG?
5. Does EPA plan to use this method on future regulated chemicals?
6. Are there any limitations to using this method?

Integrity of the SAB

Any MCLG must be based on sound science and any review must be free of any conflicts of interest. This is imperative in order to ensure a feasible maximum contaminant level (MCL) that will result in real human health benefits. The SAB panel is composed of 16 members, including 5 pediatric experts, recommended by Peter Grevatt, Director of EPA’s Office of Children’s
Health Protection (OCHP), now Director of Office of Ground Water and Drinking Water (OGWWD).

1. How does the Agency determine if there are conflicts of interest for members of the SAB panel?
2. Are there members of the SAB that the Agency does not believe have a conflict of interest, but may have a bias based upon past work?
3. Will members have to disclose whether they have received any money for perchlorate research?

**2005 National Academy of Sciences (NAS) Review**

In 2005, NAS’s NRC published its review of the state of the science, concluding the relevant effect of perchlorate inhibition of iodide uptake into the thyroid, and that the NOEL for perchlorate is 7 ug/kg/day. NAS also determined iodide uptake inhibition that may occur above the NOEL, although not adverse, was the most appropriate precursor event on which to base a Reference Dose. Starting with the NOEL, NAS applied an uncertainty factor of 10 to account for sensitive subpopulations (people with thyroid disorders, pregnant women, fetuses and infants) and set an extremely conservative reference dose for perchlorate at 0.7 ug/kg/day, which EPA translated into a Drinking Water Equivalent Level (DWEL) of 24.5 ppb.

1. Does EPA agree that perchlorate’s NOEL has been established at 7 ug/kg/day?
2. Does EPA no longer agree with the NAS-recommended reference dose (RfD) of 0.7 ug/kg/day?
3. If EPA disagrees with either of the above, please explain the areas of disagreement.

**EPA’s Approach to Sensitive Populations**

For perchlorate, the DWEL for the NAS-recommended reference is 24.5 parts per billion. EPA is now exploring an approach for perchlorate standard-setting in which it uses different water consumption rates and different body weights for different “life stages” to account for sensitive subpopulations.

1. Is the use of different water consumption rates and different body weights for different “life stages” a standardized approach? Where has EPA used this approach before?
2. Because the reference dose is defined as the exposure that is likely to be without appreciable risk over a lifetime, including for sensitive subpopulations, what is the justification for including a further adjustment for sensitive subpopulations when, as noted above, a full 10-fold uncertainty factor has already been calculated into the RfD to cover all sensitive populations—including infants?

**Reversal of EPA Decision Not to Regulate Perchlorate**

In 2008, EPA published a Federal Register notice in which it preliminarily determined not to regulate perchlorate under the SDWA. EPA provided a detailed, 20-page explanation, concluding regulation did not present “a meaningful opportunity for health risk reduction.” In 2011, EPA published a Federal Register notice reversing this determination with a decision to
regulate perchlorate under SDWA. The 2011 Federal Register notice covered a scant seven pages and did not provide a clear explanation as to why EPA was reversing its decision.

1. Between 2008 and 2011, was additional information developed on the number of persons whose drinking water contains perchlorate? As you know, California— which accounted for a significant portion of perchlorate occurrence in drinking water, and thus potential exposure — regulated perchlorate in 2008. Has the Agency assessed how the California and Massachusetts standards impacted the expected risk-reduction benefits of a federal standard?

2. Between 2008 and 2011, was additional information developed on the health risks of perchlorate? If so, was the new scientific data definitive in its conclusion? What is the overall weight of evidence regarding the health effects of perchlorate?

3. Please provide a clear explanation and documentation for the change in EPA’s judgment regarding the regulatory determination for perchlorate. Include any evidence that shows the 2005 NAS recommendation is not sufficiently conservative and health protective, and/or proves there is an adverse effect of perchlorate at levels below the NAS reference dose, or even at ten times above it.

**HRRCA Analysis**

SDWA Section 1412(b)(3)(C) dictates EPA must engage in a thorough cost benefit analysis (in this case, a Health Risk Reduction Cost Analysis (HRRCA) to: 1) accurately portray estimated benefits and costs of the regulation, and 2) determine whether the costs justify the proposed regulatory standard. While EPA has committed to completing a HRRCA, thus far it has not demonstrated a commitment to engaging in a transparent process for completing it. How do you intend to assure the public that your HRRCA analysis will be both transparent and reliable, especially understanding that independent parties will give EPA’s analysis close scrutiny?

Given the tremendous impacts of setting an unnecessarily restrictive drinking water standard for perchlorate, which, as you know, can never be relaxed, but may, as better data and information become available, be tightened in the future, on communities and water systems that are facing incredibly tight budgets, and the scientific uncertainty surrounding the expected public health benefits from a federal drinking water regulation, we urge you to proceed responsibly.

We look forward to your responses.

Sincerely,

Senator James M. Inhofe

Senator David Vitter