EPA perchlorate decision flawed, say advisers

The U.S. EPA’s preliminary decision not to regulate perchlorate in drinking water has elicited an outpouring of critical comments, including a plea from the agency’s own Science Advisory Board (SAB) for more scientific transparency and a stinging critique from the agency’s Children’s Health Protection Advisory Committee (CHPAC). The committee faulted EPA for failing to take advantage of the best new science and for using a biological model that has not been peer-reviewed.

The furor marks the latest episode in an almost-decadelong controversy surrounding the potential health effects of long-term, low-level exposure to perchlorate. The latest round pits many state and federal environmental protection risk assessors, environmental groups, and thyroid patient advocates against U.S. Department of Defense (DOD) risk assessors, assessment consultants, and many respected thyroid specialists.

Perchlorate, a major component of rocket fuel, contaminates groundwater at many DOD and NASA sites and those of their contractors. The chemical has also entered groundwater and the food chain in large quantities, in part through the past use of Chilean nitrate fertilizer. Perchlorate also is known to occur naturally.

Americans are exposed to perchlorate mainly through food, according to recent studies by the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention (CDC), but drinking water is the focus of EPA’s latest decision.

Of the possible health effects, perchlorate’s influence on the early brain development of fetuses and infants is the main concern. Perchlorate at high doses disrupts thyroid hormone function by blocking the uptake of iodine to the thyroid gland. The contaminant also blocks iodine uptake to breast milk. Iodine is an essential component of the thyroid hormones that orchestrate brain development. Thus, the effects of low-level exposure are the source of contention. Some states, notably Massachusetts, California, and New Jersey, have set drinking-water standards of 2, 6, and 5 parts per billion (ppb), respectively, to protect fetuses and infants.

For its draft determination, EPA estimated a “health reference level”, or safe threshold, of 15 micrograms per liter (or 15 ppb) and concluded that national regulations are not necessary because the chemical occurs only infrequently at levels higher than that in drinking water. The agency estimates that some 2 million Americans are served by water supplies that might exceed this level and judges that this potentially at-risk group is not large enough to justify a national standard. However, if EPA’s safe threshold estimate were as low as the standards set by the states, then the potentially at-risk population would be much larger, and a national standard would be justified.

Like many of these state assessments, EPA’s draft determination is based on a 2005 National Academy of Sciences (NAS) committee’s recommendation to use a 2002 study known as the Greer study as the basis for a perchlorate risk assessment. In that study, a small number of healthy men and women were given relatively large doses of perchlorate for a few weeks to determine at what dose iodine inhibition occurs (Environ. Health Perspect. 2002, 110, 927–937). The study found no significant inhibition at 7 micrograms per kilogram per day (µg/kg-day), a conclusion supported by four additional studies. For pregnant women and their fetuses, the NAS committee reduced the level by a factor of 10 and recommended a threshold of 0.7 µg/kg-day. EPA combined this recommendation with information on perchlorate in food to come up with a safe threshold of 15 ppb in drinking water. The agency uses a modified biological model to predict whether this threshold is also safe for infants and other sensitive populations.

SAB notes that this model is currently undergoing review and adds that the agency hasn’t allowed enough time for SAB to provide comments. “The administration has just asked us for recommendations on how to strengthen the use of science, and here we are confronted by a case of the agency moving forward when not all of the science is in,” says SAB chair Deborah Swackhamer.

CHPAC’s comments are more scathing. The committee notes that EPA’s own calculations show that at 15 ppb, bottle-fed infants would receive doses 2–5 times higher than the NAS reference dose. “This decision does not support the exquisite sensitivity of the developing brain to even small drops in thyroid hormone,”
In further comments that echo criticism expressed by many state regulators, CHPAC notes that EPA fails to account for data from a 2006 CDC study, which revealed a statistically significant association between thyroid hormone levels and perchlorate levels in women who had low iodine levels. (About one-third of adult women are estimated to have low iodine.) This large study linked changes in thyroid function to perchlorate exposure that was an order of magnitude lower than the levels in the Greer study.

In contrast, two recent studies suggest that much higher levels of perchlorate in water do not cause thyroid disruption in pregnant women and newborns, says toxicologist Michael Dourson, who directs Toxicology Excellence for Risk Assessment, a nonprofit group that has worked with the military and its suppliers on this issue. These studies, conducted in Chile (Thyroid 2005, 15, 963–975) and Israel (Thyroid 2007, 17, 843–850), also provide important new data, says Dourson, whose comments support EPA’s decision not to regulate perchlorate.

Soon after publication of the CDC study, the American Thyroid Association issued a statement casting doubt on the applicability of the study for regulatory purposes. An important point, according to this group, was that the CDC study did not find an additional effect as a result of other goitrogens—chemicals such as thiocyanate that are known to influence thyroid function at low iodine levels.

But Craig Steinmaus and colleagues at the California EPA’s Office of Environmental Health Hazard Assessment last year addressed this criticism, finding that other goitrogens, specifically thiocyanate and smoking, appear to enhance the association identified by the CDC study.

In its comments on EPA’s preliminary decision, the Office of Environmental Health Hazard Assessment suggests that EPA could take the CDC study into account by adding a safety factor of 3, which would bring the agency’s estimate of 15 ppb down to 5 ppb. This lower value would fit with the consensus reached by the states that have already set safe levels for perchlorate.

Risk assessors on both sides of this question suggest that more than enough data on perchlorate are available to allow for a well-crafted, transparent, and scientifically defensible assessment. They note that the process for developing water standards in the U.S. includes many opportunities for professional judgment—for example, figuring out how to incorporate insights from the CDC and other recent studies. Rather than rush the process, EPA should bring experts together again. “We should pick the best risk assessors, put them in a room, and let them work together,” Dourson says.

—REBECCA RENNER