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EPN COMMENTS ON PROPOSED PERCHLORATE DRINKING WATER STANDARD

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The Environmental Protection Network (EPN) is an organization comprised of over 450 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of EPA, human health and the environment. We harness the expertise of former EPA career staff and confirmation-level appointees to provide an informed and rigorous defense against current Administration efforts to undermine public health and environmental protections.

In the proposed new perchlorate drinking water standard, EPA acknowledges that the lack of robust epidemiology studies makes it very difficult to estimate the likelihood and magnitude of perchlorate's effects on neurodevelopment in fetuses and infants exposed to perchlorate through cord blood, breast milk, and formula. Despite this fact, EPA's proposed perchlorate standard is based on a reference dose (RfD) that includes the lowest possible uncertainty factor of three because the agency maintains all other uncertainty has been eliminated by the use of their Biologically Based Dose Response (BBDR) model. In our comments below, EPN describes the reasons why this uncertainty factor of three does not provide an adequate margin of safety for the perchlorate RfD and must be increased. EPN also comments that the novel approach EPA used to derive a Relative Source Contribution (RSC) for perchlorate must be peer reviewed by external experts before it can be used. Finally, EPN comments on implementation issues in the perchlorate proposal. Based on these concerns, EPN concludes that the proposed perchlorate drinking water standard is not scientifically defensible.

Risk Assessment

EPA derived the proposed Maximum Contaminant Levels (MCLs) using the BBDR model to estimate perchlorate impacts on the thyroid hormones of a pregnant woman at each gestational week from conception to week 16. The model predicts serum thyroid hormone levels of T4 given specific levels of iodine intake, thyroid stimulating hormone (TSH) feedback loop strength, and perchlorate doses. EPA then linked these model predictions of T4 levels to an epidemiology study's measurements of one day's T4 level in a pregnant woman and the intelligence quotient (IQ) of her child. EPA calculated proposed MCLs for perchlorate, which were predicted to produce a 1, 2 or 3% decrease in IQ for a child born to a woman with low iodine intake levels, low T4 levels, and weak TSH feedback strength.

EPN has a number of concerns regarding this approach. First, there were very few data available to calibrate the pharmacokinetic aspects of the model, particularly during the first trimester of pregnancy. Perchlorate and iodide absorption, metabolism and excretion are therefore uncertain. Second, pharmacodynamic data are lacking to calibrate the joint effect of varying perchlorate and iodide serum concentrations on thyroid uptake of iodide and subsequent production of T4 hormone levels from gestation to week 16. Third, the failure to conduct a systematic review of the epidemiology literature undermines the basis for linking the BBDR model results to neurodevelopmental outcomes. It is possible that the 66 studies eliminated from consideration could have provided key information for the overall weight of evidence regarding both serum thyroid function and the relative sensitivity of IQ compared to other neurodevelopmental measures. Even the five studies that EPA considered indicate that IQ is a less sensitive measure than the Mental Development Index and Psychomotor Development Index, which were evaluated in some of those studies.

Finally, EPN notes that there are multiple concerns with the epidemiology study used as the basis of the RfD. According to the American Thyroid Association, the reference range of TSH and T4 in pregnant women varies within the U.S. population and across ethnic groups. Thyroid hormone levels also vary throughout pregnancy, adding to the uncertainty in identifying the level of alteration that may lead to hypothyroidism and fetal effects. The selected epidemiology study involves a non-U.S. population, includes only a one-time measurement of T4 hormone in each pregnant woman, and does not measure iodine intake or perchlorate exposure for any of the women. This lack of critical data impairs the ability of the BBDR model to predict serum T4 hormone levels and the ability to link those hormone levels to an appropriately sensitive neurodevelopmental outcome. It is particularly concerning that EPA has not resolved the critical issues of uncertainty identified previously by the Science Advisory Board, which include the lack of epidemiology data showing a direct association between iodine inhibition and IQ decrement, predictions for lactating mothers with less than 75ug/day iodine intake, and the lack of a standard definition of hypothroxinemia. It appears that EPA is trying to set the precedent that use of a complex model with many variables, which cannot be calibrated, justifies the elimination of uncertainty factors for reference doses. That is not a scientifically defensible policy. EPN concludes that EPA cannot possibly justify the low uncertainty factor of three and should derive new RfDs before proposing a perchlorate drinking water standard.

EPN is also concerned that EPA developed a new methodology to estimate the perchlorate dose that women of childbearing age in the U.S. are getting from food but did not subject this influential analysis to expert external peer review before using it to calculate the proposed MCLs. The new method combines food consumption data for women of childbearing age, from National Health and Nutrition Examination Surveys, with Food and Drug Administration (FDA) data on the perchlorate concentrations in various types of food to calculate each study participant's daily dose of perchlorate. RSCs ranging from 56% to 88% for the three different RfDs were calculated using the 90th percentile bodyweight-adjusted perchlorate consumption based on the second-highest perchlorate concentrations measured by FDA for each type of food. EPA suggests this second-highest concentration is equivalent to a 95th percentile value but did not assign a distribution to the 20 samples available for each type of food. An expert external peer review is needed to evaluate this complex analysis, which is of great interest to women throughout the country who are unknowingly exposed to perchlorate in their food.

Implementation

In addition to our risk assessment concerns, we have the following comments regarding the implementation of the proposed perchlorate drinking water standard.

First, EPN has questions concerning EPA's assumptions about the extent and cost of the initial perchlorate monitoring required by the states and water systems. See Section VIII Monitoring and Compliance Requirements. EPA's estimate significantly overstates the number of water systems that will need to be monitored. It is highly likely that most consecutive systems will not need to to be monitored. States will use their discretion to waive the monitoring requirement where perchlorate is likely not to be found in the water system's source water. EPA must work with states to develop strong implementation guidance to minimize the initial monitoring round, as was done for most of the current regulations implemented in the middle 1990s for inorganic compounds, volatile organic compounds, and synthetic organic compounds. EPN recommends that EPA seek external comments on the high monitoring costs.

Second, EPN has major concerns about the adequacy of EPA's cost-benefit analysis of the proposed regulation. See Section XII Health Risk Reduction Analysis. EPA concluded that for all proposed MCLs, the total annual costs are substantially higher than the proposed benefits.

- The cost-benefit analysis supports the proposed MCL levels of 18, 56, and 90, where the benefits by definition are low since the expected violations to be resolved are very low. A cost-benefit analysis where the costs are much higher than the benefits weakens the validity of the proposal. EPN believes a more stringent standard is justified and that a more stringent value could result in benefits exceeding costs. EPN recommends that EPA withdrawal the current proposal and re-propose a new standard more stringent than the current proposal.
- The cost-benefit analysis itself is very weak. EPA acknowledged that they made many assumptions around the cost-benefit estimates that reduced the benefits estimate and potentially overestimated costs. *On benefits:* They purposely did not consider the obvious benefits of perchlorate treatment in addressing co-occurring violations, such as nitrate. Also, they made no assessment of treatment costs avoided by a water system's decision to switch to a new water source, which is what is happening in both Massachusetts and California to comply with their state perchlorate regulation. *On costs:* They made a very high estimate of the cost of initial monitoring, even though states have wide discretion to waive monitoring requirements for many water systems..

Third, EPN has serious concerns that EPA is including in their perchlorate proposal an option to withdraw from the 2011 regulatory determination and potentially not regulate perchlorate. See Section XV Request for Comment on Potential Regulatory Determination Withdrawal. The proposal states that recent findings suggest that perchlorate does not occur in water systems with a frequency and level of public health concern, and that the perchlorate regulation is no longer a meaningful opportunity for health risk reduction. They also point to EPA's previous determination in 2008 not to regulate perchlorate as precedent, as well as reference other EPA decisions to question regulation (e.g., aldrin) where the occurrence was very low.

EPN has identified serious flaws in the proposal and has serious questions about the scientific defensibility of the EPA perchlorate regulation, the validity of the monitoring, and cost-benefit analysis. EPN strongly recommends that EPA withdrawal the proposal and re-propose a more stringent perchlorate standard with a new cost-benefit analysis. The new proposal should delete the option to withdrawal from the 2011 regulatory determination.