COMMONWEALTH OF MASSACHUSETTS
EXECUTIVE OFFICE OF ENERGY & ENVIRONMENTAL AFFAIRS
DEPARTMENT OF ENVIRONMENTAL PROTECTION
ONE WINTER STREET, BOSTON, MA 02108 617-292-5500

DEVAL L. PATRICK
Governor

TIMOTHY P. MURRAY
Lieutenant Governor

IAN A. BOWLES
Secretary

LAURIE BURT
Commissioner

Written Testimony of

Carol Rowan West, MSPH

Director, Office of Research and Standards

Massachusetts Department of Environmental Protection

Before the

Senate Committee on Environment and Public Works

United States Senate

On

Perchlorate in Water

May 6, 2008

Thank you Chairman Boxer and Ranking Member Inhofe and members of the Committee, for inviting me to testify on the issue of perchlorate in drinking water. I am pleased to share with you a description of our work to set drinking water and cleanup standards for perchlorate, the process we followed, and lessons learned as they apply to this national issue.

As Director of the Office of Research and Standards (ORS) at the Massachusetts Department of Environmental Protection (MassDEP), I have spent over 15 years evaluating the health effects of toxic chemicals and working to set air, water and soil standards that are protective of public health. ORS follows the health assessment and standard setting protocols published by the U.S. Environmental Protection Agency (US EPA), and our work to set standards for perchlorate followed these standing procedures. During the course of my work on perchlorate, I chaired MassDEP's Perchlorate Workgroup comprised of senior managers from the Commissioner's Office, Drinking Water and Waste Site Cleanup Programs who dealt with all aspects of the standard setting work for perchlorate. I also chaired the external Scientific Advisory Committee on Health Effects who provided valuable input to our toxicological and standard setting work. MassDEP's goal in establishing a perchlorate drinking water standard was to protect public health, especially pregnant women and children from a compound for which no state or federal drinking water standard existed. MassDEP's process involved: (1) a rigorous scientific evaluation of the risks posed by perchlorate; (2) a comprehensive and innovative collaboration with major stakeholders; and (3) an effective outreach program to help manage the risk.

I. Establishing a Perchlorate Drinking Water Standard

a. How MassDEP became involved with perchlorate

MassDEP's experience with perchlorate began in April 2001. In July 2006, MassDEP became the first state in the nation to promulgate drinking water and waste site cleanup standards for perchlorate.

MassDEP's work on perchlorate began when it was first detected at Cape Cod's Massachusetts Military Reservation (MMR) in groundwater at 600 ppb in 2001. Perchlorate was also detected in the adjacent town of Bourne's water supply at concentrations less than 1 ppb. In response, the Bourne Water District (BWD) voluntarily shut three affected wells. Since there were no established drinking water standards for perchlorate, in March 2002, the BWD formally requested health protection guidance from MassDEP on drinking water. In order to assist the BWD, MassDEP toxicologists and risk assessors reviewed available information on the toxicity of perchlorate, including the draft United States Environmental Protection Agency's (US EPA) health assessment for perchlorate (U.S.EPA, 2002), which contained a draft reference dose and an associated drinking water limit of 1 ppb for perchlorate. This report as well as other information reviewed indicated that risks to sensitive subgroups, including pregnant women, fetuses, children and individuals suffering from hypothyroidism, could not be ruled out at perchlorate drinking water concentrations above 1

ppb. As these risks included the potential for serious adverse outcomes, including permanent neurological effects from *in utero* exposure, MassDEP provided the BWD with interim advice recommending that these sensitive subgroups be informed when perchlorate concentrations exceed 1 ppb and be advised to avoid consuming the water. The Massachusetts Department of Public Health supported this interim advice and US EPA Region 1 issued a statement indicating that the advice was health protective.

In 2003, the U.S. EPA (2002) draft document, which had already undergone extensive expert peer and public review, was forwarded to the National Academy of Sciences (NAS) for reassessment. Since it was anticipated that this review would not be complete for some time, MassDEP made a decision to set perchlorate standards so that public water supplies and sites would be cleaned up.

b. Assessment and Monitoring

MassDEP's Office of Research and standards met with its scientific advisory committee, scientists from DOD (Army, Navy, and Air Force), and members of the NAS to evaluate the health risks posed by perchlorate and to establish a reference dose[1] that would be used to establish drinking water and clean up standards. MassDEP's assessment emphasized protecting infants and addressing concerns about breast milk exposures leading to a lower and more protective reference dose than those established by other groups. MassDEP's perchlorate reference dose is 0.07 microgram per kilogram whereas the NAS value, supported by a majority of the NAS committee is 0.7 micrograms per kilogram. (see Appendix A for more detailed information on the derivation of the reference dose). The NAS committee was not unanimous regarding its recommended reference dose with a lower more health protective value also supported. When deriving the drinking water standard, MassDEP took into account that there are perchlorate exposures from food as well as water. To address this issue, MassDEP's protocol is to allow 20% of the reference dose to come from water ingestion and 80% to come from food ingestion. In this way, the reference dose is not exceeded and health is protected.

The US EPA has adopted the higher of the two NAS reference doses, which is ten times higher than MassDEP value. In addition, the US EPA Office of Solid Waste and Emergency Response translated that value into a drinking water limit of 24.5 ppb, a value that does not take into account perchlorate sources from food or infant breast milk exposures. US EPA's Children's Health Protection Advisory Committee wrote to Administrator Johnson advising that the 24.5 ppb being used at CERCLA sites is not protective of children's health (Children's Health Protection Advisory Committee Letter to Steven Johnson, 2006).

On a parallel track with the reference dose work, MassDEP's Drinking Water Program (DWP) issued regulations requiring the testing of all of the 500 plus public water supplies in the Commonwealth to determine the scope of the perchlorate problem. The results indicated perchlorate contamination above 1 ppb (MassDEP's interim guidance) in 10 community

[1] A reference dose is an estimate of daily exposure to the human population including sensitive subgroups that is likely to be without appreciable risk of deleterious effects during a lifetime.

water supplies across the state with levels as high as 1300 ppb. A major finding was that perchlorate contamination was more extensive than anticipated and that it was not solely linked to military sites. In depth site investigations demonstrated that perchlorate contamination was also associated with blasting using certain explosives, fireworks, medical manufacturing of specific devices, and due to its presence in certain drinking water treatment chemicals (sodium hypochlorite).

II. Scientific Support for a Perchlorate Standard that is Protective of Public Health

A few key studies have been published on perchlorate since the NAS report was published.

For example, researchers at the Centers for Disease Control (CDC) sampled perchlorate and thyroid hormone levels in approximately 2,800 people as part of a national survey. Perchlorate was detected in most of the samples, indicating widespread exposures.

The CDC researchers found an association between perchlorate levels and altered thyroid hormones in a subset of women with low dietary iodine intake. Thyroid hormones are necessary for normal growth and neurological (brain) development of fetuses, infants and children.

The CDC study, (Blount, et al, 2006) supports the conclusions of MassDEP's determination that perchlorate levels in drinking water should be regulated to protect public health.

The US Food and Drug Administration (FDA) conducts the Total Diet Study, which is designed to monitor the US food supply for chemical contaminants. FDA recently reported on the estimated average perchlorate intake from the contribution of specific food groups and total intake for 14 age/sex subgroups of the US population (FDA, 2008). FDA found perchlorate in a wide range of foods. 59% of the total samples analyzed contained perchlorate whereas 41% had no detectable levels. Perchlorate intake by the sensitive subgroup of infants was mainly from baby foods (81% of the total dose), which includes infant formula and dairy foods. Children with the highest total perchlorate intake per kilogram of body weight per day were children who are 2 years old. The brain is rapidly developing in young children putting them at high risk should the total perchlorate exposure impact the level of thyroid hormones needed for normal development. This study shows the importance of accounting for food exposures when setting a perchlorate drinking water standard.

A recent study on perchlorate levels in breast milk in lactating Boston-area women found measurable perchlorate levels in 100% of 49 human milk samples tested. Perchlorate levels were in the range of 1.3 ppb to 411 ppb, with a median value of 9.1 ppb.

III. Benefits of having a Perchlorate Drinking Water Standard

1. Under US EPA's Unregulated Contaminant Monitoring Rule, perchlorate was detected in 120 public water supplies in 26 states and 2 territories. According to Government Accounting Office testimony (GAO, 2007), perchlorate has been found by federal and state agencies in groundwater, surface water, soil or public

drinking water systems at almost 400 sites across the country in 37 states and U.S. territories. This extensive contamination puts our nation's children at risk. Based on MassDEP's experience with finding more perchlorate contamination problems due to uses beyond military one, these numbers might represent only the tip of the iceberg.

2. The generation of monitoring data on the presence of perchlorate in drinking water supplies allows environmental protection agencies to take steps to protect children's health. A variety of water treatment techniques are available for reducing perchlorate water concentrations to low ppb levels.
3. Knowing the sources of perchlorate can lead to pollution prevention (P2) practices. MassDEP has provided guidance to blasting and firework contractors to prevent future perchlorate ground water contamination problems (http://mass.gov/dep/water/drinking/percinfo.htm). P2 should deal effectively with the problem. MassDEP hopes that through P2 actions, we will be able to reduce monitoring requirements, which will lead to decreased expenses to public water suppliers.

IV. Recommendations

1. US EPA should take a leadership role to set a perchlorate drinking water standard, which protects public water supplies and children's health. Perchlorate contamination is a national issue and national action is needed.
2. Federal action will lead to consistent protection of children's health across the United States.
3. Federal action is more efficient and will eliminate the duplication of state efforts.
4. Cleanup of water supplies and sites has an additional benefit of also decreasing the levels of perchlorate in foods (including breast milk).

Appendix A

Upon consideration of the NAS report, MassDEP and the MassDEP/DPH Science Advisory Committee on Health Effects concurred with the NAS committee's view that the iodide uptake inhibition (IUI) data in the Greer et al. study constitute a reasonable basis (i.e., critical effect) for determining a reference dose (RfD), provided that the inherent limitations and uncertainties in the data are appropriately accounted for. MassDEP sees IUI, which is an early event in the putative mechanistic pathway leading to perchlorate toxicity, as a potentially adverse effect (i.e., decreasing production of thyroid hormone levels necessary for normal development), in contrast to NAS who considered this a non-adverse precursor effect. MassDEP believes that this conclusion is premature in that no quantitative determination of an IUI level of concern or, conversely, without effect, is available. The fetus, infants, children and individuals with hypothyroidism make less thyroid hormone so are more sensitive to the effects of perchlorate. MassDEP's use of this effect is consistent with US EPA policy for deriving RfDs and is reflected in the selection of an uncertainty factor for the Lowest Observed Adverse Effect Level (LOAEL) to a No Observed Adverse Effect Level (NOAEL) extrapolation. MassDEP also determined that the statistical power of the Greer study was such that a 40% effect (inhibition of iodide uptake in the thyroid) would not have been statistically detectable in the study due to the small number of subjects, a calculation that the NAS did not consider in its review. Furthermore, new data not available during the NAS review demonstrated perchlorate's widespread presence in breast milk in the US. Perchlorate was detected in 36 of 36 samples taken from a wide geographic area, at an average concentration of 10.5 microgram per liter (ug/L) and ranging up to 92 ug/l. These levels in breast milk substantially exceed recommended infant doses that can be derived based on the MA DEP RfD *as well as* both those advanced by NAS. The NAS Committee did not reach a consensus of the RfD due to differences of opinion about whether 10 or 30 would be an appropriate uncertainty factor.

References

Blount, B.C., Pirkle, J.L., Osterloh, J.D., Valentin-Blasini, L., and Caldwell, K.L. (2006). Urinary Perchlorate and Thyroid Hormone Levels in Adolescent and Adult Men and Women Living in the United States. Environmental Health Perspectives. Volume 114, Number 12.

Children's Health Protection Advisory Committee (2006). Letter to Stephen Johnson, Administrator, US EPA, 1200 Pennsylvania Avenue, NW, Washington DC.

GAO (2007) Testimony Before the Subcommittee on Environment and Hazardous Materials, House Committee on Energy and Environmental Affairs. April 25.

Murray, C.W., Egan, S.K., Kim, H., Beru, N, and Bolger, P.M. (2008) US Food and Drug Administration's Total Diet Study: Dietary intake of perchlorate and iodine. Journal of Exposure Science and Environmental Epidemiology. 1-10.

National Academy of Sciences. 2005. Health Implications of Perchlorate Ingestion. National Academy Press. Washington, DC.

Pearce, E.N. Leung, A.M., Blount, B.C., Bazrafshan, H.R., He, X., Pino, S., Valentin-Blasini, Braverman, L.E. (2007) Breast Milk Iodine and Perchlorate Concentrations in Lactating Boston-Area Women. J. Clin. Endocrinology Metabolism. 2006-2738.

U.S. Environmental Protection Agency. 2002a. Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization. External Review Draft. NCEA-1-0503.Office of Research and Development. Washington, DC