MassDEP Final Perchlorate Regulations
Response to Comments
June 19, 2006

MassDEP received comments from 31 groups/individuals. Comments were received from:

#	Name	Affiliation
1	David Dow	Sierra Club - Cape Cod Group
2	John McNabb	Clean Water Action
3	George Seaver	CCA
4	Bob Mullinix	Bourne Resident
5	Robert Muhly	US Army NREO
6	Mary Ann Nelson	Sierra Club
7	Dr. David Ozonoff	Boston University School of Public Health
8	Bruce Hoskins	Nobis Engineering
9	Carol Holley	Acton Citizens for Environmental Safety
10	Leo Picard	Mass Aggregate Asphalt Pavement Assn.
11	Gerard Cutinho	citizen
12	Chris Bathurst	Clean Water Action
13	Amanda Dolan	Purolite
14	John Sasur	Western Mass Waterworks Assn
15	Peggy Middaugh	Regional Environmental Council
16	Amanda Dolan	Purolite
17	Herwig Opdebeeck	Opdebeeck Consulting
18	David Agnew	Citizen Cape Cod resident
19	Jane Winn	Berkshire Environmental Action Team
20	Andrew J. Stackpole	Department of the Navy
21	Anthony Zuena	New England Water Works Association
22	Stephen Rosario & William Carroll	American Chemical Council & Chlorine Chemical Council
23	Jennifer Sass	NRDC
24	William Henchy	Upper Cape Regional Water Supply Council
25	Gail Charnley	Health Risk Strategies
26	Megan Amundson	Environmental League of Massachusetts
27	James Marshall	Massachusetts Water Works Association
28	Stephen Anderson	Town of Acton
29	Armin Steiner	Massachusetts Chemistry and Technology Alliance
30	Becky Smith	Clean Water Action
31	Larry L. Bingaman	Aquarion

#1 – Sierra Club – Cape Cod
David Dow

Comment: *The Massachusetts Chapter – Sierra Club has voted to support Ma. DEP's 2 ppb standard while the national club discussion occurs.*

Response: Duly Noted.

Comment: *Since EPA has developed a protocol for conducting risk assessments and for developing MCLs which Mass DEP follows…Since this approach is done by the book, I don't have much to say about this aspect of the toxicological profile and health assessment.*

Response: MassDEP based the MCL development on EPA procedures.

Comment: *The commenter suggests that MassDEP should have used a greater uncertainty factor in its derivation of the RfD for perchlorate due to uncertainties regarding cumulative exposures to perchlorate and other thyroid active chemicals from drinking water and the diet.*

Response: As discussed in detail in MassDEP's *Update to Perchlorate Toxicological Profile and Health Assessment*, MassDEP scientists carefully considered the scientific information available and used a well-established methodology to derive an RfD for perchlorate. A 100-fold uncertainty factor was included in this derivation, based on a review by MassDEP scientists, which concluded that a UF of 100 was a reasoned and scientifically appropriate value. A majority of the members of the Advisory Committee on Health Effects concurred with this decision, with some members supporting a higher value. One member supported a lower value of 30. MassDEP's proposed RfD and associated drinking water values accounts for other exposures through the use of a 20% relative source apportionment factor, which is the standard factor used by MassDEP, as well as USEPA, when other exposure pathways are likely to be significant but the data is insufficient to determine a more precise estimate. No changes proposed.

#2 - Clean Water Action
John McNabb, Jr.

Comment: *We recommend, however, that the DEP set the Maximum Contaminant Level (MCL) for perchlorate at 1.0 ppb or less. Both the health evaluation performed by DEP and other studies show that any level above 1.0 ppb would threaten sensitive populations.*

Response: When considering the full range of factors that play a role in the establishment of an MCL, including occurrence, analytical capabilities, treatment technologies, costs and other relevant risks it became clear that a risk management strategy had to be applied. In large part due to the issue of perchlorate contamination from sodium hypochlorite an MCL above the anticipated range of this contribution was proposed. This ensures that the important practice of disinfection is not undermined and that the threat of public exposure to harmful microbes is avoided. Even with the

application of what appears to be the best management practices known to date for the use of sodium hypochlorite, the introduction of perchlorate cannot be avoided. The MCL of 2.0 ppb provides the best overall protection of public health, considering the benefits of disinfection, while retaining a margin of safety for sensitive populations. MassDEP is working with EPA to develop guidelines for the use of sodium hypochlorite to minimize the presence of perchlorate.

Comment: *An MCL of 1.0 ppb should be achievable by public drinking water suppliers through definitive identification and elimination of the outside source of the contaminant or treatment, or if the use of hypochlorite is identified as the cause, through simple methods already identified by DEP such as: 1) the use of only 'fresh' batched [sic] of hypochlorite (i.e. product less than a year old); 2) requiring keeping hypochlorite in a cool area (5 degrees Celsius or less); and 3) use of alternative methods of disinfection.*

Response: MassDEP agrees that elimination of the source of contamination is one of the best ways to ensure clean drinking water. Unfortunately, experience has shown this is not always possible. Past practices may have left widespread plumes of perchlorate that cannot be definitively traced back to a responsible party. The development of guidance on the best practices for the use of sodium hypochlorite is still in its infancy. The use of alternative disinfectants may not be feasible or cost effective in all cases.

Comment: *We recommend that DEP prepare and issue Guidance in Best Management Practices to educate water suppliers that using hypochlorite for drinking water disinfection or other treatment carries the risk of perchlorate contamination. This Guidance should be accompanied by materials about how best to avoid and reduce this risk as described above and any other means of exposure reduction the DEP may identify as appropriate.*

Response: MassDEP is developing these materials in partnership with EPA.

Comment: *We also recommend that DEP amend the Drinking Water Regulations, 310 CMR 22.00, to help prevent perchlorate contamination by requiring that manufacturers of hypochlorite solutions sold to water suppliers to [sic] label their products with the bottling date, and not allow the use by water suppliers of hypochlorite solutions that are older than one year for drinking water disinfection purposes.*

Response: MassDEP, working with EPA on the use of sodium hypochlorite, will evaluate these suggestions.

Comment: *Furthermore, since any exposure to perchlorate for sensitive populations or the general public may be harmful and is preventable, we also urge DEP to adopt a Maximum Contaminant Level Goal (MCLG) of 0.0 ppb for perchlorate.*

Response: The risk assessment conducted by MassDEP does not support this comment.

Comment: *We recommend that DEP develop a program to require monitoring for unregulated contaminants (a) that were on the UCMR-1 list until the UCMR-2 program begins, and (b) that*

may be present in water supplies based on the potential threats identified in SWAP reports for each water supplier. If any unregulated contaminant is detected there should be follow-up to identify the specific source(s) and take action to reduce or eliminate its presence in drinking water.

Response: MassDEP will continue to follow EPA's lead in the identification and study of additional unregulated or emerging contaminants. However, MassDEP remains committed to taking action to protect the health of the citizens of the Commonwealth.

Comment: *MassDEP should issue an advisory suitable for local BOH to educate private well owners with appropriate steps for private well owners to take to protect themselves.*

Response: MassDEP agrees that continuing education of local Boards of Health is important and the Department commits to developing guidance to inform private well owners about perchlorate. MassDEP already has extensive information available on its website specific to private well owners, at http://mass.gov/dep/water/drinking/privatew.htm

Comment: *MassDEP should support and provide testing for private wells to give private well owners the same level of protection as public supplies.*

Response: MassDEP's statutory authority under the Drinking Water Program does not extend to the regulation of private drinking water supplies. MassDEP cannot address private wells in the same manner as it regulates public water supplies. The regulation and permitting of private wells are in the hands of local officials. However, the Department does regulate releases of oil or hazardous material (such as perchlorate) to the environment under M.G.L. c.21E and the Massachusetts Contingency Plan ("MCP"). Once Reportable Concentrations and cleanup standards are established under the MCP as described in this proposal, the Department will address private wells contaminated by perchlorate within the existing regulatory process. MassDEP seeks to ensure that contamination in a private well is addressed by the party(ies) responsible for the release.

Comment: *Ban the use of perchlorate-containing blasting agents and fireworks in Massachusetts. MassDEP should use its broad powers to initiate this ban and not simply enforce it through the water suppliers. Work with the legislature to ban perchlorate-containing materials in a Zone I, Zone II and Zone A's*

Response: In cooperation with the Division of Fire Services, the Department has issued "Best Management Practices" for use of blasting agents (http://mass.gov/dep/cleanup/laws/blasting.htm) and will issue a similar document for fireworks displays.

#3 – George Seaver

Cape Cod (oral testimony)

Comment: *What resources does MassDEP have that allows them to come to a different conclusion from the USEPA and the national Academy of Science?*

Response: MassDEP has toxicology and engineering resources that allow the agency to evaluate potential threats to public health and the environment, a responsibility given to the Department by the legislature. MassDEP also expands the resources available to it by working with other agencies (such as the Department of Public Health) and outside experts. The NAS Committee recommended a reference dose (RfD) and stopped there, stating that setting drinking water standard is better left to state and federal agencies who will follow existing policies and protocols regarding exposure factors and other parameters. The NAS Committee did not unanimously agree on their RfD recommendation as one Committee member thought the total uncertainty factor should be 30 versus 10. The NAS Committee also acknowledged that the RfD may need to be adjusted upward or downward on the basis of future research. Shortly after the NAS study was issued new information became available which MassDEP took into account when deriving its proposed RfD. The new information included the detection of perchlorate in breast milk samples, data showing widespread contamination of perchlorate in the food supply, and a biomarker study by CDC indicating perchlorate exposures beyond drinking water. Lastly, MassDEP used the same protocol for deriving a drinking water limit for perchlorate that it uses for all other chemicals for which standards and guidelines are set. The protocol includes an adjustment for perchlorate from other sources such as food. The 24.5 ppb value does not take into account the food pathway.

#4 - Robert Mullennix

Bourne Resident

Comment: *Standard is so low that MassDEP will effectively ban fireworks displays. Bourne has already stopped their display.*

Response: The decision to continue or discontinue fireworks displays should be made with all relevant information at hand, including the location of the display relative to drinking water sources, the nature of the fireworks, housekeeping measures that can be applied, and the cost of the displays themselves. MassDEP is working with the Division of Fire Services to develop and distribute *Best Management Practices* ("BMPs") for fireworks displays that will minimize potential problems associated with perchlorate. The Department believes that fireworks displays can be continued without jeopardizing a community's water supply.

Comment: *NAS determined that 24.5 ppb is safe. Is MADEP saying they are incompetent?*

Response: No. Note that the NAS Committee did not determine that 24.5ppb is safe. Rather, the NAS Committee recommended a reference dose (RfD) and stopped there, stating that setting drinking water standard is better left to state and federal agencies who will follow existing policies and protocols regarding exposure factors and other parameters. The NAS Committee did not unanimously agree on their RfD recommendation as one Committee member thought the total uncertainty factor should be 30 versus 10. The NAS Committee also acknowledged that the RfD may need to be adjusted upward or downward on the basis of future research. Shortly after the NAS study was issued new information became available which MassDEP took into account when deriving its proposed RfD. The new information included the detection of perchlorate in breast milk samples, data showing widespread contamination of perchlorate in the food supply, and a biomarker study by CDC indicating perchlorate exposures beyond drinking water. Lastly, MassDEP used the same protocol for deriving a drinking water limit for perchlorate that it uses for all other chemicals for which standards and guidelines are set. The protocol includes an adjustment for perchlorate from other sources such as food. The 24.5 ppb value does not take into account the food pathway.

Comment: *Studies show perchlorate is less toxic, why rush to set a standard?*

Response: MassDEP has been working on perchlorate since 2002. MassDEP made a decision in 2003 to move forward with setting standards for perchlorate so that contaminated groundwater would be cleaned up and public health protected. Cleaning up groundwater contamination at MMR was a major factor in the decision because the US Department of Defense stated that they would clean up to state standards. MassDEP also delayed its standard setting schedule in January 2005 in order to take into account the NAS report. MassDEP has reviewed the scientific studies on perchlorate and has not found data to show that perchlorate is far less toxic than previously found. No proposed changes.

Comment: *MADEP is rejecting the information from Chile that shows people have been drinking perchlorate with over 100 ppb of perchlorate for generations with no ill effects. Why?*

Response: MassDEP's *Addendum to "Update To Perchlorate Toxicological Profile and Health Assessment*" document *(www.mass.gov/dep/perchlorate*) provides a detailed analysis of the shortcomings of the Chilean study. For example, due to higher dietary intake of iodine in the Chilean study population, the Chilean population is not representative of the U.S. population. The Agency for Toxic Substances and Disease Registry (ATSDR) shares the same opinion.
No proposed changes.

Comment: *The number one reason for MADEP not to set a perchlorate MCL at this time is that it is just bad public health policy and a big waste of money.*

Response: Given the acute nature of the potential health effects associated with this contaminant, it was no longer prudent to wait for federal action. A review of the costs involved found them to be reasonable. The majority of public water systems will only need to conduct routine annual monitoring.

Comment: *Massachusetts found very low levels in a few locations after an extensive survey. Why is there a rush to be first-in-the-nation to set a drinking water MCL?*

Response: One of the most important outcomes of the occurrence monitoring was that perchlorate is not exclusively associated with military or aerospace activities. In fact, none of the affected Massachusetts public water systems could trace the perchlorate to these types of sources. Rather, activities such as blasting and the use of fireworks were identified or strongly suspected as the source of contamination. Given this fact our aim is to avoid additional public exposure through a combination of source protection, monitoring and, where necessary, treatment.

Comment: *MADEP seems to think that they can set a very low MCL because there isn't much perchlorate in Massachusetts. Affordability is not science.*

Response: The observed occurrence of perchlorate in Massachusetts did not influence the science behind the risk assessment. Factors such as occurrence, analytical sensitivity, the availability of treatment technologies and costs are weighed alongside the toxicological data when establishing a drinking water MCL. This practice is based on federal methodology.

#5 – US Army Northern Regional Environmental Office

Robert Mulhy

Please refer to comments and responses under #20, the Department of the Navy.

#6 -- Sierra Club

Mary Ann Nelson

Comment: *The Massachusetts Chapter – Sierra Club has voted to support Ma. DEP's 2 ppb standard while the national club discussion occurs.*

Response: Duly Noted.

Comment: *Since EPA has developed a protocol for conducting risk assessments and for developing MCLs which Mass DEP follows…Since this approach is done by the book, I don't have much to say about this aspect of the toxicological profile and health assessment.*

Response: MassDEP based the MCL development on EPA procedures.

Comment: *The commenter suggests that MassDEP should have used a greater uncertainty factor in its derivation of the RfD for perchlorate due to uncertainties regarding cumulative exposures to perchlorate and other thyroid active chemicals from drinking water and the diet.*

Response: As discussed in detail in MassDEP's *Update to Perchlorate Toxicological Profile and Health Assessment*, MassDEP scientists carefully considered the scientific information available and used a well-established methodology to derive an RfD for perchlorate. A 100-fold uncertainty factor was included in this derivation, based on a review by MassDEP scientists, which concluded that a UF of 100 was a reasoned and scientifically appropriate value. A majority of the members of the Advisory Committee on Health Effects concurred with this decision, with some members supporting a higher value. One member supported a lower value of 30. MassDEP's proposed RfD and associated drinking water values accounts for other exposures through the use of a 20% relative source apportionment factor, which is the standard factor used by MassDEP, as well as USEPA, when other exposure pathways are likely to be significant but the data is insufficient to determine a more precise estimate. No changes proposed.

#7 – Boston University, School of Public Health
Dr. David Ozonoff

Comment: *You have my full support in your efforts to regulate perchlorate. A 1 ppb is the preferred public health standard and I strongly urge DEP to promulgate it; an accompanying zero MCLG, while having no regulatory force, is a statement of principle of genuine importance.*

Response: When considering the full range of factors that play a role in the establishment of an MCL, including occurrence, analytical capabilities, treatment technologies, costs and other relevant risks it became clear that a risk management strategy had to be applied. In large part due to the issue of perchlorate contamination from sodium hypochlorite an MCL above the anticipated range of this contribution was proposed. This ensures that the important practice of disinfection is not undermined and that the threat of public exposure to harmful microbes is avoided. Even with the application of what appears to be the best management practices known to date for the use of sodium hypochlorite the introduction of perchlorate cannot be avoided. The MCL of 2.0 ppb provides the best overall protection of public health, considering the benefits of disinfection, while retaining a margin of safety for sensitive populations. MassDEP is working with EPA to develop guidelines for the use of sodium hypochlorite so as to minimize the presence of perchlorate. Additionally, MassDEP is committed to reviewing the MCL, as specified in regulation. The establishment of an MCLG of zero is usually

reserved for carcinogens and is most appropriate for those with a non-threshold mechanism of action.

#8 – Nobis Engineering
Bruce Hoskins

Comment: *There is no preponderance of evidence to support the proposed standard of 2 µg/L. The MassDEP report favors studies that show higher potential risk while de-emphasizing those studies that down play the risk. There is controversy in interpreting the studies and the discussion has devolved to scientists discrediting each other.*

Response: MassDEP's scientific process included meetings and discussions with its long-standing DEP/DPH Advisory Committee on Health Effects and invited scientists from other institutions including the U.S. Department of Defense. MassDEP also met with two members of the NAS Perchlorate Committee to share viewpoints and perspectives on the scientific information and derivation of the RfD and associated drinking water limits. The Department's draft toxicological profile describes the studies, interpretation of the findings and steps towards setting a reference dose and associated water limits, thus providing transparency to the work effort. Lastly, MassDEP views the public comment period and 6 public hearing forums to provide ample opportunities for broader input of MassDEP's work. The proposed standards have been developed following standard protocols and with substantial involvement from parties outside the agency. MassDEP believes that such a process is the best approach to determine appropriate regulations, especially when scientific uncertainty may exist.

Comment: *The Department appears to have dropped the Imminent Hazard requirements proposed in the Fall 2004 regulations.*

Response: The 2004 proposal included provisions to address Imminent Hazards posed by perchlorate in drinking water supplies. That proposal was dropped in the current version based on (a) the concurrent promulgation of both MCP cleanup standards and a drinking water MCL, and (2) new language that specifically addresses how the Waste Site Cleanup and Drinking Water programs evaluate contamination in public water supplies. (The "Harmonization" provisions proposed at 310 CMR 40.0951(3).) No further changes are proposed.

Comment: *Has MassDEP identified all possible sources of perchlorate, such as blasting, fireworks, water treatment, etc.? How much daily intake is coming from food? Does a drinking water standard make sense if this is the dominant pathway?*

Response: MassDEP has published a report, *Occurrence and Sources of Perchlorate in Massachusetts* (http://mass.gov/dep/water/drinking/percinfo.htm) and continues to research additional sources. There are no MA specific data on exposures to perchlorate from MA-grown food but there is considerable national data confirming the presence of perchlorate in foods and breast milk. Lacking more specific data, the methodology for

deriving MCLs based on USEPA guidance uses a 20% source apportionment factor to account for other exposures as was done by MassDEP.
No changes proposed.

#9 -- Acton Citizens for Environmental Safety
Carol Holley

Comment: *MassDEP should support and provide testing for private wells to give private well owners the same level of protection as public supplies.*

Response: MassDEP's statutory authority under the Drinking Water Program does not extend to the regulation of private drinking water supplies. MassDEP cannot not address private wells in the same manner as it regulates public water supplies. The regulation and permitting of private wells are in the hands of local officials. However, the Department does regulate releases of oil or hazardous material (such as perchlorate) to the environment under M.G.L. c.21E and the Massachusetts Contingency Plan ("MCP"). Once Reportable Concentrations and cleanup standards are established under the MCP as described in this proposal, the Department will address private wells contaminated by perchlorate within the existing regulatory process. MassDEP seeks to ensure that contamination in a private well is addressed by the party(ies) responsible for the release.

Comment: *Assumptions are made that the adverse effects of perchlorate end after age 12, although current science informs us that pre-frontal lobe development continues into the early twenties. No studies have yet looked associated with ADHD, ADD, dyslexia, aphasia, autism spectrum disorders, etc.*

Response: Data in earlier studies show that the brain was fully mature by age 10 or 12. Emerging data, using MRI technology (considered by many to be a crude level of analysis), however, shows that frontal brain development continues until the early twenties (Giedd et al. 1999) and myelin formation in the entire brain does not reach its peak until around age 45, and gray matter size increases in the temporal lobe until age 30 (Sowell and Peterson, 2003). What it all means and which of these dynamic processes of the brain are affected by thyroid hormones is unknown as the science is in its infancy. Based on these data, there does not seem to be any appropriate cut off age for perchlorate sensitivity. However, since the perchlorate RfD is developed to address risks to the most sensitive subgroup, the fetus and the neonate, it will be protective of everybody.

An epidemiological study that examined the association of perchlorate with autism ADHD was performed in the US. This study, although limited, did not find any association with perchlorate exposure and autism and ADHD. These endpoints are not the most sensitive indicators of the kinds of neurodevelopmental outcomes that might be predicted on the basis of prior studies of the effects of hypothyroidism on the developing nervous system. The endpoints include subtle impairments in cognitive and motor function, such as those observed in children who have untreated or inadequately treated congenital hypothyroidism. In addition, neither autism nor autism-spectrum disorder has

been observed previously in association with thyroid hormone deficiencies (NAS, 2005). No changes are proposed.

Comment: *Concern expressed about the soup of chemicals children are already exposed to, including perchlorate in food. Minimizing exposure to as many degrees as possible will minimize the adverse effects of the whole.*

Response: The above statement is consistent with MassDEP's objectives in protecting public health. No changes are proposed.

Comment: *I would like to think that there are ways to eliminate pathogens that are both cost-effective and do not cause the formation of perchlorate, and hope that a return to the 1 part per billion MCL is considered.*

Response: When considering the full range of factors that play a role in the establishment of an MCL, including occurrence, analytical capabilities, treatment technologies, costs and other relevant risks it became clear that a risk management strategy had to be applied. In large part due to the issue of perchlorate contamination from sodium hypochlorite an MCL above the anticipated range of this contribution was proposed. This ensures that the important practice of disinfection is not undermined and that the threat of public exposure to harmful microbes is avoided. Even with the application of what appears to be the best management practices known to date for the use of sodium hypochlorite the introduction of perchlorate cannot be avoided. The MCL of 2.0 ppb provides the best overall protection of public health, considering the benefits of disinfection, while retaining a margin of safety for sensitive populations. MassDEP is working with EPA to develop guidelines for the use of sodium hypochlorite so as to minimize the presence of perchlorate.

Comment: *If the cost to communities of treating potable water to reach a 1 ppb threshold is a consideration, it should be recognized that special needs children are expensive…*

Response: MassDEP believes that the 2 ppb standard is protective of public health with a margin of safety for sensitive subpopulations. Other factors, such as occurrence, analytical capabilities, treatment technologies, costs and other relevant risks, must also be considered to ensure that the standard is effectively implemented.

#10 – Mass Aggregate Asphalt Pavement Association
Leo Picard
Brox Industries, *et al.*

(Note that comments were originally submitted for the Fall 2004 MCP Revisions, so they do not exactly correspond to the Spring 2006 proposal. Mr. Leo Picard requested that these comments be included in the 2006 Public Comments.)

Comment: *The MCP revisions should recognize the potential for nonpoint sources and multiple historic sources of perchlorate to increase local background levels and limit the feasibility of cleanup to lower background or risk-based levels.*

Response: "Background" is specifically defined in the MCP in a manner that includes anthropogenic sources that are "ubiquitous and consistently present in the environment", such as from atmospheric deposition and emissions from automobiles. Multiple historic sources of any chemical (such as perchlorate, gasoline or plating wastes) in an area are multiple releases to the environment, not "local background," and are subject to the MCP assessment and cleanup requirements. The MCP allows the consideration of feasibility in determining whether a permanent or temporary solution is achievable at a site. The lack of a feasible remedial alternative cannot be used to say that a site poses No Significant Risk (i.e., is permanently cleaned up, or 'safe"). Naturally occurring perchlorate, should it be adequately demonstrated to exist at a site, would be considered background and remediation would not be required for a permanent solution. MassDEP believes that the current approach to defining and addressing "background" under the MCP is appropriate for perchlorate as well. No further changes are proposed.

Comment: *MCP revisions will place an unfair burden on a number of aggregate producers and municipalities based on historic use of blasting agents that was not negligent. Use of this material has been legally permitted and a standard industry practice that has, or will soon, end.*

Response: MassDEP welcomes the industry's examination of current practices and encourages a thoughtful use of perchlorate-containing material. Prevention (or minimization) of future perchlorate releases to sensitive environments is preferred to remediation. MassDEP also has to address historic practices that, over time, have created environmental problems. MassDEP believes the MCP provides substantial flexibility to address environmental contamination and protect public health in cost-effective ways, but the process depends on identifying and assessing potential problems. No further changes are proposed.

Comment: *MCP revisions are premature relative to MassDEP's understanding of the extent of perchlorate occurrence and its use relative to background concentrations, cleanup effort, and the relative benefits of cleanup to the public.*

Response: The occurrence monitoring conducted as part of the MCL-setting process provided significant information about perchlorate in Massachusetts. The limited number of systems reporting perchlorate concentrations greater than 1 ppb clearly indicates that perchlorate contamination of groundwater is (a) not limited to Department of Defense

facilities and (b) not a pervasive (ubiquitous) background constituent. The data indicate that perchlorate is a relatively uncommon contaminant with possible sources scattered throughout the state. Treatment technologies exist and have been demonstrated to be effective both nationally and in Massachusetts. For a community, neighborhood or family drinking perchlorate-containing water, MassDEP believes that the benefits of identifying, assessing and treating the contamination is significant. MassDEP will continue to evaluate these issues.

Comment: *The standards do not offer demonstrated risk reduction benefits in proportion to the costs of implementation of these standards.*

Response: MassDEP has identified specific health risks associated with exposure of certain sensitive subpopulations to perchlorate. The evaluation of the risk posed to an exposed population, or the magnitude of the problem, does not even begin without the trigger of MCP Reportable Concentrations, cleanup standards, MCLs and Water Supply monitoring requirements. No further changes are proposed.

Comment: *The current testing measures and health advisory are sufficient to protect public health and the industry/water supplier/municipality responses over the past couple years have demonstrated the effectiveness of this approach.*

Response: The current testing measures are, in fact, part of the process for setting a drinking water standard (MCL) for public water supplies. Continued testing without a standard is not sustainable. Water Suppliers, municipal officials and the public have recognized the need for a promulgated standard, even while disagreeing on the recommended value. Under the MCP, the absence of Reportable Concentrations for perchlorate creates uncertainty within the regulated community whenever perchlorate is found in the environment and there is no clear trigger for assessment and remediation (if necessary) of sites. The promulgation of a drinking water standard, Reportable Concentrations and cleanup standards for perchlorate clarifies the regulatory status of this contaminant and puts all regulated parties on an equal footing. No further changes are proposed.

Comment: *MCP revisions should recognize that perchlorate at most sites may have been historical and short-lived, and that monitoring may be sufficient for site closure.*

Response: While it is unlikely that perchlorate contamination found at a site is *both* historical *and* short-lived, the proposed regulations do not specify remedial strategies for perchlorate. The MCP sets out a process by which the extent of contamination is identified, risk of harm to health, safety, public welfare and the environment is assessed, remedial alternatives considered and the most cost-effective approach chosen. No changes are proposed.

Comment: *MCP revisions should recognize that small perchlorate sources (blasting for road cuts, flares, etc.) while within a GW-1 area, may have little potential to impact a drinking water source.*

Response: GW-1 areas are determined by a variety of criteria, including the presence of small drinking water supplies (e.g., private wells) that may be affected by localized contamination. It is premature to decide that no further action is necessary based on limited knowledge of site and a presumption that the release is small. The MCP process is designed so that decisions about the need for remediation and the choice of remedial alternative are based on knowledge about the site, including the extent of release and potential receptors. No changes are proposed.

Comment: *Mass Aggregate provided comments in 2004 that the then proposed MCP standards are premature relative to the scientific community's understanding of the health effects of perchlorate.*

Response: State agencies, including California, New Jersey and MassDEP, among others, have reviewed the data and found the database on the health effects of perchlorate to be sufficient for setting human health protection standards. The uncertainty factors account for database deficiency and other information gaps. No proposed changes.

Comment: *Prefer a national standard.*

Response: Mass DEP understands industries' views on the benefits of having one national standard for perchlorate, rather than differing state values. However, EPA has not made a decision about whether a national perchlorate standard will be set and if EPA does set a standard, it will not be promulgated before 2011. MassDEP is likely to be the first state in the US to set a perchlorate standard. MassDEP has committed in regulation (proposed revision to 310 CMR 22.06) to review the perchlorate drinking water standard within six years of its promulgation and decide whether to adjust the standard. No proposed changes.

Comment (19): *MassDEP appears to think they can set a low standard because there isn't much perchlorate in Massachusetts. Affordability is not science.*

Response: The observed occurrence of perchlorate in Massachusetts did not influence the science behind the risk assessment. Factors such as occurrence, analytical sensitivity, the availability of treatment technologies and costs are weighed alongside the toxicological data when establishing a drinking water MCL. This practice is based on federal methodology.

Comment (44): *In the future, when an MCL or GW-1 Standard is promulgated, DEP should work with the USEPA to ensure that risk-based discharge limits are used if perchlorate is ever regulated under NPDES.*

Response: MassDEP has shared our perchlorate work with EPA.

#11 – Gerard Cutinho

Comment: *What does it take for small public water systems, like mom and pop sandwich shops to clean up perchlorate? What is the process and approximate cost for a private well? Is it prohibitive? Is the state going to do this clean up, is somebody else going to pay for it or are these mom and pop businesses going to have to pay for it?*

Response: The common treatment process to remove perchlorate from drinking water is ion exchange. In this process water is passed through a unit that is filled with a material (resin) that captures perchlorate and thereby removes it. For small systems with low flows and moderate levels of perchlorate contamination it may be possible to use granular activated carbon (GAC) as a substitute for ion exchange. The process is similar but the costs are expected to be lower. Data suggest that a GAC installation at a small public water system (such as for a high school) would cost in the order of a $20,000 - $30,000. Under M.G.L. c21E, the responsible party is generally liable for cleanup costs.

#12 - Clean Water Action

Chris Bathurst

Comment: *MassDEP should issue an advisory suitable for local BOH to educate private well owners with appropriate steps for private well owners to take to protect themselves.*

Response: MassDEP agrees that continuing education for local Boards of Health is important and the Department commits to developing guidance to inform private well owners about perchlorate. MassDEP already has extensive information available on its website specific to private well owners, at http://mass.gov/dep/water/drinking/privatew.htm

Comment: *MassDEP should support and provide testing for private wells to give private well owners the same level of protection as public supplies.*

Response: MassDEP's statutory authority under the Drinking Water Program does not extend to the regulation of private drinking water supplies. MassDEP cannot address private wells in the same manner as it regulates public water supplies. The regulation and permitting of private wells are in the hands of local officials. However, the Department does regulate releases of oil or hazardous material (such as perchlorate) to the environment under M.G.L. c.21E and the Massachusetts Contingency Plan ("MCP"). Once Reportable Concentrations and cleanup standards are established under the MCP as described in this proposal, the Department will address private wells contaminated by perchlorate within the existing regulatory process. MassDEP seeks to ensure that contamination in a private well is addressed by the party(ies) responsible for the release.

Comment: *Ban the use of perchlorate-containing blasting agents and fireworks in Massachusetts. MassDEP should use its broad powers to initiate this ban and not simply enforce it through the water suppliers. Work with the legislature to ban perchlorate-containing materials in a Zone I, Zone II and Zone A's*

Response: In cooperation with the Division of Fire Services, the Department has issued "Best Management Practices" for use of blasting agents (http://mass.gov/dep/cleanup/laws/blasting.htm) and will issue a similar document for fireworks displays. MassDEP does not believe that an outright ban is required to reduce inadvertent releases of perchlorate from these sources.

Comment: *We recommend that the DEP set the Maximum Contaminant Level (MCL) for perchlorate at 1.0 ppb or less. The health evaluation performed by DEP shows that any level above 1.0 ppb would threaten sensitive populations.*

Response: When considering the full range of factors that play a role in the establishment of an MCL, including occurrence, analytical capabilities, treatment technologies, costs and other relevant risks it became clear that a risk management strategy had to be applied. In large part due to the issue of perchlorate contamination from sodium hypochlorite an MCL above the anticipated range of this contribution was proposed. This ensures that the important practice of disinfection is not undermined and that the threat of public exposure to harmful microbes is avoided. Even with the application of what appears to be the best management practices known to date for the use of sodium hypochlorite the introduction of perchlorate cannot be avoided. The MCL of 2.0 ppb provides the best overall protection of public health, considering the benefits of disinfection, while retaining a margin of safety for sensitive populations. MassDEP is working with EPA to develop guidelines for the use of sodium hypochlorite so as to minimize the presence of perchlorate.

Comment: *We recommend that DEP develop a program to require monitoring for unregulated contaminants (a) that were on the UCMR-1 list until the UCMR-2 program begins, and (b) that may be present in water supplies based on the potential threats identified in SWAP reports for each water supplier. If any unregulated contaminant is detected there should be follow-up to identify the specific source(s) and take action to reduce or eliminate its presence in drinking water.*

Response: MassDEP will continue to follow EPA's lead in the identification and study of additional unregulated or emerging contaminants. However, the Department is committed to taking action to protect the health of the citizens of the Commonwealth.

#13 & # 16– Purolite

Amanda Dolan

Comment: Technologies exist - and are being implemented in Massachusetts at MMR and Milbury - that can achieve the proposed 2 ppb standard, or even down to non-detect levels. (technical article submitted).

Response: MassDEP agrees that several proven treatment technologies exist that can reduce perchlorate concentration in water to less than 2 ppb.

#14 – Western Massachusetts Water Works Association

John Sasur

Comment: *Has MassDEP developed a database of potential perchlorate exposures to notify the citizens and educate them on the risks from all sources?*

Response: MassDEP has collected and made publicly available a substantial amount of information on the presence of perchlorate in the environment in Massachusetts, including a database containing results from the occurrence monitoring of public water supplies. The Department has obtained data on the locations of past fireworks displays and mapped them with the locations of public water supplies. MassDEP staff have conducted and published research on the occurrence of perchlorate in Massachusetts. The Department will continue to gather information and educate the public and regulated community on an ongoing basis. (MassDEP's perchlorate web page can be found at http://mass.gov/dep/water/drinking/percinfo.htm.)

Comment: *Has the Commonwealth taken steps to ban this material in blasting agents or fireworks?*

Response: No. In cooperation with the Division of Fire Services, the Department has issued "Best Management Practices" for use of blasting agents (http://mass.gov/dep/cleanup/laws/blasting.htm) and will issue a similar document for fireworks displays.

Comment: *Has the Commonwealth provided any grant funding language within this regulation to help systems comply with the preliminary special state-wide testing and ultimate remedial action necessary to meet the requirements of this regulation?*

Response: MassDEP has determined that perchlorate represents a threat to public health and as such should be regulated. Although no direct funding is available for water quality monitoring, the Drinking Water State Revolving Fund low interest loan program is available for water systems that need to address perchlorate contamination through capital projects such as the installation of treatment. Additionally, perchlorate monitoring is eligible to be reduced at those systems without contamination issues via the Inorganic Monitoring Waiver Program, thereby minimizing monitoring costs.

Comment: *MassDEP should establish a water treatment/source development grant program funded through the MCP and fines levied on the sources of contamination.*

> **Response:** While MassDEP levies and collects penalties under the Massachusetts Contingency Plan, the money collected goes to the Commonwealth's General Fund and is not earmarked specifically for the Department.

Comment: *Has the Commonwealth determined and published the cost of implementing this regulation?*

> **Response:** Costs were estimated and considered in the Department's deliberations. Given the low incidence of perchlorate contamination found during the 2004 monitoring the bulk of costs on a statewide aggregate basis were comprised of analytical costs for monitoring. Sample analyses were found to be about $125.00 each. This figure is comparable to other routine chemical monitoring costs (e.g. VOCs). Total costs for the few systems that may need to implement treatment would be higher but MassDEP data suggest a figure of $1.5 million dollars for a 1 million gallon per day (mgd) plant. This estimate falls between those of the more common filtration ($1 million/mgd) and iron/manganese removal ($2 – 2.5 million/mgd).

Comment: *Did the DEP provide any means of public discussion and review by citizens and water suppliers prior to setting a proposed MCL?*

> **Response:** MassDEP has participated in many activities that gave a wide range of stakeholders the opportunity to comment on many aspects of our work with perchlorate including the toxicological review of perchlorate, implementation of the occurrence monitoring, compliance determinations vis-à-vis the advisory level and now the proposal of an MCL. The public hearings on the proposed regulations are another example of these opportunities.

Comment: *Is issuing this MCL setting the stage for Massachusetts to set limits for other contaminants and to circumvent the framework of standard setting, public participation, peer review and expert testimony established by Congress and successfully implemented by EPA over the past 30 years?*

> **Response:** MassDEP will continue to follow EPA's lead in the identification and study of unregulated or emerging contaminants. However, the Department remains committed to taking action to protect the health of the citizens of the Commonwealth.

#15 -- Regional Environmental Council
Peggy Middaugh

Comment: *We recommend, however, that the DEP set the Maximum Contaminant Level (MCL) for perchlorate at 1.0 ppb or less. DEP's own health assessment and other studies show that 1 ppb is justified and achievable.*

> **Response:** When considering the full range of factors that play a role in the establishment of an MCL, including occurrence, analytical capabilities, treatment technologies, costs and other relevant risks it became clear that a risk management strategy had to be applied. In large part due to the issue of perchlorate contamination from sodium hypochlorite an MCL above the anticipated range of this contribution was proposed. This ensures that the important practice of disinfection is not undermined and that the threat of public exposure to harmful microbes is avoided. Even with the application of what appears to be the best management practices known to date for the use of sodium hypochlorite the introduction of perchlorate cannot be avoided. The MCL of 2.0 ppb provides the best overall protection of public health, considering the benefits of disinfection, while retaining a margin of safety for sensitive populations. MassDEP is working with EPA to develop guidelines for the use of sodium hypochlorite so as to minimize the presence of perchlorate. Additionally, MassDEP is committed to reviewing the MCL, as specified in regulation.

Comment: *We also recommend that DEP support and implement any additional measures to reduce or eliminate exposure to perchlorate through drinking water including the protection of water resources.*

> **Response:** MassDEP has initiated efforts to develop best management practices for the use of blasting materials and fireworks and will work with other state agencies to highlight and implement these practices. Source protection remains a strong component of our efforts to ensure safe drinking water.

Comment: *Ban the use of perchlorate-containing blasting agents and fireworks in Massachusetts. MassDEP should use its broad powers to initiate this ban and not simply enforce it through the water suppliers. Work with the legislature to ban perchlorate-containing materials in a Zone I, Zone II and Zone A's*

> **Response:** In cooperation with the Division of Fire Services, the Department has issued "Best Management Practices" for use of blasting agents (http://mass.gov/dep/cleanup/laws/blasting.htm) and will issue a similar document for fireworks displays.

17 – Opdebeeck Consulting

Herwig Opdebeeck

The commentator raised several questions. These are listed in order raised with MassDEP responses immediately following.

Comment: *The goitrogen relative potency of nitrate is about 1/200 compared to perchlorate and the MassDEP MCL for nitrate is 44500 ppb. If 2 ppb perchlorate (Massachusetts proposed MCL) is the upper limit then 400 (=2x200) ppb or 0.4 ppm is the upper limit for nitrate which means if MassDEP is right then MassDEP should then consider lowering the nitrate MCL immediately by about 100 times or 2 orders of magnitude. What is the reason that this is not done?*

> **Response:** The nitrate drinking water standard, based on evaluations by USEPA, did not consider thyroid effects. Whether the nitrate standard should be revisited to account for potential effects on the thyroid was not evaluated by MassDEP in this assessment, which focused on perchlorate, and is not at issue in this public comment period. No changes are proposed.

Comment: *When adding up the contribution of all goitrogens in the diet i.e. nitrates, thiocyanates and perchlorates and not even considering other potent goitrogens such as isoflavones, fluorine etc, the contribution of 2 ppb DW (drinking water) in the diet would represent less then 1 tenth of 1 percent, I repeat less then 1 tenth of one % (published studies leading to this conclusion are available on request). In view of this, does than this MCL contribute to health protection*?

> **Response:** MassDEP has noted that the total exposure to thyroid toxicants is ultimately of concern. Although exposures to other goitrogens are known to occur there is limited data on this issue and many uncertainties including a lack of information on the potential transport of these other goitrogens into breast milk. Exposure to other thyroid toxicants raises rather than diminishes concern about the individual component sources of exposure, especially those that are preventable, such as exposures through drinking water. MassDEP does not have regulatory authority to address toxins in the food supply.

Comment: *Iodine itself is a goitrogen in that it also induces hypothyroidism when intake of iodide is excessive (this is not about Graves Disease but Iodine induced hypothyroidism and autoimmune thyroiditis). Even then, the WHO uses an UF of only 3 starting from the dose that causes an elevation of serum TSH (thus a point of departure already much closer to hypothyroidism than the one taken in the case pf perchlorate) and based on this adopts a RfD for adults of 600 µg day-1 and extends this to pregnant women without applying an additional UF. Then the US and Canada increased this to 1100 µg/day in 2002(US Food and Nutrition Board) i.e. it were as if they used an UF of 1.5 only. If for the goitrogen Iodine instead of an UF of 3, an UF of 200 would have been used as in the case of perchlorate, the RfD would have been about 60 times less or about 10 µg day-1. This would then have been about 30 times lower than the daily recommended US intake dose for Iodine for pregnant women which is 290 µg day-1*

(and about 160 µg/day for adults). This again leads to a serious conflict situation. Doesn't this suggest again that something must be fundamentally wrong in the risks assessment?

> **Response:** No, the calculations set forth by the commenter do not suggest any fundamental problem in MassDEP's assessment. First of all MassDEP's effort to review the toxicity of perchlorate and establish a reference dose does not require an assessment of recommended daily allowances of iodine nor quantification of risks associated with excess iodine intake. However, there is considerable information on iodine, including the fact that it is a known essential nutrient. Perchlorate is not. Furthermore, the thyroid effects induced by excess iodine are attributable to a very different mechanism of action compared to that of perchlorate. Thus, the hypothetical and arbitrary application of an UF of 200 to the evaluation of excess iodine effects, as suggested by the commenter, is not appropriate. No changes proposed.

Comment: *We would like to make a comment on page 6 of your critique on the Tellez et al., 2005 study: "Also, the coexistence of perchlorate with levels of other goitrogens like lithium, nitrate, arsenic (Table 6) in the drinking water in the three Chilean cities could complicate interpretation of the dose response data and the observed effects." Wouldn't this also be the case for the Greer et al., 2002 study on which the proposed Mass. MCL is based? And shouldn't therefore also those goitrogens and other goitrogens such as dietary thiocyanates and PCBs been included in this same Greer et al., 2002 study?*

> **Response:** It is of course likely that the subjects in the Greer study would have been exposed to other thyroid toxicants and it would have been informative had data on the subjects cumulative exposures to thyroid toxicants been collected and presented in the Greer et al study. It was not and cannot be reconstructed. However, since total exposure to thyroid active agents was not controlled for in the study a bias towards the null hypothesis of no perchlorate effect is introduced, decreasing the statistical power of an already weak study to detect an effect. This supports MassDEP's approach to evaluating the results of the Greer study.

Comment: *We would like to make a comment on your critique on the Braverman et al., 2005 study (page 11 and 12): The full title of the paper reads as follows: "The Effect of Perchlorate, Thiocyanate, and Nitrate on Thyroid Function in Workers Exposed to Perchlorate Long-Term" This is a study involving the most important goitrogens. Question: Why hasn't the opportunity been taken to comment on the other goitrogens and the total goitrogen background in this study as this is an essential and critical point missing in the Greer et al., 2002 study on which the Mass. proposed MCL is based? Indeed this seems to be a relevant issue for MassDEP as well since MassDEP mentions itself as comment on the Tellez et al., 2005 study: "Also, the coexistence of perchlorate with levels of other goitrogens like lithium, nitrate, arsenic (Table 6) in the drinking water in the three Chilean cities could complicate interpretation of the dose response data and the observed effects". Therefore, since all 3 most important goitrogens in the Braverman study were measured for the first time in the same study, this then would not have "complicated" the interpretation in this case but may have clarified it instead and may have been a valuable contribution towards the evaluation of the "total goitrogen effect".*

Response: As noted previously, the fact that other exposures occur does not obviate the need to address perchlorate exposure associated with drinking water. MassDEP's technical report and addendum note that this study is of limited usefulness because of a number of factors including the fact that it addresses occupationally exposed adults.

Comment: *Kelp is considered a health food but, when taking into account its iodine content that can exceed several tenths of thousands ppb of perchlorate, it should present a health problem instead (see question 3). Mostly it does not. No explanations were ever given or found but we recently know that it contains high doses of perchlorate that would then neutralize partially the toxic effect of iodine. As 2 ppb still represents about 1015 molecules i.e. about one million times one billion molecules and since with the latest analysis techniques down to 1 ppt (pp trillion), natural perchlorate is found everywhere even in the most pristine locations and since perchlorate is, like iodine, also naturally found in places like the oceans, and in view of what was said before, couldn't it then be possible that, setting those perchlorate levels so low, that this fragile natural balance would be broken instead and lead to a real but latent problem?*

Response: The health benefit or risk of kelp consumption was not addressed by MassDEP. No change proposed.

Comment: *Indeed when comparing the around 20 ppb levels in perchlorate found in beer and wine from several countries with the proposed Mass. MCL of 2 ppb, it was not difficult to conclude that this could potentially raise a trade issue between nations as the consumption of less than ½ glass of beer or wine could easily exceed the maximum allowed daily intake thru drinking water.*

Response: International trade issues are outside the scope of MassDEP regulations. MassDEP's derivation of a reference dose assumes 80% of the contribution to the total perchlorate dose comes from sources other than drinking water.

Additional Comments:

- *I thought the nitrate MCL is not 10 ppm nitrate as mentioned but 44.5 ppm (it would be 10 ppm when expressed in Nitrogen (N) content). Please clarify.*
- *I quote from the MassDEP study:" The Occurrence and Sources of Perchlorate in Massachusetts", August 2005,Section 4.1.4.,2nd §: "From a regulatory perspective, the 4-orders-of-magnitude disparity between the current nitrate drinking water standard of 10 mg/L and MADEP perchlorate drinking water advisory of 1 µg/L suggests that an increased concern and emphasis on perchlorate is not unfounded" Comments: There is certainly a disparity but in view of my questions above, I suggest the disparity should rather be seen between an already existing MCL of the goitrogen nitrate which translates into a perchlorate equivalent of about 250 ppb and a new proposed one of 1-2 ppb. This disparity could also indirectly be illustrated by commenting the blasting sites report: If indeed this equivalency would have been taken into account then it would have been clear that either the blasting apparently caused the nitrate levels to increase to over several times the proposed MCL of 2pbb when expressed in equivalent perchlorate levels (Millbury) or that, most probably, the nitrate levels were at least partially caused by other sources (from agriculture or simple mineralization of organic matter when*

disturbing the soil by blasting or other means; nitrate levels in ground water of several thousand ppb are common and natural and are frequently found even under native forests and other pristine areas).(We cannot draw any conclusions on this relationship from the Westford or Boxborough sites as it is not shown in that publication which specific wells are referred to in the graph).

Response: The additional comments noted above either do not directly address the perchlorate drinking water standard, which is the subject of this comment period, or raise issues relating to the nitrate drinking water limit which was previously addressed.

18 – David Agnew

Cape Cod Resident

Comment: *As a believer in the Peter Principle, I would favor a standard of zero parts per billion, but to be more realistic, I encourage the DEP to adopt a standard of 1 ppb. I also support the prohibition of fireworks and explosives within water supply areas.*

Response: When considering the full range of factors that play a role in the establishment of an MCL, including occurrence, analytical capabilities, treatment technologies, costs and other relevant risks it became clear that a risk management strategy had to be applied. In large part due to the issue of perchlorate contamination from sodium hypochlorite an MCL above the anticipated range of this contribution was proposed. This ensures that the important practice of disinfection is not undermined and that the threat of public exposure to harmful microbes is avoided. Even with the application of what appears to be the best management practices known to date for the use of sodium hypochlorite the introduction of perchlorate cannot be avoided. The MCL of 2.0 ppb provides the best overall protection of public health, considering the benefits of disinfection, while retaining a margin of safety for sensitive populations. MassDEP is working with EPA to develop guidelines for the use of sodium hypochlorite so as to minimize the presence of perchlorate. The establishment of an MCLG of zero is usually reserved for carcinogens. Cancers have not been identified as an adverse health outcome of perchlorate exposure.

In cooperation with the Division of Fire Services, the Department has issued “Best Management Practices” for use of blasting agents (http://mass.gov/dep/cleanup/laws/blasting.htm) and will issue a similar document for fireworks displays.

#19 – Berkshire Environmental Action Team
Jane Winn

Comment: *Perchlorate is not normally found in soil and groundwater, therefore any level is alarming.*

Response: Research indicates that under some conditions, perchlorates may be found naturally in the environment. In Massachusetts, however, the results of the occurrence monitoring of public water supplies indicates that most, if not all, the sources of perchlorate in the state are from anthropogenic (man-made) sources. While the presence of any anthropogenic material in soil or groundwater may be alarming, it is not sufficient to trigger cleanup. The MCP process is designed so that decisions about the need for remediation and the choice of remedial alternative are based on knowledge about the site, including the extent of release, potential receptors and the risk posed by the contaminants. The statute (M.G.L. c.21E) also requires, *to the extent feasible*, that a permanent solution include measures to reduce contaminant levels to background. MassDEP believes that this is a time-tested, measured approach. No changes are proposed.

Comment: *Since perchlorate was found in Berkshire County, it would have been appropriate to hold a public hearing on the standard in the County, ideally in Williamstown.*

Response: Recognizing the substantial public interest, MassDEP scheduled six hearings at locations across the state over a period of three weeks in order to provide an opportunity for all interested parties to be heard. Unfortunately hearings could not be scheduled in all communities affected by perchlorate contamination. MassDEP appreciates the time and effort dedicated to providing comments on this regulatory proposal and the Department wants to emphasize that <u>*all*</u> comments are considered equally, if they are submitted at a hearing or in writing before the end of the comment period.

20 -- Department of the Navy
Andrew J. Stackpole

[Note: The following section provides responses to written comments provided to MassDEP by the Department of Defense on 4/7/06 (Mr. Robert Muhly), and on 5/9/06 b (Mr. Andrew J. Stackpole) on MassDEP's 2006 perchlorate document entitled *Update to "Perchlorate Toxicological Profile and Health Assessment" and Addendum: Review of New Studies on Perchlorate*. These two written comments are similar in content, except that the 5/9/06 version has included a few additional comments, and this document is thus reviewed and addressed in subsequent paragraphs.]

Comment: *Establishing background levels at sites will be very important as cleanup is typically done to the established background level.*

> **Response:** Naturally occurring perchlorate, should it be adequately demonstrated to exist at a site, would be considered background and remediation would not be required beyond background for a permanent solution, consistent with the current regulations. MassDEP believes that the current approach to defining and addressing "background" under the MCP is appropriate for perchlorate as well. No further changes are proposed.

Comment: *Perchlorate effects on thyroid function occur only at higher concentrations. The sentence ---- perchlorate disrupts normal function of the thyroid gland." Should be changed to state accurately: "--- At sufficiently high levels, perchlorate disrupts normal function of thyroid gland." This applies to the "Perchlorate Fact Sheet/Q/A". What are the health effects of perchlorate? Section and Update to "Perchlorate Toxicological Profile and Health Assessment", March 2006: Executive Summary, page ix.*

> **Response:** MassDEP agrees with the commenter that perchlorate may interfere with normal thyroid function at sufficiently high doses. Change is proposed to include "at sufficiently high levels perchlorate disrupts normal function of the thyroid gland."

Comment: *The NAS recommends an RfD of 7 x 10^{-4} mg/kg/day which is derived from human data and includes a sensitive population protection factor of 10. The MA DEP toxicity profile advocates an RfD of 7 x 10^{-}5 mg/kg/day, which incorporates an additional order of magnitude reduction from the NAS RfD. This additional uncertainty factor is based on issues already accounted for in the NAS RfD and is unwarranted.*

> **Response:** MassDEP disagrees. The Department has followed the standard protocol developed by USEPA for the application of Uncertainty Factors. An additional uncertainty factor was deemed necessary for LOAEL to NOAEL adjustment because:
>
> - The study lacked statistical power to detect any effect since few subjects were included the study. This conclusion is based on a detailed statistical analysis conducted by MassDEP, presented in the *Update to "Perchlorate Toxicological Profile and Health Assessment"* document. The NAS did not perform such an analysis.
> - Individual perchlorate-induced iodide uptake inhibition response at the LOAEL was obscured by group averaging.

- The MassDEP/DPH Advisory Committee on Health Effects supported considering the lowest dose as the LOAEL.

An uncertainty factor for database deficiency was deemed to be necessary because of:

- lack of data on chronic exposure toxicity,
-
- emerging data on perchlorate in breast milk, and lack of knowledge in the dynamics of perchlorate and iodine interaction at the breast NIS.

Detailed discussions on uncertainty factors regarding LOAEL to NOAEL extrapolation and database deficiency are found in MassDEP's perchlorate documents entitled "Perchlorate Toxicological Profile And Health Assessment, 2004", and Update to "Perchlorate Toxicological Profile and Health Assessment, 2006," and "Review of New Studies on Perchlorate, 2006". No changes are proposed.

Comment: *MA DEP uses a 20% drinking water source contribution factor when developing the MCL. Even though 20% is the US EPA default value, no source contribution studies substantiate this drinking water contribution.*

Response: The need for a 20% source contribution factor is supported by the:

- presence of perchlorate in a variety of food types and beverages, and
- lack of data to quantitatively evaluate the relative contribution of other sources.

Use of a 20% RSC is consistent with MassDEP's standard protocol for deriving drinking water guidelines and MCP cleanup standards. For detailed discussions on the topic refer to Update to "Perchlorate Toxicological Profile and Health Assessment, 2006," and "Review of New Studies on Perchlorate, 2006". No changes are proposed.

Comment: *It is not clear, from looking at the spreadsheet on the MA DEP website, what RfD values is used to determine the proposed MCP Numerical Standards for perchlorate.*

Response: The MCP Numerical Standards adopt the proposed Perchlorate MCL as the GW-1 groundwater standard, employ the proposed 7.0×10^{-5} mg/kg-day Reference Dose to calculate the S-1, S-2 and S-3 soil standards, and use a target surface water benchmark level of 59 µg/L for the development of the GW-3 groundwater standard.

Comment: *The RfD used to derive the MCL was 7×10^{-5} mg/kg/day, assuming a 70 kg person drinking 2 liters of water and RSC of 20%, which resulted in ≈0.5 µg/L. The proposed MCL, however, is recommended to be 2 µg/L based.*

Response: MassDEP's perchlorate MCL is based on both toxicity evaluations and risk management considerations. Factors that lead to the recommended MCL of 2 µg/L other than toxicity include: the scope of the problem; the availability and feasibility of testing and treatment technologies; and data that demonstrated that perchlorate can be introduced into drinking water when certain disinfection chemicals are used.

Comment: *Sensitive sub populations: This documents description of potential sensitive subpopulations is not consistent with current understanding of the mode of action of perchlorate toxicity. --------- While it is true that these individuals would have more serious outcomes from further reduction in thyroid hormones, there is a developing body of evidence that shows that these conditions are not related to the NIS and do not predispose the individuals to decrease in iodide absorption. In fact, it is beginning to become clear that many of the conditions outlined in this section (iodine deficiency, sub-clinical and some frank hypothyroid states) induce homeostatic responses that include elevation of thyroid stimulating hormone, with resulting induction of the thyroid. This induction causes the increase of the number of NIS's resulting in decrease in the thyroid susceptibility to perchlorate. It is also important to note that women suffering from frank hypothyroid states usually can not become pregnant without supplementation with thyroid hormone under a physicians care and they would be extremely unlikely to discontinue care during pregnancy.*

Response: It is true that there are data to indicate that iodine deficiency could trigger an increase in thyroid stimulating hormone (TSH), which in turn increases the synthesis of NIS protein to trap the available iodine in the blood stream and to ultimately increase iodine uptake into the thyroid gland. Although the trapping mechanism is efficient, the iodine levels in the blood limit the iodine levels that reach the thyroid gland. In such situations, the absolute amount of iodine that is detected in thyroid gland is low, and just measuring iodide uptake inhibition alone could be misleading. Moreover, the chronic stimulation of TSH may to lead to thyroid abnormalities such as goiter and thyroid cancer. That is why people living even in mildly iodine deficient areas have thyroid-related problems, and children born in these areas have neurological deficits despite the compensatory mechanisms activated by iodine deficiency. In such populations, any factor that can reduce iodide uptake further could aggravate the thyroid-related problems. Various studies have shown that the effects of iodine deficiency are more pronounced in iodine deficient people that consume, the goiterogen, thiocyanate in the diet than people suffering from iodine deficiency alone (Delange et al, 1982, 1983).

The most frequent cause of sub-clinical or clinical hypothyroidism is autoimmune thyroiditis. A well designed study (Caturegli, et al., 2000) has shown that one of the mechanisms (among many others, such as antibodies directed against thyroglobulin and thyroid peroxidase) for the hypothyroidism in autoimmune thyroiditis is chronic suppression of the NIS gene transcription by a specific cytokines thus decreasing iodide uptake in to the thyroid gland. It is hard to induce the NIS in autoimmune thyroiditis when gene transcription is chronically suppressed, and any factor that inhibits the few NIS protein molecules that are expressed will aggravate the hypothyroidism.

Studies indicate that pregnant women who are on thyroid supplementation need increased doses of thyroxin due to the stress pregnancy induces on the thyroid gland. If such pregnant women are exposed to perchlorate, the thyroxin dose may have to be increased further to get the optimum level of thyroxin in the blood.

Comments. (Issue a) *The contention by MassDEP that the NOEL of 0.007 mg/kg in the Greer study is not a NOEL but actually a LOEL and* **(issue b)** *under certain conditions may actually be an adverse effect is not adequately explained. This contention is an important part of the MassDEP's risk assessment and should be fully explained and contrasted with the NRC's use of that value as the NOEL.* **(Issue c)** *MassDEP may also want to detail the conditions under which low level inhibition of iodide uptake could be in itself be an adverse effect. It would also be useful for the MassDEP to propose toxicology studies that they would like to see to address this question. This a question that will continue to arise because of changes in the thinking of the scientific community*

Responses:

Issue a: MassDEP scientists, with input from MassDEP/DPH Committee on Health Effects, carefully reviewed the NAS-NRC perchlorate report. MassDEP's decision to treat the lowest dose group from the Greer study as a minimal effect level rather than a no effect level (as assumed by the NRC committee) was based on a detailed statistical analysis, which concluded that it was inappropriate to discount the dose-related but non-statistically significant effect observed at the lowest dose in the Greer publication due the very weak statistical power of the study to even detect an effect. The NRC committee did not conduct such a statistical analysis of the data. This is discussed at length in the *Update to Toxicological Profile and Health Assessment* and *Addendum* documents and no revisions are proposed.

Issue b: Although this issue is discussed in several sections of the *Update to Toxicological Profile and Health Assessment* further clarifying language will be added to this document. MassDEP already states that, *"we see IUI, which is an early event in the putative mechanistic pathway leading to perchlorate toxicity as a potentially adverse effect"* and explains its decision to use IUI as the critical effect and point of departure in deriving an RfD. We will further clarify that: 1) IUI constitutes an appropriate point of departureas it is a known precursor to adverse effects and not merely an indirect marker; and, 2) since a scientifically-based safe level of IUI that would not potentially lead to adverse downstream effects has not been established, in particular for the fetus and infants, IUI itself should be treated as adverse and used as the POD in deriving an RfD.

Issue c: Additional research to resolve uncertainties is needed including studies that address the level of IUI that is associated with adverse effects, especially in the most sensitive subgroups, fetuses, neonates and premature neonates and effects from exposures to multiple thyroid toxicants. As these research issues are beyond the scope of this assessment we do not propose to change the documents to address this issue.

MassDEP is committed to considering additional scientific studies as they become available and will establish in regulation (proposed in 310 CMR 22.06) an obligation to review the perchlorate drinking water standard within six years of promulgation.

Comment: *The Statement on page 5 in the Statistical Considerations section that "they saw no a priori reason to assume that the shape of the dose-response curve was linear in the one of extrapolation below the low dose group response" is an important issue. In actuality, competitive inhibition of a molecule at its receptor site is assumed to be 1st order or pseudo 1st event and is accurately predicted by the double reciprocal (lineweaver-Burke) transformation of the Michaelis-Menton equation.*

Response: The comment refers to a statement from the U.S. EPA's responses to comments on their draft perchlorate assessment document which MassDEP referenced as part of its criticism of the Greer et al paper identification of a NOEL. We concur with the commenter that competitive inhibition of a molecule at its receptor site can, and often does follow the Michaelis-Menten (MM) model and is linear on a plot of the reciprocals of both sides of the MM equation. However, the data on perchlorate are not sufficiently complete to indicate whether the inhibition of the NIS by perchlorate conforms to this model or not. The implications of this uncertainty on the shape of the perchlorate dose-response curve for inhibition of radioactive iodide uptake inhibition are that the location of the predicted NOEL from the curve fit to the dose response data is imprecise, but nevertheless lower than the experimental LOEL of 0.007 mg/kg-d. This is because 0.007 mg/kg-d is the lowest dose of the data set and the shape of the fit curve to the data points would not change at doses equal to or greater than 0.007. Below that value, the shape of the curve could change, affecting any estimates of the true NOEL. Greer et al. employed some elements of the benchmark dose evaluation process recommended by EPA, but were criticized by EPA for not following that process fully to evaluate the perchlorate dose-response relationship for this data set. The underlying points of criticism of the Greer et al study's NOEL presented in the paragraph containing the statement referred to by the commenter still stand: that the dose identified by Greer et al of 0.007 mg/kg-d as a NOEL was not a valid NOEL.

Comment: *The second paragraph on page 21 (Final page of the "update document") in which the MassDEP derives a drinking water standard is confusing. In earlier sections the MassDEP has chosen an RfD of 0.0007 mg/kg-d and a RSC of 20%. This does not* seem to support 2 ppb standard.

Response: When considering the full range of factors that play a role in the establishment of an MCL, including occurrence, analytical capabilities, treatment technologies, costs and other relevant risks it became clear that a risk management strategy had to be applied. In large part due to the issue of perchlorate contamination from sodium hypochlorite an MCL above the anticipated range of this contribution was proposed. This ensures that the important practice of disinfection is not undermined and that the threat of public exposure to harmful microbes is avoided. Even with the application of what appears to be the best management practices known to date for the use of sodium hypochlorite the introduction of perchlorate cannot be avoided. The MCL of 2.0 ppb provides the best overall protection of public health, considering the benefits of disinfection, while retaining a margin of safety for sensitive populations.

Comment: *On page 3 of the addendum document the MassDEP authors speculate that the decreased iodine excretion in the Taltal population may be due to "overcompensation" phenomenon that could result from induction of the symporter protein by goitrogens which ultimately increases iodide uptake into the thyroid". It is important---------- This induction has the effect of both increasing the percent absorption of available iodide and making the system refractory to perchlorate toxicity. In other words requires higher amount of perchlorate to produce measurable decrease in iodide absorption.*

> **Response:** MassDEP agrees with the commenter, and has expressed this view on page 6 of the addendum document where the high levels of perchlorate in Taltal may have caused compensatory mechanisms (increased TSH levels with subsequent induction of the NIS) to occur attenuating the perchlorate-related thyroid effects. These compensatory responses may be partly responsible for the lack of dose-response in this population. The pregnant women in Taltal were iodine sufficient and the induced NIS could transport more iodine into the thyroid, which would not be the situation in iodine deficient pregnant women. No changes are proposed.

Comment: *The statement on page 3 that 6% of the pregnant women in all three cities of the Chilean study were diagnosed with hypothyroidism during pregnancy and placed on thyroxin during pregnancy is evidence against (not for) a high prevalence of iodine deficiency in this group. The women diagnosed with hypothyroidism were probably suffering from subclinical hypothyroid condition prior to pregnancy and only became frankly hypothyroid because of the demand s of pregnancy. Such sub-clinical hypothyroid stats are usually the result of an autoimmune condition involving the thyroid cells. This condition is much more prevalent in populations that consume an excess of iodine because storage of iodine or thymoglobulin makes the thyroid antigenetically identifiable and susceptible to attack. In summary, the hypothyroid condition was probably due to former consumption of excess iodine and not to any effects of perchlorate.*

> **Response:** MassDEP stated on page 3 of the addendum document that 6% of the pregnant women in all three cities were diagnosed with hypothyroidism during pregnancy and placed on thyroxin treatment. This finding is in contrast to the reported 0.8% hypothyroidism value for normal pregnant women tested during pregnancy in the United States. Excess iodine exposure is known to cause autoimmune thyroiditis and the biomarker for this endpoint are increased thyroid peroxidase antibody and thyroglobulin antibody titers. The authors did not assess if the women with hypothyroidism had increased levels of these antibodies compared to the women that did not become hypothyroid during the progression of pregnancy. We do not have the raw data to see if such a relationship exists in the hypothyroid women. The conclusion is that the rate of hypothyroidism in the Chilean pregnant women is higher than that observed in the US. No changes are proposed. A perchlorate effect can't be completely ruled out.

Comment: *The statement that T3 values in Chanaral were lower than in Taltal is further evidence that perchlorate is not having an effect, because, if it were producing hypothyroidism, the levels of T3 in Taltal (the community with highest levels of perchlorate) would be lower than the other communities.*

> **Response:** This lack of dose-response is discussed on page 6 the update document entitled: Update to "Perchlorate Toxicological Profile and Health Assessment" and Addendum: Review of New Studies on Perchlorate. See also the response for comment # 75.

Comment: *The comment that the Chilean studies are not applicable to the US population because of high consumption of iodide in that population is only partially correct. Due to health concerns sources of iodide in drinking water have recently been removed from the Chilean population and dietary levels of iodine are now much reduced. Current consumption of iodide in the study population are greater than the current consumption in the United States but less than the consumption in the United States 20 years ago.*

> **Response:** Comparison of iodine intake between current Chilean and US populations remains to be done. Depending on the results of future data from this area may be more comparable. MassDEP remains concerned about the current status of iodine consumption in the United States. As reported on page 2 of the addendum document, for example, 50% of pregnant women studied in Boston had iodine intake below the U.S recommended daily allowance and 9% had levels consistent with iodine deficiency. No changes are proposed.

Comment: *The Critique of the iodine deficient rodent study as having "No thyroid or pituitary hormone levels' is not correct. The study was supported by extensive analysis of hormones in the pilot phase and analysis of hormones in the main study on the day necropsy. Moreover, the MA DEP has not chosen hormone analysis for their critical event point of departure (POD). But has chosen inhibition of iodide uptake by the NIS for the NOEL/LOEL of this assessment. In light of this choice this study seems to be an ideal candidate for consideration because it is the only study available that contemplates the effect of perchlorate on thyroidal iodine deficient animals it is also* ----------

> **Response:** The iodine deficient rodent stud*y* that was available for MassDEP analysis included hormone analysis of the iodine deficient rats before perchlorate treatment and not after perchlorate treatment. The T4 levels in these rats were decreased despite the presumed iodide uptake increase in these rats. Measuring iodide uptake inhibition alone could be misleading unless accompanied by intrathyroidal iodine content and thyroid and pituitary hormone measurements.
>
> The iodine deficient rodent study mentioned in the comment was not conducted in the most sensitive subgroup, the pregnant rat and its fetus. There are similar iodine deficient rodent studies in pregnant rats and their fetuses designed to investigate the effects of perchlorate in these animals. These studies and the study described in the above comment are discussed on page 12 of the addendum. No changes are proposed.

Comment: *The MA DEP " Update to Perchlorate Toxicological Profile and Health Assessment " and the Addendum recommend an MCL of 0.5 ppb while the proposed rule is an MCL of 2 ppb; what is the basis for this difference.*

> **Response:** MassDEP's perchlorate MCL is based on both toxicity evaluations and risk management considerations. Factors evaluated other than perchlorate toxicity include: the scope of the problem; the availability and feasibility of testing and treatment technologies; and data that indicated that certain disinfectant products may introduce perchlorate into drinking water.

Comment: *It seems in appropriate that no mention is made of the Chilean human studies (Snow et al.,) which concludes no health effects for humans (including pregnant women and their offspring) at levels up to 200 ppb in drinking water. This study should be included. However, if MA DEP chooses not to include it, the elimination of this or any important study from consideration needs to be explained.*

> **Response:** Despite contacting the U.S. Department of Defense scientists working on this issue, the Snow, *et al.* paper referenced here has not been located.

21 --- New England Water Works Association

Anthony Zuena

Comment: *NEWWA has also heard concern that there may be some difficulties in that the new specifications for analytical methods may preclude valid historical data from being grandfathered for the purpose of sampling waivers. It would be unfortunate if a minor and potentially unnecessary revision [to] the analytical method caused many systems the expense of duplicating their occurrence data to demonstrate that they did not have perchlorate in their water.*

> **Response:** MassDEP has proposed that monitoring data collected after January 1, 2004, may be grandfathered to avoid the initial monitoring requirement (two samples for groundwater systems, four samples for surface water systems). The intent here is to use occurrence data collected under the requirements of 310 CMR 22.06D, Special Monitoring for Perchlorate, in a determination of an appropriate monitoring frequency under the new regulation. Systems that did not detect perchlorate during the 2004 monitoring would be eligible to go straight to annual monitoring. Additionally, MassDEP is proposing that perchlorate would be added to the list of contaminants for which monitoring waivers are available.

Comment: *NEWWA calls upon DEP to make a public commitment as part of the regulatory promulgation process to review and revise the perchlorate standard as new information, EPA action, or change in the occurrence from other sources, indicates that this action was too conservative.*

> **Response:** The proposed regulations include the following language at 310 CMR 22.06(2), "The Department will review and revise as necessary the perchlorate MCL within 6 years of its promulgation, taking into account new data on health effects, sources and occurrence, treatment techniques and associated issues, analytical feasibility and any other relevant information."

Comment: *NEWWA is strongly supportive of DEP's recognition of the importance of not interfering with proper disinfection of water. …The health protective benefits of disinfection far outweigh whatever small incremental benefit might accrue from establishing a slightly lower perchlorate MCL.*

> **Response:** Application of a risk management strategy to the use of sodium hypochlorite for disinfection and its potential to contribute perchlorate to treated water led MassDEP to the proposed MCL.

Comment: *How will DEP deal with potential contributions from sewage plants upstream of water intakes? Given that there is clear local evidence that this can be a problem, can DEP work to minimize the potential impact on water supplier, without adding any additional burden on publicly owned wastewater treatment plants?*

> **Response:** MassDEP's experience in the Merrimack and Concord Rivers has shown that where the discharge of perchlorate into a sewer system can be identified it can be addressed at a facility level upstream of both the Publicly Owned Treatment Works and the Public Water System.

Comment: *DEP has proposed a maximum contaminant level standard for perchlorate which is not only the first in the nation, but appears to be more conservative than all other health advisory levels currently on the books or being considered by other states.*

> **Response:** Both Maryland and New Mexico currently use a guideline of 1 ppb.

Comment: *"…the relatively small contribution of water to perchlorate sources has the unfortunate effect of lowering the allowable amount of the daily dose that can come from water. We understand that given the uncertainty of how much all other sources of perchlorate will contribute, DEP is conservatively attributing 20% of the body burden to water for adults" and further urges MassDEP to aggressively act to reduce other sources of exposure.'*

> **Response:** MassDEP is working to cleanup and thus limit exposures to perchlorate associated with hazardous waste sites and to protect public health from perchlorate in drinking water supplies. Exposures attributable to dietary sources other than drinking water are not within the regulatory authority of MassDEP.

Comment: *In this case the commenter expressed concern that MassDEP had second-guessed the NAS panel and erroneously concluded that the Greer study did not identify a no observed adverse effect level.*

> **Response**: MassDEP scientists, with input from MassDEP/DPH Committee on Health Effects, carefully reviewed the NASperchlorate report. Many points of agreement were noted. MassDEP's decision to treat the lowest dose group from the Greer study as a minimal effect level rather than a no effect level (as assumed by the NAS committee) was based on a detailed statistical analysis and was not a guess. The NAS committee did not conduct a statistical analysis of the data. As discussed in MassDEP's *Update to Perchlorate Toxicological Profile and Health Assessment* document, a scientifically based safe level of iodine uptake inhibition (IUI) has not been established. This is one reason why MassDEP concluded it was not appropriate to treat the IUI effects observed in the Greer et al study as non-adverse and chose to use an uncertainty factor approach applied to the lowest dose group in the study, where a dose-related but non-statistically significant effect but was reported, rather than a Bench Mark Dose approach based on a minimal % inhibition. The NASstatement that 75% inhibition would be needed to see adverse downstream effects was not supported by any data, analysis or references. During one of MassDEP's Advisory Committee on Health Effects meetings a member of the NAScommittee stated the 75% value was not derived by any quantitative analysis but was based on an a clinical observation that loss of a large fraction of the thyroid can be tolerated in adults. The applicability of this observation to pregnant women and neonates was not addressed and no data was provided not could be located regarding the sample size, population characteristics or criteria used to determine whether effects of concern might have occurred. No changes are proposed.

Comment: *The commenter expressed concern that MassDEP has "adopted excessively conservative risk assumptions, particularly as they are at odds with the conclusions of the NAS".*

> **Response:** The NAS committee was itself not unanimous in its conclusions, with one member supporting a higher uncertainty factor to account for deficiencies in the data including the small sample size in the Greer study. As detailed in MassDEP's *Update to Perchlorate Toxicological Profile and Health Assessment* a well-established method was used to assess the toxicological data on perchlorate and to derive an RfD. The resulting RfD and drinking water limit are not, given the available scientific data, excessively conservative. No changes are proposed.

Comment: *"A cleanup standard of 2 ppb without an appropriate analytical method will cause significant error and create unnecessary expense. Despite the Commonwealth of Massachusetts' experience, we are concerned about the use of EPA Method 314.0 and its "enhancements." Method 314.0 is not only unreliable for determining perchlorate concentrations below 4 ppb in drinking water, and that EPA has moved beyond this method to improved techniques.*

> **Response-** This response addresses the commenter's concern about the use of the modified EPA Method 314.0. MassDEP acknowledges that advancements in technology

occur over time thus leading to the development of new methods. In recognition of newer technologies, different approved methods have been allowed by MassDEP and are quoted in the proposed regulation changes. The commenter is directed to the listing of approved analytical methods for the analysis of perchlorate samples (Inorganic Contaminants Analytical Methods) at 310 CMR 22.06(16)(a) where EPA Methods 314.0, 314.1, 331.0 and 332.0 have been listed.

All methods listed in the proposed regulation changes are appropriate, including EPA Method 314.0 as modified to achieve performance requirements in 310 CMR 22.06(4). Contrary to creating significant error and unnecessary expense, MassDEP believes that the ion chromatography methods listed offer an accurate, economical alternative to more costly methods such as LC/MS, LC/MS/MS, IC/MS, or IC/MS/MS. The Department is confident about the performance of modified EPA Method 314.0 based on MassDEP approved laboratories' demonstration to the Department that they can achieve the stringent performance requirements of 310 CMR 22.06D(4). This demonstration included successful performance in two out of a total of three proficiency test (PT) studies. The principal objective of the MassDEP low-level perchlorate PT study was to evaluate the ability of laboratories to reliably detect and quantitate perchlorate at or above a concentration of 1.0 µg/L in a typical MA drinking water matrix without incurring false positives at or above this concentration. No evidence of unreliability as indicated by the successful laboratory participation of PT studies and the meeting of the stringent quality control requirements in the modified method was noted by the Department.

22 -- Chlorine Chemistry Council & American Chemical Council Stephen Rosario & William Carroll

Comment: *An MCL of 2 ppb is overly conservative and should b e revised to be consistent with conclusions of the USEPA and National Research Council's Committee.*

Response: MassDEP, U.S. EPA's Children's Health Protection Advisory Committee, the states of New Jersey and California and other scientists have recommended public health protection levels in drinking water which are below a concentration of 24.5 ppb. The EPA's Drinking Water Equivalent Level (DWEL) does not account for exposures to perchlorate beyond drinking water even though a number of studies have measured widespread levels of perchlorate in a variety of foods. MassDEP and the U.S. EPA's Children's Health Protection Advisory Committee believe that 24.5 ppb of perchlorate in drinking water isn't protective for infants who could be exposed via breast milk or formula.

Comment: *There is no indication that these low levels of perchlorate in sodium hypochlorite pose any health risk to drinking water consumers.*

Response: MassDEP has found that normal use of sodium hypochlorite for disinfection could result in up to several tenths of a ppb of perchlorate in treated water. Testing of

sodium hypochlorite solutions has shown levels in one case as high as 26,000 ppb in the purchased material and 1,600 ppb in the diluted day tank (solution that is added to the water) that resulted in a finished water concentration of 2.1 ppb. Mass DEP has requested that U.S. EPA further study this issue.

Comment: *The proposed MCL could impose costly obligations on community water systems, businesses, and individuals in Massachusetts, without any corresponding benefit to public health.*

Response: MassDEP disagrees. The Department's review of the toxicological data concludes that an MCL of 2 ppb is necessary to protect public health and therefore does justify the costs of this regulation.

23 National Resources Defense Council (NRDC)

Jennifer Sass

Comment: *EPA weakened its DWEL. 24.5 ppb makes no adjustment for infant body weight; RSC factors and EPA's own Children's Health Protection Advisory Committee disagreed.*

Response: MassDEP agrees that the 24.5ppb value adopted by EPA as a DWEL does not take into account the points raised by NRDC. MassDEP concurs with NRDC that this level is weaker than previous drinking water values considered by EPA such as 1 ppb. While EPA never adopted 1 ppb as an official DWEL, the assessment upon which it was based had undergone external scientific peer review. MassDEP's toxicological profile and health assessment for perchlorate utilizes an infant's body weight, intake rate and RSC. MassDEP has seen the correspondence from US EPA's Children's Health Protection Advisory Committee that 24.5 ppb is not protective of children.

Comment: *NRDC shares MassDEP view that National Research Council's (NRC's) RfD did not fully account for uncertainties. NRDC also concurs with scientists from ME and CT that NRC failed to consider key factors in their approach to determining an RfD. The NRC RfD is higher than what is needed to protect public health.*

Response: While the NAS-NRC's reference dose has an uncertainty factor of 10, MassDEP and its advisory committee thought an uncertainty factor of 30 would be the minimum value that would be protective and some members of the committee recommended 100 or 300. All of the issues supporting these uncertainty factors are contained in MassDEP's "*Update To Perchlorate Toxicological Profile and Health Assessment*" document and include concerns about the NAS no observed effect level and identifying a level of iodine uptake inhibition that is a non-adverse effect as also raised by health experts from Connecticut and Maine. MassDEP also recognizes that the NAS committee was not unanimous in its uncertainty factor recommendation. One member of that NAS committee recommended an uncertainty factor of 30 to account for the small number of subjects and the lack of chronic data.

Comment: *NRDC supports 20% RSC*

Response: MassDEP acknowledges NRDC's support for a 20% RSC value.

Comment: *NRDC comments on MassDEP's breast milk calculations.*

Response: NRDC has reviewed MassDEP's calculations indicating that perchlorate water levels must be low (<1.4 ppb) in order for breast milk values not to exceed the NAS RfD. MassDEP presents this information in a footnote, which we believe is a reasonable approach.

Comment: *NRDC provided 4 scenarios demonstrating that a perchlorate standard below 1 ppb would be appropriate based on the available data. NRDC recommends adjusting the RfD for a child's body weight of 10kg and default daily water consumption rate of 1 liter per day.*

Response: NRDC provided information on drinking water limits in the range of 0.046 ppb to 0.16 ppb based on scenarios involving infants, children age 2 and under, and for adults. MassDEP did not include calculations based on a child's body weight and water ingestion rate in its draft updated perchlorate toxicological profile and health assessment report but notes that the exposure assumptions used by NRDC are consistent with values MassDEP would typically use for children age 2 years and younger.

Comment: *NRDC believes an adjustment factor of more than 100 is supported by the available science. NRDC supports a total uncertainty factor 300 when deriving an RfD using the lowest dose in the Greer study.*

Response: This viewpoint is consistent with the views of some of the members of the MassDEP/DPH Advisory Committee on Health Effects. It results in drinking water perchlorate limits below 1ppb (i.e., 0.137 ppb and 0.161 ppb) using MassDEP's protocol. MassDEP scientists concluded and the majority of the advisory committee agreed that an uncertainty factor of 100 was appropriate.

Comment: *NRDC has commented that MassDEP has failed to consider the interactions of other contaminants that also inhibit iodine uptake (e.g., nitrate, thiocyanate).*

Response: MassDEP discussed this issue in its *Update to "Perchlorate Toxicological Profile and Health Assessment"* under data gaps and in support of an uncertainty factor for database insufficiency.

Comment: *MA DEP's proposed 2 ppb standard is a commendable step in the right direction, but we strongly recommend that the State finalize a standard of no more than 1 ppb to better protect vulnerable populations, including newborn infants.*

Response: When considering the full range of factors that play a role in the establishment of an MCL, including occurrence, analytical capabilities, treatment technologies, costs and other relevant risks it became clear that a risk management

strategy had to be applied. In large part due to the issue of perchlorate contamination from sodium hypochlorite an MCL above the anticipated range of this contribution was proposed. This ensures that the important practice of disinfection is not undermined and that the threat of public exposure to harmful microbes is avoided. Even with the application of what appears to be the best management practices known to date for the use of sodium hypochlorite the introduction of perchlorate cannot be avoided. The MCL of 2.0 ppb provides the best overall protection of public health, considering the benefits of disinfection, while retaining a margin of safety for sensitive populations. MassDEP is working with EPA to develop guidelines for the use of sodium hypochlorite so as to minimize the presence of perchlorate.

Comment: *Perchlorate monitoring mandated by MA DEP in 2004 revealed that perchlorate contamination was more widespread than suggested by data collected pursuant to the EPA Unregulated Contaminant Monitoring Rule (UCMR).*

Response: Analytical methods had been improved between the UCMR monitoring and our 2004 efforts allowing for lower detection limits.

#24 -- Upper Cape Regional Water Supply Council
William Henchy

Comment: *"We support the proposed detection limit at 1 ppb. Any detection limit below 1 ppb appears to be unreliable, based on current sampling technology."*

Response MassDEP is confident that the approved perchlorate testing laboratories can achieve a Method Reporting Limit (MRL) of 1.0 μg/L with a perchlorate Method Detection Limit (MDL) approximately 1/3 of the MRL. This confidence is based in part on a carefully crafted Proficiency Testing (PT) policy in which each laboratory received two whole volume PT samples prepared in a mixed common anion solution at a conductivity typical of, if not higher than, most MA public water supplies (500 μS/cm at 25°C). In the first PT study – one sample was a blank without added perchlorate and the other was spiked with perchlorate at 1.04 μg/L (assigned value). In this study, all laboratories, except two that are not MassDEP-approved, successfully analyzed the spiked sample, reporting a perchlorate concentration within ± 2 standard deviations of the study mean. In this PT study, the results clearly demonstrate that, in a water matrix with a conductivity typical of most MA drinking water supplies, 15 of the 17 participating laboratories (including all MassDEP-approved laboratories) reliably detected and quantitated perchlorate at a concentration of 1 μg/L without incurring false positives at 0.5 μg/L or higher. The MassDEP approved perchlorate testing laboratories have continued to perform well on subsequent low-level perchlorate PT studies. No proposed changes.

Comment: *The proposed "Harmonization" language in the MCP is useful and necessary. Strongly urge MassDEP to substitute the word "regulations" for the word "requirements" in the proposed language. Commenter expressed concern about policy being enforced as standards.*

Response: The proposed language makes specific reference to "applicable provisions of 310 CMR 22.00 and any other requirements specified by the Department *pursuant to its authority under M.G.L. c. 111, s.160 and 310 CMR 22.00*" (emphasis added), tying the requirements to explicit statutory and regulatory authorities. However, in order to address complicated environmental problems, these authorities are often expressed as performance standards that provide regulated parties and MassDEP flexibility to implement the best approach, considering many factors. MassDEP believes the current language is consistent with the applicable statute and regulations and reflects the proper application of its authority. No further changes are proposed.

Comment: *Strongly supports a legally enforceable clean up standard for perchlorate, given the Department of Defense pledge to comply with any duly promulgated, legally binding perchlorate cleanup standard.*

Response: Duly noted.

Comment: *The promulgation of "policies" and "health advisories" which contain substantive standards for drinking water supplies, as has occurred in the past and with perchlorate and in other settings, is inappropriate and unlawful.*

Response: Section 310 CMR 22.03(8) of the Massachusetts Drinking Water Regulations describes the Department's authority in this area:

In the event the Department finds on the basis of a health assessment made by the Department's Office of Research and Standards that the level of any contaminant found in water collected within the distribution system and/or at the sampling point at the entry to the distribution system, pose an unacceptable health risk to consumers, acting alone or in combination with other contaminants, public water system shall take appropriate actions to reduce the level of contaminant concentrations to levels the Department deems safe or remove the source of supply from service by the deadline specified by the Department. The supplier of water shall be required to monitor the source as directed by the Department, provide public notification and notify the Department of the actions it intends to take in response to a finding that a source of supply poses an unacceptable risk to health.

MassDEP's past requirements for public water systems with regards to perchlorate flow directly from this regulation. MassDEP set an interim guideline for perchlorate in response to a request from the Bourne Water District in 2001.

Comment: *…there remains a critical lack of input into the scientific process*

Response: MassDEP's scientific process included meetings and discussions with its long-standing DEP/DPH Advisory Committee on Health Effects and invited scientists from other institutions including the U.S. Department of Defense. MassDEP also met with two members of the NAS Perchlorate Committee to share viewpoints and perspectives on the scientific information and derivation of the RfD and associated drinking water limits. The Department's draft toxicological profile describes the studies, interpretation of the findings and steps towards setting a reference dose and associated water limits, thus providing transparency to the work effort. MassDEP views the public comment period and 6 public hearing forums important opportunities for broader input of MassDEP's work.

Comment: *We support a six-year review of any MCL for perchlorate.*

Response: MassDEP is committed to a review of the MCL, as specified in regulation.

#25 -- Health Risk Strategies

Gail Charnley

Comment: *The commenter states that there is no defensible scientific basis for the proposed perchlorate standard.*

Response: MassDEP disagrees. The scientific basis for MassDEP's perchlorate RfD is presented in detail in the agency's *Update to Perchlorate Toxicological Profile and Health Assessment.* This document reflected input from, and was reviewed by, the MassDEP-DPH Advisory Committee on Health Effects, a panel of independent scientists with extensive expertise in the areas of toxicology, risk assessment and epidemiology. This independent committee concluded that the basis of the proposed standard was well supported and appropriate. No change proposed.

Comment: *The commenter argues that a higher perchlorate standard should be adopted because the nitrate drinking water standard is associated with a much higher level of potential iodine uptake inhibition.*

Response: The nitrate drinking water standard, based on evaluations by USEPA, did not consider thyroid effects. Whether the nitrate standard should be revisited to account for potential effects on the thyroid was not evaluated by MassDEP in this assessment, which focused on perchlorate, and is not at issue in this public comment period. Drinking water limits for chemicals that act through the same or related mechanisms may not scale directly to toxic equivalencies, because final MCLs consider a number of additional factors, including technical and economic feasibility. No change proposed.

Comment: *The commenter notes that people are exposed to many thyroid toxicants through drinking water and the diet and suggests that despite these exposures there is "absolutely no evidence of an epidemic of hypothyroidism or adverse thyroid-related health effects".*

Response: MassDEP agrees that there is no epidemic of clinical hypothyroidism. As noted by the MassDEP/DPH Advisory Committee on Health Effects, hypothyroidism is an extreme endpoint and adverse effects of great concern (neurodevelopment damage) may occur in the absence of clinical disease. The available epidemiological data remains insufficient to conclude that exposure to thyroid active agents, including perchlorate, have been without any health impact. The results of some studies, including Tellez et al, 2005, suggest that effects may in fact occur. Widespread exposures to multiple thyroid toxicants, which can act through multiple pathways, limits the ability of epidemiological studies to associate exposures with specific effects.

Comment: *The commenter suggests that perchlorate intake from drinking water at 2 ppb would constitute a small share of total human goitrogen intake and therefore a higher drinking water limit for perchlorate is warranted.*

Response: There remains considerable uncertainly regarding the total, and the population distribution of, exposure to thyroid toxicants. Exposures to other thyroid toxicants, and from sources other than drinking water, do occur but this fact provides no legitimate justification for allowing levels of perchlorate in drinking water that endanger public health. In order to address total exposures to thyroid toxicants, exposures attributable to individual chemicals and exposure pathways must be addressed. This approach was supported by the MassDEP/DPH Advisory Committee on Health Effects. No change proposed.

#26 –Environmental League of Massachusetts

Megan Amundson

Comment: *The Environmental League of Massachusetts would like to commend DEP on its work to date in dealing with the perchlorate threat in Massachusetts. The regulations that DEP developed to deal with future perchlorate contamination are strong and measured.*

Response: Duly noted.

Comment: *We urge you to examine additional unregulated contaminants and set drinking water standards for those as well to avoid another emergency situation.*

Response: MassDEP will continue to follow EPA's lead in the identification and study of additional unregulated or emerging contaminants. MassDEP remains committed to taking action to protect the health of the citizens of the Commonwealth.

#27 – Massachusetts Water Works Association
James Marshall

Comment: *Ban the use of perchlorate-containing blasting agents and fireworks in Massachusetts. MassDEP should use its broad powers to initiate this ban and not simply enforce it through the water suppliers. Work with the legislature to ban perchlorate-containing materials in a Zone I, Zone II and Zone A's*

> **Response:** In cooperation with the Division of Fire Services, the Department has issued "Best Management Practices" for use of blasting agents (http://mass.gov/dep/cleanup/laws/blasting.htm) and will issue a similar document for fireworks displays.

Comment: *MassDEP should establish a water treatment/source development grant program funded through the MCP and fines levied on the sources of contamination.*

> **Response:** While MassDEP levies and collects penalties under the Massachusetts Contingency Plan, the money collected goes to the Commonwealth's General Fund and is not earmarked specifically for the Department.

Comment: *Commenter stated that "The difference between MassDEP and USEPA values raises serious concern about the standard setting process. Rejecting industry-supported studies because of a suspicion of bias is not scientific."*

> **Response:** MassDEP's proposed perchlorate MCL is lower than USEPA's drinking water equivalent level (DWEL), which is not an MCL. USEPA's protocol for deriving a MCL for non-carcinogens includes a source apportionment adjustment to DWELs to account for exposures beyond drinking water. USEPA guidance recommends that a source apportionment value of 20% be used in cases where data indicate that other sources of exposure to the chemical in question exist but where the data is insufficient to determine these levels precisely. This is the case for perchlorate and the use of the 20% factor is consistent with the Department's protocol for deriving drinking water guidelines and MCP groundwater cleanup standards. An equivalent USEPA MCL based on the USEPA DWEL and a 20% source apportionment factor equals 4.9 ppb. The proposed MassDEP MCL is lower than this equivalent value because the Department used a more health protective RfD value in its derivation, which is explained in the Department's *Update to Perchlorate Toxicological Profile and Health Assessment*. The application of risk management criteria addressing chlorination of drinking water supplies led to the final MCL value of 2 ppb. MassDEP reviewed studies based on scientific merit.

Comment: *Commenter suggests that basis of MADEP 2 ppb standard is that not everything is known and claims the final MCL is unreasonable.*

> **Response:** MassDEP used a well-established method to evaluate the toxicity data and derive an RfD including appropriate steps to account for data gaps. The MassDEP/DPH

Committee on Health Effects concluded that the approach used and conclusions reached were scientifically supported. No changes proposed.

Comment: *Commenter suggested there is a credibility gap when MassDEP stringently regulates drinking water and makes no effort to address the major sources of perchlorate in our diet.*

Response: Dietary sources of perchlorate exist and may be very significant. MassDEP does not have the jurisdiction or regulatory authority to address these sources. MassDEP decided that a standard for perchlorate was needed because: 1) this chemical was detected at the Mass Military Reservation and subsequently in other MA water supplies; 2) the department was asked for guidance by public water suppliers; 3) children are at risk; and, 4) there was no EPA standard in place.

Comment: *Commenter states that MassDEP has never performed a simple study to determine if non-drinking water sources of exposure are actually a concern in MA. MA should be obligated to use MA-specific data not national data.*

Response: There are no MA specific data on exposures to perchlorate from MA-grown food but there is considerable national data confirming the presence of this contaminant in foods. Perchlorate has also been detected in breast milk and urine samples at levels indicative of significant exposures from sources other than drinking water. Lacking more specific data, the methodology for deriving MCLs based on USEPA guidance uses a 20% source apportionment factor to account for other exposures as was done by MassDEP. Use of a 20% RSC is consistent with MassDEP's protocol for deriving drinking water guidelines and MCP cleanup standards and the Department's application of the 20% RSC for perchlorate is consistent with its use for other chemicals. No changes proposed.

Comment: *Commenter suggests that a probabilistic study by Douglas Crawford-Brown et al suggests an MCL slightly below 20 ppb would be protective.*

Response: The probabilistic study referenced by the commenter was reviewed and found to be uninformative. The paper includes incorrect statements and assumptions. For example the paper: (1) states that "….the (EPA) DWEL converts the RfD into an associated concentration in drinking water, taking into account the Relative Source Contribution (RSC) for water vs. other exposures routes". This is incorrect, as the DWEL does not include a RSC; and, (2) the authors argue that an RSC factor is not needed because the subjects in the Greer study were exposed to the other dietary sources that would be of concern in the US population and thus these were already accounted for in the study. This is incorrect. The iodine uptake inhibition dose-response determined in the Greer study was based on controlled, incremental doses of perchlorate over and above any other existing exposures. Any drinking water limit derived from data from this study would therefore still require an appropriate RSC adjustment. Furthermore, the assessment and its conclusions are based on the EPA DWEL, which lacks an RSC factor and is based on an RfD that MassDEP scientists and the MassDEP/DPH Advisory Committee on Health Effects viewed as being too high.

Comment: *Studies show perchlorate to be far less toxic than MassDEP believes. Why the rush to regulate?*

> **Response**: MassDEP used a well-established method to evaluate the toxicity data and derive an RfD including appropriate steps to account for data gaps. The MassDEP/DPH Committee on Health Effects concluded that the approach used and conclusions reached were scientifically supported. MassDEP has been working on perchlorate since 2001. MassDEP made a decision in 2003 to move forward with setting standards for perchlorate so that contaminated groundwater would be cleaned up and public health protected. MassDEP also extended its standard setting schedule in January 2005 at the request of the U.S. Department of Defense to take into account the NAS report. MassDEP has reviewed the scientific studies on perchlorate and has not found data to show that perchlorate it far less toxic than previously found. No changes proposed.

Comment: *It is suggested that the costs for public notification, treatment or development of new supplies for systems with perchlorate contamination less than 15 ppb should be borne by the Commonwealth.*

> **Response:** MassDEP has determined that perchlorate represents a threat to public health requiring regulation. Although no direct funding is available for public notification, the Drinking Water State Revolving Fund low interest loan program is available for water systems that need to address perchlorate contamination through capital projects such as the installation of treatment. Additionally, perchlorate monitoring is eligible to be reduced at those systems without contamination issues via the Inorganic Monitoring Waiver Program thereby minimizing monitoring costs.

Comment: *MWWA is not opposed to the regulation of perchlorate in drinking water by MADEP. The process to set a MCL and the choice of an appropriate MCL would have been enhanced had MADEP chosen to engage MWWA and the water supply community in open and frank discussions on the matter over the course of the past two years.*

> **Response:** MassDEP has participated in many activities that gave a wide range of stakeholders the opportunity to comment on many aspects of our work with perchlorate including the toxicological review of perchlorate, implementation of the occurrence monitoring, compliance determinations vis-à-vis the advisory level and now the proposal of an MCL. These public hearings on the proposed regulations are another example of these opportunities.

#28 – Town of Acton
Stephen Anderson

Comment: *MassDEP should issue an advisory suitable for local BOH to educate private well owners with appropriate steps for private well owners to take to protect themselves.*

Response: MassDEP agrees that continuing education for local Boards of Health is important and the Department commits to developing guidance to inform private well owners about perchlorate. MassDEP already has extensive information available on its website specific to private well owners, at http://mass.gov/dep/water/drinking/privatew.htm

#29 -- Massachusetts Chemistry and Technology Alliance
Armin Steiner

Comment: *Perchlorates can be formed in measurable quantities during lightning storms.*

Response: Research has indicated that perchlorate can be formed during lightning storms, but that appears to be more problematic in arid climates, not the Northeast United States. Further, the occurrence monitoring conducted to support the development of the proposed MCL has demonstrated that perchlorate is *not* ubiquitous in Massachusetts groundwater.

Comment: *MCTA recommends that MassDEP set a maximum concentration closer to 24.5 ppb.*

Response: MassDEP and the MassDEP/DPH Advisory Committee on Health Effects, along with the U.S. EPA's Children's Health Protection Advisory Committee, the states of New Jersey and California and other scientists have recommended drinking water limits less than 24.5 ppb to protect public health, especially sensitive subgroups. The US Centers for Disease Control recently tested human subjects and found that they all tested positive for perchlorate exposure even though their drinking water had non-detectable levels of perchlorate, indicating significant exposures from another source. Mass DEP and the U.S. EPA's Children's Health Protection Advisory Committee believe that a level of 24.5 ppb of perchlorate in drinking water isn't protective of infants who could be exposed via breast milk or formula. No proposed changes.

Comment: *EPA has studied perchlorate since at least 1999 and established preliminary guidelines for groundwater contamination in drinking waters from 4 to 18 ppb. A number of studies recommend higher levels as safe. EPA in 2006 issued a new RfD based on NRC and the EPA maximum concentration in drinking water is 24.5 ppb, 12 times higher than the proposed DEP standards.*

Response: The 4 to 18 ppb range was based on a study published in 1952, where only 6 subjects with hyperthyroidism were given a single dose of perchlorate. This EPA guidance of 4 – 18 ppb for superfund sites also recommended carefully considering a

value at the lower end of the range. MassDEP has reviewed the scientific studies, including many not available to the NAS, has followed its standing protocol for deriving drinking water limits and does not think 24.5 ppb is safe for sensitive subgroups. No proposed changes.

Comment: *The Massachusetts Chemistry and Technology Alliance commends the Department of Environmental Protection for addressing potential health hazards caused by perchlorates in drinking water and proposing the establishment of maximum standards for perchlorate contamination. However, we contend that the proposed levels in drinking water and in groundwater are too difficult and too costly to achieve, and are considerable lower than the guidelines established by EPA.*

Response: Established treatment technologies, such as ion exchange, have been installed both in Massachusetts and other states that are both reliable and cost effective in removing perchlorate to levels below 2 ppb.

Comment: *Municipalities that have changed their method of disinfecting drinking water from the extremely hazardous compound chlorine to the less hazardous chemical sodium hypochlorite (bleach), will at times have severe difficulties reaching the proposed level of less than 2 ppb of perchlorate without additional treatment requiring the installation of costly equipment.*

Response: MassDEP's experience with the introduction of perchlorate through the use of sodium hypochlorite has shown that in most cases the resulting levels of perchlorate is in the order of a few tenths of a part per billon. In the one case where hypochlorite was shown to be the cause of slightly more than 2 ppb in the finished water the application of best management practices has successfully lowered the perchlorate without the installation of any additional treatment.

Comment: *The current proven technologies available for reducing perchlorate levels in drinking water as well as groundwater are near the asymptotic part of the removal curve at 2 to 4 ppb, making the removal of the last 3 to 5 ppb cost prohibitive.*

Response: The treatment data reviewed by MassDEP do not support this comment. Treatment costs expressed either in terms of resin replacement costs or as the percentage of resin utilization does not approach an asymptotic limit until an effluent level well below 1 ppb.

#30 - Clean Water Action

Becky Smith

Comment: *MassDEP should issue an advisory suitable for local BOH to educate private well owners with appropriate steps for private well owners to take to protect themselves.*

Response: MassDEP agrees that continuing education for local Boards of Health is important and the Department commits to developing guidance to inform private well

owners about perchlorate. MassDEP already has extensive information available on its website specific to private well owners, at http://mass.gov/dep/water/drinking/privatew.htm

Comment: *MassDEP should support and provide testing for private wells to give private well owners the same level of protection as public supplies.*

Response: MassDEP's statutory authority under the Drinking Water Program does not extend to the regulation of private drinking water supplies. MassDEP cannot address private wells in the same manner as it regulates public water supplies. The regulation and permitting of private wells are in the hands of local officials. However, the Department does regulate releases of oil or hazardous material (such as perchlorate) to the environment under M.G.L. c.21E and the Massachusetts Contingency Plan ("MCP"). Once Reportable Concentrations and cleanup standards are established under the MCP as described in this proposal, the Department will address private wells contaminated by perchlorate within the existing regulatory process. MassDEP seeks to ensure that contamination in a private well is addressed by the party(ies) responsible for the release.

Comment: *Ban the use of perchlorate-containing blasting agents and fireworks in Massachusetts. MassDEP should use its broad powers to initiate this ban and not simply enforce it through the water suppliers. Work with the legislature to ban perchlorate-containing materials in a Zone I, Zone II and Zone A's*

Response: In cooperation with the Division of Fire Services, the Department has issued "Best Management Practices" for use of blasting agents (http://mass.gov/dep/cleanup/laws/blasting.htm) and will issue a similar document for fireworks displays.

Comment: *We recommend, however, that the DEP set the Maximum Contaminant Level (MCL) for perchlorate at 1.0 ppb or less. Both the health evaluation performed by DEP and other studies show that any level above 1.0 ppb would threaten sensitive populations.*

Response: When considering the full range of factors that play a role in the establishment of an MCL, including occurrence, analytical capabilities, treatment technologies, costs and other relevant risks it became clear that a risk management strategy had to be applied. In large part due to the issue of perchlorate contamination from sodium hypochlorite an MCL above the anticipated range of this contribution was proposed. This ensures that the important practice of disinfection is not undermined and that the threat of public exposure to harmful microbes is avoided. Even with the application of what appears to be the best management practices known to date for the use of sodium hypochlorite the introduction of perchlorate cannot be avoided. The MCL of 2.0 ppb provides the best overall protection of public health, considering the benefits of disinfection, while retaining a margin of safety for sensitive populations. MassDEP is working with EPA to develop guidelines for the use of sodium hypochlorite so as to minimize the presence of perchlorate.

Comment: *We recommend that DEP develop a program to require monitoring for unregulated contaminants (a) that were on the UCMR-1 list until the UCMR-2 program begins, and (b) that may be present in water supplies based on the potential threats identified in SWAP reports for each water supplier. If any unregulated contaminant is detected there should be follow-up to identify the specific source(s) and take action to reduce or eliminate its presence in drinking water.*

Response: MassDEP will continue to follow EPA's lead in the identification and study of additional unregulated or emerging contaminants. The Department remains committed to taking action to protect the health of the citizens of the Commonwealth.

31 – Aquarion

Larry L. Bingaman

Comment: *Aquarion recognizes that there is an ongoing debate over what level of perchlorate is acceptable in drinking water supplied to the public, especially sensitive subpopulation groups. Aquarion seeks to provide the highest quality, safest water to its customers at a reasonable cost. It is important to Aquarion that MA DEP establish a firm, fair and consistent standard that will protect the public health and allow Aquarion to provide safe drinking water. A firm standard will also allow Aquarion to obtain reimbursement from others responsible for perchlorate contamination to keep rates as low as possible. Since the proposed standards accomplish these goals, Aquarion supports the 2 ppb contamination cleanup standards proposed by MA DEP.*

Response: Duly noted.

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