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# Assembly California Legislature

JOHN LAIRD  
ASSEMBLY MEMBER, TWENTY-SEVENTH DISTRICT



STATE CAPITOL  
P.O. BOX 942846  
SACRAMENTO, CA 95834-0027  
PHONE (916) 227-2027  
FAX (916) 319-2127

DISTRICT OFFICES  
SANTA CRUZ COUNTY  
301 OGDEN STREET, SUITE 218B  
SANTA CRUZ, CA 95060  
PHONE (831) 426-2300  
FAX (831) 426-2300  
MONTEREY AND SANTA CLARA COUNTIES  
300 PACIFIC STREET, SUITE 555-11  
MONTEREY, CA 95040  
PHONE (831) 549-2367  
FAX (831) 424-2367

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## PERCHLORATE MAXIMUM CONTAMINANT LEVEL PROCESS

We are currently waiting for both the state and federal governments to set maximum contaminant levels for perchlorate. The level that is set will have important repercussions for both the industries that utilize perchlorate and those affected by perchlorate contamination. Here is a description of the regulatory process to establish these levels.

### General California Maximum Contaminant Level (MCL) Process

California uses a two step process, risk assessment and risk management, in establishing safe levels for a constituent in drinking water. Under the California Safe Drinking Water Act, the Department of Health Services (DHS) is charged with setting primary drinking water standards. These standards must be as stringent as or more stringent than the corresponding federal standard for a given constituent. DHS must set the primary drinking water standards (a.k.a. maximum contaminant levels (MCLs)) at levels as close as possible to the corresponding public health goals, to the extent technologically and economically feasible.

The first step in the process of developing an MCL for any constituent in drinking water is the development of a Public Health Goal (PHG) for the constituent by Cal/EPA's Office of Environmental Health Hazard Assessment (OEHHA).

In setting the PHG, OEHHA focuses on protecting human health.<sup>1</sup> OEHHA sets PHG's using the most current principles and methods used by practitioners in the fields of epidemiology, risk assessment and toxicology. Where the science is not complete, OEHHA is directed to add in an additional margin of safety after considering other factors such as synergistic effects, groups with particular sensitivities and additional potential pathways of exposure. In the case of perchlorate, infants and people with thyroid problems may be at particular risk.

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<sup>1</sup> In this risk assessment portion, OEHHA evaluates the risk to public health posed by the contaminant and, based on the results of the risk assessment, establishes a PHG. The PHG is the level at which the contaminant will not pose a significant risk of either acute or chronic effects to human health. In determining the PHG for a contaminant, OEHHA is allowed to consider only health-related data. A PHG is not an enforceable regulatory number; rather, it is the health-related number that is used to determine the regulatory MCL.

Only after the PHG is established can the Department of Health Services (DHS) establish the MCL. Note that Health and Safety Code § 116365(a) requires DHS to set the MCL as close to the PHG as is technically and economically feasible. Technical feasibility may include factors such as laboratories' ability to detect or analyze constituents. Cost factors may include cost of monitoring and cost of treatment.<sup>2</sup>

### **Establishment of a Perchlorate MCL for California**

The Public Health Goal:

In 2002, SB 1822, by Senator Byron Sher, passed which set specific deadlines for the issuance of the state PHG and MCL. Pursuant to H&S Code § 116293 OEHHA was required to establish the PHG for perchlorate by January 1, 2003 and DHS was required to establish the MCL for perchlorate by January 1, 2004.

Three reviewers selected by the University of California in October of 2003 commenced an independent peer review of the proposed PHG. That peer review is now complete as of January 13, 2004. OEHHA staff feels that the review comments can be addressed and that the reviewers are generally supportive of OEHHA's approach in establishing this PHG.<sup>3</sup>

The draft perchlorate PHG proposed by OEHHA is 2-6 ppb. There was no consensus by the UC reviewers for the final PHG. Their recommendations varied depending on the uncertainty factor used and the level of public health protection to be achieved: Peer Reviewer #1 recommended 180-220 ppb; Peer Reviewer #2 recommended 2 ppb; Peer Reviewer #3 recommended 18.6 ppb.

The law clearly requires OEHHA to set the PHG (the risk assessment portion) at a level based "exclusively on public health considerations" and to take into account a host of safety factors, including synergistic effects of other contaminants, exposure levels, and sensitive sub-populations. [see Health and Safety Code Section 116365 (c)]. In this case, key factors of concern include potential disruption of thyroid hormone production that could affect metabolism, brain development and growth. Pregnant women and their developing fetuses are sensitive sub-populations of concern.

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<sup>2</sup> In the risk management portion of the process, DHS adopts the MCL. In order to determine feasibility, DHS evaluates the water treatment technologies that are available to reduce concentrations of the contaminant and the costs of using those technologies. After balancing the public considerations of allowing concentrations of the contaminant in public water supplies that are above the PHG against the cost of reducing the concentration, DHS sets the MCL that is the enforceable standard and represents the highest concentration of the contaminant that may be present in public water supplies.

<sup>3</sup> OEHHA actually completed a proposed draft PHG in March of 2002. This draft PHG suggested a PHG up to 6 ppb. At the time, the degeral draft perchlorate risk assessment by the U.S. EPA proposed a 1 ppb drinking water equivalent level. However, both SB 1822 deadlines were delayed when a court ordered an additional scientific peer review pursuant to a challenge by Lockheed Martin Corp. and Kerr-McGee Chemical LLC.

Unless any problems arise, OEHHA feels that the PHG will likely be issued within the required 60 days.

However, perchlorate manufacturers and users and some utilities/water suppliers argue that OEHHA should delay further any determination until the National Academy of Sciences (NAS) completes its review at the federal level. The Association of California Water Agencies has taken this position. They argue that the review NAS will provide the best science on the issue. While this review is not expected until fall of 2004 some think it might take as long as 2 years.<sup>4</sup>

DHS cannot proceed with the MCL process until the PHG is established. Until the MCL is established the DHS will continue to use 4 ppb as the action level.

#### The Maximum Contaminant Level:

Once the perchlorate PHG is established, DHS can start formulating the MCL (the risk assessment portion). In setting the MCL deadline at January 1, 2004, SB 1822 envisioned the maximum time needed by DHS to establish the perchlorate MCL after they receive the PHG to be one year. If it only takes them a year that would put the establishment of the MCL sometime in early to mid 2005.<sup>5</sup>

Upon receiving the perchlorate PHG, DHS will begin its internal process of conducting the technical and economic feasibility study. In this process DHS:

- selects possible draft MCL concentrations for evaluation
- evaluates the occurrence data
- evaluates available analytical methods and estimate monitoring costs at various draft MCL concentrations
- estimates population exposures at various draft MCL concentrations of the chemical
- identifies best available technologies for treatment
- estimates treatment costs at the possible draft MCL concentrations
- reviews the costs and associated health benefits (health risk reductions) that result from treatment at the possible draft MCL concentrations
- selects a MCL for proposal from the possible draft MCL concentrations considered above.

In formulating the proposed MCL, DHS will assess whether or not there is adequate justification to set the MCL at a level higher than the PHG because of cost or technical feasibility. This should take about 2-3 months.

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<sup>4</sup> Remember that the NAS has no regulatory authority to set either a PHG or MCL federal equivalent. U.S. EPA must act to do that. Indeed, in July 2003, the U.S. EPA decided that it would no longer pursue efforts to formulate safety standards for any of the constituents on the current federal contaminant candidate list (including perchlorate).

<sup>5</sup> On the other hand, DHS has known that this PHG would be coming for some time and has reportedly commenced some of the tasks not directly dependent on having a final PHG, which could shorten the time period required to publish a draft MCL.

With non-carcinogenic constituents DHS generally goes with the PHG. Perchlorate is non-carcinogenic. (With carcinogenic constituents DHS takes into consideration risk levels from 1:1,00,000 to 1:10,000.)

Once DHS establishes their proposed MCL, which includes a statement of reason and a fiscal impact, the document goes to several agencies for review: DHS' Office of Regulations, DHS' Budget Office, the Department of Finance, the Health & Human Services Agency (HHS).

Review by the Department of Finance (DOF) is the major review. Generally, DOF reviews of this type takes 2-3 months. However, DHS expects that there may be some slow down due to the need for educating the DOF and the new administration at the decision-making level.

Once the DOF approves the document, the proposal is sent to the Office of Administrative Law (OAL) for review and publication in the *California Regulatory Notice Register* announcing the availability of the regulation for a 45-day public comment period. If changes are made at this point the document will be put out for another 15-day public comment period. A public hearing can be requested but generally they are not.<sup>6</sup> These hearings are not give and takes, just an additional comment opportunity.

DHS must respond to each comment. Depending on the complexity and number of comments the response period can take 1-3 months.

DHS is expecting most of the comments to come from the manufacturers who use perchlorate and the U.S. Department of Defense (DOD). They will likely argue that attaining the level set is too low to attain health goals and is too costly. In addition DHS expects the manufacturers to argue that the fiscal impact analysis did not take into consideration the cost to the manufacturers.

Once DHS completes its responses to the comments OAL has 30 days to review the responses.

After the public comment process is completed the proposed MCL is sent to the DHS Director's Office for approval followed by a final review by the OAL. Upon approval by the OAL, the regulation is filed with the Secretary of State and becomes effective 30 days later unless DHS asks for immediate implementation.

According to DHS this process takes about one year from the time they receive the PHG. Unless there are complications we can expect a MCL by mid-2005.

According to DHS, the Governor's executive order to halt regulations that are in process will not affect the establishment of a perchlorate MCL. The executive order was directed at regulations already in the review process. Because the DHS review process had not started

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<sup>6</sup> However, given the extensive lobbying effort at the state level in the legislature and with the administration to have the setting of the PUG delayed until the NAS report is complete, active participation in any public comment periods can be expected.

they can proceed and can address the executive order requirements in their review. The executive order requires that the review contain:

- 1) The impact of the adopted, amended or repealed regulations on California businesses as required by California Government Code section 11346.3;
- 2) The authority for the adopted, amended, or repealed regulations pursuant to California Government Code sections 11342.1 and 11342.2; and
- 3) Conformity of the adopted, amended, or repealed regulations with the criteria set forth in California Government Code section 11349.1, of necessity, authority, clarity, consistency, reference and non-duplication.

### **Federal establishment of a perchlorate MCL**

The first step in establishing a federal MCL is the establishment of a Reference Dose (RD). This is similar to the state establishing a PHG.

The U.S. EPA has taken a two-step approach in establishing the RD for perchlorate. In the first step U.S. EPA undertook a nation-wide testing of drinking water systems for perchlorate to determine whether it is a widespread problem requiring a national standard.

The second step involves the risk assessment to establish a RD. The RD is the amount of the constituent that U.S. EPA considers safe if consumed every day. U.S. EPA published its draft risk assessment that proposed a RD of 1 ppb of perchlorate in drinking water. However, the Bush administration has pulled the draft back claiming that more work needed to be done.

Apparently, DOD is lobbying the administration for a RD of 200 ppb.

The federal MCL cannot be established until the RD is formally adopted. In the process of establishing a federal MCL, U.S. EPA must take into consideration the economic and technical feasibility of meeting the MCL.

U.S. EPA has asked the NAS to review its analysis and the underlying scientific studies that are the basis for the draft RD. This analysis is due back to the U.S. EPA by December 2004. However, some feel the NAS study could take up to 2 years. That would take us to 2006. Then the U.S. EPA could take another 2 years (2008) to redraft their RD.

U.S. EPA will then recommend a final RD for perchlorate. Based on economic, technical and other considerations the U.S. EPA will set the MCL as close to the RD as is feasible. This second phase could take an additional 2 years. That puts us to 2010.

The Bush administration claims that the entire process will only take 2 years, giving us a final federal MCL in 2006.

While the state can impose a more restrictive MCL than the federal government, the legal effect of the state MCL regarding federal clean-ups is not settled. Apparently, at Super Fund

sites the state MCL would be considered an alternate regulation that the federal government is supposed to follow. However, the DOD has argued that they would not have to follow the more restrictive state MCL.<sup>7</sup>

In addition the DOD is seeking an exemption from the state regulations for themselves and their sub-contractors.

**Discussion:**

In the absence of state or federal MCLs for perchlorate California uses 4 ppb as an action level for drinking water.

In the absence of a state-set MCL, or if the federal MCL is more protective than the state standard, the federal MCL is the standard used.

However, if there is no federal MCL, or the state MCL is more protective than the federal MCL, the state standard prevails. There are some, such as DOD, who may argue in certain instances such as Superfund sites the, presumably, more relaxed federal standard should apply. In addition, the DOD is currently seeking an exemption from state standards for themselves and their sub-contractors.

Even under the most optimistic scenario the federal MCL may not be finalized before the state MCL.

The state MCL process is moving forward but is about one to one and a half years behind the statutory deadline. There may be further delays along the way, in particular if the administration is listening to the manufacturers.

The level of the MCL could have a large effect on the perchlorate issue in south Santa Clare County. Currently, California is using 4 ppb as the "action level". Of the 1500 wells tested in the Morgan Hill/San Martin area about 450 have tested between 4 and 10 ppb, with most of them at the lower end. The rest of the wells have tested below 4 ppb. If the MCL is set higher or lower than 4 ppb it could have a great impact on how we view the perchlorate issue in this area.

For instance, if the MCL is set at the low end of the PHG, 2 ppb, many more wells than 450 will then be considered contaminated. If, however, the MCL is set higher than 4 ppb we will see a reduction in wells that are considered contaminated. If it is set as high as 10 ppb nearly all the wells will be considered safe.

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<sup>7</sup> In June 2003, former Cal/EPA Secretary Winston Hickox sent a letter requesting federal cooperation in cleaning up DOD installations in California. Assistant Deputy Under Secretary of Defense for Environment John Paul Woodley, Jr. provided an equivocal answer in July 2003. Follow up letters from individual Regional Water Quality Control Boards requesting perchlorate information at military installations remain unanswered.