



Established in 1918 as a public agency

Coachella Valley Water District

Directors:

Patricia A. Larson, President
Peter Nelson, Vice President
Tellis Codekas
Franz W. De Klotz
Russell Kitahara

Officers:

Steven B. Robbins, General Manager-Chief Engineer
Julia Fernandez, Board Secretary

February 15, 2011

Redwine and Sherrill, Attorneys

File: 0022.114.32

Michael Baes (mbaes@oehha.ca.gov)
Pesticide and Environmental Toxicology Branch
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
1515 Clay St., 16th floor
Oakland, CA 94612

Dear Mr. Baes:

Subject: Draft Public Health Goal for Hexavalent Chromium in Drinking Water

We appreciate the opportunity to provide comments on the draft public health goal (PHG) for hexavalent chromium (Cr6). Coachella Valley Water District (CVWD) provides domestic water, wastewater, recycled water, irrigation/drainage and regional storm water protection services to a population of 265,000 throughout the Coachella Valley.

The Office of Environmental Health Hazard Assessment (OEHHA) draft Cr6 PHG of 0.02 parts per billion (ppb) is calculated from cancer observed in the National Toxicology Program rodent study completed in 2007. Specifically, this calculation is based on cancer found in the small intestines of 5 of the 50 male mice exposed to drinking water containing 90,000 ppb of Cr6 for 2-years or the typical life span of a mouse. The male mice in this study that received doses of 5,000 ppb, 10,000 ppb and 30,000 ppb showed no statistically significant increase in cancer when compared to cancer observed in control mice receiving no Cr6 in their drinking water. It was also the case that female mice, male rats and female rats used in the NTP study showed no increase in cancer after ingesting Cr6 in their drinking water for a 2-year life span at levels up to 600 times higher than the current California drinking water maximum contaminant level (MCL) of 50 ppb for all forms of chromium, including Cr6.

While this data clearly shows a threshold below which no increased cancer was observed in the rodents, OEHHA is allowed to use a default linear dose response model when there is insufficient data to explain the mode of action by which the 5 male mice developed cancer in their small intestines. This gap in science is used by OEHHA to move forward with a precautionary linear model assumption and to disregard the fact that no increased cancer was found in rodents when Cr6 levels in their drinking water were less than 1,000 times greater than the current drinking water MCL for chromium.

OEHHA continues to disregard this important gap in the science used to support the draft Cr6 PHG. For example, one of the important findings of the peer review completed on the 2009 draft Cr6 PHG is that the majority of reviewers concluded that the rodent data used from the NTP study to develop the draft PHG is consistent with a non-linear (threshold) dose response curve. OEHHA has failed to acknowledge this important outcome of the peer review. Dr. Cohen states, "It is clear that the data presented in the Draft document (c.f. Figure 13; *Editorial note: abscissa needs the addition of units as the values shown do not correspond to any of the reported doses in Tables 5 and 6*) shows that tumor formation in the mice as a function of Cr6+ level in drinking water is not linear." Dr. Rossman provides several reasons objecting to the use of a linear dose response model for the draft PHG and supporting his statement, "The assumption is that Cr(VI) in drinking water has a mutagenic MOA with no threshold. This is not valid for the following reasons." Dr. Snow states, "Based on this study, along with very limited evidence of tumor response at lower levels of Cr6, there is very limited evidence for a linear dose response. It is more likely, due to the high probability of extracellular conversion of the Cr6 to the much less toxic Cr3, that uptake and bioavailability of the Cr6, in itself, will exhibit a non-linear (threshold) dose response."

OEHHA has also disregarded and twisted the scientific opinion of one of the most highly respected toxicologists on the subject of Cr6 toxicology. Dr. Silvio De Flora has studied Cr6 toxicity for over 30 years and many of his studies are referenced in the draft PHG. Dr. De Flora provided scientific support for the threshold mechanisms for Cr6 toxicity and carcinogenicity in comments to OEHHA dated October 19, 2009. Dr. De Flora also explained, using simple logic, the problem with OEHHA using the default linear assumption. While the study results include statistically significant decreases in certain tumors in the Cr6 exposed rodent test groups, these findings do not support a health benefit from ingesting Cr6 just as the statistically significant increase in cancer observed in male mice at the highest Cr6 dose is not biologically significant and does not bear relevance to human exposures.

The NTP study report is actually based on three distinct studies: a clinical study, a histopathology study, and a tissue distribution study. While the clinical study is used to support the PHG, the histopathology and tissue distribution studies are given little consideration by OEHHA. The tissue distribution study clearly showed no increase in Cr6 levels in the tissues studied when rodents ingested 5,000 ppb of Cr6 for one year. Likewise, rodents exposed to 5,000 ppb of Cr6 for 2-years in the histopathology study showed no excess cancers. This NTP data supports the well-established observation that the reductive capacity of the mammalian stomach can convert Cr6 to the non-toxic reduced form of chromium even at levels 100 times greater than the current California drinking water MCL for chromium. OEHHA and the peer reviewers also failed to identify some important information missing from the tissue distribution study. The scope of this study included the collection of samples of 4 specific tissues from each of the 10 animals selected from each test group. However, the summary tables (Table J1 and J2) for this study only include results for 3 to 6 animals depending on the tissue. No explanation has been provided for why the additional tissue data has not been made available to the public. Cr6 levels in these remaining tissues could be used to help evaluate the mode of action of Cr6 in the digestive tract of rodents.

OEHHA takes the position that using a more precautionary linear model assumption when there is a gap in available science is justified and the best way to reduce health risks. CVWD disagrees with this position. OEHHA should recognize that their risk assessments can have a serious negative impact on public health when PHG's are overly precautionary. OEHHA risk assessments are used by California Department of Health Services staff to weigh the costs and benefits of setting drinking water MCLs. Overly precautionary PHG's inflate the health benefits and can mistakenly be used by CDPH to justify adopting lower and more costly drinking water MCLs without a corresponding health benefit. This action would then commit limited community resources to unnecessarily remove constituents from drinking water based on inflated health benefits and reduces the community resources available to address real health threats.

CVWD believes OEHHA's role in completing risk assessments should be driven by using good science and not just the best available data. This role starts by helping to design research studies in a manner that will provide good science. Studies that focus on exposing rodents to unrealistic levels of an element to illicit an adverse response do not provide the good science needed to properly predict potential health risks at realistic low levels of exposure. Studies designed to properly evaluate the mode of action and provide sufficient information to determine if a threshold dose response exists for the subject element is critical to completing an accurate risk assessment. This is particularly important when the element is known to occur naturally in California drinking water like Cr6. The likelihood of a negative impact on public health caused by overly precautionary PHG's is greater for elements that occur naturally in drinking water.

The obvious gap in science used to support the draft Cr6 PHG has already been identified and studies are ongoing to help determine the mode of action for Cr6 toxicity observed in rodents. These studies are nearing completion and are designed to provide a more thorough understanding of the mode of action and other critical issues that should be included in a Cr6 risk assessment for drinking water. The U.S. Environmental Protection Agency believes these studies are important enough to be considered before completing the national Integrated Risk Information System risk assessment for Cr6. CVWD urges OEHHA to follow the progress of this work and to consider the results of these studies before completing the risk assessment needed to support a California drinking water PHG for Cr6.

If you have any questions, please call me at extension 2286.

Yours very truly,



Steve Bigley
Environmental Services Manager

SB:ch\eng\wr\11\FEB\Cr6 PHG Comments