



Association of California Water Agencies

Leadership Advocacy Information *Since 1910*

February 15, 2011

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, California 94612

Re: Proposed Public Health Goal for Hexavalent Chromium in Drinking Water

To Whom It May Concern:

The Association of California Water Agencies (ACWA) appreciates the opportunity to comment on the proposed public health goal (PHG) for hexavalent chromium in drinking water. ACWA represents nearly 450 public water agencies in California that collectively supply over 90% of the water delivered in California for domestic, agricultural and industrial uses.

We have the following specific comments on the proposed PHG for hexavalent chromium in drinking water.

Initial comment period

During the initial comment period for the PHG, we made several comments regarding the draft technical comment that we would like to reiterate in this letter.

As indicated in the draft PHG document, several studies previously estimated that saliva and stomach fluids have the capacity to reduce hexavalent chromium to trivalent chromium in amounts much larger than the “maximum plausible levels of hexavalent chromium in water that would likely be ingested by humans...” The document further asserts that “...exhaustion of the capacity of saliva and gastric fluids to reduce hexavalent chromium appears unlikely.”¹ ACWA understands other studies exist and are referenced in the document providing evidence that complete reduction may not always occur, but we believe the administered doses in the NTP study are so large they easily overwhelmed the reductive capacity of both the oral cavity and the stomach in the rodents. This is especially significant as the NTP study did not find excess cancers at the lowered studied doses in both rats and mice. Equally as important, the stomach

¹ “Draft Public Health Goal for Hexavalent Chromium in Drinking Water,” Office of Environmental Health Hazard Assessment, December 2010

composition of humans and rodents is very different, with humans having a much more sophisticated and higher level of gastric juices than rodents.

In addition, we have concerns with the interpretation and use of data from a key study submitted as evidence that hexavalent chromium in drinking water is a human carcinogen. The Borneff et al study is seriously flawed due to the fact there was only a single-dose level examined and an ectromelia epidemic affected both control and treated groups with significant loss of mice. ACWA still feels this study should not be considered in the development of the PHG.

NTP Study Results

Upon reviewing the results again of the 2007 study by the National Toxicology Program, another key study used in the development of the draft hexavalent chromium PHG, it has come to our attention that a certain percentage of the results were not available to the public for review.

This report is actually based on three distinct studies: a clinical study, a histopathology study, and a tissue distribution study. In the latter study, 200 mice and 200 rats were given hexavalent chromium in their drinking water at five different concentrations, 0, 5, 20, 60, and 180 mg/L. After 6, 13, 182, and 371 days 10 rats and 10 mice from each of the five exposure groups were sacrificed and various organs and excreta were removed, weighed, and analyzed to determine chromium concentration.

The organs exposed to the largest concentrations of chromium and that were in most immediate contact with the chromium were the forestomach, glandular stomach, serum, and red blood cells. In examining the results provided it is clear that after a year of exposure to 5 mg/L of hexavalent chromium, none of the mice or rats showed any higher concentrations of chromium in these four tissues than did the mice or rats in the control population exposed to no hexavalent chromium. Further, none of the rodents exposed to 5 mg/L hexavalent chromium for two years in the histopathology showed any excess cancers. The NTP data supports the well-established observation that the reductive capacity of the mammalian stomach can convert hexavalent chromium to the non-toxic reduced chromium at even very high concentrations.

In addition, we believe this point would be made clearer if the public had access to the results of the full study. In examining the results of the tissue distribution study as presented in Tables J1 and J2 of the above mentioned study, only three results are presented for each exposure group per sample period instead of ten. In addition, there are six results for plasma instead of three, which is the case for all of the other tissues. We are uncertain as to why this data has not been made available to the public, but we believe that the results are a critical part of the study and would be of great significance in order to begin evaluating the mode of action of hexavalent chromium in the digestive tract of rodents. ACWA encourages OEHHA to work with NTP to make the additional information publicly available. The complete set of 10 results per organ would have been very helpful to ACWA in its effort to assess OEHHA's draft PHG document.

Peer Review of 2009 Draft PHG

In addition, one of the results of the peer review 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."

ACWA believes this peer review provides strong support for additional research to fill the obvious gap in the current science related to the dose response model used to calculate the draft PHG from the NTP rodent study. By using a default linear dose response model, when the data supports a non-linear dose response, OEHHA is justifying an overly conservative PHG based on an assumption that represents the most critical driver for the PHG calculation. OEHHA should make filling this gap in the research supporting the draft PHG one of its highest priorities.

Additional Studies

ACWA believes the best available science should be used in the development of risk assessments, such as the draft hexavalent chromium PHG developed by OEHHA and EPA's toxicological review currently underway. As stated above, we also feel additional information and studies on the potential risks of a drinking water contaminant only serve to strengthen the validity of the hexavalent chromium PHG, particularly because of the statements made by the peer reviewers and the statement in OEHHA's draft technical document that "there is not a consensus as to the precise mechanism(s) of carcinogenesis [for hexavalent chromium]."² Comments were made during the 2009 comment period, such as those submitted by Dr. Silvio De Flora, which also posed significant questions about existing data and should be considered carefully when finalizing the PHG.³ Further, the California Department of Toxic Substances Control (DTSC) indicated in a 2008 internal memo that the NTP study does not address the mode of action of hexavalent chromium via the ingestion pathway.

We are aware of some significant new studies addressing the health effects of hexavalent chromium. These studies are nearing completion and could potentially provide a more thorough understanding of hexavalent chromium's mode of action and other critical issues that

² "Draft Public Health Goal for Hexavalent Chromium in Drinking Water," Office of Environmental Health Hazard Assessment, December 2010, <http://www.oehha.ca.gov/water/phg/pdf/123110Chrom6.pdf>

³ <http://www.oehha.ca.gov/water/phg/pdf/112509deflora.pdf>

should be included in a risk assessment. ACWA urges OEHHA to follow the progress of this work and consider the results of this study and others that might emerge as soon as they are completed in order to ensure the subsequent hexavalent chromium MCL is based on the best available science.

ACWA and its member agencies' highest priority continues to be protecting public health while ensuring a reliable water supply for consumers. We look forward to working with you and the appropriate stakeholders as OEHHA and the California Department of Public Health address this very important issue.

If you have questions, please contact Danielle Blacet, ACWA regulatory advocate, at 916-441-4545 or danielleb@acwa.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Timothy H. Quinn". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Timothy H. Quinn
Executive Director