



February 7, 2011

Mr. Michael Baes  
Pesticide and Environmental Toxicology Branch  
Office of Environmental Health Hazard Assessment  
California Environmental Protection Agency  
1515 Clay St., 16th floor  
Oakland, CA 94612

Re: Draft Revised Public Health Goal for Hexavalent Chromium in Drinking Water

Dear Michael,

Once again, we are submitting comments on behalf of the Southern California Water Committee, an organization comprised of water agencies and professionals in the field of water resources management, on the revised draft Public Health Goal (draft PHG) for Hexavalent Chromium (Cr (VI)) of 20 parts per trillion (ppt), released for public comment by the Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency (CalEPA) on December 31, 2010. Additionally, we have assessed that recent changes to the reference materials in the Draft PHG announced by OEHHA on January 25, 2011, resulting in new values used in the calculation of the Cr(VI) PHG, warrant a formal review because of the potential implications for all MCLs and PHGs that are based on health effects that are calculated by drinking water consumption rates.

Another careful review of the draft PHG once again shows fundamental flaws in the risk assessment process and science used by OEHHA to propose this radically reduced PHG, which, if promulgated as a drinking water standard, may not be achievable or even reliably measurable with current technology. While the Southern California Water Committee previously provided elaborate comments with an indexed appendix, we wish to cite specific objections to the revised draft PHG, many of which are extensions of the previous shortcomings we cited:

The Draft December 2010 Public Health Goal document contains the following deficiencies:

- While purporting to meet the requirement to use the best science in decisions that relate to protecting public health, OEHHA continues to follow the practice of using default assumptions rather than chemical-specific information and sound science to inform the risk assessment. Data about the mode of action of Cr(VI) has been recently obtained as part of a major research initiative that began in early 2009, and these data will be presented in March at the 2011 meeting of the Society of Toxicology ("Southern Study").
- Failure to address comments from peer reviewers of the August 2009 PHG document, the draft December 2010 PHG document and expert panel comments on the draft 1999 PHG document.

- Inadequate response to public comments on earlier PHG documents, including:
  - Lack of any mode of action (MOA) consideration, especially when MOA forms the overarching conceptual framework for cancer risk assessment (EPA, 2005a).
  - Regarding the MOA, lack of consideration of interspecies differences in toxicokinetics of Cr(VI) and the failure to recognize that pathologies seen in rodents are likely portal-of-entry effects.
  - Regarding the MOA, lack of consideration of nonlinear toxicodynamic effects of Cr(VI) that likely underlie the cancer response. These effects include reactions with DNA, oxidative stress, inflammation and disruption of gene networks that regulate the cell cycle. Instead, the draft December 2010 PHG document correctly assumes that its metabolic products of Cr(VI) are DNA-reactive and wrongly assumes that DNA-reactivity equates to mutagenicity.
  - Lack of consideration of nonlinearity and the presence of a threshold. Although Appendix A, titled "Carcinogenic Threshold?" gives lip service to the idea of a threshold, this appendix considers only reductive capacity and absorption, and because of the lack of any consideration of MOA, fails to take into account epigenetic changes that underlie the tumor response that likely do have thresholds. The lack of consideration of MOA also prevented exploration of the use of precursor effects as recommended in EPA's Guidelines for Carcinogen Risk Assessment (EPA, 2005a).
  
- Use of deficient scientific literature, including:
  - The use of two highly flawed studies in mice and humans respectively (Borneff et al., 1968; Zhang and Li, 1987) to attempt to establish a link between Cr(VI) exposure and gastrointestinal cancer in humans. The use of these studies is in direct contradiction of the advice of an expert panel convened at the University of California in 2001 to review the 1999 PHG document.
  - Attempt to impeach the results of the Gatto et al. (2010) meta-analysis that found no association between occupational exposure to Cr(VI) and gastrointestinal cancer in humans.
  - Although the draft December 2010 PHG document made several suggestions to "improve" the meta-analysis, it is unlikely that any of these suggestions would alter the results.
  
- Inappropriate use of the age-sensitivity adjustment detailed in OEHHA (2009) because of lack of consideration of MOA. In addition, it was difficult to validate the calculations that employed this adjustment because the necessary data were scattered throughout the document.
  
- Failure to explore the uncertainty associated with dose-response modeling. The narrative and tables describing the modeling were very brief and difficult to follow. The number of animals at risk for the various dose groups in NTP (2008) was changed from those in the draft August 2009 PHG document without explanation, and neither set of values were the results of the commonly used poly-3 survival adjustment (Portier and Bailer, 1989).

- The arbitrary use of values utilized to determine drinking water consumption rates that can potentially affect all other PHGs and MCLs thus calculated. This change has resulted in new values used in the calculation of the PHG:
  - The revised drinking water consumption rates have decreased, even though they are said to be “upper 95<sup>th</sup> percentile values estimated by OEHHA,” as were the original consumption rates. For example, the original drinking water rate for a 70kg adult was 3.15 liters/day and it is now 2.66 liters/day. The question arises, will OEHHA go back to the 3.15 liter/day value when the Director adopts their draft document?
  - The drinking water rates selected by OEHHA will affect all the MCLs that are based on health effects and all the PHGs. The larger the volume of water consumed, the lower the allowable concentration of the contaminant.
  - When OEHHA uses the 95% upper confidence limit in determining the cancer potency slope for Cr(VI) and the 95<sup>th</sup> percentile of the upper bound for water intake, it is combining two conservative assumptions that will produce an even more conservative result. U.S. EPA does not recommend this approach. U.S. EPA used the 90<sup>th</sup> percentile for the drinking water rate in determining an acceptable concentration for fluoride. The 90<sup>th</sup> percentile is closer to the traditional 2 liters/day drinking water consumption rate.
  - OEHHA does not distinguish between direct and indirect consumption of tap water. Indirect consumption results when tap water is used in preparing food and beverages. In the case of Cr(VI), this is important because Vitamin C, or ascorbic acid, is well known to reduce Cr(VI) to Cr(III). Orange juice, lemon juice, fruit juices, and brewed beverages like coffee and tea made from tap water will result in reduction of Cr(VI). Yet there is no adjustment for this in OEHHA’s tap water consumption rates.

Once again, our overall recommendation is that OEHHA begin with a good faith commitment to examine the MOA and develop the risk assessment with consideration of the human relevance of the effects seen in rodents. U.S. EPA recognizes the importance of imminent research results, and has delayed its IRIS review process to ensure consideration of best available science. OEHHA, too, should await the results of this research initiative, since the results will better inform the state’s understanding of how ingested hexavalent chromium affects humans and may modify some of the state’s default assumptions on mode of action. Additionally, we also urge OEHHA to incorporate literature that has been thus far ignored; take into account thoughtful and technical public comments; and eliminate arbitrary use of reference materials in calculating drinking water consumption rates.

Sincerely,



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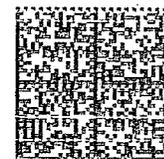
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