October 19, 2009

Pesticide and Environmental Toxicology Branch
Office of Environmental Health Hazard Assessment (OEHHA)
California Environmental Protection Agency
1515 Clay Street, 16th Floor
Oakland, California 94612

Attention: Public Health Goals (PHG) Project

Thank you for the opportunity to provide comments on the OEHHA’s August 20, 2009 released draft PHG for Hexavalent Chromium (chromium 6). On behalf of the Raymond Basin Management Board, we have the following comments:

**Important First Step**

Under state law, the California Department of Public Health (CDPH) uses PHGs to develop the state’s regulatory drinking water standards. The PHG is component in the CDPH process of developing a drinking water standard. State law requires CDPH to set drinking water standards as close to the corresponding PHG as is economically and technically feasible, placing primary emphasis on protection of public health. *In the August 20, 2009 release the OEHHA Director Dr. Joan Denton said, “This draft public health goal document is the first in the nation that identifies a health-protective level of chromium 6 in drinking water. The final goal will be an important first step in the development of a state drinking-water standard”.*

We agreed with Director Denton that PHG is an important first step. That is why OEHHA must develop the PHG for chromium 6 using the latest studies and tools.

**Good Science**

The California Health and Safety Code specifically requires that OEHHA employ the most current practices and methods used by health science experts when proposing a new PHG, Cal H&SC Sec.116365(c)(1). OEHHA did not comply with its own and EPA’s procedures for calculating the PHG. As pointed out by the Department of Toxic Substances Control (DTSC) in an October 23, 2008 memo on the PHG, the method employed by OEHHA to calculate the PHG ignored recent advances in assessing carcinogenesis. EPA guidance specifically requires alternate means of assessing the results of cancer bioassays where
appropriate scientific data is available. In contrast, OEHHA ignored all other options for calculation of cancer potency and simply adopted the EPA’s default “linear extrapolation” procedure for this PHG. In fact, the DTSC and scientific peer reviewers from the University of California suggested that an analysis of alternative approaches should have been included in the draft PHG documents.

The August 20, 2009 release states that “The draft OEHHA chromium 6 assessments considered all available scientific information. The PHG is based on a study published by the National Toxicology Program in 2007 in which laboratory rats and mice were given drinking water containing high levels of chromium 6. Some of the laboratory animals developed gastrointestinal tumors. OEHHA, CDPH and other groups requested the research to provide data needed to develop a chromium 6 PHG and drinking water standard.”

However, the OEHHA has used exactly the kind of overly speculative theories that it was warned not to use by both the Risk Assessment Advisory Committee and the prior peer reviewers. DTSC has indicated this so-called Helicobacter Hypothesis is speculative, lacks relevance to developing the PHG and it should be eliminated from the document as it is speculation. However, OEHHA with absolutely not scientific basis, use this as the primary basis for linking tumor findings in animal studies to the possible occurrence of stomach cancer in humans ingesting chromium in water.

OEHHA only relied on studies that have been superseded by more recent findings. It also chose to reinterpret other studies that do not fit its own conclusions while also ignoring data that did not support its conclusion. For example, OEHHA’s evaluation of the 1987 Zhang J and Li X assessment of chromium pollution of water supplies in China and in 1997, the lead co-author of the 1987 study expanded the assessment of the data found no statistically relevant link between stomach cancer in humans and consumption of water containing chromium 6. There are other examples where OEHHA similarly reevaluated published data and studies to support OEHHA’s hypothesis which the 2008 Peer Reviewers noted as “overreaching” and DTSC’s memo concluded inadequately addressed the with of evidence. This subjective process of picking and choosing data regardless if there is a scientific basis to obtain a predetermined answer should not be the process to develop the PHG giving the importance of this task.

In fact, DTSC recognized the importance of the Hamner Research program in addressing the “mode of action” (MOA) of chromium and said that the studies should be “prerequisites to any revisions to the OEHHA public health goal for chromium 6.” By issuing a PHG without waiting for this information, OEHHA is not taking account of the most up-to-date science.
Setting Unreasonable Goals without Basing on Good Science

Without this guess work along with selective data gathering and evaluation, OEHHA would not have adequate basis for selecting a 0.060 ppb PHG. Instead OEHHA would have to come to the same conclusion as DTSC.

OEHHA should implement and use the latest cancer risk assessment tools and processes to develop the PHG. It may resulted in an analysis similar to that conducted by the federal Agency for Toxic Substances and Disease Registry who identified a daily dose that is 500-fold high than the draft PHG, yet still protective of human health. As DSTC stated, “there are serious consequences associated with overly conservative analysis that fail to account for a carcinogenic MOA.”

In addition, by proposing PHG that is so far below currently detectable levels without applying the good science nonbiased process, OEHHA has unnecessarily if not irresponsible to called into question the safety of California’s water supply. Given the potentially enormous consequences to the State of California, it is essential that OEHHA be required to rigorously follow the most current procedures and apply the most up-to-date science before adopting a PHG for chromium 6.

The draft PHGs show fundamental defect in the lack of risk assessment process and good science used by OEHHA to propose this drastically reduced PHG. If the final standard is close to 0.06 ppb, this may not be achievable or even measurable with current technology. Lastly, by not following the most current principles of risk assessment in developing this PHG, OEHHHA will create confusion between its practices and the guidance and health assessments provided by other federal and state agencies charged with protecting human health and the environment.

Sincerely,

[Signature]
Anthony Zampiello
Raymond Basin Management Board
Executive Officer