Office of Environmental Health Hazard Assessment

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MEMORANDUM

TO: Harold J. Singer, Executive Officer
Lahontan Regional Water Quality Control Board
2501 Lake Tahoe Boulevard
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FROM: George V. Alexeeff, Ph.D., D.A.B.T.
Acting Director

DATE: August 17, 2011

SUBJECT: PROPOSED PUBLIC HEALTH GOAL FOR HEXAVALENT CHROMIUM

Thank you for your inquiry of July 19, 2011 requesting guidance on the use of the new Public Health Goal (PHG) for hexavalent chromium (Cr VI) as a possible replacement standard for drinking water in Hinkley, California. On July 27, 2011, the Office of Environmental Health Hazard Assessment (OEHHA) published its PHG for Cr VI. Consequently, this PHG is no longer proposed but has been officially established by OEHHA at 0.02 parts per billion (ppb). This puts California in the position of having in place a non-mandatory goal for Cr VI without a corresponding state or federal regulatory standard. We appreciate that this may create challenges for regional water boards. The current situation in Hinkley described in your letter is one such example.

You have posed five specific questions to OEHHA covering three different aspects of the newly finalized PHG for Cr VI:

1. Whether the PHG is appropriate for use as a drinking water replacement standard?
2. Whether the PHG is scientifically justified given the comments of Dr. Joshua W. Hamilton, Ph.D.?
3. Whether evaporative coolers (a.k.a., swamp coolers) pose an inhalation risk by increasing the concentration of airborne Cr VI?

Responses to these questions have been prepared by OEHHA staff and are attached. Feel free to contact me at (916) 322-6235 if you require further information on how California's PHG for Cr VI was developed.

Attachment

Question 1. When is OEHHA scheduled to adopt the proposed PHG for hexavalent chromium?

Answer 1. The PHG for hexavalent chromium is now final and was posted on our Web site on July 27, 2011. It can be accessed at http://oehha.ca.gov/water/phg/072911Cr6PHG.html.

Question 2. What is OEHHA's position on the applicability of the proposed PHG as a value that would be protective of public health related to potential exposure of residents in Hinkley? If OEHHA's response is that use of the PHG is not applicable, please indicate if the current CA MCL is protective of public health and should be the standard that is used as the basis for providing replacement water. If neither the proposed PHG nor the CA MCL are the appropriate values to use, what would be an appropriate value that would be protective of public health?

Answer 2. By law, PHGs are determined by OEHHA's scientific assessments of the health risks posed by drinking water contaminants. In the case of hexavalent chromium, the PHG identifies a level of the metal in drinking water (0.02 ppb) that would pose no more than a one-in-one million cancer risk to individuals consuming water with that level of the contaminant daily over a 70-year lifetime. The PHG is a non-regulatory guideline that does not define an acceptable level of a contaminant in drinking water. State law requires the California Department of Public Health (CDPH) to set state Maximum Contaminant Levels for contaminants as close to the corresponding PHGs as is economically and technically feasible. In setting MCLs, CDPH considers important information (i.e., economic costs, technical feasibility, detection limits and water-supply issues) that by law OEHHA cannot consider when it develops PHGs.

Question 3. What is OEHHA's position on the comments by Dr. Joshua W. Hamilton Ph.D. (Attachment 3) on the scientific basis for the development of the PHG by OEHHA, specifically points 8-10 and 12?

Answer 3.

Comment 8-1: "For example, the lowest Cr(VI) concentration that caused tumors in animals in the National Toxicology Program study [4] which was the foundation for the draft PHG, was 20,000 µg/L. Notwithstanding, OEHHA proposed a PHG of 0.02 µg/L, *one million times lower* than the concentration that caused cancer in mice from a lifetime of drinking water exposure."

Response 8-1. The lowest Cr VI concentration causing a statistically significant increase in tumors compared to controls was 30,000 µg/L for adenomas and carcinomas of the small intestines of male mice (NTP, 2008). While the second sentence of this comment is literally true, it misses a critical point. Due to the limited number of mice used in the two-year bioassay (NTP, 2008), the absence of tumors at the lower Cr VI drinking water concentrations should not be interpreted as a threshold for tumor induction. Indeed, the genotoxic mechanism of action of Cr VI discussed in

the PHG document suggests that tumors would have been increased at dose levels well below those tested in the bioassay if more animals had been used in the experiment.

Comment 8-2: "The calculations embodied in the draft PHG do not represent 'established science.'"

Response 8-2. This statement is contradicted by the following:

1. Standard methodology was followed to model the rodent tumor data (U.S. EPA, 2005; OEHHA, 2009).
2. Professors from both the University of California and other universities reviewed the draft PHG documents. While there was not unanimity regarding the choice of method for modeling the rodent tumor data, the consensus opinion was that OEHHA had modeled the data according to the best current practices (see Responses to Comments document, available at http://oehha.ca.gov/water/phg/072911Cr6PHG.html).
3. Both the U.S. EPA (2010) and the New Jersey Department of Environmental Protection (2009) chose the same methodology as OEHHA for calculating the cancer potency of Cr VI. All three organizations derived the identical cancer potency value, suggesting that "established science" had been followed.

Comment 8-3: "And even if the draft PHG is adopted, regulators should not assume that exposures of the type and duration that would be experienced by Hinkley residents will result in any adverse health impacts. In fact, there is no way to confirm any of the risk assessors' assumptions in constructing the models that ostensibly support the draft PHG, or to determine whether there are any measurable health effects as a result of exposures at 0.02 µg/L. They reflect a highly conservative, overly-protective regulatory limit that assumes a lifetime of exposure, but they do not represent levels that suggest a significant or immediate health threat."

Response 8-3. It is not possible to measure tumor incidence in rodents at low Cr VI concentrations in drinking water because too many animals would be needed (U.S. EPA, 2005). Thus, the commenter is correct in suggesting that tumor induction cannot be measured in rodents exposed to Cr VI in the parts per billion (ppb) and parts per trillion (ppt) ranges. However, the best carcinogenicity data we have for exposures at low dose levels come from the human A-bomb survivors. Those data indicate a linear relationship between dose and cancer incidence that extends to the lowest dose levels analyzed for any carcinogen (Brenner *et al.*, 2003). Therefore, linear extrapolation is indicated for genotoxic carcinogens (U.S. EPA, 2005; OEHHA, 2009). This methodology was used in the PHG document to quantify the cancer risks posed by concentrations of Cr VI in the ppb and ppt ranges.

Comment 9-1: "Similarly, OEHHA is explicit that the draft Cr(VI) PHG is not and should not be used as a regulatory or cleanup standard: 'PHGs are not regulatory requirements, but instead represent non-mandatory goals....PHGs are not developed as target levels for cleanup of ground or ambient surface water contamination, and may

not be applicable for such purposes, given the regulatory mandates of other environmental programs.' ([3] p. iii.)"

Response 9-1. The commenter is correct in stating that PHGs are not developed as groundwater cleanup standards. Rather, PHGs are used by the California Department of Public Health (DPH) in establishing primary drinking water standards (State Maximum Contaminant Levels or MCLs).

Comment 9-2: "In sum, the draft Cr(VI) PHG as its name implies, is at most a goal, not a regulatory level, and in no way should exposures to concentrations above 0.02 µg/L be interpreted as an immediate health risk to Hinkley residents nor should this proposed goal be used to set action or cleanup levels."

Response 9-2. The value 0.02 µg/L is the 70-year exposure level estimated to be associated with a one in one million increased risk of cancer. In other words, one extra case of cancer would be expected in a population of one million persons consuming drinking water for seventy years at this concentration. A drinking water concentration ten times higher would yield a ten-fold higher risk (for example).

Comment 10-1: "The initial draft Cr(VI) PHG drew on two principal studies: The 1968 Borneff, et al., animal study [6], and the 1987 Zhang and Li epidemiology study. [7] Both are outdated and flawed, and they have been rejected by EPA and mainstream toxicology experts as a foundation for toxicology risk assessment."

Response 10-1. U.S. EPA's current Draft Toxicological Review of Hexavalent Chromium (2010) contains an extensive discussion of the epidemiology study by Zhang and Li (1987). This study is an important part of that document's discussion of the human relevance of the rodent tumor data. The final PHG document does the same. It should be noted that the U.S. EPA document specifically supports the re-analysis of the original Zhang and Li (1987) study conducted by Beaumont *et al.* (2008). Dr. Beaumont is one of the authors of the final PHG document. With regard to Borneff *et al.* (1968), discussion of this study was moved to the Appendix of the PHG document on the advice of peer reviewers. The study was included in the Appendix so as to generate a PHG document that cites all significant studies that tested Cr VI carcinogenicity via the oral route. Neither Borneff *et al.* (1968) nor Zhang and Li (1987) is used to calculate the PHG of 0.02 µg/L. That calculation is based on rodent tumor data from NTP (2008).

Comment 10-2: "EPA's draft Profile appropriately omits any reference to the Borneff study in its review of key animal studies. While the draft profile discusses the Zhang study and three follow-up analyses, it correctly states that it should not be used for risk assessment purposes. The panel agreed with these assessments. Thus, there is already significant disagreement between the draft PHG and EPA's draft Cr(VI) Toxicology Profile."

Response 10-2. Borneff *et al.* (1968) is reviewed in the Draft U.S. EPA Toxicology Review of Hexavalent Chromium (2010). As mentioned above in Response 10-1, Zhang and Li (1987) is thoroughly evaluated in the U.S. EPA document, where it is an important part of the discussion concerning the human relevance of the rodent data.

Also as noted above, U.S. EPA selected the re-analysis of Zhang and Li (1987) by Beaumont *et al.* (2008) over Kerger *et al.* (2009) as representing the most useful re-analysis of the original data. Dr. Beaumont is one of the authors of the PHG document. Lastly, the OEHHA PHG document and the U.S. EPA document develop identical cancer potencies for Cr VI via the oral route. This does not support the claim in Comment 10-2 that "there is already significant disagreement between the draft PHG and EPA's draft Cr(VI) Toxicology Profile."

Comment 10-3: "The panel's consensus was that the pending studies provided important new information that was critical to an overall understanding of Cr(VI), and should be incorporated into the EPA's Profile. Thus, the panel urged EPA to wait for these studies to be published so that they may be taken into account in their assessment."

Response 10-3. OEHHA will review papers and materials relating to the American Chemistry Council study of Cr VI toxicology when they are published. If the study produces compelling information that should be reflected in the PHG document, OEHHA will take appropriate action.

Comment 12-1: "In addition, OEHHA concluded that exposure by inhalation during showering did not contribute significantly to the overall risk. And even with conservative assumptions regarding exposure during showering, the contribution to risk from inhalation was 180 times lower than that from drinking water exposure."

Response 12-1. This is correct. Less than one percent of the cancer risk due to Cr VI in drinking water was due to inhalation during showering compared to over 99 percent due to ingestion.

Question 4. What is OEHHA's position on the validity of footnote No. 5 in Attachment 3?

Answer 4.

Footnote 5: "The PHG associated with inhalation exposure may be readily calculated from the information in the draft PHG assessment by removing the contribution from oral exposures. The PHG associated with inhalation exposure is 3.6 µg/L."

Response to Footnote 5. It is not clear what Dr. Hamilton was trying to say in footnote 5. A PHG for a carcinogen is determined to be the drinking water concentration associated with a 10^{-6} cancer risk due to all applicable routes of exposure. The PHG for Cr VI in drinking water is 0.02 µg/L. This is based on exposure via ingestion and via inhalation during showering. Since so little Cr VI is inhaled during showering, a PHG based only on ingestion is identical (after rounding) to that based on ingestion plus inhalation during showering: 0.02 µg/L. The correct and useful interpretation is that the fractional cancer risk due to inhalation of Cr VI is very small, and that inhalation exposure cannot be used as a basis for establishing the PHG.

Question 5. What is OEHHA's position on Dr. Hamilton's conclusion that swamp coolers do not pose an inhalation risk? If OEHHA believes that Dr. Hamilton's

conclusions are not supported by the available information (including but not necessarily limited to the references cited), does OEHHA believe that swamp coolers could pose a risk, and if so, at what hexavalent level? If OEHHA believes that the available information is insufficient to reach a conclusion, would OEHHA be willing to perform an evaluation of a typical residence in Hinkley to determine if the use of swamp coolers with water which contains low levels of hexavalent chromium poses a health risk to the residents? This evaluation could be in collaboration with the Agency for Toxic Substances Disease Registry which has done similar studies on other constituents.

Answer 5. We agree with Dr. Hamilton's conclusion that swamp coolers do not increase the concentration of airborne Cr VI. Thus, with regards to Cr VI, swamp coolers do not constitute an inhalation health risk. This is based on the following studies located in the scientific literature:

1. Finley *et al.* (1996) demonstrated that swamp coolers operating with water containing concentrations of Cr VI up to 20 mg/L did not increase the concentration of Cr VI in indoor air. The American Society for Testing and Materials (ASTM) Method D5281 was used. This allowed measurement of total Cr VI in the air, whether in the form of fumes, aerosols or particulates.
2. Paschold *et al.* (2003a) determined that indoor swamp coolers lowered rather than raised the levels of airborne particulate matter ($PM_{2.5}$ and PM_{10}) potentially harboring Cr VI.
3. Paschold *et al.* (2003b) extended their previous study (Paschold *et al.*, 2003a) by analyzing the elements comprising airborne particulate matter ($PM_{2.5}$ and PM_{10}) collected in the presence of swamp coolers. They found no evidence that swamp coolers introduced metals from the cooling water into the indoor air, whether in the form of particulates or aerosols.

These studies appear to have been well-conducted and the conclusions are warranted by the data. Therefore, the data on hand support Dr. Hamilton's conclusion that swamp coolers do not increase the concentration of airborne chromium.

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