



290 South Main Street, #817 • Sebastopol, CA 95472 • US@ncriverwatch.org

April 14, 2022

Clerk to the Board
Ms. Jeanine Townsend
State Water Resources Control Board
P.O. Box 100
Sacramento, CA 95812-0100

Re: Comment Letter – Hexavalent Chromium Workshop

To Whom it May Concern:

California River Watch (“CRW”), an Internal Revenue Code section 501(c)(3) nonprofit public benefit corporation dedicated to protecting, enhancing, and helping to restore the surface and ground waters of California, appreciates the opportunity to provide public comment to the State Water Resources Control Board (“SWRCB”) regarding the proposed administrative draft of the hexavalent chromium maximum contaminant level (“MCL”). Specific to the issue of hexavalent chromium, CRW is the named plaintiff in current and ongoing litigation against the City of Vacaville in federal court alleging levels of hexavalent chromium in the potable drinking water provided by the City above the proposed MCL of 10ppb.

Following from its work on the issue of hexavalent chromium in drinking water, CRW supports all of the proposed amendments to 22 CCR sections 64431, 64432, 64447.2, 64465, and 64481, including the associated tables and appendices. In support of the SWRCB’s administrative draft, CRW incorporates by reference and attaches the “expert opinion” of Max Costa, Ph.D. that was provided to the federal district court in the Vacaville matter in 2018. Dr. Costa, whose qualifications and experience at New York University and the National Institutes of Health are identified in his report, states on page 7 “that the MADL [maximum allowable dose level] of 8.2 ug/day and the withdrawn MCL of 10 ug/L are baseline or minimal standards to protect the public from imminent and substantial harm.”

CRW looks forward to the SWRCB moving forward with adoption of the proposed amendments and enforcing the associated “compliance” deadlines. CRW is available, at the SWRCB’s request, to supplement its public comment with additional documents in support of the SWRCB’s proposal.

Thank you for the opportunity to provide public comment.

Larry Hanson
Board President

Attachment

Costa Toxicologist Consultants, Inc.

208 First Street, Unit 3 Hoboken, N.J. 07030

October 1, 2018

This report summarizes my opinions in this litigation. Based on my qualifications and experience as set forth in my Curriculum Vitae. I am qualified to render the opinions herein.

Summary of Qualifications and Experience

Briefly, I have been Professor and Chairman of the New York University, School of Medicine, Department of Environmental Medicine for 26 years. I am also Professor in the Department of Biochemistry and Molecular Pharmacology at NYU School of Medicine. I am currently Principal Investigator of an NIH, National Institute of Environmental Health Science Core Center grant, and Principal Investigator on several other major National Institute of Health research grants involving metal carcinogenesis.

In the past, I have held the position of Deputy Director of the NYU Cancer Center and Director of an NYU National Cancer Institute-funded basic science Cancer Center.

I have published 414 peer-reviewed manuscripts principally in the area of toxicology, cancer etiology, and carcinogenesis. My H index, a measure of the impact of my publications through their citation in the literature, is 79 (can be found in Google Scholar).

I have studied the toxicity of hexavalent chromium in numerous human studies. I have been involved with many national and international committees including preparing the International Agency for Research on Cancer's document on hexavalent chromium, nickel, and welding fumes. I have authored the United States Environmental Protection Agency's criteria document which was beneficial in helping to remove lead from gasoline.

Much of my interest in research and academic activities has centered on understanding human exposure to carcinogens as well as the causes of human cancers and other diseases

Opinion

The levels of hexavalent chromium in the City of Vacaville's drinking water may present an imminent and substantial endangerment to the health of those exceeding the maximum allowable dose level (MADL) of 8.2 µg/day or those exposed to levels 500 times or more than the California Public Health Goal (PHG) of 0.02 µg/L for periods as little as one year. Sub-populations including fetuses, pregnant women, infants, children, elderly, and the health-impaired have a heightened risk over the general public.

Based upon my review of the findings of the State of California, the records and reports produced by or for the City of Vacaville, the expert report of Larry Russell, Ph.D., the expert report of Nicholas Cozzi, Ph.D., and peer reviewed epidemiological and toxicology studies including my own, it is my opinion that levels of hexavalent chromium in the City of Vacaville's drinking water above 10 µg/L for a period of less than a year may present an imminent and substantial endangerment to health as discussed in detail below. Sub-populations known to be more susceptible to hexavalent chromium, such as fetuses, pregnant women, infants, children, elderly, and the health-impaired, are at an increased health risk over the general population.

Hexavalent chromium has been long known as one of the most potent carcinogens via inhalation. There is now unequivocal evidence that hexavalent chromium is also carcinogenic by the oral route of exposure. Oral and dermal exposure to hexavalent chromium poses significant health risks other than cancer. Drinking hexavalent chromium results in genotoxicity at sites in the body distal to the site of entry. This clearly indicates that chromium reaches those sites in the toxic hexavalent form. The hexavalent ionic form of chromium is very water soluble and easily enters living cells. Once inside the cell, highly unstable hexavalent chromium at any amount generates reactive metabolites that damage macromolecules such as DNA or is itself reduced to forms that produce toxicity. Hexavalent chromium interferes with essential physiological functions known to lead to numerous disorders before or other than cancer such as birth defects, reproductive damage, organ damage, and aggravating or triggering auto-immune disease. (*See* discussion of Willits REMCO below). Cancer is not the only harm resulting from exposure to hexavalent chromium. Cancer is the terminal result of long term exposure and harm.

Chromium exists in two major forms the trivalent and the hexavalent form which differ in toxicity by 500 to 1,000 fold. (Costa, 1997; Costa and Klein, 2006.) Trivalent chromium is relatively harmless and a nutritional supplement. Hexavalent chromium is similar to a Trojan horse given that it looks like a nutrient our body needs

(sulfate and phosphate) and is actively taken up into our cells by transporters. (Costa and Klein, 2006.) In contrast, the trivalent form is not taken up into cells readily and has low toxicity. As such, symptoms from exposure to hexavalent chromium develop over time, sometimes over months, sometimes years, depending upon a number of factors including the level and frequency of exposure. As discussed more thoroughly below, the levels of hexavalent chromium reported by the City of Vacaville in its water which exceed by more than 500 times the Public Health Goal (PHG)¹ or exceed the Maximum Allowable Dose Level (MADL) of 8.2 µg/day under the Safe Drinking Water and Toxic Enforcement Act (Prop 65) for Developmental and Reproductive Toxicity, may present an imminent and substantial endangerment to the health of those exposed to this water at those levels.

Hexavalent chromium has been known to be a human carcinogen since the early 1900's. Due to its extensive use in the past, hexavalent chromium is a major component of most United States Superfund toxic waste dump sites. There are probably more epidemiological studies demonstrating that hexavalent chromium causes lung and other types of cancer than any other carcinogen studied. (Costa, 1997; Gibb, Lees et al., 2000; Costa and Klein, 2006.)

Hexavalent chromium is one of the most potent Class 1 human carcinogens known to man. (Cohen, Kargacin, et al., 1993; Costa, 1997; Costa and Klein, 2006.) The Class 1 designation by *The International Agency for Research on Cancer* means there is sufficient epidemiological evidence to classify this agent as a known human carcinogen. Hexavalent chromium can produce any type of cancer depending upon genetic susceptibility, quantity, and route of exposure. (Costa, 1997.) It is important that persons living or working in the City of Vacaville for extended periods of time not be exposed to this carcinogen at the levels found in Vacaville's drinking water of more than 500 times the PHG since it can enter the human body by inhalation, ingestion, and through the skin, causing cancer by any route of exposure. (Smith and Steinmaus, 2009; Langard, 1990; Gibb, Lees, et al., 2000.)

The EPA "acceptable" cancer risk level is one cancer per one million people. The California PHG applicable to drinking water set by the Office of Environmental Health Hazard (OEHHA) is 0.02 µg/L based upon this one cancer in one million. This quantity is so small that one could not begin to see it with the human eye. Based upon studies by EPA and peer reviewed research, including my own, toxicity is known to be linear for hexavalent chromium within the dose ranges of exposure by Vacaville recipients.

¹ With regard to non-cancer risk of toxic metals, the EPA's the public health goal (MCLG) and Maximum Contamination Levels (MCLs) are set at the same value, e.g. the MCLG (aka PHG) for cadmium, a highly toxic metal, is 5 µg/L and the MCL is 5 µg/L as well.

Hexavalent chromium 500 times the PHG of 0.02 µg/L (10 µg/L) would increase the rate of cancer by 500 times. Instead of one in one million the cancer risk would be one in 2,000. Both Federal and State Maximum Contamination Levels (MCLs) are required to be set as close to the PHG as is technologically and economically feasible. With regard to cancer-causing contaminants, the outer limit for a specific MCL is that it may not present more than a one in 10,000 excess individual cancer risk during a lifetime exposure to the contaminant. (National Primary Drinking Water Regulations.) Therefore, a one in 2,000 risk factor is considered by toxicologists as significant requiring some action to bring the risk factor down to “acceptable” levels.

The most common cancer which develops following exposure to hexavalent chromium is lung cancer. (Langard, 1990.) Studies also show elevations of stomach, brain, GI, prostate, leukemia, lymphoma, urinary tract, renal, bladder, and bone cancers from exposure to hexavalent chromium. (Costa, 1997, Costa and Klein, 2006.) Generally these cancers develop with a latency period up to 15 to 20 years. Hexavalent chromium is known to cause birth defects during pregnancy and has also been reported to have effects on sperm in experimental animals. (Remy, L.L. , et al., 2017; Goldberg, Lebowitz, et al., 1990; Kanojia, Junaid, et al.,1998.)

The recent UCSF Willits REMCO study discussed below underscores the fact that hexavalent chromium does not have to cause cancer to produce harm. In fact, if cancer develops, it is precisely because harm has been occurring over a long period of time. Hexavalent chromium causes damage to the liver and kidneys, depresses the immune system, and can enter every cell of the body potentially producing widespread injury to every major organ. (Cohen, Kargacin, et al., 1993, Costa, 1997.) Because it looks the same as the nutrients sulphate and phosphate, it is actively taken up into cells by carriers that would normally transport these essential nutrients. The California PHG of 0.02 µg/L for non-carcinogenic effects is identified based on liver toxicity (mild chronic inflammation, fatty changes) in female rats in the National Toxicology Program (NTP). (NTP Study, 2008.) Other studies have also indicated adverse effects in the liver and blood forming tissues.

Animal experiments have long been acceptable and reliable determiners of the harm posed by various toxins. Numerous animal experiments have demonstrated that oral exposure to hexavalent chromium resulted in clear findings of cancers in both sexes of rats and mice. Multiple studies on the developmental toxicity of hexavalent chromium demonstrate numerous developmental and reproductive abnormalities including decreased viability, decreased fetal weights, changes in placental weights, increased frequencies of external and skeletal anomalies, lengthening of the estrous cycle, decreased mating and fertility indices, decreased numbers of implantation sites, increased

frequencies of implantation loss, ovarian alterations, reduced sperm count, defective sperm motility, and genetic gamete damage. Hexavalent chromium is of specific concern to pregnant women since that toxin crosses the placental barrier.

Administration of hexavalent chromium to mice via drinking water (Borneff, *et al.*, 1968) resulted in a statistically significant increase in stomach tumors compared to controls (OEHHA analysis). Administration of hexavalent chromium in drinking water provided to male and female rats resulted in statistically significant increases in papillomas or carcinomas of the oral cavity. Administration of hexavalent chromium in drinking water provided to male and female mice resulted in statistically significant and dose-related increases in adenomas or carcinomas (combined) of the small intestine in both sexes. (NTP Study, 2008.)

A statistically significant increase in human stomach tumors due to hexavalent chromium in drinking water has been detailed by Zhang. (Zhang and Li, 1987.) Linos documented a statistically significant increase in primary liver cancer mortality in Oinofita, Greece. (Linos *et al.*, 2011.)

In a recent study in the Northern California city of Willits, significant developmental and reproductive harm due to hexavalent chromium exposure was detailed.² For a period from approximately from 1963 until the plant closed in 1995 REMCO used hexavalent chromium for electroplating. The population of Willits was approximately 3,400 in the 1960s, 3,100 in the 1970s, 4,000 the 1980s, 5,006 in the 1990s, and 5,073 in 2000.

The recent 2017 UCSF Willits REMCO hexavalent chromium exposure study was highly significant. The actual detrimental reproductive effects of non-occupational hexavalent chromium exposure in human females and their infants was identified and reported. The study determined that the birth rate was abnormally low and did not recover until 12 years after closure of the REMCO plant. While REMCO was using hexavalent chromium, perinatal jaundice and birth defect rates were abnormally high, but improved post-closure. Risk for abnormal birth weight and term was high and remained high over the study period. The UCSF team found that women living in Willits had an abnormally high risk of pregnancy loss, whether stratified by generation, age group, or pre- and post-plant closure. Regardless of when exposed, these women continued to have significantly higher rates of in-hospital terminations, as animal studies of hexavalent chromium

² *Reproductive outcomes after non-occupational exposure to hexavalent chromium, Willits California, 1983-2014*; Family Health Outcomes Project, Family and Community Medicine, School of Medicine, University of California San Francisco; Environmental Health (2017) 16:18.

exposure predict. Non-pregnant women had a significantly higher risk of reproductive organ conditions and neoplasms.³

Based upon a health risk assessment performed by the federal Agency for Toxic Substances and Disease Registry in 2006, the levels of hexavalent chromium to which the inhabitants of Willits were exposed via oral route is far less than the current exposure levels of portions of the Vacaville populace such as Mr. Brown in Leisure Town. Those exposed over an extended period to drinking water wells with levels of hexavalent chromium in the 10 µg/L to 30 µg/L range face the highest risk of harm. In addition to hexavalent chromium, the City of Vacaville's potable water contains other contaminants known to have negative synergetic effects.⁴ The current paradigm for the assessment of the health risk of chemical substances focuses primarily on the effects of individual substances for determining the doses of toxicological concern in order to inform appropriately the regulatory process and therefore underestimates the effects of actual exposure since synergistic toxins are not included in these studies.

Under Prop 65 for Developmental and Reproductive Toxicity, the MADL for hexavalent chromium, based upon a 116 lb. female, is 8.2 µg/day by the oral route of exposure. At 10 µg/L, a person will exceed the MADL after consuming approximately 3½ cups of Vacaville's drinking water. According to data from the Center for Disease Control through its National Health and Nutrition Examination Surveys, the average daily amount of total water Americans consume is 3.1 liters, or 13.1 cups. Men drink more water than women about 14.8 cups (3.5 liters) of fluids a day for men and 11.8 cups (2.8 liters) a day for women. Young children drink about 5.9 cups of water per day and teens about 10 cups. Based upon these studies, and Dr. Larry Russell's Expert Report, City of Vacaville drinking water recipients are well within the average for consumption of drinking water if not above due to the dry climate and hot summers.

Populations characterized by elevated stomach pH are likely to absorb hexavalent chromium at a greater rate than a normal adult.⁵ For this population, oral intake of hexavalent chromium would be expected to result in a higher effective dose compared to individuals with a normal pH stomach. Infants have increased susceptibility due to increased pH levels in the stomach. The normal pH of an adult's stomach is 1.5 to 3.5.

³ It is likely that in Willits the reproductive damage to men's gametes (sperm) during the time of exposure was higher than that for women due to the fact that, unlike women, after puberty men are continuously producing new gametes.

⁴ See DRINC data on Vacaville - <http://sdwis.waterboards.ca.gov/PDWW/>

⁵ This population includes persons with anemia, pancreatic tumors, infection with *Helicobacter pylori*, some autoimmune diseases, and those consuming antacids.

Infants' stomachs are near neutral pH (pH 7) during the first days to weeks after birth, and stomach pH levels generally remain higher than adults during the first 3 months of life. (OEHHA, 2001.) As such it can be predicted that infants exposed to elevated hexavalent chromium will result in a greater lifetime risk of harm including cancer. (OEHHA, 2009.)

Conclusion

Human exposure to even small amounts of hexavalent chromium is very dangerous, especially exposure over an extended period of time as occurs to the residents and workers in the City of Vacaville. There is ample factual as well as scientific evidence vetted both by peer review (in the case of scientific research) and public review (in the case of the PHG, MCL, and MADL) to conclude, within a reasonable degree of certainty, that a person or fetus exposed to drinking water supplied by the City of Vacaville at levels above 500 times the PHG is at a significant increased risk of adverse health effects. The health risk increases depending upon the sub-population (e.g. fetuses, infants, etc.) and exposure (dose and time).

I have reviewed the evidence on the developmental and reproductive toxicity of hexavalent chromium presented by the California Environmental Protection Agency Office of Environmental Health Hazard Assessment Reproductive and Cancer Hazard Assessment Section (OEHHA, 2009), the PHG study for hexavalent chromium in drinking water prepared by the Pesticide and Environmental Toxicology Branch of Office of Environmental Health Hazard Assessment California Environmental Protection Agency (OEHHA, 2011), the recent UCSF epidemiological study, and the documents related to this litigation. Based upon this review, my review of the research in this area, and my extensive work in this field, it is my opinion that the MADL of 8.2 µg/day and the withdrawn MCL of 10 µg/L are baseline or minimal standards to protect the public from imminent and substantial harm.



Max Costa, Ph.D.

References (other than those identified in my attached CV)

Agency for Toxic Substances and Disease Registry, Priority List of Hazardous Substances, Division of Toxicology, U.S. Department of Health and Human Services.

Agency for Toxic Substances and Disease Registry, Toxicological Profile for Chromium, Division of Toxicology, U.S. Department of Health and Human Services.

Agency for Toxic Substances and Disease Registry, Evaluation of Exposures to Contaminants from the Former Abex/remco Hydraulics Facility Willits, Mendocino County, California, EPA Facility Id: CAD000097287, August 2, 2006.

City of Vacaville documents provided through discovery in this litigation.

Centers for Disease Control and Prevention website.

Cohen, M. D., B. Kargacin, et al. (1993). "Mechanisms of chromium carcinogenicity and toxicity." Crit Rev Toxicol 23(3).

Cozzi, Nicholas, Ph.D., Expert Report, October 1, 2018.

DPH-11-005 Hexavalent Chromium MCL, August 4, 2013.

Environmental Health Hazard Assessment California Environmental Protection Agency, August, 2009.

Evidence on the Developmental and Reproductive Toxicity of Chromium (hexavalent compounds), Reproductive and Cancer Hazard Assessment Section Office of Environmental Health Hazard Assessment California Environmental Protection Agency, August, 2009.

Gibb, H. J., P. S. Lees, et al. (2000). "Lung cancer among workers in chromium chemical production." Am J Ind Med 38(2).

Goldberg, S. J., M. D. Lebowitz, et al. (1990). "An association of human congenital cardiac malformations and drinking water contaminants." J Am Coll Cardiol 16(1).

Guidelines for Carcinogen Risk Assessment EPA/630/P-03/001B, March 2005.

Guidelines for Drinking-water Quality, World Health Organization, 4th ed., 2011.

International Programme on Chemical Safety Environmental Health Criteria - Chromium, World Health Organization Geneva, 1988.

Kanojia, R. K., M. Junaid, et al. (1998). "Embryo and fetotoxicity of hexavalent chromium: a long-term study." Toxicol Lett 95(3).

Langard, S. (1990). "One hundred years of chromium and cancer: a review of epidemiological evidence and selected case reports." Am J Ind Med.

National Primary Drinking Water Regulations, 56 Fed. Reg. 3547.

OSHA - Hexavalent Chromium, Publication 3373-10, 2009.

Publically available documents including, but not limited to, the City of Vacaville's General Plan and Urban Water Management Plan, and documents at regulatory agencies such as the State Water Resources Control Board, Regional Water Quality Control Board, California Department of Toxic Substances Control, and data uploaded to public sites such as GeoTracker, Envirostor, DRINC and GAMA.

Public Health Goal for Hexavalent Chromium (CrVI) in Drinking Water Prepared by Pesticide and Environmental Toxicology Branch Office of Environmental Health Hazard Assessment California Environmental Protection Agency July, 2011.

Remy, L. L., Byers, V. and Clay T. *Reproductive outcomes after non-occupational exposure to hexavalent chromium, Willits California, 1983-2014*; Family Health Outcomes Project, Family and Community Medicine, School of Medicine, University of California San Francisco; *Environmental Health* (2017) 16:18.

Russell, Larry, Ph.D., Expert Report, October 1, 2018.

Silver, S. and T. K. Misra (1984). "Bacterial transformations of and resistances to heavy metals." Basic Life Sci 28.

Smith, A. H. and C. M. Steinmaus (2009). "Health effects of arsenic and chromium in drinking water: recent human findings." Annu Rev Public Health 30.