BEFORE THE PUBLIC UTILITIES COMMISSION
OF THE STATE OF CALIFORNIA

In the Matter of the Application of California-American Water Company (U 210 W) for a Certificate of Public Convenience and Necessity to Construct and Operate its Coastal Water Project to Resolve the Long-Term Water Supply Deficit in its Monterey District and to Recover All Present and Future Costs in Connection Therewith in Rates.	Application 04-09-019 (Filed September 20, 2004; Amended July 14, 2005)

PUBLIC TRUST ALLIANCE
COMMENT ON PROPOSED SETTLEMENT AGREEMENT

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I. Introduction

The Public Trust Alliance joined in the settlement discussions in this action to help ensure that public trust values were reflected in any agreement among the parties. We believe that it does help to protect public trust resources and values. Therefore, we support the settlement agreement.

An important aspect of the public trust doctrine is the affirmative duty of public agencies to protect public trust values, which have been broadly construed to include the viability of river ecosystems and the long-term availability and quality of public drinking water. The Regional Project itself is evidence that it is feasible to protect public trust uses on the Carmel River while guarding public health and other public values, and that the parties take their public trust responsibilities seriously. We believe that this project is the soundest alternative among those presented. Moreover, the overall process that produced the Regional Project has welcomed and maximized the participation of stakeholders and has served as a vehicle for the parties to "rise to the occasion" to resolve the long crisis of water overdraft and implement broad public-interest values. We believe it would be impossible at this point to capture similar benefits via any other project, and we hope to be part of the critical mass that helps move the project forward in the interests of broad constituencies rather than stopping it and extending the status quo and the perpetual clash of narrow interests.

In a time of economic and climatic crisis, it becomes more important to concentrate on the contours of long term responsibility than to argue and point fingers at fleeting short term indicators or current market prices which are notoriously unreliable in measuring long term public value. We support this project because it provides a positive example to other jurisdictions with similar water shortage issues. We want to make sure that future generations of

Californians will live in an ecologically viable California.

We particularly support provisions in the settlement agreement that provide for ongoing public input, the adoption of a value engineering approach to cost reduction, which provides for ongoing analysis of ways to reduce costs while maintaining the goals of the project; the commitment to life-cycle cost analysis; and the authority of local agencies to go beyond the bare minimum legal requirements in protecting the public health of their constituencies.

II. The Boron Issue

We would like to address in more detail the public health issue related to the use of double pass technology to reduce exposure to boron/other potentially harmful elements. Water Purchase Agreement section 9.7(b) on Water Quality states:

> TDS Standards. In addition to Legal Requirements, MCWD also recognizes that the Product Water may require treatment to meet reasonable standards of acceptance to MCWD's customers and CAW's customers and to the public. Such Legal Requirements or standards for acceptability may require that, after mixing, the Product Water TDS constituents, including without limitation boron, sodium and chlorides, be further reduced to comply with such standards and a "second pass" treatment of all or a portion of the Product Water may be necessary. Furthermore, regarding boron or other contaminants, the Parties may implement a margin of safety that exceeds the current minimum legal requirements, and may acquire the appropriate technology to achieve this margin of safety. In addition to cost and Legal Requirements, factors that shall be considered in reaching such a decision include the protection of susceptible sub-populations, consistency with Best Industry Practice, anticipation of possible tightening of regulatory standards, evolving technology, the uncertainty levels underlying regulatory standards, and the relative cost-effectiveness of acting proactively vs. retrofitting. After taking into account the foregoing factors, if a second pass or other form of treatment is required to ensure that the applicable standards and/or Legal Requirements will be met, such second pass or other treatment shall be deemed necessary and reasonable when required to ensure that the applicable standards and/or Legal Requirements will be met.

A. BACKGROUND

Boron is an inorganic compound found in the natural environment, particularly in rocks, soil, groundwater, and seawater. Boron enters the environment mainly through the weathering of rocks, boric acid volatilization from seawater, and volcanic and geothermal activity.[1] Boron is typically present in higher levels in desalinated seawater than in drinking water obtained from surface water or groundwater because seawater contains more boron, and single pass desalination technologies are not fully effective in reducing boron levels to standards of 1.0 mg/L or less. Boron levels after single-pass RO commonly exceed some guidelines and the EPA health reference level.

Drinking water and diet are the primary avenues of oral exposure to boron. Boron is present in significant amounts in food because it is found in soil and is taken up by plants. The average intake of boron in the U.S. diet ranges from 0.85 mg B/day (4-8 year old child) to 1.47 mg B/day (male vegetarian). Dietary levels can be as high as 5-6 mg/day for some individuals.[2] "Recent studies" have been cited to raise the level of boron considered to be a safe level in drinking water. Underlying these studies are revised assumptions regarding the percentage of boron exposure that is properly attributable to drinking water. Citing low dietary levels of boron in the U.S., agencies such as the World Health Organization have concluded that drinking water may account for 40% of the exposure to boron, up from 20% in prior studies. We are uneasy

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[1] See, e.g., EPA, Summary Document from the Health Advisory for Boron and Compounds 1 (2008 *Prepared by Health and Ecological Criteria Division (HECD), Office of Science and Technology (OST), Office of Water (OW) for Office of Groundwater/Drinking Water (OGWDW), OW, U.S. EPA. Document Number: 822-S-08-00.* Boron concentrations in rocks and soils are typically less than 10 ppm, although concentrations as high as 100 ppm have been reported in shales and some soils. The overall average concentration in the earth's crust has been estimated to be 10 ppm. Concentrations reported in sea water range from 0.5-9.6 ppm, with an average of 4.6 ppm. Fresh water concentrations range from <0.01-1.5 ppm. To a lesser extent, boron is released to the environment via human activities (industrial air emissions, agricultural chemicals, and industrial and municipal wastes). Boron is present in household sewage because of the boron used in detergents.

[2] Id., p. 2.

about this development because we believe that it reduces the margin of safety for individuals who consume higher-than-average amounts of boron in their diets. The revised assumption also appears to reduce the margin of safety for individuals who have substantial exposures to boron via the workplace or other avenues of exposure. Recent studies have also reduced uncertainty factors that serve the purpose of maximizing margins of safety when science is not yet in a position to know, measure, and predict everything. Again, such changes make us uneasy for the people who will be drinking the water.

B. HEALTH EFFECTS

EPA noted in 2008 that studies in laboratory animals conducted by oral exposure have identified the developing fetus and the testes as the two most sensitive targets of boron toxicity in multiple species. The testicular effects that have been reported include reduced organ weight and organ:body weight ratio, atrophy, degeneration of the spermatogenic epithelium, impaired spermatogenesis, reduced fertility, and sterility. The mechanism for boron's effect on the testes is not known, but the available data suggest an effect on the Sertoli cell, resulting in altered physiological control of sperm maturation and release. Developmental effects have been reported in mice, rabbits, and rats. The developmental effects that have been reported following boron exposure include high prenatal mortality; reduced fetal body weight; and malformations and variations of the eyes, CNS, cardiovascular system, and axial skeleton. Increased incidences of short rib XIII (a malformation) and wavy rib (a variation), and decreased incidence of rudimentary extra rib on lumbar I (a variation), were the most common anomalies in both rats and mice. Cardiovascular malformations, especially interventricular septal defect, and variations were the frequent anomalies in rabbits. Fail et al. (1998) attributed reduced fetal growth, the most sensitive developmental endpoint, to a general inhibition of mitosis by boric acid, as documented in studies on the mammalian testis, insects, yeast, fungi, bacteria, and viruses.[3]

C. APPLICABLE REGULATORY SCHEME FOR BORON IN DRINKING WATER

1. Federal Law

a. Safe Drinking Water Act

The Safe Drinking Water Act authorizes the U.S. EPA to set limits on contaminants in public drinking water supply systems. EPA must establish National Primary Drinking Water Regulations (NPDWRs) for contaminants that may cause adverse public health effects.[4] The Safe Drinking Water Act also requires EPA to list unregulated contaminants that are known or anticipated to occur in public water systems and may require a national drinking water regulation in the future. Every five years, EPA must publish a list of contaminants called the Contaminant Candidate List (CCL) and decide whether to regulate at least five contaminants from the list.[5] An important underpinning of the process is the EPA) Integrated Risk Information System (IRIS). IRIS is EPA's database on what science has said about the risks of particular chemicals.

b. EPA Determinations

Boron was considered in the EPA's second Drinking Water Contaminant Candidate List (CCL2).[6] Based on a survey indicating limited amounts of boron in ground and surface water

[3] EPA, HEALTH EFFECTS SUPPORT DOCUMENT FOR BORON, at 7.5 Synthesis and Evaluation of Major Noncancer Effects and Mode of Action, EPA Document Number EPA-822-R-08-002 January, 2008. [citations omitted]
[4] See 40 CFR Part 141.
[5] See EPA website, http://www.epa.gov/safewater/ccl/index.html.
[6] Final Federal Register posted on February 24, 2005.

[not desalinated water], EPA made a determination that it was not necessary to regulate boron with a national primary drinking water regulation (NPDWR).[7]

In CCL2, the EPA defined a reference dose of 0.2 mg/kg/day (.16 rounded up). A reference dose is "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime."[8] The reference dose was conservatively estimated based on developmental effects in rats as well as applied uncertainty factors based on the extrapolation of data from animals to humans. EPA also calculated a health reference level (HRL) of 1.4 mg/L or 1,400 µg/L for boron, using the reference dose of 0.2 mg/kg-day.[9] EPA noted that there may be sensitive subpopulations, including developing fetuses and individuals with impaired kidney function.

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[7] EPA, Chapter 3: Boron, REGULATORY DETERMINATIONS SUPPORT DOCUMENT FOR SELECTED CONTAMINANTS FROM THE SECOND DRINKING WATER CONTAMINANT CANDIDATE LIST (CCL 2): PART II: CCL 2 CONTAMINANTS UNDERGOING REGULATORY DETERMINATION (June 2008). EPA evaluated boron occurrence in drinking water using data collected from 989 ground water public water systems (PWSs) by the National Inorganics and Radionuclides Survey (NIRS). Boron was found at levels greater than EPA's Health Reference Level (and ½ the HRL) in several of the ground water systems surveyed by NIRS. The NIRS data indicate that approximately 4.3 percent of the ground water Public Water Systems had detections of boron at levels greater than 700 µg/L (1/2 the HRL), affecting approximately 2.9 percent of the population served by these ground water systems. Approximately 1.7 percent of the ground water PWSs had detections of boron at levels greater than 1,400 µg/L (the HRL), affecting approximately 0.4 percent of the population served by these ground water systems. Because NIRS only investigated ground water systems, the Agency evaluated the results of a survey funded by the American Water Works Association Research Foundation (AwwaRF) to gain a better understanding of the potential occurrence of boron in surface water systems. Of 341 samples analyzed for boron, approximately 67 percent represented ground water sources and 33 percent represented surface water sources. Of the ground water sources, 3.1% had boron concentrations that exceeded the HRL of 1,400 µg/L; the highest observed concentration was approximately 3,300 µg/L. In contrast, none of the surface water sources exceeded the boron HRL of 1,400 µg/L, and the highest concentration in surface water was 345 µg/L. Taking this surface water information into account, the Agency believes the overall occurrence and exposure from both surface and ground water systems together is likely to be lower than the values observed for the NIRS ground water data. Because boron is not likely to occur at levels of concern when considering both surface and ground water systems, the Agency concluded that an NPDWR does not present a meaningful opportunity for health risk reduction.

[8] U.S. EPA, Health Effects Support Document for Boron, section 4.3.2, EPA Document Number EPA-822-R-08-002 (January 2008).

[9] An HRL is a benchmark against which to measure the occurrence data; it is not a Health Advisory guideline. For noncarcinogens such as boron, the HRL is calculated by multiplying the Agency Reference Dose by a 70 kg body

EPA has issued Health Advisories for boron.[10] Health Advisories set forth concentrations of drinking water contaminants at which adverse health effects are not anticipated to occur over specific exposure durations (one-day, ten-days, several years, and a lifetime).

Current EPA Drinking water standards and health advisories for boron[11]:

1-day health advisory for a 10-kg child	3 mg/L (from 4 in 2004)
10-day health advisory for a 10-kg child	3 mg/L (up from .9 in 2004)
Ref. Dose (mg/kg/day)	.2 (up from .09 in 2004)
DWEL (drinking water equiv. level)	7 mg/L (up from 3 in 2004)
Lifetime	6 mg/L (up from .6 in 2004)
10^{-4} Cancer risk	No data
National primary drinking water standards	None

EPA Health Advisories serve as informal technical guidance to assist Federal, State and local officials, and managers of public or community water systems in protecting public health when emergency spills or contamination situations occur. They are not legally enforceable Federal standards. The HAs are subject to change as new information becomes available.[12]

2. State Law

Although the Federal Government does not regulate boron in drinking water or require public drinking water systems to monitor for this contaminant, some states have drinking water standards or guidelines for boron (California, Florida, Maine, Minnesota, New Hampshire and Wisconsin). The State of California has adopted a notification level for boron at 1 mg/L (California Department of Public Health, Drinking Water Notification Levels and Response

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weight and a 20 percent default Relative Source Contribution (RSC) and dividing the product by a drinking water intake of 2 L/day. 73 Fed. Reg. 44251-44261.

[10] EPA Drinking Water Health Advisory for Boron (Document Number: 822-R-08-013 May 2008).

[11] EPA, Drinking Water Standards and Health Advisories 8 (Summer 2009).

[12] U.S. EPA, Drinking Water Health Advisory for Boron 1 (May 2008) Document Number: 822-R-08-013.

Levels: An Overview 2007).[13]

3. Does the Public Trust Doctrine Apply?

The public trust doctrine is primarily a state doctrine notable for its continuing expansion to new uses. Among many other environmental application, courts have recognized the doctrine's applicability to drinking water resources.[14] California does not currently recognize the public trust doctrine as applicable to groundwater, reflecting the majority view.[15] Nevertheless, drinking water derived from groundwater is a possible area for expansion of the doctrine, particularly in states where there is a scarcity of water and an overdraft of groundwater.[16]

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[13] CDPH website at http://www.cdph.ca.gov/certlic/drinkingwater/Documents/Notificationlevels/NotificationLevels.pdf.

[14] Mayor v. Passaic Valley Water Comm'n, 539 A.2d 760, 765 (N.J. Super. Ct. Law Div. 1987) and cases cited therein (persuasive authority only for California courts). See, e.g., Rettkowski v. Dep't of Ecology, 858 P.2d 232, 239 (Wash. 1993). According to the Passaic Valley decision, "it is clear that since water is essential for human life, the public trust doctrine applies with equal impact upon the control of our drinking water reserves. . . . Ultimate ownership rests in the people and this precious natural resource is held by the state in trust for the public benefit.

The court stated further: "It is clear that the broad doctrine acknowledging the public nature of the resource pertains to the water gathered and distributed by the Commission. It belongs to, and is for the common use of, the public, and those who take it into their possession hold it in trust for the public good. The purpose and function of the Commission can only be to provide water of the highest quality at the lowest economically feasible cost. Funds derived from the sale of such water are held in trust for the benefit of the public which is being served."

. . .

"As Judge (now Justice) Handler said in *State v. No. Jersey Dist. Water Supply,* 127 *N.J. Super.* 251 (App.Div. 1974)

"This controversy must be understood in the perspective of the State's overriding concern and obligation to safeguard the public health. [Citation omitted] This encompasses a comprehensive power, coupled with a correlative duty, to control and conserve the use of its water resources for the benefit of all its inhabitants. [Citation omitted] It is a paramount governmental policy that such water supplies must be pure in quality, and be economically and prudently managed for the benefit of the public. [Citation omitted] Designed to protect and promote the general health, safety and welfare, statutes regulating public water resources must be liberally construed to advance and achieve this underlying beneficient [sic] policy. [*Id.* at 260; citation omitted]"

[15] See, e.g., Santa Teresa Citizen Action Group v. City of San Jose (2003), 7 Cal. Rptr. 3d 868 (Cal. App. 6 Dist. 2003) (stating that the public trust doctrine "has no direct application to groundwater sources"); Joseph Sax, *We Don't Do Groundwater: A Morsel of California Legal History*, 6 U. DENV. WATER L. REV. 269, n.217; Center for Progressive Reform, *Restoring the Trust: An Index of State Constitutional and Statutory Provisions and Cases on Water Resources and the Public Trust Doctrine (*September 2009), progressivereform.org/articles/PubTrust_State_table_2009.pdf.

[16] An expanding minority of states has applied the public trust doctrine to groundwater. For example, New Hampshire has determined legislatively that groundwater and surface water combined are an "invaluable public

If the public trust doctrine is so applied in California, the duties of entities managing groundwater will expand beyond the current statutory mandates. The public trust doctrine is frequently analogized to private trust law.[17] Duties of a trustee include a duty to protect the assets of the trust (groundwater/drinking water) from damage and a strict duty of loyalty to the beneficiaries of the trust (the citizens present and future). As trustee, the government must manage the resources prudently and in a manner that reflects public trust "values."[18] Mary Christina Wood notes that "While all government officers owe a duty to uphold the public interest--as reflected in their oath of office --the trust duty of loyalty is an elevated duty associated with fiduciary offices. In the natural resources arena, government officials exert control over the people's assets. The trust functions are much different, and more weighty than

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resource" to be conserved and managed for the public good. It codified the public trust as extending to all waters of the state above and below ground. In 2003, Massachusetts passed the Environmental Endangerment Act in which 'natural resources' are defined as 'land, fish, wildlife, biota, air, water, groundwater and drinking water supplies belonging to, managed by, held in trust by, appertaining to or otherwise controlled by the commonwealth or any local government.' Although this does not explicitly extend the public trust to groundwater, it may serve to limit the traditional common law rule of absolute ownership. In addition, the Connecticut Environmental Protection Act extended the public trust to groundwater, among other natural resources. It states that there is a 'public trust in the air, water, and other natural resources of the state of Connecticut and that each person is entitled to the protection, preservation and enhancement of the same.'" Evan Mulholland, *Groundwater Quantity Regulation in Vermont: A Path Forward*, VERMONT JOURNAL OF ENVIRONMENTAL LAW, VOL. 8 2006-2007, *available at* http://www.vjel.org/journal/pdf/VJEL10046.pdf (summarizing groundwater legislation in several states). In Vermont, a grassroots campaign produced legislation that declares groundwater a "public trust" resource and allows public trust lawsuits to protect groundwater. The Vermont legislation, which builds on prior legislation regarding groundwater, is unique in its refusal to "grandfather" pre-existing withdrawals. See Felicity Barringer, *Bottling Plan Pushes Groundwater to Center Stage in Vermont*, NEW YORK TIMES (August 20, 2008), http://www.nytimes.com/2008/08/21/us/21water.html?_r=1&em. In Hawaii, the courts have declared groundwater to be a public trust resource. In re Water Use Permit Applications, 94 Haw. 97; 9 P.3d 409 (2000); In re Wai'ola O Moloka'i, Inc., 103 Haw. 401, 83 P.3d 664 (2004) (out-of-basin transfer of groundwater). Legislation has been introduced in Michigan that would place groundwater within the public trust. *See, e.g.,* Scripps Lays Out Plan to Protect Michigan's Waters: Placing waters in the public trust will protect the Great Lakes (September 02, 2009), http://101.housedems.com/news/article/scripps-lays-out-plan-to-protect-michigans-waters/placing-waters-in-the-public-trust-will-protect-the-great-lakes; Bill seeks to put state's groundwater into public trust (2/3/2010), http://www.oxfordleader.com/Articles-i-2010-02-03-233940.113121-sub14475.113121_Bill_seeks_to_put_states_groundwater_into_public_trust.html.

[17] *Id.* The interests of future generations are at issue with regard to boron, because fetuses, infants and children have been identifies as susceptible sub populations.

[18] Illinois Central Railroad v. Illinois, 146 U.S. 387 (1892).

the bureaucratic functions of other offices dealing with human services, economic development, criminal and moral matters, education, and the like. . . . ."[19]

Even if we begin from the premise that public trust principles are not currently applicable to the water used for this project, and that agencies are therefore not REQUIRED to adhere to the high standards applicable to trustees, they are not precluded from going beyond the minimum standards imposed by law. In fact, the parties seek to do so at several points in the settlement agreement, including the provision regarding boron. This is a positive feature that benefits the public.

D. FACTORS AFFECTING CONFIDENCE IN CURRENT REGULATORY REQUIREMENTS

There are several factors that reasonably impel the parties to look beyond minimum requirements regarding boron. One is the problematic role of local officials and their agencies. Local officials implementing desalination projects are caught between cost and public health issues. Although boron is not specifically regulated in product water in the United States, consumer expectations may pressure desalination planners to design future seawater plants to follow these current guidelines. Treatment to these levels will increase the cost of new seawater desalination plants, provoking public resistance. A New York Times article on gaps in the Safe Drinking Water Act noted that "Some officials overseeing local water systems have tried to go above and beyond what is legally required. But they have encountered resistance, sometimes

[19] Wood, Mary Christina. (2009, January 1). Instilling a fiduciary obligation in governance *The Free Library*. (2009). Retrieved April 27, 2010 from http://www.thefreelibrary.com/Instilling a fiduciary obligation in governance.-a0196728993. (Section B, 1.)

from the very residents they are trying to protect, who say that if their water is legal it must be safe."[20]

On the other hand, officials that fail to take every possible precaution may subject their agencies to extremely expensive litigation by individuals who believe that their health has been compromised by exposure to elements in desalinated water. Not to mention the public health costs if current regulatory guidance is eventually found to be insufficiently protective.

a. Limited Guidance in the Desalination Context

The Problem: Water quality guidance, based on an analysis of the human health effects of boron in drinking water and considering other sources of exposure, is needed to support decisions for desalination process design. The EPA has decided not to develop an MCL or health-based MCLG for boron because of its lack of occurrence in most groundwater and surface water and has encouraged affected states to issue guidance or regulations as appropriate. Therefore, most U.S. utilities lack clear guidance on what boron levels in drinking water are suitably protective of public health. [21]

If seawater desalination becomes a significant source for drinking water supply in the United States, additional regulatory attention or national guidance may be needed. [22] EPA's decision not to regulate boron was based on a survey of groundwater and surface water used by water suppliers, not on conditions prevailing for desal product water. Indeed, commentators

[20] Charles Duhigg, *That Tap Water Is Legal but May Be Unhealthy*, THE NEW YORK TIMES (Dec. 17, 2009), http://www.nytimes.com/2009/12/17/us/17water.html?_r=1&ref=us&pagewanted=print.
[21] Ch. 8, WATER QUALITY ISSUES IN DESALINATED PRODUCT WATERS Desalination: A National Perspective (Water Science and Technology Board, Nat. Academies Press, 2008), available online at http://www.nap.edu/openbook.php?record_id=12184&page=1. See also Executive Summary at aquadoc.typepad.com/waterwired/files/12184_EXS.pdf.
[22] Ch. 5, 138 et seq., WATER QUALITY ISSUES IN DESALINATED PRODUCT WATERS Desalination: A National Perspective (Water Science and Technology Board, Nat. Academies Press, 2008), available online at http://www.nap.edu/openbook.php?record_id=12184&page=1.

have identified the development of desal-specific regulatory guidance as a priority.[23] If that guidance sets a stricter limits, desal planners may benefit from incorporating a higher margin of safety now, rather than risking health violations or expensive retrofits later.

b. Safe Drinking Water Act

There are additional issues that might reasonably affect consumer confidence in the current determinations under the Safe Drinking Water Act. EPA's regulatory process under the Safe Drinking Water Act has been slow and cumbersome since the Act was passed.[24] However, the environmental regulatory process came under particular fire during the George W. Bush administration, which generally expanded the role of regulatory process provided for increased input from industry and government polluters, and delayed or defeated regulation and dissemination of information to the public in some cases.[25] There were allegations of regulatory

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[23] Id.

[24] As enacted in 1974, the SDWA directed EPA to establish national interim primary drinking water standards within 90 days and revise the standards after a National Academy of Sciences study recommended MCLs. EPA promulgated 16 interim standards, based on recommendations of a 1962 U.S. Public Health study. Although the NAs issued its report in 1977, by 1986 EPA had proposed final MCLs for only 8 chemicals. Amendments in 1986 instructed EPA to regulate 83 chemicals by 1989 and to add 25 chemicals to the list by every 3 years after 1989. By January 1991, EPA had promulgated MCLs for 67 of the 83 mandated chemicals and pledged to set new standards for 108 contaminants by 1995, a goal it did not meet. Amendments in 1996 rescinded the provision for regulating 25 chemicals every 3 years and in its place directed EPA to publish a list of contaminants not now subject to regulation but that are known to occur in public water systems (the CCL process) and to decide every 5 years whether to regulate at least 5 contaminants on the list. Once EPA decides to regulate, it has 24 months to propose an MCLG and MCL and another 18 months to promulgate the proposal. Percival et al, Environmental Regulation: Law Science and Policy 480 (3rd Ed. Aspen Law and Business). (In recent years, EPA has consistently determined not to regulate any of the contaminants on the list. Between 2004 and 2008, EPA completed assessments for only 16 substances. The time for completing an assessment of a chemical can range up to ten years. The regulatory process lags behind the rate at which industries introduce new chemicals. The more time that passes, the longer the queue grows. OMB Watch, In Drinking Water, What's Legal Can Be Poisonous (Matthew Media 12/17/2009), http://www.ombwatch.org/node/10655; OMB Watch, EPA Regains Control of Toxic Chemical Studies (June 2, 2009), http://www.ombwatch.org/node/10066.

[25] One of many examples was the treatment of coal ash waste ponds, which released high levels of boron and other, legally regulated contaminants in drinking water. According to a joint report of Earthjustice and the Environmental Integrity Project, during the Bush Administration, the EPA made a concerted effort to delay the release of a comprehensive EPA risk assessment detailing the dangers that coal ash disposal ponds posed to drinking water. A 2002 screening study, the precursor to EPA's 2007 risk assessment, identified the same astronomical cancer risks and dangers to aquatic life from coal ash dumps, but it was not made public until March 4, 2009—seven years after

laxity in protecting public health and the environment across a number of issues and statutory protective schemes, with the scientific community playing a prominent role in the criticism. These include allegations of EPA being ordered to mislead the public[26] and allegations regarding the doctoring of scientific reports.[27]

Criticism extended to the IRIS database, the scientific underpinning for EPA regulation. According to a congressional report, by the end of the Bush Administration, EPA's IRIS process was broken: The Bush Administration's Office of Information and Regulatory Affairs (OIRA) used its position at the top of the Executive branch to force EPA to undergo a multi-year, interagency review ostensibly designed to establish a new process for creating new or updated IRIS database entries. At the same time, OIRA both supplied detailed scientific challenges to proposed IRIS entries and coordinated scientific comment from agencies across the government. OIRA's own scientific comments on proposed listings included detailed editorial comments that would have changed the import and meaning of the scientific findings in EPA's documents. All of this was done in secret, without any acknowledgment to the public or the Congress that OIRA was calling the shots. As a result of the IRIS process breaking down, public health offices across the country and around the world, as well as concerned citizens, were left without the reliable,

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its publication. Freedom of Information Act requests to EPA during the Bush Administration were denied or resulted in the production of documents with the cancer and noncancer risk estimates blacked out. COMING CLEAN: WHAT EPA KNOWS ABOUT THE DANGERS OF COAL ASH: A SUMMARY OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY'S 2007 HUMAN AND ECOLOGICAL RISK ASSESSMENT OF COAL COMBUSTION WASTES 2 (Report by Environmental Integrity Project and Earthjustice (May 2009), http://www.wvgazette.com/static/coal%20tattoo/coalashreport.pdf.

[26] Laurie Garrett, EPA Misled Public on 9/11 Pollution: White House Ordered False Assurance on Air Quality, Report Says, Long Island NY Newsday (Aug. 23, 2003), available at http://www.commondreams.org/headlines03/0823-03.htm.

[27] Distorting and Suppressing Climate Change Research, Scientific Integrity in Policymaking, http://www.webexhibits.org/bush/5.html (Report of the Union of Concerned Scientists). See also, other tabs/links on this page.

expanding, up-to-date database of chemical risks that they had come to rely upon, in the view of the congressional report.[28]

A regulatory roadblock was also apparent in the CCL process. Not one chemical has been added to the list of chemicals regulated by the Safe Drinking Water Act since 2000. In 2003 and 2005, EPA determined that no regulation was needed for any of the contaminants on the CCL list.[29] Thus, although more than 60,000 chemicals are used within the United States (in addition to naturally occurring contaminants such as arsenic and boron), only 91 contaminants are regulated by the Safe Drinking Water Act.[30]

The Obama-era E.P.A. has issued a statement emphasizing that a top priority of Lisa P. Jackson, who took over the agency in January 2009, is to improve how regulators assessed and managed chemical hazards. "Since chemicals are ubiquitous in our economy, our environment, our water resources and our bodies, we need better authority so we can assure the public that any unacceptable risks have been eliminated," the EPA wrote. "But, under existing law, we cannot give that assurance." Ms. Jackson has asked Congress to amend laws governing how the EPA assesses chemicals, and has issued policies to insulate the agency's scientific reviews from outside pressures.[31] Whether these actions will affect standards for boron or other contaminants addressed in double pass desalination technology remains to be seen. So far, under the current

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[28] Nipping IRIS in the Bud: Suppression of Environmental Science by the Bush Administration's Office of Management and Budget (Report by the Majority Staff of the Subcommittee on Investigations and Oversight of the Committee on Science and Technology House of Representatives to Subcommittee Chairman Brad Miller, June 11, 2009), http://science.house.gov/publications/caucus_detail.aspx?NewsID=2499.

[29] See OMB Watch, In Drinking Water, What's Legal Can Be Poisonous (Matthew Media 12/17/2009), http://www.ombwatch.org/node/10655. See also EPA website, http://www.epa.gov/safewater/ccl/reg_determine2.html; Charles Duhigg, *That Tap Water Is Legal but May Be Unhealthy*, THE NEW YORK TIMES (Dec. 17, 2009), http://www.nytimes.com/2009/12/17/us/17water.html?_r=1&ref=us&pagewanted=print.

[30] Duhigg, *Id*.

[31] Charles Duhigg, *That Tap Water Is Legal but May Be Unhealthy*, THE NEW YORK TIMES (Dec. 17, 2009), http://www.nytimes.com/2009/12/17/us/17water.html?_r=1&ref=us&pagewanted=print.

administration, EPA is reconsidering a prior decision not to regulate perchlorate in drinking water.[32]

E. GENERAL REGULATORY UNCERTAINTIES

a. How Are Health Levels Set?

1. Definitions

"Risk assessment" refers to a formal or informal procedure producing a quantitative estimate of environmental risk. For example, risk assessment is often used to estimate the expected rate of illness or death in a population exposed to a hazardous chemical.

"Risk analysis" is used more broadly to include quantitative and qualitative evaluation of all relevant attributes of environmental hazards, risks, adverse effects, events and conditions that lead to or modify adverse effects, and populations or environments that influence or experience adverse effects.

"Risk management" is the process of deciding what should be done about a hazard, the population exposed, or adverse effects, implementing the decision, and evaluating the results. It also refers to decision making at the program or agency level, for example, deciding which hazards should be managed and in what order. Comparative (or relative) risk analysis and cost-

[32] In 2008, the US EPA determined that a national drinking water regulation for perchlorate would not present "a meaningful opportunity for health risk reduction for persons served by public water systems," and requested public comment on this preliminary determination. EPA received many negative comments on its decision, including one from MassDEP, which published a paper on the "Basis of the Massachusetts Reference Dose and Drinking Water Standards for Perchlorate" in the journal *Environmental Health Perspectives*. EPA is now reconsidering their decision not to regulate perchlorate in drinking water. A Federal Register notice issued August 19, 2009, contains EPA's re-evaluation of their decision and includes new evaluations of the impacts and risks of perchlorate on infants and children and associated health risk limits for drinking water. EPA is seeking comments from the public on its re-evaluation. Discussion by Mass. Dept. of Envtl. Protection at http://www.mass.gov/dep/water/drinking/percinfo.htm.

benefit analysis are aids to risk management.[33] These are commonly regarding as policy decisions.

2. Uncertainties in the Process

Although it is common to think of risk assessment as a purely scientific process, the risk assessment methodology actually includes many policy-related decision points. A National Academy of Science report describes some 50 points in the risk assessment process at which a choice is required among several scientifically plausible options.[34] These decision points include which dose response curve to employ, how to characterize risk information, whether animal studies will be accepted as indicative of human health effects, the weight to be accorded to different kinds of information. The Academy of Natural Sciences has noted that "Ideally, setting the Primary Drinking Water Standards would be based entirely on sound scientific evidence as to the risk presented by the substance being regulated. In reality, risk assessment remains an inexact science, and a number of political and economic factors enter into the decision making."[35]

Risk analysis is widely viewed as a potentially valuable tool for summarizing scientific information obtained from animal experiments and studies of accidental or occupational human exposures to hazards. But, people disagree about how risk analysis should be used and how much influence it should have on government decisions. Regulated industries and many academics support legislation that would increase use by environmental policy makers of risk

[33] Linda-Jo Schierow, Resources, Science, and Industry Division, Congressional Research Service, IB94036: The Role of Risk Analysis and Risk Management in Environmental Protection (September 6, 2001), http://www.ncseonline.org/nle/crsreports/risk/rsk-1.cfm.
[34] Percival et al, Environmental Regulation: Law Science and Policy 453-54, citing National Research Council, Risk Assessment in the Federal Government: Managing the Process 5-8 (1983).
[35] Roland Wall, Standards for Safe Drinking Water (November 2001), http://www.ansp.org/museum/kye/natural_resources/2001_drinking_water.php.

analysis, arguing that it is a scientific and objective basis for making rational risk management decisions.

Other academics and most environmentalists stress the limitations of risk analysis.[36] Critics of risk analysis argue that the science used in risk analysis is immature and suitable only for assessing immediate threats or the risk of developing cancer. In addition, they warn that risk analysis oversimplifies the problems faced by policymakers and managers of environmental programs, for example, by generally focusing on one hazard and one effect at a time, or on problems or aspects of problems that already are well understood. Critics of risk analysis also assert risk assessment methods are complex and easily manipulated for political purposes. Thus, it is argued, the decision-making process may be less democratic to the extent it is ostensibly based on risk.[37]

3. Objectivity of Studies: Industry Sponsorship

In 2004, the U.S. EPA's National Center for Environmental Assessment (NCEA)[38] announced its finding that people can safely consume more than twice the amount of boron

[36] Linda-Jo Schierow, Resources, Science, and Industry Division, Congressional Research Service, IB94036: The Role of Risk Analysis and Risk Management in Environmental Protection (September 6, 2001), http://www.ncseonline.org/nle/crsreports/risk/rsk-1.cfm.

[37] Linda-Jo Schierow, Resources, Science, and Industry Division, Congressional Research Service, IB94036: The Role of Risk Analysis and Risk Management in Environmental Protection (September 6, 2001), http://www.ncseonline.org/nle/crsreports/risk/rsk-1.cfm.

[38] EPA's Office of Research and Development conducts research to help ensure that efforts to reduce environmental risks are based on the best available scientific information. The National Center for Environmental Assessment (NCEA), a major component of ORD, is EPA's national resource center for human health and ecological risk assessment. NCEA conducts risk assessments, carries out research to improve the state-of-the-science of risk assessment, and provides guidance and support to risk assessors. NCEA occupies a critical position in ORD between (1) researchers in other ORD components generating new findings and data and (2) regulators in the EPA program offices and regions who must make regulatory, enforcement, and remedial action decisions. As a result, NCEA plays an important role as a consultant to EPA programs and regions on the use of science in environmental decision making and also influences the direction of environmental research.

previously considered harmless. NCEA increased its allowable daily dose of boron from 6.3 milligrams to 14 milligrams per day. [39]

The revision was the result of a multi-year assessment of more than 200 studies on boron's health effects, some of which were completed recently by scientists at the University of California, Irvine, and the Research Triangle Institute. NCEA conducted its risk assessment on boron to update the EPA's Integrated Risk Information System (IRIS), a database of human health effects associated with exposure to more than 500 substances found in the environment. IRIS is widely considered one of the world's most robust databases in this field.

However, at least some of the studies that find a lower health risk for boron have been sponsored by companies within the boron industry. Borax mining company Rio Tinto has sponsored studies at UC Davis and UCLA that focused on expanding the evidence that the reproductive effects of borates seen in animals would not occur in humans, except by abuse. According to Rio Tinto, "It has long been felt that even at abusive doses, effects are unlikely to occur in humans. To examine this, a study to compare different dosing regimes in rats on blood levels and reproductive effects was conducted. Data indicate fewer reproductive effects in rats with daily peak blood boron levels (analogous to abuse dosing) compared to rats with a continual blood boron level."[40]

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[39] Rio Tinto Press Release, Susan Keefe, 661/287-5484,
ENVIRONMENTAL PROTECTION AGENCY RAISES SAFETY LIMITS FOR BORON CONSUMPTION: *Review of 200 Studies Results in Increasing Levels Considered Safe for People* (August 5, 2004), http://www.borax.com/news38.html.

[40] Rio Tinto, Explore the World We Live In: Programmes, http://www.riotinto.com/library/microsites/socEnv2002/content/world/program/93_prod_rsrch_humtox.html. See also, Rio Tinto Press Release, Health and Safety Effects, http://www.borax.com/borates4a.html. See further, James R. Coughlin, Ph.D. The Big Picture: Groundbreaking news on boron's nutritional essentiality Pioneer Magazine (February 1998), http://www.borax.com/pioneer30.html (discussing sponsors of a series of boron symposiums at UC Irvine.

4. Uncertainty Factors

Uncertainty factors (UFs) are applied in arriving at a reference dose to account for recognized uncertainties in extrapolation from experimental conditions to lifetime exposure for humans. These UFs cover somewhat broad areas of uncertainty, such as “animal-to-human” (interspecies; UF) and “sensitive human” (interindividual; UF) extrapolations. The default uncertainty factor is 100, a level that provides a maximum margin of safety.[41]

Uncertainty factors were an issue in recent revisions of boron standards by EPA and WHO. At EPA, NCEA reduced its uncertainty factor for boron from the default level of 100 to 66 - a precedent-setting policy change. Uncertainty factors are mathematical formulas applied to data which are used to protect populations from hazards that cannot be assessed with high precision. The World Health Organization employed an uncertainty factor of 60 and also changed assumptions regarding the amount of boron exposure attributable to drinking water. WHO relied on “extensive data from the USA and UK” indicating that “dietary intakes of the group of primary concern” are low in relation to the tolerable daily intake, and increased allowable proportion of exposure via drinking water from 20% to 40%.[42] With those changes, WHO justified a guideline of 2.4/L.

EPA recognizes that other plausible science-based standards exist, based on different assumptions regarding uncertainty factors and other assumptions. A range of water quality levels (0.5 to 1.4 mg/L) have been proposed as protective of public health based on different assumptions in the calculations. EPA also notes state drinking water guidelines as follows:

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[41] This includes a 10-fold factor for intraspecies variability (this is the default value); and a 10-fold factor for interspecies differences (this is the default value)

[42] WHO, Boron in drinking-water: Background document for development of WHO Guidelines for Drinking-water Quality 14, WHO/HSE/WSH/09.01/2 (2009), whqlibdoc.who.int/hq/2009/WHO_HSE_WSH_09.01_2_eng.pdf

California, 1000 µg/L (1 mg B/L); Wisconsin, 900 µg/L (0.9 mg B/L); Florida, Maine, and New Hampshire, 630 µg/L (0.63 mg B/L); and Minnesota, 600 µg/L (0.6 mg B/L) (HSDB, 2006d).[43]

A logical question seems to arise: whether revisions in uncertainty factors or other assumptions reflect policy goals rather than a strict concern with public health and new scientific studies. Possible policy concerns include minimizing costs for areas with high natural boron levels in their drinking water and lack of cost effective technology. Guidelines appear to be set at a level that reflects those achievable with cost-effectiveness concerns. Regulators acknowledge this specifically in some cases. For example, in setting a level for British Columbia, regulators recommended that the total concentration of boron in drinking water should not exceed 5.0 mg/L. This maximum acceptable concentration was set because the available treatment technologies are inadequate to reduce boron concentrations in local drinking water supplies to less than 5.0 mg/L. Because boron concentration levels in British Columbia's surface and ground water are less than this value, boron toxicity is not expected to pose a significant risk to drinking water.[44] The former WHO standard of .5 was designated as provisional because it was viewed as unattainable using cost-effective technology.

III. Conclusion

The water quality provision is only one of many Regional Project implementation provisions that reflect public interest concerns and attempt to balance them appropriately and responsibly with cost concerns. We urge the Commission to oversee not only an "efficient" allocation of public water and public funding, but a "responsible" one as well, and to help forge a

[43] EPA, Health Advisory, supra, at 6.0. Some of the cited standards have since been revised.
[44] Ambient Water Quality Guidelines for Boron, Overview Report pursuant to Section 2(e) of the Environmental Management Act, original signed by Margaret Eckenfelder, Assistant Deputy Minister, Water, Land and Air Protection, July 23, 2003, http://www.env.gov.bc.ca/wat/wq/BCguidelines/boron/boron.html.

project that stakeholders can be proud of and one that can serve as a model. The very capacity of our land to support life is at stake in public decisions like this. It has been suggested that "where the agency has choices in formulating or operating projects such as dams, roads, and facilities, the trust duty requires selecting the alternative that rebuilds the natural assets at stake."[45]

Signed: April 30, 2010

Respectfully submitted,

____/s/_________________

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