SOUTHERN CALIFORNIA WATER COMMITTEE INCORPORATED

September 30, 2010

Lisa Perez Jackson, Administrator, U.S. EPA
Ariel Rios Federal Building
1200 Pennsylvania Avenue, NW, Mail Code: 1101A, Room 3000
Washington, DC 20460

Re: Opposition by the Southern California Water Committee to the development of a federal MCL for perchlorate

Dear Secretary Jackson:

As I am sure you are aware, the California Office of Environmental Health Hazard Assessment (OEHHA) is engaged in a statutorily required five-year review of the Public Health Goal (PHG) for perchlorate under its drinking water law. California's action may have an important impact on your agency's decision to consider whether or not to regulate perchlorate as a federal drinking water contaminant. For your information, we have attached two items: (1) a letter from our organization to OEHHA Director Joan Denton opposing any change in the current PHG of 6 ppb adopted in March, 2004 in California; and (2) a list of the of our organization's membership in Southern California. While you consider the necessity of a federal maximum contaminant limit (MCL) for perchlorate we would like you also to consider this short cover letter regarding a federal MCL and the attached letter to Dr. Denton.

As we emphasized in the attached letter, our organization is committed to regulation and change where supported by best available science that ensures that the drinking water we provide to the citizens of our state is clean and safe. By ensuring such safety, we build public confidence in our water supplies and deliver water at cost effective and affordable rates. To maintain that confidence, it is critical that there is best available scientific support for any proposed PHG or MCL.

For all of the following reasons The Southern California Water Committee is opposed to the adoption of a federal MCL:

1. As established by the science set forth in the attached letter, the levels of perchlorate found in the environment will not have an adverse effect on public health. The current California PHG and federal HCL were derived from a "no observed effect level." The federal Safe Drinking Water Act requires that MCLs be based on adverse effects to human health -- which in the case of perchlorate, has not been demonstrated in humans exposed to environmental levels of perchlorate. This conclusion was supported by the National Academy of Science in 2004 and has not been refuted by subsequent scientific research.

2. The vast majority of regulatory significant levels of perchlorate in drinking water in the United States are found in California or in water sources like the Colorado River, which are used for California drinking water. The three biggest wholesalers of water from the Colorado River in California, Nevada and Arizona are actively involved in the bankruptcy proceedings of the company responsible for the contamination (and cleanup) of the Colorado River. This issue can now be decoupled from the federal MCL issue so that its resolution does not require a federal MCL. For US EPA to develop an MCL, federal law requires that the contaminant at issue be "known to occur or there is a substantial likelihood that it will occur in public water systems with a frequency and at levels of public health concern." It does not appear to us that perchlorate satisfies that standard.

3. Federal law also requires that, regulation must present "a meaningful opportunity for health risk reduction for persons served by the public water systems." Given the low levels of perchlorate in the environment and the lack of occurrence at meaningful levels in public water system wells across the country, it makes no sense for US EPA to pursue an MCL for perchlorate. Further, we understand that EPA's Office of Inspector General has concluded that iodine supplementation is the more direct and more broadly effective solution to iodine insufficiency-- the primary concern with perchlorate. Therefore, none of the three statutory requirements that US EPA must meet to pursue an MCL appear to be satisfied.

4. Further, as you can see from the attached California letter, our organization is quite concerned about the amount of regulatory attention perchlorate is receiving, particularly when EPA's own Office of Inspector General, after looking at the impact of all goitrogens, concluded that perchlorate contributes less than one percent to environmentally induced iodine uptake interference in the thyroid.

5. Finally, Southern California water sources are severely constrained. The more requirements that are placed on drinking water contaminants than are justified using the best available science, the worse the water supply problem will become and the more expensive each successive solution becomes without providing significantly safer drinking water.

US EPA need not regulate perchlorate in the country's drinking water and certainly should avoid taking actions that make drinking water contaminant solutions substantially more complicated and expensive without adverse impacts on the public health.

Sincerely,

Richard W. Atwater, Executive Director , Southern California Water Committee

cc: Peter S. Silva, Assistant Administrator, Office of Water, U.S. EPA
Michael H. Shapiro, Principal Deputy Assistant Administrator, Office of Water, U.S. EPA
Robert W. Perciasepe, Deputy Administrator, U.S. EPA

SOUTHERN CALIFORNIA WATER COMMITTEE INCORPORATED

June 25, 2010

Joan E. Denton, Ph.D.
Office of Environmental Health Hazard Assessment California EPA
1001 "I" Street
Sacramento, CA 95812

RE: OEHHA's Current Re-evaluation of the Public Health Goal for Perchlorate

Dear Dr. Denton:

The Southern California Water Committee and its members (see attached partial list) work to ensure that the drinking water provided by the state's water purveyors is clean and safe to human health. In doing so, we rely on sound comprehensive science. Only by basing health standards and treatment plant best practices on accepted science can we assure continued public confidence in their water supplies, and delivery of the water by water purveyors at cost effective and affordable water rates.

We compliment the Office of Health Hazard Assessment (OEHHA) for consistently pursuing that same goal. In this light, as you re-evaluate the Public Health Goal (PHG) for perchlorate, we want to register our concern over any potential lowering of the Public Health Goal given the available accepted science. It is our belief that there is no new scientific or public health justification for California to lower its health protective standard of 6 parts per billion (ppb) for that PHG first set in March 2004.

Is a change scientifically warranted?

More than 50 years of scientific investigations, including a landmark National Academy of Sciences (NAS) review, have established a clear and consistent conclusion – the low levels of perchlorate do not present a credible risk of harm to public health. Based on the NAS report published in 2005, and the overall weight of scientific evidence, US EPA has established an interim health reference level (HRL) for perchlorate of 15 ppb. US EPA has concluded the 15 ppb HRL protects all sensitive populations – including infants – but is also considering whether to adopt a drinking water standard for perchlorate, a compound (salt) not currently regulated at the federal level.

As noted, OEHHA originally adopted a PHG for perchlorate of 6 ppb in March 2004. In 2006, the Department of Health Services (now the Department of Public Health) adopted a drinking water standard or maximum contaminant level (MCL) for perchlorate of 6 ppb, which became effective in October of 2007. In 2008, several environmental organizations petitioned OEHHA to review the perchlorate PHG. California statute requires OEHHA to review its existing PHGs once every

five years to determine whether new scientific data is available that necessitates revision of an existing PHG. OEHHA has since begun the review process for the perchlorate PHG.

While additional studies on perchlorate and human health have been conducted since the PHG was first established, the weight of scientific evidence continues to support the conclusion that the current 6 ppb MCL is highly health protective. In fact, California's existing PHG for perchlorate is already more stringent than the current interim federal HRL of 15 ppb. The PHG is based upon the Greer et al. (2002) clinical study, where human subjects were exposed to perchlorate in drinking water without adjusting for background exposures, such as through food. The results of this study demonstrate with great precision how the human body responds to perchlorate exposure. The Greer study was also used as the critical study for the evaluation of public health risks from perchlorate in drinking water by EPA (2005), The National Academy of Science (2005), the Agency for Toxic Substances and Disease Registry (ATSDR-2008) and Cal EPA's OEHHA (2004). While raising some new issues to further evaluate perchlorate's possible public health ramifications, it is our considered opinion that none of the new studies provide scientific basis for changing the perchlorate PHG to a more stringent level.

In addition, water purveyors often face credibility issues with their customers when a drinking water standard is changed. This task becomes even more difficult when modest changes are made with PHGs and MCLs already adopted at highly health protective levels.

Finally, we direct you to EPA's Office of Inspector General's April 19, 2010 report, entitled "Scientific Analysis of Perchlorate", which considers the cumulative effects of multiple sodium iodide stressors on public health. The OIG report concludes that "EPA's perchlorate RfD is conservative and protective of human health, and further reducing the perchlorate exposure below the RfD does not effectively lower risk. OIG goes on to say that: "Against established EPA risk assessment procedures, EPA derived the perchlorate RfD from a nonadverse biological effect instead of an adverse affect." We would appreciate your review and comment on this new report, especially as it may relate to OEHHA's reconsideration of the current perchlorate PHG.

Critical Issues affecting California under a more stringent California PHG/MCL.

California is currently experiencing one of its worst droughts in modern times. Southern California drinking water purveyors will likely receive a fraction of their regular allotment of drinking water this year, and for the foreseeable future. An unnecessary more stringent revision of the perchlorate PHG, followed by a similar change in the MCL at this time would only serve to exacerbate the current water supply crisis. Specifically, lowering the PHG/MCL could remove a number of drinking water wells from service throughout the state. Such a situation may leave California without sufficient water supplies to meet the state's water use needs, and without materially improving the public's health.

Investments have already been made in expensive water treatment facilities based on compliance with current standards. In California, lowering the perchlorate MCL could render some of these investments inadequate or much more expensive to operate. By lowering the PHG/MCL, the volume of impacted groundwater becomes much larger, requiring more extensive remediation. California water agencies cannot afford to make major new capital investments every few years to keep pace with shifting drinking water standards. Furthermore,

with the advent of chemical fingerprinting technology (allowing for distinction among multiple sources, including fertilizer, within a single plume) and data from the US Geological Survey showing natural perchlorate occurrence in arid regions, a lowering of the MCL is likely to result in imposition of substantial new costs on water ratepayers.

On behalf of our diversified membership, we ask you to take these concerns very seriously as you complete your work on the re-evaluation of the current PHG for perchlorate. Given the consequences noted above, the scientific and public health rationale must be compelling and sufficiently significant to warrant a lowering of the PHG.

Sincerely,

Ron Gastelum, Interim Executive Director, Southern California Water Committee.

cc:

Linda Adams, Secretary of the California EPA
Cindy Tuck, Undersecretary of the California EPA
Gary Yamamoto, Chief of the Division of Drinking Water Safety and Environmental Management, Department of Public Health
Dan Pellissier, Deputy Cabinet Secretary, Resources & Environment

Enclosure: Southern California Water Committee Membership List (partial list)

Southern California Water Committee, Inc.

Membership

Benefactor

County of Kern
County of Los Angeles
County of Orange
County of Riverside
County of San Bernardino

Founder

AECOM Technology Corporation
Black & Veatch Corporation
California-Nevada Conference of Operating Engineers
Camp Dresser & McKee, Inc. (CDM)
Hatch Mott MacDonald
Kern County Water Agency
Majestic Realty Company
MWH
Metropolitan Water District of Southern California
Paramount Farming Company
Parsons
Psomas
RBF Consulting
San Bernardino Valley Municipal Water District
Santa Margarita Water District
Southern California Edison

Sponsor

Best Best & Krieger LLP
Cordoba Corporation
Niagara
The Procter & Gamble Paper Products Company

Patron

Anheuser-Busch, Inc.
Building Industry Association of Southern California
California Domestic Water Co.
Central Basin Municipal Water District
City of Hemet
City of Indio
City of Los Angeles
City of Ontario
Coachella Valley Water District
Independent Oil Producers Agency
Johnson Machinery Co.
Knott's Berry Farm
La Jolla Cove LLC
McCormick, Kidman & Behrens, LLP
Moulton Niguel Water District
Newhall Land & Farming Company
Sea World of California
The Irvine Company

AT&T
Borchard Companies, Inc.
C J Segerstrom & Sons
Castaic Lake Water Agency
City of Chino
City of Indian Wells
City of Laguna Woods
City of Los Angeles Department of Water & Power
City of Riverside
Falcon Waterfree Technologies
Imperial Irrigation District
Inland Empire Utilities Agency
Kennedy/Jenks Consultants, Inc.
Krieger & Stewart
Milk Producers Council
Orange County Farm Bureau
Richard K. Jemison
SunCal Companies

SCWC Membership

AECOM Technology Corporation
Aera Energy LLC
Albert A. Webb Associates
Alston & Bird LLP
Anheuser-Busch, Inc.
Arcadis-US
Arvin-Edison Water Storage District
Association of California Water Agencies
AT&T
Best Best & Krieger LLP
Black & Veatch Corporation
Borchard Companies, Inc.
Brownstein Hyatt Faber Schreck
Building Industry Association of Southern California
Burke, Williams & Sorensen, LLP
C J Segerstrom & Sons
California-American Water Company
California Domestic Water Company
California-Nevada Conference of Operating Engineers
California Water Service Co.
Camp Dresser & McKee (CDM)
Carollo Engineers
Castaic Lake Water Agency
Central Basin Municipal Water District
Chase Bros.
Chino Basin Water Conservation District
Chino Basin Watermaster
City of Anaheim
City of Bakersfield
City of Cerritos
City of Chino
City of Downey
City of Escondido
City of Huntington Beach
City of Huntington Park
City of Indian Wells
City of Indio
City of La Quinta
City of La Verne
City of Laguna Woods
City of Los Angeles Department Of Water & Power
City of Los Angeles
City of Mission Viejo
City of Oceanside
City of Pasadena
City of Rancho Santa Margarita
City of Rialto
City of Santa Monica
City of Thousand Oaks
Coachella Valley Water District
Construction Industry Coalition on Water Quality
Cordoba Corporation
County of Kern
County of Los Angeles
County of Orange
County of Riverside
County of San Bernardino
CP Kelco
Cucamonga Valley Water District
Dee Jasper & Associates, Inc.
Desert Water Agency
Downey Brand Attorneys, LLP
East Valley Water District
Eastern Municipal Water District
Ecobility Corporation
El Toro Water District
Falcon Waterfree Technologies
Flow Science Incorporated
Fruit Growers Laboratory, Inc.
Germania Corporation
Golden State Water Company
H. M. Holloway, Inc.
Hatch Mott MacDonald
Honeywell International, Inc.
Hunter Industries Incorporated
Imperial Irrigation District
Independent Oil Producers Agency
Inland Empire Utilities Agency
International Paper
Irvine Ranch Water District
J & D Star Dairy
Johnson Machinery Co.
Kennedy/Jenks Consultants, Inc.
Kern Co Council of Governments
Kern County Farm Bureau, inc.
Kern County Water Agency
Kern Delta Water District
Knott's Berry Farm
Krieger & Stewart
La Jolla Cove, LLC
Laer Pearce and Associates
Lagerlof, Senecal, Bradley, Gosney & Kruse, LLP
Laguna Beach County Water District
Lake Hemet Municipal Water District
Las Virgenes Municipal Water District
Latham & Watkins
LegiSight, LLC
Lewis Planned Communities
Limoneira Company
Los Angeles County Economic Development Corporation
Mactec Engineering & Consulting
Majestic Realty Company
Mayer Brown, LLP
McCormick, Kidman & Behrens, LLP
Mellano & Company
Mesa Consolidated Water District
Metropolitan Water District of Southern California
Milk Producers Council
MJF Consulting
Mojave Water District
Monte Vista Water District
Montgomery Watson Harza , Inc.
Moulton Niguel Water District
Municipal Water District of Orange County
MWH
Newhall Land & Farming Company
Newland Communities, LLC
Niagara
Nossaman, LLP
Orange County Farm Bureau
Orange County Water District
Paramount Farming Company
Pardee Homes
Parsons
Psomas
Rancho California Water District
RBF Consulting
Redwine & Sherrill
Renewable Resources Group
Richard K. Jemison
Riverside County Chapter of the Building Industry Association
Riverside County Farm Bureau, Inc
Rose Hills Memorial Park & Motuary
Rosedale-Rio Bravo Water Storage District
San Bernardino Valley Municipal Water District
San Diego County Farm Bureau
San Diego County Water Authority
San Gorgonio Pass Water Agency
San Luis Rey Indian Water Authority
Sanitation District of Los Angeles County
Santa Ana Watershed Project Authority
Santa Margarita Water District
Sea World of California
Semitropic Improvement District of Semitropic Water Storage District
South Coast Water District
Southern California Edison
Southern California Golf Association
Southwest Regional Council of Carpenters
Stacy A. Roscoe
Suburban Water Systems
SunCal Companies
Sunrise Company
Temple-Inland
The Irvine Company
The Procter & Gamble Paper Products Co.
The Rogers Group
Three Valleys Municipal Water District
United States Gypsum Company
Upper San Gabriel Valley Municipal Water District
Vallecitos Water District
Valley County Water District
Valley Industry & Commerce Association
Vista Irrigation District
Water Association of Kern County
Water Replenishment District of Southern California
Watson Land Company
West Basin Municipal Water District
West Valley Water District
Western Municipal Water District
Wheeler Ridge-Maricopa Water District

9-22-10

October 8, 2009

Mr. Eric Burneson
Office of Ground Water and Drinking Water
Standards and Risk Management Division
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: California Agriculture Industry Comments on Docket Identification (ID) EPA-HQ-OW-2008-0692-Perchlorate Supplemental Request for Comments

Dear Mr. Burneson:

The undersigned California agriculture groups appreciate the opportunity to comment on USEPA's August 19, 2009, Federal Register notice seeking comment on "additional approaches available for analyzing data related to EPA's perchlorate regulatory determination." Since a national primary drinking water standard for perchlorate would directly impact public perception of the safety of agricultural commodities known to contain trace amounts of perchlorate, it is critical that EPA establish the appropriate science-based methodology before proceeding with a final regulatory determination.

The California agriculture industry is a $37 billion industry that produces more than 350 different crop and livestock commodities and generates an estimated $100 billion in related economic activity. California agriculture accounts for approximately 7.5% of all employment and supports more than a million on-farm jobs. California agriculture is also the leading global exporter of agricultural commodities, sending almost 20% of our agricultural production to foreign markets.

EPA's Proposed Alternative Health Reference Levels are Not Scientifically Justified and will Undermine Public Confidence in the Safety of Agricultural Commodities.

EPA's August 19, 2009, Federal Register notice states that the "additional alternatives under consideration could result in health reference levels which are much lower than the level identified in the October 2008 notice." This statement causes great concern for the California agriculture industry because it implies that exposure to trace amounts of perchlorate may be harmful to human health, when in fact, the rich body of scientific literature on perchlorate does not support this conclusion. It is well established that many agricultural commodities contain trace amounts of perchlorate, but these levels are widely recognized as being orders of magnitude below any level that may pose a risk of adverse human health effects. EPA's promotion of the alternative health reference level concept will needlessly rekindle public concern about the safety of agricultural commodities and

will drive some consumers away from these products to avoid perchlorate exposure. The negative impacts on public health associated with such a shift in dietary habits will vastly outweigh the risk of harm associated with exposure to trace amounts of perchlorate.

We are further concerned that the food scares which will follow from setting a regulatory threshold below the existing natural background level of perchlorate in the environment will significantly disadvantage agricultural exports. Agricultural commodities make up a significant portion of all U.S. food exports. Given the long history of our Asian trading partners taking retaliatory actions for what they deem to be U.S. protectionism -- we are particularly concerned in light of the Obama Administration's recent announcement to impose tariffs on Chinese tire manufacturers -- a regulatory determination which does not take into consideration the presence of naturally occurring perchlorate will provide an unfortunate opportunity for the Chinese government to make good on their threats to punish U.S. agricultural exports.

The NAS Report Remains the Most Comprehensive Scientific Review on the Health Effects of Perchlorate to Date.

The National Academy of Sciences conducted a thorough inquiry of the perchlorate health effects literature in a highly professional and independent manner. The Panel's 2005 recommendations, based upon the best science available, continue to be validated by new scientific studies on perchlorate health effects and exposures.

It is critically important to bear in mind that the NAS panel views its recommended perchlorate reference dose (RfD) as providing a large margin of safety because it is based on a No-Observed-Effect-Level (NOEL) -- inhibition of iodine uptake by the thyroid – rather than the traditional approach of starting from a No-Observed-Adverse-Effect-Level (NOAEL). The NOEL is the level below which exposure to a substance fails to elicit any biological response at all, and in the case of perchlorate is orders of magnitude below the levels at which adverse effects may occur. The NAS perchlorate panel further reduced this NOEL by a factor of 10 to account for variations in human response, leading them to conclude that their recommended RfD is highly health protective, even for sensitive subpopulations.

Further downward adjustment of the RfD based on body weight and water consumption rates at various life stages, as contemplated in EPA's proposed alternative health reference levels, is needlessly duplicative and provides no additional health protection for any population. Moreover, EPA has not presented any scientific evidence indicating why its current perchlorate health reference level (15 ppb), which is based on the most sensitive sub-population (the pregnant woman/fetus), and which incorporates a ten-fold safety factor to account for variability in human response, is inadequate.

US FDA's Food Sampling Results Reveal that Perchlorate Concentrations are Below any Meaningful Level of Concern and that Iodine Intake Actually Exceeds NAS-Recommended Levels for all Groups Across the US Population.

When perchlorate was first discovered in food, the U.S. FDA began sampling produce and bottled water in an effort to characterize perchlorate occurrence in food. FDA later expanded its perchlorate sampling program to include other vegetables, fruits and milk to gain a greater understanding of the range of foods containing perchlorate. FDA's work included a total dietary survey (TDS), the results of which were provided to US EPA for use in determining total perchlorate exposure in the US population.

The Total Dietary Survey is a market basket survey of various foods analyzed for perchlorate and iodine, conducted by FDA from 2003–2006. In early 2008, FDA published its testing results for 285 food samples in each of three cities in each of the four regions of the country. FDA evaluated the food data based upon estimated food consumption patterns of 14 age/sex groups from 6-11 month-old infants up to 70+ year-old men and women.

FDA found that the average daily intake of perchlorate was well below both the NAS' recommended RfD and USEPA's current 15 ppb health reference level (HRL). FDA identified children 2 years of age as having the highest average intake of perchlorate at 0.35 to 0.39 ug/kg body weight/day, which at the upper end is slightly more than half of the RfD, but still below the HRL.

These results, taken together with the results of EPA's 2006 tests of nearly 40,000 water samples from across the U.S.,[1] which show that perchorate levels were less than seven parts per billion in 99% of the samples, provide no evidence that individuals ingest perchlorate at daily doses exceeding the Reference Dose. They also suggest that there is little likelihood that such exposures would occur. This conclusion is further supported by data from the U.S. Centers for Diseases Control's National Health and Nutrition Examination Survey (NHANES) biomonitoring dataset (see below).

For iodine, FDA found that each of the 14 age/sex groups, including infants, children, and women of childbearing age exceeded the average intake levels estimated by the NAS to meet requirements for healthy individuals.

In light of these findings, FDA continues to stand by its prior recommendation that consumers should not alter their infants' and children's diets or eating habits. Indeed, many of the foods at issue are major dietary sources of iodine and other nutritionally essential substances.

[1] Office of Water: *The Analysis of Occurrence Data from the First Unregulated Contaminant Monitoring Regulation (UCMR1) in support of Regulatory Determinations for the Second Drinking Water Contaminant Candidate List* (EPA 815-D-06-008);

EPA's Calculation of the Relative Source Contribution for its 2008 Preliminary Regulatory Determination also Reveals that Perchlorate Exposure from Food is Below any Meaningful Level of Concern.

U.S. EPA uses the US Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey (NHANES) biomonitoring dataset in concert with the FDA TDS dataset to estimate the relative proportional intake of perchlorate from both food and water sources. The NHANES data provide the best available measure of actual human exposure to perchlorate from all sources, including food and water, using urinary perchlorate concentrations from a large U.S. population cohort. The overall exposure to perchlorate from all sources based on the NHANES data is below any meaningful level of concern identified in the available scientific literature. Thus, as a fraction of total exposure, intake of perchlorate from food alone must be well below any meaningful level of concern. FDA's TDS and food sampling data, which provides an approximation of human exposure to perchlorate from food, validates this conclusion.

Recent Epidemiological Data, Including the Blount (2006) Analysis of NHANES Data, Should Not Be Used as a Basis for a New Perchlorate Regulatory Determination.

The undersigned groups support EPA's decision to base its perchlorate regulatory determination on the NAS RfD. Some have argued that the Blount (2006b) results, which show a slight correlation between perchlorate in urine and changes in thyroid hormone levels in women with sub-optimal iodine levels, should be given considerable weight in EPA's review of its preliminary regulatory determination. In fact, the Blount analysis has several limitations which necessarily impede its use in drawing conclusions regarding the health effects of perchlorate, particularly for purposes of risk assessment and regulatory decision making. Chief among these is the fact that Blount (2006b) does not establish direct causation, only an association between two independent data sets. A number of intervening factors could cause or contribute to the reported decrease in thyroid hormone levels, including methodological issues such as the use of relevant measures of thyroid function (total T4 versus free T4) and appropriate biomonitoring data (24 hour urine versus spot urine samples). Second, even if changes in thyroid hormone levels were considered adverse (they are not), the changes identified in Blount (2006b) were not outside the normal ranges for thyroid hormone levels. Third, estimated perchlorate doses based on the urinary concentrations were below the level that can trigger inhibition of iodide uptake, the non-adverse precursor effect that is the basis of the NAS NOEL.

The Blount (2006b) results conflict with the overwhelming body of scientific evidence showing that perchlorate has no effect on the thyroid at environmentally relevant levels. Similar concerns have been raised by independent organizations such as the American

Thyroid Association[2], and a key member of the NAS perchlorate panel has indicated that the NAS RfD remains sufficiently health protective[3].

Conclusion

Based upon the best available scientific evidence, including exposure and occurrence data developed since the National Academy of Sciences issued its findings in January, 2005, the undersigned conclude that the regulatory thresholds contemplated in EPA's above referenced notice are not scientifically justified and are substantially more stringent than necessary to ensure protection of public health. Moreover, the US Food and Drug Administration's (FDA) food sampling data and total dietary survey, and the relative source contribution calculated by USEPA for its 2008 preliminary regulatory determination demonstrate conclusively that total perchlorate exposure in the US population is well below established levels of human health concern for both the general public and sensitive subpopulations.

For the reasons articulated above, the California agricultural industry encourages USEPA to act on its October 10, 2008 preliminary regulatory determination for perchlorate, which the weight of scientific evidence demonstrates to be highly health protective. We appreciate USEPA's consideration of our comments and we remain committed to working with USEPA, USDA and FDA to preserve the safety and integrity of our products and their contribution to balanced, healthy diets.

Sincerely,

Agricultural Council of California
California Citrus Mutual
California Cotton Ginners and Growers Association
California Farm Bureau Federation
California Floral Council
California Grape and Tree Fruit League
Grower-Shipper Association of Central California
Imperial Valley Vegetable Grower Association Ventura County Agricultural Association
Nisei Farmers League
Ventura County Agricultural Association
Western Growers Association
Western Plant Health Association
Western United Dairymen

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[2] The American Thyroid Association in 2007 concluded that the CDC study findings were "intriguing," but limited in their application to the setting of exposure standards. (http://www.thyroid.org/professionals/publications/statements/06_12_13_perchlorate.html).

[3] In April 2007 - *after* publication of the CDC study - NAS panelist Dr. Robert Utiger, senior physician with the Harvard Institutes of Medicine, testified before Congress and stated: "I continue to believe that a reference dose of 0.007 mg/kg/day (24.5 ppb) is quite adequate."

Bob Howd
(COA 10-0007)

DUPLICATE

October 1, 2010

Dr. Joan Denton, Director
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95814

Subject: OEHHA review of current public health goal for perchlorate

Dear Dr. Denton:

The Office of Environmental Health Hazard Assessment (OEHHA) recently posted a notice on its website, entitled *"Initiation of Risk Assessments for Chemicals in Drinking Water, July, 2010,"* indicating that a new perchlorate risk assessment is "nearing completion." The notice did not indicate a target timeframe for release of a draft risk assessment to the public. In light of this news and our long standing interest in perchlorate regulation, the undersigned organizations would like to advise OEHHA of our views concerning the substantial body of scientific information that has become available since the perchlorate public health goal (PHG) was first established in 2004, the implications of a lower PHG on the public's perception of the safety of agricultural commodities and the implications of a corresponding reduction in the current drinking water maximum contaminant level (MCL) on the future reliability of water supplies for agricultural operations and other beneficial uses.

The California agriculture industry is a $37 billion industry that produces more than 350 different crop and livestock commodities and generates an estimated $100 billion in related economic activity. California agriculture accounts for approximately 7.5% of all employment and supports more than a million on-farm jobs. California agriculture is also the leading global exporter of agricultural commodities, sending almost 20% of our agricultural production to foreign markets.

For the reasons articulated below, our organizations strongly recommend that OEHHA reaffirm its existing 6 part per billion (ppb) PHG.

State of The Science on Perchlorate

The 2005 NAS Report Remains the Most Comprehensive Scientific Review on the Health Effects of Perchlorate to Date.

The National Academy of Sciences conducted a thorough inquiry of the perchlorate health effects literature in a highly professional and independent manner. The Panel's 2005 recommendations, based upon the best available science, was cited by OEHHA in 2005 as validating its 2004 PHG. The NAS report itself continues to be validated by new scientific studies on perchlorate health effects and exposures.

It is critically important to bear in mind that the NAS panel views its recommended perchlorate reference dose (RfD), equivalent to 24.5 ppb in drinking water, as conservative and health protective because it is based on a No Observed Effect Level (NOEL) -- inhibition of iodine uptake by the thyroid – rather than the traditional approach of starting from a No Observed Adverse Effect Level (NOAEL). As you are well aware, exposures below the NOEL fail to elicit even the most benign biological responses. In the case of perchlorate, the NOEL has been established with a high degree of certainty at a level that is orders of magnitude below levels at which adverse effects may occur. The NAS perchlorate panel further reduced this NOEL by a factor of 10 to account for variations in human response, leading the panel to conclude that their recommended RfD is highly health protective, even for sensitive subpopulations.

OEHHA's 2004 benchmark dose analysis set the point of departure for the perchlorate PHG at approximately half of the NAS-recommended NOEL. Further downward adjustments to account for exposures to sensitive populations, and exposures from sources other than water yielded a PHG approximately 4 times more stringent than the NAS RfD. More importantly, because both the NAS RfD and the OEHHA PHG are set so far below any level that could lead to potential adverse health effects, it is impossible to quantify any difference in potential health benefits between these two values.

The 2010 USEPA OIG Report Further Validates the NAS' 2005 Recommendations.

USEPA's Office of Inspector General (OIG) final report on April 19, 2010 entitled "Scientific Analysis of Perchlorate" incorporates most of the new perchlorate literature developed between the issuance of the NAS report in 2005 and 2009. The OIG report acknowledges that several substances impact the thyroid's ability to utilize iodide for hormone production. OIG identifies these "sodium iodide symporter (NIS) stressors" as including perchlorate, thiocyanate, nitrate and most prominently, the lack of iodide. OIG conducted an independent risk assessment considering cumulative exposure to these NIS stressors, consistent with current USEPA risk assessment guidelines.

Perhaps the most striking conclusion from the OIG analysis is that addressing iodine deficiency among sensitive populations is likely to be a more effective public health protection strategy than regulating any one of the NIS stressors in isolation, as OEHHA and the California Department of Public Health have already done and which USEPA is currently considering for perchlorate. With respect to perchlorate, the OIG report specifically concludes that USEPA's perchlorate RfD, which is the same as the NAS-recommended RfD, "is conservative and protective of public health, and further reducing the perchlorate exposure below the RfD does not effectively lower risk."

Of even greater import to OEHHA's reevaluation of the current perchlorate PHG is the OIG's conclusion that "addressing moderate and mild iodine deficiency that occurs in about 29% of the U.S. pregnant and nursing population appears to be a more effective approach of increasing (thyroid iodine uptake) to healthy levels during pregnancy and nursing, thereby reducing the frequency and severity of permanent mental deficits in children." OIG also notes that this finding is consistent with a recommendation by the National Academy of Sciences in its 2005 report on perchlorate health effects that "consideration be given to adding iodide to all prenatal vitamins."
We recognize that the state of California lacks the authority and resources to implement an iodine supplementation program on its own, and that such action would require a coordinated effort

involving federal agencies including the Department of Health and Human Services, the Food and Drug Administration and the U.S. Department of Agriculture. However, as the OIG report implies, this approach is likely to yield actual public health benefits and would certainly be far more cost effective for both public and private sector stakeholders than attempting to further regulate perchlorate or any other "NIS stressor" in drinking water. An iodine supplementation strategy would offer the added benefit of preventing unnecessary public alarm over the safety of drinking water and foods containing these substances.

The Overwhelming Weight of Evidence from the Post-NAS Report Literature Supports the Conclusion that the NAS-Recommended RfD Remains Highly Health Protective.

To address uncertainties in the data available to the NAS, the Panel report recommended additional research regarding questions about long-term exposure to perchlorate among sensitive populations, specifically pregnant women and their fetuses, and newborns. Since the NAS report was published, several studies and reports have emerged which address aspects of those issues, and their findings — which provide additional support for the NAS conclusions — can be summarized as follows:

- Women of reproductive age are very unlikely to ingest perchlorate at levels higher than the California maximum contaminant limit (MCL) of 6 ppb (Blount et. al. 2007; Mendez et. al, 2009).
- Exposure to environmental levels of perchlorate during and after pregnancy does not affect the iodine nutrition of, or cause adverse effects in, fetuses or infants (Blount et. al, 2009; Pearce et. al., 2007).

- Ambient perchlorate represents less than 1 percent of the iodide inhibition caused by goitrogenic anions (nitrate, thiocyanate and perchlorate) to which humans are exposed (OIG, 2010; Tarone, 2010).

Some have argued that the Blount (2006) results, which show a slight correlation between perchlorate in urine and changes in thyroid hormone levels in women with sub-optimal iodine levels, should be given considerable weight in OEHHA's review of its current perchlorate PHG. Importantly, however, scientists reviewing this study have indicated its findings are inconsistent with underlying physiology, have yet to be confirmed, and more likely reflect inherent anomalies of the database used for the research. In fact, the Blount analysis has several limitations which necessarily impede its use in drawing conclusions regarding the health effects of perchlorate, particularly for purposes of risk assessment and regulatory decision making. Chief among these is the fact that Blount (2006) does not establish direct causation, only an association between two variables. A number of intervening factors could cause or contribute to the reported decrease in thyroid hormone levels, including methodological issues such as the use of relevant measures of thyroid function (total T4 versus free T4) and appropriate biomonitoring data (24 hour urine versus spot urine samples). Second, even if changes in thyroid hormone levels were considered adverse (they are not), the levels identified in Blount (2006) were not outside the normal ranges for thyroid hormone levels. Third, estimated perchlorate doses based on the urinary concentrations were below the level that can trigger inhibition of iodide uptake, the non-adverse precursor effect that is the basis of OEHHA's current PHG.

The Blount (2006b) results conflict with the overwhelming body of scientific evidence showing that perchlorate has no effect on the thyroid at environmentally relevant levels. Further, even if the results were not in conflict, they still support the premise that low levels of perchlorate exposure do not pose a risk of adverse health effects.

A Lower PHG Will Undermine Public Perception of Food Safety and Invite New Trade Restrictions.

It has been established that select agricultural commodities may contain trace amounts of perchlorate, but these levels are widely recognized as being orders of magnitude below any level that may pose a risk of adverse human health effects.

The US Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey (NHANES) biomonitoring data provide the best available measure of actual human exposure to perchlorate from all sources, including food and water, using urinary perchlorate concentrations from a large U.S. population cohort. The overall exposure to perchlorate from all sources based on the NHANES data is well below any meaningful level of concern identified in the available scientific literature.

When it was established in 2004, OEHHA's perchlorate PHG inspired unwarranted public concern about the safety of implicated agricultural commodities and helped to prompt public pronouncements by the U.S. Food and Drug Administration (FDA) discouraging changes in dietary practices. An unjustified lowering of the perchlorate PHG will rekindle and intensify the 2004 food scare, once again driving consumers away from agricultural products to avoid perchlorate exposure. While FDA continues to reassure the public that the negative health impacts associated with such a shift in dietary habits vastly outweigh the risk of harm associated with exposure to trace amounts of perchlorate, these statements may not be sufficient to overcome media-generated hysteria about the safety of implicated agricultural products.

As we stated in our January 5, 2004 letter to then Cal-EPA Secretary Terry Tamminen, experience suggests that a lower PHG would become the benchmark for all other exposure pathways, starting with food and milk, regardless of significant variations in consumption patterns and relative contribution to total perchlorate exposure. The media does not explain these and other important issues to the public. The consequence of such superficial reporting on perchlorate in food and milk is that consumers stop buying implicated commodities. For perishable products such as lettuce this outcome has devastating financial consequences. The National Food and Agriculture Policy Project (based out of Arizona State University) estimated a loss on the order of $5 billion (over 8 years), just at the farm gate for California desert area producers of lettuce and leafy vegetables from a sustained "perchlorate scare".

We are further concerned that the food scares which will follow from setting a perchlorate PHG below background levels typically found in the environment will significantly disadvantage agricultural exports. Agricultural commodities make up a significant portion of all U.S. food exports. Given the long history of some trading partners taking retaliatory actions for what they deem to be U.S. protectionism -- we are particularly concerned that a PHG which does not take into

consideration the presence of naturally occurring perchlorate and or trace levels will provide an unfortunate opportunity for trade partners to punish California, Arizona and U.S. agricultural exports.

A Lower PHG and Corresponding Reduction in the MCL Will Undermine Water Supply Reliability and Impose New Costs on Water Users.

California's water supply system is in a state of crisis, and the agriculture industry is disproportionately impacted relative to other sectors of the economy. After several years of drought and recent federal court decisions dedicating ever larger volumes of surface water supplies to habitat and species protection, water deliveries to agricultural operations have dwindled to a fraction of what is necessary to sustain current production levels.

Even on the heels of above average precipitation this past winter and spring, State Water Project contractors serving Central and Southern San Joaquin Valley farmers received only 40% of their requested allocations. Our members are fallowing thousands of acres of production capacity due to lack of adequate water deliveries. As water supplies become more constrained, delivery prices also increase and some agricultural operations cannot effectively amortize this cost. In the last few years, some small California farming operations have shut down completely. Unemployment rates in California farming communities are at historic highs, well above the 12.3 percent statewide average, and consumers are paying higher prices for imported agricultural products.

Part of the solution to a sustainable water supply is restoration of contaminated groundwater which could be used to supplement increasingly limited surface water supplies. Over the past decade, California voters have supported ballot initiatives dedicating billions of dollars of bond revenue to protection and restoration of California water supplies. In October of 2009, the Governor announced approval of an additional $717 million in American Recovery and Reinvestment Act and State funding for 160 water quality projects throughout California. Much of this money is still being allocated to new projects based on criteria designed to maximize the water quality benefit of each dollar spent. However, a lowering of the perchlorate PHG, followed by a corresponding change in the MCL, could unnecessarily limit the number of water quality improvement projects that can be undertaken with these resources.

A 2009 study published by the American Water Works Association suggests the cost to remove perchlorate from California drinking water sources to a level below California's current standard could amount to hundreds of millions of dollars. The unintended consequence of a lower PHG and MCL would be to squander huge amounts of public resources on a relatively small handful of groundwater cleanup projects, leaving many other potential water supply sources unfit for potable uses, including food crop irrigation.

OEHHA should reaffirm its existing 6 ppb PHG.

The overwhelming weight of scientific evidence, including studies published since the National Academy of Sciences issued its 2005 report on perchlorate, strongly support the conclusion that OEHHA's current 6 ppb Public Health Goal remains highly health protective. This fact, coupled with the adverse public health implications of a new and more pronounced "perchlorate scare", the potential for further water supply restrictions, and collateral impacts on industries such as agriculture, lead to the

inevitable conclusion that OEHHA should reaffirm its existing 6 ppb PHG.
If you have questions or would like to discuss this further, please contact Hank Giclas of Western Growers via email at hgiclas@wga.com or by phone at (949) 885-2205.

Respectfully submitted,

Western Growers
California Farm Bureau Federation
Agricultural Council of California
Grower-Shipper Association of Central California
Grower-Shipper Association of San Luis Obispo and Santa Barbara Counties
Imperial Valley Vegetable Growers Association
Ventura County Agriculture Association
Western Plant Health Association
Western United Dairymen

Cc: Scott Reid and Dan Pellisier, Governor's Office
Cindy Tuck, Cal/EPA
A.G. Kawamura, Department of Food and Agriculture

Office of Environmental Health Hazard Assessment

Joan E. Denton, Ph.D., Director
Headquarters • 1001 I Street • Sacramento, California 95814
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Linda S. Adams
Secretary for Environmental Protection

Arnold Schwarzenegger
Governor

October 29, 2010

Western Growers
California Farm Bureau Federation
Agricultural Council of California
Grower-Shipper Association of Central California
Grower-Shipper Association of San Luis Obispo and Santa Barbara Counties
Imperial Valley Vegetable Growers Association
Ventura County Agriculture Association
Western Plant Health Association
Western United Dairymen

Dear Agricultural Coalition members:

Thank you for your letter of October 1, 2010, regarding the review of the Public Health Goal (PHG) for perchlorate being conducted by the Office of Environmental Health Hazard Assessment (OEHHA). We appreciate the interest you have shown in our work, and we share your concern about the need for a careful and reasoned review of the toxicity of drinking water contaminants.

Our draft review of perchlorate is nearing completion, and we expect it will be posted in the near future for public comment. As you note, the National Academy of Sciences' (2005) review supported the use of the "Greer" study for perchlorate risk assessment and the recent U.S. Environmental Protection Agency Office of the Inspector General's report concluded that a higher drinking water level than the current PHG of 6 ppb is adequately health-protective. We are considering these conclusions as well as other available information on maternal/child responses to perchlorate exposures in our re-analysis. Upon release of this draft, we will welcome all comments on our specific approach and conclusions concerning the development of a health-protective level.

Please bear in mind that OEHHA is required by the California Safe Drinking Water Act to base PHGs exclusively on public health considerations, while the Department of Public Health (DPH) is directed to consider technological and economic feasibility in developing the Maximum Contaminant Levels. Therefore those parts of your comments which address economic issues associated with perchlorate regulation are more properly addressed to DPH.

Thanks again for your interest in our PHG program.

Sincerely,

Joan E. Denton, Ph.D.

Joan Denton, Ph. D., Director
Office of Environmental Health Hazard Assessment

September 27, 2010

JOAN DENTON, PH.D.
Director, Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95814

Subject: OEHHA review of 2004 Public Health Goal for Perchlorate.

Dear Dr. Denton:

On behalf of the California Building Industry Association (CBIA), representing over 3,500 companies involved in all aspects of homebuilding and the development and redevelopment of communities; the California Business Properties Association (CBPA) the recognized voice of the commercial, industrial and real estate industries representing over 12, 000 companies; and the California Major Builders Council (CMBC) comprised of twenty four of the largest builders and developers in the state of California we are writing to express our views concerning the Office of Environmental Health Hazard Assessment's (OEHHA) pending review of its current Public Health Goal (PHG) for perchlorate in drinking water.

On June 25th of this year the Southern California Water Committee (SCWC) wrote to you expressing the view that "there is no new scientific or public health justification for California to lower its health protective standard of 6 parts per billion (ppb)" for perchlorate. We concur with this assessment of the available science, and are writing to amplify SCWC's stated concern that "an unnecessary more stringent revision of the perchlorate PHG, followed by a similar change in the (maximum contaminant level) MCL would only serve to exacerbate the current water supply crisis".

California has been an acknowledged leader in establishing a link between land use and water supply. Within the last decade, there has been an increased emphasis on demonstrating water supply security for new development. In 2001, two bills were enacted to draw a tighter connection between water supply and land use planning. Senate Bill 610 (Costa) requires retail water agencies to prepare a water supply assessment as part of the CEQA review of larger-scale (500 units or more) projects. Senate Bill 221 (Kuehl) requires retail water agencies to provide written verification of the availability of a sufficient supply of water as a condition of tentative map approval for those same-scale projects. The Legislature enacted both planning bills as a partial response to its own long standing lack of support for infrastructure investment.

As California's Legislature moved away from financing storage options such as dams and reservoirs and as imported supplies from major sources such as the State Water Project and the Colorado River became less predictable, local water agencies began developing a more diversified and sophisticated portfolio of supplemental supplies to ensure water reliability. From water transfers to local groundwater supplies to off-stream storage to reclamation, conservation and conjunctive use, local water agencies have become the frontline planner and developer of new water supplies.

All of these sources of supplemental water supply are absolutely essential in order to meet the requirements of Senate Bills 610 and 221 and to ensure that the water needs of a growing and prospering California are met in the years ahead. By extension, the resources available to develop and protect these sources must be allocated and invested in a manner that maximizes water supplies. The imposition of lower drinking water standards not based upon the best available science will result in misallocation of these resources on groundwater cleanup and treatment projects which will not yield additional public health benefits, much less additional water supplies. To the contrary, such action would further restrict access to water supplies,

placing even greater pressure on water purveyors, ratepayers and the commercial, residential and retail real estate industries.

Despite recent legislation postponing a ballot initiative to raise $11.1 billion in additional revenue for new water supply projects, many billions in public and private investments are already committed to these purposes. As the SCWC notes in its June 25 letter, "lowering the PHG/MCL could remove a number of drinking water wells from service throughout the state." On the heels of a three year drought, with recent court decisions dedicating greater volumes of surface water supplies to species and habitat protection and the demands of a growing population rapidly outpacing our aging water supply infrastructure, California cannot afford to sacrifice additional drinking water sources to well meaning but unnecessary drinking water standards.

The continued erosion of California's water supply to competing demands is also a significant impediment to the recovery of an industry which has historically ranked first among the state's leading industries in terms of economic output. Between 2005 and 2009, the rapid decline of new housing construction resulted in an approximately 80% drop in total economic output and an 84% decrease in employment in our industry[1]. The impact of the housing industry decline is most pronounced in Los Angeles, Orange and San Diego Counties, which also happen to be among the most water supply-constrained regions in the state. We cannot hope to reverse this trend in the absence of a viable water supply.

We recognize that access to safe, high quality sources of drinking water is essential to the future prosperity of this industry and the state as a whole. California regulators cannot afford to continue making water policy decisions in a vacuum particularly when those decisions will not yield the intended benefits, are not supported by the overwhelming weight of scientific evidence and promise to further constrain already limited water supplies.

We strongly urge California water policy makers to help regional and local water agencies retain the flexibility necessary to meet increasing demands on limited water supplies. An action by OEHHA to reaffirm its existing, health protective 6 ppb PHG for perchlorate would be a significant step in the right direction.

Sincerely,

Richard Lyon
Vice President, Government Affairs
California Building Industry Association

Rex S. Hime
President and CEO
California Business Properties Association

Edward P. Manning
California Major Builders Council

[1] Center for Strategic Economic Research; The Economic Benefits of Housing in California, July 29, 2010.

CalChamber™
CALIFORNIA CHAMBER OF COMMERCE

November 4, 2010

Joan E. Denton, Ph.D.
Office of Environmental Health Hazard Assessment California EPA
1001 "I" Street
Sacramento, CA 95812

RE: OEHHA's Current Re-evaluation of the Public Health Goal for Perchlorate

Dear Dr. Denton:

The CalChamber, California Chamber of Commerce, with over 15,000 members, representing one-fourth of the private sector workforce in California and serving as an advocate and resource for large and small California employers to ensure fair legislation and a pro-business climate, is writing to express our views concerning the Office of Environmental Health Hazard Assessment's (OEHHA) pending review of its current Public Health Goal (PHG) for percholorate in drinking water. Our belief is that there is no new scientific or public health justification for California to lower its health protective standard of 6 parts per billion (ppb) for that PGH first set in March 2004.

The CalChamber agrees with the views expressed in the letters submitted to OEHHA by: the Southern California Water Committee on June 25, 2010, the Agriculture Coalition Letter submitted on October 1, 2010 and the joint letter submitted by the California Building Industry Association, California Business Properties Association and the California Major Builders Council on September 27, 2010.

In 2005 The National Academy of Sciences (NAS) conducted a thorough inquiry of the perchlorate health effects and established a clear and consistent conclusion, that the low levels of perchlorate in water do not present a credible risk of harm to public health. Based on the NAS report, and the overall weight of scientific evidence, US EPA has established an interim health reference level (HRL) for perchlorate of 15 ppb. US EPA has concluded the 15 ppb HLR protects all sensitive populations, including infants, but is also considering whether to adopt a drinking water standard for perchlorate, a compound (salt) not currently regulated at the federal level.

As noted, OEHHA originally adopted a PHG for perchlorate of 6 ppb in March 2004. In 2006, the Department of Health Services (now the rdepartment of Public Health) adopted a drinking water standard or maximum containment level (MCL) for perchlorate of 6 ppb, which became effective in October of 2007. In 2008, several environmental organizations petitioned OEHHA to review the perchlorate PHG. California statute requires that OEHHA review its existing PHGs every five years to determine whether new scientific date is available that necessitates revision of an existing PHG. OEHHA has since begun the review process for the perchlorate PGH.

The CalChamber recognizes that many areas in our state suffer from dwindling supplies of natural resources, especially water. Water is vital to the people and the economy of California. In order to protect the people, businesses and agriculture in California, we need to ensure that water is safe, available and affordable. Investments have already been made in expensive water treatment facilities based on compliance with current standards. In California, lowering the perchlorate MCL could render some of these investments inadequate or much more expensive to operate.

1215 K Street, Suite 1400
Sacramento, CA 95814
916 444 6670
www.calchamber.com

We ask you to take these concerns very seriously as you complete your work on the re-evaluation of the current PHG for perchlorate.

Sincerely,

Valerie Nera
Policy Advocate

Cc: Linda Adams, Secretary of the California Environmental Protection Agency
Cindy Tuck, Undersecretary of the California Environmental Protection Agency
Dan Pellissier, Deputy Cabinet Secretary, Resources & Environment

VN:am

Anne –
Bob –
Craig –
Ed
– George

June 3, 2009

Dr. Joan Denton, Director
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95814

Subject: **Agriculture Industry Comments on OEHHA's Review of the Current Public Health Goal for Perchlorate in Drinking Water.**

Dear Dr. Denton:

The undersigned representatives of the California agricultural industry are pleased to submit the following comments on the Office of Environmental Health Hazard Assessment's review of the public health goal (PHG) for perchlorate in drinking water. California agriculture is a diverse and important sector of the California economy. It is a $37 billion industry that produces over 350 different crop and livestock commodities and generates an estimated $100 billion in related economic activity. California agriculture accounts for approximately 7.5% of all employment and supports over a million on-farm jobs. California agriculture is also the leading global exporter of agricultural commodities, sending almost 20% of our agricultural production to foreign markets.

Based upon the best available scientific evidence, including exposure and occurrence data developed since the perchlorate PHG was issued in March of 2004, the undersigned conclude the current 6 ppb PHG is more than sufficiently stringent to ensure protection of public health (to be sure, the margin of safety incorporated in the PHG is extraordinary, and likely is well beyond what is necessary for public health protection). Continued scientific support for the existing California standard is confirmed by the US Food and Drug Administration's (FDA) food sampling data and total dietary survey, and US EPA's calculated relative source contribution. Together, these data demonstrate conclusively that total perchlorate exposure in California (and in the rest of the US population) is well below established levels of human health concern, including sensitive subpopulations.

The NAS Report Remains the Most Comprehensive Scientific Review on the Health Effects of Perchlorate to Date.

The undersigned supported OEHHA's 2004 decision to issue the PHG as an interim number, pending review of the findings from a separate assessment of the perchlorate health effects literature by the National Academy of Sciences. OEHHA ultimately determined that the NAS panel's findings, issued in January of 2005, were consistent

with its 2004 perchlorate PHG. The NAS panel conducted a thorough scientific inquiry in a highly professional and independent manner. Moreover, the Panel's 2005 recommendations, based upon the best science then available, continue to be validated by new scientific studies on perchlorate health effects and exposures.

It is critically important to bear in mind that the NAS panel views its recommended perchlorate reference dose (RfD) as providing a large margin of safety because it is based on a No-Observed-Effect-Level (NOEL) as opposed to the traditional approach of starting from a No-Observed-Adverse-Effect-Level (NOAEL). OEHHA's benchmark dose is derived from the same precursor effect, inhibition of iodine uptake by the thyroid, rather than an actual adverse effect (hypothyroidism). By virtue of incorporating additional uncertainty factors and exposure adjustments for the most sensitive subpopulations, OEHHA's PHG is four times lower than the NAS RfD. Thus the NAS panel's conclusion that their RfD is highly health protective, even for sensitive subpopulations, can be stated even more emphatically in the context of OEHHA's PHG.

<u>US FDA's Food Sampling Results Reveal that Perchlorate Concentrations are Below any Meaningful Level of Concern and that Iodine Intake Actually Exceeded NAS-Recommended Levels for all Groups Across the US Population.</u>

When perchlorate was first discovered in food, the US FDA began sampling produce and bottled water in an effort to characterize perchlorate occurrence in food. FDA later expanded its perchlorate sampling program to include other vegetables, fruits and milk to gain a greater understanding of the range of foods containing perchlorate. FDA's work included a total dietary survey (TDS), the results of which were provided to US EPA for use in determining total perchlorate exposure in the US population.

The Total Dietary Survey is a market basket survey of various foods analyzed for perchlorate and iodine, conducted by FDA from 2003-2006. In early 2008, FDA published its testing results for 285 food samples in each of three cities in each of the four regions of the country. FDA evaluated the food data based upon estimated food consumption patterns of 14 age/sex groups from 6-11 month-old infants up to 70+ year-old men and women.

FDA found that the average daily intake of perchlorate was well below both the NAS' recommended RfD and health reference level (HRL). FDA identified children 2 years of age as having the highest average intake of perchlorate at 0.35 to 0.39 ug/kg body weight/day, which at the upper end is slightly more than half of the RfD, but still below the HRL.

For iodine, FDA found that each of the 14 age/sex groups, including infants, children, and women of childbearing age exceeded the average intake levels estimated by the NAS to meet requirements for healthy individuals.

In light of these findings, FDA continues to stand by its prior recommendation that consumers should not alter their infants' and children's diets and eating habits.

Indeed, many of the foods at issue are major dietary sources of iodine and other nutritionally essential substances.

EPA's Calculation of the Relative Source Contribution for its Preliminary Regulatory Determination also Reveals that Perchlorate Exposure from Food is Below any Meaningful Level of Concern.

U.S. EPA uses the US Centers for Disease Control's National Health and Nutrition Examination Survey (NHANES) biomonitoring dataset in concert with the FDA TDS dataset to estimate the relative proportional intake of perchlorate from both food and water sources. The NHANES data provide the best available measure of actual human exposure to perchlorate from all sources, including food and water, using urinary perchlorate concentrations from a large U.S. population cohort. The overall exposure to perchlorate from all sources based on NHANES is below any meaningful level of concern. Thus, as a fraction of total exposure, intake of perchlorate from food alone is well below any meaningful level of concern. FDA's TDS and food sampling data, which provides an approximation of human exposure to perchlorate from food, validates this assertion.

The Blount (2006) Analysis of Perchlorate Data has Several Limitations and OEHHA Should Not Rely on its Conclusions to Make Decisions Regarding the Adequacy of the Current PHG.

Some have argued that the Blount (2006b) results, which show a slight correlation between perchlorate in urine and changes in thyroid hormone levels in women with sub-optimal iodine levels, should be given considerable weight by OEHHA in its review of the current perchlorate PHG. In fact, the Blount work has several limitations which necessarily impede its use in drawing conclusions regarding the health effects of perchlorate, particularly for purposes of risk assessment and regulatory decision making. Chief among these is the fact that Blount (2006b) does not establish direct causation, only an association between two independent data sets. A number of intervening factors could cause or contribute to the reported decrease in thyroid hormone levels, including methodological issues such as the use of relevant measures of thyroid function (total T4 versus free T4) and appropriate biomonitoring (24 hour urine versus spot urine samples). Second, even if changes in thyroid hormone levels were considered adverse (they are not), the changes identified in Blount (2006b) were not outside of the normal ranges for thyroid hormones. Third, estimated perchlorate doses based on the urinary concentrations were below the level that can trigger inhibition of iodide uptake, the non-adverse precursor effect that is the basis of the NOEL. Moreover, the Blount (2006b) results conflict with the overwhelming body of scientific evidence showing no effect of perchlorate on the thyroid at environmentally relevant levels. Dr. Blount himself has acknowledged the limitations of his results. Similar concerns have been raised by independent organizations such as the American Thyroid Association, and a key member of the NAS perchlorate panel has indicated that the NAS RfD remains sufficiently protective:

- The American Thyroid Association in 2007 concluded that the CDC study findings were "intriguing," but limited in their application to the setting of exposure standards.
(http://www.thyroid.org/professionals/publications/statements/06_12_13_perchlorate.html)

- In April 2007 - *after* publication of the CDC study - NAS panelist Dr. Robert Utiger, senior physician with the Harvard Institutes of Medicine, testified before Congress and stated: "I continue to believe that a reference dose of 0.007 mg/kg/day (24.5 ppb) is quite adequate."

For the reasons articulated above, the California agricultural industry encourages OEHHA to retain its existing 6 ppb PHG, which the weight of scientific evidence demonstrates to be highly health protective. We appreciate OEHHA's consideration of our comments and we remain committed to working with your agency and Cal-EPA to preserve the safety and integrity of our products and their contribution to balanced, healthy diets.

Sincerely,

Agricultural Council of California

California Citrus Mutual

California Cotton Ginners and Growers Association

California Farm Bureau Federation

California Grape and Tree Fruit League

Grower-Shipper Association of Central California

Grower-Shipper Association of Santa Barbara and San Luis Obispo Counties

Imperial Valley Vegetable Grower Association

Ventura County Agricultural Association

Western Growers Association

Western Plant Health Association

cc: Linda Adams, Secretary, Cal-EPA
Cindy Tuck, Undersecretary, Cal-EPA
A.G. Kawamura, Secretary, Department of Food and Agriculture
William Brown, Undersecretary, Department of Food and Agriculture
Dr. George Alexeeff - OEHHA
Allan Hirsch - OEHHA
Michael Prosio - Governor's Office
Bob Gore - Governor's Office

Association of California Water Agencies

Leadership Advocacy Information *Since 1910*

August 29, 2008

Mr. Michael Baes
PHG Project
Pesticide and Environmental Toxicology Branch
Office of Environmental Health Hazard Assessment
1515 Clay Street, 16th Floor
Oakland, CA 94612

Subject: Comments on the Review of the Perchlorate PHG

Dear Mr. Baes:

The following are comments developed by the Association of California Water Agencies (ACWA) relative to the review of the Public Health Goal (PHG) for perchlorate. ACWA represents over 450 public water agencies in California that collectively supply over 90% of the water delivered in California for domestic, agricultural and industrial uses.

We understand that the review is being undertaken at the request of several environmental groups and for purposes of the Office of Environmental Health Hazard Assessment (OEHHA) statutorily prescribed five year review of previously adopted PHGs. We appreciate the opportunity to provide these initial comments and request that the comment period be extended beyond September 1, 2008 to allow inclusion of additional comments and material as noted below.

At the outset we request a clarification as to the procedure OEHHA plans to follow relative to the public comment period related to this review process. Is OEHHA planning on following the process for preparing a PHG that is outlined in the Health and Safety Code sections PHG (116365 (c)(3) (A) – (D)) or will it be a different process? If so, can OEHHA provide us with an outline of such a process? ACWA is concerned that it is not clear what the process is or what standards will be applied to the review as the public comment period announced by OEHHA seems too short for the preparation of cogent and useful comments.

It is critical that the process for re-evaluating the PHG be transparent, equitable, based on new, sound science. It must also provide ample opportunity for the public to comment.

In addition, we have the following technical comments:

1) Perchlorate is a goitrogen, a chemical that blocks the uptake of iodide to the thyroid, resulting in hypertrophy of the thyroid, i.e. goiter. Sustained iodide deficiency can cause additional effects beyond goiter, including hypothyroidism and, of greatest concern, hypothyroxinemia. Maternal iodide deficiency and hypothyroxinemia during pregnancy and nursing can result in neurodevelopmental deficits in children, historically referred in its more extreme forms as cretinism. It is this health endpoint that is the key to the determination of the current PHG. OEHHA determined that exposure to drinking water containing less than 6 ppb of perchlorate did not pose an excess public health risk of this outcome.

2) The NGO's letter made a case that recent research would indicate that a much lower number than 6 ppb would be justified. However, ACWA does not agree that this is the case based on the studies

cited. The letter cites the 2007 study by Pearce et al. 2007[1] indicating that perchlorate is actively transported into milk by nursing mothers. While this is certainly true, the study also indicates *"Breast milk iodine content was significantly correlated with urinary iodine per gram creatinine and urinary cotinine, but was not significantly correlated with breast milk or urinary perchlorate."* The letter also cites Kirk et al. 2007 which did not find any correlation between perchlorate concentrations in breast milk and iodide concentrations, as did the earlier work by Kirk et al 2005[2]. Most interesting, Kirk et al. 2007 reported that drinking water did not appear to be a significant vector for exposure to perchlorate. The study concludes, *"The fact that higher levels of perchlorate were present in milk samples from subjects' drinking water treated by reverse osmosis indicates that drinking water is not necessarily the principal vector for perchlorate exposure."* Moreover, one of these participants (E) used a reverse-osmosis system connected to a municipal water supply, which we have repeatedly analyzed: The perchlorate concentration in the feed water ranged from 0 to 4 µg/L, with rare excursions > 2 µg/L. Clearly, her perchlorate intake through drinking water would not account for the observed expression in breast milk. This fact—**that drinking water is not generally an important vector for perchlorate exposure**—is consistent with measurements of urinary perchlorate versus drinking-water perchlorate reported by Valentin-Blasini et al. 2005" (emphasis added).[3] These studies would not indicate that the PHG estimated by OEHHA five years ago in any way underestimated the risk.

3) The letter cites prominently one specific study, Blount 2007[4], an analysis of the NHANES 2001-2002 study. This study showed a negative association between urine perchlorate concentrations (uncorrected for creatinine) and T4 serum concentrations in women with low urine iodide concentrations. It was not shown that this actually lowered the T4 serum concentration outside of normal concentration range (5 – 12 mcg/dL). Further, Blount reports that the mean serum T4 concentration was 8.4 mcg/dL with a 95% confidence interval covering 7.97 – 8.58 mcg/dL for women aged 12 and over. This means that about 95% of the women in this study had T4 serum concentrations within 5% of the mean and well within the normal range. The study did not provide any indication that any women were hypothyroxinemic, or if they were that these women had lower iodide or higher perchlorate concentrations than the other women in the study. Interestingly, Blount found no correlation between iodide urine concentrations and perchlorate concentrations, which is consistent with the breast milk studies cited above. Once more, while informative, this study does not indicate that the current PHG is an underestimate or fails to provide adequate public health protection.

4) The NGO letter makes extensive references to numerous studies indicating that perchlorate is widely distributed in various food sources and ubiquitous in human exposure studies. Although not indicated in the letter, this indicates, as research above supports, drinking water is a relatively minor source of human exposure to perchlorate. The Blount study found perchlorate in all participants across the United States while the USEPA's Information Collection Rule found perchlorate in relatively few drinking waters (Kimbrough & Parekh 2007) and generally in very small concentrations.

5) Along the same lines, the NGO letter notes that the Blount 2007 study found not just perchlorate but nitrate and thiocyanate in considerable concentrations. This is indeed important as the H&SC states *"(C) To the extent information is available, the public health goal shall take into account each of the following factors: (i) Synergistic effects resulting from exposure to, or interaction between, the contaminant and one or more other substances or contaminants."* Both of these chemicals are also

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[1] Pearce, E.N., Leung, A.M., Blount, B.C., Bazrafshan, H.R., He, X., Pino, S., Valentin-Blasini, L., Braverman, L.E., J Clin. Endocrin Metab, 7 Journal of Clinical Endocrinology & Metabolism, doi:10.1210/jc.2006-2738, February 20, 2006

[2] Kirk AB, Martinelango PK, Tian K, Dutta A, Smith EE, Dasgupta. PK Perchlorate and iodide in dairy and breast milk. Environ Sci Technol 39:2011-2017, 2005

[3] Valentin-Blasini L, Mauldin JP, Maple D, Blount BC. Analysis of perchlorate in human urine using ion chromatography and electrospray tandem mass spectrometry. Anal Chem 77:2475-2481, 2005

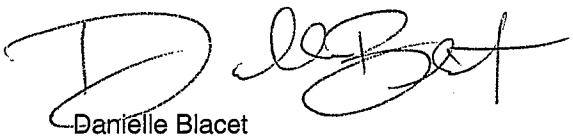
[4] Blount BC, Valentin-Blasini L, Osterloh JD, Mauldin JP, Pirkle JL. Perchlorate Exposure of the US Population, 2001-2002. J Exposure Sci Environ Epidemiol. Doi: 10.1038/sj.jes.7500535, 2006

goitrogens, just like perchlorate, albeit less potent. Nitrate and thiocyanate are both goitrogens which have been shown to occur in almost all of the subjects in the NHANES 2001-2002 study (Blount 2007) and occur widely in food products. Nitrate is nearly ubiquitous in drinking water (Kimbrough & Parekh, 2007).[5] Thiocyanate is thought to be about 1/10th as potent as perchlorate but has a half-life that is considerably longer, 8 hours for perchlorate (Greer et al. 2002)[6] vs. 1–6 days (Junge 1985; Schulz et al. 1979) for thiocyanate. Blount reports that the geometric mean concentration of thiocyanate among study participants was 1,200 mcg/L (95% CI 1,080 – 1,330), while the geometric mean concentration of perchlorate was 2.84 mcg/L (95% CI 2.54 – 3.18). The ratio of the geometric means is 422:1 and converting the thiocyanate into a "perchlorate equivalent concentration" (PEC), the ratio would be 42:1 thiocyanate to perchlorate. Tonacchera et al. (2004)[7] determined the relative potency of perchlorate vs. nitrate to be 1:240 and for the effects of multiple goitrogens to be additive. Blount (2007) reported the geometric mean concentration of nitrate in the NHANES 2001-2002 study to 38,000 mcg/L (95%CI 35,900 – 40,300) so the ratio of the geometric means of nitrate to perchlorate would be 13,000:1. Correcting for the relative potency of nitrate, the PEC ratio of nitrate to perchlorate would 56:1. Based on the NHANES 2001-02 study results as presented by Blount, the overall "goitrogenic burden" from perchlorate is less than 1% as compared to nitrate and thiocyanate, most of which does not come from drinking water as noted above. It is clear that co-occurring contaminants with similar health effects may have contributed more to the observed outcomes than perchlorate alone. These data do not suggest that the current PHG is excessively high.

ACWA reserves the right to provide additional comments as new information is introduced. Specifically we encourage OEHHA to review and consider in its analysis the forthcoming study being finalized by the American Water Works Association (AWWA) (a re-review of the NHANES report on perchlorate). We anticipate that this study will be available in the next 30-60 days. Following our review of this document and others being finalized at this time we may submit further comments for your consideration.

Thank you for the opportunity to provide comments. If you have any questions regarding this matter, please contact me at 916-441-4545. We look forward to working with you and your staff in this important endeavor.

Sincerely,



Danielle Blacet
Regulatory Advocate

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[5] Kimbrough, D.E. and Parekh, P.: Occurrence and co-occurrence of perchlorate and nitrate in California drinking water sources. Journal/American Water Works Association, 99 (9); 126-132, 2007

[6] Greer MA, Goodman G, Pleus RC, Greer SE. 2002. Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans. Environ Health Perspect 110:927-937 2002.

[7] Tonacchera, M.; Pinchera, A.; Dimida, A.; Ferrarini, E.; Agretti, P.; Vitti, P.; Santini, F.; Crump, K.; Gibbs, J. Relative potencies and additivity of perchlorate, thiocyanate, nitrate, and iodide on the inhibtion of radioactive iodide uptake by the human sodium iodide symporter. Thyroid 14, 1012-1019, 2004