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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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July 6, 2007

Mr. George Gray
Assistant Administrator
Office of Research and Development
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 10460

Dear Mr. Gray:

Thank you for appearing before the Subcommittee on Environment and Hazardous Materials on Wednesday, April 25, 2007, at the hearing entitled "Perchlorate: Health and Environmental Impacts of Unregulated Exposure." We appreciate the time and effort you gave as a witness before the subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the questions and include the text of the Member's question along with your response.

To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business on Monday, July 20, 2007. Your written responses should be delivered to 2125 Rayburn House Office Building and faxed to (202) 225-2899 to the attention of Rachel Bleshman. An electronic version of your response should also be sent by e-mail to Ms. Bleshman at rachel.bleshman@mail.house.gov. Please send your response in a single Word or WordPerfect formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please have your staff contact Rachel Bleshman at (202) 225-2927.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Albert Wynn, Chairman
Subcommittee on Environment and Hazardous Materials

The Honorable John Shimkus, Ranking Member
Subcommittee on Environment and Hazardous Materials

The Honorable Joe Barton and the Honorable John Shimkus

1. There is increasing information about the prevalence of perchlorate in the environment from Chilean nitrate fertilizer and natural occurrence, including several studies by Texas Tech mentioned in your recently released proposal for regulatory determinations under the second Contaminant Candidate List (CCL2). How does EPA intend to factor natural occurrence into its decision whether to regulate as well as in cleanup decisions, especially where there are no anthropogenic sources?

2. The ubiquity of perchlorate formed from natural sources means that all study populations likely have had natural exposure from ubiquitous sources. Isn't this statement relatively equal to what is shown in the Blount study? Doesn't that mean that mankind has likely always had this level of exposure without respect to anthropogenic sources?

3. The National Academy's recommended level, upon which EPA's reference dose (RfD) is based, is protective of all sensitive populations and that conclusion has since been reiterated by National Academy members, including the chair. Do you see anything to suggest that the National Academy was wrong?

4. It is my understanding that the National Academy based its recommendation upon a level that has absolutely no scientific effect, that is, no measurable effect whatsoever, on human beings. Is that approach more conservative than the traditional EPA approach?

5. It is my understanding that perchlorate is the primary ingredient in solid rocket propellant and has been used for decades by DOD, NASA, and defense industry in the manufacturing, testing, and firing of rockets and missiles. It is also my understanding that there is currently only one domestic manufacturer of ammonium perchlorate, and alternatives are limited. To what extent does EPA's regulatory process allow for the consideration of national security concerns in situations where a decision could impact the manufacturing of a product that is essential to our national security?

The Honorable Albert R. Wynn

1. Section 120 of CERCLA requires that not later than six months after the inclusion of any Federal facility on the National Priorities List (NPL), any agency of the United States, in consultation with Environmental Protection Agency, must commence a remedial investigation and feasibility study (RIFS) for such facility (42 U.S.C. § 9620(e)(1)). Based upon information provided to the Committee by EPA, there are at least 34 Department of Defense (DOD) facilities with perchlorate contamination on the NPL. (See Appendix 1, DOD NPL Facilities with Known Perchlorate Contamination). For each facility, please provide the date it was listed on the NPL and whether an RIFS has been commenced. For each DOD facility where an RIFS was commenced, please indicate the date it was commenced, and if applicable, completed, and a description of the scope of work of the RIFS and whether it addresses perchlorate contaminated groundwater.

2. By letter dated July 16, 2003, EPA notified DOD that is was discontinuing involvement at the Camp Bonneville Base Realignment and Closure (BRAC) Site in Vancouver, Washington, citing a lack in the level of collaboration by DOD. (See Appendix 2, Letter from EPA Region 10 to Col. Richard Conte, Director of Public Works, Ft. Lewis, Washington.) EPA states in the letter "that the site lacks the necessary level of site characterization information on which to base long-term remedial decisions." According to information submitted by EPA to the Committee, Camp Bonneville had detections of perchlorate in groundwater at 380 ppb. At the April 25th hearing EPA was asked "why did EPA walk away from the table rather than use its enforcement authority?" In response, you indicated that you would take the question for the record. Please explain why EPA chose to "discontinue its involvement" with the Camp Bonneville Site rather than use any of its enforcement tools to compel DOD to perform the necessary sampling?

3. Has EPA exercised any of its enforcement authorities against DOD to compel the Department to undertake remedial action at any DOD facility where perchlorate contamination in groundwater is present? If so, please identify the site, the enforcement action and provide supporting documentation.

4. You also stated at the hearing that "I do want to say that with respect to the debate over perchlorate as a contaminant of concern is over. . . We aren't hearing from DOD that perchlorate is not a contaminant." Was there a time when the Department of Defense asserted that perchlorate was not a contaminant? If so, why did the Department not think perchlorate was a contaminant? Did the Department's position that perchlorate was not a contaminant form a basis for the Department's failure to implement any remedial action plans at any DOD facility that has perchlorate contaminated groundwater? Additionally, please describe why the "debate over perchlorate as a contaminant of concern is over."

5. At the April 25th hearing you also testified that "We have not had the same problems with DOD willing to go out and sample." Was there a time when DOD was unwilling to sample for perchlorate in groundwater at its facilities? If so, please describe the time period and circumstances.

The Honorable Albert R. Wynn (continued)

6. Were there specific instances where DOD or any of its components were unwilling to sample or resisted sampling at any DOD facility? If so, please identify them.

7. On February 25, 2005, the American Water Works Association ("AWWA") sent a letter to EPA "urging the Agency to make perchlorate a top priority, and to regulate this contaminant as expeditiously as feasible consistent with the requirements of the Safe Drinking Water Act. Has EPA responded to AWWA's February 25, 2005, letter? If EPA did, in fact, respond to AWWA's February 25, 2007, letter please provide the Committee with a copy of the Agency's response. If not, please explain why the Agency failed to respond to a letter from a major drinking water association.

8. Assistant Administrator Grumbles testified at the April 25th hearing before the House Subcommittee on Environment and Hazardous Materials that the "EPA is not able to make a preliminary determination for perchlorate at this time because in order to evaluate it against the three statutory criteria, the agency believes additional info may be needed to fully characterize perchlorate exposure and to determine whether regulating perchlorate in drinking water presents a meaningful opportunity for health risk reduction." The Unregulated Contaminant Monitoring Rule (UCMR) sampling conducted by EPA of the various public water supplies in the United States indicated that between 5 to 15 million Americans are exposed to elevated amounts of perchlorate in their drinking water. In addition to the sampled public water supplies that have identified perchlorate contamination, there are a considerable number unsampled water systems where perchlorate maybe present but have not been identified, such as the case in Foxboro, Massachusetts, that tested its water supply even though it was under no obligation to do and found perchlorate in the drinking water at a level of 1,300 ppb. Given the estimated number of Americans that are known to have perchlorate in their drinking water doesn't this fact along with the CDC's biomonitoring data finding that levels of perchlorate common in the population were associated with small to medium changes in thyroid hormone levels represent a "meaningful opportunity for health risk reduction for persons served by public water systems," as set forth in Section 42 U.S.C. § 330g-1(b) (1) (A) (iii) of the Safe Drinking Water Act? If not, please explain why not.

9. Is it correct that even though EPA's RfD of 24.5 ppb. includes a safety factor of 10, that factor may be inadequate because it is based on a low-effect level, not on a no-effect level and fails to take into account how long people are being exposed? Is it also true that EPA's uncertainty factor of 10 does not cover the types of exposure differences across life stages?

10. On March 8, 2006, the Children's Health Protection Advisory Committee issued a letter to EPA recommending that the Agency lower the preliminary remediation goal (PRG) of 24.5 ppb. at Superfund sites for perchlorate in groundwater because it was not protective of children's health and specifically neurodevelopmental risks. (See Appendix 3, Letter from Melanie Marty, Ph.D. Chair, Children's Health Protection Advisory to Stephen L. Johnson, Administrator, USEPA). In response, you issued a letter stating that "because the fetus is most sensitive

to the effects of perchlorate exposure, the pregnant women is an appropriate focus when assessing exposure to perchlorate." (See Appendix 4, May 11, 2006, letter to Dr. Melanie Marty from Susan Parker Bodine, Assistant Administrator.) While EPA acknowledges the susceptibility of fetuses of pregnant women, the Agency does not acknowledge that nursing infants may even be more susceptible as they could receive daily doses that are greater than the RfD if the mother is exposed to 24.5 ppb. of perchlorate in tap water because the maternal supply of thyroid hormone that was present in utero is no longer available. Please describe the basis for EPA's conclusion that the postnatal period (nursing infants) is less sensitive to perchlorate's mode of action than the RfD and does not apply to this life stage?

11. In 2001, EPA conducted a study of a broad array of fertilizers and other raw materials and found that all products surveyed were devoid of perchlorate except for those known to contain or to be derived from mined Chilean saltpeter. Is it correct that EPA's study, *Survey of Fertilizers and Related Materials for Perchlorate*, EPA Report 600-R-01-049, July 2001, also found that prior to 2001 commercial fertilizers that contained Chilean nitrate salts, accounted for 0.14 percent of the U.S. fertilizer application?

12. In 2002, EPA published its draft assessment for perchlorate recommending an RfD of 1 ppb. In 2003, the draft assessment was submitted for review by the National Academy of Sciences (NAS), which two years later in January 2005 and at a cost of $750,000, published a report recommending an RfD of 24.5 ppb. In February 2005, EPA issued guidance adopting the NAS recommendation of RfD of 24.5 ppb. In April 2007, EPA indicated that it was not in a position to make a determination on whether or not to set a drinking water standard for perchlorate in drinking water stating that the Agency needed more data in order to generate a relative source contribution. Please provide EPA's rationale for not using the relative source contribution default assumption of 20 percent to generate the MCLG and choosing instead to delay making a preliminary determination whether to regulate perchlorate in drinking water for several years under the auspices of waiting for more specific information.

13. Referring to Table 5, entitled UCMR 1 Occurrence and Population Estimates for Perchlorate at Various HRL Thresholds in the Drinking Water of the *Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List – Preliminary Determinations,* is it correct that if EPA were to utilize the relative source contribution default assumption of 20 percent to generate MCLG then the estimated HRL would be approximately 5 ppb.?

14. Given the 2006 Centers for Disease Control and Protection (CDC) study showing adverse effects on human thyroid hormone levels at perchlorate levels below the RfD of 24.5 ppb. and common in United States women, is the Agency going to re-evaluate the RfD? If not, please explain how the current RfD of 24.5 ppb. can be justified in light of the evidence suggesting greater sensitivity in the general population than was demonstrated in the Greer study?

The Honorable Albert R. Wynn (continued)

15. At the April 25, 2007, hearing before the Subcommittee on Environment and Hazardous Materials, Assistant Administrator Grumbles testified that "Based on the reference dose, the Agency has sufficient information on health effects to inform a regulatory determination. We have sufficient data on the occurrence of perchlorate in public water supplies; however, Mr. Chairman, we still need to more fully characterize and understand perchlorate exposure before a determination can be made." Please explain in detail, including the exact methodology and references to applicable Agency guidance and regulations, how EPA plans to combine Food and Drug Administration (FDA) food data with the CDC biomonitoring data to determine the dietary component to daily perchlorate exposure.

16. At Aberdeen Proving Ground, a Superfund National Priorities List (NPL) site located in Aberdeen, Maryland, four production wells that provide drinking water for the City of Aberdeen were closed in 2002 because of perchlorate contamination. Ground water samples taken within the well field showed a large plume of perchlorate with levels up to 21 ppb. EPA advised the Committee in a June 27, 2003, letter to then Ranking Member Dingell that EPA "proposed the concept of installing several groundwater extraction wells to reduce the migration of most contaminated water which was having an impact on the City of Aberdeen's drinking water wells." The letter also states that "EPA's Region 3's management will brief EPA Headquarters and will make a decision regarding what actions are warranted." Please provide an explanation as to why EPA chose not to use its authority under RCRA Section 7003 to compel DOD to install the groundwater extraction wells at Aberdeen Proving Ground to address the migrating plume of perchlorate?

17. Given that FDA has determined and EPA has acknowledged the presence of perchlorate in certain foods and milk, how can the EPA's preliminary remediation goal (PRG) of 24.5 ppb., which is based on the perchlorate RfD and appropriate exposure assumptions be justified as a screening value when it does not consider non-water sources of exposure?

18. EPA's January 2006, *Assessment Guidance for Perchlorate*, states that in a case where the Remedial Investigation (RI) may indicate that individuals at a site may be exposed to perchlorate through multiple pathways "contribution from non-water sources should be considered based on site-specific data until further national guidance on relative source contribution is developed." Is it correct that there is not one Superfund site where perchlorate is a contaminant of concern from multiple pathways that has utilized site-specific food data or any other applicable data in the formulation of the RI? If not, please identify the site where perchlorate contribution for non-water sources has been considered utilizing site-specific food data or other applicable data and include a copy of the site-specific data, and how it was applied in the RI process.

The Honorable Albert R. Wynn continued

19. Please describe in detail how EPA will determine what the "relative source contribution" will be for perchlorate including a detailed explanation of the decision process, the list of factors that will be considered and reference to applicable Agency guidance or regulations, as well as prior examples of deriving a relative source contribution for a contaminant in drinking water.

20. In cases where contaminated groundwater does not present a situation that could potentially result in adverse health effects, would EPA require ground water remediation to preserve other beneficial uses such as irrigation or to protect the aquifer as a future source of drinking water? Please describe EPA's groundwater remediation policy and criteria.

21. Various studies have shown that nursing and bottled fed infants could receive doses of perchlorate from breast milk above EPA's RfD of 24 ug/L. Recent studies have determined the existence of perchlorate doses that were above EPA's RfD of 24 ug/L for infants drinking reconstituted formula made with water containing perchlorate (Baier-Anderson et al. 2006)(Kirk et al. 2005) and have also estimated that nursing infants could receive doses above the RfD even without considering the added exposure associated with EPA's preliminary remedial goal of 24 ug/L (Pearce et al. 2007 and Kirk et al. 2007). Please describe whether the Agency is considering the impact of perchlorate on nursing and bottle-fed infants and/or whether the Agency intends to utilize the above referenced studies or conduct its own studies on the impact of perchlorate on nursing and bottle-fed infants.

The Honorable Albert R. Wynn continued

19. Please describe in detail how EPA will determine what the "relative source contribution" will be for perchlorate including a detailed explanation of the decision process, the list of factors that will be considered and reference to applicable Agency guidance or regulations, as well as prior examples of deriving a relative source contribution for a contaminant in drinking water.

20. In cases where contaminated groundwater does not present a situation that could potentially result in adverse health effects, would EPA require ground water remediation to preserve other beneficial uses such as irrigation or to protect the aquifer as a future source of drinking water? Please describe EPA's groundwater remediation policy and criteria.

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APPENDIX 1

DOD NPL FACILITIES WITH KNOWN PERCHLORATE CONTAMINATION

AL	Reg. 4	ANNISTON ARMY DEPOT
AL	Reg. 4	REDSTONE ARMY ARSENAL
CA	Reg. 4	EDWARDS AFB RESEARCH LAB
CA	Reg. 9	MATHER AFB
CA	Reg. 9	FORMER MCAS EL TORO
IL	Reg. 5	SANGAMO/CRAB ORCHARD
KS	Reg. 7	FORT RILEY
MA	Reg. 1	MASS MILITARY RESERVATION
MD	Reg. 3	FT. MEADE
MD	Reg. 3	NAVAL SURFACE WELFARE – INDIAN HEAD
MD	Reg. 3	ABERDEEN PROVING GROUND
MO	Reg. 7	LAKE CITY ARMY AMMUNITION PLANT
NJ	Reg. 2	PICATINNY ARSENAL
TN	Reg. 4	ARNOLD ENGINEERING DEVELOPMENT CENTER
TX	Reg. 6	LONE STAR AMMUNITION
TX	Reg. 6	LONGHORN SITE 4
TX	Reg. 6	LONGHORN SITE 12
TX	Reg. 6	LONGHORN AAP SITE 16
TX	Reg. 6	LONGHORN SITE 17
TX	Reg. 6	LONGHORN SITE 18/24
TX	Reg. 6	LONGHORN SITE 29
TX	Reg. 6	LONGHORN SITE 46
TX	Reg. 6	LONGHORN SITE 47
TX	Reg. 6	LONGHORN SITE 47A
TX	Reg. 6	LONGHORN SITE 47B
TX	Reg. 6	LONGHORN SITE 50
VA	Reg. 3	DAHLGREN
WV	Reg. 3	ALLEGHANY BALLISTICS LAB
AZ	Reg. 9	YUMA MARINE CORPS
CA	Reg. 9	NAVY WEAPON STATION SEAL BEACH
CO	Reg. 8	ROCKY MOUNTAIN ARSENAL
IA	Reg. 8	IOWA ARMY AMMUNITION
MA	Reg. 1	DEVENS RESERVE FORCES
OR	Reg. 10	UMATTILLA ARMY DEPOT

APPENDIX 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
1200 Sixth Avenue
Seattle, Washington 98101

July 16, 2003

Reply To
Attn Of: ECL-112

Commander, Ft. Lewis
Directorate of Public Works
ATTN: AFZH-PW MS 17
(Attn: Col. Richard Conte, Director of Public Works)
Box 339500
Ft. Lewis, WA 98433-9500

Subject: EPA Withdrawal from Camp Bonneville Base Closure Team

Dear Col. Conte:

This letter is to notify the United States Army of the Environmental Protection Agency's (EPA's) decision to discontinue involvement with the Base Closure Team (BCT) at the Camp Bonneville Base Realignment and Closure(BRAC) site. This is a decision that EPA has not made lightly. However, given the particular circumstances at Camp Bonneville, EPA has made a management decision to reallocate its limited staff resources to other urgent cleanup needs in Region 10. As Camp Bonneville is among the Department of Defense (DoD) installations included in a Memorandum of Understanding (MOU) between DoD and EPA, we have consulted with our Headquarters Program Office on this matter and they have concurred with our decision.

We made this decision knowing the State of Washington's Department of Ecology (Ecology) has increased its staff for Camp Bonneville. Ecology also has issued an enforcement order for Camp Bonneville. As a result of their increased investment at this site, Ecology requested that EPA not continue in a concurrent oversight role. We have decided to withdraw from the BCT; however, we want to go on record with our ongoing concerns, in the interest of supporting Ecology's, the Army's, and the public's interest in addressing the human health and environmental issues at Camp Bonneville.

After the initial round of base closure legislation, the Department of Defense (DoD) developed guidance which relied on bottom up decision-making by the military service, EPA, the state, and other stakeholders. The BCT was meant to work collaboratively to make cleanup decisions and facilitate reuse of the property. The DoD model and BCTs have been successful in accomplishing those goals at both NPL and non-NPL BRAC sites all over the country including Region 10. In Region 10, the BCT model worked well at Sand Point Naval Station, Seattle, Washington; Fort Greeley, Delta Junction, Alaska; and at Adak Island Naval Air Station, Alaska.

In the case of Camp Bonneville; however, there has not been the level of collaboration that is typical in the BRAC process. Over the past seven years of EPA involvement through the BCT, we have made every effort to assist the Army in characterizing the risks to human health and the environment at the Camp Bonneville site. EPA has sought to provide information and comments to help improve the site characterization activities relating both to munitions and other contamination. We also provided comments to address what we believe are other significant shortcomings of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) cleanup process that was being implemented. On many issues, the Army has not been responsive to EPA's comments. Enclosure 1 provides examples of significant data gaps and procedural shortfalls at Camp Bonneville which are one result of the lack of cooperation and collaboration in the BCT process.

Even though the Army has completed a number of removal actions, the site lacks the necessary level of site characterization information on which to base long-term remedial decisions. We are also concerned that decisions about property transfer need to be based on better information than is currently available. There is only limited understanding about the nature and extent of contamination primarily from munitions and unexploded ordnance (UXO), but also in limited areas related to chemical releases. We believe that this information could have been developed had the Army incorporated our comments into their characterization workplans and related analyses over the past seven years.

We have made our concerns and comments known to Ecology. We will continue to provide support to Ecology on an "as needed" basis. Please contact me at (206) 553-4181 or at eaton.thomas@epa.gov with any questions or concerns.

Sincerely,

/S/

Thomas Eaton, Associate Director
Office of Environmental Cleanup

Enclosure

cc:	Tim Nord, Ecology	*sent via e-mail only*
	Barry Rogowski, Ecology	""
	Jim Woolford, EPA	""
	Brian Vincent, Clark County	""
	Karen Kingston, RAB co-chair	""
	Eric Waehling, Army	""
	Nancy Harney, EPA	

Enclosure1:

Camp Bonneville Data Gaps

Significant data gaps at Camp Bonneville BRAC site include:

1. lack of geophysical investigations for the detection of subsurface UXO/munitions in areas of concern such as the proposed Regional Park, the artillery/mortar/rocket Impact Area, and Demolition Area 1 (Approximately 1% of Camp Bonneville has previously been geophysically surveyed for subsurface UXO/munitions, 99% has not been surveyed);
2. lack of Remedial Investigations (RI) on the nature and extent of contamination from UXO/munitions, and soil and groundwater contamination at known disposal areas such Demolition Areas 1, 2,and 3;
3. lack of an RI to determine the presence/absence of soil and groundwater contamination in the Impact Area due to munitions residues (No soil or groundwater sampling data currently exists for the Impact Area);
4. lack of public review and comment on the proposed response action (EE/CA or Feasibility Study) to take place on Demolition Area 1, including review of the CERCLA standards the Army expects to attain and how these standards were derived;
5. demonstration of attainment of published cleanup standards (ARARs and TBCs) for Demolition Area 1/landfill 4;
6. lack of lead hazard assessment for Camp Killpack where child-occupied facilities are forecasted by the County;
7. improvement of QA/QC procedure for all site sampling including adherence to accepted, published standards (MTCA specified QA/QC is only a starting point);
8. assessment of QA/QC deficiencies from past field efforts to determine if these sampling events should be redone;
9. additional sampling of small caliber firing ranges to account for low sampling density;
10. surface clearance of UXO/munitions the entire Camp including "wildlife" areas which will inevitably be vulnerable to trespass; additionally surface clearance is a required step in conducting subsurface UXO/munitions clearance.
11. location of additional downgradient wells near demolition area 2 that are within 100 feet from Ecology's best estimate of the location of past demolition practices; and
12. lack of an RI/FS for all Camp areas which includes hazardous waste issues, ordnance clearance, and assessment and removal if necessary of ordnance residue.

Examples of CERCLA compliance issues and coordination problems:

1. noncompliance with various parts of CERCLA and the NCP including inappropriate use of time-critical removal authority;
2. refusal to publish in any federal CERCLA Decision Documents clear statements of the applicable requirements for cleanup actions taken, such that regulators and the public may track the Army's compliance; and
3. unilaterally making field changes without consulting regulators, in some cases rendering the field work useless.

APPENDIX 3

Children's Health Protection Advisory Committee

FACA Members:

Melanie A. Marty, Ph.D., Chair
Cal/EPA, Office of Environmental Health Hazard Assessment
1515 Clay St. 16th Floor
Oakland CA 94612
(510) 622-3154

Laura Anderko, RN, Ph.D.
Henry Anderson, M.D.
John Balbus, M.D., MPH
Sophie Balk, M.D.
Ms. Beatriz Barraza-Roppe
Ms. Claire Barnett
Mr. Angelo Bellomo
David Carpenter, M.D.
Ms. Shelly Davis, Esq.
Mark Dickie, Ph.D.
Maureen Edwards, M.D. MPH
Natalie Freeman, M.D., Ph.D.
Howard Frumkin, M.D., Ph.D.
Gary Ginsburg, Ph.D.
Daniel A. Goldstein, M.D.
Mr. Richard J. Hackman
Woodie Kessel, M.D.
Mr. Robert Leidich
Janet Mostowy
Lourdes Soto de Laurido, Ph.D., MPH
William Sanders, Ph.D.
Kristin Thomas, MS Ed
Anne Turner-Henson, RN, DSN
Ms. Susan West Marmagas
Charles Yarborough, M.D., MPH

March 8, 2006

Stephen L. Johnson, Administrator
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: Perchlorate PRG and water contamination

Dear Administrator Johnson:

The Children's Health Protection Advisory Committee (CHPAC) is writing to express concern over a recent assessment guidance issued by the U.S. EPA, Office of Solid Waste & Emergency Response (OSWER). The OSWER guidance creates a groundwater preliminary remediation goal (PRG) for perchlorate at Superfund sites that is not protective of children's health. The new PRG is not supported by the underlying science and can result in exposures that pose neurodevelopmental risks in early life. The new PRG can lead to exposures that are well above USEPA's IRIS RfD for perchlorate. The CHPAC finds it disturbing that this change in the PRG was made without dissemination of a decision support document or any opportunity for public input. We recommend that OSWER lower the PRG, taking into account infant exposures and susceptibility. We also recommend that USEPA's Office of Ground Water and Drinking Water (OGWDW) develop a Maximum Contaminant Level (MCL) for perchlorate, and in the interim, issue a health advisory for potable water that takes into account early life exposures.

Background

On January 26, 2006 OSWER released a PRG that would allow remediation of perchlorate at Superfund sites to a higher level (24.5 μg/L) than the previous screening level (4-18 μg/L). This establishes a potable water PRG, which is a critical starting point for site cleanup. USEPA is required to develop PRGs in a health protective manner to enable broad future use of the site, with site-specific factors enabling the risk manager to adjust the cleanup target.

Risk of neurodevelopmental toxicity can occur from perchlorate exposure because perchlorate impairs the uptake of iodide by the thyroid, which can decrease thyroid hormone production and affect brain development. This is especially important in infants because they do not have stores of thyroid hormone, and are no longer supported by maternal thyroid hormone following birth. What may be considered by some to be a precursor effect in normal adults (inhibition of iodide uptake by the thyroid) may be an adverse effect during this sensitive life stage, especially in concert with exposure to other thyroid toxicants (e.g., PCBs, PBDEs) and because perchlorate may decrease iodine levels in human milk.

The CHPAC acknowledges that EPA's RFD incorporates a ten-fold uncertainty factor to protect the fetuses of pregnant women who might have hypothyroidism or iodide deficiency. This factor was used to account for interindividual differences that lead to uncertainty in assessing perchlorate risk. However, the uncertainty factor does not cover the types of exposure differences across life stages discussed in this letter.

The OSWER Perchlorate PRG Does Not Protect Infants and Should be Lowered

Perchlorate is a well-recognized endocrine disruptor at sufficiently high doses, targeting the thyroid and thus creating risk of neurodevelopmental toxicity. A key concern is the nursing infant because of the potentially high exposure rate associated with this pathway, and the high susceptibility at this life stage. The following points highlight the fact that nursing infants could receive daily doses that are greater than the RfD if the mother is exposed to 24.5 μg/L perchlorate in tap water. The supporting calculations are provided in the appendix to this letter.

Infant Exposures

- Perchlorate is actively transported into human milk leading to nursing infant exposure to perchlorate; current data suggest this is associated with concomitant lowering of iodide in human milk (Kirk, et al., 2005; Tellez, et al., 2005, see Appendix to this letter). Both of these factors increase the risk of neurodevelopmental toxicity due to perchlorate anti-thyroid effects occurring in the susceptible postnatal period.
- The current PRG (24.5 μg/L) would allow a nursing mother to ingest approximately 54 μg of perchlorate per day. Based upon the Chilean three-cities database (Tellez, et al., 2005), this would yield a human milk perchlorate concentration of 28 to 46 μg/L.
- **This would lead to a nursing infant exposure that is approximately 5 to 10 times higher than the perchlorate RfD.**
- This analysis does not account for variability in perchlorate exposure. Assessment of the entire population distribution would identify high-exposure individuals that would be at greater risk than currently estimated.
- Bottle-fed babies can also receive perchlorate exposure above the RfD through tap water used to reconstitute formula and juices, or directly fed to the infant. This perchlorate exposure may not be quite as high as in breast-fed infants; however, it is still a concern.

Infant are a Susceptible Population

Not only are infants more exposed, they are also susceptible to the neurodevelopmental effects of perchlorate because of the following early life factors:

- The central nervous system (CNS) is still developing but the maternal supply of thyroid hormone that was present *in-utero* is no longer available; thyroid hormone does not transfer into breast milk in significant amounts.
- The developing CNS in infants is sensitive to small deficits in thyroid hormone levels as evidenced by later indices of neurocognitive function (Oerbeck, et al., 2003; Heyerdahl and Oerbeck, 2003; Rovert and Daneman, 2003);
- Infants are not born with adequate thyroid hormone reserves and so must make new thyroid hormone on a continual basis to meet the demands of brain growth (Delange, 1998; van den Hove, et al., 1999).
- Immaturities in renal function at birth may lead to slow clearance of perchlorate, as urinary excretion is the major elimination pathway. Data from rats on perchlorate toxicokinetics in neonates (Clewell, et al., 2003) may not be highly relevant (see Appendix).

These factors, coupled with the infant exposure estimates, indicate that the PRG of 24.5 μg/L in drinking water is not protective. The PRG would produce above-RfD perchlorate exposure in infants who are susceptible to endocrine disruption and adverse neurodevelopmental impacts. While RfDs are generally considered chronic toxicity values, applying the perchlorate RfD to a shorter, critical window of susceptibility and high exposure in infancy is warranted. The OSWER cleanup PRG should apply the RfD to infants just as it is applied to pregnant women.

Lack of Consideration of an RSC

Groundwater cleanup targets are normally based upon the chemical's RfD and a relative source contribution (RSC) factor. The RSC accounts for that part of the exposure that comes from non-drinking water sources. The OSWER PRG is set without accommodation for other exposure sources. This is an obvious concern given the recent widespread detection of perchlorate in lettuce and milk (USFDA, 2004). Drinking water standard setting for perchlorate in New Jersey and Massachusetts has used an RSC of 0.2 (20% from water) while the California RSC is 0.6 (NJ Drinking Water Quality Inst., 2005; Ting, et al., 2006).

Use of an appropriate RSC could lower the PRG to a range that would ensure maternal intake of perchlorate is below a level which poses a risk of adverse neurodevelopmental outcome for the fetus and nursing infant.

The CHPAC recommends that OSWER lower the PRG considering the following points:

- The OSWER PRG ignores the higher exposure and susceptibility of infants, and could lead to nursing and bottle-fed infants being exposed to daily doses

that are well above the perchlorate RfD; the PRG needs to protect this susceptible population.

- The OSWER PRG does not account for perchlorate exposures from foods, which are in addition to drinking water. By omitting the RSC and not accounting for infant exposure, the PRG now allows for greater-than-RfD doses to the mother and her developing fetus and to nursing infants. OSWER should lower the PRG with an appropriate RSC and adjustment for exposure to infants.

The scientific issues discussed above are also central to the ongoing OGWDW deliberation of whether to set a Maximum Contaminant Level (MCL) for perchlorate. The CHPAC has been closely monitoring this deliberation for the past year and is concerned that there is still no decision about a perchlorate MCL.

OGWDW Regulatory Determination on Perchlorate

The CHPAC encourages OGWDW to establish a national drinking water standard for perchlorate, and in so doing, to fully consider both the prenatal and postnatal exposures and risks. Perchlorate has been known to contaminate groundwater at over 400 locations nationwide (GAO, 2005) and biomonitoring data demonstrate widespread exposure (Valentin-Blasini, 2005). We encourage the Agency to fully consider the particular susceptibility of the fetus as well as the infant who may be exposed through breastfeeding or reconstituted formula. We believe that technology (e.g., cleanup methods) exists to protect infants from perchlorate exposure.

Setting a federal MCL will greatly facilitate the discovery and control of drinking water contamination by this pervasive chemical. It would also help decrease a key uncertainty identified by the CHPAC: we do not know the perchlorate level in pre-constituted infant formula and other drinks. The water that goes into ready-to-use formulations is not currently required to be tested for perchlorate, although we are aware that manufacturers may purify water that goes into pre-constituted formula. Setting a federal MCL would require widespread testing of water supplies and thus provide greater confidence that both commercial and home-reconstituted infant formulations are made with water free of perchlorate contamination.

We recognize setting an MCL can be a lengthy process. In the interim, it is important for OGWDW to develop a drinking water health advisory for perchlorate. Such advisories normally factor in the RSC and can account for early life windows of high intake rate and susceptibility. A drinking water health advisory can inform the many state and federal programs that may detect perchlorate in drinking water supplies and need a public health protective guideline. The OSWER PRG is not intended for this purpose, but some risk managers may extend its use to such applications. This would be most unfortunate given the concerns expressed above that the current PRG is not protective of infants. Therefore, it is especially important for OSWER to lower the PRG and for OGWDW to develop an interim health advisory for perchlorate.

Summary and Recommendations

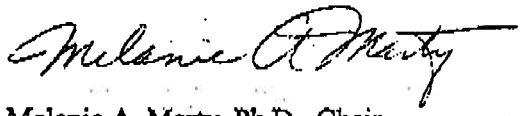
Perchlorate is an important endocrine toxicant because of widespread exposure and the potential for impairment of the thyroid during critical stages of brain development. The risk posed by this environmental agent is preventable by appropriate Agency action.

The CHPAC recommends that:

- OSWER lower the perchlorate PRG, using a more comprehensive risk assessment that includes postnatal exposures and health risks.
- OSWER use an RSC factor of less than 100% to account for the non-drinking water sources of perchlorate.
- OGWDW set an MCL for perchlorate that protects both the pre-and post-natal exposure periods.
- OGWDW develop an interim health advisory that addresses the early life exposure and susceptibility issues raised above.

We would be happy to discuss any of the points or recommendations raised in this letter with you or your staff. We would also like to be informed of the Agency's progress in protecting the public from perchlorate and to be provided with the documentation for any future guidance on perchlorate remediation. We thank you in advance for your consideration of these issues.

Sincerely,



Melanie A. Marty, Ph.D., Chair
Children's Health Protection Advisory Committee

Cc: Susan Bodine, Assistant Administrator, OSWER
Barry Breen, Deputy Assistant Administrator, OSWER
Benjamin Grumbles, Assistant Administrator, OW
Michael Shapiro, Deputy Assistant Administrator, OW
William Sanders, Interim Director, OCHPEE
Joanne Rodman, Assistant Director, OCHPEE

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Appendix

1) Relationship between iodide and perchlorate levels in human milk.

A sodium iodide transporter protein akin to that in the thyroid exists in mammary tissue. It transports iodide into human milk, and perchlorate id able to take iodide's place and be selectively pumped into milk (Clewell, et al., 2003). This can lead to nursing infant exposure to perchlorate, while at the same time leading to lower levels of iodide in milk. Kirk, et al. (2005) demonstrate an inverse correlation between perchlorate and iodide concentrations in human milk in a small number of US samples that were over 10 μg/L perchlorate. Tellez, et al. (2005) did not see a correlation, inverse or otherwise, between perchlorate and iodide concentrations in human milk across three Chilean cities with widely differing concentrations of perchlorate in drinking water. However, there does seem to be a factor that depresses iodide levels in human milk in these Chilean cities relative to the U.S. On average, Chilean human milk iodide concentrations were 40% lower than in US women in spite of the fact that iodide intake rates are known to be higher in these Chilean cities than in the US (Tellez, et al., 2005; Kirk, et al., 2005). The factor responsible for the lower-than-expected human milk iodide in Chile may be perchlorate intake as baseline (dietary) exposure to perchlorate is approximately 3 times higher in Chile as compared to the US. This is seen by comparing perchlorate biomonitoring data in Atlanta against the three Chilean cites (Valentin-Blasini, et al., 2005). The reason the Chilean cross-sectional study did not find an inverse correlation between human milk levels of perchlorate and iodide is unclear but comparisons are available only on the basis of group mean (Tellez, et al., 2005); regression analysis of the entire dataset would be a more sensitive method to determine whether there is a significant relationship between these human milk parameters in Chile. Evidence in rats for an inverse relationship between maternal perchlorate exposure and iodine levels in breast milk (Clewell, et al., 2003) supports the evidence for such a relationship in human milk.

2) Calculations of nursing infant perchlorate dose stemming from the OSWER cleanup target (24.5 μg/L) and comparison to the EPA RfD:

Nursing Infant Dose (μg/kg/d) = (μg/L in human milk/ug perchlorate ingestion-day)*[(24.5 μg perchlorate/L water)* (L water ingested/day) + (baseline US dietary ingestion rate, μg/d)]*(L human milk ingested/day/infant body weight)

Parameter values:

a) Relationship between human milk perchlorate and maternal perchlorate intake:

i) μg/L in human milk – data for the 3 Chilean cities (Tellez, et al., 2005).
Antofagasta: Cannot use the data due to extreme outlier and high variability;
Chanaral: **Mean = 18.3 μg/L**; SD = 17.7
Taltal: **Mean = 95.6 μg/L**; SD=54.6

ii) μg perchlorate excreted/g creatinine:
Antofagasta: Min: 2.9; 10th%: 8.64; 25th%: 12.96; Med: 22.7; 75th%:43.2; 90th%: 59.4; Max:: 75

Chanaral: Min: 12; 10th%: 17; 25th%: 27; Median: 37; 75th%:63; 90th%: 155; Max: 210
Taltal: Min: 20; 10th%: 45; 25th%: 70; Median: 120; 75th%:190; 90th%: 295; Max: 395

iii) μg perchlorate excreted /day = above #'s * creatinine excretion/d (1.08 g/d) (Tellez, 2005; Knuppel, 1979)
Antofagasta: Min: 3.1; 10th%: 9.3; 25th%: 14; Median: 24.5; 75th%:46.7; 90th%: 64; Max: 81
Chanaral: : Min: 13; 10th%: 18.4; 25th%: 29.2; **Median: 40**; 75th%: 68; 90th%: 167; Max: 227
Taltal: Min: 21.6; 10th%: 48.6; 25th%: 75.6; **Median: 129.6**; 75th%:205; 90th%: 319; Max: 427

Assume μg excreted/day = μg intake/day

Estimate of relationship between μg/L human milk to μg ingested/day is thus:
Chanaral: 18.3 μg/L / 40 μg/d = **0.458 (units of d/L)**
Taltal: 95.6 μg/L / 129.6 μg/d = **0.737 (d/L)**

b) Lactating mother water ingestion rate (ml/d): mean = 1189 ml/d, SD=699; 50th percentile = 1063; **90th% 2191**; 95th% = 2424 (from CSEFH, USEPA, 2000, Table 4-13)

c) Dietary perchlorate ingestion rate per day from food and other baseline sources in US (Atlanta data – Valentin-Blasini, et al., 2005)
μg perchlorate excreted/g creatinine:
Atlanta: Min: 2.5.; 10th%: 3.1; 25th%: 4.8; **Median: 7.8**; 75th%:10.0; 90th%: 16.2; Max: 20
μg perchlorate excreted /day = above #'s * creatinine excretion/d (1.08 g/d) (Tellez, 2005; Knuppel, 1979)
Atlanta: Min: 2.7; 10th%: 3.35; 25th%: 5.2; **Median: 8.4**; 75th%:10.8; 90th%: 15; Max: 21.6

d) Infant human milk consumption rate at 2 wks of age: **634 ml/d**, SD = 149.5; range = 416-922. (CSEFH, 2000; page2-4)

e) Infant body wt at 2 weeks age (kg): avged across sex:
5th% = 2.76; 25th%= 3.34; **Median = 3.69**; 75th%=4.07; 95th%=4.57

Exposure and Risk Calculations:
Nursing infant exposure dose = (0.458 or 0.737 d/L) *[(24.5 μg/L * 2.191 L/d) + 8.4 μg/d] * (0.634 L human milk/d) / 3.69 kg body wt) = **4.9 – 7.9 μg/kg/d**

RfD = 0.7 μg/kg/d

Nursing infant Hazard Index = 4.9 or 7.9 / 0.7 = 7 to 11

Note: Hazard Index is influenced by the way in which the milk to perchlorate intake ratio was calculated. The cited literature reports the mean human milk concentrations and the median urinary perchlorate; it will take a full distributional analysis to calculate the mean urinary perchlorate; this will enable the construction of a mean milk to mean intake ratio. This ratio may be slightly lower than the mean milk to median intake ratio presented above. Therefore, we round our estimate of nursing infant hazard index downward to **5 to 10 fold** pending further analysis.

3) Perchlorate Toxicokinetics in the Neonate

Perchlorate is cleared primarily via the urine with protein binding tending to retain perchlorate in serum and retard its excretion (Clewell, et al., 2003). Human infants have immature renal function and less urinary clearance of many water soluble chemicals (Morselli, 1989; Kearns and Reed, 1989, Ginsberg, et al., 2002), suggesting that slow clearance is another infant susceptibility factor to perchlorate. Rat toxicokinetic data show that in spite of higher dose rate from nursing, pups had lower perchlorate serum concentration than adult rats (Clewell et al., 2003; NAS, 2005, Appendix E). These data are of questionable relevance to human infants given the variety of cross-species differences in the ontogeny of toxicokinetic systems (Ginsberg, et al., 2004). Other factors also affect the utility of neonatal rat data from this study (Clewell, et al., 2003): a) rat dams drink 80% of the daily output of pup urine which inflates the adult dose and serum level of perchlorate relative to the neonate; b) lactating dams and pups were dosed with radioactive iodide which may affect perchlorate toxicokinetics, especially with regards to competition for serum binding sites in the neonate which has limited binding capacity. These factors discourage the use of nursing rat pup data (Clewell, et al., 2003) to describe the toxicokinetics of perchlorate in human infants.

APPENDIX 4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 11 2006

OFFICE OF
SOLID WASTE AND
EMERGENCY RESPONSE

Melanie A. Marty, Ph.D., Chair
Children's Health Protection Advisory Committee
California Environmental Protection Agency
Office of Environmental Health Hazard Assessment
1515 Clay St. 16th Floor
Oakland, California 94612

Dear Dr. Marty:

Thank you for your letter of March 8, 2006, to Administrator Johnson conveying the Children's Health Protection Advisory Committee's recommendations to the Agency for the risk management of perchlorate; specifically, recommendations relating to the Agency's development of a Superfund preliminary remediation goal (PRG) and a Safe Drinking Water Act (SDWA) maximum contaminant level (MCL) and interim health advisory.

As you know, in January 2005 the National Academy of Sciences National Research Council issued its report, "*Health Implications of Perchlorate Ingestion*," which provided state-of-the-science advice on perchlorate toxicity. The National Research Council recommended that EPA base its perchlorate reference dose (RfD) on a level at which we expect no statistically or biologically significant increase in an observable nonadverse effect—an approach that is more protective than EPA's traditional approach of basing RfDs on adverse health effects. The National Research Council specifically considered the risks to the most susceptible individuals in recommending an RfD, and in this instance identified the fetuses of pregnant women who have hypothyroidism or iodide deficiency as the subpopulation most sensitive to the effects of perchlorate exposure. To protect this subpopulation, the National Research Council recommended that the RfD be derived by taking the dose at which no observable effect, non-adverse or adverse, is anticipated in healthy adults, and reducing it further by an order of magnitude. After reviewing these findings, EPA based its RfD of 0.0007 mg/kg-day on the National Research Council's recommendations.

In January 2006, EPA's Office of Solid Waste and Emergency Response (OSWER) issued its Assessment Guidance for Perchlorate, which recommended a PRG of 24.5 micrograms/liter (or parts per billion). The PRG is based on the perchlorate RfD and appropriate exposure assumptions. It is important to remember that PRGs are not final cleanup levels, but are merely the starting point for site-specific goals. Our regulations require that PRGs be further evaluated, and modified as necessary, as information becomes available during the remedial

investigation/feasibility study, prior to establishing final remediation goals or clean-up levels. OSWER's recommended PRG was established to ensure that the most sensitive subgroup is protected against a nonadverse effect—a health-protective approach that is informed by the conclusions of the National Research Council. Because the fetus is most sensitive to the effects of perchlorate exposure, the pregnant woman is an appropriate focus when assessing exposure to perchlorate. The exposure assumptions that EPA used to develop its PRG are consistent with those of pregnant women, as well as being the standard exposure assumptions that the Agency uses to calculate PRGs generally. (See *Risk Assessment Guidance for Superfund (RAGS): Volume I. Part B, Development of Risk-based Preliminary Remediation Goals, Interim,* EPA/540/R-92/003, Dec. 1991.) EPA continues to examine the perchlorate science to ensure that our policies are appropriately health-protective, and has been consulting with other federal researchers to provide information on intake, distribution and excretion of perchlorate in humans at various life stages.

With regard to the Committee's recommendation that the PRG take into account an appropriate relative source contribution factor, OSWER's guidance is clear that exposure to non-water sources of perchlorate at Superfund sites should be considered based on site-specific data. EPA recognizes that perchlorate has been detected in samples of some foods. Although additional data collection efforts are underway, EPA has determined that current data are too limited to characterize exposure to perchlorate on a national scale. Until such data are available, the approach outlined in OSWER's guidance is currently the most scientifically defensible approach to considering non-water exposure to perchlorate at Superfund sites.

The Committee also recommended that EPA develop an MCL for perchlorate, and, in the interim, that EPA issue a drinking water health advisory for perchlorate. EPA's Office of Water (OW) has an established process for determining whether or not a chemical should be regulated in drinking water and an MCL established. Using criteria specified in the SDWA, this regulatory process determines: (1) if the contaminant may have an adverse health effect; (2) if the contaminant occurs in public water systems with a frequency and at levels of public health concern; and, (3) if regulation presents a meaningful opportunity for health risk reductions for persons served by public water systems. Perchlorate and other contaminants on EPA's second Candidate Contaminant List are currently being evaluated as part of this regulatory determination process.

As part of this process, OW is analyzing the nationally representative occurrence data for perchlorate that was collected as part of the Unregulated Contaminant Monitoring Rule (UCMR) sampling conducted at public water systems. As the Agency continues to review health effects in light of perchlorate occurrence and other information, including data on the relative source contribution, the Agency may take one or more affirmative steps as provided for in SDWA, such as issuing a health advisory, if needed, or issuing a preliminary regulatory determination.

EPA will continue to evaluate new scientific information on perchlorate as it becomes available, to ensure the protection of children's health. Thank you again for your contribution to this important effort.

Sincerely,

Susan Parker Bodine
Assistant Administrator

cc: Benjamin Grumbles, OW
George Gray, ORD