

EPA Response to Follow-up Questions

from

House Energy and Commerce Committee

April 25, 2007 Hearing on Perchlorate

The Honorable Joe Barton and the Honorable John Shimkus – Grumbles

1. Can you explain how the health effects studies and science related to perchlorate is different from the studies related to lead, mercury, PCBs, and other contaminants? Were there more conclusive determinations that lead to EPA making a determination regarding risks to public health? Why has EPA chosen to defer a determination of whether an MCL should be set for perchlorate?

The health effects studies and science related to perchlorate are not considered to be fundamentally different from the available studies related to lead, mercury, and PCBs. In fact, there are extensive available data for all of these contaminants and EPA has used the available data on perchlorate to set a reference dose (RfD), in accordance with the recommendations of the National Academy of Sciences. This RfD, in combination with exposure information, is being used to make a regulatory determination regarding exposure to perchlorate in drinking water. In making a regulatory determination for perchlorate, the Agency is following the process laid out by Congress in the 1996 Amendments to the Safe Drinking Water Act. As described in the May 1, 2007 Federal Register Notice, EPA has deferred a decision on perchlorate in order to more fully characterize total perchlorate exposure and the relative contribution of perchlorate from drinking water versus food sources. We will be evaluating data for perchlorate in food that will be released by the FDA in the fall of 2007 as well as CDC human exposure data. The Agency expects to make a preliminary determination shortly after release of the FDA results this fall.

2. During the hearing you disagreed, calling it “not entirely accurate,” a characterization of EPA having rejected “the advice from the Children’s Health Office.” Would you please respond with your version of how EPA received and is responding to the complaints of the Children’s Health Protection Advisory Committee?

Administrator Johnson received a letter from the Children’s Health Protection Advisory Committee (CHPAC) on March 8, 2006, which provided several recommendations to the Agency. The recommendations included: 1) the Office of Solid Waste and Emergency Response (OSWER) perchlorate preliminary remediation goal (PRG) does not protect infants and should be lowered and 2) the OSWER perchlorate PRG should have a relative source contribution to account for exposures from food. Assistant Administrator Bodine responded on behalf of the Agency on May 11, 2006.

In response to CHPAC, the Agency indicated that the PRG was based on the perchlorate reference dose recommended by the National Academies of Science (NAS). The NAS recommended that EPA base its perchlorate reference dose (RfD) on the inhibition of iodide

uptake by the thyroid, an effect that they identified as nonadverse. The no observed effect level (NOEL) for this effect was chosen as the point of departure for the derivation of the RfD. The NAS stated that the use of this biochemical event provides a conservative, health protective approach to risk assessment. As part of their assessment, the NAS specifically considered the risks to the most susceptible individuals in recommending an RfD, and identified the fetuses of pregnant women who might have hypothyroidism or iodide deficiency as the subpopulation most sensitive to the effects of perchlorate exposure. The NAS recommended that an uncertainty factor of 10 be applied to the NOEL to protect this sensitive population. Furthermore, because the fetus is the most sensitive to the effects of perchlorate exposure, the pregnant woman is an appropriate focus when assessing exposure to perchlorate. As a result, EPA used its standard body weight (70 kg) and drinking water intake (2 liters/day) assumptions to derive the PRG.

In the May 11, 2006 response, the Agency also indicated that the PRG is not a final cleanup level, but merely the starting point for developing site-specific remediation goals. As a matter of standard practice (and in accordance with the National Contingency Plan), preliminary remediation goals are further evaluated and modified, if necessary, before final clean-up goals are established based on information that becomes available during the remedial investigation feasibility study. This may include assessing factors, such as actual and potential exposure pathways through environmental media and actual and potential exposure routes. While there is information available that indicates that perchlorate has been found in food, the information available at the time of our response to CHPAC (and currently) was too limited to calculate, on a national level, the relative exposure to perchlorate from water as opposed to food (the RSC). Therefore, EPA's Assessment Guidance for Perchlorate recommends that the contribution from non-water sources of perchlorate should be considered based on site-specific data until further national guidance on relative source contribution is developed. It is appropriate to consider such information in determining the final clean up goal, and thus, the remedy for the site.

As the Agency moves forward in making the preliminary regulatory determination for perchlorate in drinking water, we will consider all available data regarding the effects of perchlorate on subgroups (such as infants, children, pregnant women, the elderly and individuals with a history of serious illness) to assess if any are at greater risk of adverse health effects as a result of perchlorate in drinking water.

3. Do you believe the standard setting process described in the Safe Drinking Water Act is working? Do you believe it is necessary, appropriate, or wise for Congress to dictate which contaminants you should regulate under the Safe Drinking Water Act?

EPA believes that the process laid out in the 1996 Amendments is working and that science should drive the decision-making process. In accordance with SDWA Section 1412(b), EPA must determine whether or not to regulate a contaminant after providing notice of a preliminary regulatory determination and opportunity for public comment. EPA's determination to regulate a contaminant must be based on the following findings:

- the contaminant may have an adverse effect on the health of persons;
- the contaminant is 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; and

- regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

EPA has not made a preliminary regulatory determination for perchlorate, because the Agency believes additional information is needed to more fully characterize perchlorate exposure and determine whether regulating perchlorate in public drinking water systems presents a meaningful opportunity for public health protection. We expect to have the additional information we need to make a determination later this year upon release of the FDA Total Diet Study.

4. 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?

With respect to considering a contaminant for drinking water regulation, it is irrelevant if the contaminant is from natural or man-made sources – the only relevant factors are whether a contaminant may pose an adverse health effect, the contaminant's frequency and magnitude of occurrence in drinking water provided by public water systems, and whether regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

The Agency monitored for perchlorate in a nationally representative sample of public water systems as part of the first round of monitoring under the Unregulated Contaminant Monitoring Rule (UCMR1). Perchlorate was detected at concentrations above the 4 ppb detection limit in approximately 2 percent of the 34,000 samples collected. Perchlorate was detected in at least one sample taken at 160 of 3,858 public water systems (4% of systems) located in 26 states and 2 territories. Close to 40% of the systems that detected perchlorate were in California. The Agency did not attempt to determine the source of perchlorate in public water systems that detected perchlorate.

With respect to site specific clean up decisions, remedial project managers assess conditions at the site to identify concentrations of perchlorate present at a site. If perchlorate is found at a site, the investigators try to determine whether the perchlorate is naturally occurring; due to widespread anthropogenic contamination, as might be associated with regional use of perchlorate-contaminated fertilizer; due to specific releases from site-related activities, e.g. explosives manufacturing or use; or due to an as-yet-unidentified release. In addition, the remedial investigation also assesses the likelihood of current or potential exposure to perchlorate and what consequences to human health and the environment such exposure might have. The decisions of whether and how to cleanup perchlorate depend on these findings. Under Superfund, EPA would typically look to other response authorities for widespread contamination not associated with specific sources, since it is program practice not to clean up below background (Role of Background in the CERCLA Cleanup Program, OSWER 9285.6-007P, May 1, 2002, available at <http://www.epa.gov/oswer/riskassessment/pdf/role.pdf>.) Additionally CERCLA 104(a)(3)(A) restricts the authority to take an action in response to the release or threat of release of a "naturally

occurring substance in its unaltered form or altered solely through naturally occurring processes or phenomena, from a location where it is naturally found.”

- 5. 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?**

It is true that the Blount et al. (2007) study that evaluated perchlorate in urine samples indicated widespread human exposure to perchlorate. This is why it is important for EPA to carefully assess the relative source contribution of perchlorate – through the diet and drinking water. EPA cannot speculate as to whether the Blount findings would indicate that “mankind has likely always had this level of exposure.” However, as noted in the previous response, when making drinking water regulatory determinations, it is irrelevant if a contaminant is from man-made or natural sources. The only relevant factors are whether a contaminant may most an adverse health effect, the contaminant's frequency and magnitude of occurrence in drinking water provided by public water systems, and whether regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

- 6. 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?**

No, EPA sees nothing to suggest that the NAS was wrong. EPA continues to support the NAS report and continues to endorse the EPA RfD. As with any chemical, we will, however, continue to review new science that could inform our future decision-making.

- 7. 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?**

Yes, the approach used by the NAS is more conservative than EPA's traditional approach. Using a no observed effect level (NOEL) that occurs before the adverse effect is a conservative approach to hazard assessment.

- 8. 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?**

EPA has not yet determined whether or how it would be appropriate to take national security

considerations into account when determining whether to regulate a contaminant in drinking water, or how significant any national security concerns are relevant to regulating perchlorate in drinking water. The law does not explicitly provide for taking national security issues into account when determining whether to regulate a contaminant.

The Honorable Joe Barton and the Honorable John Shimkus -- Gray

- 1. The Safe Drinking Water Act requires EPA to use the best available, peer-reviewed science. What steps have you taken to ensure that you have the best available science?**

EPA uses the best available peer-reviewed data and analyses in evaluating adverse health effects. In developing its health assessment for perchlorate (<http://www.epa.gov/iris/subst/1007.htm>), the Agency submitted the draft health assessment to the National Academy of Sciences (NAS), the preeminent scientific body in the nation, to conduct an additional peer review. EPA continues to support the NAS report and continues to endorse the EPA RfD, which follows the NAS's recommendations. NAS's evaluation was based on the scientific evidence available at the time of their report in 2005. As with any chemical, we will continue to review new science that could inform our future decision-making.

- 2. Did you have any reason after looking at NAS' independent review to conclude that its work was flawed or biased? Do you feel that using NAS' work comports with the science requirements in the Safe Drinking Water Act for best available, peer-reviewed, objective scientific analysis on the health effects of perchlorate?**

EPA has no reason to believe that the NAS review was either flawed or biased. We believe their final report represented the best available public health information regarding the adverse effects of perchlorate on human health. The NAS perchlorate committee took into consideration presentations made at the committee's public meetings, public comments, and comments provided by technical experts on the draft report. We believe that this effort comports with the requirements outlined in the Safe Drinking Water Act to ensure the use of best available science.

- 3. In your opinion, is the RfD sound and appropriate for decision making and protective of the most sensitive subpopulations?**

Yes, the RfD for perchlorate is sound and appropriate for decision-making and protective of the most sensitive populations (fetuses of pregnant women who might have hypothyroidism or iodine deficiency). We will, however, continue to review new science that could inform our future decision-making.

4. **Just because we detect minuscule quantities of a substance such as perchlorate in water, food or body fluid samples does not mean we should assume that there is harm, does it?**

Correct. The presence of a contaminant does not necessarily mean that a harmful effect has occurred or will occur. For harm to occur, people must be exposed to the contaminant in quantities sufficient to lead to toxicity.

5. **Do you feel confident that you used the best available science to come up with the reference dose on perchlorate?**

Yes, EPA is confident that the Agency used the best available science to derive a reference dose for perchlorate.

6. **The NAS report, *Human Biomonitoring for Environmental Chemicals* (2006), says that interpreting biomonitoring data depends on the availability of various types of other information, including exposure, toxicity, toxicokinetics. In light of this guidance, do you think the CDC studies are preferable to the NAS report for setting a Reference Dose (safe exposure level) for perchlorate?**

Regarding the use of CDC biomonitoring data, EPA continues to evaluate this and other recent data on perchlorate health effects. The researchers acknowledged that the results were unanticipated based on previous studies and recommended further research to affirm the findings. EPA continues to support the NAS report and continues to endorse the EPA RfD. We will, however, continue to review new science that could inform our future decision-making.

7. **In your experience, is it typical for EPA to set a Reference Dose based on an observed effect in humans that is not even adverse? Given that NAS started with a clearly nonadverse effect, and also added a 10-fold uncertainty factor, wouldn't it be reasonable to believe that EPA's RfD is protective of sensitive subpopulations and exposures from food?**

It is not typical for EPA to set a reference dose on an observed effect in humans that is not adverse. Therefore, the approach used by the NAS is more conservative than EPA's traditional approach.

EPA's definition of an RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It is reasonable to believe that EPA's RfD is protective of sensitive populations' perchlorate exposures. The RfD should be compared against combined exposure from all oral sources (e.g., dietary, water, and contaminated soil).

- 8. What is the occurrence data for perchlorate in drinking water? Is it widespread in drinking water, and at what levels? How many people are exposed at levels above the level the National Academy of Sciences says is safe even for the most sensitive subpopulation, such as iodine deficient pregnant women and their fetuses?**

The Agency monitored for perchlorate in a nationally representative sample of public water systems as part of the first round of monitoring under the Unregulated Contaminant Monitoring Rule (UCMR1). Perchlorate was detected at concentrations above the 4 ppb detection limit in approximately 2 percent of the 34,000 samples collected. Perchlorate was detected in at least one sample taken at 160 of 3,858 public water systems (4% of systems) located in 26 states and 2 territories. Close to 40% of the systems that detected perchlorate were in California. Please note that the NAS recommended the RfD, which EPA adopted in 2005. The RfD was converted by EPA to a drinking water equivalent level (DWEL) of 24.5 ppb (assuming a 70 kg body weight and 2 liters/day drinking water consumption rate). However, the Agency cannot determine an appropriate health reference level (HRL) until it has more information to inform a relative source contribution - that is, the amount of perchlorate that may come from other sources, such as food. Table 5 in EPA's May 1, 2007 Federal Register Notice provides additional estimates of the population exposed at different potential HRLs. The population served by public water systems with at least one detection above a given potential HRL ranges from 1 million at an HRL of 25 ppb to 14.6 million at an HRL of 5 ppb.

- 9. 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?**

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With respect to site specific clean up decisions, remedial project managers assess conditions at the site to identify concentrations of perchlorate present at a site. If perchlorate is found at a site, the investigators try to determine whether the perchlorate is naturally occurring; due to widespread

anthropogenic contamination, as might be associated with regional use of perchlorate-contaminated fertilizer; due to specific releases from site-related activities, e.g. explosives manufacturing or use; or due to an as-yet-unidentified release. In addition, the remedial investigation also assesses the likelihood of current or potential exposure to perchlorate and what consequences to human health and the environment such exposure might have. The decisions of whether and how to cleanup perchlorate depend on these findings. Under Superfund, EPA would typically look to other response authorities for widespread contamination not associated with specific sources, since it is program practice not to clean up below background (Role of Background in the CERCLA Cleanup Program, OSWER 9285.6-007P, May 1, 2002, available at <http://www.epa.gov/oswer/riskassessment/pdf/role.pdf>.) Additionally CERCLA 104(a)(3)(A) restricts the authority to take an action in response to the release or threat of release of a “naturally occurring substance in its unaltered form or altered solely through naturally occurring processes or phenomena, from a location where it is naturally found.”

10. 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?

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11. 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?

No, EPA sees nothing to suggest that the NAS was wrong. EPA continues to support the NAS report and continues to endorse the EPA RfD. We will, however, continue to review new science that could inform our future decision-making.

12. 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?

Yes, the approach used by the NAS is more conservative than EPA's traditional approach. Using a no observed effect level (NOEL) that occurs before the adverse effect is a conservative approach

to hazard assessment.

The Honorable Albert R. Wynn {same questions sent to all 3 AAs}

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 (EPA), 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.

EPA is working with its ten regional offices to collect the data requested in your question. We will make every effort to collect this data and transmit it to the Committee in a timely fashion. We expect to be able to provide a substantive response to your question later this month.

2. By letter dated July 16, 2003, EPA notified the Department of Defense that it 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, Assistant Administrator Bodine indicated that she 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?

Camp Bonneville is a non-NPL BRAC site. While EPA participated on the Base Closure Team in accordance with DoD's BRAC policy and guidance, the state of Washington has lead regulatory oversight responsibility and the Washington Department of Ecology (Ecology) was very interested in taking full oversight responsibility for Camp Bonneville. Ecology had increased their staff assigned to work on this site and suggested to EPA that there was no need for both federal and state oversight. EPA did not think it would be appropriate nor was there a need to issue an enforcement order to the Army given the fact that the state was overseeing the cleanup of the site under the state's own cleanup law known as the Model Toxics Control Act. EPA decided to honor the state's request.

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.

In general, at DoD sites listed on the CERCLA National Priorities List, EPA seeks to negotiate Federal Facility Agreements (FFAs) with the responsible DoD service. Those FFAs, which are legally enforceable agreements, govern how the DoD service will investigate and clean up environmental contamination. EPA has also used the Safe Drinking Water Act to compel DoD to address perchlorate contamination in ground water. Specifically:

Camp Edwards on the Massachusetts Military Reservation, Massachusetts, (NPL/BRAC)

EPA issued an order to DoD under the Safe Drinking Water Act to compel DoD to undertake remedial action at the site. A comprehensive plan for ground water cleanup has been completed for the Demolition Area 1 site at Camp Edwards. The cleanup plan was finalized and approved by EPA with the review and concurrence of the Massachusetts Department of Environmental Protection and announced on November 2, 2006. Under the plan, DoD is to treat and remove perchlorate to below 2.0 parts per billion (the Massachusetts perchlorate regulatory standard). The source of perchlorate contamination was removed from the soil in 2004.

Picatinny Arsenal, New Jersey (NPL)

Under the Federal Facilities Agreement (FFA) with the Army, there have been approximately 160 operable units (OUs) subject to a CERCLA investigation at Picatinny Arsenal. The investigation of these OUs has included the sampling of ground water, soil, sediment and surface water. Since 2000, DoD has sampled for perchlorate in ground water where it may have been released at an OU. Perchlorate has only been detected at one OU at Picatinny.

Redstone Arsenal, Alabama (NPL/BRAC)

The Army and NASA have separate, but coordinated, cleanup activities underway. Although EPA has an FFA in place with NASA, the FFA between the Army and EPA remains under negotiation. Remedial Investigations (RI) by the Army, which include investigating perchlorate releases, are underway with EPA and Alabama Department of Environmental Management oversight. No RODs or remedial actions are underway that involve perchlorate since the Army's investigation stage is not complete.

Longhorn Army Ammunition Plant, Texas (NPL)

EPA has an FFA in place with the Army at this site. The plant has two operating units with perchlorate ground water contamination that will eventually be addressed under RODs. The RODs are delayed pending final action of a site-wide ecological risk assessment. The FFA for Longhorn requires the Army to implement the remedy selected in the ROD once the ROD is final.

Iowa Army Ammunition Plant, Iowa (NPL)

Under the FFA with the Army, EPA requested that sampling for perchlorate be performed. DoD has conducted the sampling; however, no notable actionable levels of perchlorate have been found and no active response/remedial actions have yet been required.

Lake City Army Ammunition Plant, Missouri (NPL)

At EPA's request, DoD conducted perchlorate sampling under the FFA. A (Remedial Investigation/Feasibility Study (RI/FS) was completed for the Northeast Corner OU 3. The ROD to address the perchlorate ground water contamination is currently under review for signature by the Army, the Missouri Department of Natural Resources, and EPA. The cleanup goal for perchlorate contamination is 24.5 ug/L.

Nebraska Ordnance Plant, Nebraska (non-NPL)

EPA has an FFA with the Army Corps of Engineers and the State of Nebraska at this former ordnance plant. EPA also has a separate order with the University of Nebraska for this site under which the University sampled for perchlorate. EPA issued a ROD in 1997 for ground water cleanup, which the Army Corps is required to implement under the FFA. The site includes a defunct fireworks facility. The Corps states that it does not believe that perchlorate was used at the former ordnance plant and any perchlorate contamination would be associated with the defunct fireworks facility. EPA has sampled for perchlorate at this site. The current data does not indicate that remedial action is necessary.

El Toro Marine Corps Air Station, California (NPL/BRAC)

Under the FFA with the Navy, a final RI was released in December, 2006. A draft FS was submitted in January 2007, a draft final FS is planned for November 2008, and a draft ROD is planned for September 2009. The draft final FS is being delayed to perform additional ground water monitoring and pilot studies on the treatment of perchlorate. The Navy has evaluated ground water remedial alternatives in the draft FS using the California proposed maximum contaminant level (MCL) of 6 ppb.

Edwards Air Force Base, California (NPL)

Under the FFA, the Air Force is conducting full scale treatability studies on perchlorate contamination. In addition, RODs are being planned to address the perchlorate ground water contamination.

Umatilla Army Depot, Oregon (NPL/BRAC)

Under the FFA, the Army sampled for perchlorate in 2001 and 2003. A decision on what action will be taken to address the perchlorate contamination is pending.

Boardman Bombing Range, Oregon (non-NPL)

At the Navy Boardman Bombing Range, an operational range, EPA has issued a CERCLA § 104(e) Information Request letter to the Navy to gather additional information regarding the disposal on the range of military munitions that may contain perchlorate. The Navy has responded to this request for information, and their response is currently being reviewed.

4. Assistant Administrator Bodine 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."

Assistant Administrator Bodine's knowledge of past DoD positions regarding perchlorate is based on both the May 2005 report by the Government Accountability Office (GAO) entitled, "Perchlorate: A System to Track Sampling and Cleanup Results is Needed" and the July 2005 DoD Report to the Congress, entitled "Perchlorate in the Southwestern United States."

The May 2005 GAO report states:

"According to EPA and state officials, DoD has been reluctant to (1) sample on or near active installations because there is no specific regulatory standard for perchlorate or (2) sample where DoD determined the criteria to sample were not met as outlined in its policy. Except where there is a legal requirement to sample at a particular installation, DoD's perchlorate policy does not require sampling unless the two conditions of release and exposure are met."

The July 2005 DoD report states:

"In the absence of otherwise properly promulgated and applicable state or Federal standards, the Department will continue to evaluate the extent of perchlorate contamination at installations and address sources of contamination that present an unacceptable risk to public health, safety, or the environment, in consultation with Federal, state, and local authorities using available sampling data and related information. Such responses will occur on a case-by-case basis, reflecting the individual circumstances of sites where perchlorate contamination is found. When a standard for perchlorate is promulgated, the Department is poised to effectively address perchlorate contamination attributable to DoD activities."

Since the issuance of the "Policy on DoD Required Actions Related to Perchlorate," on January 26, 2006, by Philip W. Grone, Deputy Undersecretary of Defense (Installations and Environment), it is current DoD policy to address perchlorate found at levels at or above 24 ppb. The January 2006 policy expressly superseded the September 2003 DoD perchlorate sampling policy discussed in the May 2005 GAO Report.

5. At the April 25th hearing Assistant Administrator Bodine 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.

Assistant Administrator Bodine's knowledge of past DoD positions regarding perchlorate is based on both the May 2005 report by the GAO entitled, "Perchlorate: A System to Track Sampling and Cleanup Results is Needed" and the July 2005 DoD Report to the Congress, entitled "Perchlorate in the Southwestern United States." Again, since the issuance of the "Policy on DoD Required

Actions Related to Perchlorate," on January 26, 2006, by Philip W. Grone, Deputy Undersecretary of Defense (Installations and Environment), it is current DoD policy to address perchlorate found at levels above 24 ppb.

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.

Before DoD's January 2006 Perchlorate Policy was issued, EPA Regions at times required intervention from EPA Headquarters to obtain permission for a DoD component to sample for perchlorate. However, following communication between EPA headquarters and the Headquarters of the particular Service involved, permission to sample would be given.

For example, at Aberdeen Proving Ground (APG), Aberdeen, MD the Army initially conducted sampling whenever the Army, EPA or the Maryland Department of the Environment (MDE) believed sampling was necessary. Subsequently, DoD facilities were required to obtain permission from above the base level to conduct sampling for perchlorate. In turn, APG then required a letter from EPA requesting perchlorate sampling. When EPA requested perchlorate sampling by letter, APG requested and obtained permission to conduct the perchlorate sampling. DoD has since revised its policy and APG is now able to sample for perchlorate when EPA, MDE and the Army suspect perchlorate contamination, without requesting permission from higher levels in the Army. APG continues to sample for perchlorate when there is reason to suspect its presence.

As stated at the hearing, DoD has revised its stance on perchlorate. At some sites discussions continue regarding *where* to sample, or *whether sampling for perchlorate is indicated* by past property use, not whether perchlorate is a contaminant that must be addressed. Such discussions are ongoing at two sites:

Navy Boardman Bombing Range, Boardman, OR (non-NPL, Operational Range)

EPA has been working with the Navy on this non-NPL site to obtain samples for 9 existing on-site monitoring wells for perchlorate for the past three to four years. A number of the wells surrounding the Boardman Range that were sampled by EPA Region 10 and the Oregon Department of Environmental Quality in 2003 and 2004 show detections of perchlorate on the west, north, and east sides of the Range. EPA Region 10 recently issued an enforceable CERCLA 104(e) Information Request letter to the Navy to gather additional information regarding the disposal of military munitions that may contain perchlorate on the Boardman Bombing Range. EPA received the Navy's response to the 104 (e) request which had sought information regarding used and unused waste military munitions, open detonation activities, burial, disposal and transfer of munitions waste, and types of explosives used at the Range. EPA is currently reviewing the detailed information it received from the Navy..

Fairchild Air Force Base, Spokane, WA (NPL)

EPA has been working with the Air Force to conduct sampling for perchlorate for approximately a year at this base. The Air Force has reviewed historical information regarding prior site activities, including the types of fuels previously stored at the base, in order to determine if there is a potential for perchlorate contamination. EPA found low levels of perchlorate in samples taken outside the base boundaries and will be conducting sampling on base in the near future to determine if

perchlorate is coming from the base.

- 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.**

EPA did not provide a formal response to the AWWA’s February 25, 2005 letter. The Agency interacts regularly with the association’s leadership and has conveyed through discussions and presentations at AWWA conferences how the Agency has been carefully considering whether to regulate perchlorate in drinking water.

- 8. You 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.**

The UCMR data from 3,061 large public water systems (PWS) and 797 randomly selected small PWSs provides a robust national assessment of the occurrence of perchlorate. Perchlorate was detected at concentrations above the 4 ppb detection limit in approximately 2 percent of the 34,000 samples collected. The data also showed that perchlorate was detected in at least one sample of 152 large PWS and 8 small PWS out of 3,858 PWSs (4% of systems). EPA is also evaluating the perchlorate drinking water occurrence data collected by the California Department of Health Services and the Massachusetts Department of Environmental Protection.

Nevertheless, EPA believes information is needed to more fully characterize perchlorate exposure

and determine if a national primary drinking water rule presents a “meaningful opportunity for health risk reduction for persons served by public water systems.” EPA is working with the FDA and CDC to assess total perchlorate exposure and to better understand perchlorate exposure from sources other than drinking water, such as food. As the Blount et al. (2007) study that assessed perchlorate exposure showed, all subjects had perchlorate in their urine even though EPA and other monitoring have shown that perchlorate is not detectable in the majority of drinking water systems. EPA believes an informed relative source contribution is necessary to determine if regulating perchlorate in public drinking water systems would present a meaningful opportunity for public health risk reduction.

Regarding the CDC biomonitoring data, EPA continues to evaluate this and other recent data on perchlorate health effects. EPA notes that the Blount et al. (2006) study does not purport to demonstrate that a population has been adversely affected. The researchers acknowledged that the results were unanticipated based on previous studies and recommended further research to affirm the findings.

- 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?**

Please note that EPA’s RfD is 0.0007 mg/kg-day and the Drinking Water Equivalent Level (DWEL) is 24.5 ppb. The RfD for perchlorate is based on a no observed effect level (NOEL) , not a “low-effect level”, and applies to daily oral exposure to the human population for a lifetime.

The use of a 10-fold uncertainty factor for human variability in the derivation of the perchlorate RfD is “intended to account for ...variation in susceptibility among the members of the human population (i.e., inter-individual or intraspecies variability)” as defined in the IRIS Glossary (www.epa.gov/iris). According to the NAS report (page 178), “A full factor of 10 should be used for the intraspecies factor to protect the most sensitive population—the fetuses of pregnant women who might have hypothyroidism or iodide deficiency.”

- 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, Assistant Administrator Bodine 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?

In response to CHPAC, the Agency indicated that the PRG was based on the perchlorate RfD, recommended by the National Academy of Sciences (NAS) and adopted by EPA in 2005. The NAS recommended that EPA base its perchlorate RfD on the inhibition of iodide uptake by the thyroid, an effect that they identified as nonadverse. The no observed effect level (NOEL) for this effect was chosen as the point of departure for the derivation of the RfD. The NAS stated that the use of this biochemical event provides a conservative, health protective approach to risk assessment. As part of their assessment, the NAS specifically considered the risks to the most susceptible individuals in recommending an RfD, and identified the fetuses of pregnant women who might have hypothyroidism or iodide deficiency as the subpopulation most sensitive to the effects of perchlorate exposure. The NAS recommended that an uncertainty factor of 10 be applied to the NOEL to protect this sensitive population. Furthermore, because the fetus is the most sensitive to the effects of perchlorate exposure, the pregnant woman is an appropriate focus when assessing exposure to perchlorate. As a result, EPA used its standard body weight (70 kg) and drinking water intake (2 liters/day) assumptions to derive the PRG.

Since the release of the NAS report and the issuance of PRG guidance for perchlorate, a number of studies have been published. The Agency is currently engaged in ongoing analyses of National Health and Nutrition Examination Survey (NHANES) data with CDC and monitoring other research activities from the private sector. These data will be evaluated as they become available to inform our future decision-making.

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?

Yes, perchlorate was positively detected in only those materials known to be derived from Chilean nitrate salts. These fertilizers were found to constitute about 0.14% of U.S. fertilizer application at the time of the release of the report. More recent data is not available.

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 Science (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.

Please note that EPA's RfD that was based on the NAS report and adopted in 2005 is 0.0007 mg/kg-day and the Drinking Water Equivalent Level (DWEL) is 24.5 ppb. For the regulatory determination process, EPA typically performs a screening analysis using a 20 percent relative source contribution (a default RSC) to derive a health reference level (HRL) or health value. We then use this health value to evaluate drinking water occurrence data. The 20 percent RSC is the lowest and most conservative RSC used in the derivation of health values for non-carcinogenic compounds. Over the course of 2004 to 2006, information on perchlorate became available that influenced our decisions on how to best address the regulatory determination for perchlorate. Knowing that perchlorate was being found in foods, we recognized that the choice of an appropriate RSC and the resulting health value could impact EPA's determination of whether regulation of perchlorate (in drinking water) represents a meaningful opportunity for health risk reduction. Our May 1, 2007, Federal Register Notice further discusses the importance of the RSC.

The Agency does not intend to "delay making a preliminary determination whether to regulate perchlorate in drinking water for several years." EPA is awaiting results from the FDA's Total Diet Study to help the Agency evaluate the RSC. FDA's study is due to be published in the fall of 2007. EPA and CDC are also evaluating biomonitoring data on urinary perchlorate as a direct indicator of the dose of ingested perchlorate from food and water. EPA intends to move expeditiously to publish a preliminary determination for perchlorate once the Agency has analyzed the data and determined the best approach to evaluating the opportunity for public health risk reduction. EPA anticipates this could be done shortly after the release of the FDA study this fall. EPA may be able to publish a final regulatory determination for perchlorate as part of the final CCL 2 regulatory determinations due by July 2008. If not, the Agency will publish its final determination for perchlorate as soon as possible thereafter.

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.?

Yes, the HRL associated with a 20% RSC would be 5 ppb.

14. Given the 2006 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?

Please note that EPA's RfD is 0.0007 mg/kg-day and the DWEL is 24.5 ppb. The CDC researchers acknowledged that the results were unanticipated based on previous studies and recommended further research to affirm the findings. The current RfD is based on a recommendation by the NAS,

which itself was based on the best scientific information available. EPA continues to support the NAS report and continues to endorse the EPA RfD. As with any chemical, we will, however, continue to review new science that could inform our future decision-making

- 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 FDA food data with the CDC biomonitoring data to determine the dietary component to daily perchlorate exposure.**

EPA has not yet determined how it will characterize perchlorate exposure and proceed with a preliminary regulatory determination. EPA described several options for using the FDA food data and the CDC biomonitoring data to characterize total perchlorate exposure and estimate a relative source contribution in its May 1, 2007 Federal Register Notice. The options are described in detail on pages 24047 and 24048. The Agency has received public comments on these potential options and is evaluating this input.

- 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?**

At the time EPA was contemplating taking an action to address the perchlorate plume at Aberdeen Proving Ground, the existing EPA guidance suggested a level of 4-18 ppb as a trigger to address contaminated ground water. While there were some geoprobes in the plume which collected water samples above 18 ppb, EPA generally does not use geoprobe data to support such actions, including enforcement actions. Monitoring well data is used to support such actions and the perchlorate concentrations in monitoring wells were generally below 10 ppb. The highest level found in a City of Aberdeen production well was just above 4 ppb for a short period of time and was usually much lower. There were many other production wells with much lower levels of perchlorate, which produced blended water that was delivered to the City’s residents. Perchlorate concentrations in the distributed water never exceeded 1 ppb. Region 3 did not consider the plume to be an immediate threat to human health, but was concerned that the contamination might pose a

potential future threat if levels increased.

In response to this potential threat, EPA proposed a limited pump and treatment remedy to the Army. The Army did not believe that the levels at that time posed a risk to the public to warrant such action. The City of Aberdeen also raised concerns with the pump and treat solution, because the City could not produce enough water to supply its customers and the remedy proposed by EPA would further tax their water supply. EPA decided to have its research group in Ada, Oklahoma produce a ground water model to determine the impacts the remedy would have on the City's water supply. This was a complicated task and took much longer than Region 3 anticipated. Before this modeling effort was completed, the City of Aberdeen installed ion exchange treatment systems on its most contaminated wells, and the new Office of Solid Waste and Emergency Response (OSWER) guidance regarding the PRG of perchlorate of 24.5 ppb was issued. Since the average level of perchlorate in the plume is well below 24.5 ppb and since the water supplied to the public is generally below 0.5 ppb, and usually non-detectable, Region 3 does not believe that remedial action is warranted.

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?

The 2006 OSWER guidance on perchlorate recommended a revised PRG of 24.5 ppb based on the EPA reference dose released following the issuance of the NAS study. The revised guidance simply replaced the preliminary reference dose with the final reference dose set by ORD.

EPA's Assessment Guidance for Perchlorate (January 26, 2006) provides guidance on the development of PRGs for perchlorate. Typically, PRGs are specific statements of desired endpoint concentrations or risk levels (55 Fed. Reg. 8713 (March 8, 1990)) that are conservative, default endpoint concentrations used in screening and initial development of remedial alternatives before consideration of information from the site-specific risk assessment. However, PRGs are not final cleanup levels, but merely the starting point for identifying site-specific goals. As a matter of standard practice (and in accordance with the National Contingency Plan), PRGs are further evaluated and modified, if necessary, before final clean-up goals are established based on information that becomes available during the remedial investigation/feasibility study. This may include assessing factors, such as actual and potential exposure pathways through environmental media and actual and potential exposure routes.

While the currently available data are too limited to calculate dietary exposure to perchlorate on a national scale, the guidance indicates that exposure to non-water sources of perchlorate, such as food, can contribute to the overall exposure to perchlorate at Superfund sites and should be considered based on site-specific data. Therefore, EPA's Assessment Guidance for Perchlorate recommends that contribution from non-water sources of perchlorate should be considered based on site-specific data where assessors believe that there may be significant exposures to perchlorate from such sources. In such instances, it is appropriate to consider such information in determining the final clean up goal, and thus, the remedy for the site. In addition, if a State has

promulgated a drinking water standard for perchlorate (e.g., Massachusetts adopted 2 ppb as a drinking water standard), that value is likely to be used as an applicable or relevant and appropriate value (ARAR) and would be used as the ground water cleanup level for sites in that state.

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.

To our knowledge, EPA is currently developing a site-specific relative source contribution for perchlorate from non-drinking water sources at only one NPL site, which is discussed below. While we believe our knowledge is complete, we are canvassing the Regions and will report back to you if we find any new situations where EPA is developing site-specific relative source contributions to modify the perchlorate PRG for a final cleanup decision.

In Region 9, a unique opportunity arose in 2006 to collaborate with researchers at the University of California-Davis and CDC's National Center for Environmental Health. This collaboration intends to provide a site-specific perchlorate exposure estimate for the population in the vicinity of the Aerojet Superfund Site in Rancho Cordova, consistent with the OSWER directive of January 26, 2006. The Aerojet Site is anticipated to have the first ROD for perchlorate-contaminated ground water since the OSWER memorandum. The University of California in an earlier research effort had already sampled a population from the area and had archived (frozen) urine samples, which appeared appropriate for use in estimating perchlorate exposure independent of contaminated drinking water sources. An Interagency Agreement (IAG) to fund perchlorate biomonitoring analyses was fully completed in the first quarter of FY 2007 and data are expected to be submitted at the end of 2007.

The following description is taken from the IAG documentation:

- The project objectives are to provide a quantitative estimate of the mean and range of current and recent perchlorate exposure for women of childbearing age in the greater Sacramento Area, based on CDC-developed analytical procedures for urinalysis using first morning urine samples from an appropriate population sample. The data should be sufficient to support the calculation of a site-specific health-based cleanup value for the Aerojet site using EPA's IRIS reference dose.
- The project will accomplish the objectives by: 1) Obtaining appropriate archived biomonitoring samples through collaboration with the University of California at Davis (UC – Davis) which has already collected and archived appropriate urine samples for a separate National Institute of Health, Superfund Basic Research Program Grant (NIH). 2) After shipment of the samples to CDC, CDC researchers will follow state-of-the art

analytical procedures developed by CDC to analyze these samples for analytes needed to estimate perchlorate exposures. 3) Report results, methodologies and quality assurance information will be provided to EPA in a preliminary report by (December 2007), followed by preparation and submittal of a full report expected to be suitable for publication.

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.

EPA has not yet determined how it will characterize perchlorate exposure and proceed with a preliminary regulatory determination. EPA described several options for estimating a relative source contribution in its May 1, 2007 Federal Register Notice. The options described in detail on pages 24047 and 24048. The Agency has received public comments on these potential options and is evaluating this input.

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.

The NCP clarifies that the “The goal of EPA’s Superfund approach is to return usable ground waters to their beneficial uses within a timeframe that is reasonable given the particular circumstances of the site.” (See 55 FR 8732, March 8, 1990)

A response action under CERCLA may be appropriate when a risk assessment indicates there is or may be an exceedance of the CERCLA risk range or when there is or may be an exceedance of regulatory standards that help define protectiveness (such as MCLs). Generally, both conditions do not need to be present, and one is not dependent on the other.

“The results of the baseline risk assessment are used to determine whether remediation is necessary, to help provide justification for performing remedial action, and to assist in determining what exposure pathways need to be remediated.” (See 55 FR 8709, March 8, 1990).

The NCP preamble notes that “to the degree that the state or local governments have classified their ground water, EPA will consider these classifications and their applicability to the selection of an appropriate remedy.” (See 55 FR 8733, March 8, 1990.) If such designation is not available, the NCP preamble states: “A determination is made as to whether the contaminated ground water falls within Class I, II, or III. [Class I and II are current and potential drinking water aquifers. Class III aquifers are ground waters that are not a source of drinking waters.] (Guidance for making this determination is available in “EPA Guidelines for Ground-Water Classification” (Final Draft, December 1986).)” (See 55 FR 8732, March 8, 1990.)

The NCP anticipated that some restorations might be more appropriately achieved in a more timely

manner than others. In particular, the NCP notes: "More rapid restoration of ground water is favored in situations where a future demand for drinking water from ground water is likely and other potential sources are not sufficient." (See 55 FR 8732, March 8, 1990)

"For Class III ground water (i.e., ground water that is unsuitable for human consumption -- due to high salinity or widespread contamination that is not related to a specific contamination source -- and that does not have the potential to affect drinkable or environmentally significant ground water), drinking water standards are not ARARs and will not be used to determine preliminary remediation goals. Remediation timeframes will be developed based on the specific site conditions. The beneficial use of the ground water (e.g., agricultural or industrial use), if any, is determined; and the remediation approach will be tailored for returning the ground water to that designated use. Environmental receptors and systems may well determine the necessity and extent of ground water remediation. In general, alternatives for Class III ground waters will be relatively limited, and the focus may be, for example, on preventing adverse spread of the significant contamination or source control to prevent exposure to waste materials or contamination." (See 55 FR 8732, March 8, 1990)

In summary, EPA's ground water response action is directly linked to ground water classification. The response action may be more rapid for drinking water situations, and the remediation timeframe should be based on site specific conditions and the beneficial use of the water.

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.

Please note that EPA's RfD is 0.0007 mg/kg-day and the DWEL is 24.5 ppb. EPA will consider the effect of perchlorate on subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly and individuals with a history of serious illness) to assess if any of these groups are at greater risk of adverse health effects as a result of perchlorate in drinking water. The NAS identified the fetuses of pregnant women who might have hypothyroidism or iodide deficiency as the subpopulation most sensitive to the effects of perchlorate exposure. In making a regulatory determination, EPA's key consideration is whether regulation of perchlorate in drinking water will present a meaningful opportunity for health risk reduction in sensitive populations. With respect to the study by Pearce et al. (2007) that looked at subjects in the greater Boston area, drinking water samples collected from water systems in the Boston area, as part of the UCMR monitoring and monitoring required by Massachusetts, did not show perchlorate contamination. As the paper noted, the source of perchlorate exposure is unknown and merits further investigation. As mentioned above, as with any chemical, EPA will continue to review new science that could inform our future decision making.