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PERCHLORATE: HEALTH AND ENVIRONMENTAL IMPACTS OF UNREGULATED EXPOSURE

HEARING

BEFORE THE

SUBCOMMITTEE ON ENVIRONMENT AND HAZARDOUS MATERIALS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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PERCHLORATE: HEALTH AND ENVIRONMENTAL IMPACTS OF UNREGULATED EXPOSURE

WEDNESDAY, APRIL 25, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENVIRONMENT
AND HAZARDOUS MATERIALS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2322 of the Rayburn House Office Building, Hon. Albert R. Wynn (chairman) presiding.

Members present: Representatives Stupak, Capps, Solis, Butterfield, Shimkus, Stearns, Shadegg, Radanovich, and Barton.

Staff present: Caroline Ahearn, Karen Torrent, Ann Strickland, Richard Frandsen, Chris Treanor, Margaret Horn, and Jerry Couri.

OPENING STATEMENT OF HON. ALBERT R. WYNN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MARYLAND

Mr. WYNN. I would like to call this hearing to order. Today we have a hearing on Perchlorate: Health and Environmental Impacts of Unregulated Exposure. As part of this hearing, we will discuss H.R. 1747, introduced by one of our distinguished members of the subcommittee, Representative Hilda Solis. For purposes of making opening statements, the Chair, the ranking members of the subcommittee, and the full committee will each be recognized for 5 minutes. All other members of the subcommittee will be recognized for 3 minutes. Those members may waive the right to make an opening statement and when first recognized to question witnesses, instead add those 3 minutes to their time for questions.

Without objection, all members have 5 legislative days to submit opening statements for the record. At this time, the Chair would recognize himself for an opening statement.

As I indicated, we are here today to hold a hearing on this very important bill, H.R. 1747, and the subject of perchlorate regulation. For almost a decade, EPA has delayed taking action to place safe limitations on the amount of perchlorate that is present in our drinking water and in our environment.

Perchlorate presents a risk to human health in vulnerable populations, including women and children by inhibiting the uptake of iodine by the thyroid gland. Impairment of thyroid function in

pregnant women can affect the fetus and infants and result in delayed development and decreased learning capability.

In fact, since 1996, EPA has failed to promulgate any drinking water standards for any new emerging contaminants, except for those that had a statutory deadline or were court ordered via consent decree. Nor, for that matter, has the Agency even identified any new emerging contaminants. This administration has consistently taken the position that additional information is needed before any regulatory action can be taken. This stalling approach is a recurrent theme that continues to not only impair the health of our citizens, but also contributes to the ongoing degradation of our environment.

It appears this administration has cleverly employed a strategy of passing the issue around between relevant agencies so to avoid setting a safe drinking water standard for perchlorate. An examination of the regulatory history of perchlorate reveals no other conclusion but that EPA has failed to take appropriate regulatory action in a timely manner. Beginning in 2002, EPA had set a recommended assessment of 4 to 18 parts per billion (ppb.), and a reference dose of 1 ppb. A reference dose (RfD) is an estimate of the amount of chemical that a person can be exposed to on a daily basis that is not anticipated to cause adverse health effects over a person's lifetime.

DOD, which has approximately 60 known sites with perchlorate contamination, was less than enthusiastic about EPA's proposed 1 ppb. assessment and advocated for a much higher threshold, 200 ppb. Although DOD is sampling and monitoring for perchlorate, to date there has not been one completed remedial action for perchlorate at any of these facilities. DOD's reason for not cleaning up is that they are waiting for a Federal drinking water standard.

So in 2003, instead of moving the administrative process forward in response to pressure from the administration and from DOD, EPA agreed to divert the process by sending 2002 draft assessment to the National Research Council of the National Academy of Sciences for review. Eighteen months later, in January 2005, at a cost of taxpayers of a quarter million dollars, the NAS issued a findings recommending 24.5 ppb. This RfD is significantly higher than the 1 ppb. that EPA originally recommended.

Now, as recently as a couple of weeks ago, EPA stated that it is going to continue to delay on a decision on whether to regulate perchlorate because it needs additional information to fully characterize perchlorate exposure and determine whether regulating perchlorate in drinking water presents a meaningful opportunity for health risk reduction.

The additional information, that EPA alleges that it needs, relates to other exposure pathways, such as the food supply and breast milk and more study of the effect on human health. This excuse, I believe, is suspect. In 2003, FDA began studying the extent of perchlorate in our food supply and came out with finding in 2004 about the existence of perchlorate in lettuce and milk.

Based on these findings, FDA conducted an additional study which was completed in 2005. Unfortunately, the FDA is not publishing these findings. Instead, the FDA has indicated it needs to

do even more study to adequately determine the full impact of perchlorate on our food supply.

CDC studies have found that there are at least 43 million women who are iodine deficient, whose health is at risk through the impact of perchlorate that prevents the uptake of needed iodine. These studies and samplings undertaken by EPA, CDC, FDA, and DOD leave no question that perchlorate contamination is pervasive in our environment and that it has infiltrated our Nation's drinking water supplies and food.

Consequently, the health of our citizens continues to be at risk. Despite all this evidence, the EPA's inaction continues. Because of the detrimental health and environmental impact of perchlorate, we can no longer wait for EPA to take action. The time to regulate perchlorate is now. We, as a country, can no longer put the health of our citizens and the state of our environment aside while information gathering exercises continue.

For these reasons, we believe it is important to have this hearing today to consider the legislation H.R. 1747, which puts an end to this running time clock and enables us to move forward. I applaud Congresswoman Solis for her leadership on this issue and look forward to the testimony from our two panels, who are here with us today.

At this time, I would like to recognize our distinguished ranking member of the subcommittee, Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. Before I start my time, if I could engage in a colloquy with you. If it is OK with you, I would like to do that.

Mr. WYNN. Certainly.

Mr. SHIMKUS. A couple concerns, and I appreciate the time you and I have spent on the floor last night and the time that your staff met with my staff on just some process issues. One is, as we know, the hearing was initially noticed as a hearing and then changed to a legislative hearing, which causes us some concern. Not concerns, I think, that we can't overcome, but a lot of people who represent rural America, and this whole safe drinking water issue is—and I still have people in my congressional district that are on wells.

So there is an issue about natural occurring issues. How safe is safe? What is the cost of hooking up people to water systems that are on well systems right now? And a cost/benefit analysis of that. How are the State regulators going to regulate it? Who is going to bare the cost of testing, especially in small areas.

And since the folks that we have here today, some of those don't represent some of those issues, I would respectfully ask that, as we move through this process and gather the information needed, that we also take another run at making sure some of the stakeholders, especially again the folks that I am concerned with, some of the rural areas, that they have a chance to look at the language and see what kind of costs are incurred, address the natural occurring issues, and then we can really move forward.

Because the bottom line is if it is hazardous to health, I want to be on board and be supportive. We just want to make sure that we have a normal process. And we will help you expeditiously do this. I mean it is not an attempt to try to delay this process, but I would

like to make sure that the other stakeholders get a chance to testify.

Mr. WYNN. Well, I want to thank you for your comments, and I want to show you that I am very sensitive to the concerns of rural America. You may not know this, but my family comes from a rural background in North Carolina. And I certainly appreciate the concern of people who may be operating on wells or other situations in rural communities.

I would be happy to work with you on this to make sure that we can get the input that the committee needs with regard to concerns that those folks may have at State level, rural communities, what have you. Because we want to have a fair process. We also want to have a process that allows for the maximum input from all segments of the community and the country in order to come up with a process that works. In addition, when the bill passes, there will be an 18-month process of regulatory proceedings that will also provide for additional input. So I think we will have a good opportunity to make sure those concerns are addressed. But I do want to assure that in this subcommittee, we will be happy to work with you to get that done.

Mr. SHIMKUS. And I appreciate that. Maybe if it is a formal process or an informal process, just one last effort to be able to make sure that everyone has their say. And they may say nothing, so then we can move forward.

Mr. WYNN. Well, as I said, I am happy to work with you on that, and if you give me the information, we can sit down and talk about how we can get that done. If the gentleman would like to make a further opening statement.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ARIZONA

Mr. SHIMKUS. I would. Thank you, Mr. Chairman. Mr. Chairman, thank you for calling this hearing on the health and environmental impacts of perchlorate, and I hope you would recognize the complexity of the issue and prospectus, follow the past practices and wishes and committee precedences.

Clearly, good legislation requires that Members understand the issues enough to vote intelligently on them. And I think in our colloquy, we have addressed some of those issues. As far as perchlorate's presence in drinking water is concerned, I am glad that we are holding this hearing. As I said before in our first hearing, that protecting public health should be our core work in this committee. We have known for decades that perchlorate can inhibit the uptake of iodine from the thyroid.

In fact, in the past, it was even used to treat adults with hyperthyroidism as a way to properly regulate iodine in the thyroid. What is not known though is how much perchlorate Americans are unintentionally ingesting and at what level it becomes a public health problem. This question should be resolved by credible, objective science. I am not a scientist by training, nor are the majority of my colleagues here on this panel. That is why I believe it isn't Congress's job to make arbitrary decisions about when and how EPA should regulate perchlorate.

In fact, EPA was so backlogged with unfinished yet mandated regulations that Congress and the Safe Drinking Water Act amendments of 1996, took itself out of the mandatory drinking water regulation business, and replaced it with directions to EPA that it use deliberate, rigorous and objective science in making any further rules on drinking water contaminant levels. This may not satisfy some who want rapid regulatory production out of EPA, but it is where I think good public policy is best served. I know that some Members in various parts of the country are concerned that EPA is not moving with enough speed to issue mandatory enforceable limits on perchlorate in drinking water, especially because they think Superfund cleanups in their communities have been delayed because of it.

I share their frustration, as I have a community identified in the GAO in 2005 that sits just outside my district with very elevated amounts of perchlorate in the ground water. But I do not yet think we should legislate on this matter. A congressional mandate to regulate a contaminant in drinking water is no guarantee that it will occur soon.

Take radon as an example. In 1986, Congress mandated that a Federal standard for radon in drinking water be established. EPA first proposed a radon standard in 1991 but hadn't completed it in 1996 when Congress told them to get one in place by 2001. In 2007, there is still no Federal drinking water standard for radon. If you accept the premise that perchlorate levels in drinking water are a public health problem and used any of the previous and conflicting studies on it to set a maximum contaminant level for perchlorate in drinking water, you would have either severely compromised human health or required much more expansive water treatment than was necessary to combat the problem. And that is the cost issue that I am referring to.

Even now, both the National Academy of Sciences and the Centers for Disease Control studies call for additional research in their conclusion. We must get the science right first, or we minimize the very goals we hope EPA can achieve. I look forward to hearing the testimony of the witnesses. I especially want to welcome Dr. Utiger and thank him for being here today. Today I hope to learn how much of a public health problem perchlorate ingestion is, but I am also interested to hear the level of disagreement among scientists over the health effects of perchlorate on humans.

Mr. Chairman, I thank you for this time. Thank you for the colloquy, and I yield back.

Mr. WYNN. Thank the ranking member for his comments. At this time, the Chair will recognize Mr. Stupak for an opening statement.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. Well, thank you, Mr. Chairman, and I hope we no longer delay this legislation. It has been going on for way, way, way too long. I want to salute Ms. Solis for her leadership.

While we don't have any public water systems in Michigan that are affected by this perchlorate, it is a major concern. Yesterday, I held a hearing in Oversight and Investigations on food safety con-

taining *E. coli*, salmonella, and other dangerous contaminants. And the reason why I make the point is because perchlorate has also been found. FDA has found perchlorate at harmful levels in lettuce, tomatoes, milk, and other foods processed where the water has been contaminated by this chemical. Way back when, on Oversight and Investigations, we had hearings on Camp Lejeune, NC, with the water contamination down there. We send these young men off, and their children are drinking the water. And we have cancer rates in Camp Lejeune, which are way too high, which many people believe is due to the perchlorate.

The EPA has basically chosen to ignore this problem. What we have heard for years is that they are going to do something. So what happens on April 11? They announce that they don't believe there is enough information on perchlorate to set a standard for drinking water. Enough is enough. Our agencies are not protecting the American people, whether it is EPA, whether it is FDA. This Congress must act. We have a new direction in this Congress. I am glad Ms. Solis is taking the lead on this for so many years. Let us move this legislation. There is time. Everyone can be heard. They want to be heard, they could have been heard. Let us move. No more delays. Move this legislation please, Mr. Chairman. I am pleased to be part of this committee. I look forward to working with you to move this legislation as quickly as possible as we need it for the safety of the American people.

Mr. WYNN. I thank the gentleman for his opening statement. I want to assure him I share your sense of urgency, and I think that is what our new majority is bringing to this issue, a sense of urgency that we need to get things done, move this process forward. We want to get the necessary information, but we don't want to engage in stalling or delay. At this time, the Chair will recognize Mr. Stearns for an opening statement.

OPENING STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. STEARNS. Thank you, Mr. Chairman. I thank you and the ranking member, Mr. Shimkus, for calling this meeting. I hear my colleague talking about the urgency of this, but I feel on this side that we are concerned that we are not able to hear testimony from States, water utilities, or any other stakeholders before possibly considering legislation to regulate such a complex issue.

Perchlorate has been found across the country, and in recent years, has emerged as a contaminant of concern. I think we all understand that. However, many questions remain about when human health is affected by various levels of ingestion of this perchlorate. Used in the 1950's, we know, to treat Graves disease. Perchlorate is now widely used in rockets and missiles and others. Perchlorate salts are widely used to manufacture various products, including fireworks, airbags, and road flares.

But perchlorate has also been found naturally to occur at levels exceeding 1,000 parts per million in natural minerals in New Mexico, California, Canada, and Bolivia. This prompted the EPA to state in its latest assessment "it is not clear at this time what proportion of perchlorate found in public water supplies or entering the food chain comes from natural sources."

In February 2005, the EPA established its official reference dose of perchlorate and translated that number to a drinking water equivalent level of 24.5 ppb., which is consistent with the recommended reference dose included in the National Academy of Science report. Ultimately for the EPA to further regulate perchlorate with an MCL, it needs to meet three statutory requirements. One, that perchlorate may have an adverse effect on a person's health. Two, that perchlorate is either known or is likely to occur in public drinking water systems at levels of public health concern. And three, regulation of perchlorate in drinking water systems presents a meaningful opportunity for health risk reduction.

My colleagues, within the last month, EPA announced that it needs further research on the health effects of perchlorate before making a regulatory determination, stating "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 information may be needed to fully characterize perchlorate exposure and determine whether regulating perchlorate in drinking water presents a meaningful opportunity for health risk reduction."

Mr. Chairman, the National Academy of Sciences, the Centers for Disease Control, and the Environmental Protection Agency have all recommended that further research be conducted on the possible health effects of perchlorate. I think it would be wise to listen to the advise of the experts and to not make arbitrary decisions about when and how EPA should be regulating perchlorate. And again I thank you for this hearing, and I look forward to the testimony.

Mr. WYNN. I thank the gentleman for his testimony. I do want to assure the minority that we presented the customary opportunity to provide witnesses, and Dr. Utiger was presented to us as a witness from the minority side. But, as I indicated to the ranking member, we are certainly willing to consider additional information that you wanted to provide.

At this time, I want to recognize the person who has been a real champion on this issue, that brought this issue forward and is spearheading the effort to get action on it. I am pleased to recognize the vice chairman of the subcommittee, Representative Hilda Solis.

OPENING STATEMENT OF HON. HILDA L. SOLIS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. SOLIS. Thank you, Chairman Wynn. I really can't tell you how my community and folks that I have talked to across the country about this issue, what a precedent this is for us at this moment. As a member on this committee for the last few years, we have had discussions on this issue. And while we haven't, in the minority, been able to actually present a bill, I am glad to see that today the residents and constituents that we are fighting for every single day will know that we made an attempt here to present what I think is a very balanced bill.

I do want to correct, for the record, that I did receive a letter from the Association of Metropolitan Water Agencies, and I would

like to quote the letter, one of their statements that "we believe your bill will reduce potential health risks, save water providers and rate payers future treatment expenses, and protect sources of drinking water" so I know that this will be entered into the record. I know that the gentleman, Mr. Shimkus, has stated that there wasn't an effort to fully bring everybody to the table.

Mr. SHIMKUS. Would the gentlewoman yield?

Ms. SOLIS. Let me finish.

Mr. SHIMKUS. OK.

Ms. SOLIS. I would just like to state I think it is great that today we have EPA and DOD here jointly to help us talk about the issue. And my premise here is that safety and protection are first and foremost, and that has always been my attempt. I think that Members here do need to know more about how perchlorate affects the drinking water system and the health and well being of women and children. And people that we also work with and tend to, as they serve on our military bases. I remember very distinctly having that long discussion here about Camp Lejeune and the fact that we did not have adequate representation from DOD at that time, and did not, as a result, get that information. So I am happy that we can begin and embark on that right now.

I will yield very quickly because I only have——

Mr. SHIMKUS. Yes, I would say that is fine, but rural water and no water. I have no water districts. I have places with wells, so that is kind of the issue.

Ms. SOLIS. I would also like to just refer to a graph that is up on the chart there. This is a public systems of detectable perchlorate contamination throughout the country, and we have highlighted different areas where members of our committee have jurisdiction. So you can look and see for yourself where this impact really is. I would like to submit it for the record those letters, and really like to thank the public because in the State of California, we have been a leader in this issue.

And I know that there are other States that likewise have done that, but they have waited so long, 11 years waiting to see that EPA will come to the table and set some appropriate standard. And I have yet to see that. I hope that this will move us in the right direction. Yes, there will be costs that will be paid, but the higher cost of not protecting our environment, protecting the well being of our citizens, is first and foremost. And that is what EPA is charged with.

So I hope that we can work in the spirit of cooperation, and again I want to thank all the members of our committee that have come on as cosponsors. This is a bipartisan bill. I do want to make that very clear, and there are people that are very, very much wanting to see something happen because the cost for not cleaning up is also taken up by our consumers and ratepayers. And those individuals in my particular district have had to forego not having water provided, several wells that have been shut down in one city in the community of Baldwin Park, where we now have the first attempt to clean up perchlorate, could be possibly a lead model for how we deal with this issue across the country.

So again I want to thank all our witnesses for being here, and I really want to thank our chairman for conducting this hearing today. Thank you very much, and I yield back.

Mr. WYNN. I thank the gentlelady. Without objection, her full statement and her correspondence will be entered into the record. At this time, the Chair will recognize Mr. Butterfield for an opening statement.

Mr. BUTTERFIELD. Mr. Chairman, I don't have a formal opening statement, but I too want to thank you for convening this hearing today and having these witnesses to come forward. And looking at the material that was furnished to me in advance of this hearing today, it looks like my State of North Carolina is seriously impacted. And so I am looking forward to the testimony of the witnesses. Thank you. I yield back.

Mr. WYNN. I thank the gentleman. The gentleman, Mr. Radanovich, is recognized for an opening statement.

Mr. RADANOVICH. Thank you, Mr. Chairman. I will waive the opening statement.

Mr. WYNN. Are there any other opening statements? Seeing none, this will conclude opening statements by the Members. Any other statements may be submitted for the record.

[The prepared statement of Mr. Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you, Mr. Chairman, for holding this hearing on the health and environmental impacts of perchlorate.

The debate surrounding perchlorate has been going on since 1998 when the EPA placed it on a list of contaminants for regulation under the Safe Drinking Water Act.

Multiple studies have been conducted on perchlorate and it was even placed on a second list of contaminants eligible for regulation.

Yet, the EPA still feels that they do not have sufficient information on whether perchlorate in drinking water or our food is a potential health hazard.

In March 2007, the EPA stated that they will take no further action on the issue of perchlorate.

In the absence of a national standard, the States have been left to regulate perchlorate levels. In Texas, we have our own perchlorate industrial clean up level.

Perchlorate remediation has occurred in some contamination sites. But a clear federal remediation policy has not been established.

The DOD has adopted its own perchlorate clean up policy until a Federal or State clean up standard in place.

With no Federal standard and only one State clean up standard, the DOD is essentially doing the EPA's work.

We all know that the EPA has a complicated system of both scientific and policy procedures before they enact any new regulations.

Sometimes this is helpful, but sometimes these procedures leave both communities and industries unclear and uncertain about the EPA decisions.

Currently, our office is wading through the process of having a toxic waste site in our district declared a Superfund. We are just beginning the process, but already we are experiencing some unexplained delays.

Some people think that the EPA is delaying action on perchlorate and not fully justifying themselves in the process. Today is their opportunity to answer their critics.

Thank you Mr. Chairman, I yield back my time.

Mr. WYNN. We would now like to turn to our first panel of witnesses, and again I would like to welcome them and thank them for appearing before us.

We have with us today Mr. John Stephenson, Director of the Natural Resources and Environment and Prevention Division Government Accountability Office. Dr. James Pirkle, Deputy Director for Science, the Centers for Disease Control. Dr. Robert Brackett, Director, Center for Food Safety and Applied Nutrition, the Food and Drug Administration. Mr. Ben Grumbles, Assistant Administrator, Office of Water, U.S. Environmental Protection Agency. And Alex Beehler, Assistant Deputy Under Secretary of Defense, Environmental Safety and Occupational Health, U.S. Department of Defense.

Again we are delighted to have you here, and we will now hear 5-minute opening statements from the panel. I am sorry, Ms. Bodine, forgive me. And, Mr. Gray, as well. We are delighted to have you here as well. We would like to have your 5-minute opening statements. Of course, your full testimony is included in the record. Mr. Stephenson.

STATEMENT OF JOHN STEPHENSON, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, GOVERNMENT ACCOUNTABILITY OFFICE

Mr. STEPHENSON. Mr. Chairman and members of the subcommittee, thank you for the opportunity to discuss GAO's work on perchlorate. My testimony attempts to provide some perspective for today's hearing by describing the extent of perchlorate contamination in the United States and by summarizing the numerous studies that have been conducted on the health effects of perchlorate in the past decade.

Perchlorate, as you have already heard, is a primary ingredient in rocket fuel. About 90 percent of the perchlorate produced in the United States is manufactured for use by the Department of Defense and NASA, with total production quantities averaging several million pounds a year.

Private industry also has used perchlorate to manufacture automobile airbags, fireworks, flares and commercial explosives. Perchlorate forms salts that are readily dissolved and transported in water. People are exposed to perchlorate primarily by ingesting it in drinking water and food, or by manufactured products that contain the chemical.

EPA does not systematically track or monitor perchlorate releases or the status of clean-up activities. As a result, it was difficult for us to determine the full extent of perchlorate contamination in the United States. We analyzed data from EPA, DOD, the U.S. geological survey, and State agency, and as shown in—do you have a figure to put up there on the board? We have a map. Well, it is a little bit difficult to see, but as shown in this figure, we identified nearly 400 sites across the country where perchlorate has been found in ground water, surface water, soil, and public drinking water systems in concentrations ranging from 4 ppb. to more than 3.7 million ppb. As you can see, the red States are where most of the incidents were found.

Although these sites are located across 37 States in U.S. territories, more than half were in California and Texas. Public drinking water systems accounted for more than one-third of the sites.

That is 153 public water systems serving a population of nearly 17 million people who were exposed to perchlorate.

The source of perchlorate contamination is very difficult to determine. In fact, the source could not be determined for over half of the 400 sites we identified. Figure 2, the next figure please, shows that of those sites where the sources could be identified, almost 65 percent of the contamination came from defense and aerospace activities, such as propellant manufacturing, rocket motor research, and test firing our explosives disposal.

Although some cleanups are occurring on a case-by-case basis, EPA and DOD both told us they do not routinely clean up contaminant sites primarily because there is no Federal standard or specific Federal requirement for doing so.

Meanwhile, at least nine States including Maryland and Massachusetts have established drinking water standards or advisories levels for perchlorate that have been used to require cleanup.

In our May 2005 report, we also identified and summarized the results of 90 studies published since 1998 on the health risk of perchlorate. While many were inconclusive, 26 of the studies indicated that perchlorate had an adverse effect on human health, and in particular, thyroid function. A list of these studies can be found in the appendix of our report. The National Academy of Sciences reviewed many of the same studies that we looked at in reaching its conclusion about the human health effects of perchlorate ingestion and safe levels of exposure. However, the Academy's call for additional research to help resolve questions about its effects specifically on pregnant women.

As you will hear from Dr. Pirkle next, how CDC's recent research offers answers to some of these questions by describing the effects of perchlorate on thyroid hormone in women, and its subsequent effect on central nervous system development in the fetus.

So, Mr. Chairman, notwithstanding the growing body of research on perchlorate, EPA's position has not significantly changed in the past 10 years. Perchlorate has remained on EPA's contaminant of concern list under the Safe Drinking Water Act since 1998. And on April 11, this year, as you mentioned, EPA reaffirmed its decision not to regulate perchlorate, citing the need for additional research.

Although we took no position in our report on the drinking water standard, leaving that to the experts, we did recommend that as a minimum, EPA work with DOD and the States to develop a formal tracking mechanism of reliable information on sites contaminated with perchlorate and the status of cleanup efforts.

While both EPA and DOD disagreed with our recommendation, we continued to believe that the inconsistency and omissions in available data that we found during the course of our review underscore the need for a systematic way to collect more reliable information on the full extent of perchlorate contamination.

Mr. Chairman, that concludes the summary of my prepared statement, and I will be happy to answer questions at the appropriate time.

[The prepared statement of Mr. Stephenson follows:]

United States Government Accountability Office

GAO

Testimony
Before the Subcommittee on Environment and Hazardous Materials, House Committee on Energy and Commerce

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PERCHLORATE

EPA Does Not Systematically Track Incidents of Contamination

Statement of John B. Stephenson, Director
Natural Resources and Environment

GAO-07-797T

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Highlights

Highlights of GAO-07-797T, a testimony before the Subcommittee on Environment and Hazardous Materials, House Committee on Energy and Commerce

April 25, 2007

PERCHLORATE

EPA Does Not Systematically Track Incidents of Contamination

Why GAO Did This Study

Perchlorate has been used for decades by the Department of Defense, the National Aeronautics and Space Administration, and the defense industry in manufacturing, testing, and firing missiles and rockets. Other uses include fireworks, fertilizers, and explosives. Perchlorate is readily dissolved and transported in water and has been found in groundwater, surface water, and soil across the country. Perchlorate emerged as a contaminant of concern because health studies have shown that it can affect the thyroid gland, which helps regulate the body's metabolism, and may cause developmental impairment in fetuses of pregnant women. In 2005, EPA set a reference dose of 24.5 parts per billion (ppb)—the exposure level not expected to cause adverse effect in humans.

Today's testimony updates GAO's May 2005 report, *Perchlorate: A System to Track Sampling and Cleanup Results is Needed*, GAO-05-462. It summarizes GAO's (1) compilation of the extent of perchlorate contamination in the U.S. and (2) review of peer-reviewed studies about perchlorate's health risks. GAO's 2005 report recommended that EPA work to track and monitor perchlorate detections and cleanup efforts. In December 2006, EPA reiterated its disagreement with this recommendation. GAO continues to believe such a system would better inform the public and others about perchlorate's presence in their communities.

www.gao.gov/cgi-bin/getrpt?GAO-07-797T

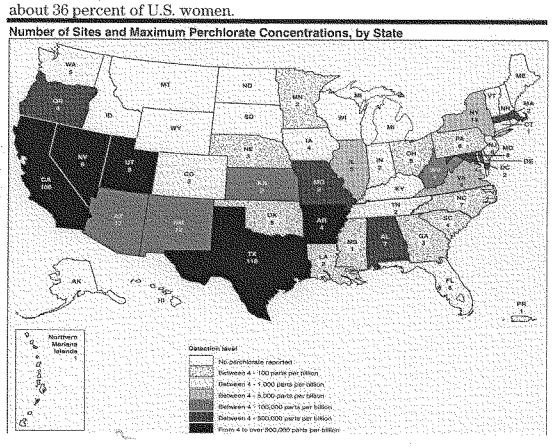
To view the full product, including the scope and methodology, click on the link above. For more information, contact John Stephenson at (202) 512-3841 or stephensonj@gao.gov.

What GAO Found

Perchlorate has been found at 395 sites in the U.S.—including 153 public drinking water systems—in concentrations ranging from 4 ppb to more than 3.7 million ppb. More than half the sites are in California and Texas, with the highest concentrations found in Arkansas, California, Texas, Nevada, and Utah. About 28 percent of sites were contaminated by defense and aerospace activities related to propellant manufacturing, rocket motor research and test firing, or explosives disposal. Federal and state agencies are not required to routinely report perchlorate findings to EPA, which does not track or monitor perchlorate detections or cleanup status. EPA recently decided not to regulate perchlorate in drinking water supplies pending further study.

GAO reviewed 90 studies of health risks from perchlorate published from 1998 to 2005, and one-quarter indicated that perchlorate had an adverse effect on human health, and thyroid function in particular. In January 2005, the National Academy of Sciences also reviewed several studies and concluded that they did not support a clear link between perchlorate exposure and changes in the thyroid function. The academy did not recommend a drinking water standard but recommended additional research into the effect of perchlorate exposure on children and pregnant women. More recently, a large study by CDC scientists has identified adverse thyroid effects from perchlorate in women with low iodine levels that are found in about 36 percent of U.S. women.

Number of Sites and Maximum Perchlorate Concentrations, by State



Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss our work on perchlorate, a chemical most commonly used in rocket fuel. A combination of human activity and natural sources has led to the widespread presence of perchlorate in the environment. Perchlorate has been used for decades by the Department of Defense (DOD), the National Aeronautics and Space Administration (NASA), and the defense industry in the manufacturing, testing, and firing of missiles and rockets. According to the Environmental Protection Agency's (EPA) estimates, 90 percent of the perchlorate produced in the United States is manufactured for use by the military and NASA, with total typical production quantities averaging several million pounds per year. Private industry also has used perchlorate to manufacture automobile airbags, fireworks, flares, and commercial explosives. Natural sources include certain atmospheric processes and Chilean nitrate salts (saltpeter) that have been mined and refined to produce commercial fertilizers for use in the U.S. Perchlorate forms salts that are readily dissolved and transported in water and that have been found in groundwater, surface water, and soil across the country. People are exposed to the perchlorate primarily by ingesting it in drinking water and food, or by working to manufacture products that contain the chemical. Health studies have shown that exposure to perchlorate can affect the thyroid gland, which helps regulate the body's metabolism, and may cause neurodevelopmental impairment in fetuses of pregnant women.

In 2003, EPA, DOD, NASA, and the Department of Energy asked the National Academy of Sciences to review the risks of exposure to perchlorate. In January 2005, the Academy recommended a reference dose of 0.0007 milligrams of perchlorate per kilogram of body weight per day, an estimated daily exposure level that is not expected to cause adverse effects in the children and pregnant women—the most sensitive human populations. This reference dose equates to a drinking water equivalent level of 24.5 parts per billion.[1] In February 2005, EPA adopted the Academy's reference dose for perchlorate, but it has not established a national federal standard for perchlorate in drinking water or other

[1]The drinking water equivalent level is based on a reference adult weighing 70 kilograms (or 154 pounds) drinking 2 liters of water per day, assuming that all perchlorate exposure comes from drinking water.

regulatory requirements to clean up perchlorate in groundwater, surface water, or soil, citing the need for additional study about the health effects of perchlorate exposure.

My testimony today is based largely on our 2005 report for this Committee and summarizes (1) our analysis of the estimated extent of perchlorate found in the United States and (2) the results of our review of published studies on the health effects of perchlorate.[2] In the 2005 report, we recommended that EPA develop a tracking system for perchlorate releases and cleanup efforts across the federal government and state agencies. This statement also includes information from my February 2007 testimony about EPA's recent response to our recommendation.[3]

To provide an estimate of the extent of perchlorate found in the United States, we compiled and analyzed data on perchlorate detections from EPA, DOD, the U.S. Geological Survey, and state agencies. To identify studies of the potential health risks from perchlorate, who conducted them, and what methodologies were used, we conducted a literature search for studies of perchlorate health risks published since 1998, interviewed DOD and EPA officials on what studies they considered important in assessing perchlorate health risks, and examined the references of each study for other studies we had not obtained. We identified 125 studies on perchlorate and the thyroid, of which we reviewed 90 that were relevant to our review. A more detailed description of our scope and methodology is presented in appendix I of our 2005 report.

In summary, we found the following:

- As of our May 2005 review, perchlorate had been found by federal and state agencies in groundwater, surface water, soil, or public drinking water systems at almost 400 sites across the country in concentrations that ranged from 4 parts per billion (ppb) to more than 3.7 million ppb. However, there is not a standardized approach to reporting perchlorate data nationwide, therefore there may be more

[2]GAO, *Perchlorate: A System to Track Sampling and Cleanup Results is Needed,* GAO-05-462 (Washington, D.C.: May 20, 2005).
[3]GAO, *Environmental Information: EPA Actions Could Reduce the Availability of Environmental Information to the Public,* GAO-07-464T (Washington, D.C.: February 6, 2007).

contaminated sites than we identified. These sites are located across 37 states and U.S. territories, but more than half were found in California and Texas. The sources of perchlorate at the sites vary, but the greatest known source is defense and aerospace activities such as propellant manufacturing, rocket motor research and test firing, or explosives disposal. More than one-third of the sites were public drinking water systems, where perchlorate concentrations ranged from 4 to 420 ppb. Fourteen of these 153 public water systems had concentration levels above 24.5 parts per billion, the drinking water equivalent of EPA's perchlorate reference dose. EPA and state officials told us they had not cleaned up contaminated public drinking water systems, principally because there was no federal drinking water standard or specific federal requirement to clean up perchlorate. Further, it is difficult to determine the extent of perchlorate in the United States or the status of any cleanup actions because EPA does not centrally track or monitor perchlorate detections, environmental releases, or cleanup activities.

- Recent research indicates that low-level perchlorate exposure may adversely affect the thyroid and increase the risk of neurodevelopmental impairment in fetuses of pregnant women. In our May 2005 review, we identified and summarized 90 peer-reviewed studies published from 1998 to 2005 on the health effects of perchlorate. The findings of 26 of these studies indicated that perchlorate had an adverse effect on thyroid function and human health. Most studies on adult populations were unable to determine whether the thyroid was adversely affected, because adverse effects of perchlorate on the adult thyroid, such as cancer, may happen over longer time periods than are generally observed in a research study. In contrast, the adverse effects of perchlorate on human development can be more easily studied and measured within study time frames, and 18 studies found adverse effects on development resulting from maternal exposure to perchlorate. We also found that some studies considered the same perchlorate dose but found different effects. The precise cause of the different results may be attributed to the studies' designs or to the physical conditions—such as sex, age, and blood iodine levels—of studies' subjects. Such unresolved

questions were one of the bases for the differing conclusions among EPA, DOD, and other researchers on perchlorate doses and human health effects. In its January 2005 report, the National Academy of Sciences called for additional research on perchlorate exposure to help resolve questions about its effect on children and pregnant women. More recently, an October 2006 CDC study found that, for women with lower iodine levels, perchlorate reduced the thyroid hormone that helps regulate metabolism and that plays a part in central nervous system development in the fetus.

We concluded in our report that EPA needed more reliable information on the extent of sites contaminated with perchlorate and the status of cleanup efforts, and recommended that EPA work with the Department of Defense and the states to establish a formal structure for tracking perchlorate information. In December 2006, EPA reiterated its disagreement with the recommendation stating that perchlorate information already exists from a variety of other sources. However, we continue to believe that the inconsistency and omissions in available data that we found during the course of our study underscore the need for a more structured and formal tracking system.

Background

According to EPA, perchlorate can interfere with the normal functioning of the thyroid gland by competitively inhibiting the transport of iodide into the thyroid, which can then affect production of thyroid hormones. The fetus depends on an adequate supply of maternal thyroid hormone for its central nervous system development during the first trimester of pregnancy. The National Academy of Sciences reported that inhibition of iodide uptake from low-level perchlorate exposure may increase the risk of neurodevelopmental impairment in fetuses of high-risk mothers—pregnant women who might have iodine deficiency or hypothyroidism (reduced thyroid functioning). The Academy recognized the differences in sensitivity to perchlorate exposure between the healthy adults used in some studies and the most sensitive population and the fetuses of these high-risk mothers. Consequently, the Academy included a 10-fold uncertainty

factor in its recommended reference dose to protect these sensitive populations. The Academy also called for additional research to help determine what effects low-level perchlorate exposure may have on children and pregnant women.

EPA has issued drinking water regulations for more than 90 contaminants. The Safe Drinking Water Act, as amended in 1996, requires EPA to make regulatory determinations on at least five unregulated contaminants and decide whether to regulate these contaminants with a national primary drinking water regulation. The act requires that these determinations be made every five years. The unregulated contaminants are typically chosen from a list known as the Contaminant Candidate List (CCL), which the act also requires EPA to publish every five years. EPA published the second CCL on February 24, 2005. On April 11, 2007, EPA announced its preliminary determination not to regulate 11 of the contaminants on this list. The agency also announced that it was not making a regulatory determination for perchlorate because EPA believed that additional information may be needed to more fully characterize perchlorate exposure and determine whether regulating perchlorate in drinking water presents a meaningful opportunity for health risk reduction.

Several federal environmental laws provide EPA and states authorized by EPA with broad authorities to respond to actual or threatened releases of substances that may endanger public health or the environment. For example, the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended, authorizes EPA to investigate the release of any hazardous substance, pollutant, or contaminant. The Resource Conservation and Recovery Act of 1976 (RCRA) gives EPA authority to order a cleanup of hazardous waste when there is an imminent and substantial endangerment to public health or the environment, and one federal court has ruled that perchlorate is a hazardous waste under RCRA.[5] The Clean

[5] *Castaic Lake Water Agency v. Whittaker Corp,* 272 F. Supp. 2d 1053 (C.D. Cal. 2003). The conclusion that perchlorate is a hazardous waste was the first step in the court's analysis of whether perchlorate is a hazardous substance under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). (The definition of hazardous substances under CERCLA includes hazardous waste under RCRA.)

Water Act's National Pollutant Discharge Elimination System (NPDES) provisions authorize EPA, which may, in turn, authorize states, to regulate the discharge of pollutants into waters of the United States. These pollutants may include contaminants such as perchlorate. The Safe Drinking Water Act authorizes EPA to respond to actual or threatened releases of contaminants into public water systems or underground sources of drinking water, regardless of whether the contaminant is regulated or unregulated, where there is an imminent and substantial endangerment to health and the appropriate state and local governments have not taken appropriate actions. Under certain environmental laws such as RCRA, EPA can authorize states to implement the requirements as long as the state programs are at least equivalent to the federal program and provide for adequate enforcement.

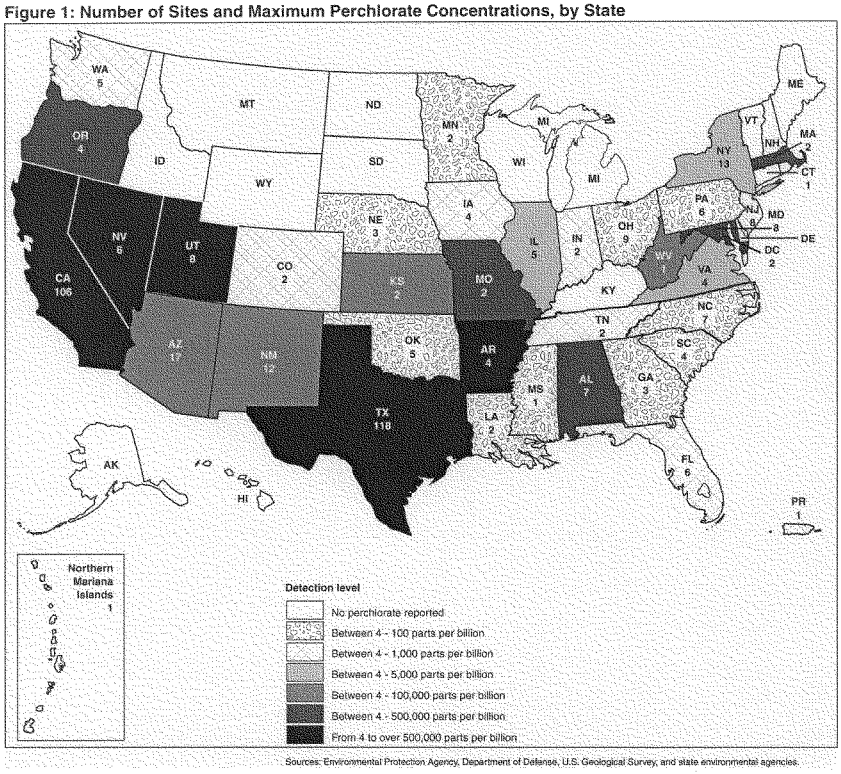
In addition, some states have their own environmental and water quality laws that provide state and local agencies with the authority to monitor, sample, and require cleanup of various regulated and unregulated hazardous substances that pose an imminent and substantial danger to public health. For example, the California Water Code authorizes Regional Water Control Boards to require sampling of waste discharges and to direct cleanup and abatement, if necessary, of any threat to water, including the release of an unregulated contaminant such as perchlorate. Finally, according to EPA and state officials, at least 9 states have established nonregulatory action levels or perchlorate advisories, ranging from under 1 part per billion to 18 parts per billion, under which responsible parties have been required to sample and clean up perchlorate. For example, according to California officials, the state of California has a public health goal for perchlorate of 6 parts per billion and has used the goal to require cleanup at one site.

Perchlorate Has Been Found At 395 Sites Including 153 Public Drinking Water Systems

Because information on the extent of perchlorate contamination was not readily available, we thoroughly reviewed available perchlorate sampling reports and discussed them with federal and state environmental officials. We identified 395 sites in 35 states, the District of Columbia, and 2 commonwealths of the United States where perchlorate

has been found in drinking water, groundwater, surface water, sediment, or soil. The perchlorate concentrations ranged from the minimum reporting level of 4 parts per billion to in more than 3.7 million parts per billion—a level found in groundwater at one of the sites. Roughly one-half of the contaminated sites were found in Texas (118) and California (106), where both states conducted broad investigations to determine the extent of perchlorate contamination. As shown in figure 1, the highest perchlorate concentrations were found in five states—Arkansas, California, Nevada, Texas, and Utah—where, collectively, 11 sites had concentrations exceeding 500,000 parts per billion. However, most of the 395 sites did not have such high levels of contamination. We found 271 sites where the concentration was less than 24.5 parts per billion, the drinking water concentration equivalent calculated on the basis of EPA's reference dose.

Figure 1: Number of Sites and Maximum Perchlorate Concentrations, by State

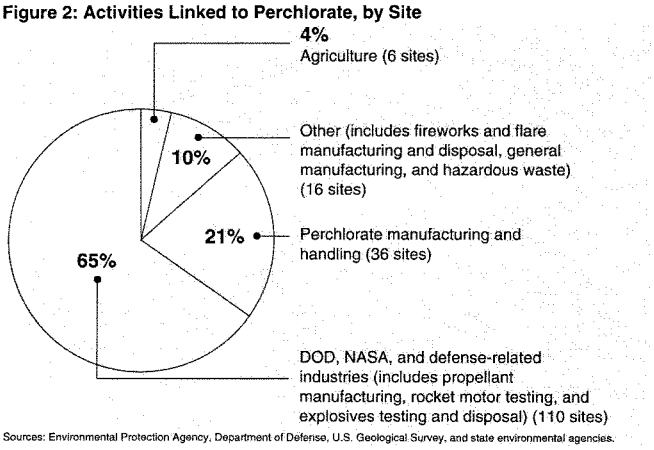


Sources: Environmental Protection Agency, Department of Defense, U.S. Geological Survey, and state environmental agencies.

According to EPA and state agency officials, the greatest known source of contamination was defense and aerospace activities. As shown in figure 2, our analysis found that, at 110 of the 395 sites, the perchlorate source was related to propellant manufacturing, rocket motor testing firing, and explosives testing and disposal at DOD, NASA, and defense-related industries. Officials said the source of the contamination at another 58 sites was agriculture, a variety of other commercial activities such as fireworks and flare manufacturing, and perchlorate manufacturing and handling. At the remaining sites, state agency officials said the source of the perchlorate was either undetermined (122 sites) or naturally occurring (105 sites). Further, all 105 sites with naturally occurring

perchlorate are located in the Texas high plains region where perchlorate concentrations range from 4 to 59 parts per billion.

Figure 2: Activities Linked to Perchlorate, by Site



Sources: Environmental Protection Agency, Department of Defense, U.S. Geological Survey, and state environmental agencies.

Of the sites we identified, 153 were public drinking water systems. The Safe Drinking Water Act's Unregulated Contaminant Monitoring Regulation required sampling of public drinking water systems for a 12-month period between 2001 and 2003. . As of January 2005, 153 (about 4 percent) of 3,722 systems that were sampled and reported reported finding perchlorate to EPA. Located across 26 states and 2 commonwealths, these 153 sites accounted for more than one-third of the sites we identified where perchlorate concentrations reported ranged from 4 parts per billion to 420 parts per billion but averaged less than 10 parts per billion. Only 14 of the 153 public drinking water systems had concentration levels above 24.5 parts per billion, the drinking water equivalent calculated on the basis of EPA's revised perchlorate reference dose. California had the most public water systems with perchlorate, where 58 systems reported finding perchlorate in drinking water. The highest drinking water perchlorate concentration of 420 parts per billion was found in Puerto Rico in 2002. Subsequent sampling in Puerto Rico did not find any perchlorate, and officials said the source of the initial finding was undetermined.

These 153 public drinking water systems that found perchlorate serve populated areas, and an EPA official estimated that as many as 10 million people may have been exposed to the chemical. EPA officials told us they do not know the source of most of the contamination found in public drinking water systems, but that 32 systems in Arizona, California, and Nevada were likely due to previous perchlorate manufacturing at a Kerr McGee Chemical Company site in Henderson, Nevada. Regional EPA and state officials told us they did not plan to clean up perchlorate found at public drinking water sites until EPA establishes a drinking water standard for perchlorate. In some cases, officials did not plan to clean up because subsequent sampling was unable to confirm that perchlorate was present.

EPA officials said the agency does not centrally track or monitor perchlorate detections or the status of cleanup activities. As a result, it is difficult to determine the extent of perchlorate contamination in the U.S. EPA maintains a list of sites where cleanup or other response actions are underway but the list does not include sites not reported to EPA. As a result, EPA officials said they did not always know whether other federal and state agencies found perchlorate because, as is generally the case with unregulated contaminants, there is no requirement for states or other federal agencies to routinely report perchlorate findings to EPA.

For example, DOD is not required to report to EPA when perchlorate is found on active installations and facilities. Consequently, EPA region officials in California said they did not know the Navy found perchlorate at the Naval Air Weapons Station at China Lake because the Navy did not report the finding to EPA. Further, states are not required to routinely notify EPA about perchlorate contamination they discover. For example, EPA region officials in California said the Nevada state agency did not tell them perchlorate was found at Rocketdyne, an aerospace facility in Reno, or that it was being cleaned up. EPA only learned about the perchlorate contamination when the facility's RCRA permit was renewed.

Recent Research Indicates that Perchlorate Exposure May be a Concern for Pregnant Women

In our May 2005 review, we conducted a literature search for studies of perchlorate health risks published from 1998 to 2005 and identified 125 studies on perchlorate and the thyroid. After interviewing DOD and EPA officials about which studies they considered important in assessing perchlorate health risks, we reviewed 90 that were relevant to our work. The findings of 26 of these studies indicated that perchlorate had an adverse effect on thyroid function and human health. In January 2005, the National Academy of Sciences considered many of these same studies and concluded that the studies did not support a clear link between perchlorate exposure and changes in the thyroid function or thyroid cancer in adults. Consequently, the Academy recommended additional research into the effect of perchlorate exposure on children and pregnant women but did not recommend a drinking water standard.

DOD, EPA, and industry sponsored the majority of the 90 health studies we reviewed; the remaining studies were conducted by academic researchers and other federal agencies. Of these 90 studies, 49 were experiments that sought to determine the effects of perchlorate on humans, mammals, fish, and/or amphibians by exposing these groups to different doses of perchlorate over varied time periods and comparing the results with other groups that were not exposed. Twelve were field studies that compared humans, mammals, fish, and/or amphibians in areas known to be contaminated with the same groups in areas known to be uncontaminated. Both types of studies have limitations: the experimental studies were generally short in duration, and the field studies were generally limited by the researchers' inability to control whether, how much, or how long the population in the contaminated areas was exposed. For another 29 studies, researchers reviewed several publicly available human and animal studies and used data derived from these studies to determine the process by which perchlorate affects the human thyroid and the highest exposure levels that did not adversely affect humans. The 3 remaining studies used another methodology.[6] Many of the studies we reviewed contained only research findings, rather than conclusions or observations on the health

[6]The number of study types is greater than the total number of studies because 3 studies used a combination of experimental design and data analysis methodologies.

effects of perchlorate. Appendix III from our 2005 report provides data on these studies, including who sponsored them; what methodologies were used; and, where presented, the author's conclusions or findings on the effects of perchlorate.

Only 44 of the studies we reviewed had conclusions on whether perchlorate had an adverse effect. However, adverse effects of perchlorate on the adult thyroid are difficult to evaluate because they may happen over longer time periods than can be observed in a typical research study. Moreover, different studies used the same perchlorate dose amount but observed different effects, which were attributed to variables such as the study design type or age of the subjects. Such unresolved questions were one of the bases for the differing conclusions in EPA, DOD, and academic studies on perchlorate dose amounts and effects.

The adverse effects of perchlorate on development can be more easily studied and measured within typical study time frames. Of the studies we reviewed, 29 evaluated the effect of perchlorate on development, and 18 of these found adverse effects resulting from maternal exposure to perchlorate. According to EPA officials, the most sensitive population for perchlorate exposure is the fetus of a pregnant woman who is also nearly iodine-deficient. However, none of the 90 studies that we reviewed considered this population. Some studies reviewed the effect on the thyroid of pregnant rats, but we did not find any studies that considered perchlorate's effect on the thyroid of nearly iodine-deficient pregnant rats.

In January 2005, the National Academy of Sciences issued its report on EPA's draft health assessment and the potential health effects of perchlorate. The Academy reported that although perchlorate affects thyroid functioning, there was not enough evidence to show that perchlorate causes adverse effects at the levels found in most environmental samples. Most of the studies that the Academy reviewed were field studies, the report said, which are limited because they cannot control whether, how much, or how long a population in a contaminated area is exposed. The Academy concluded that the studies did not support a clear link between perchlorate exposure and changes in the thyroid function in newborns and hypothyroidism or thyroid cancer in adults. In its report, the

Academy noted that only 1 study examined the relationship between perchlorate exposure and adverse effects on children, and that no studies investigated the relationship between perchlorate exposure and adverse effects on vulnerable groups, such as low-birth-weight infants. The Academy concluded that an exposure level higher than initially recommended by EPA may not adversely affect a healthy adult. The Academy recommended that additional research be conducted on perchlorate exposure and its effect on children and pregnant women but did not recommend that EPA establish a drinking water standard. To address these issues, in October 2006, CDC researchers published the results of the first large study to examine the relationship between low-level perchlorate exposure and thyroid function in women with lower iodine levels. About 36 percent of U.S. women have these lower iodine levels. The study found decreases in a thyroid hormone that helps regulate the body's metabolism and is needed for proper fetal neural development in pregnant women.

Mr. Chairman, this concludes my testimony. I would be pleased to answer any questions that you or other Members of the Subcommittee may have at this time.

GAO Contacts and Staff Acknowledgments

For further information about this presentation, please contact me, John Stephenson, at (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Contributors to this testimony include Steven Elstein, Assistant Director, and Terrance Horner, Senior Analyst; Richard Johnson, Alison O'Neill, Kathleen Robertson, and Joe Thompson also made key contributions.

(360840)

Mr. WYNN. Thank you. Dr. Pirkle.

STATEMENT OF JAMES PIRKLE, M.D., PH.D., DEPUTY DIRECTOR FOR SCIENCE, NATIONAL CENTER FOR ENVIRONMENTAL HEALTH, THE CENTERS FOR DISEASE CONTROL AND PREVENTION

Dr. PIRKLE. I am pleased to be here today to discuss the results of two studies by CDC researchers investigating exposure to perchlorate in the U.S. population and the relationship between exposure to perchlorate and thyroid function.

Using a new method developed at CDC to measure perchlorate in human urine, our laboratory measured perchlorate in the urine of participants in CDC's national health and nutrition examination survey in 2001 and 2002. This survey is designed to provide health and nutritional information for the civilian, non-institutionalized U.S. population.

The survey also measured in these people serum levels of two thyroid hormones, Total Thyroxin, also called Total T4, and Thyroid Stimulating Hormone, commonly referred to as TSH. From their analyses of the results, CDC researchers published two papers. The first paper examined perchlorate exposure in the U.S. population for people age 6 years and older. Measurable amounts of perchlorate were found in the urine of all 2,820 survey participants, indicating widespread human exposure in the U.S. population.

Levels of perchlorate in children were higher than those found in adolescents and adults, and this difference was statistically significant. For adults, CDC researchers compared the levels found in the population with the EPA reference dose. We found that only 11 adults out of 1,532 had estimated dose levels exceeding this reference dose. For adults, the median estimated dose was about one-tenth the reference dose, and a 95th percentile was about one-third the EPA reference dose. Similar calculations for children are not yet available, pending evaluation of proper equations to make these dose estimates for children.

The second paper examined the relationship between urine perchlorate levels and thyroid hormone level, specifically Total Thyroxin and TSH, for people age 12 years and older. Perchlorate at high doses is already known to decrease thyroxin levels, and, in fact, in the past, perchlorate was used therapeutically to lower thyroxin levels. This study examined perchlorate at levels common in the U.S. population, perchlorate levels that are much lower than those used therapeutically to intentionally reduce thyroxin.

The results of this study show that for men no relationship was found between perchlorate levels and levels of thyroid hormones. For women who had urine iodine levels less than 100 micrograms per liter, we found that perchlorate levels common in the U.S. population were significantly associated with small to medium-sized changes in both thyroxin and TSH levels. That is, higher perchlorate levels were associated with decreased levels of thyroxin and increased levels of TSH. 36 percent of women in the U.S. population have these lower urinary iodine levels, a percentage that corresponds to about 43 million women.

For women with urinary iodine levels greater than 100 micrograms per liter, perchlorate levels showed a statistically significant association with TSH but not with thyroxin. This was the first study to evaluate perchlorate exposure and thyroid function in women with these lower urinary iodine levels. The finding of an association between perchlorate exposure and thyroid hormone levels in these women was unexpected based on previous research and will prompt further study.

CDC researchers are planning a second study to affirm and build upon their findings. Adequate intake of iodine has previously been recognized as important for healthy thyroid function. These study results would reinforce that recommendation for women.

In summary, these two studies found low-level perchlorate exposure to be widespread in the U.S. population. Among men, perchlorate levels were not associated with changes in thyroid hormone levels. Among women with lower levels of iodine in their urine, perchlorate exposure that is common in the U.S. population was associated with small to medium-sized changes in thyroid hormone levels. Adequate intake of iodine substantially diminishes the association of perchlorate with thyroid hormone levels in women.

Mr. Chairman, this concludes my prepared statement, and I will be happy to respond to any questions at the appropriate time.

[The prepared statement of Dr. Pirkle follows:]

Testimony
Committee on Energy and Commerce
Subcommittee on Environment and Hazardous Materials
United States House of Representatives

CDC's Perchlorate Biomonitoring Activities and Study Results

Statement of
James Pirkle, M.D., Ph.D.
Deputy Director for Science
National Center for Environment Health
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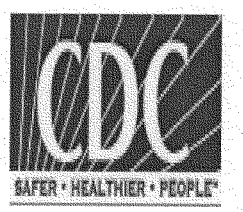

For Release on Delivery
Expected at 10:00 a.m.
Wednesday, April 25, 2007

Good morning Mr. Chairman and Members of the Subcommittee:

My name is Dr. James Pirkle, Deputy Director for Science in the Division of Laboratory Sciences of the National Center for Environmental Health at the Centers for Disease Control and Prevention (CDC).

I am pleased to appear here today before the Subcommittee to discuss results of two studies conducted by CDC researchers investigating exposure to perchlorate in the U.S. population and the relationship between exposure to perchlorate and thyroid hormone levels.

In my presentation, I will first provide a brief background on CDC's National Biomonitoring Program and efforts to measure perchlorate, then discuss results of our study examining perchlorate exposure in the U.S. population, and finally, discuss findings from our study that focused on the relationship between exposure to perchlorate and hormone levels.

Briefly, perchlorate is a chemical compound used in solid rocket propellant, explosives, pyrotechnics, flares, and a few other products. It also can form naturally in the atmosphere, producing trace levels in precipitation. Perchlorate in irrigation water can contaminate crops. High doses of perchlorate are known to reduce the amount of thyroid hormone produced; in the past, perchlorate was one medical treatment used to reduce the excessive amount of thyroid hormone produced in people with hyperthyroidism. Therapeutic doses of perchlorate used

in the 1950s and 1960s to treat hyperthyroidism were much higher than levels that people are exposed to in the environment.

The Division of Laboratory Sciences at CDC's National Center for Environmental Health conducts the National Biomonitoring Program, which measures environmental chemicals, such as perchlorate, in blood and/or urine to assess the exposure of the U.S. population and exposure of selected population groups. Our laboratory has been conducting work in biomonitoring for 32 years and currently can measure more than 400 chemicals in human blood or urine. Biomonitoring measurements are reported in the scientific literature and, since 2001, in CDC's *National Report on Human Exposure to Environmental Chemicals*. As part of this National Biomonitoring Program, CDC researchers developed a method to measure perchlorate in urine and published that method in the peer-reviewed literature in 2005. This method has an excellent ability to measure perchlorate even at low levels and to distinguish perchlorate from other chemicals.

Using this new method, our laboratory measured perchlorate in the urine of participants in CDC's National Health and Nutrition Examination Survey (NHANES) for the years 2001-2002. The NHANES survey is designed to provide a unique assessment of the health and nutritional status of the civilian non-institutionalized U.S. population. The survey has been conducted multiple times since the early 1970s. For the survey years 2001-2002, NHANES also measured serum levels of two thyroid hormones in survey participants. These

hormones are total thyroxine, also called total T4, and thyroid stimulating hormone, commonly referred to as TSH. In the future, NHANES will evaluate additional measures of thyroid function.

From their analysis of the results, CDC researchers published two papers, the first describing levels of urinary perchlorate in people aged 6 years and older, and the second examining the relationship between levels of urinary perchlorate and thyroid hormone levels in people aged 12 years and older.

In the first paper, which described perchlorate exposure in people aged 6 years and older in the U.S. population, the researchers found measurable levels of perchlorate in the urine of all 2820 survey participants, indicating widespread human exposure to this chemical in the United States. The researchers also found that levels of perchlorate in children were higher than levels found in adolescents and adults, and this difference was statistically significant.

The researchers compared the levels found in the population with the Environmental Protection Agency (EPA) reference dose. The EPA reference dose is defined as an estimate of a daily exposure to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime. The EPA reference dose for perchlorate is 0.7 micrograms per kilogram of body weight per day. The National Academy of Sciences recommended this reference dose in 2005. For adults, equations to estimate dose from urine perchlorate concentrations are available. We calculated dose estimates for each adult in the

2001-2002 survey on the basis of each person's urine perchlorate level and found that only 11 adults (out of 1532 people) had levels exceeding this reference dose (RfD). The median estimated total daily perchlorate dose for adults was about one-tenth of the RfD, and the 95th percentile was about one-third of the RfD.

The second study examined the relationship between urine perchlorate levels and thyroid hormone levels – specifically total thyroxine and TSH. Thyroxine and TSH measurements were available for people aged 12 years and older. Thyroxine regulates the body's metabolism and is important for proper development of the brain. TSH is secreted by the pituitary gland and regulates the production of thyroxine by the thyroid gland. When the thyroid is not producing adequate amounts of thyroxine, TSH levels increase in order to stimulate more production. At high doses, perchlorate is known to block iodine uptake into the thyroid, causing decreased production of thyroxine and increased production of TSH. This second study examined perchlorate levels of the U.S. population, levels that are much lower than those previously known to decrease thyroxine and increase TSH.

Among men, the researchers found no relationship between perchlorate levels and levels of the thyroid hormones thyroxine and TSH. After the initial analyses of the results obtained for women, the researchers divided women for further analysis into two groups: those with urinary iodine levels above and below a cut-off of 100 micrograms per liter. This cut-off is based on a World Health

Organization finding that the frequency of goiter from hypothyroidism increases in populations that have a median urinary iodine level of less than 100 micrograms per liter. It is reasonable to hypothesize that people with lower urinary iodine levels could be more vulnerable to a perchlorate effect on thyroid function.

The researchers found that, among women who had urinary iodine levels that were less than 100 micrograms per liter, perchlorate levels were associated with both thyroxine and TSH levels. For both thyroxine and TSH, these associations were statistically significant and consistent in direction with those expected from perchlorate inhibition of iodine uptake into the thyroid. That is, higher perchlorate levels were associated with lower levels of thyroxine and higher levels of TSH. However, thyroid hormone levels remained within clinically normal ranges. Thirty-six percent of women in the U.S. population have urinary iodine levels less than 100 micrograms per liter, a percentage that corresponds to about 43 million women.

Among women with urinary iodine levels greater than or equal to 100 micrograms per liter, the researchers found that perchlorate levels showed a statistically significant association with TSH but not with thyroxine. Change in TSH levels is a more sensitive indicator of decreased thyroid function, which may account for this finding in this group of women.

This was the first study to examine the association of perchlorate with thyroid hormone levels in women who had levels of urinary iodine that were less than 100 micrograms per liter. The differences we saw in study findings between men and women merit further research. Other research has shown that women have higher rates of hypothyroidism than men.

The finding of an association between perchlorate exposure and thyroid function in these women was unexpected based on previous research and has prompted further study. CDC researchers are planning a second study to affirm their findings and evaluate additional measures of thyroid function.

Adequate intake of iodine has previously been recognized as important for healthy thyroid function. Our study results would reinforce that recommendation for women.

In summary, these two studies show that low perchlorate exposure is widespread in the U.S. population but generally is below the EPA RfD in our study population of women aged 20 years and older. Among men, perchlorate levels were not associated with hormone levels. Among women with lower levels of iodine in their urine, perchlorate exposure that is common in the U.S. population was associated with small- to-medium-size changes in thyroid hormone levels. Adequate intake of iodine substantially diminishes the association of perchlorate exposure with thyroid hormone levels in women.

Copies of both studies have been provided to the Committee. The publication "Urinary Perchlorate and Thyroid Hormone Levels in Adolescents and Adult Men and Women Living in the United States" is available on line at:

http://www.ehponline.org/members/2006/9466/9466.pdf

Mr. Chairman, this concludes my prepared statement. Thank you for giving me the opportunity to speak before the Subcommittee. I would be happy to respond to any questions that you or other Members of the Subcommittee may have.

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Perchlorate Exposure of the US Population, 2001–2002

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Perchlorate is commonly found in the environment and can impair thyroid function at pharmacological doses. As a result of the potential for widespread human exposure to this biologically active chemical, we assessed perchlorate exposure in a nationally representative population of 2820 US residents, ages 6 years and older, during 2001 and 2002 as part of the National Health and Nutrition Examination Survey (NHANES). We found detectable levels of perchlorate (>0.05 μg/l) in all 2820 urine samples tested, indicating widespread human exposure to perchlorate. Urinary perchlorate levels were distributed in a log normal fashion with a median of 3.6 μg/l (3.38 μg/g creatinine) and a 95th percentile of 14 μg/l (12.7 μg/g creatinine). When geometric means of urinary perchlorate levels were adjusted for age, fasting, sex and race-ethnicity, we found significantly higher levels of urinary perchlorate in children compared with adolescents and adults. We estimated total daily perchlorate dose for each adult (ages 20 years and older), based on urinary perchlorate, urinary creatinine concentration and physiological parameters predictive of creatinine excretion rate. The 95th percentile of the distribution of estimated daily perchlorate doses in the adult population was 0.234 μg/kg-day [CI 0.202–0.268 μg/kg-day] and is below the EPA reference dose (0.7 μg/kg-day), a dose estimated to be without appreciable risk of adverse effects during a lifetime of exposure. These data provide the first population-based assessment of the magnitude and prevalence of perchlorate exposure in the US.
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Keywords: *perchlorate, human, urine, exposure assessment, biomonitoring, NHANES.*

Introduction

Perchlorate is an inorganic anion that is synthesized primarily as ammonium perchlorate for use as an oxidant in solid rocket propellant (Mendiratta et al., 1996). Perchlorate can also form naturally in the atmosphere (Dasgupta et al., 2005) leading to trace levels in precipitation and is concentrated geologically in some locations such as regions of west Texas (Dasgupta et al., 2005) and northern Chile (Urbansky et al., 2001). A combination of human activities and natural sources has led to the widespread presence of perchlorate in the environment. The US Environmental Protection Agency (EPA) included perchlorate on the Drinking Water Candidate Contaminant List and requires public water systems to monitor and report perchlorate in drinking water (EPA, 1998, 1999). As of November 2005, perchlorate was detected at least once in 4.1% of community drinking water systems from 26 different states and two territories, with levels ranging from the method detection limit of 4 μg/l to a maximum at 420 μg/l (EPA, 2005b). Perchlorate exposure from the diet is likely, due to the contamination of vegetable crops irrigated with perchlorate-containing water (Yu et al., 2004) or fertilized with Chilean nitrate (Urbansky et al., 2001). Milk can also contain perchlorate, possibly from perchlorate contamination of forage crops (Kirk et al., 2003; Capuco et al., 2005).

The prevalence of trace levels of perchlorate in the environment leads to human exposure. Environmental perchlorate exposure is of possible health concern because much larger doses of perchlorate have been shown to competitively inhibit iodide uptake by the thyroid gland (Wyngaarden et al., 1953; Greer et al., 2002); sustained inhibition of iodide uptake could potentially lead to hypothyroidism. The thyroid plays a crucial role in energy homeostasis and neurological development. Hypothyroidism can lead to metabolic problems in adults and abnormal development in children (Braverman and Utiger, 2000).

Useful human exposure data can be obtained by directly measuring levels of an environmental toxicant in the human body (i.e., biomonitoring) (Pirkle et al., 1995). Urinary perchlorate provides a reasonable measure of human exposure because 70–95% of a perchlorate dose is excreted unchanged in the urine with a half-life of ~8 h (Anbar et al., 1959; Lawrence et al., 2000; Greer et al., 2002). Sensitive and selective methods are needed to quantify perchlorate anion in urine in the presence of much higher levels of chloride, sulfate and phosphate anions. We recently developed a sensitive and

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[1]The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention

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selective analytical method capable of quantifying perchlorate in human urine as low as 0.05 μg/l (Valentin-Blasini et al., 2005). In this paper, we have applied this method to measure perchlorate in urine samples collected from a representative sample of 2820 persons, aged 6 years and older, as part of the 2001–2002 National Health and Nutrition Examination Survey (NHANES).

Subjects and methods

Study Design

NHANES is conducted by the National Center for Health Statistics of the Centers for Disease Control and Prevention (CDC). This survey is designed to assess the health and nutrition status of the civilian, non-institutionalized US population (CDC, 2004). The sampling design for NHANES is based on a complex multistage probability design, which includes selection of primary sampling units (counties), household segments within the counties and finally sample persons from selected households. Data were collected through a household interview and a standardized physical examination, which was conducted in a mobile examination center. In NHANES 2001–2002, urine and serum specimens were collected from each participant, aged 6 years and older, during one of three daily scheduled examination periods (i.e., morning, afternoon and early evening). Sociodemographic information and medical histories of the survey participant and the family were collected during the household interview. NHANES 2001–2002 was conducted in 30 locations throughout the US (CDC, 2004), with a random one-third subsample consisting of 2892 NHANES study participants collectively representing the civilian, non-institutionalized US population, aged 6 years and older. Overall, the survey interview response rate was 83.9% and the exam response rate was 79.6%. Perchlorate measurements were conducted on the 2820 study participants with available urine specimen.

Demographic Variables

Sociodemographic data were self-reported by study participants. Age was grouped as children (6–11 years), adolescents (12–19 years) and adults (≥20 years), consistent with the *Third National Report on Human Exposure to Environmental Chemicals* (CDC, 2005). Similarly, a race/ethnicity variable was derived from self-reported questionnaire data, resulting in four categories of race/ethnicity: non-Hispanic white, non-Hispanic black, Mexican Americans and others. Non-Hispanic blacks and Mexican Americans were over-sampled as part of NHANES; urinary perchlorate data were weighted to adjust for this oversampling (CDC, 2004). Data are not presented separately for the 'other race/ethnic groups' because of the small number of individuals in this group; however, these individuals are included in the analyses of the overall population and age and sex population groups.

Table 1. Characteristics of the population with urinary perchlorate measured, US, NHANES[a] 2001–2002.

Category	(n)	(%)
Age		
6 years and over	2820	100.0
6–11 years	374	13.3
12–19 years	828	29.4
20 years and over	1618	57.4
Sex		
Female	1485	52.7
Male	1335	47.3
Race/ethnic groups		
Non-Hispanic White	1228	43.5
Non-Hispanic Black	681	24.1
Mexican American	708	25.1
Other race/ethnic groups	203	7.2

[a]National Health and Nutrition Examination Survey.

Table 1 provides the study population characteristics by age, sex and race-ethnicity.

Laboratory Methods

During the physical examinations, spot urine specimens were collected from participants, aliquoted, and stored cold (2–4°C) or frozen until shipment. Samples collected for perchlorate measurements were shipped on dry ice to the CDC's National Center for Environmental Health. Urine samples were stored frozen (−70°C) for 3–4 years. Experiments evaluating storage at −70°C for >2 years indicate no changes in urinary perchlorate levels under these storage conditions. Urinary perchlorate was analyzed using the method of Valentin-Blasini et al. (2005). Briefly, 0.5 ml of urine was spiked with an isotopically labeled internal standard and diluted 1:1 with deionized water. This solution was subsequently analyzed using ion chromatography–electrospray ionization–tandem mass spectrometry. Perchlorate was quantified based on the peak area ratio of analyte to stable isotope-labeled internal standard. Two quality control pools were analyzed in each analytical batch with unknown samples. Reported results met the accuracy and precision specifications of the quality control/quality assurance program of the Division of Laboratory Sciences, National Center for Environmental Health, CDC (similar to rules outlined by Westgard (Westgard et al., 1981)). During analysis of urine for perchlorate, we analyzed these two quality control pools multiple times ($n = 117$) with an interday precision of 2.8% relative SD at 71 ± 2.0 μg/l and 3.0% relative SD at 4.7 ± 0.14 μg/l. In addition, reproducibility of the assay was evaluated by re-analysis of 5% of the samples, yielding an average relative percent difference of 1.5% (95% confidence interval (CI) 1.1%–2.0%). Absolute assay accuracy was verified by the blind analysis of four

different perchlorate reference solutions (AccuStandard, New Haven, CT, USA) prepared in synthetic urine (CST Technologies, Great Neck, NY, USA). We assessed perchlorate contamination by lot screening all reagents and analyzing blanks with each batch of unknowns; no contamination problems were identified.

Urinary creatinine concentrations were determined using an automated colorimetric method on a Beckman Synchron AS/ASTRA clinical analyzer (Beckman Instruments Inc., Brea, CA, USA) at the Coulston Foundation (Alamogordo, NM, USA) in 2001 and Collaborative Laboratory Services (Ottumwa, IA, USA) in 2002 (CDC, 2004). Perchlorate concentrations were adjusted using creatinine concentrations to correct for variable water excretion rates in the spot urine samples.

Estimation of Total Daily Perchlorate Dose

We estimated total daily perchlorate dose based on measured spot urine perchlorate and creatinine concentrations, and estimated daily creatinine excretion rate (g/day) computed from each individual's measured weight, height, age and sex. Specifically, daily creatinine excretion was calculated for adults based on the Cockcroft–Gault equation (Cockcroft and Gault, 1976) as modified by Mage et al. (2004), where $k = 1.93$ for males and 1.64 for females:

$$\text{Adult } g\,\text{creatinine/day} = 10^{-6} * k * (140 - \text{age[yr]}) * \text{wt(kg)}^{1.5} * \text{ht(cm)}^{0.5}$$

Daily perchlorate dose was then estimated using the following formula:

$$\text{Perchlorate dose} = \mu\text{g perchlorate/g urinary creatinine} * \text{g creatinine/day} * 1/\text{wt(kg)}$$

Daily perchlorate dose is not presented for children and adolescents due to the limited validation of formulas for these age groups. Also, we assumed that 100% of perchlorate intake is absorbed and excreted unmetabolized in the urine (Anbar et al., 1959; Lawrence et al., 2000). This assumption leads to underestimation of perchlorate dose in lactating women because perchlorate is secreted in human milk (Capuco et al., 2005; Kirk et al., 2005) as well as urine. Based on questionnaire data, only 26 study participants were actively lactating during the study period.

Statistical Analysis

Univariate and regression analysis of perchlorate data used survey-specific sample weights to account for differential probabilities of selection and non-response. Geometric means and percentiles of urinary perchlorate were calculated using SUDAAN PROC DESCRIPT (SUDAAN v. 9.0.0, Research Triangle Institute, Research Triangle Park, NC, USA), with CI estimated based on the method of Korn and Graubard (1998). SUDAAN PROC REGRESS was used for analysis of covariance (ANCOVA) of perchlorate levels with predictor variables of age group, sex, race/ethnicity, fasting and urinary creatinine. The ANCOVA model used to calculate the adjusted geometric means included a continuous variable for urinary creatinine and categorical variables defining age (6–11, 12–19, 20+ years), fasting (<8 h since last meal or ≥8 h), sex and race/ethnicity groups. Separate adjusted means are provided for sex by race/ethnicity groups because of significant interaction between these two groups. Estimates of the CI were calculated using the Taylor series linearization method (SUDAAN Users Manual, 2001).

Table 2. Geometric means and selected percentiles of urinary perchlorate concentrations (μg/l) for the US population aged 6 years and older, NHANES[a] 2001–2002.

			Selected percentiles						
Category	N	GM[b]	5th	10th	25th	50th	75th	90th	95th
Total	2820	3.54 (3.29–3.81)[c]	0.78 (0.68–0.91)	1.1 (0.96–1.1)	2.0 (1.8–2.1)	3.6 (3.4–3.9)	6.2 (5.7–6.9)	10 (8.9–11)	14 (11–17)
Age: 6–11 years	374	4.93 (4.22–5.76)	1.1 (0.78–1.5)	1.6 (1.2–2.4)	3.1 (2.6–3.7)	5.2 (4.3–6.3)	8.1 (6.8–9.3)	11 (9–14)	19 (12–23)
Age: 12–19 years	828	3.80 (3.44–4.20)	0.76 (0.47–1.2)	1.1 (0.78–1.5)	2.4 (2.0–2.6)	4.4 (3.8–4.7)	6.8 (6.2–7.3)	10 (8.9–11)	12 (11–17)
Age: ≥20 years	1618	3.35 (3.08–3.65)	0.78 (0.69–0.87)	1.0 (0.97–1.1)	1.9 (1.7–2.0)	3.5 (3.2–3.7)	5.8 (5.2–6.5)	9.9 (8.6–11)	12 (11–16)
Males	1335	4.19 (3.93–4.46)	1.1 (0.88–1.2)	1.3 (1.2–1.6)	2.4 (2.3–2.6)	4.4 (4.2–4.5)	7.0 (6.3–7.8)	11 (9.4–12)	13 (11–17)
Females	1485	3.01 (2.74–3.31)	0.65 (0.54–0.82)	0.93 (0.82–1.0)	1.6 (1.3–1.7)	3.1 (2.7–3.4)	5.3 (4.9–5.9)	9.2 (8.2–11)	13 (11–16)
Non-Hispanic white	1228	3.51 (3.18–3.88)	0.78 (0.66–0.95)	1.0 (0.94–1.2)	1.9 (1.7–2.2)	3.6 (3.4–4.1)	6.2 (5.6–7)	10 (8.7–11)	14 (11–18)
Non-Hispanic black	681	3.51 (3.07–4.02)	0.76 (0.6–0.99)	1.1 (0.82–1.3)	2.0 (1.8–2.4)	3.6 (3.1–4.1)	5.8 (5.0–6.9)	9.1 (7.8–12)	14 (11–19)
Mexican American	708	4.02 (3.48–4.64)	1.0 (0.63–1.2)	1.4 (1.1–1.5)	2.3 (1.9–2.8)	4.4 (3.6–4.9)	7.1 (5.8–8.2)	11 (9.4–13)	14 (12–17)
Females, age 15–44	662	3.40 (3.00–3.85)	0.62 (0.37–0.83)	0.85 (0.62–1.2)	1.5 (1.2–1.9)	2.9 (2.4–3.4)	5.0 (4.0–6.4)	9.2 (7.2–12)	13 (9.1–17)

[a]National Health and Nutrition Examination Survey.
[b]Geometric mean.
[c]95% CI.

Results

We found perchlorate in all 2820 urine samples tested from NHANES 2001–2002, with levels ranging from 0.19 to 160 μg/l. Geometric means and selected percentiles of weighted perchlorate concentrations in the NHANES urine samples are shown in Table 2 (in μg/l) and Table 3 (in μg/g of creatinine). The geometric means and selected percentiles of the population are presented for the total population as well as population groups defined by age, sex and race-ethnicity.

Women of reproductive age (15–44 years) are also listed based on the recent classification of the pregnant woman/developing fetus as a potentially susceptible population (NAS, 2005). We found that women of reproductive age had urinary perchlorate levels with a median of 2.9 μg/l (CI 2.4–3.4 μg/l), 2.97 μg/g creatinine (CI 2.64–3.30 μg/g) and a 95th percentile of 13 μg/l (CI 9.1–17 μg/l), 12.1 μg/g creatinine (CI 8.15-18.1 μg/g). Of the 662 women of reproductive age, a subset ($n = 115$) were pregnant at the time of the study. The pregnant women in the study had median urinary perchlorate levels of 3.5 μg/l (CI 1.8–5.4 μg/l); 3.27 μg/g creatinine (CI 2.23–4.88 μg/g).

Children had higher median urinary perchlorate levels (5.2 μg/l; 5.79 μg/g creatinine) compared with adults (3.5 μg/l; 3.25 μg/g creatinine). We applied an ANCOVA model to further evaluate the higher levels of unadjusted urinary perchlorate observed in children compared with adolescents and adults. The adjusted geometric means for urinary perchlorate levels in each demographic group are shown in Table 4 and Figure 1. After adjustment for age, urinary creatinine, fasting, sex and race/ethnicity, urinary perchlorate levels were higher in children compared with adolescents ($P < 0.001$) or adults ($P < 0.001$). We found a significant interaction between sex and race/ethnicity and present the data for these demographic groups accordingly. Non-Hispanic white males had higher adjusted urinary perchlorate levels than non-Hispanic white females ($P = 0.01$) and non-Hispanic black males ($P < 0.001$). Fasting for 8 or more hours was associated with decreased urinary perchlorate ($P < 0.001$), likely due to a lack of dietary intake and the relatively short physiological half life of perchlorate in the human body (Anbar et al., 1959; Lawrence et al., 2000).

The geometric means and selected percentiles of estimated daily perchlorate doses for adults are shown in Table 5.

Discussion

We report the distribution of perchlorate levels in urine samples collected from a representative sample of 2820 US residents, aged 6 years and older. Based on these results, perchlorate exposure appears to be wide-spread in the US population. Human exposure to perchlorate may occur via several different routes. Perchlorate from both natural and

Table 3. Geometric means and selected percentiles of urinary perchlorate (μg/g creatinine) for the US population aged 6 years and older, NHANES[a] 2001–2002.

Category	N	GM[b]	Selected percentiles							
			5th	10th	25th	50th	75th	90th	95th
Total	2818	3.56 (3.34–3.80)[c]	1.10 (0.976–1.20)	1.40 (1.30–1.52)	2.17 (1.97–2.39)	3.38 (3.18–3.66)	5.61 (5.29–6.00)	9.35 (8.22–10.3)	12.7 (11.1–14.1)
Age: 6–11 years	374	5.71 (5.22–6.25)	1.91 (1.64–2.38)	2.50 (2.25–2.88)	3.64 (3.27–4.11)	5.79 (5.19–6.25)	8.33 (7.41–9.74)	13.0 (11.2–16.0)	17.4 (13.1–22.6)
Age: 12–19 years	827	2.95 (2.64–3.29)	0.922 (0.712–1.10)	1.17 (1.06–1.33)	1.88 (1.60–2.06)	2.89 (2.56–3.39)	4.48 (3.96–5.23)	7.12 (6.57–8.10)	9.87 (7.46–13.4)
Age: ≥20 years	1617	3.46 (3.20–3.73)	1.09 (0.932–1.21)	1.40 (1.27–1.54)	2.11 (1.93–2.36)	3.25 (3.04–3.59)	5.36 (4.93–5.92)	9.02 (7.61–10.2)	12.3 (10.2–14.4)
Males	1335	3.40 (3.20–3.60)	1.06 (0.891–1.16)	1.36 (1.24–1.52)	2.09 (1.94–2.27)	3.25 (3.04–3.47)	5.35 (4.93–5.86)	8.75 (7.52–9.87)	11.4 (10.1–12.7)
Females	1483	3.72 (3.39–4.09)	1.13 (1.01–1.25)	1.48 (1.30–1.60)	2.25 (1.96–2.58)	3.59 (3.20–4.10)	5.99 (5.33–6.67)	10.0 (8.15–12.1)	13.4 (11.4–16.0)
Non-Hispanic white	1227	3.76 (3.46–4.08)	1.24 (1.09–1.37)	1.54 (1.41–1.69)	2.32 (2.03–2.65)	3.54 (3.22–4.02)	5.82 (5.43–6.25)	9.42 (8.30–10.5)	12.7 (11.2–14.3)
Non-Hispanic black	680	2.53 (2.24–2.86)	0.656 (0.461–0.997)	1.00 (0.856–1.09)	1.49 (1.29–1.63)	2.54 (2.12–2.84)	4.07 (3.51–4.93)	6.87 (5.93–8.43)	10.0 (8.33–12.2)
Mexican American	708	3.77 (3.23–4.39)	1.20 (0.944–1.35)	1.52 (1.30–1.72)	2.20 (1.90–2.53)	3.51 (3.02–4.44)	6.05 (4.93–7.64)	10.4 (8.37–13.0)	14.4 (11.5–17.4)
Females, age 15–44	662	3.12 (2.72–3.57)	0.930 (0.645–1.10)	1.21 (1.05–1.39)	1.86 (1.61–2.05)	2.97 (2.64–3.30)	4.89 (3.91–6.25)	8.40 (6.32–11.7)	12.1 (8.15–18.1)

[a]National Health and Nutrition Examination Survey.
[b]Geometric mean.
[c]95% CI.

Table 4. Geometric means for urinary perchlorate (μg/l), adjusted by analysis of covariance for race/ethnicity, sex, age, fasting and urinary creatinine for ages 6 and older, NHANES 2001–2002.

Category	Adjusted geometric mean	95% confidence interval
6–11 years of age (children)	5.40[a]	(4.66–6.27)
12–19 years of age (adolescents)	3.30	(2.96–3.67)
≥20 years of age (adults)	3.41	(3.12–3.72)
Males: non-Hispanic whites	3.92[b]	(3.58–4.29)
Males: non-Hispanic blacks	2.61	(2.30–2.96)
Males: Mexican-Americans	3.94	(3.42–4.55)
Females: non-Hispanic whites	3.41[c]	(2.98–3.93)
Females: non-Hispanic blacks	3.03[d]	(2.66–3.47)
Females: Mexican-Americans	3.83	(3.12–4.70)
Fasting <8 h	3.89[e]	(3.56–4.25)
Fasting ≥8 h	3.37	(3.08–3.69)

[a]Higher than adolescents and adults ($P<0.001$).
[b]Higher than male non-Hispanic blacks ($P<0.001$).
[c]Lower than male non-Hispanic whites ($P=0.01$).
[d]Higher than male non-Hispanic blacks ($P=0.02$).
[e]Higher than fasting ≥8 h ($P<0.001$).

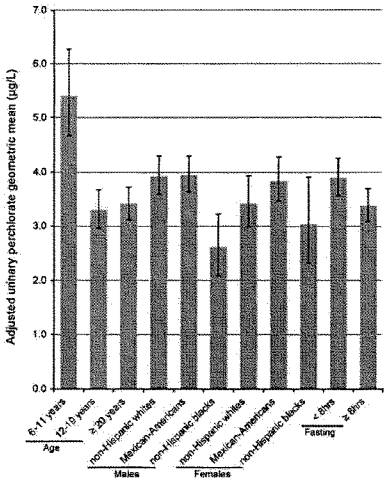

Figure 1. Geometric means and 95th percentile confidence intervals for urinary perchlorate (μg/l), adjusted by analysis of covariance for race/ethnicity, sex, age, fasting and urinary creatinine for ages 6 and older, NHANES 2001–2002.

anthropogenic sources can contaminate drinking water and food crops. Exposure can also result from inhalation of dust containing perchlorate, especially in occupational settings (Gibbs et al., 1998). Measuring perchlorate in human urine assesses the combined exposure from all sources.

The demographic group with the highest levels of urinary perchlorate was children, similar to previously published results for urinary iodine (Caldwell et al., 2005). Covariate-adjusted urinary perchlorate levels were statistically higher in children compared with both adolescents and adults, even after adjusting for urinary creatinine (Table 4). These age-associated differences in urinary perchlorate levels could represent differences in pharmacokinetics, the relationship of dose per body weight and/or exposure. For example, dietary habits such as the consumption of milk and green leafy vegetables vary across age and ethnicity groups. Samples of dairy milk and green-leafy vegetables have been reported to contain perchlorate (Hogue, 2003; Kirk et al., 2003; FDA, 2004; Capuco et al., 2005; Jackson et al., 2005). Therefore, increased consumption of these foods could increase perchlorate exposure (Blount et al., 2006).

Several small studies have also found measurable perchlorate levels in human urine or milk. For 61 adults living in Georgia, all urine samples contained measurable levels of perchlorate, with a median of 3.2 μg/l and a log-normal distribution (Valentin-Blasini et al., 2005). Similar background levels of perchlorate (median 5.5 μg/l) were detected in urine from 13 subjects in a Southern California study (Braverman et al., 2006). Kirk et al. (2005) reported measurable levels of perchlorate in all samples of breast milk collected from 36 women residing in 18 different states (mean 10.5 μg/l).

Other previously published studies did not report measurable background levels of perchlorate, likely due to inadequate analytical sensitivity (Lawrence et al., 2000; Greer et al., 2002; Gibbs et al., 2004; Braverman et al., 2005); therefore, application of these methods resulted in reported urinary background values of less than method detection limits of 500 μg/l (Lawrence et al., 2000), 20 μg/l (Greer et al., 2002; Merrill et al., 2005) and 5 μg/l (Gibbs et al., 2004; Braverman et al., 2005). Significantly higher levels of urinary perchlorate were found in populations in northern Chile consuming tap water with perchlorate levels as high as 114 μg/l (Tellez et al., 2005). As expected, urinary perchlorate levels in these highly exposed Chilean populations (median 35 μg/l) were significantly higher than the levels found in this study.

Occupational exposure to perchlorate can lead to levels and doses that are much higher than those observed for this sample of the US population (Gibbs et al., 1998; Lamm et al., 1999; Braverman et al., 2005). Occupational survey data indicate that less than 10,000 US workers actively handle perchlorate (CDC, 1995). This small number of workers should have a minimal impact on population estimates presented here.

Measurement of a single spot urine sample was used to assess individual exposure. Urinary perchlorate levels are

Table 5. Geometric mean and selected percentiles of estimated perchlorate dose (μg/kg-day) for the US population aged 20 years and older, NHANES[a] 2001–2002.

Category	N	GM[b]	Selected percentiles		
			5th	50th	95th
Total	1532	0.066 (0.060–0.071)[c]	0.020 (0.017–0.023)	0.064 (0.059–0.069)	0.234 (0.202–0.268)
Males	726	0.071 (0.066–0.077)	0.021 (0.019–0.027)	0.069 (0.063–0.074)	0.249 (0.208–0.292)
Females	806	0.061 (0.054–0.067)	0.018 (0.015–0.022)	0.059 (0.054–0.066)	0.215 (0.184–0.260)

[a]National Health and Nutrition Examination Survey.
[b]Geometric mean.
[c]95% CI.

presented both as micrograms per liter and as micrograms per gram of urinary creatinine to allow for comparisons between different demographic groups and adjustment for differences in urinary dilution (Barr et al., 2005). For a single person, more precise exposure estimates could be derived by averaging perchlorate levels from two or three spot urine samples. However, for population estimates such as geometric means and percentiles, results of multiple persons are averaged. For these point estimates, use of a single spot urine sample from each individual would constitute one source of random error, not bias. As a source of random error, this would lead to less statistical power to detect differences in perchlorate levels between groups of interest.

Urine is the principal route by which non-lactating humans excrete perchlorate (Anbar et al., 1959; Lawrence et al., 2000). During lactation human mammary tissue expresses the sodium iodide symporter (Wolff, 1998), and thus significant transfer of perchlorate into human milk is likely. The presence of micrograms per liter concentrations of perchlorate in milk collected from US women (Kirk et al., 2005) confirms lactation as a relevant perchlorate excretion path. Additional data from another lactating mammalian species (dairy cattle) confirm that a substantial portion of a perchlorate dose can be excreted in milk (Capuco et al., 2005). If lactating women are secreting perchlorate in milk, then urine-based estimates of total perchlorate exposure for these individuals are likely to be lower than actual. However, the overall impact of lactation on our population estimates of perchlorate exposure is likely to be minimal because only 26 of the 2820 participants in our study population reported that they were currently breastfeeding a child.

Our initial measurements indicate that perchlorate exposure is widespread. The toxicological impact of perchlorate exposure at these levels is an area of ongoing research. The EPA recently set the reference dose (RfD), a dose estimated to be without appreciable risk of adverse effects during a lifetime of exposure, for perchlorate at 0.7 μg/kg-day (EPA, 2005a). This RfD was recommended by the National Academy of Sciences expert panel in their perchlorate risk assessment (NAS, 2005). To compare our measured perchlorate concentrations in spot urine samples with this toxicological benchmark dose, we estimated daily dose based on physiological parameters and measured spot urine perchlorate and creatinine. Estimation of perchlorate dose in adults revealed a median of 0.066 μg/kg-day and a 95th percentile of 0.234 μg/kg-day. These estimated perchlorate dose levels are lower than the current EPA reference dose of 0.7 μg/kg-day. Only 11 adults had estimated perchlorate exposure in excess of the reference dose.

The NAS has specified pregnant women, fetuses and infants as populations who may be more sensitive to the potential health effects of perchlorate exposure (NAS, 2005). Mild hypothyroidism during pregnancy can be associated with subsequent cognitive deficits in children (Haddow et al., 1999; Klein et al., 2001). Additionally, active expression of the sodium iodide symporter in the placenta and lactating breast tissue allows perchlorate exposure of the mother to be distributed to the developing fetus and infant. Perchlorate measurement began at 6 years of age in our study, so we do not have exposure information for infants. Women of reproductive age can be used as a surrogate population for assessing fetal exposure. Women of reproductive age had a median estimated perchlorate dose of 0.057 μg/kg-day and a 95th percentile of 0.214 μg/kg-day. Daily perchlorate exposure doses were also estimated for the pregnant women in the study who had complete data sets for age, height and weight ($N = 110$). This population of pregnant women had an estimated median perchlorate dose of 0.066 μg/kg-day. These estimated perchlorate dose levels are lower than the current EPA reference dose of 0.7 μg/kg-day.

Conclusions

We assessed urinary perchlorate levels in a US reference population and present the data here stratified by age, sex and race/ethnicity. We found perchlorate in all human urine samples tested, indicating widespread trace-level perchlorate exposure in the general population. We estimated daily perchlorate dose and found that the 95th percentile of

estimated dose is less than the EPA RfD. The results provide information for risk modeling and provide a reference range for comparisons with results from other potentially exposed population groups. These data provide the first population-based assessment of the magnitude and prevalence of perchlorate exposure in the US.

Acknowledgements

We thank the staff at the National Center for Health Statistics and Westat who were responsible for planning and conducting the National Health and Nutrition Examination Survey (NHANES), and E Gunter and C Pfeiffer for managing the National Center for Environmental Health's involvement with NHANES. We thank J Morrow for technical assistance, and K Caldwell for helpful discussions of data.

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Mr. WYNN. Dr. Brackett.

STATEMENT OF ROBERT BRACKETT, PH.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, THE FOOD AND DRUG ADMINISTRATION

Mr. BRACKETT. Thank you and good morning, Mr. Chairman and members of the subcommittee. I am Dr. Robert Brackett, director for the Center of Food Safety and Applied Nutrition at FDA. I want to thank you for the opportunity to testify about FDA's efforts to measure and assess the presence of perchlorate in food and beverages. And I am pleased to be here today with my colleagues from CDC, EPA, and DOD.

All of us at FDA take our responsibility to protect the Nation's food supply very seriously. And to better understand the potential of food, as an exposure pathway of perchlorate, we began in 2003 to sample and analyze a variety of foods to determine the occurrence of perchlorate and estimate the resulting human exposure through consumption of those foods. These studies will allow us to characterize exposure to perchlorate from foods and will be used in scientific support for any further action that might be needed to protect public health.

As a first step in our investigation, FDA developed a rapid and scientifically accurate method to measure the presence of perchlorate in foods, and this method can detect perchlorate at levels as low as 1 ppb. for produce, 3 ppb. for milk, grain products, and fish, and one-half ppb. for bottled water.

In December 2003, FDA began an initial exploratory survey of a small number of domestically produced foods that we anticipated might contain higher levels of perchlorate due to the location of where the food was grown and its high water content. The first collection of data, conducted from December 2003 through August 2004, involved two phases. In the first phase of the survey, 150 samples of lettuce and 50 samples of bottled water were collected and analyzed for perchlorate. In the second phase on the survey, beginning in August of 2004, we collected and analyzed the following: 120 samples of milk, 55 samples of tomato, 45 of carrot, 45 of cantaloupe, and 35 of spinach.

To inform the public of FDA's progress and to share its initial exploratory data, in November 2004, we posted on FDA's Web site the initial set of perchlorate data. These data included perchlorate levels found in our samples of lettuce, bottled water, and milk. And FDA also posted a set of questions and answers on perchlorate to explain the survey data and provide better context to the public.

The values for perchlorate found in food stuff sampled in 2004 were similar to those reported by researchers outside the Agency, and the data confirmed that we should continue to investigate the occurrence of perchlorate in a greater variety of foods and in other regions in the country.

In February 2005, FDA issued a second survey assignment to obtain information on the distribution of the perchlorate in a wider variety of foods. The survey called for a total 450 samples, domestic and imported, to be collected in two phases during fiscal year 2005. The first phase was a collection of additional samples of tomatoes, carrots, spinach, and cantaloupe, and a collection of a wide variety

of foods that included fruits and fruit juices, vegetables, and grain products. The second phase consisted of collecting additional types of fruits, vegetables, and grain products as well as aquaculture fish.

In a separate survey assignment issued in December 2004, FDA collected and analyzed 105 farm milk samples, 105 associated feed samples, and 105 water samples from dairy farms in top milk-producing States. And this was done in order to determine the potential source of contamination at the farm level.

In addition, we collected and analyzed 228 baby food samples obtained in markets nationwide. Separately, we also collected and analyzed 21 samples of infant formula, and we plan to collect and analyze an additional 40 infant formula samples in 2007.

FDA has compiled a preliminary mean perchlorate exposure assessment for the general population, based on our 2004–05 exploratory survey data for 27 types of food and beverages. Our analysis has been reviewed by three external government experts, and it has been shared with the interagency working group. And when finalized, we plan to release the exploratory exposure assessment to the public. It is important to reiterate that this preliminary exposure assessment is based on food data that does not represent the complete diet of the U.S. and is therefore not necessarily a reflection of perchlorate exposure to the general U.S. population.

We do, however, expect to have representative exposure estimates following our analysis of data collected under our total dietary study or TDS. Through the TDS dietary intakes of various nutrients and contaminants by the U.S. population can be estimated. Since its inception in 1961, the TDS has grown to encompass many substances, including pesticide residues, industrial chemicals, and toxic and nutrient elements.

The foods collected in the TDS represent the major components of the diet of U.S. populations, and in this, foods are prepared as they normally would be and consumed prior to analysis. So the analytical results provide the basis for a realistic estimate of the dietary intake of the substances that are under the study.

During fiscal year 2005 and 2006, FDA analyzed samples from the total dietary survey for perchlorate, and we do plan to publish in late 2007 an assessment of the exposure to perchlorate from food based on the level found in the TDS study. Because of the size of the data set and the design of the study, these data will provide a more robust estimate of the exposure of U.S. consumers to perchlorate through food consumption.

Currently FDA is continuing to test samples of specific food types collected through additional targeted surveys, as described in my written testimony, and will continue to work with our partners at USDA and EPA to determine the occurrence of perchlorate in foods and conduct an assessment of the dietary exposure. FDA is aware that other data on perchlorate levels in foods are under development, and we welcome external research that can assist us in describing the distribution of perchlorate in foods and developing exposure estimates.

Consumers should not view the low levels of perchlorate in their foods we have tested as an indicator of so-called risk of eating certain foods. At this time, FDA continues to recommend that consum-

ers eat a balanced diet, choosing a variety of foods that is low in trans fat and saturated fat and rich in high-fiber grains, fruits, and vegetables.

Thank you for the opportunity to discuss this important public health issue with you, and I will be happy to answer any questions you may have.

[The prepared statement of Mr. Brackett follows:]

Testimony
Committee on Energy and Commerce
Subcommittee on Environment and Hazardous Materials
United States House of Representatives

FDA's Role in Measuring and Assessing Perchlorate Levels in Food and Beverages

Statement of
Robert E. Brackett, Ph.D.
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 a.m.
Wednesday, April 25, 2007

Mr. Chairman and Members of the Subcommittee, I am Dr. Robert E. Brackett, Director of the Center for Food Safety and Applied Nutrition (CFSAN). Thank you for the opportunity to testify about the actions taken by the U.S. Food and Drug Administration (FDA) to measure and assess the presence of perchlorate in food and beverages.

We at FDA take our responsibility to protect the nation's food supply very seriously. To better understand the potential for food to provide an exposure pathway for perchlorate, we began in 2004 to sample and analyze a variety of foods to determine the occurrence of perchlorate and to estimate resulting human exposure through consumption of those foods. This information will be used to help determine whether additional action might be needed to protect the public health. The following statement will describe our past, ongoing, and planned data collection and analyses.

Background

Perchlorate is an industrial chemical contaminant that is used as a propellant in rockets, in fireworks and flares, and for other purposes. Perchlorate has also been found to occur naturally, and there is preliminary evidence that it can be generated under certain climatic conditions. The relative contribution to perchlorate levels in food of man-made versus natural perchlorate is not known. Perchlorate at high doses (e.g., therapeutic, pharmacologic) can interfere with iodide uptake into the thyroid gland, interfering with thyroid hormone production.

Sustained inhibition of iodide uptake can lead to hypothyroidism, which can lead to metabolic problems in adults and abnormal development *in utero* and in infancy.

There is a potential for perchlorate contamination in food, most likely through the use of contaminated irrigation water, processing water, and, with respect to bottled water, which is a "food" regulated by FDA, source waters for bottling. However, we do not know the relative contribution of any particular source of perchlorate to that found in foods. Recognizing this potential for perchlorate contamination in food, FDA in 2004 and 2005 conducted exploratory surveys to investigate the occurrence of perchlorate in certain foods and is using the data collected in these surveys to develop preliminary assessments of human exposure to perchlorate through food. In addition, we added perchlorate as a chemical that we analyzed as part of our 2005/2006 Total Diet Study, which is a long-running FDA program using well-established sampling methods and exposure models. We have additional investigations planned. These studies, described more fully below, will allow us to characterize exposure to perchlorate from food, and may be used as scientific support for any action by FDA that might be needed to protect the public health.

Detection of Perchlorate in Foods

As a first step in our investigation of perchlorate in foods, FDA developed a rapid and scientifically accurate method to measure the presence of perchlorate in

foods. This method, a sensitive and specific ion chromatography-tandem mass spectrometry (IC-MS/MS) method, was first developed for use on a limited number of foods, including lettuce, milk, and bottled water. The method is described on the FDA Web site at www.cfsan fda.gov/~ dms/clo4meth.html and it has been published.[i] The method was updated during fiscal year 2005 for determining perchlorate in grain products, fruits and fruit juices, fish, and shrimp. The smallest amounts of perchlorate this method can quantify are 1 part per billion (ppb) for produce, including fruits and fruit juices; 3 ppb for milk, grain products, fish, and shrimp; and 0.5 ppb for bottled water.

Fiscal Year 2004 Perchlorate Survey and Preliminary Exposure Assessment

In December 2003, FDA began an initial exploratory survey to investigate perchlorate levels in various foods, particularly in produce and bottled water. The initial survey called for a total of 500 samples of domestic origin to be collected and analyzed by the FDA. The first collection of data, which spanned from December 2003 until August 2004, involved two phases. For the first phase of the survey, 150 samples of lettuce and 50 samples of bottled water were collected and analyzed for perchlorate. The second phase of the survey, conducted beginning in August 2004, called for collection and analysis of 120 milk, 55 tomato, 45 carrot, 45 cantaloupe, and 35 spinach samples.

In November 2004, FDA posted on its Web site the initial set of perchlorate data collected from December 2003 to August 2004 to inform the public of FDA's progress and share its initial exploratory data. The data included perchlorate levels found in lettuce, bottled water, and milk samples collected as part of the exploratory survey issued in December 2003 (http://www.cfsan.fda.gov/~dms/c1o4data.html). FDA also posted Perchlorate Questions and Answers to explain and provide context to the survey data (http://www.cfsan.fda.gov/~dms/clo4qa.html). Some additional samples, also collected in 2004 but not analyzed until 2005, were later posted at this site.

The values for perchlorate found in the foods sampled in 2004 were similar to those reported by other researchers external to FDA. These data confirmed that we should continue to investigate the occurrence of perchlorate in a greater variety of foods and in other regions of the country, which we proceeded to do in 2005, as discussed below. It is important to note that the results we obtained are preliminary and do not reflect the distribution of perchlorate in the U.S. food supply. The sampling methodology used was not intended to be representative; rather, it was specifically targeted at foods that we anticipated to contain higher levels of perchlorate due to where the food was grown and its high water content.

We want to stress that the 2004 preliminary perchlorate exposure assessment was based on perchlorate data collected in 2004 for a small number of food types and a small number of samples within a food type. Additionally, these

samples came from areas where there was known perchlorate occurrence, thus they are not representative of samples throughout the U.S. Because of these limitations, it would not be appropriate to consider the 2004 preliminary exposure assessment to be a reflection of the actual perchlorate exposure of the U.S. population.

Fiscal Year 2005 Perchlorate Survey and Updated Preliminary Exposure Assessment

In February 2005, FDA issued a second perchlorate survey assignment to obtain information on the distribution of perchlorate in a wider variety of foods. This survey called for a total of 450 samples, domestic and imported, to be collected in two phases during fiscal year 2005. The first phase consisted of collection of additional samples of tomatoes, carrots, spinach, and cantaloupe, and collection of a wider variety of foods that included fruits and fruit juices such as apples, oranges, and grapes; vegetables such as broccoli; and grain products such as cornmeal and oatmeal. The second phase consisted of the collection of additional types of fruits, vegetables and grain products, as well as aquaculture fish.

As part of a separate survey assignment issued in December 2004, FDA collected and analyzed for perchlorate content in 105 farm milk samples, 105 associated feed samples, and 105 water samples from dairy farms in top milk producing states to determine potential sources of contamination at the farm

level. In addition, FDA collected and analyzed a total of 228 baby food samples, including a few infant formula samples, obtained from four market baskets (57 samples per market basket) under the FDA's Total Diet Study (TDS) survey program (described in more detail below). Separately, we also collected and analyzed a total of 21 samples of different types of infant formula and have plans to collect and analyze an additional 40 infant formula samples in 2007.

FDA has compiled the preliminary results of the mean perchlorate exposure assessment for the general population (all persons aged 2 and above), based on FY 2004/2005 exploratory survey data for 27 types of food and beverages (milk, fruit and fruit juices, vegetables, grain products, and seafood (aquaculture fish and shrimp). The analysis of these preliminary results has been reviewed by three external government experts and has been shared with the Interagency Working Group. When finalized, we plan to release the updated exploratory exposure assessment. It is important to reiterate that this preliminary exposure assessment is based on non-representative food data and is not necessarily a reflection of perchlorate exposure to the U.S. population. We expect to have representative exposure estimates following the analysis of the total diet study which is described below.

Total Diet Study

FDA's Total Diet Study (TDS), sometimes called the market basket study, is an ongoing program to determine the levels of various contaminants and nutrients in

foods. Using data obtained through the TDS program, dietary intakes of the analyzed substances by the U.S. population can be estimated. Since its inception in 1961 as a program to monitor for radioactive contamination of foods, the TDS has grown to encompass additional substances, including pesticide residues, industrial chemicals, and toxic and nutrient elements.

The foods collected in the TDS (referred to as the TDS food list) represent the major components of the diet of the U.S. population. The food list is based on results of national food consumption surveys and is updated from time to time to reflect changes in food consumption patterns. Currently, there are about 280 foods collected and analyzed in the TDS. A unique aspect of the TDS is that foods are prepared as they would be consumed (table-ready) prior to analysis, so the analytical results provide the basis for realistic estimates of the dietary intake of these analyzed substances.

In FY 2005 and 2006, FDA analyzed samples from the TDS survey for perchlorate to obtain information on the distribution of the contaminant in a wide variety of foods. FDA plans to publish, in late 2007, an assessment of the exposure to perchlorate from food, based on the levels in TDS foods collected and analyzed during FY 2005/2006. Because of the size of the dataset and the design of this study, these data will provide a robust estimate of the exposure of U.S. consumers to perchlorate through food consumption than the updated preliminary exposure assessment, based on the 2004/2005 targeted sampling.

Additional Steps

In FY 2007, FDA is continuing to test samples of specific food types collected through additional targeted surveys (e.g., infant formulas, sweet potatoes, celery, green peppers, grapes, apples, oranges, apple juice, whole wheat bread, aquaculture catfish, aquaculture salmon, and shrimp). Information on the distribution of perchlorate in a wider variety of foods obtained from these surveys will further enhance FDA's assessment of the dietary exposure of U.S. consumers to perchlorate. FDA will continue to inform the public of its findings as more knowledge is gained.

FDA continues to work with the U.S. Department of Agriculture (USDA) and the EPA to determine the occurrence of perchlorate in foods for continuing assessment of the dietary exposure to perchlorate. FDA is aware that other data on perchlorate levels in foods are under development and welcomes external research that can assist us in describing the distribution of perchlorate in foods and in developing exposure estimates.

Recommendations for Consumers

Consumers should not view the low levels of perchlorate in the foods tested as an indicator of the "risk" of eating certain foods, particularly when many of the foods are important components of a nutritious and balanced diet. Some of these food items are also important sources of iodine. Until more is known concerning perchlorates occurrence in foods, FDA continues to recommend that

consumers eat a balanced diet, choosing a variety of foods that are low in *trans* fat and saturated fat, and rich in high-fiber grains, fruits, and vegetables.

Thank you for the opportunity to provide this information and discuss these important public health issues with you.

Endnotes

[i] Krynitsky, A.J., R.A. Niemam, and D.A. Nortrup. 2004. Determination of Perchlorate Anion in Foods by Ion Chromatography-Tandem Mass Spectrometry. Anal. Chem. 76:5518-5522.

Mr. WYNN. Thank you. Mr. Grumbles.

STATEMENT OF BENJAMIN H. GRUMBLES, OFFICE OF WATER, U.S. ENVIRONMENTAL PROTECTION AGENCY, ACCOMPANIED BY SUSAN BODINE, ASSISTANT ADMINISTRATOR, SOLD WASTE AND EMERGENCY RESPONSE, ENVIRONMENTAL PROTECTION AGENCY, AND GEORGE GRAY, ASSISTANT ADMINISTRATOR, RESEARCH AND DEVELOPMENT, ENVIRONMENTAL PROTECTION AGENCY

Mr. GRUMBLES. Thank you, Mr. Chairman and members of the subcommittee. I am Ben Grumbles, and I am accompanied by George Gray and Susan Bodine, all of the U.S. Environmental Protection Agency, and we appreciate the opportunity to testify on EPA's important efforts regarding perchlorate. EPA is committed to using the best available science on perchlorate and to ensure that our policies continue to protect public health and the environment. We have been working with other Federal agencies to gather and understand data needed to assess the risk of perchlorate to human health and the need for risk management actions.

The first thing I would like to do is to mention the efforts with respect to assessing health risks of perchlorate. As you know and has been described by Members, the National Academy of Science has reviewed the Agency's 2002 draft perchlorate risk assessment. In the final report, published in January 2005, the NAS recommended the Agency use a reference dose of 0.0007 milligrams per kilogram per day. EPA endorsed this recommendation and reviews the NAS report as the basis for establishing our reference dose, which was subsequently posted on the Integrated Risk Information System database in February 2005.

The NAS recommended the use of a human study conducted by Greer as the principal study. Because this study was based on healthy adult men and women, an uncertainty factor of 10 was applied to the no observed effect level identified from the Greer data to protect the most sensitive population, that is the fetuses of pregnant women who might have hypothyroidism or iodine deficiency. The NAS indicated that deriving the reference dose to prevent a non-adverse precursor effect, which would precede an adverse effect, is a conservative and health-protective approach to perchlorate risk assessment.

EPA is very interested in the findings on perchlorate exposure and thyroid function recently reported by CDC researchers. They recommend additional research to affirm and build upon the findings, and we look forward to reviewing the studies. In the meantime, Mr. Chairman and members of this committee, we believe the current reference dose is a scientifically appropriate value for use in our decision-making.

In addition, to reduce potential risks at contaminated sites, EPA issued guidance in January 2006 that recommended a revised preliminary remediation goal of 24.5 ppb. And again, this was based on the reference dose adopted by the Agency following the NAS study and was calculated based on standard exposure values of 70 kilograms body weight and 2 liters of water consumer per day.

I want to reiterate that the preliminary remediation goals are not final cleanup levels. They are merely the starting point for

identifying site-specific goals. They are developed based on readily available information and modified as necessary as more information becomes available. And in addition, if a State has promulgated a drinking water standard for perchlorate, that value would be considered as an ARAR [Applicable or Relevant and Appropriate Requirement] term under the Superfund statute and used as the groundwater cleanup level for sites in that State.

Perchlorate has been found at 49 NPL [National Priorities List] sites out of 1,562 current and deleted sites. At approximately 31 sites, perchlorate concentrations in groundwater or drinking water exceed the 24.5 ppb. level. Effective perchlorate treatment systems are in operation at a number of sites, and EPA will continue to track the progress at all NPL sites where a cleanup decision has not yet been made in order to ensure the groundwater is treated to levels that are protective of human health and the environment.

Now, with respect to Safe Drinking Water Act, EPA is working to identify appropriate risk management actions for perchlorate following the established process in the Safe Drinking Water Act to determine whether Federal regulation would present a meaningful opportunity for health risk reduction. The Agency is placing a high priority on making a regulatory determination for perchlorate as soon as possible. Let me repeat that. The Agency is placing a high priority on making a regulatory determination for perchlorate as soon as possible.

As has been discussed in 1998, perchlorate was placed on the first CCL list. When the first set of regulatory determinations were released in 2003, EPA did not have sufficient information to make a determination, and so we added to the second contaminant candidate list. The administrator recently signed a Federal registered notice with preliminary regulatory determinations for contaminants on the second CCL list. The notice describes why the Agency is not making a preliminary determination on perchlorate at this time, and it provides an extensive update on our research and review of the issue.

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.

EPA collected drinking water occurrence data during the first round of the unregulated contaminant monitoring program, which requires short-term monitoring for specific contaminants to support regulatory development. A total of 3,858 water systems were monitored for perchlorate from 2001 and 2003. It was detected at levels above the minimum reporting level of 4 ppb. in approximately 2 percent of the more than 34,000 samples analyzed. The average concentration detected was 9.8 ppb., and the median concentration was 6.4 ppb.

Before the Agency can make a preliminary regulatory determination, we need to better understand total perchlorate exposure and the relative source contribution.

Mr. Chairman, I would just conclude by saying that all of us share the goal of safe and affordable water. Clearly, there are dif-

ferences in how we achieve that goal. EPA is committed to using the best available science and to making a regulatory determination on perchlorate as soon as possible. Thank you, Mr. Chairman.

[The prepared statement of Mr. Grumbles follows:]

TESTIMONY OF

BENJAMIN H. GRUMBLES
ASSISTANT ADMINISTRATOR FOR WATER

GEORGE GRAY
ASSISTANT ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT

SUSAN BODINE
ASSISTANT ADMINISTRATOR FOR SOLID WASTE
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U.S. ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE

ENVIRONMENT AND HAZARDOUS MATERIALS SUBCOMMITTEE
HOUSE ENERGY AND COMMERCE COMMITTEE
UNITED STATES HOUSE OF REPRESENTATIVES

April 25, 2007

Good morning, Mr. Chairman and Members of the Committee. I am Benjamin H. Grumbles, Assistant Administrator for Water at the United States Environmental Protection Agency (EPA). I am here today with Assistant Administrators George Gray and Susan Bodine. One of Administrator Stephen L. Johnson's key principles for the Agency is using the best available science for decision-making to accelerate the pace of environmental protection in our country while maintaining our country's economic competitiveness.

We appreciate the opportunity to provide you with the history of our efforts in evaluating perchlorate. We will describe our research efforts to assess the risk of perchlorate to human health. We will discuss our risk management efforts related to contaminated sites. Finally, we will describe our on-going efforts to determine the need for managing potential risks posed by perchlorate in drinking

water. We are working with other federal agencies, including the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), to gather and understand data needed to inform our decision-making. We are committed to using the best science on perchlorate to ensure that our policies continue to protect public health and the environment.

Research

EPA has been working on the science related to perchlorate for more than ten years. In the 1997 Appropriations Bill, Congress directed EPA to work with the Department of Defense (DoD), the National Institute of Environmental Health Sciences (NIEHS), and other Federal and state agencies to assess the state of the science on the health effects and ecological impacts from perchlorate environmental contamination. Previous to the Congressional directive, EPA had been closely following occurrence data that showed perchlorate releases to the environment and had determined that an assessment of the human health effects was warranted because of the potential for perchlorate to be present in drinking water.

As a result of the Appropriations Bill, the Interagency Perchlorate Steering Committee (IPSC), co-chaired by EPA and the DoD, was formed in January 1998 to bring together government representatives from the EPA, DoD, National Aeronautics and Space Administration (NASA), NIEHS, and affected State, Tribal, and local governments. The IPSC worked to foster needed research and to serve as a clearinghouse for technology transfer and cross-agency communication and coordination. The health effects subcommittee of the IPSC developed a testing strategy that was based on perchlorate's established anti-thyroid effects in order to address data gaps for derivation of a health risk benchmark level known as a reference dose (RfD). The RfD is an estimate of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of adverse effects during a lifetime.

The Agency released its first (December 1998) draft risk assessment for perchlorate in January 1999 and subjected it to independent external scientific peer review at a public peer review meeting. The 1998 draft document was revised to address peer review comments and to include the results of newer studies. EPA released a revised draft assessment in January 2002, which was subject to another round of independent external peer review and public comment. While the reviewers endorsed the Agency's approach and methods of analysis, the major issues identified by peer reviewers included the choice of the principal study (an animal study), the selection of thyroid hormone disruption as the critical endpoint and the appropriate application of uncertainty factors.

Following the second external peer review, several other federal agencies, including the DoD, NASA, and the Department of Energy (DOE) raised continuing issues with EPA's draft assessment and with the peer review. Subsequently, in consultation with EPA, the Interagency Working Group (IWG) on perchlorate (which had evolved from the IPSC in 2002 and co-chaired by OMB and the Office of Science and Technology Policy) requested a third external peer review of the draft perchlorate assessment and sent the January 2002 external review draft to the National Academy of Sciences (NAS) for immediate and accelerated review. This review was funded by EPA, DOD, DOE, and NASA. The NAS released their report in January 2005. The NAS panel recommended that the Agency use an RfD of 0.0007 mg/kg/day based on a human study (Greer et al., 2002). EPA endorsed this recommendation and used the NAS panel report "Health Implications of Perchlorate Ingestion" as the basis for establishing its RfD which was subsequently posted to the Integrated Risk Information System (IRIS) database in February 2005.

In carrying out their analysis, the NAS recommended the use of a human study (Greer et al., 2002) as the principal study. Because this study was based on healthy adult men and women, an uncertainty factor of 10 was applied to the no observed effect level (NOEL) identified from the Greer data to protect the

most sensitive population, i.e., the fetuses of pregnant women who might have hypothyroidism or iodide deficiency. The NAS indicated that deriving the RfD to prevent a nonadverse precursor effect, which would precede an adverse effect, is a conservative and health-protective approach to perchlorate risk assessment.

The Agency has a great deal of interest in the findings regarding perchlorate exposure and thyroid function that were recently reported by CDC researchers. The CDC researchers recommend additional research to affirm and build upon their findings, and we look forward to reviewing these additional studies. EPA will be monitoring analyses of NHANES data by CDC and other research activities from the federal and private sectors which may further inform the health effects of perchlorate. These data will be evaluated as they are made available to inform future assessment and research activities. In the meantime, we believe the current RfD is a scientifically appropriate value for use in Agency decision-making.

Risk Management for Contaminated Sites

Prior to the release of the 2005 NAS study and the subsequent issuance of EPA's January 2006 Assessment Guidance for Perchlorate, EPA's Superfund program used guidance that recommended a range of 4 to 18 ppb perchlorate in ground water as a preliminary remediation goal (PRG) to identify sites that may present a risk warranting cleanup. These values were recommended in the Agency's 1999 Interim Assessment Guidance for Perchlorate and a January 2003 memo from then Assistant Administrator Marianne L. Horinko to EPA's Assistant Administrators and Regional Administrators. These values were calculated based on EPA's preliminary RfD and standard exposure values of 70 kg body weight and 2 liters of water consumed per day.

PRGs are developed based on readily available information, such as chemical-specific applicable or relevant and appropriate requirements (ARARs) or other reliable information and are modified, as necessary, as more information

becomes available during the Remedial Investigation/Feasibility Study (RI/FS). PRGs are not final cleanup levels, but merely the starting point for identifying site-specific goals. In accordance with the National Contingency Plan (NCP), the PRGs should be modified, as necessary, as more information becomes available at specific sites. This may include assessing factors such as actual and potential exposure pathways through environmental media and actual and potential exposure routes.

On January 26, 2006, EPA issued guidance which generally recommended a revised PRG of 24.5 ppb based on the RfD adopted by the Agency following the issuance of the NAS study. As is the case for all Superfund sites addressed under the NCP, final remediation goals are determined when the remedy is selected. Final remediation goals are developed considering such factors as concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a life time or part of a lifetime, incorporating an adequate margin of safety.

While there is information available which indicates that perchlorate has been found in food, EPA believes that the currently available data are too limited to calculate, on a national level, the relative exposure to perchlorate from water as opposed to food, which we refer to as the relative source contribution (RSC). However, where there are adequate data to estimate a site-specific RSC for drinking water, the final ground water cleanup level at a Superfund site may be modified accordingly. 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 would be considered an ARAR and used as the ground water cleanup level for sites in that state.

Based on the results of the NAS review and EPA's development of a revised PRG, the DoD issued their own policy on January 26, 2006, which adopted 24 ppb perchlorate as the level of concern for managing perchlorate in ground water. Both of the 2006 guidances were coordinated through the IWG.

Perchlorate has been found at 49 National Priorities List (NPL) sites out of 1562 current and deleted sites. Of these 49 sites, 15 are private sites and 34 are Federal Facilities. At approximately 31 sites, perchlorate concentrations in ground water or drinking water exceed 24.5 ppb.

Effective perchlorate treatment systems are already in operation at the San Gabriel, NASA-JPL, Lawrence Livermore (Site 300), and Aerojet sites in California, and at the Kerr-McGee site in Nevada. No Records of Decision (ROD) on perchlorate clean-up levels have been finalized at any Superfund sites since EPA issued the revised Guidance in 2006. EPA will continue to track the progress at all NPL sites where a cleanup decision has not yet been made in order to ensure the ground water is treated to levels that are protective of human health and the environment.

Risk Management for Drinking Water

The Agency has placed a high priority on making a regulatory determination for perchlorate as soon as possible. However, we want to ensure that any regulation presents a meaningful opportunity for health risk reduction.

The Safe Drinking Water Act (SDWA) has an established process for determining if unregulated contaminants pose a sufficient risk to public health to warrant regulation. The law requires the Agency to develop a Contaminant Candidate List (CCL), which is a list of unregulated contaminants that may require regulation. Perchlorate was placed on the first CCL which was released in 1998 and carried on to the second CCL which was published in February of 2005.

In making a determination to regulate a contaminant under the SDWA, the law requires EPA to consider three questions:

- Is the contaminant likely to cause an adverse effect on the health of persons?
- Is the contaminant known or likely to occur in public water systems at a frequency and level of public health concern?
- In the sole judgment of the Administrator, does regulation present a meaningful opportunity to reduce risk for persons served by public water systems?

When the Agency issued the first set of regulatory determinations for nine contaminants on the first CCL in 2003, we did not have sufficient information to make a regulatory determination for perchlorate. The Agency's risk assessment had not yet been finalized and we were continuing to collect occurrence data from public water systems under the first round of unregulated contaminant monitoring.

The Agency recently signed a Federal Register Notice with preliminary regulatory determinations for 11 contaminants on the second CCL. The Notice describes why the Agency is not making a preliminary determination on perchlorate at this time. While the Agency now has an RfD and drinking water occurrence data, we need to more fully characterize and understand perchlorate exposure. The Notice provides an extensive update on the Agency's review of perchlorate, including a summary of recent research, and requests comment on approaches the Agency has under consideration to help arrive at a final decision.

Health Effects

Based on the RfD, the Agency has sufficient information on health effects to inform a regulatory determination. However, as with any chemical, the Agency will continue to review any new research findings on perchlorate as they become available.

Occurrence in Drinking Water

To support our regulatory development process, the Agency requires short-term monitoring for specific contaminants under the Unregulated Contaminant Monitoring program (UCMR). During the first round of this program, 3,858 water systems were monitored for perchlorate during a one-year period between 2001 and 2003. This monitoring was designed to provide an assessment of perchlorate occurrence in public water supplies that was broadly representative of community water systems throughout the country.

Perchlorate was detected at levels above the minimum reporting level of 4 parts per billion (ppb) in approximately 2 percent of the more than 34,000 samples analyzed. The average concentration of the detected values was 9.8 ppb and the median concentration was 6.4 ppb. The samples in which perchlorate was detected were collected from 160 of 3,858 public water systems (4% of systems) located in 26 states and 2 territories.

We have determined that the existing data on the occurrence of perchlorate in public water supplies is sufficient to support our regulatory decision-making and, as such, it is not necessary to conduct additional perchlorate monitoring under the second UCMR. Additionally, monitoring under the second UCMR would not be completed until 2010 and the Agency intends to make a determination before that time. If necessary, EPA can require additional monitoring at a later time if new information indicates that additional sampling is warranted. If EPA determines that regulation of perchlorate in drinking water is necessary, on-going compliance monitoring of perchlorate would be part of any new standard.

Relative Source Contribution and Other Sources of Exposure

Before the Agency can make a determination as to whether it is appropriate to regulate perchlorate in drinking water, we need to better

understand total perchlorate exposure and the RSC (i.e., exposure to perchlorate from water as opposed to food sources).

An increasing number of studies have reported the presence of perchlorate in samples of various foods and, with this and other food information becoming available, use of a default assumption for the RSC may not be the best means to determine whether it is appropriate to regulate perchlorate in drinking water. We need to determine whether setting a drinking water standard would provide a meaningful opportunity to reduce risk for people served by public water systems, and we need to understand how public exposure compares to the RfD and what portion of the exposure comes from food versus water.

In the fall of 2004, EPA began to focus its attention on the food sampling results reported by FDA, titled "Exploratory Data on Perchlorate in Food." This initial data set included results from samples of bottled water, lettuce, and milk. While perchlorate was rarely detected in bottled water, it was consistently identified in milk and lettuce collected from this exploratory survey. Because these foods (milk, in particular) are widely consumed across most demographics, EPA realized that it would be necessary to further evaluate exposure through food consumption before making a regulatory determination on perchlorate.

On January 11, 2005, members of the NAS Panel on the Health Implications of Perchlorate Ingestion conducted a public briefing to discuss the findings detailed in their report. In response to a question posed at the briefing, panel members stated that exposure to perchlorate through food requires further study. At that time, EPA began to collect all available information pertaining to the study of perchlorate in food and, with the help of exposure analysts in the Office of Pesticide Programs, began to perform preliminary estimates of perchlorate exposure, based upon the data reported by FDA and other researchers. However, EPA determined that the readily available data at that time were too limited (in food type, sample size, geographic coverage, etc.) to

produce reliable estimates and accurately characterize food-borne exposure to perchlorate on a national scale.

The FDA has been conducting surveys to determine perchlorate levels in food since 2004. EPA's Federal Register Notice describes results from FDA studies and other published studies. The Agency is particularly interested in reviewing the results and associated exposure assessment from FDA's 2006 Total Diet Study when it has been peer reviewed and finalized. This will be the most comprehensive assessment of food exposure to date and is designed to provide estimates of total food exposure by region based on a representative market basket approach.

Researchers have also begun to investigate perchlorate occurrence in humans by analyzing for perchlorate in urine, breast milk and amniotic fluid. For example, CDC has included perchlorate in its National Biomonitoring Program which develops methods to measure environmental chemicals in humans. With this information, the CDC can obtain data on levels and trends of exposure to environmental chemicals in the U.S. population.

While food and other pathways may be important sources of perchlorate exposure, the Agency believes the currently available food data are inadequate to develop a better informed RSC. While the Agency awaits completion of the FDA Total Diet Study, we are also considering other options to better characterize exposure. These options could serve as an alternative and/or supplement to using food data to determine the RSC. Specifically, the Agency is considering, and seeking comment on the potential to use urine biomonitoring data to estimate perchlorate exposure. We have described a number of approaches in our Federal Register Notice and are seeking comment on their potential utility in informing a determination as to whether federal regulation of perchlorate in drinking water is necessary to protect public health.

Conclusion

The Agency is committed to examining the perchlorate science to ensure that our policies are protective of public health. Our cooperation with scientists across federal agencies, facilitated by the Interagency Working Group, has helped our assessment of perchlorate science. It allows us to share the considerable expertise of senior government scientists, as well as ensure that each Agency's research and analysis benefits from the findings of counterparts who are evaluating similar issues in other agencies. As new science and information become available, we will review and analyze the studies in conjunction with the body of other research that contributes to our understanding of perchlorate toxicity and exposure, particularly with respect to the effects on pregnant women and children. If the science suggests that changes should be made to any current or future EPA policies or decisions, the Agency will take appropriate action to protect public health.

Mr. WYNN. Thank you. Mr. Beehler.

STATEMENT OF ALEX BEEHLER, ASSISTANT DEPUTY UNDER SECRETARY OF DEFENSE, ENVIRONMENT, SAFETY, AND OCCUPATIONAL HEALTH, U.S. DEPARTMENT OF DEFENSE

Mr. BEEHLER. Thank you, Chairman Wynn, Ranking Member Shimkus, and distinguished members of the subcommittee. I appreciate the opportunity to appear before you today to address the Department of Defense activities relating to perchlorate, especially as there continues to be some misperceptions. I ask that my written testimony be submitted for the record, and I will provide brief summary remarks.

Let me first start by introducing Ms. Shannon Cuniff, who has been organizing the Department's response to perchlorate since her arrival in March 2004.

DOD relies on perchlorate as an oxidizer in explosives, pyrotechnics, rocket fuel, and missiles because it is by far the most efficient and stable propellant oxidizer available.

Over the past several years, research has revealed a number of non-DOD natural and manmade sources of perchlorate, such as road flares, fireworks, certain natural mineral formations, and fertilizers that can cause low-level, widespread contamination. Now, that an ability to differentiate between different sources of perchlorate exists, responsible parties can be identified with greater confidence.

Since November 2002, DOD policy specifically directs perchlorate assessment. DOD's most recent perchlorate policy of January 2006 requires perchlorate sampling in drinking water, groundwater, and wastewater discharges. The policy establishes a 24 ppb. level of concern in water. That is based on EPA's reference dose. This level of concern is simply a departure point for site-specific risk analyses in the absence of any applicable Federal or State standards. DOD has and will continue to comply with applicable Federal and State standards regarding perchlorate.

DOD has adopted a three-pronged approach to risk management of perchlorate. Number 1, assessing potential releases. Number 2, taking appropriate response actions where necessary. And No. 3, investing in R&D. Through fiscal year 2006, perchlorate sampling has been conducted at 237 DOD installations former properties. The majority of samples taken at sites where perchlorate releases may have occurred have resulted either in non-detect or levels well below the current EPA reference dose.

DOD and the State of California have worked collaboratively to develop a prioritization protocol where 924 current and formerly used defense sites in California were jointly reviewed. So far, 97 percent do not currently appear to pose a threat to drinking water related to perchlorate. The remaining 3 percent are still under joint review.

Site-specific risk assessments are conducted under the Defense Environmental Restoration Program (DERP) and CERCLA in coordination with EPA and/or State regulators. The DERP Annual Report to Congress provides summaries of cleanup actions at DOD installations. Even before there was any clear regulatory requirement, DOD began response actions at a number of bases including

Massachusetts Military Reserve, Redstone Arsenal, Vandenburg, and Edwards Air Forces Bases, and the Naval Weapons Industrial Reserve Plant.

DOD has invested over $114 million in research related to perchlorate to advance the state of technology regarding perchlorate treatment in water and has found suitable substitutes for a number of military specific applications, such as simulators that account for a majority of perchlorate expended in Army training ranges. Work is also underway to eliminate perchlorate in pyrotechnic flare compositions and in solid rocket propellants.

DOD's six drinking water treatment technology demonstrations in the Inland Empire have added approximately 5,000 gallons per minute of new treatment capacity with reduced cost. DOD performed this work even though there is no evidence that perchlorate found in this area results from current or former DOD installations.

The latest round of DOD-wide perchlorate sampling data shows that we are taking appropriate response actions and DOD installations overall do not appear to be a significant source of perchlorate releases to the Nation's drinking water. We believe that DOD has acted responsibly as the science and understanding of perchlorate has evolved.

In closing, Mr. Chairman, I sincerely thank you for this opportunity to highlight the department's activities related to perchlorate.

[The prepared statement of Mr. Beehler follows:]

HOLD UNTIL RELEASED
BY THE COMMITTEE

STATEMENT OF

MR. ALEX BEEHLER
ASSISTANT DEPUTY UNDER SECRETARY OF DEFENSE
(ENVIRONMENT, SAFETY, & OCCUPATIONAL HEALTH)

BEFORE THE
SUBCOMMITTEE ON ENVIRONMENT AND HAZARDOUS MATERIALS
OF THE
HOUSE ENERGY AND COMMERCE COMMITTEE

April 25, 2007

Chairman Wynn, Congressman Shimkus, and distinguished members of the Subcommittee, I appreciate the opportunity to appear before you today to address the Department of Defense's activities related to the chemical compound perchlorate, especially as there continue to be some misperceptions about the Department's response to perchlorate.

Overview

Perchlorate is both man-made and naturally occurring. Since the 1940s, DoD has used potassium and ammonium perchlorate as an oxidizer in explosives, pyrotechnics, rocket fuel, and missiles. It is by far the safest, most efficient and stable propellant oxidizer available. Perchlorate has a high ignition temperature, controllable burn rate, and stable chemical characteristics that reduce handling and storage risks and the likelihood of unexpected detonations.

Private industry uses perchlorate in explosives, the production of matches, dyes, road flares, fireworks, and paints. It is also found naturally in some fertilizers used in agriculture. Perchlorate is highly soluble in water and EPA and several states have taken or are considering measures to address public health concerns.

DoD Policy

Due to a potential public health threat, DoD has had perchlorate policies specifically directing perchlorate assessment since November 2002. DoD's most recent perchlorate policy, generated in January 2006, requires perchlorate sampling in drinking water, groundwater, and wastewater discharges. In this policy, DoD also established a 24 part per billion (ppb) "level of concern" in water that is based on the science review by the National Academy of Sciences and EPA's reference dose. The DoD "level of concern" is simply a departure point for site-specific risk analyses in the absence of any applicable Federal or state standards. Site-specific risk

analyses may include consideration of the relative source contribution of perchlorate in food and water. I want to make it clear to the Committee that DoD has, and will continue to comply with applicable Federal or state standards regarding perchlorate.

DoD's Integrated Risk Management Approach to Perchlorate

DoD has adopted a three-pronged approach to risk management of perchlorate -- Assessment of potential releases, taking appropriate response actions where necessary, and investing in research and development.

Assessment of Potential Releases

Cumulatively through FY 2006, perchlorate sampling has been conducted at 237 DoD installations or former properties. The majority of samples taken at sites where perchlorate releases may have occurred have resulted either in "non-detects" or levels well below the current EPA reference dose, which translates to a drinking water equivalent level of 24.5 ppb; in fact, of the 146 installations that reported sampling in FY 2006, only nine installations reported a detection above 4 ppb in any media. Eight installations indicated detection above 24 pbb in a media. Some of these detections are in point-source wastewaters subject to limits in state discharge permits. Since 2004, sampling results have been posted on our publicly accessible web site (https://www.denix.osd.mil/denix/Public/Library/Water/Perchlorate/perchlorate.html).

Perchlorate has been a particular concern in California. DoD and the State of California worked collaboratively to develop a prioritization protocol for assessing DoD sites with *potential* perchlorate releases. I emphasize the word "potential" -- 924 current and formerly used Defense sites in California were jointly reviewed by DoD and the State – so far, 97 percent do not currently appear to pose a threat to drinking water related to perchlorate. The remaining 3

percent have some confirmation sampling underway or the completed assessments are still being reviewed by Californian regulatory agencies.

Response Actions

Site-specific risk assessments are conducted under the Defense Environmental Restoration Program (DERP), the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and in accordance with the National Contingency Plan. They are also conducted in coordination with EPA and/or state regulators. Where a site-specific assessment indicates that a release presents an unacceptable risk to human health or the environment, DoD is taking appropriate response actions. The DERP Annual Report to Congress provides summaries of cleanup actions at DoD installations. This report is publicly available at https://www.denix.osd.mil/denix/Public/News/news.html#osd

Even before there was any clear regulatory requirement, DoD began cleanup at a number of bases including Massachusetts Military Reservation; Redstone Arsenal, Alabama; Vandenberg Air Force Base, California; Edwards Air Force Base, California; and the Naval Weapons Industrial Reserve Plant McGregor, Texas. At McGregor, the Navy's in-situ biological treatment system is treating perchlorate in groundwater and soil; this is the first – and world's largest – full-scale bio-wall application for groundwater remediation of perchlorate and volatile organic compounds. Recent groundwater data shows a marked decrease in the amount of perchlorate in groundwater. In fact, last October, McGregor became the first U.S. Navy facility to receive a "Ready for Reuse" determination from the EPA. This verifies that environmental conditions at the property are protective of human health and the environment for its current and future commercial, industrial and agricultural uses.

Research and Development

DoD has invested over $114 million in research related to perchlorate toxicity, treatment technologies, perchlorate substitutions in munitions and training materials, perchlorate recycling, and analytical and detection advancements. Our investments are paying dividends -- we have advanced the state-of-technology regarding perchlorate treatment in water and have found suitable substitutes for a number of military-specific applications.

For example, our research and development has achieved advances in ex-situ treatment using bio-reactors and ion exchange, and in-situ treatment using bioremediation, permeable reactive barriers, substrate injection, soil composting, and phytoremediation. In Fiscal Years 2005 through 2007, DoD competitively selected and deployed six water treatment technology demonstrations in California in Rialto, Colton, Fontana, West Valley and East Valley. Both the water purveyors and the California Department of Health Services were involved. These projects added approximately 5,000 gallons per minute of new treatment capacity in the Inland Empire region with significant cost reduction potential in capital and operation and maintenance costs.

Regarding military unique applications, research and development has led to finding perchlorate substitutes for ground burst simulators and hand grenade simulators. These simulators accounted for a majority of expended perchlorate on Army training ranges in past years. Production of the replacement is scheduled to begin in 2008. Work is underway to eliminate perchlorate in pyrotechnic flare compositions. Lab-scale testing has identified perchlorate-free red, green, and yellow signal flare compositions and they are currently in the full-scale demonstration phase. Finally, alternatives to potentially replace ammonium

perchlorate in solid rocket propellants are undergoing testing and evaluation. The alternatives must meet high performance specifications and have a low environmental burden.

Over the past several years, the nation has learned more about a number of natural and man-made sources of perchlorate that can cause low-level, wide-spread contamination. These sources include road flares, fireworks, certain natural mineral formations, and agricultural fertilizers. The situation is far more complex than originally thought. Now that an ability to differentiate between different sources of perchlorate exists, responsible parties can be identified with greater confidence.

Conclusion

The latest round of DoD-wide perchlorate sampling data shows that we are taking appropriate response actions and DoD installations, overall, do not appear to be a significant source of perchlorate releases to the nation's drinking water. In summary, we believe that DoD has acted responsibly at each step as the science and understanding of perchlorate has evolved. Protection of human health and the environment is an important component within DoD's mission. In closing, I sincerely thank the Committee for this opportunity to highlight the Department's activities related to perchlorate.

Mr. WYNN. Thank you, Mr. Beehler. This concludes the opening statements of our first panel, and the Chair would like to recognize himself now for 5 minutes of questioning. I want to go directly to you, Mr. Beehler, because I was a bit confused. Did you state in one of your statistical points that 97 percent of the sites did not pose a threat to human health?

Mr. BEEHLER. As far as the work that we have done in conjunction with the State of California, we have reviewed in the State of California 924 sites jointly.

Mr. WYNN. Well, did you say that 97 percent of them didn't pose a threat? Is that your contention?

Mr. BEEHLER. That is what the State of California has determined, and we agree with them.

Mr. WYNN. Did DOD determine or did California determine?

Mr. BEEHLER. The State of California determined jointly with DOD.

Mr. WYNN. That there was no threat to human health?

Mr. BEEHLER. That is correct.

Mr. WYNN. All right. Well, if that is the case, why did you say that you are waiting? And maybe this is not DOD's position, but it was reported by Mr. Stephenson that DOD's position was that you were waiting on EPA to develop a safe drinking water standard.

Mr. BEEHLER. Mr. Chairman, we are not. We are stepping out. We have stepped out over the past several years. That is why I have indicated in my testimony, both written and oral, that we have undertaken sampling.

Mr. WYNN. Let me just jump in. I think you are doing some things to sample and monitor. I don't deny that. But my question though is you said that there was substitutes available for the use of perchlorate in your explosives. Why aren't you using the substitutes?

Mr. BEEHLER. Mr. Chairman, what I said was that we have spent millions of dollars developing technology to make sure that in certain areas, for instance, we can come up with substitutes such as——

Mr. WYNN. So you don't have them or you do have them?

Mr. BEEHLER. And these things have to be tested to make sure that they are effective. In the case of simulators, the testing is complete, and we are now basically substituting those simulators so that within a matter of about 12 months there will be no more simulators used by the Army that has perchlorate. We are doing similar testing with the hope that in propellants and flare compositions that we have the same effective credibility, and therefore we can effectively make the substitutes.

Mr. WYNN. Thank you. Mr. Stephenson, was it your position that DOD was waiting on EPA? Was that your finding?

Mr. STEPHENSON. No, what we said is they are on a case-by-case basis. They are doing some monitoring and cleanup. We haven't looked at this in the last 18 months, so there may be more action since our report was issued. What we said is that until there is a standard, their position is that they are not required to do anything.

Mr. WYNN. Well, isn't that the same as waiting on a standard?

Mr. STEPHENSON. Well, to me it is. I don't——

Mr. BEEHLER. Well, I beg to differ with that testimony.

Mr. WYNN. Thank you. I am asking Mr. Stephenson. I think the last comment clarified. He interpreted it as waiting on a standard. Mr. Stephenson, what percent is caused by human activity?

Mr. STEPHENSON. At the time we looked at the data of those 400 sites, there was almost half of them where the source could not be determined. So some of that could be naturally occurring, as Mr. Shimkus reported. But it is very difficult to determine what the source is. That is why we are suggesting that more comprehensive data needs to be developed.

Mr. WYNN. Well, the question I have is whether manmade or naturally occurring, does it enter the drinking water supply?

Mr. STEPHENSON. Well, you can't say until you know the sources of the contamination. We know of those 400 sites, certainly at least half of them were manmade causes.

Mr. WYNN. All right.

Mr. STEPHENSON. And DOD accounts for 90 percent of the use of the material.

Mr. WYNN. OK, Dr. Pirkle, you were saying that you felt that there was widespread exposure to perchlorate. I think you cited 43 million women, or was it 43 million individuals?

Dr. PIRKLE. We actually found widespread exposure. Every single person that we sampled in the survey 6 years and older, 2,820 people, 100 percent had measurable levels of perchlorate in their urine. It was 43 million women who had low levels of iodine, which put them in the at-risk group for changes in thyroid hormone levels resulting from perchlorate exposure. But in terms of widespread exposure, we found measurable levels of perchlorate in all persons that we tested in our survey.

Mr. WYNN. Did you come to a conclusion about whether this low iodine level posed a significant health risk?

Dr. PIRKLE. The low iodine level?

Mr. WYNN. Yes. Wasn't that what you said that you found low iodine level in 43 million women, in urine of 43 million women?

Dr. PIRKLE. Right, the concept is that perchlorate is likely to have a larger effect in people who have low amounts of iodine since it blocks iodine uptake into the thyroid. And so it was women with low urinary iodine that were at risk that supported the finding of an association between perchlorate exposure and changes in thyroid hormone levels. So, yes, 43 million women we would consider at risk for thyroid hormone changes from exposure to perchlorate.

Mr. WYNN. That would seem to be a pretty significant potential risk. I see my time has expired. I would like to call on the ranking member, Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. The first thing, as a conservative Republican, that I want to be accused of is defending of bureaucracy. So I will not go in that direction, but I do have some questions, and I would like to refer these to Mr. Grumbles. This is the tried-and-true Chairman Dingell approach. If you can answer with a "yes" and "no" answer, I would appreciate it. Are you following the procedures laid out in the Safe Drinking Water Act, as amended, in determining whether to regulate perchlorate?

Mr. GRUMBLES. Yes.

Mr. SHIMKUS. Mr. Grumbles, some of my colleagues think that you and the Agency are stalling. Are you stalling?

Mr. GRUMBLES. No.

Mr. SHIMKUS. Does the Agency believe that the regulatory timelines of 1 year to propose an MCL for perchlorate and 18 months to go final with it are realistic and better serve the goal of setting an appropriate standard?

Mr. GRUMBLES. Can I provide you something more than a "yes" or "no" on that? We don't have an official position on the legislation.

Mr. SHIMKUS. But this is a legislative hearing.

Mr. GRUMBLES. I do have concerns.

Mr. SHIMKUS. This is a legislative hearing.

Mr. GRUMBLES. There is not an official——

Mr. SHIMKUS. Isn't it?

Mr. WYNN. If it is a legislative hearing, why don't you let the witness answer?

Mr. SHIMKUS. Just asking.

Mr. GRUMBLES. I would have concerns about the schedule and taking the decision away from the Agency. I think the general approach should be to let the science drive the result, and so I would have concerns about the schedule that is laid out.

Mr. SHIMKUS. Do you have a problem with the three legal requirements of the Safe Drinking Water Act regarding to the regulation of contaminants?

Mr. GRUMBLES. No.

Mr. SHIMKUS. Do you think that a statutory exemption to them, not matter how well meaning, limits your ability to set a health protection level?

Mr. GRUMBLES. Well, we are working with the 1996 amendments. We think that is a very good approach. It requires a lot of effort, a lot of coordination. But we think it is the vision of the subcommittee in 1996 to put that structure into place, to look at health effects and occurrence and whether there is a meaningful opportunity to reduce risks to human health with public water systems is a good one that we should continue to work through that process.

Mr. SHIMKUS. OK, let me ask you and, I think, Mr. Stephenson. Assuming that we want credible science, real science, to help dictate standards, and obviously the concerns from my colleagues is we are not moving fast enough. What can we do here to speed up the process so that if we move on a standard, it is a credible, well-intentioned, scientifically-based standard, and we are ready to assume those costs? Is there anything we can do through language or through expenditures of funds to help speed up this conglomeration of scientific information and knowledge? Mr. Stephenson?

Mr. STEPHENSON. It is a complicated issue, but at a minimum, what our work showed is it is very difficult to determine how widespread perchlorate exposure is. So even requiring better monitoring than it currently being done as Mr. Grumbles mentioned there has been one look at drinking water facilities over a 1-year period between 2001 and 2003. That was enough evidence for them to answer that part of the requirement to set a drinking water standard.

Now, we are looking at more research. We are not a scientific organization so——

Mr. SHIMKUS. Let me go to Mr. Grumbles. Is there anything we can do to kind of speed this process up?

Mr. GRUMBLES. Well, I think we truly welcome the congressional oversight and the interest in getting to the end of this complex process that the statute envisioned in the 1996 amendments. And we are putting at a high priority on getting to the end of that process, and what it really hinges on——

Mr. SHIMKUS. If you can summarize, I have two more points I want to make before my time is up.

Mr. GRUMBLES. OK. Well, we think the key is to let the scientists among the agencies inform the administrator so that he can, in his sole judgment, make that determination about meaningful opportunities to reduce risk.

Mr. SHIMKUS. Great, thank you. And we address this letter from the Association of Metropolitan Water Agencies that was submitted in support of legislation. And they represent huge water companies. What we don't have is letters of support from the NAWC, which is the for-profit water companies, the AWWA, which is a mid-size, like the city of Springfield, the State capital of Illinois, or even the rurals as I mentioned earlier. And that is kind of my concern that we have everybody involved with.

And just referring to the committee's staff, this comes from the GAO on the map. We said MCL. The MCL will mandate national standards and testing. And we have States that have no perchlorate, none. But the burden of testing and research will be placed upon the ratepayers and the citizens and may delay deployment of water. Thank you, Mr. Chairman.

Mr. WYNN. The gentleman's time is—I believe Mr. Stupak is next, but you wanted to defer. That would be fine. I would like to call on Ms. Solis.

Ms. SOLIS. Thank you, Mr. Chairman. I would like to just state for the record also that in fact we don't know where perchlorate is. And in many cases, the ratepayers, because we don't have any relief from the Federal Government or DOD, are having to pay for much of the cleanup. In particular, in my district, Riverside and San Bernardino where we are finding more exposure. I can't understand why we continue to talk about the science, the science, the science, when we know that exposure does have devastating effect on communities.

I have a lot of questions. I probably won't be able to get through all of them, but I want to begin with Mr. Grumbles, if I might. The Metropolitan Water District in southern California is one of the Nation's largest providers that treats drinking water. They work with helping to move 1.5 billion gallons of water through its distribution system, serving 18 million people. In recent correspondence, Metropolitan stated that perchlorate contamination of local groundwater basins remains a serious threat to local water supplies.

According to your written testimony, one of Administrator Johnson's key principles for EPA is to "use the best available science for decision making to accelerate the pace of environmental protection." And as you are aware, the State Drinking Water Act author-

izes the U.S. EPA to set a national health-based standard for drinking water to protect against both naturally occurring and manmade contaminants.

Since the Act was last amended in 1996, has the EPA set drinking water standards for any new emerging contaminants which were not otherwise required by the Safe Drinking Water Act or by consent decree? A yes or no.

Mr. GRUMBLES. The short answer is no.

Ms. SOLIS. OK.

Mr. GRUMBLES. The longer answer is that we have them on our list for additional research and information and review.

Ms. SOLIS. OK, I would like to ask Mr. Beehler about Department of Defense history regarding perchlorate contamination. Beginning back in 2002, each year since, the Department of Defense actively sought exemptions from public health and environmental laws which protect drinking water supplies from chemical constituents and military munitions, including perchlorate.

In a letter dated June 27, 2003, the EPA reported that the Defense Department is deferring any cleanup action, including the interim measure, until completion of a final perchlorate standard regarding cleanup at Aberdeen Proving Grounds.

And in May 2005, a GAO office report noted that according to EPA and State officials, the Department of Defense has been reluctant to sample on or near active installations because there is no Federal regulatory standard for perchlorate. According to the most recent DOD information that was provided to the committee, there are 61 Superfund Federal facility sites where either the soil, sediment, surface, or groundwater is contaminated with perchlorate. Thirty-four of these are Department of Defense facilities with sampling results that exceed EPA's current reference dose guidance level of 24 ppb. This includes facilities with extremely high levels of perchlorate.

In fact, Mr. Grumbles's written testimony indicates "no record of decision on perchlorate cleanup levels have been finalized at any Superfund site since EPA issued the revised guidance of 2006." So my question is: at any of the 61 Federal facilities, have they completed a record of decision under CERCLA documenting the nature and extent of the contamination or selected remedy?

Mr. BEEHLER. I will take that for the record. I would like to say three things. Number 1, I was not at DOD prior to January 2004. So I cannot comment on what transpired in 2003. And we have since 2004 engaged in sampling. We have done response actions at at least 12 different sites which we have provided the House Energy Commerce Committee——

Ms. SOLIS. Thank you very much.

Mr. BEEHLER [continuing]. take action without having had——

Ms. SOLIS. Excuse me. I have limited time. My next question is again for Mr. Grumbles. In a letter dated July 16, 2003, the EPA region 10 relinquished its concurrent oversight role for cleanup. In a letter, Region 10 noticed some disturbing behavior patterns in the letter, which state "on many issues, the Army has not been responsive to EPA's comments. Significant data gaps in procedurals at Camp Bonneville are the result of lack of cooperation and collaboration in the base closure team process. Again, the site lacks

a necessary level of site characterization information. We believe this information could have been developed had the Army incorporated our comments into their characterization, work plans, and related analysis over the past 7 years."

The letter notes that the Army's refusal to publish in any Federal Superfund decision documents clear statements of applicable requirements for cleanup actions taken, which are needed for regulators and the public to track the Army's compliance. It also noted that the Army unilaterally made field changes without consulting regulators and in some cases rendering field work useless. Rather than use its authority, EPA relinquished its concurrent oversight role for cleanup.

To me, this case exemplifies the ongoing refusal of DOD to cooperate and the failure of EPA to use its enforcement authority. Mr. Beehler, why was the Army not responsive to Region 10 comments?

Mr. BEEHLER. I will have to look into that. I will provide the committee with the facts and the answer.

Ms. SOLIS. And, Mr. Grumbles, why did EPA walk away from the table rather than use enforcement authority?

Mr. GRUMBLES. I am going to defer to Ms. Bodine.

Mr. WYNN. I would like Ms. Bodine to go ahead and complete her answer, but then the gentlelady's time will have expired.

Ms. BODINE. Could you tell me the date of that letter because I would like to state that since January 2006——

Ms. SOLIS. July 16, 2003.

Ms. BODINE. Since January 2006, when EPA put out its preliminary goal, DOD also put out guidance on perchlorate also establishing the 24.5 as a level of concern. We haven't had the same problems with DOD being willing to go out and sample. Now, we have responsibilities for oversight at NPL sites. We have to make sure that CERCLA is being met. We have some responsibilities at BRAC sites. We do have order authority if there is an imminent and substantial endangerment. But as to this specific site, I will too take the question for the record. But I do want to say that with respect to the debate over whether perchlorate is a contaminant of concern, that debate is over. Obviously EPA believes that. We aren't hearing from DOD that it is not a contaminant.

Ms. SOLIS. Mr. Chairman, I just want to submit the letter that is dated July 16 for the record.

Mr. WYNN. Certainly. Without objection the letter is admitted for the record.

Mr. WYNN. The Chair is pleased to recognize the ranking member of the full committee, the gentleman from Texas, Mr. Barton.

Mr. BARTON. Thank you, Mr. Chairman. I am not so much going to ask questions. Just make a brief statement. I understand that you and Ranking Member Shimkus had a dialog at the beginning of this hearing in which Mr. Shimkus expressed some consternation that what was an oversight hearing has turned into a legislative hearing. We are certainly not opposed to legislating in this area, but if that is the will of you and Mr. Dingell, we do want to use regular order. And I understand that you and Mr. Shimkus have agreed to have a second hearing, and if we are going to do this, let us do it right.

This is a serious issue. Ms. Solis has a bill that she has put in. We had, on the minority, several other witnesses. If we had known it was a legislative hearing, we would have liked to have asked, and as far as I know, you and Mr. Dingell would have approved their appearance. So I am told at the staff level that you and Mr. Shimkus have an agreement, and we will go forward.

But we know that you get to set the agenda, but we like to know what the agenda is so that we can work with you because this is an issue that has been around, and it needs to be addressed in a bipartisan comprehensive fashion. And I would be happy to yield to you for any comments if you would like to respond to that.

Mr. WYNN. I thank the ranking member. I want to clarify we did not agree to a second hearing. We agreed that we would work together to get any input that was felt was lacking. At the staff level—and you are right—there is some staff level considerations. It was discussed as early as April 9 that this hearing would cover the legislative bill before us today. We also provided the standard opportunity for the minority to offer witnesses. They have offered one witness, but the other witnesses weren't mentioned to us at that time.

We have followed essentially regular order in proceeding is my opinion. But the point is we want to work together in a bipartisan fashion. We realize that there are concerns. Ranking Member Shimkus talked about the concerns of rural communities. We certainly don't want to ignore them. We want to find ways to make sure that those concerns or the concerns of the States are included in our deliberations. So my commitment to him was that I would work with him to make sure any concerns that he had were taken under consideration.

Mr. BARTON. Are you ruling now that a second hearing is purely a legislative hearing? Is that something that you are not interested in doing?

Mr. WYNN. I don't know that that is necessary at this time. I am willing to have further conversations with Mr. Shimkus, but given the nature of the bill, the bill is not attempting to regulate itself. The substance of the bill is basically to ask EPA to regulate. So it is not as though we are making any real decisions here, other than saying EPA needs to adopt a sense of urgency and move forward. So there is no content on which a second hearing could——

Mr. BARTON. Well, we don't have any utilities represented. There is only one representative from a State. There is a gentleman on one of the panels from Connecticut, I believe. I really do think if the intent is to legislate, we need to be a little bit more public about it, and I would hope that we could have at least one more hearing. But I don't want to belabor the point. Just that I was a little surprised. Now, maybe it is my job these days to be surprised so——

Mr. WYNN. No, we don't want there to be any surprises, and I certainly hope that there wouldn't be any. And, as I said, I certainly would like to hear what Mr. Shimkus or your side has to offer in terms of additional information. But we did make a standard and regular procedure offer of witnesses.

Mr. BARTON. Well, I yield back my time, Mr. Chairman. We look forward to working with you.

Ms. SOLIS. Mr. Chairman, would you yield just for 1 minute?

Mr. WYNN. I am happy to yield to you.

Mr. BARTON. Well, it is my time, but I will be happy to yield to the gentlelady from California.

Ms. SOLIS. Thank you, Mr. Barton. I would just like to offer that we have heard from the utilities, and we do have letters of support that are going to be included in the record. And we certainly want to hear from rural America. We certainly want to hear from other interested parties, but we have had this discussion time and time again in as many years as I have served on this committee. And I think that we are not forcing EPA to set one standard. We are saying you have a job for due diligence, and that should be carried out. We have waited 11 years. Thank you, Mr. Chairman.

Mr. BARTON. I yield back.

Mr. WYNN. I thank the gentleman. At this time, recognize the gentleman from Michigan, Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman. Dr. Brackett, you indicated to your 2004 and 2005 studies, where do the tomatoes, lettuce, spinach, what part of the country did that come from?

Mr. BRACKETT. That initially came from the areas that we thought might have the highest risk so it would be the western States.

Mr. STUPAK. Western States, Salinas Valley?

Mr. BRACKETT. I don't recall exactly where. I think there were some from Salinas, some from Arizona as well.

Mr. STUPAK. Well, Salinas Valley was the subject of our hearing yesterday again with all the *E. coli,* salmonella, and now perchlorate. Has the EPA ever looked at quarantining this area for leafy produce and vegetables, things like that?

Mr. BRACKETT. EPA, FDA?

Mr. STUPAK. Yes, FDA.

Mr. BRACKETT. At this point, we don't have quarantine authority to do that if there was something like that.

Mr. STUPAK. OK, is that something you would like to have?

Mr. BRACKETT. Well, I guess we would have to look at finding out why one would need it or how one could——

Mr. STUPAK. Well, you had 20 outbreaks in 10 years in that area. And according to your testimony you found perchlorate in lettuce, tomatoes, and spinach in the produce being produced in this area. Is that concerning?

Mr. BRACKETT. Does it concern us that we have that problem, perchlorate? Well, we are interested in finding out. But the important——

Mr. STUPAK. Well, doesn't it concern you when you put perchlorate with the *E. coli*, with the salmonella in the same part of the country?

Mr. BRACKETT. No, because they are independent sort of problems. In the case of *E. coli* and salmonella, those are serious problems. We know that there is a serious health effect. In the case of perchlorate, much of our survey is to establish the baseline.

Mr. STUPAK. But perchlorate doesn't aggravate or exacerbate that problem?

Mr. BRACKETT. Not to my knowledge.

Mr. STUPAK. Has the FDA tested that?

Mr. BRACKETT. Tested whether it aggravates——

Mr. STUPAK. Perchlorate and *E. coli* found in similar plants, or do you just do one test for *E. coli* and one for salmonella?

Mr. BRACKETT. They are separate analyses. When we go and do an assignment for perchlorate, it is just for perchlorate unless it is part of the TDS and with a whole range of different ingredients.

Mr. STUPAK. So you would only do it for perchlorate. You wouldn't do it for *E. coli* then?

Mr. BRACKETT. No, these are surveillance samples to establish baseline. We actually have done that for *E. coli* as well in certain assignments.

Mr. STUPAK. Alright, have you thought about putting out any public alert about the presence of perchlorate in food supply?

Mr. BRACKETT. Not at this point. Once our assessment of exposure and working with our colleagues at EPA and with CDC, if we identify that it actually presents a risk, at that point, we have some options that we would do including alerting the public, at least certain subpopulations.

Mr. STUPAK. Well, are you concerned that perchlorate is a concern for developing fetuses and young children?

Mr. BRACKETT. Absolutely. We are concerned, but we want to make sure that there is in fact a true risk there that we would have to take an action for.

Mr. STUPAK. What is going to determine the risk?

Mr. BRACKETT. Well, I think that the scientists that evaluated this. We rely a lot on our colleagues at CDC to take the data that we have——

Mr. STUPAK. Well, when do you think that will be taking place, when you will make some determination whether or not perchlorate is a risk to fetuses?

Mr. BRACKETT. Well, I think it will have to wait until all of the exposure assessments are done.

Mr. STUPAK. And when is that going to be?

Mr. BRACKETT. Well, the one based on our analyses of the 2004–05 is imminent. The report will come out anytime soon.

Mr. STUPAK. Any time soon, can you define that? The last time I asked, the EPA took 13 years, and we are still waiting.

Mr. BRACKETT. Well, I would say it is at the end of the pipeline. We are just waiting for it to be published.

Mr. STUPAK. Is the pipeline sooner than soon?

Mr. BRACKETT. I would say within months at the longest.

Mr. STUPAK. OK.

Mr. BRACKETT. But the more important part is really the TDS data where you have a broad representation of the human diet, and that will take later in the year in the form of a scientific publication.

Mr. STUPAK. And, Ms. Bodine, when you move from a standard of 4 ppb. to 24 ppb., why that increase?

Ms. BODINE. In 1999 and then reaffirmed in 2003, there was a risk range between 4 ppb. and 18 ppb.

Mr. STUPAK. Right.

Ms. BODINE. That was based on a provisional RfD that had been developed by EPA.

Mr. STUPAK. And now it went to 24, right?

Ms. BODINE. Because the Agency adopted a final reference dose, and so we changed our preliminary remediation goal to reflect that final reference dose. And, in fact, that was the only change that we made.

Mr. STUPAK. To 24 though? That's a significant change. That is 25 percent increase in the ppb. Did Department of Defense have input in increasing that to 24 ppb.?

Ms. BODINE. No, we took the ORD reference dose that was in our IRIS system and translated that into the preliminary remediation goal, just as we had done when we had the range of 4 ppb. to 18 ppb. We used exactly the same methodology. It was just using the final RfD reference dose that EPA had adopted.

Mr. STUPAK. OK. Mr. Beehler, in answering Ms. Solis, there has been no RODS on any military sites. There has been no records of decisions for cleanup on any, right? You have moved a little dirt. You have done some test pilots, but there has been no real cleanup. There has been no RODS entered.

Mr. BEEHLER. Well, No. 1, I said earlier that I would take for the record to confirm whether or not there had been RODS. Number 2, as I said earlier, you can do response actions. You don't need RODS, and as we have provided the staff, we have done response actions at at least 12 different sites that have affected——

Mr. STUPAK. No cleanups? None have been completed? Nothing has been cleaned up?

Mr. BEEHLER. Yes, there is a complete at the Navy Industrial Site in McGregor, TX, that has been given an EPA complete. Also, at White Oak, which did have a ROD—there White Oak in Maryland in the chairman's district. We performed cleanup there for perchlorate-contaminated soil, and that has also been completed.

Mr. STUPAK. OK.

Mr. WYNN. The gentleman's time has expired. At this time, the Chair will recognize Mrs. Capps from California.

Mrs. CAPPS. I want to thank you, Mr. Chairman, for having this hearing today and for the testimony of the witnesses, both in this panel and the one to come.

We know that perchlorate can damage the mental and physical development of people. Even very low levels of this dangerous chemical block the ability to produce hormones that are essential for brain function and development.

In my first question, I want to ask about how the exposure to perchlorate interferes with the thyroid gland. Dr. Pirkle, in your testimony today, you gave a very detailed explanation of CDC's thyroid study. Can you tell me whether CDC has a high level of confidence in the findings of that study? It is a simple answer.

Dr. PIRKLE. A high level of confidence? I would say the simple answer is "yes".

Mrs. CAPPS. Thank you. Mr. Gray, I would like to ask about your Agency. If you had used the CDC study, is it your belief that the reference dose might have decreased?

Mr. GRAY. Our reference dose is based upon advice that we received from the National Academy of Sciences that was designed to protect the most sensitive subpopulation with a margin of safety——

Mrs. CAPPS. But you are aware—I mean you listened to the testimony?

Mr. GRAY. Sure, and the work that has been done by CDC is top quality data, one of the leading——

Mrs. CAPPS. Would it have affected the reference dose?

Mr. GRAY. It would have been considered as part of the broad range of scientific information.

Mrs. CAPPS. That is kind of not a straight answer.

Mr. GRAY. No, it would have been considered, but I would suggest that a lot of scientists might agree, in fact, with the CDC conclusions that their results were unexpected and that further research is needed to confirm them.

Mrs. CAPPS. All right, I am going to move on, but I think that is very important to establish because the CDC has a high level of confidence in their study. I would love to talk now about children's health as it has been described today. And I want to thank Dr. Ginsberg for the written statement that he has prepared for the second panel.

Last year, EPA's Children Health Protection Advisory Committee expressed concern with EPA's preliminary remediation goal of 24.5 ppb. They said the goal was not protective of children's health, and that is a quote, because among other reasons, it failed to account for perchlorate exposures from food such as milk and lettuce. They also asked EPA to issue a maximum contaminant level for perchlorate in the interim. A health advisory for potable water that takes into account early life exposure. Unfortunately, EPA rejected this advisory committee's request. EPA says its guidance is protected because the NAS study, upon which the guidance is based, built in a factor of 10 to address the risk of the most sensitive populations, infants and children.

It also said that prospective Superfund sites should consider site-specific data including impacts to food supplies. I am concerned that public health is not being served here. My question to you, Mr. Grumbles, isn't it true that the built-in safety factor of 10 that EPA is relying on applies only to an individual's susceptibility in water and does not address other pathways of exposure, such as breast milk and food? Just a "yes" or "no" answer is good.

Mr. GRUMBLES. I would say that what you said about us rejecting the advice from the Children's Health Office is not entirely accurate. We are still looking at options such as the health advisory.

Mrs. CAPPS. Right, you are looking at options, but you didn't take it under immediate consideration.

Mr. GRUMBLES. Well, we have adopted the National Academy of Sciences's recommendations on reference dose because of a couple things, the conservative approach and looking at iodine uptake integration. It is a tenfold safety factor——

Mrs. CAPPS. Can I get to that point?

Mr. GRUMBLES. Sure.

Mrs. CAPPS. Is it true that your tenfold safety factor is based upon exposure just to water and not to other pathways such as breast milk and food?

Mr. GRAY. I would like to address that if I may please. Our reference doses are set irrespective of the exposures that are out there, the way in which the exposure occurs. What we then have

to determine, and part of what Mr. Grumbles's office is trying to understand, is the relative contribution to exposure that comes from food and what comes from water. But all of those go together in determining whether an exposure approaches the reference dose. The reference dose is independent of the route of exposure.

Mrs. CAPPS. You mean so it is inclusive then of food, breast milk, and water?

Mr. GRAY. Or any other source of exposure that might occur.

Mrs. CAPPS. So it is done on adults and children? Is this universe so inclusive then for children, for nursing infants?

Mr. GRAY. What we have done was our reference dose is an attempt in the way in which the Agency always proceeds to find a level of exposure that we believe—though there is some uncertainty around it—a level of exposure below which no adverse effects should occur. We got advice from the National Academies, and we adopted that level. The next thing we have to do to understand the situation that may be happening in the world is to understand how much exposure might be happening and how close we are coming to that reference dose. That is what we are actively doing right now.

Mrs. CAPPS. All right. Now, I am prevented from asking what I think is the most substantive question, but I am going to make it in the form of a final statement, if I could, one more second. To me, given the serious health threat posed by documented widespread exposures, I believe it is true that as early as 2005, the EPA was in a position to issue a drinking water standard for perchlorate. And my question is why has this not happened?

Mr. GRAY. During the period 2004–05 as the Agency has been focused on completing the statutory process that this subcommittee put into the statute and that we embrace, the key question was is there a meaningful opportunity to reduce the risk of human health for those consuming public water systems. And the key for us is the relative source contribution. That is what we are focused on, and so during that period of time, 2004–05, we were sharing information with scientists from other agencies, such as CDC and FDA. We are very much aware there were some very important new information coming onto the scene. New science, the Total Diet Study that Dr. Brackett was referring to. And that, to us, has been the key. I understand Congresswoman Solis is frustrated and wants us to make a "yes" or "no" answer on regulation, but the key for us has been over the last couple years and months to get a better sense of the total exposure. We have the data we need on occurrence. We have a reference dose, and the key has been the additional routes of exposure.

Mrs. CAPPS. With all due respect, sir, until you have a standard, there is no way to enforce it. And we could have a standard now. It is not going to be perfect, but we owe it to this country to have an established standard——

Mr. WYNN. The gentlelady's time is concluded. I don't believe there are any other questions of this panel; however, I know, because of the time limitations, the members of the committee have other questions that they want answers. So without objection, I would like to have members of the committee submit written questions to all of the panelists as they see fit. And I would request to

the panelists that they respond accordingly. Without objection, so ordered. And I want to again thank the panelists for their participation today.

Which will bring us to our second panel. I would like to introduce the panel first. We have with us Dr. Anila Jacob, the senior scientist at the Environmental Working Group. It is a delight to have her. Also we have Dr. Gary Ginsberg from the Connecticut Department of Public Health, and Dr. Robert Utiger from the Harvard Institute of Medicine. What we would like to do is have 5-minute opening statements from each of our witnesses, and that will be then followed by questions from the members. Dr. Jacob.

STATEMENT OF ANILA JACOB, M.D., SENIOR SCIENTIST, ENVIRONMENTAL WORKING GROUP

Dr. JACOB. Thank you. Mr. Chairman, distinguished members of the subcommittee, I am a senior scientist at the Environmental Working Group, a non-profit research and advocacy organization. I am also a practicing physician with board certification in internal medicine. Thank you for this opportunity to testify. The main points that I am going to make today are perchlorate contamination in the environment poses a significant threat to the health of millions of U.S. residents, particularly pregnant women and infants, and children have a right to be protected from environmental contaminants that may interfere with their optimal growth and cognitive development.

Perchlorate contamination in the environment has become a significant threat to public health. Many in the public health community have suspected this for years, but a recent series of major studies by scientists at the Centers for Disease Control and Prevention and academic institutions have confirmed these concerns.

These studies establish that exposure to perchlorate is widespread and that levels of perchlorate that are found in people are associated with significant decreases in thyroid hormone levels. Perchlorate has long been established in the medical literature as a potent compound with a proven capacity to lower thyroid hormone levels. This is important because lower thyroid hormone levels in pregnant women and infants are an established risk factor for abnormal brain development in the fetus and intellectual deficits in children.

The issue that has challenged public health officials over the last decade has been establishing the significance of the public health threat presented by the levels of perchlorate that are actually found in people. In the past year, this question has largely been answered. Two critical 2006 studies from the CDC have established that exposure to perchlorate is widespread and that the levels found in people are associated with statistically significant, measurable, and adverse changes in thyroid hormone levels.

In the first study, the CDC tested the urine of almost 3,000 people and found that perchlorate was in every person that they tested. They also found that perchlorate levels in children were 60 percent higher than in adults, meaning that kids are exposed to more perchlorate than adults, relative to their size.

In the second study, the CDC looked at the association between thyroid hormone levels and perchlorate in over 2,000 people. That

found that levels currently considered "safe" by the EPA were strongly associated with lowered thyroid hormone levels in a particularly vulnerable group of women, those with lower iodine levels. One-third of American women fall into this category. This is the first study to identify this group of women as particularly vulnerable to perchlorate.

Based on these CDC results, perchlorate exposure at just 5 ppb. could alter thyroid hormone levels in more than 2 million women of childbearing age in the U.S. from the normal into the abnormal range. If this happens during pregnancy, they would require medication to restore their thyroid hormone levels to the normal range to avoid adverse effects on brain development in their fetus.

Even more alarming are results from three recent CDC and academic studies on the content of perchlorate in U.S. breast milk. In all three studies, every single sample of breast milk tested was found to contain perchlorate. In addition, the average levels of perchlorate in breast milk in all three studies would expose infants to a level that exceeds the EPA RfD or safe daily dose. Breast milk seems to contain relatively higher concentrations of perchlorate when compared with average blood and urine levels in the population. This means that infants get a larger dose relative to their small size, not unlike an infant taking an adult dose of medicine, except in this case, it is a larger dose of a toxic compound.

To summarize, recent studies show that exposure to perchlorate at levels considered safe by the EPA are associated with significant harmful effects on thyroid hormone levels in adult women with lower iodine levels. Studies on U.S. breast milk by CDC and academic scientists show universal contamination in tested samples and strongly indicate that a significant number of breast-fed infants may be regularly exposed to perchlorate levels, which exceed EPA's safe dose.

This raises an important question. If perchlorate exposure far below the EPA RfD is linked to significant thyroid hormone changes in adult women, wouldn't one expect that perchlorate levels in breast milk that are well above the EPA RfD would present greater risk to breast-fed infants? The overwhelming weight of the evidence suggests that yes, these levels of perchlorate in breast milk will alter normal thyroid hormone levels and present a real threat to exposed infants. These findings elevate perchlorate into the first tier of known environmental hazards, along with compounds like mercury and lead, where the science clearly justifies strong protective measures by public health agencies.

These findings also demonstrate that the current EPA RfD of 24.5 ppb. is not protective of public health. It is not "safe." Recent research demonstrates that exposure to perchlorate at environmentally relevant levels poses a significant health threat to millions of U.S. residents, particularly pregnant women and infants. Therefore, I strongly support the efforts of Representative Solis and the cosponsors of the Safe Drinking Water for Healthy Communities Act of 2007. We must find the political will to enact this legislation, which is a critical step in establishing a health protective drinking water standard for perchlorate.

Our children have a right to be protected from environmental contaminants that may interfere with their optimal development.

As a physician, I believe that a safe drinking water standard or maximum contaminant level of no higher than 1 ppb. is necessary.

Thank you, Mr. Chairman. This concludes my prepared statement.

[The prepared statement of Dr. Jacob follows:]

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STATEMENT OF ANILA JACOB, MD, MPH

Senior Scientist
Environmental Working Group

Hearing on
Perchlorate: Health and Environmental Impacts of Unregulated Exposure
Before the
House of Representatives
Subcommittee on Environment and Hazardous Materials
of the
Committee on Energy and Commerce
Wednesday, April 25, 2007, at 10 am

Submitted for the Record

Mr. Chairman, distinguished Members of the Subcommittee: my name is Anila Jacob, and I am a Senior Scientist at the Environmental Working Group (EWG), a nonprofit research and advocacy organization based in Washington, DC, and Oakland, California. I am also a practicing internist. I would like to start by thanking the members of the committee for this opportunity.

Today, I will present data from research studies conducted by the Centers for Disease Control and Prevention (CDC) and academic scientists and published in highly respected peer reviewed journals that demonstrate that exposure to perchlorate is widespread and especially harmful to vulnerable populations. I will also outline why the current US Environmental Protection Agency (EPA) Reference Dose (RfD) of 24.5 parts per billion (ppb) is not protective of public health and why, as a physician, I believe that a maximum contaminant level (MCL) of no higher than 1 ppb for drinking

water is a necessary public health measure.

Summary

A series of major studies by the CDC and other scientists have confirmed what many in the public health community have suspected for years – that perchlorate contamination in the environment has become a significant threat to public health. These studies establish that exposure to perchlorate is widespread and that the levels of perchlorate that are found in people are associated with significant decreases in thyroid hormone levels.

Perchlorate has been long established in the medical literature as a potent compound with known capacity to lower thyroid hormone levels. Low thyroid hormone levels in pregnant women and infants, in turn, are an established risk factor for abnormal brain development in the fetus and intellectual deficits in children.

The question that has challenged public health professionals for the past decade is establishing the significance of the public health threat presented by the levels of perchlorate to which people are actually exposed. In the past year, this question has been largely resolved.

We now know that perchlorate in the environment and, more importantly, perchlorate levels detected in women of childbearing age and in breast milk are associated with statistically significant, measurable, and adverse changes in thyroid hormone levels that present very real health risks to infants and children.

These findings elevate perchlorate from the ranks of potential health threats into the first tier of known environmental hazards, along with compounds like mercury and lead, where the science clearly justifies strong protective measures by public health agencies.

These findings also demonstrate that the current EPA RfD of 24.5 ppb is not protective of public health; it is not "safe." Therefore, I strongly support the efforts of Representative Solis and the cosponsors of the *Safe Drinking Water for Healthy Communities Act of 2007*, H.R. 1747. This legislation is a critical step in establishing a health protective drinking water standard for perchlorate. As a physician, I believe that a safe drinking water standard (or MCL) of no higher than 1 ppb is a necessary measure.

Mechanism of Action of Perchlorate

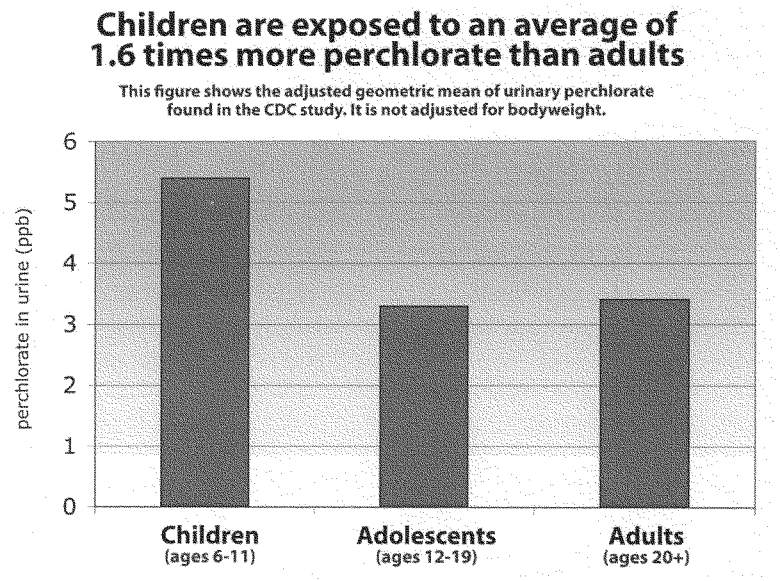
Iodine is the main building block of thyroid hormone. Perchlorate is a chemical contaminant that inhibits the uptake of iodine into the thyroid gland, thereby interfering with normal thyroid hormone production. Thyroid hormone is critical for normal growth and cognitive development in the fetus, infants, and young children. Inadequate thyroid hormone levels during the fetal period and infancy can result in intellectual deficits that persist throughout life (1).

Evidence of Exposure

In a recent study by scientists at the CDC, detectable levels of perchlorate were found in the urine of every one of 2,820 US residents (ages 6 and older) in a nationally representative sample, demonstrating that exposure to perchlorate is

ubiquitous in the US (2).

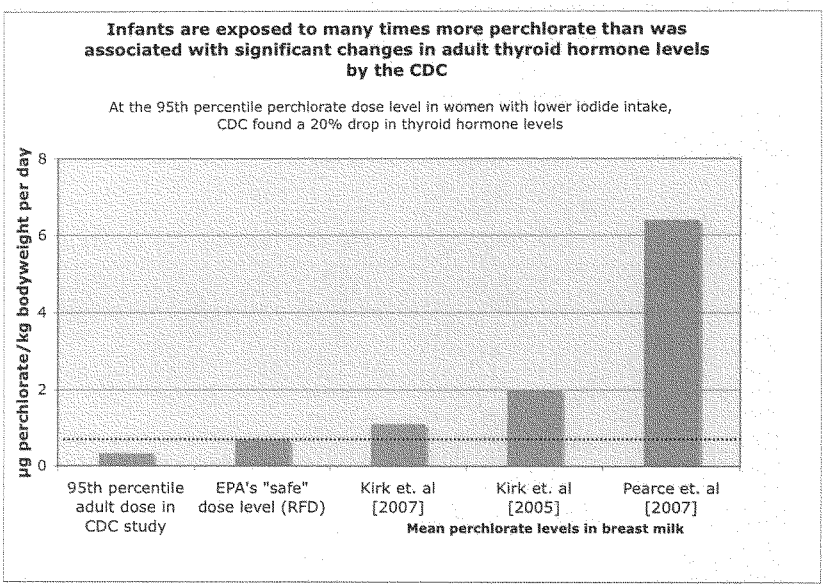
The findings in this study raise concerns. Urinary perchlorate levels in children ages 6 to 11 were 1.6 times higher than levels in adults, showing that children carry more perchlorate in their bodies than adults and, therefore, have higher exposures.



Blount BC, Valentin-Blasini L, Osterloh JD, Mauldin JP, Pirkle JL. 2006. Perchlorate exposure of the U.S. population, 2001-2002. Journal of Exposure Science and Environmental Epidemiology. Oct 18: epub ahead of print.

In three additional studies from CDC and academic scientists published in the past two years, samples of breast milk from different parts of the country were tested. Every single sample of breast milk in all three studies was positive for perchlorate. While this is startling in itself, what is more troubling is that average levels of perchlorate in breast milk in these studies would expose a significant number of

breast fed infants to perchlorate levels above the EPA's recommended dose, or RfD (3,4,5).



Further, in all three breast milk studies, a significant number of samples contained insufficient levels of iodine to meet the requirements of breast fed infants, meaning that not only would babies drinking this breast milk be exposed to hazardous levels of perchlorate by EPA's standards, but they would also be deficient in the iodine necessary to counteract the thyroid hormone lowering effects of the compound, thereby magnifying potential health effects of perchlorate in these infants.

Evidence of Effect on Thyroid Hormone Levels

In another study from 2006, CDC scientists analyzed both perchlorate and thyroid hormone levels in more than 1,000 American women (6). They found that in those women with lower iodine levels (one third of American women), perchlorate exposure far below the EPA RfD of 24.5 ppb was associated with significant changes in thyroid hormone levels.

For a subset of women in the study with lower iodine, exposure to perchlorate as low as 5 ppb in drinking water was associated with decreases in thyroid hormone levels to the extent that the women would require treatment with thyroid hormone if they became pregnant in order to prevent abnormal brain development in their fetus. When the findings from this study are extrapolated to the US population, our analysis finds that 2 million women of childbearing age are at risk for abnormal thyroid hormone levels during pregnancy (see attached figure). This CDC study is the first to identify women with lower iodine levels as particularly susceptible to the effects of perchlorate exposure (6).

In other words, exposures at levels significantly lower than the EPA RfD of 24.5 ppb, the level EPA presumes is "safe," were linked with a lowering of thyroid hormone levels that can cause significant adverse health effects in exposed women and their fetus.

Vulnerable Populations

Developing Fetus

Adequate thyroid hormone levels are critical for normal brain development in the

fetus (1,9). The developing fetus is completely dependent on maternal thyroid hormone during the first trimester. After that, the fetus begins to produce its own thyroid hormone, but still receives about 30 percent of its total from the mother for the remainder of the pregnancy. Any thyroid hormone deficiency in the mother has repercussions for her fetus.

As mentioned earlier, women with lower iodine levels that are exposed to perchlorate levels as low as 5 ppb in drinking water can have significant decreases in T4, a critical thyroid hormone (6). If this happens during pregnancy, they may not be able to provide adequate levels of thyroid hormone to their developing fetus. Given that maternal contribution of thyroid hormone to the fetus is so significant throughout pregnancy, any maternal shortage can have long-term consequences for her fetus. Studies have shown that even subtle fluctuations in maternal thyroid hormone levels during pregnancy can have long-term impacts on the IQ of her child (7,8).

Infant

Breast milk does not contain a significant amount of thyroid hormone, so infants are completely reliant on their own production of the hormone. Infants also have higher turnover of thyroid hormone and have very little of the hormone in reserve when compared with adults. Therefore, infancy is a unique time in development during which increased production and rapid turnover of thyroid hormone, coupled with a lack of stored hormone, combine to make infants particularly vulnerable to any factors which impact thyroid hormone production. Exposure to perchlorate during this critical stage could result in shortages of thyroid hormone, prompting one study author to note "given these demands of the neonatal thyroid, it is likely that

perchlorate induced inhibition of iodide uptake has a greater impact in neonates...." (1). Adequate levels of thyroid hormone are critical to normal growth and cognitive development in infants (1,9).

Iodine

The status of iodine nutrition in the United States has a direct bearing on susceptibility of the population to perchlorate since perchlorate is a direct inhibitor of iodine uptake by the thyroid gland and higher iodine levels can overcome the effects of perchlorate. In the US, only 60 percent of the population currently uses iodized salt. Urinary iodine levels, an indicator of iodine nutrition, have decreased significantly in the US population in the last several decades. However, even with these decreases, CDC scientists noted in a recent analysis that iodine nutrition for the country is considered to be adequate (10).

There have been some suggestions that increasing iodine intake through iodized salt and vitamins may be an effective antidote to the health effects of perchlorate contamination. There are several problems with this strategy. Almost 40 percent of the population currently does not use iodized salt, and public health campaigns to change consumer habits could take years before any significant changes are seen. People with certain health conditions such as hypertension, congestive heart failure, and chronic kidney disease must restrict their salt intake, making salt a poor source of iodine for them. In addition, infants, a high risk population for perchlorate exposure, do not eat solid foods to which iodized salt could be added. Finally, universal salt iodization can expose a significant proportion of the population to excess iodine, which has been linked to autoimmune thyroid disease and certain types

of thyroid cancer. Iodine fortification of foods was decreased in the 1970's because of these health concerns related to excessive iodine intake (10).

In summary, iodine nutrition in the US is considered to be adequate. Even so, exposure to perchlorate at environmentally relevant doses has been associated with decreases in thyroid hormone levels in women with lower, but not abnormal, iodine levels. Increasing iodine intake in these women could help counteract the effects of perchlorate but it would be impossible to selectively identify them within the general population. Therefore, at a time when iodine nutrition in the US is considered to be adequate and there are known adverse effects associated with excessive iodine intake, it is difficult to justify asking the whole population to increase its collective iodine intake to counteract the effects of a chemical pollutant in a selective, vulnerable population. A health protective MCL for perchlorate in drinking water that takes into account vulnerable populations would serve the same purpose without adverse effects.

Perchlorate in Food

Perchlorate has been found in a variety of produce items and cows milk. The source of perchlorate in food is thought to be, in part, contaminated irrigation water and forage crops (2), but the source of much of the perchlorate in food remains uncertain. One of the breast milk studies mentioned earlier was done in a city where there is no known exposure to perchlorate in drinking water (5). Even so, every sample in the study contained perchlorate, and the average level of perchlorate in this breast milk would expose infants to doses well above what the EPA considers safe. This suggests that food is an important source of perchlorate exposure, but

more information of food contamination is needed.

In light of additional CDC work showing universal perchlorate contamination for all individuals tested, it is reasonable to assume that women and infants in communities where there is additional exposure to perchlorate through the combination of contaminated drinking water and food may have even higher levels of the contaminant in their breast milk when compared with those women with exposure through food only. It is imperative that the EPA act to protect women and children in these communities from what all data indicate is a hazardous combination of exposure to perchlorate from food and water. The first step in that process is a tough, protective drinking water MCL.

State Actions on Perchlorate:

Several states, including New Jersey, Massachusetts, and California have already addressed the issue of perchlorate in drinking water by either already setting or planning to set a MCL that is far lower than the current EPA recommendation. While none of these states have proposed a MCL as low as 1 ppb, their standards would still be far more protective of public health than the current EPA recommendation. But beyond these state borders, millions of people drink perchlorate contaminated water and live in states with little regulatory capacity. They depend on the federal government to protect them and EPA must fulfill this responsibility.

Summary Points

Evidence that Current EPA RfD is Not Protective of Public Health

- A recent CDC study shows that perchlorate exposure at levels far below EPA RfD is

associated with significant changes in thyroid hormone levels in women with lower iodine levels.

- Studies on US breast milk by CDC and academic scientists indicate that breast fed infants may be regularly exposed to perchlorate levels which exceed EPA RfD, prompting the question "If perchlorate exposure far below EPA RfD are associated with significant thyroid hormone changes in women with lower iodine, what are levels in breast milk that exceed EPA RfD doing to the health of breast fed infants?"

Implications

- Millions of women of childbearing age may have inadequate thyroid hormone levels when they become pregnant, putting their fetus at risk for abnormal brain development.
- Millions of breast fed infants may be at risk for thyroid insufficiency due to perchlorate contamination of breast milk, which can interfere with normal development.

Conclusion

- Recent research from respected CDC and academic scientists demonstrate that exposure to perchlorate at environmentally relevant levels poses a significant health threat to millions of US residents, particularly pregnant women and young infants. We must find the political will to enact legislation to address this issue as soon as possible; what is at stake is entirely too important for this action to be delayed any longer.

Recommendations

- The EPA must set a federal MCL for perchlorate that takes into account the most recent research, including the CDC study from last fall (2) and the recent breast milk studies (3,4,5). The MCL must also account for the contribution from contaminated food to daily perchlorate exposure. It is technologically feasible to treat contaminated water sources to levels below 1 ppb. As a physician, I feel that the public health measure that would reduce exposure in the shortest amount of time and reach the greatest number of people is to set the MCL for perchlorate in drinking water no higher than 1 ppb.

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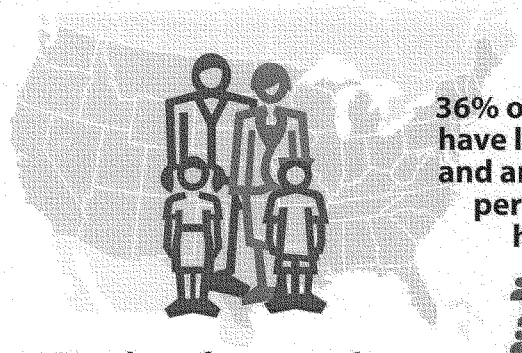
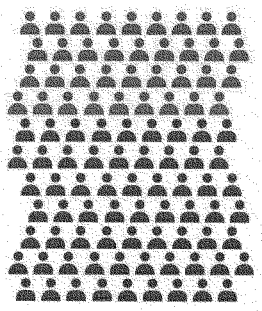
CDC study found exposure to perchlorate associated with disruption of thyroid hormone levels in women

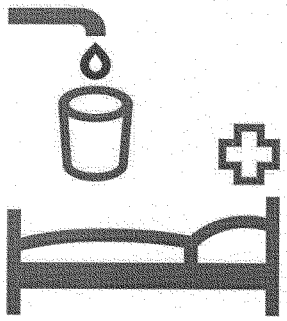


36% of American women have lower iodine intake and are at higher risk for perchlorate-related health effects.



Number of women of childbearing age (15-44) with lower iodine intake

United States
22,167,719



10% of these low iodine women could become subclinically or clinically hypothyroid if they ingested water with 5 ppb perchlorate.

United States
2,216,772

If these women became pregnant, they would be treated to restore thyroid hormones to normal levels.

Blount BC, Pirkle JL, Oserloh JD, Valentin-Blasini L, Caldwell KL. 2006. Urinary Perchlorate and thyroid hormone levels in adolescent and adult men and women living in the Unites States. Environmental Health Perspectives 114(12): 1865-71.

Mr. WYNN. Thank you very much. Dr. Ginsberg.

STATEMENT OF GARY L. GINSBERG, PH.D., CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

Mr. GINSBERG. Thank you, Mr. Chairman and subcommittee members. I am Gary Ginsberg. I am a toxicologist at the Connecticut Department of Public Health. I also am an adjunct faculty at Yale University, and I am assistant clinical professor of medicine at the University of Connecticut School of Community Medicine. I serve on one National Academy of Sciences panel right now, which is on improving EPA's risk assessment and technology. And I just finished up serving on the NAS panel on biomonitoring, which released its report to Congress in 2006.

And I want to emphasize that just for one moment because one of the things that is really pressing right now with the release of the CDC data are how we are going to understand the levels of perchlorate in urine in terms of an exposure dose. And the NAS panel and the biomonitoring report that I helped write presents a road map on how to do that. And actually I just published a paper in 2007 that takes the CDC urinary data in conjunction with the Chilean urinary data and provides a methodology on how to understand exposure in the general U.S. population, not just exposure in one person or exposure at the median or the mean, but the full distribution of exposure and how to bring that biomonitoring data into a holistic risk assessment in which one can then understand how we can protect at the 90th percentile or the 95th percentile the population in terms of the background levels of exposure. So to say at this point that we don't have enough exposure information when, as a biomonitoring person, which is where I come from in the State department of public health that has a lot of biomonitoring research going on, to say that we don't have enough exposure information and we need to wait for another FDA report, which will have lots of uncertainties because whenever you try to construct exposure pathways based upon how much is in cantaloupe, how much is in grapes, how much do people eat, what is the 90th percentile for this food source and that food source.

As a State risk assessor and health official, I don't want to have to tell people well, we have to worry a little bit about you eating that much cantaloupe during pregnancy. We want to be able to have standards and enough conservativisms and enough of the biomonitoring data in our risk assessment that we are not basing it upon how much is in a certain food source and what we think certain people are eating. Because we know people, especially during pregnancy, will do different things than what the assumptions are.

Now, a lot of this, and the basic gist of my testimony is that it is smart public health policy to regulate perchlorate as quickly as possible because if we don't do that, and we are already not doing that, it leaves the potential open that our children won't be so smart and that we will have more children left behind academically.

When environmental threats to intelligence have surfaced in the past, action has been taken to decrease that threat, whether it has been lead, mercury, or PCBs. To be honest with you, the level of emergence of the perchlorate database is not where it is with the

50, 60, 70 years worth of data we have for lead or mercury. But nevertheless, it is quite strong and, I think, compelling in terms of understanding that exposure is very widespread, that exposure is at levels of potential health concern not only to in-utero development, which has been recognized as the perhaps most sensitive period, but also to post-natal and breast-fed infants.

And the reason for that is twofold. Number 1, breast milk is the critical source of iodine for the nursing infant. There is hardly any thyroid hormone in breast milk so the neo-nate is on its own, and this delicate arrangement is going to be interfered with by perchlorate in two ways. One, perchlorate itself is actively transported into breast milk. It sort of an excretory pathway for the breastfeeding woman. So it is being excreted into the nursing infant. And then the second concern is that it is blocking iodine excretion into breast milk. So it is a double jeopardy for the nursing infant, which makes that life stage—because brain development is actively occurring at that point—makes that life stage a particular concern. And we do have good data on neo-nates and how sensitive they are to decreases in thyroid hormone levels.

So then there is the toxicology. For EPA to set an MCL out, they have to have a good grip on the toxicology. And what the CDC study has done is it has shown us that since the National Academy of Sciences report came out, the NAS gave us some sense of comfort that there is a safety factor involved with the standard, with the RfD. However, what CDC has done is they have shown us that there really isn't that kind of a safety margin or that kind of comfort level with where the RfD was set.

In fact, I published a commentary in 2005 that said that I didn't think at that point that the NAS RfD was even set, considering all the uncertainties and all the health implications. And then we go to 2006, and we see the CDC report. And that says that there really is no margin of safety. There is no comfort level with the current RfD, and in fact, they should be lowering it.

Then on top of that, we have the exposure profile, and we know from the UCMR that were sampled a lot of public water supplies in 2001 and 2005, that there is widespread exposure to roughly 5 to 15 million people in this country to elevated levels of perchlorate.

But then we have places like Foxboro, MA, which would not be normally sampled if it wasn't for the proactive work of State regulators to sample municipal wells in small districts, finding 1,300 ppb. of perchlorate in an area that would not normally get tested. So without having a Federal——

Mr. WYNN. Dr. Ginsberg, I think you——

Mr. GINSBERG. The bottom line is without having a Federal MCL, there is no testing. The women in Foxboro, MA, would have no way of knowing that they were at risk if it wasn't for some proactive work by some State risk assessors. And so that is the reason why we need an MCL right away because there is ongoing exposure and no testing.

[The prepared statement of Mr. Ginsberg follows:]

Testimony Relevant to H.R. 1747
To Amend the Safe Drinking Water Act to Require a National Primary Drinking Water Standard for Perchlorate

Testimony Provided by Gary L. Ginsberg, Ph.D.
Connecticut Department of Public Health
To the House Subcommittee on Environment and Hazardous Materials of the Committee on Energy and Commerce
April 25, 2007

Thank you for the opportunity to present testimony today on perchlorate health effects and the issue of a perchlorate Maximum Contaminant Level or MCL. My name is Gary Ginsberg. I am a toxicologist at the Connecticut Department of Public Health in Hartford CT where I am involved in environmental risk assessment and standard setting for drinking water, air quality and soil contamination. I am also an adjunct faculty member at Yale University and am an assistant clinical professor in the University of Connecticut School of Community Medicine. I currently serve on a National Academy of Science Panel on Improving USEPA's Risk Assessment Methods and recently completed service on the NAS Panel on Human Biomonitoring. Finally, I serve on the Children's Health Protection Advisory Committee, a group which reports directly to USEPA Administrator Johnson on that agency's efforts to protect children from environmental threats. My publication record is largely in the area of children's vulnerability to toxic chemicals. For more details, see my curriculum vitae (attached). I must also note that my testimony was prepared independently by me and does not represent the official position of the Connecticut Department of Public Health, Yale University or the University of Connecticut.

My testimony today can be summed up by saying: Its **smart** public health policy to regulate perchlorate as quickly as possible. I emphasize the word smart because perhclorate has the potential to make our children less smart and academically left behind. When environmental threats to intelligence have surfaced in the past, action has been taken to remove the threat: lead, mercury, and PCBs are prime examples. Perchlorate is another threat to human intelligence, one in which the evidence may not yet be as compelling as with the iron-clad cases of lead or mercury, but which still represents an important public health concern. It's a risk that warrants protecting public health via the establishment of a drinking water MCL.

Do we have direct evidence of a perchlorate effect on brain function? Yes, that is in laboratory animals where several studies showed that perchlorate dosing in pregnant rats leads to effects on the behavior of offspring (ARL, 1998; Bekkedal, 2000). These effects resulted from perchlorate interference in thyroid function. The National Academy of Science review in 2005 discounted the rat data because rats may be more sensitive to thyroid disruption than humans (NAS, 2005). However, after the NAS review, evidence has emerged that at low exposures common across our population, perchlorate appears to disrupt the thyroid gland in humans (Blount, et al., 2006). That CDC study found an association between perchlorate exposure in the general population and altered thyroid status in the direction you'd expect from an anti-thyroid agent (low thyroid hormone, high TSH). The effect was only seen in women and only in those women with low iodide intake. This increases the concern that pregnant women could be especially at

risk from perchlorate because of their gender and because pregnancy increases demands for many nutrients including iodide (Glinoer, 2001). One may ask why should anyone have low iodide intake when most table salt is iodized? Well the data show that iodide intake in the US population has decreased considerably from where it was in the 1970s (Hollowell, et al., 1998) and this roughly corresponds to our increasing consumption of fast food. Even though fast food is salty, the kind of salt used is not iodized (Wright, 2002). In the CDC study, approximately 36% of the women were in the low iodide, high risk group. So, we have many vulnerable women who, when they become pregnant are passing their vulnerability onto their developing baby in terms of low iodide intake and exposure to perchlorate.

This is important because the developing brain is sensitive to even small changes in thyroid hormone levels. We all know that large decreases in thyroid hormone cause cretinism, severe underdevelopment of the brain (Delange, 1996). Smaller deficiencies can cause more subtle effects, but effects that are still important and measured as lowered IQ and poorer performance in school (Smallridge and Ladenson, 2001). At typical environmental levels of exposure, we don't expect perchlorate to create cretins, but we have every reason to expect perchlorate, if not properly regulated, to erode brain development, learning and intelligence. These effects can be prevented by establishing a perchlorate drinking water standard that is protective of health effects in utero and also in babies once born.

In considering whether to set an MCL, USEPA must review the toxicology and exposure data. Apparently the Agency considers the toxicology data adequate because it has established a reference dose or RfD on its IRIS database. This RfD is the same as that recommended by the 2005 NAS report, and it has been used by EPA's Office of Solid Waste and Emergency Response (OSWER) to establish a Preliminary Remediation Goal at waste sites of 24.5 ug/L. I agree with the Agency that there is a great deal of toxicology data in both animals and humans for the establishment of a health benchmark for perchlorate. However, I disagree with the RfD chosen as it is based upon a small number of human subjects in limited testing (Greer, et al., 2002) and in which it appears that some individuals may have been more sensitive, but that sensitivity was not considered in the RfD derivation. Our commentary published in 2005 critiqued the NAS/EPA RfD , making a case for why it should be lower and more health protective. That commentary is included as an attachment (Ginsberg and Rice, 2005). The October 2006 CDC study is more powerful than the study used by NAS and EPA to set the RfD as it involved thousands of subjects rather than only 30, it divided the population based upon known risk factors including low iodide intake, and it included a reliable exposure measure, urinary levels of perchlorate. That study appears to bear out our concerns about the RfD as the association between perchlorate exposure and impaired thyroid function occurred at background population exposures that are 10 fold below the RfD. This is analyzed in our more recent publication (Ginsberg, et al., 2007), also presented as an attachment. These findings of perchlorate effects in a key subgroup of the population (the 36% of women with low iodide intake) indicates that the stakes are higher than originally thought with perchlorate and that it would be highly imprudent to not regulate

the public's drinking water exposure. The CDC data also make a strong case for an overhaul of the RfD so that it more fully reflects the human epidemiology and laboratory data. Do the data exist to do this? Yes, I believe they do. Are there uncertainties with relying on a single epidemiology study as the primary driver in establishing dose response? Perhaps, but these uncertainties are no greater than those present in the current RfD which is based upon a single study in humans in which the sensitivity of the individuals and of the test method to detect a low dose perchlorate effect is questionable.

The other main component in setting a perchlorate MCL is exposure. One needs to know about exposure to make sure there is enough of it from drinking water to merit USEPA action vis-à-vis setting an MCL. Additionally, one needs to know the various sources of exposure to know what percentage of the daily dose is coming from food and what percentage can be allowed to come from drinking water. The goal of the MCL is to keep the total daily exposure below the RfD. On the issue of data sufficiency for determining the need for an MCL, USEPA's Unregulated Contaminant Monitoring Rule in 2001-2005 required the testing of several thousand public water supplies across the country for perchlorate and found detections averaging approximately 10 ppb in 160 such systems in 26 states. These systems serve 5-17 million people, depending upon how one calculates the distribution of water from these supplies (USEPA, FR 4/11/07). Results from that screening program are summarized in the following figure:

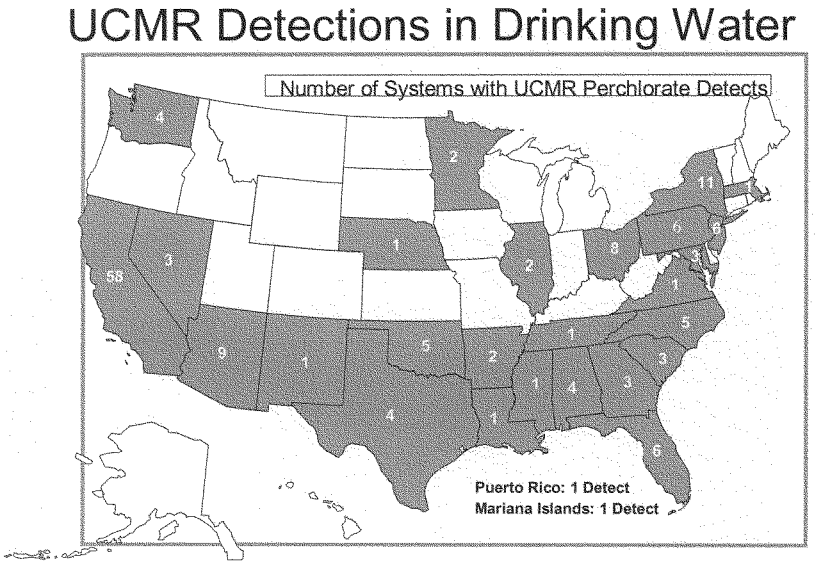


Figure from USEPA Region 9

While these detections are not very common, they are common enough to expose large numbers of people to risky levels of perchlorate. This is only a screen of large public supplies. Smaller systems may be more vulnerable to hot spot groundwater contamination. So the UCMR data may underestimate the number and in some cases, the severity of exposure to perchlorate. For example, data collected in 2004 by the Massachusetts Dept of Environmental Protection (MassDEP) showed that 9 smaller public supplies around the state were contaminated with perchlorate with the highest detection in Boxboro at 1300 ppb. The table below shows this and the other 8

perchlorate detections. The use of perchlorate in blasting projects was clearly the largest risk factor in this limited database.

Since perchlorate has no odor or taste, monitoring programs are needed to uncover contamination. **Without an MCL, there is no monitoring requirement** and so the pregnant women in Boxboro would not know that they are exposing themselves and their developing babies to dangerous levels of this contaminant. Fortunately, in this particular case the state government required proactive sampling and uncovered these perchlorate hotspots and required mitigation.

Perchlorate Occurrence Monitoring

March – October 2004 - Public Water Supply Data Only (693 systems)

Town	Maximum (µg/L)	Source?
Boxboro	1,300	Blasting
Chesterfield	8.9	Fireworks
Hadley	3.8	Unknown
Millbury	45	Blasting
Southbridge	3.1	Unknown
Tewksbury	3.3	Industry
Westford	3.7	Blasting
Westport	3	Fireworks
Williamstown	10	Fireworks

Massachusetts Department of ENVIRONMENTAL PROTECTION

Data from MassDEP Website http://www.mass.gov/dep/brp/dws/percinfo.htm

The other side of the exposure coin is how much is coming from drinking water and how much from food. The current database is far from complete but indicates substantial contamination can exist in certain produce as well as in dairy. There are still

datagaps for a variety of other foods. Exactly how this adds up to a dietary background of exposure can take considerable research and time to iron out. It is inappropriate to wait for all types of exposure information before setting an MCL. The standard default assumption when there is an indication of extensive exposure via non-water sources is that 80% of the RfD comes from these non-water sources, thus allowing 20% to come from drinking water. This sets the relative source contribution or RSC at 0.2, a reasonably conservative default that has worked quite well in protecting public health from drinking water contaminants like perchlorate for decades.

Several states have already moved forward and developed a statewide drinking water target for perchlorate. The state MCL in Massachusetts is 2 ug/L, the Public Health Goal in California is 6 ug/L and the target level in New Jersey is 5 ug/L. In each case, exposure and risk experts in state government grappled with the issue of the RSC and were able to make an informed decision on how to proceed. I encourage USEPA to do the same in an expeditious fashion given that undetected and unregulated exposures are ongoing as we speak.

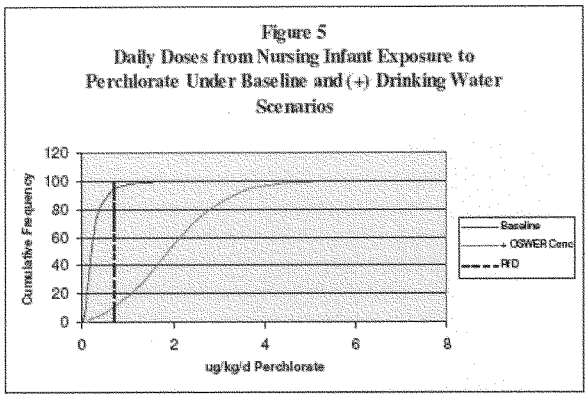
In fact, I point USEPA to our analysis of the CDC data that was published in Environmental Health Perspectives in early 2007 (Ginsberg, et al., 2007). In that paper (also attached) we demonstrate the utility of the CDC data in showing the background dietary exposure of the population to perchlorate as converted from the urinary biomonitoring data. We demonstrate that approximately 30% of the current RfD comes from the diet for adults but that because of the greater exposure in nursing infants,

approximately 80% of the RfD dose comes to the infant via the mother's diet. Thus, our analysis supports the default RSC of 0.2, which by the way is the value used in Massachusetts and New Jersey. It is important to remember that if the RfD itself were lowered because of the new CDC data as I describe above, then the RSC would accordingly shift – diet would then take up a larger portion allowing less to come from drinking water. In my judgement, the reasonably conservative and historically accepted default for the RSC of 0.2 is appropriate to enable standard setting to move forward.

Its also important to recognize the special vulnerability of the nursing infant to perchlorate. This was the main subject of our 2007 publication in Environmental Health Perspectives (Ginsberg, et al., 2007, attached). We spent considerable effort summarizing the literature that shows that after birth the brain is still growing rapidly and that it is still highly dependent upon thyroid function for proper development. However, in this case it is the infant's own thyroid that is needed as there is virtually no thyroid hormone in breast milk – so the infant is on its own. The baby's thyroid gland does not have a store of thyroid hormone to count on and so must continually make new hormone to keep up with the demands of a rapidly growing being. This keeps the baby's thyroid very busy. To support this, the nursing infant gets all of its iodide needs from breast milk. Perchlorate does two things to interfere with this rather delicate arrangement. First, perchlorate gets pumped into breast milk by the same type of transporter that pumps it into the thyroid gland. This causes the nursing infant to get a substantial dose of perchlorate that can potentially interfere with the baby's thyroid gland and brain development. But the effect of perchorate is compounded by its inhibition of iodide movement into breast milk. This creates a double jeopardy for the nursing infant – lower

iodide intake at the same time that it is getting a risky level of perchlorate. As we point out in our 2007 paper, it is imperative to fully consider nursing infants when establishing a perchlorate MCL.

Finally I come to the matter of the OSWER PRG for perchlorate of 24.5 ug/L, set by that branch of USEPA in January, 2006. While this is only a preliminary remediation goal, it also takes on the authority of the only federal groundwater/drinking water reference value for use in making site determinations. It effectively says that if the groundwater at a site is below 24.5 ug/L there is little need to analyze the situation further or clean it up. Given the complex array of contaminants and exposure pathways common at Superfund sites, perchlorate will likely not be addressed if its below the OSWER PRG. This federal perchlorate level is also a main subject of our 2007 publication. Our analysis shows that it is set too high to be protective of the developing fetus in utero or the nursing infant. The following figure from our paper shows how the OSWER PRG is likely to push many nursing infants above the RfD, and remember this is the RfD established by the NAS and that doesn't take into account the new CDC data.



The figure shows that under baseline conditions where the only exposure of the mother is to perchlorate in the diet, most of the nursing infants are below the RfD. However, the red line shows the case where mothers are allowed to drink tap water at the OSWER PRG in addition to their background exposure. This pushes most infants well above the RfD. This shows that the OSWER PRG is far from protective of the nursing infant and further, our analysis shows that it is not protective of the developing fetus.

Based upon these risks the OSWER PRG needs to be lowered. In fact, the current situation is about as bad from a public health perspective as possible – not only don't we have a federal MCL, but the only federal guideline we do have is a value from OSWER that puts brain development in the fetus and nursing infant at risk. The vacuum created by not having a federal MCL for perchlorate creates the following public health problems:

- Lack of sampling and detection: without an MCL there is no requirement for public water supplies to test; literally millions of U.S. residents are exposed to perchlorate at potentially adverse levels without the knowledge of drinking water customers or regulators;
- No unifying standard to determine the need for mitigation: in the spotty cases where sampling will occur, results may come in from local areas of contamination; the lack of an MCL requires state or local authorities to develop their own standard; this creates a patchwork of differing values across the country which causes uneven protection of public health and confusion/loss of confidence on the part of the public;
- The default value that currently exists is the OSWER PRG – a value that is clearly inadequate to protect public health.

In summary, thank you for this opportunity to present my perspective on the public health issues surrounding the lack of an MCL for perchlorate. While I would normally support USEPA's science gathering and deliberative process to run its course, I feel that in this case a rich biomonitoring and health effects database is available to move forward towards an MCL. Further, given the immediacy of the public exposures and potential health effects, it is imperative to move forward in a timely manner. While an MCL established in the near future will contain a degree of uncertainty, this would likely be no greater than the uncertainty associated with most other MCLs that are currently in place.

Therefore, I support the bill before the House of Representatives (H.R. 1747) to require the development of an MCL for perchlorate in a timely manner.

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Mr. WYNN. Thank you for your testimony. Dr. Utiger.

Dr. UTIGER. Often said as "you tiger."

Mr. WYNN. You tiger, alright.

STATEMENT OF ROBERT UTIGER, M.D., HARVARD INSTITUTE OF MEDICINE

Dr. UTIGER. Mr. Chairman, members of the committee, my name is Robert D. Utiger. I am trained in internal medicine and subsequently in endocrinology. In my career, I have been interested in the thyroid for over 40 years, and my research and clinical activities have been in the areas of thyroid physiology and thyroid disease.

I was a member of the NAS committee on the health implications of perchlorate, and I participated in the discussion and the review of the literature. I, of course, in no way speak for the committee. And as you all know, it was disbanded on completion of its report in 2005.

In looking at the data at that time, we focused on five prospective studies in which known amounts of perchlorate were given to normal human subjects in doses ranging from 0.007 milligrams per kilogram to as high as 9 milligrams per kilogram. The first study I mentioned looked at iodine uptake by the thyroid in 2 weeks. The longest study looked at iodine uptake and serum thyroid hormone at TSH concentrations for 6 months in people given 0.04 milligrams per kilogram of body weight. The 0.007 milligrams per kilogram body dose had no effect on the thyroid at an uptake, nor on serum thyroid hormone or DSH concentrations. The 6-month study at a much higher dose had no effect on any of those measurements at all.

We chose as our—I guess I would call it departure point—the 0.07 milligrams per kilo because it involved perhaps the most extensive studies. There were higher doses, and higher doses did have a small effect on thyroid uptake of iodine. But again no change in thyroid hormone concentrations in that 2-week interval.

We then added an uncertainty factor of 10, reaching what we called a reference dose of 0.007 milligrams per kilo. And this was, in our view, the limit, if you will, for the total dose whatever the source. And we didn't examine the sources. We knew that there was perchlorate in water supplies in somewhere. There was just a little bit of data about food available at that time, but we didn't deal with any sources or any particular sources.

The EPA used that number to generate, I guess, a proposed water standard, but that is entirely out of the realm of the committee. I continue to believe that that reference dose, 0.007 milligrams per kilo, which includes a factor of 10 to protect those who might be more vulnerable, is quite adequate. Part of the reason, I think, that is that we chose no inhibition of iodine uptake as the mechanism, if you will. And we didn't consider that an adverse effect, but even if it was an adverse effect, the pituitary thyroid system had very sufficient compensatory ability. So if something inhibits the production of thyroid hormone by 10 or 15 percent, there is a defense for it, and the defense is fairly rapidly activated and generally quite effective, particularly if the thyroid gland is fundamentally normal, as it is in people who are taking perchlorate.

Perchlorate does one thing to the thyroid and one thing only in sufficient dose, and that is inhibit iodine uptake. So as I said, I continue to support that value as an overall reference dose. How it is distributed, of course, is something that we were not charged to address and certainly did not address.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Utiger follows:]

Statement for the House of Representatives'

Committee on Energy and Commerce

Subcommittee on Environment and Hazardous Materials

Hearing on the Health and Environmental Effects of Perchlorate

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Personal Information

Education and Training

M.D., Washington University School of Medicine, 1957
Residency Training: Barnes Hospital, St. Louis, 1957-61, 1963-4
Postdoctoral training: Endocrinology Branch, National Cancer Institute, Bethesda, MD, 1957-1963

Faculty Appointments

Instructor and Assistant Professor of Medicine, Washington University School of Medicine, 1964-69
Associate Professor and Professor of Medicine, University of Pennsylvania School of Medicine, 1969-79
Verne Caviness Professor of Investigative Medicine, University of North Carolina School of Medicine, 1979-89
Clinical Professor of Medicine, Harvard Medical School, 1989-present

Other

Editor-in-Chief, *Journal of Clinical Endocrinology and Metabolism*, 1982-88
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Editor, *Clinical Thyroidology*, 2001-present
Co-Editor, *The Thyroid: A Fundamental and Clinical Text*, 6th, 7th, 8th, and 9th editions
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Personal Statement: I wish to make it clear that I am writing and speaking only for myself, not the National Academy of Sciences Committee (which in any event was disbanded when its report was completed and presented to the public in 2005). Also, I have never had any financial or other relationship with any manufacturer of perchlorate or of any perchlorate-containing products.

I take full responsibility of the content of this statement, but wish to acknowledge the assistance of Ellen Mantus, Ph.D., National Academy of Sciences, for preparation of some of the illustrations.

The Thyroid Gland and Its Hormones

The Thyroid Gland

The thyroid gland is a butterfly-shaped structure located in the front of the neck lying along the trachea. It weighs approximately 1 to 1.5 grams at birth and 10 to 20 grams in adults. It contains of millions of follicles, each of which consists of a single layer of cells surrounding a cavity (lumen) containing thyroglobulin (Tg), a protein found only in the thyroid gland (Figure 1). Thyroglobulin is the framework for production and the storage of the two thyroid hormones, thyroxine (T_4) and triiodothyronine (T_3).

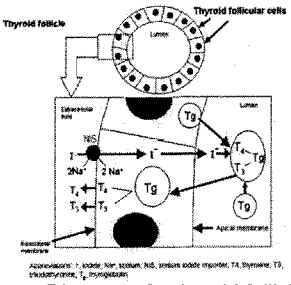


Figure 1. Diagram of a thyroid follicle and individual thyroid cell, showing the path of iodine and the formation of T_4 and T_3 with a thyroid cell and the adjacent lumen.
From Health Implications of Perchlorate Ingestion. National Academy of Sciences. Washington, DC. 2005:37.

Thyroid Hormone

There are two thyroid hormones, thyroxine (T_4) and triiodothyronine (T_3) (Figure 2), and they are the only active substances that contain iodine (I).

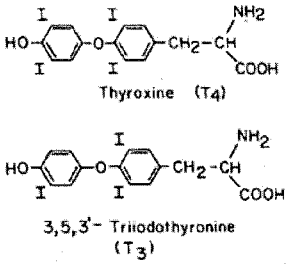


Figure 2. Structures of thyroxine (T_4) and triiodothyronine (T_3).

All of the thyroxine but only about 35% of the triiodothyronine produced each day comes from the thyroid gland. The remainder of the triiodothyronine is formed by removal of one iodine atom from thyroxine in most if not all tissues. Triiodothyronine is

the biologically active thyroid hormone, having in tissues approximately 100 times more activity than thyroxine. Nonetheless, thyroxine (T_4) is the term usually used, because it is the form of thyroid hormone that is most often measured and also given to people with hypothyroidism (thyroid deficiency).

Iodine and Thyroid Hormone

The iodine (as negatively charged iodide) needed to synthesize thyroxine and triiodothyronine must come from external sources (food and water). Once absorbed into the blood stream, it is transported into thyroid cells via a specific molecule known as the sodium/iodide symporter (NIS, Figure 1). (This symporter is also present in salivary glands, the stomach, and mammary glands, but iodide in these tissues is not further metabolized and returns to the blood stream.) Once inside thyroid cells, iodide rapidly traverses the cell and is transported into the lumen, where it is oxidized and combines with residues of tyrosine (an amino acid) within the thyroglobulin molecules to form the two hormones. The thyroglobulin is stored in the lumen or taken up by the cells and broken down to its constituent components, including thyroxine and triiodothyronine. The two hormones then are secreted into the blood stream.

Both thyroxine and triiodothyronine are largely bound to several proteins in the blood stream (>99%), and <1% is present as the free hormone. Therefore, there is a substantial reservoir of the two hormones in the circulation, should secretion from the thyroid temporarily decrease.

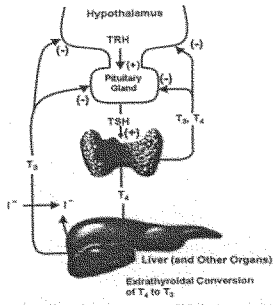
Entry and Action of Thyroid Hormone in Cells

Free thyroxine and free triiodothyronine in serum are carried into cells by transporter molecules in the cell membranes. Triiodothyronine is also available to cells because it is produced from thyroxine in them. Thus, there are two sources of triiodothyronine in cells, some enters the cells from the circulation and produced from thyroxine in the cells.

Many actions of thyroid hormone are stimulatory. It increases the production of several proteins in the heart, thereby increasing heart rate and contractility. In the liver, it increases the production of many different proteins required for growth, metabolism, and energy production. It also stimulates the production of proteins in the brain, most obviously during development. In contrast, in the pituitary gland, it inhibits the production of pituitary gland hormone known as thyroid-stimulating hormone (TSH, thyrotropin), a process termed negative feedback, which ultimately leads to a decrease in hormone synthesis by the thyroid gland.

Regulation of Thyroid Hormone Production

Thyroid hormone production is regulated primarily by the action of TSH (Figure 3). Pituitary secretion of TSH is inhibited by thyroxine and triiodothyronine and stimulated by a decrease in the two hormones. TSH secretion is also stimulated by thyrotropin-releasing hormone, produced in the hypothalamus. The conversion of thyroxine to triiodothyronine in many non-thyroid tissues is regulation by nutritional and illness-related factors.



TRH, thyrotropin-releasing hormone; TSH, thyroid-stimulating hormone (also thyrotropin); T_4, thyroxine; T_3, triiodothyronine; I^-, iodide: (-), inhibitory (negative) action; and (+), stimulatory (positive) action.

Figure 3. Diagram of hypothalamic-pituitary-thyroid Axis. TRH, thyrotropin-releasing hormone T_3 with a thyroid cell and the adjacent lumen. From Health Implications of Perchlorate Ingestion. National Academy of Sciences. Washington, DC. 2005:44.

The first mechanism provides a very sensitive defense against increases and especially decreases in thyroid hormone production. The second mechanism provides for rapid changes in the availability of T_3 in different tissues, especially in response to illness or starvation.

Iodide Nutrition and Metabolism

Iodide is essential component of thyroxine and triiodothyronine (Figure 2). It can be obtained only by ingestion of foods or liquids that naturally contain it or of foods to which iodide was added during processing (iodization). Foods with a high iodide content include seafood and sea products (kelp and seaweed), dairy products, eggs, commercial bakery products, and vegetables. Sea salt contains iodide, and iodized salt is widely available (and mandated by law in many countries).

Dietary iodide is absorbed and distributed rapidly (as iodide) through the blood stream, which also contains iodide released from the thyroid gland during hormone secretion and from extrathyroidal deiodination of the hormones. Iodide leaves the circulation by transport into the thyroid or by excretion in the urine.

The World Health Organization (WHO) recommends a dietary intake of 150 μg/day for adults, 200 μg/day for pregnant women, 90-120 μg/day for children 2-11 years old, and 50 μg/day for infants less than 2 years old. The Food and Nutrition Council of the Institute of Medicine of the National Academies recommends a slightly higher intake, 220 μg/day, for pregnant women (IOM 2000).

At those intakes there are no manifestations of thyroid dysfunction.

Progressively lower intakes are associated with thyroid enlargement (goiter), biochemical evidence of thyroid hormone deficiency, and ultimately, in those with severe iodide deficiency, hypothyroidism. The WHO definitions of iodide deficiency are: intake from 50 to 99 μg/day, mild iodide deficiency; intake of 20 to 49 μg/day, moderate iodide deficiency; and intake <20 μg/day, severe iodide deficiency. (Iodide intake is not measured directly but is usually estimated as the amount of iodide in a liter of urine.)

In 2001-2001, iodide intake in the United States averaged about 150 μg/day, based on measurements of urinary iodide excretion in several thousand children and adults (median urinary iodide excretion, 145 μg/L) (Caldwell et al., 2005). This value was about 50% lower than the value in 1971-1974. The value was less than 50 μg/day days in 12% of adults (15% of women of childbearing age and 7% of pregnant women). There were no differences in serum TSH and thyroxine concentrations between those with urinary iodide values less than 50 μg/L and those with higher values; apparently, the iodide intake in the former group was not low enough to cause a fall in T_4 secretion.

The reasons for the decrease in iodide intake in the United States between 1971-1974 and 2001-2002 are not known, but they include lower salt intake (iodized salt contains iodide at approximately 70 μg/g), less use of iodide in the baking and dairy industries, and less addition of iodide to animal feed.

Iodide deficiency is more prevalent in many other countries, and in many others it has been largely prevented by iodization of salt. I know of no reports of perchlorate exposure in areas of iodide deficiency.

Alterations in Thyroid Hormone Production

Severe iodide deficiency is one of many conditions that can reduce thyroid hormone production (and is the most common worldwide). Others include iodide excess, various drugs, congenital abnormalities of development of the thyroid gland, congenital deficiencies of thyroid hormone synthesis, and diseases that damage the thyroid gland. The range of thyroid deficiency in these conditions varies greatly, from those that are almost undetectable and fully compensated by the mechanism described below to severe hypothyroidism. Among infants, hypothyroidism can result in severe abnormalities in neural and skeletal development; in adults, it can result in substantial disability.

When thyroid gland synthesis and secretion of thyroid hormone fall as a result of iodide deficiency or any cause, the serum concentrations of the hormones fall. That results in a rapid increase in TSH secretion. If the thyroid is severely damaged or has been removed surgically or if the dose of an offending drug is high, TSH has little effect. Serum thyroid hormone concentrations continue to fall, and although TSH secretion increases further, severe hypothyroidism occurs. When the problem is iodide deficiency or if thyroid damage or drug blockade is incomplete, the initial increase in serum TSH concentrations stimulates synthesis and secretion of the two thyroid hormones sufficiently to raise their serum concentrations to normal or near normal. The rise in turn lowers TSH secretion to, or almost to, its original level. The person has no or few manifestations of hypothyroidism, although the thyroid gland may enlarge. Indeed, thyroid enlargement may be the only evidence that thyroid hormone production was low and TSH secretion was high earlier.

In conclusion, there is a potent mechanism—increased TSH secretion by the pituitary gland—to compensate for thyroid hormone deficiency. This compensation is activated by very small decreases in thyroid hormone production, and it effectively restores thyroid hormone production to normal or near normal even when the initial insult is substantial, for example, a fall in iodide intake (see next section).

Iodide Deficiency and Other Perturbations

The effects of iodide deficiency, depending on its severity, provide an example of the compensatory mechanism. People with mild iodide deficiency have normal serum thyroid hormone and TSH concentrations, but about 5-10% have some thyroid enlargement. Those with moderate deficiency also have normal serum thyroid hormone and TSH concentrations, but about 20-30% have thyroid enlargement. People with severe iodide deficiency may have slightly low serum thyroid hormone concentrations and high serum TSH concentrations, and over 30% have thyroid enlargement; overt hypothyroidism occurs only if iodide intake is below about 5-10 μg/ day. As iodide intake declines, thyroid uptake of iodide increases because of an increase in the number of transport (NIS) molecules. This change constitutes another compensatory response; it is facilitated by an increase in TSH secretion but probably occurs even in the absence of an increase. Also, there is a shift to production of triiodothyronine, which contains less iodide but has more activity than thyroxine. In summary, there is remarkable compensation for the effects of iodide deficiency so that even when iodide intake is low normal or near-normal thyroid hormone production and TSH production are maintained. However, severe deficiency in iodide intake (below 20μg/day) in pregnant women may result in major neurodevelopmental deficits and goiter in their offspring, and similar iodide deficiency in infants and children may result in smaller but still important neurodevelopmental deficits.

Iodide excess and therapy with lithium provide additional examples of the compensatory mechanism. In doses of 1,000 μg/day or more, iodide has an antithyroid action in healthy subjects. In 1-2 weeks, serum thyroid hormone concentrations fall by 10-15% and serum TSH concentrations increase by about 50%. Those changes subside if intake of excess iodide continues. A similar pattern of changes in serum thyroid hormone and TSH concentrations occur in people with many thyroid disorders, including autoimmune thyroiditis, in which the thyroid is damaged by immune mechanisms and surgical removal of one side of the thyroid gland. In summary, many substances and conditions lower thyroid hormone secretion and result in a rise in TSH secretion. If the thyroid gland is not seriously damaged, the serum concentrations may return to normal, or so near to normal that there are few if any consequences.

Thyroid Hormone Actions in Developing Fetuses and Newborn Infants

Triiodothyronine is required for normal development of the central nervous system. Its actions include stimulation of the development and growth of nerve cells and supporting cells, the formation of connections between neurons, the formation of the myelin sheaths of nerves, and the development of the compounds transmit signals from one nerve cell to another. The resulting abnormalities in neurologic and neuropsychologic development, although variable and determined at least in part by when the deficiency occurred, are permanent, indicating that the correct timing of the

expression of genes in the brain during development is critical. However, the linkage between the biochemical abnormalities in the brain and the developmental abnormalities is not clear. Thyroid hormone is also needed for normal skeletal development and growth.

Effects of Perturbations of Maternal, Fetal, and Child Thyroid Function on Fetal and Child Development

The manifestations of hypothyroidism in infants vary, according to whether the mother, the fetus, or both have hypothyroidism and how long it persists. The abnormalities are greatest when both mother and fetus are affected; this is most likely to occur in regions of severe iodide deficiency. The consequences of severe maternal and fetal hypothyroidism during fetal life and in newborn infants include microcephaly (small brain), mental retardation, deaf-mutism, and movement disorders. These abnormalities are not reversible. However, the abnormalities can be largely prevented by administration of iodide to the mothers early during their pregnancies. That finding underlies the importance of the availability of thyroid hormone from the mother before fetal thyroid secretion begins.

The infants of mothers who have mild iodide deficiency have larger thyroid glands and higher serum TSH concentrations at birth than do those of mothers whose iodide intake is higher. Otherwise, they appear to be neurologically and physically normal.

Newborn infants who have hypothyroidism may have other abnormalities, including lethargy, poor muscle tone, poor feeding, and constipation, if not at birth then thereafter. The changes are similar to those that occur in older children and adults with hypothyroidism, and, in contrast with the neurologic abnormalities, they are reversible with adequate treatment.

Fetal and Neonatal Hypothyroidism

Infants who have even severe congenital hypothyroidism usually appear normal at birth. Their serum thyroid hormone concentrations are low, not very low, indicating that some maternal thyroid hormone crossed the placenta. Their serum TSH concentrations are high and rise further soon after birth. Those infants can be identified as having hypothyroidism by measurements of TSH or thyroxine in blood collected a few days after birth; this screening has been in place in the United States for about 30 years. Infants identified by neonatal screening have normal neural development and growth if aggressive thyroxine treatment is started within the first 2 or 3 weeks after delivery.

After birth, not only maternal thyroid hormone but also other maternal factors that might have affected fetal thyroid secretion are cleared from the infant's blood stream. Whether those substances alter a newborn infant's thyroid function depends on the dose and rate of clearance of the substance and the infant's maturity. The efficacy of prompt treatment of newborn infants found to have hypothyroidism by screening makes it unlikely that any rapidly cleared substance that reached the fetus from the mother and reduced thyroid secretion in the fetus, but no longer reached the infant after birth could cause postnatal hypothyroidism of sufficient severity to cause developmental delay.

That conclusion is born out by the uncommon clinical situation described below.

Hyperthyroidism (an overactive thyroid gland) occurs in about one in 2,000 pregnant women. Some of these women require treatment with an antithyroid drug throughout their pregnancies. The antithyroid drugs cross the placenta in sufficient quantities to cause fetal hypothyroidism. After birth, no more drug reaches the infant, the hormonal changes disappear rapidly, and the infants develop normally. Many years ago, some pregnant women with hyperthyroidism were treated successfully with potassium perchlorate. Most of the infants were normal, but one had slight thyroid enlargement that disappeared soon after birth.

Perchlorate and the Thyroid Gland

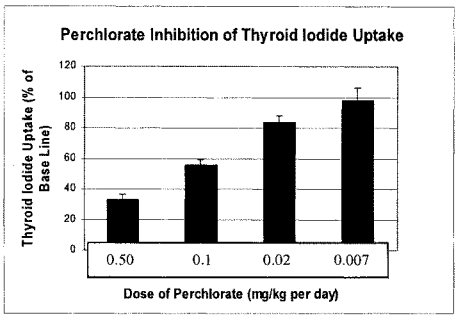
Perchlorate potentially can affect thyroid function because of its ability to block the transport of iodide into thyroid cells. As noted above, it competitively inhibits iodide transport into these cells. The fact that the inhibition is competitive means that it can be overcome by higher iodide concentrations of iodide, and, in laboratory studies, perchlorate did not inhibit uptake of iodide when high concentrations of iodide were present.

After recognition in the 1950s of the ability of perchlorate to block uptake of iodide in animal and then human thyroid tissue, it was given on a long-term basis in doses of 400 to 2000 mg (5.7 to 28.5 1 mg/kg body weight) daily to patients with hyperthyroidism, with the goal of reducing thyroid hormone synthesis and secretion. It proved to be safe, but its actions could be overridden by iodide, and about 10 years later it was replaced by newly developed antithyroid drugs.

Perchlorate Administration in Healthy Subjects

Potassium perchlorate has been was given to a total of 72 healthy men and women for from 14 days to 6 months. The doses ranged from 0.007-9.2 mg/kg per day, assuming 70-kg body weight. The largest and longest of these studies are reviewed here.

Study 1. In a 14-day study, perchlorate was given in varying doses (0.5 to 0.007 mg/kg body weight) to 36 normal subjects (Greer et al. 2002). The lowest dose (0.007 mg/kg per day) did not statistically significantly inhibit thyroid uptake of radioactive iodide, but higher doses did inhibit uptake in a dose-dependent manner (Figure 4). There were no changes in serum thyroid hormone or TSH concentrations to suggest thyroid hormone production was adversely affected in this or any of the other studies.



Study 2. Administration of perchlorate (0.007 and 0.04 mg/kg body weight or placebo) to 13 normal subjects for 6 months (Braverman LE et al. 2006). There was no decrease in thyroid radioiodide uptake or change in serum thyroid hormone or TSH concentrations in the subjects given perchlorate (Table 1).

Clinical Study of Perchlorate

24-Hour Thyroid Iodide Uptake

	Baseline, 3 and 6 Months
Five subjects, 0.007 mg/kg per day	No decrease
Four subjects, 0.04 mg/kg per day	No decrease

Summary of Findings of These and the Three Other Available Clinical Studies

A dose of 0.007 mg/kg per day of perchlorate did not inhibit thyroid iodide uptake when given to healthy subjects for 2 weeks, 3 months, and 6 months. A dose of 0.04 mg/kg per day, which would inhibit thyroid iodine uptake by about 30% if given for two weeks, had no effect at 3 and 6 months (Lawrence JE et al.2000; Lawrence JE et al. 2001; Brabant G et al. 1992).

There were no changes in serum thyroid hormone or TSH concentrations in any of the studies.

Model of Mode of Action of Perchlorate on the Thyroid Gland

Figure 5 shows what I believe is the correct model to assess and explain the action of perchlorate on the thyroid gland and the possible consequences of its action. This model also forms the basis for the conclusion that inhibition of thyroid iodine uptake in not an adverse effect.

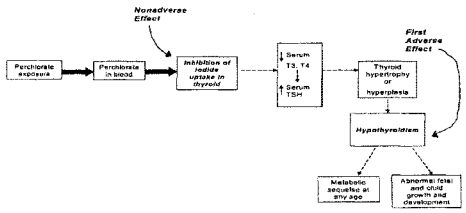


Figure 5. Mode-of-action model for perchlorate action showing the nonadverse effect of perchlorate used by the Perchlorate Committee in determining the reference dose of perchlorate.
From Health Implications of Perchlorate Ingestion. National Academy of Sciences. Washington, DC. 2005:167.

If there is no inhibition of thyroid iodine uptake, then there cannot not be any adverse effect. Furthermore, as noted before, there likely would be complete compensation within days for any mild to even moderate decrease in thyroid iodide uptake, as a result of increased TSH secretion, an increase in iodide transport into the thyroid gland, and increased conversion of thyroxine to triiodothyronine in many tissues.

This choice of no inhibition of thyroid iodine as a no-effect level led to the conclusion that 0.007 mg/kg body weight of perchlorate was safe, to which an uncertainty factor of 10 was added, yielding a reference dose to accommodate subjects, such as pregnant women, fetuses, and infants, perhaps more sensitive to the thyroid inhibitory action of perchlorate, resulting in a reference dose of 0.0007 mg/kg body weight. Furthermore, given the multiple compensation mechanisms, to cause declines in thyroid hormone production that would have adverse health effects, iodide uptake would most likely have to be reduced substantially for several months or longer.*

There are other data supporting this recommendation, such as studies of pregnant women, newborn infants, and children lining in a town in Chile where the water contains 114 μg of perchlorate per liter and studies of newborn screening for hypothyroidism.

I continue to believe that the reference dose of 0.007 mg/kg body weight for perchlorate will protect all people for any harmful effects, and with a wide margin of safety.

Respectfully submitted.

Robert D. Utiger, M.D.

*One way to minimize the action of perchlorate on the thyroid is to increase iodide intake. Indeed, such an increase would benefit the entire U.S. population, given that iodide intake decreased by approximately 50% between 1971-1964 and 2001-2002, and conversely the proportions of people with mild or moderate iodide deficiency increased substantially. This could be done by increasing the iodide content of salt, making salt iodination mandatory, and adding iodide to all multiple vitamin products.

New References Describing In Vivo Studies Published since The Perchlorate Committee's Report Was Report Was Completed in 2005 (incomplete)

Blount BC, et al. 2006. Urinary perchlorate and thyroid hormone levels in adolescent men and women living in the United States. Environ Health Perspect. 114:1865-1871.

Braverman LE, et al. 2006. Effects of six months of daily low-dose perchlorate exposure on thyroid function in healthy volunteers. J Clin Endocrinol Metab 91:2721-2724.

Tellez RT, et al. 2005. Long-term environmental exposure to perchlorate through drinking water and thyroid function during pregnancy and the neonatal period. Thyroid 15:963-975.

Multiple studies of measurements of perchlorate (and sometimes iodide) content of foods, beverages, and water have been published.

References relevant to studies of thyroid physiology and disease and the clinical studies of perchlorate may be found in the Report of the Committee on Health Implications of Perchlorate Ingestion. 2005. National Academy of Sciences. Washington, DC:68-74.

Mr. WYNN. I thank you for your testimony. I would like to thank all the witnesses. And now I would like to ask a few questions. Dr. Utiger, I just want to make sure I am understanding you. Are you basically saying that there is no perchlorate problem in this country?

Dr. UTIGER. Well, in certain areas there is where we know the water content is very high. So there probably is in some places.

Mr. WYNN. So in the situation such as Ms. Solis, it could be a serious problem?

Dr. UTIGER. In certain areas where the water and food stuff content is very high, yes, there could be a problem.

Mr. WYNN. How many people were in your study?

Dr. UTIGER. In the five studies that I mentioned, there were a total of about 80. Most of them were very small, five, six subjects in each of these groups.

Mr. WYNN. All right, thank you.

Let me ask you, Dr. Jacob. I want to make sure that you are clear. You believe that 24.5 RfD is inadequate. Is that your position?

Dr. JACOB. Correct.

Mr. WYNN. And the reason for your position is—why do you believe it is unacceptable?

Dr. JACOB. We find through the CDC studies, which had almost 2,000 people, 2,000 to 3,000 people, depending on the study that you are looking at. We find that women that are exposed to levels far below that have significant changes in their thyroid hormone levels.

Mr. WYNN. The existence of perchlorate in breast milk, would you have any position or thoughts on how that occurs, what is the pathway involved there?

Dr. JACOB. Well, as Dr. Ginsberg mentioned, there is a particular transporter within breast tissue that actually transports perchlorate into breast milk. And when we compare the levels in breast milk versus levels in blood and urine, the are actually higher on average. So it seems like it is actually concentrating perchlorate. And babies are so much smaller than adults, so any dose they get is going to be magnified, and that is why their doses are actually above the RfD.

Mr. WYNN. Dr. Utiger, did you deal with infants in your study?

Dr. UTIGER. I am sorry?

Mr. WYNN. Did you deal with infants in your study?

Dr. UTIGER. There have been no prospective studies in which infants were given perchlorate. There is a community in Chile——

Mr. WYNN. Well, that is fine. I don't want to go to Chile at this point. I just wanted to ask a couple of questions. Dr. Ginsberg, can you elaborate a little bit more on the brain development issue? Because I thought that was something that the committee ought to know more about in terms of how perchlorate is affecting brain development.

Mr. GINSBERG. Well, brain development certainly occurs in utero and then also post-natally. There is arguments about whether brain development, where it stops. But certainly in the early postnatal period when a nursing infant is going to be exposed through

breast milk, there are very important windows of brain development.

Mr. WYNN. Now, do you concur with Dr. Jacob with respect to RfD or the inadequacy of the RfD?

Mr. GINSBERG. Yes, in 2005, our commentary on environmental health perspective said that the National Academy of Sciences study didn't fully consider the uncertainties, and in fact, in the 2002 EPA risk assessment, they considered the low dose that NAS used as an effect level. And the National Academy decided that that was a no effect level. We found in reviewing that that the low dose probably was an effect level for four out of the seven people that were exposed, which is a very small sample. But that probably was an effect level for four of those people.

Mr. WYNN. OK, and I think you really have kind of focused in on the key question that seems to be emerging at this hearing is do we wait until we determine whether it is cantaloupes or water before we make a drinking water standard. Was that basically your position that we should move forward?

Mr. GINSBERG. That and the fact that there are millions of people exposed right now that we don't know who they are. We don't know what to tell them because we can't identify them. So without having an MCL, there is no requirement to test in large and small public water systems. If we knew where they were, a State like mine could then set our own standard and say that at least from that perspective, these water systems need to prevent exposure because at least we would know who is exposed.

Mr. WYNN. OK, thank you. I don't think I have any further questions. Yield to the ranking member for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman. Dr. Ginsberg, you know that some States have set a standard?

Mr. GINSBERG. Exactly, yes.

Mr. SHIMKUS. The other question I have is are you speaking on behalf of the Connecticut Department of Public Health?

Mr. GINSBERG. No, I am not.

Mr. SHIMKUS. Not with Dr. Galvin or Dr. Iwan?

Mr. GINSBERG. No, they certainly know that I am here today.

Mr. SHIMKUS. But you are not speaking on behalf of the State government, the State organization?

Mr. GINSBERG. That is true.

Mr. SHIMKUS. Thank you. And this is really a pretty good slide, this GAO slide that is in the majority. How much perchlorate is identified in the State of Connecticut on this map?

Mr. GINSBERG. The public water systems were tested in 2001 and 2003, and there were no detections above 4 ppb.

Mr. SHIMKUS. Thanks. I appreciate that. And, Dr. Jacob, you support—and talk about the CDC study, 2,000, which is a good sample size. How many of those were under 6 years old?

Dr. JACOB. None were under 6.

Mr. SHIMKUS. So if we are talking about children and the impact on children and unborn children—I am a pro-life Member of Congress. I am very concerned about the unborn children. Then don't you think we should do some research on folks 6 and under? I mean we do that for prescription drugs. We have a special pathway to make sure that prescription drugs have efficacy for them. So in

the CDC, which has a good sample size, if we are going to say, I think, research on the effects of children under six might be meritorious, don't you think?

Dr. JACOB. I agree, but——

Mr. SHIMKUS. Thank you. I appreciate that. Dr. Utiger, is the United States an iodine-sufficient country? And you have to be quick because I have no time.

Dr. UTIGER. It is considered such according to the World Health Organization.

Mr. SHIMKUS. Let me go to the next question. How important and simple is getting more iodine in your diet to solving thyroid-related illnesses?

Dr. UTIGER. Eating more foods that contain iodine, taking multivitamins that contain iodine——

Mr. SHIMKUS. OK, let me go to the next question. Are there medical treatments to help iodine deficiency or hypothyroidism? Can't even say the word.

Dr. UTIGER. Well, you can treat iodine deficiency by giving iodine. We treat hypothyroidism by giving thyroid hormone if the thyroid gland is damaged, et cetera.

Mr. SHIMKUS. Is thyroid enlargement the truest test of thyroid malfunction?

Dr. UTIGER. No.

Mr. SHIMKUS. How do you test for thyroid enlargement?

Dr. UTIGER. It is done by a physical examination or ultrasonography, and it is not very accurate.

Mr. SHIMKUS. Can you do this test on pregnant women?

Dr. UTIGER. Those tests, yes.

Mr. SHIMKUS. Are you aware of any perchlorate studies that have culled their data from thyroid enlargement?

Dr. UTIGER. No.

Mr. SHIMKUS. You mentioned that the conversion of T4 to T3 in many non-thyroid tissues is regulated by nutritional and illness-related factors. Can you explain the illness factors that play a role?

Dr. UTIGER. Poor nutrition, a whole array of illnesses may result in inhibition of the conversion of thyroxin, T4, to tritothyronine in many individual tissues. Amongst them is hypothyroidism which actually increases in tissues, including the brain, the conversion of thyroxin to tritothyronine which is the most active thyroid hormone in tissues.

Mr. SHIMKUS. Thank you. And I will end with this series of questions. If the EPA were to set an MCL, what would be the cost of a water district to test for that? Dr. Jacob, do you know?

Dr. JACOB. My concerns are more with the health effects.

Mr. SHIMKUS. So the answer is no, you don't know?

Dr. JACOB. Correct.

Mr. SHIMKUS. Dr. Ginsberg?

Mr. GINSBERG. The analytical costs are coming down. Right now, you can get down to about 1 ppb. for about $125.

Mr. SHIMKUS. One ppb. per—for just the test?

Mr. GINSBERG. For the test itself.

Mr. SHIMKUS. And in States like Connecticut that really have no significant exposure, that cost would be incurred by?

Mr. GINSBERG. Well, that was limited sampling in Connecticut, and that was a detection level of 4.

Mr. SHIMKUS. OK.

Mr. GINSBERG. The cost would go to the ratepayers.

Mr. SHIMKUS. Dr. Utiger, you don't know?

Dr. UTIGER. I don't know anything about the cost, sir.

Mr. SHIMKUS. Let me ask if there is perchlorate in the drinking water, what is the cost to reduce it? And I will give you an option. Based upon this map, we have various levels. We have no perchlorate, 4 to 100 ppb., 4 to 1,000 ppb., 4 to 5,000 ppb., 4 to 100,000 ppb. So what would be the cost to clean up drinking water to each one of these standards? Dr. Jacob, do you know?

Dr. JACOB. Again, I am more concerned with the cost in terms of health.

Mr. SHIMKUS. Dr. Ginsberg?

Mr. GINSBERG. It is fairly straightforward ion exchange resin columns.

Mr. SHIMKUS. So what would be the cost for each one? And is there a multiple cost for the increased——

Mr. GINSBERG. Yes, that is beyond my expertise.

Mr. SHIMKUS. OK, you don't——

Mr. GINSBERG. But the methodology exists.

Mr. SHIMKUS. Dr. Utiger?

Dr. UTIGER. I don't know, sir.

Mr. SHIMKUS. OK, thank you, Mr. Chairman. I yield back my time.

Mr. WYNN. Thank you. At this time, I recognize Ms. Solis for questions.

Ms. SOLIS. Thank you. My question actually is for Dr. Jacob. Dr. Jacob, we heard a lot about the different tests that were being done by EPA previously in other studies. And they typically looked at adults weighing in between an average, I believe, of 150 pounds. Could you distinguish for me what it would mean if we tested infants or someone that weighed 10 pounds, 7 pounds? What are we talking about here in difference of the exposure of perchlorate?

Dr. JACOB. It would mean that if the same dose were given to me and then given to say a 10-pound baby, it would probably have 10 times the effect, or the blood levels would be significantly higher in the baby because they are much smaller. Is that the question that you are asking?

Ms. SOLIS. Do you think that the standard that is currently set at 24 ppb. now, is not adequate? I mean because, as you said in your statement, that there is potential harm. And I think you mentioned 1 point. Is it 0.1 or——

Dr. JACOB. We are asking for no higher than 1 ppb. to keep those protected.

Ms. SOLIS. You know we had a representative from FDA, and I didn't get a chance to really ask him a question, but in terms of finding where the sources are, the groundwater in the district that I represent is contaminated with perchlorate. And we have several fields, strawberry fields and other agriculture, smaller agricultural areas. I wonder about those larger facilities that have been exposed to perchlorate and adjacent to those farming areas, what might happen to, say, a woman who is giving birth there and the multiple

effects here. I mean drinking water, and then eating perhaps some of the products that are being grown there. And I look as an example right now in the State of California in Fresno where this is a very, very contentious issue right now. Could you comment on that?

Dr. JACOB. I agree that contribution from food is significant, but that shouldn't delay your decision on water. Actually for the people that are getting exposure from food and water, at least if we can regulate it to the best that we can do in water, it will minimize their exposure from that source at least. So for the millions of people that are exposed again from food and water, at least we can start with the water and then move on.

Ms. SOLIS. Dr. Ginsberg, in terms of some of the questioning that occurred here, we don't know where all the sources of perchlorate are or might be?

Mr. GINSBERG. Right, and I am saying that biomonitoring studies such as has been done by CDC already is giving us a fairly good picture of how much baseline exposure from the diet because in their study, they knew that most of those people were not exposed from drinking water. So we have a dietary background exposure as broadcast in their urine results, and that could be used to move on in a risk assessment context to say here is what is coming from baseline diet, and now what percentage of the RfD is that? Whatever RfD you pick, which I think the current RfD is on the high side, but even with that RfD, you could then say this is the baseline exposure from diet that we understand from CDC. Now, that takes up to 30 percent, 50 percent, 80 percent, whatever percentage of the RfD that is, the rest of that is what is left behind that you can attribute to and allow to come from water. And that is how you set your MCL. We have that information. The level of uncertainty currently in the database for perchlorate is smaller than we typically have for most other things we already have MCLs for.

Ms. SOLIS. I just want to state also for the record that many of the water purveyors in my area and my district have gone way beyond what they are required to do. I think they really tried to do as much as they can to provide for healthy, safe standard for our drinking water. We have had so many wells that have been shut down where literally the impact has been on DOD vendor type services that have been provided in a very heavy industrialized mixed-use community where you have houses, you have homes, you have schools, you have these facilities that neighbor our communities.

We do understand that there is an urgency and that many of our water purveyors understand that when this is reported, that wells have to be closed. There is a very serious approach that has to be taken, and obviously I think that is what the basis of this hearing is about.

I do want to mention one last thing though that in the testimony that was provided by the EPA Assistant Administrator, he notes the Greer study that was done in 2002, and my question is for Dr. Jacob again. The study is based on healthy adults and women with an uncertainty factor of 10 that was applied. Again, we have heard about the study in previous years here in this committee, and I

would just ask you again is it a standard approach to just look at the adult population and not the infant population?

Dr. JACOB. With regard to the Greer study, no. The Greer study had far fewer number of participants than the CDC study, and they did not look at the iodine status of individuals. Now, we know that that is very important.

Ms. SOLIS. So it is somewhat inadequate then is what you are saying?

Dr. JACOB. I believe so.

Ms. SOLIS. Thank you very much. I will yield back my time.

Mr. WYNN. I thank the gentlelady. The Chair will recognize the gentlelady from California, Mrs. Capps.

Mrs. CAPPS. Thank you. I want to concentrate on the topic that was just briefly touched upon at the end of my time with questioning the first panel for the bulk of my 5 minutes. But just to clarify, Dr. Jacob, clarification of your statement about testing on children. I want to ask—you are not saying you support testing children for non-therapeutic testing of chemicals. Correct? Right?

Dr. JACOB. Correct.

Mrs. CAPPS. We extrapolate for children. This is based on a long history with lead, right, for children when we extrapolate for children?

Dr. JACOB. And I would like to say that we know enough about children's physiology to know that they would probably be even more vulnerable to the effects of perchlorate than adults.

Mrs. CAPPS. And another clarification. Dr. Ginsberg, do you agree with Dr. Utiger that people should eat more salt to solve the perchlorate problem?

Mr. GINSBERG. Well, it is sort of like fluoridating water. We decided to fluoridate water so that there would be a uniform level of protection of dental hygiene, knowing that people can get fluoride in various ways in their own personal life. People can get iodine through various ways in their own personal life, but we don't have any control over that. But by regulating perchlorate to make sure that is not a major risk factor, that takes that out of the equation.

Mrs. CAPPS. Well, I have been troubled sitting here thinking about over the years what we have known about lead and how we, as a society, have responded to that. And you are here to advise us. And thinking about now how much we know about lead and what steps we have had to take as a society to remediate and even more recently. But pregnant women know to avoid fish now because of mercury content. Unfortunately, that is a health factor. And I was troubled to hear perchlorate mentioned in the same way, in the same breath, so to speak, in terms of that we have a responsibility here that we have some contamination that most of the public has no idea about.

Now, the first step to doing that is to establish a standard, and that is what I am so concerned about. The serious health threat is known, correct? I mean this exposure, as early as 2005, EPA had data that was in a position to issue a drinking water standard. And I asked the first panel why has that not happened. I want to ask you to give us advice. Is it serious enough that we should be dealing with this? I am going to concentrate, Dr. Utiger, on Dr. Jacob and Dr. Ginsberg just because you said already that you think it

is safe based on the NAS study. And then if you want to talk about the safety factor of 10 which leads to the covering of children too.

Dr. JACOB. As I stated earlier, I do believe this is a serious health threat. I think we need to be proactive about public health threats, and I am sorry about the uncertainty factor.

Mrs. CAPPS. Well, that is what I heard from the first panel, that they are not quite sure yet. I will ask you. Is there enough data that we can be certain and that we should establish a standard?

Dr. JACOB. I believe the CDC data and the breast milk studies are more than adequate.

Mrs. CAPPS. So that we are irresponsible if we do not have a standard in this country?

Dr. JACOB. We should hasten the process.

Mrs. CAPPS. And what about the risk factor of 10?

Dr. JACOB. Well, we know that that is not protective of breast-fed infants because simply the levels that are being found in breast milk exceed that.

Mrs. CAPPS. So that was an attempt to cover children, but it really doesn't address that situation. And for your opinion, Dr. Ginsberg?

Mr. GINSBERG. Well, you asked about whether we knew enough in 2005. We actually had EPA's risk assessment in 2002, which was targeting towards a drinking water number of 1 ppb.. And then that got taken into the National Academy process and came back with 24.5 ppb. And we think that—in Connecticut at least—or at least I think that they had it closer to being right originally and that going through all of this discussion and debate and process has lead to some confusion about how much weight to put on a particular study, the Greer study of an N of seven at the low dose level, which is being called a no-effect level, which is, which we see from the CDC study is far from a no-effect level in the general population.

So I think that to move forward in this, EPA needs to fully take a stock of the CDC study, look at the no-effect level from that study and make a determination if one can be determined, and make a determination of what the proper RfD is when you fully consider the population data that we have got and then look at the exposure information that is also in the CDC study. And then they can set a relative source contribution from that, which we published in our 2007 paper as a model way of how to proceed forward.

Mrs. CAPPS. And do you have any further things to say on the factor of 10?

Mr. GINSBERG. Well, I don't want that to be confused with the exposure pathways analysis. That is separate, as Dr. Gray talked about earlier. The factor of 10, I think, is inadequate because, No. 1, it is not based upon a no-effect level. It is based upon a low-effect level, and it does not take into account how long people are exposed. Those people were exposed for 14 days.

Mrs. CAPPS. Well, Mr. Chairman, I know my time is up, but I would just like to address to you that I know there is some misunderstanding of what kind of a hearing this is. But I feel impressed enough by what I have heard today that I would encourage our subcommittee to either have a real hearing on legislation, because I am very frustrated with the EPA's stance at the moment,

or just go right into a markup. That would be my humble suggestion.

Mr. WYNN. Well, your point is well taken.

Mrs. CAPPS. Thank you.

Mr. WYNN. This is a real hearing though.

Mrs. CAPPS. This is a real hearing? Thank you.

Mr. SHIMKUS. Thank you, Mr. Chairman, and I am not going to ask any additional questions. I want to thank the panelists. I want to thank you. I do think this was a very good hearing. I think a lot of questions got aired out, a good debate, and my final point, just to keep this in perspective, we just helped with a rural water district in my district that got a USDA rural development loan for $201,000 to do a water line out 10 miles to hook up 15 households. We just need to understand that what is happening in Los Angeles, we still have people in well systems. And that is kind of the point of my debate, and I know you all are concerned with public health and safety issues. So thank you, Mr. Chairman.

Mr. WYNN. I thank the gentleman for his observation. I would note that, believe it or not, my district also has some rural areas that we are concerned about. Mainly though I want to thank the witnesses for their testimony. It was very helpful for us today. There are no further witnesses. I would remind Members that they may submit additional questions for the record to be answered by the relevant witnesses. The questions should be submitted to the committee clerk in electronic form within the next 10 days. The clerk will notify the offices of the procedures. This concludes our questions and concludes our hearing for today. Thank you.

[Whereupon, at 12:20 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

ASSOCIATION OF
WATER AGENCIES

March 28, 2007

The Honorable Hilda Solis
Vice Chair
Subcommittee on Environment and Hazardous Materials
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Representative Solis:

Drinking water contamination by the rocket fuel component perchlorate has been a concern for the drinking water community for many years. As local stewards of public health, we believe that if perchlorate presents a public health risk, then the Environmental Protection Agency (EPA) should establish a maximum contaminant level for it. We believe that your bill will reduce potential health risks, save water providers and ratepayers future treatment expenses, and protect sources of drinking water.

We appreciate that your legislation preserves the process in the Safe Drinking Water Act Amendments of 1996 requiring regulations to be developed based on sound science and utilizing cost-benefit analyses. Just as important, we appreciate that your bill provides for a reasonable amount of time – two-and-a-half years - for the standard-setting process to take place.

As you have noted, the Department of Defense is responsible for 90 percent of perchlorate contamination in the United States, but, unfortunately, the Department's leadership has resisted our calls for cleaning up the chemical, despite its threat to drinking water supplies. What's more, the Department has stated that only the establishment of a drinking water standard would prompt the Department to cleanup contaminated sites. We hope that your legislation will provide the impetus for the Department to be a good steward of our water supplies by cleaning up its perchlorate contamination.

Also, we look forward to working with you to ensure that EPA monitors the Department's cleanup progress and to ensure that drinking water systems are not left responsible for the cost to remove perchlorate from water supplies.

Thank you for your leadership on this critical issue.

Sincerely,

Diane VanDe Hei
Executive Director

AMWA is an organization of the largest publicly owned drinking water providers in the United States, collectively serving more than 127 million people with safe drinking water.

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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. Alex Beehler
Assistant Deputy Under Secretary of Defense
Environment Safety and Occupational Health
U.S. Department of Defense
The Pentagon
Washington, DC, 20301-3400

Dear Mr. Beehler:

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 **Friday, 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 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

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

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.
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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.

Administrator Johnson
March 6, 2006

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

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

Administrator Johnson
March 6, 2006

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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.

CHARRTS No.: HEC-01-001
Hearing Date: April 25, 2007
Committee: HEC
Member: Congressman Barton, Congressman Shimkus
Witness: Mr. Beehler
Question: #1

Question: You state in your testimony that DOD has been working with the States and will continue to comply with applicable Federal or state standards regarding perchlorate. How have the States reacted to the risk assessments conducted under the Defense Environmental Restoration Program?

Answer: We'd like to reiterate that DoD complies with Applicable or Relevant and Appropriate Requirements. Risk assessments conducted by DoD are done in consultation with States and, for National Priorities List (NPL) sites, EPA. DoD makes every attempt to reach consensus with regulators on risk assessments. For the most part, DoD has been able to reach consensus with regulators on risk assessments.

CHARRTS No.: HEC-01-002
Hearing Date: April 25, 2007
Committee: HEC
Member: Congressman Barton
Witness: Mr. Beehler
Question: #2

Question: As was stated in the hearing, perchlorate has been a particular concern in California. What is the California Perchlorate Sampling Prioritization Protocol and what were the results?

Answer: Generally, California has been a success story regarding DoD's response to perchlorate issues. Representatives from the State of California's Environmental Protection Agency, Department of Toxic Substances Control, State Water Resources Control Board, Regional Water Quality Control Boards, and the DoD Regional Environmental Coordinator for Federal Region IX jointly produced the *Prioritization Protocol for Perchlorate Impacts to Drinking Water from Department of Defense Facilities in California (Protocol)* dated 25 August 2004. A training workshop was held in July 2004 to explain the Protocol to the users.

The Protocol was designed as an initial screening tool to identify and prioritize sites for sampling based on proximity to drinking water supply sources. A primary component of the Protocol is the Relative Priorities Table, used to assign relative priorities to individual sites. The relative priority for a site is dependent on the distance from the site to a drinking water supply source, whether or not the drinking water supply has been impacted, and whether or not perchlorate was released at the site. The Protocol considers sites that are within one mile or between one and five miles from a drinking water supply source. The Relative Priorities Table assigns the highest priority to sites where perchlorate releases have impacted drinking water sources, and the lowest priority to sites for which existing information indicates no evidence of a release.

In summary, the Protocol is used for initial screening of DoD sites that may have used perchlorate to determine if there could be *potential* perchlorate contamination, and a possible pathway of exposure. We emphasize the word potential -- 924 sites were jointly reviewed by the State and DoD technical personnel. So far, 97 percent do not appear to pose a current threat to drinking water based on the screening criteria used in the protocol. The remaining 3 percent either have some type of response action or confirmation sampling underway or the assessments are being reviewed by Californian regulatory agencies.

Despite the fact that DoD installations do not appear to be a major source of perchlorate contamination in California, DoD has invested over $18 million in water treatment and remediation technologies for perchlorate in Southern California. Working closely with local water purveyors, approximately 5000 GPM new treatment capacity has been added and the technologies have reduced estimated capital and operation/ maintenance costs.

CHARRTS No.: HEC-01-003
Hearing Date: April 25, 2007
Committee: HEC
Member: Congressman Barton
Witness: Mr. Beehler
Question: #3

Question: In your oral statement and in questions, you seemed to indicate that there were some common misperceptions about the Defense Department's activities related to perchlorate. What are these misperceptions?

Answer: There are two common misperceptions about DoD and perchlorate. First, while it is sometimes stated that DoD will not initiate response actions for perchlorate without the promulgation of a Maximum Contaminant Level (MCL), this is not true. Examples are provided in answers below. Second, while DoD is a major *purchaser* of perchlorate, it is not the sole user of perchlorate, nor, does it appear from the data examined (such as the California prioritization protocol), that DoD facilities are a major source of perchlorate *detections* in public drinking water supplies.

Irrespective of MCL promulgation, DoD has been taking appropriate *response* actions for perchlorate, and for contaminated sites that include perchlorate, under a number of statutory authorities and in coordination with EPA and State regulators. "Response action" is a comprehensive term under CERCLA that includes site investigations, risk assessments, treatability studies, removal actions, and remedial actions. In many cases, the Department has conducted expeditious soil cleanups as removal actions in accordance with the National Contingency Plan. Removal actions can be taken before formal Records of Decision (RODs) are completed and these responses are coordinated with regulators. Likewise, pilot treatment projects – such as the treatment unit at Edwards Air Force Base -- can be constructed and placed into service as part of the investigation stage even before RODs are signed. These pilot treatment projects often remove substantial contamination as part of the feasibility and verification process conducted prior to deploying the technology full scale. *Thus, RODs alone are not an effective or complete measure of an agency's response or cleanup activities.*

Prior to the National Academy of Sciences review of perchlorate science in January of 2005 and EPA's subsequent posting of a reference dose, no final federal peer-reviewed toxicity values for perchlorate had been adopted. Yet, before 2005, while the risks to human health related to low levels of perchlorate were being determined, DoD initiated responses at sites determined by risk assessments to pose a potential risk to the public and the environment, using best available toxicity information at the time.

DoD has worked hard to dispel the myth that action cannot be taken until an MCL exists; in fact, we have been developing with EPA and the Environmental Council of States (ECOS) a series of white papers to provide further interagency advice on how to respond to emerging contaminants and how to select toxicity values when there are no toxicity values in the EPA Integrated Risk Information System (IRIS). The Department has also established a process within DoD to identify emerging contaminants at an early stage, determine if they are used by DoD, assess the impacts to DoD of potential changes in regulatory status, and develop proactive

risk management options for DoD program managers to respond to these chemicals.

Initial reactions by the public and regulators are often that DoD must be the source of perchlorate contamination because of the portrayal of perchlorate releases almost singularly from rocket fuel. As States and local authorities examine the evidence closer, they are coming to different conclusions as in the results thus far for the California prioritization protocol for perchlorate sites. Other specific examples are:

On April 10, 2007 the California House Natural Resources Committee, Subcommittee on Water and Power, led by Rep. Grace F. Napolitano (D-CA), held an oversight field hearing on "Sustainable Water Supplies for the West: Part 1 – Protecting Groundwater Resources." At the hearing, Mr. Robert E. Martin, General Manager, East Valley Water District, Highland, CA provided the following testimony:

> "Based upon research conducted by our regional water quality control board (Santa Ana Region), we have concluded that our perchlorate problem can be traced back to fertilizer brought in from South America in the early 20th century and used on orange groves that are now part of our service area. Since these deliveries were made generations ago and land ownership has changed, often many times, there is little hope of our securing funding help from principal responsible parties. This means that the customers of the East Valley Water District will have to bear the cost of building and operating complex perchlorate treatment systems."

In a March 14, 2005 letter to EPA Assistant Administrator Ben Grumbles, Mr. Robert Golledge, Commissioner, Massachusetts Department of Environmental Protection stated the following:

> "In March 2004, the Department initiated the process to establish a drinking water maximum contaminant level (MCL) for perchlorate by promulgating regulations requiring all public water supplies to test for perchlorate. Several rounds of sampling have been completed statewide. Nine public water supplies have detected perchlorate, seven of the nine have perchlorate ranging from just below 1 ppb to slightly above 3 ppb. However, two water supplies had greater than 45 ppb, one as high as 1300 ppb. When confronted with the perchlorate plume at Massachusetts Military Reservation in 2001, most thought the primary source of perchlorate contamination was the result of military training activities. None of the nine water supplies that have tested positive for perchlorate in Massachusetts appear to have any connection to military bases or activities."

CHARRTS No.: HEC-01-004
Hearing Date: April 25, 2007
Committee: HEC
Member: Congressman Barton
Witness: Mr. Beehler
Question: #4

Question: You stated that of the 146 installations that reported assessments in FY 2006, only 9 reported detection above 4 ppb in any media. Is this trend a result of increased monitoring and assessment and does it demonstrate a turning point in perchlorate detections at DOD installations?

Answer: The actual testimony states that: "...only nine installations reported a detection between 4 ppb and 24 ppb in any media: drinking water, surface water, groundwater, or soil. Eight installations indicated detection above 24 ppb in any of these media."

DoD has a few installations with some large concentrations of perchlorate from past weapons related activities that are being addressed satisfactorily under the Defense Environmental Restoration Program (DERP) (e.g., Edwards Air Force Base, Naval Weapons Industrial Reserve Plant (NWIRP) McGregor, Redstone Arsenal). The remaining installations, for the most part, have low levels of perchlorate detections under the screening levels in soils and the Drinking Water Equivalent Level (24 ppb). Overall, from the data we have examined, we believe that most DoD perchlorate releases are contained on DoD installations and are not contaminating public drinking water supplies. The apparent reduction in sites with perchlorate detections may be a result of several factors:

- Installations have eliminated discharges by installing closed-loop systems to contain and treat water from "hog-out" operations where expired propellant/oxidizer is removed and replaced.
- Increased reductions in wastewater discharges.
- Greater awareness of the risks associated with perchlorate releases.
- Better management practices for munitions deactivation.
- Completion of response actions.

CHARRTS No.: HEC-01-005
Hearing Date: April 25, 2007
Committee: HEC
Member: Congressman Barton
Witness: Mr. Beehler
Question: #5

Question: You mentioned that alternatives to potentially replace ammonium perchlorate in solid rocket propellants are undergoing testing and evaluation. The alternatives must meet high performance specifications and have a low environmental burden. Do performance or environmental externality issues exist with these alternatives? Will you have these on line by 2008?

Answer: Two parallel programs are underway to develop alternatives for ammonium perchlorate (AP) in solid rocket propellants. One is sponsored by the Strategic Environmental Research and Development Program (SERDP), managed by the Office of the Secretary of Defense. The other program is sponsored by the Army Environmental Quality Technology Program, managed by the Department of the Army and coordinated with rocket and missile Program Managers. Although testing is being performed in both the SERDP and Army programs, programmatically these efforts support only Research and Development (i.e., current work is developing new chemicals and performing in-laboratory testing, *not* field-testing full-scale rocket motors). The SERDP effort is working on an AP alternative solid-rocket propellant based on chemicals such as ammonium dinitramide and hydroxyl ammonium nitrate. The Army effort is developing a completely new hybrid-rocket motor concept to replace solid rocket motors that is a combination of gelled and solid materials.

Perchlorate replacements will not be implemented unless they are able to meet all performance criteria, safety *and* known or reasonably anticipated environmental requirements. Performance requirements and methods of evaluating them are both well established in the rocket propellant community. Safety and environmental performance evaluation are also well-established by Acquisition Policy. Environment, safety and occupational health (ESOH) considerations are documented in the program acquisition strategy, the Programmatic Environment, Safety and Occupational Health Evaluation, Environmental Assessments (in accordance with the National Environmental Policy Act), and Toxicity Clearances. Program Executive Officers and Program/Project/Product Managers have traditionally used these documents to assess the risks of using hazardous materials versus substitutes.

Recently, the U.S. Army Research, Development and Engineering Command initiated the Environmental Health Assessment (EHA) as a pilot program to evaluate energetic materials prior to acquisition – during research and development. EHAs evaluate persistence, fate and transport, and health criteria (human and environmental) in a comprehensive framework. These EHAs are based on the available data consistent with the Research, Development, Test and Evaluation level of effort, and use a proposed American Society for Testing and Materials (ASTM) guideline, WK9121 "New Assessment of Environmental Health Impacts in the Research, Development, Testing, and Engineering of New Munitions" that identifies what data are needed at specific technology stages. The EHA has been established as an iterative means of

communication between the rocket scientists and the environmental health professionals. This use of the EHA is coordinated with the Assistant Secretary of the Army for Acquisition, Logistics and Technology's Environmental Support Office. SERDP is developing a similar protocol for use within their program.

We will not have the rocket propellant substitutes for perchlorate on line by 2008. As mentioned above, alternatives for rocket propellants are still in early research and development. Research and Development monies are programmed in the Army to develop these alternatives; however, there will still be requirements for additional funding to mature this program through Applied Research by FY2012. SERDP funding is at a similar level. In order to find a replacement for perchlorate or an alternative design for heavy lift rocket motors *and* then implement it for *all* systems in acquisition, a substantial investment will be required – estimated on the order of hundreds of millions of dollars. Regardless of funding level, it is considered a high-risk research program -- meaning that a solution is not readily apparent. It will take time to develop, demonstrate, and implement alternatives to perchlorate depending on the system in which perchlorate is now used.

We do expect to have substitutes for perchlorate for the Army's ground burst and grenade simulators on line in 2008. The testing is complete, and we are now preparing production capability to manufacture the new simulators. The Army estimates that no more perchlorate-containing ground burst and grenade simulators will be used within a matter of about 12 months. The DoD is currently developing propellant and pyrotechnic compositions to meet performance requirements and reduce safety and environmental impacts, which will eventually be made into perchlorate substitutes in next-generation weapons systems. It should be noted that the introduction of perchlorate-free ground burst and grenade simulators after mid- FY2008 will eliminate the largest single source (35-70 percent) of the expended potassium perchlorate on Army training ranges.

The DoD is currently developing perchlorate alternatives for five additional simulators/training items as well as pyrotechnic delays, incendiaries, and primers, and a perchlorate alternative in a handheld smoke and obscurant device (SOD), with a long-term plan to leverage these results on other systems. Initial implementation of these items is expected to range from 2009-2011 based on successful product development.

CHARRTS No.: HEC-01-006
Hearing Date: April 25, 2007
Committee: HEC
Member: Congressman Barton
Witness: Mr. Beehler
Question: #6

Question: Your testimony talks about the research work that the Defense Department has sponsored on various sources of perchlorate. Has the Department examined forensic techniques as part of this work? What is the nature of this research and any results?

Answer: Yes, DoD contributed to the larger body of forensic techniques, including sponsoring research to prove that existing methods such as isotopic ratios are robust enough to differentiate perchlorate sources. For example, using these established isotopic analysis techniques, we are now able to distinguish.between naturally occurring perchlorate and that which is manufactured. NASA has used this technique to differentiate perchlorate releases from its Jet Propulsion Laboratory in California from other sources, such as fertilizers. On-going research shows promise in using the same techniques to distinguish between various types of manufactured perchlorate. Also, there were no cost-effective methods for getting and concentrating groundwater samples for laboratory analysis. DoD funded the development of a cost-effective sampling process.

CHARRTS No.: HEC-01-007
Hearing Date: April 25, 2007
Committee: HEC
Member: Congressman Wynn
Witness: Mr. Beehler
Question: #7

Question: Is it correct that there is no appreciable difference in the cost of remediating incremental levels of perchlorate in groundwater? If not, please explain why not.

Answer: From an engineering perspective, there is little difference in treating 1,000 gallons of groundwater to a level of 4 ppb versus 10 ppb. The same technology is used. There will be a relatively small incremental difference in operating cost for the same amount of groundwater. However, a large cost differential may arise depending on how much groundwater needs to be treated to achieve a cleanup level of 4 ppb versus 10 ppb for example. Costs could rise considerably if 100,000 gallons needed to be treated vice 1,000 gallons.

CHARRTS No.: HEC-01-008
Hearing Date: April 25, 2007
Committee: HEC
Member: Congressman Wynn
Witness: Mr. Beehler
Question: #8

Question: At the April 25, 2007, hearing before the Subcommittee on Environment and Hazardous Materials, when asked if any Department of Defense (DOD) Federal facility that has perchlorate contaminated groundwater had completed a record of decision under CERCLA, you responded that you would "take that for the record." Is it correct that DOD has not completed a Record of Decision addressing the remediation of perchlorate contaminated groundwater at any of DOD's 34 Superfund National Priorities List (NPL) facilities that have perchlorate contaminated groundwater? If DOD has completed a Record of Decision addressing the remediation of perchlorate contaminated groundwater at any of DOD's 34 Superfund NPL facilities that has perchlorate contaminated groundwater, please provide the name of the facility, and a copy of a fully executed Record of Decision.

Answer: The attached Table A provides data for the DoD National Priority List (NPL) sites provided in Appendix 1 to your letter. Non-NPL installations including the Naval Weapons Industrial Reserve Plant (NWIRP) in McGregor, TX, and the former Naval Service Warfare Center (NSWC) in White Oak, MD, have Records of Decision (RODs). It is important to note that certain forms of cleanup actions can be initiated before a ROD. For example, "removal actions" (e.g., soil excavation/disposal) can often be completed prior to a formal ROD. Likewise, pilot treatment projects can be constructed and placed into service as part of the Feasibility Study stage. In fact, this is often the case for emerging contaminants with no proven treatment technology. These pilot treatment projects often remove substantial contamination before they are validated and scaled up. Thus, RODs alone are not an effective or complete measure of an agency's response or cleanup activities. The attached table reinforces the Department's belief that either appropriate response actions are being taken or that perchlorate levels are below levels of concern or applicable regulatory levels.

DOD NPL FACILITIES WITH KNOWN PERCHLORATE CONTAMINATION
(List Provided by House Energy & Commerce Committee)

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

CHARRTS No.: HEC-01-009
Hearing Date: April 25, 2007
Committee: HEC
Member: Congressman Wynn
Witness: Mr. Beehler
Question: #9

Question: Section 120 of CERCLA requires that not later than six months after the inclusion of any Federal facility on the NPL, any agency of the United States, in consultation with 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 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.

Answer: The attached Table A provides data for the DoD National Priority List (NPL) sites provided in Appendix 1 to your letter. It is important to note that perchlorate may not have been considered a "contaminant of concern" by either DoD or regulators at the time the RI/FS was initiated or completed. Perchlorate response actions may have been initiated subsequent to the initial RI/FS. For example, a remedial action selected for another contaminant may also be addressing perchlorate. To portray an accurate picture of DoD's perchlorate response, we have provided additional information in the attached table to show these subsequent perchlorate related actions. We interpret the "scope of the RI/FS" to mean what were the contaminants of concern. We have added a column to show the primary contaminants of concern. There may be multiple RI/FSs at the installation with different start and completion dates. We have provided the date of the initial RI/FS, then focused on any RI/FSs related to perchlorate. Note that in a number of cases, the initial RI/FS was started before NPL listing.

CHARRTS No.: HEC-01-010
Hearing Date: April 25, 2007
Committee: HEC
Member: Congressman Wynn
Witness: Mr. Beehler
Question: #10

Question: By letter dated July 16, 2003, EPA notified the Department of Defense that is was discontinuing involvement at the Camp Bonneville Base Realignment and Closure (BRAC) Site in Vancouver, Washington, citing a lack of collaboration by DOD. (See Appendix 2, Letter from EPA Region 10 to Col. Richard Conte, Director of Public Works, Ft. Lewis Washington). In the letter EPA states that "the site lacks the necessary level of site characterization information on which to base long-term remedial decisions." EPA further states that "[t]here is only a limited understanding about the nature and extent of contamination primarily from munitions and unexploded ordnance (UXO) but also limited areas related to chemical releases." At the April 25th hearing, you were asked "why the Army was not responsive to Region 10's comments?"

Answer: Camp Bonneville, Washington, was recommended for closure by the 1995 Base Realignment and Closure (BRAC) commission. The Army established a BRAC Cleanup Team (BCT) which included the U.S. EPA Region 10, the Washington Department of Ecology (WDOE), and Camp Bonneville to achieve consensus on efforts to arrive at accelerated cleanup and installation transfer. The lead regulator for cleanup issues prior to Camp Bonneville being listed on BRAC was WDOE and they continue to be the lead regulator post BRAC.

Since 2003, the Army has been negotiating with WDOE and Clark County concerning the transfer of Camp Bonneville and the cleanup actions necessary to transfer the facility to Clark County via a deed for Conservation Conveyance. The level of clean up at Camp Bonneville is dependent upon the proposed land use and any land use restrictions needed; in 2003 these had not been determined by Clark County. At the time of the Region 10 EPA letter, the Army was conducting multiple studies and investigations to identify what contamination remained on Camp Bonneville. Early in the negotiation for the transfer of Camp Bonneville, WDOE asserted its regulatory role as lead regulatory agency and requested that EPA provide a supporting regulatory role. The Army has been responding to WDOE concerning cleanup requirements at Camp Bonneville since 2003.

In late 2006, the Army and WDOE reached agreement for the transfer of Camp Bonneville to Clark County. On October 3, 2006, the Governor of the State of Washington approved the transfer of Camp Bonneville to Clark County via a deed for Conservation Conveyance. In addition, the Army and Clark County agreed to an Environmental Services Cooperative Agreement (ESCA) in which the Army provides funds to Clark County so that it will achieve regulatory closure at Camp Bonneville. Subsequently, Clark County transferred ownership and responsibility for environmental remediation of Camp Bonneville to the Bonneville Conservation Restoration and Renewal Team, Inc (BCRRT). In addition, Clark County, the BCRRT, the WDOE, and the Attorney General's Office for the State of Washington entered into an enforceable agreement, Prospective Purchase Consent Decree, on October 13, 2006, to ensure Clark County and the BCRRT appropriately addressed and achieved regulatory

closure for the environmental contamination and the known or suspected presence of UXO and other munitions and explosives of concern on the property. Environmental remediation activities are underway in accordance with the Environmental Services Cooperative Agreement (ESCA) and the Prospective Purchase Consent Decree (PPCD). Upon completion of cleanup by BCRRT and approval by the WDOE, the BCRRT will transfer Camp Bonneville back to Clark County and Camp Bonneville will be used as park lands in accordance with the Conservation Conveyance.

CHARRTS No.: HEC-01-011
Hearing Date: April 25, 2007
Committee: HEC
Member: Congressman Wynn
Witness: Mr. Beehler
Question: #11

Question: Has DOD completed a remedial action, as opposed to a removal action, at any DOD facility where perchlorate in groundwater is present? If so, please provide the name of the facility, a description of the remedial action and include supporting documentation.

Answer: Some remedial actions for groundwater are underway but not completed (see examples below and the attached Table A for documentation). Groundwater treatment often requires many years to achieve the site-specific remediation goal and thus completion of the remedial action. When a treatment system has been constructed and put into operation, this is called "remedy in place." When the remedial objectives have finally been achieved, this is called "response complete." Viewing only "completed" remedial actions would not provide an accurate picture of DoD's actual perchlorate responses. The Department believes the Committee is seeking to ascertain if DoD is responding appropriately to perchlorate releases. To do so, *all* response actions must be considered in a temporal context (e.g., when a toxicity value was established; when regulators considered perchlorate as a contaminant of concern). "Removal actions" (e.g., soil excavation/disposal), in effect, often achieve the same level of cleanup as a final remedial action. Even before EPA promulgated a toxicity value for use in site-specific risk assessments, DoD began response actions at a number of bases with perchlorate detections. Examples of installations with response actions underway include the following:

- Massachusetts Military Reservation (MMR). Removal actions have been completed for contaminated soils. Groundwater contaminated with RDX and perchlorate is being remediated through a groundwater treatment system in place and operating. All investigations and actions were fully coordinated with EPA Region 1 and Massachusetts.
- Longhorn Army Ammunition Plant, TX. A fluidized bed reactor was added to a TCE groundwater treatment system in 2001 to remove perchlorate from an effluent. There is no groundwater use and actions were taken to protect Caddo Lake (drinking water supply). Soil covers were placed over two soil sites which contained high perchlorate concentrations to prevent runoff into streams. Final RODs are being developed to address remaining soil contamination through soil removal and disposal. All actions have been fully coordinated with EPA Region 6 and Texas.
- Naval Weapons Industrial Reserve Plant (NWIRP), McGregor, TX. At McGregor, the Navy completed a Record of Decision (ROD). An in-situ biological treatment system is treating perchlorate in groundwater and soil; this is the first – and world's largest – full-scale bio-wall application for groundwater remediation of perchlorate and volatile organic compounds. Recent groundwater data shows a marked decrease in the amount of perchlorate in groundwater. In fact, last October, the NWIRP McGregor became the very first U.S. Navy facility to receive a Ready for Reuse determination from EPA. This

verifies that environmental conditions at the property are protective of human health and the environment for its current and future commercial, industrial and agricultural uses. (See attached EPA press release.)

- Former NSWC, White Oak, MD. White Oak has a number of completed RODs. The RODs primarily address other key contaminants, but the treatment systems put in place under the RODs are also addressing perchlorate. All actions have been coordinated with EPA Region 3 and Maryland, and both agencies concurred with the remediation goal for perchlorate.
- Redstone Arsenal, AL. Perchlorate was detected in soil and groundwater. A Remedial Investigation report was completed in July 2005. A Feasibility Study is underway to analyze remedial options. A health risk evaluation was conducted for surface water off-base, which concluded that there was no health risk to recreational users and residents. Sampling showed non-detectable levels in the Tennessee River. Drinking water is supplied by the municipal water system. There is no human consumption of groundwater either on-base or off-base, and thus no threat to human health. The Arsenal is working closely with EPA and the Alabama Department of Environmental Management (ADEM). Based on evaluations so far, there does not appear to be a threat to public health.
- Vandenberg AFB, CA. Perchlorate was detected in groundwater, but drinking water supplies have not been affected. The Air Force initiated a pilot treatment process that uses injections of lactate and a dechlorinating agent to groundwater The pilot study was successful, and both trichloroethylene (TCE) and perchlorate were removed to non-detectable levels in one month. Planning is underway to scale up the pilot treatment process to complete TCE and perchlorate removal at this site.
- Edwards AFB, CA. Perchlorate was detected in soil and groundwater at Edwards AFB, Drinking water supplies have not been affected. In May 2003, Edwards AFB implemented a pilot project/treatability study to evaluate the effectiveness of using ion-exchange technology for removing perchlorate from groundwater. As of January 2007, the system has treated 32.1 million gallons and removed 133.7 pounds of perchlorate from the groundwater. This pilot treatment system continues to operate. Also, a treatability study that examined the effectiveness of flushing to remove perchlorate from soil at Edwards AFB demonstrated almost complete removal of perchlorate from the soil column.

CHARRTS No.: HEC-01-012
Hearing Date: April 25, 2007
Committee: HEC
Member: Congressman Wynn
Witness: Mr. Beehler
Question: #12

Question: Was there a time when DOD did not consider perchlorate to be a contaminant? If the answer is "yes," was that a basis for DOD's choosing not to undertake remedial actions at federal facilities with perchlorate contamination in the groundwater? When did DOD agree that perchlorate was a contaminant?

Answer: In the past, it may not have been clear whether perchlorate was considered a "pollutant and contaminant" in the context of the Comprehensive Environmental Response, Compensation, and Liability Act and whether a response was required. This was especially true since there was no peer-reviewed toxicity level in EPA's Integrated Risk Information System (IRIS) until early 2005. However, as noted above, even before EPA promulgated a toxicity value for use in site-specific risk assessments, DoD began response actions at a number of bases with perchlorate detections. Starting in September of 2003, DoD issued a series of specific policies aimed at ensuring appropriate perchlorate response actions as the science and understanding of perchlorate evolved. On January 26, 2006, DoD issued the "Policy on DoD Required Actions Related to Perchlorate" which clarified sampling and response requirements and superseded the September, 2003, DoD perchlorate sampling policy.

To resolve a number of issues involving perchlorate and other emerging contaminants, DoD sponsored an emerging contaminants forum in November 2005 with States and EPA and other federal agencies. As a result, DoD and the Environmental Council of States formed a work group on emerging contaminants. The work group has developed a number of products aimed at clarifying risk communication, risk assessment and risk management for emerging contaminants. One of the products, called the *Identification and Selection of Toxicity Values/Criteria for CERCLA and Hazardous Waste Site Risk Assessments in the Absence of IRIS Values,* has been particularly valuable in helping determine toxicity values for use in human health risk assessments for emerging contaminants like perchlorate.

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

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July 6, 2007

Mr. Robert E. Brackett
Director
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dear Mr. Brackett:

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 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 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

AUG 0 6 2007

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) the opportunity to testify at the April 25, 2007, hearing entitled "Perchlorate: Health and Environmental Impacts of Unregulated Exposure." Dr. Robert Brackett, Director, Center for Food Safety and Applied Nutrition, testified on behalf of FDA. We are responding to the letter of July 6, 2007, you sent in follow-up to the hearing.

We have re-stated each question in bold type, followed by FDA's response.

The Honorable Joe Barton and the Honorable John Shimkus

1. **Do you think that an appropriate way to protect the sensitive subpopulation of concern (pregnant and nursing mothers and their babies) would be to ensure that their prescription prenatal vitamins contain adequate iodine (150 µg/day), as recommended by the American Thyroid Association and as mentioned in the NAS report? What further actions do you think are reasonable for FDA to take in this regard?**

FDA recently reviewed the labels of various prenatal vitamin supplements. Product labels indicated that all of the prenatal dietary supplements that were examined contained iodine levels ranging from 150-300 µg.

FDA will continue to monitor additional scientific studies conducted by the Centers for Disease Control and Prevention (CDC) and other organizations with respect to the effect of perchlorate exposure on iodide uptake. As new information is made available, we will consider what additional measures may be necessary and prudent to prevent public health problems in vulnerable populations that may become apparent.

2. **In its recently released proposal for regulatory determinations under the second Contaminant Candidate List (CCL2), EPA stated that it had insufficient exposure information, particularly from food, in order to move forward with a regulatory determination for perchlorate. EPA also identified the option of relying on urinary biomonitoring data such as the type released by CDC and relied upon by Dr. Blount in his fall 2006 population study. Do you believe that this type of data, which provides results on total exposure in humans, would better serve EPA rather than relying on exposure modeling data, which is subject to information gaps and therefore increases the level of uncertainty?**

FDA believes it is the Environmental Protection Agency's (EPA) decision to determine if biomonitoring data or exposure modeling data would better serve EPA in determining whether it had sufficient exposure information to move forward with a regulatory determination for perchlorate.

3. **I understand that other compounds in food besides perchlorate, like nitrates, also inhibit iodine uptake. Is this true? If so, since milk, meats and lots of foods we eat everyday contain nitrates, do you think these compounds pose a risk in the diet?**

Nitrate occurs in a wide variety of foods naturally, especially in vegetables, or as added, such as in processed meats. Although nitrate is known to inhibit iodide uptake, FDA is not aware of any information demonstrating that the presence of nitrate, either naturally or added, in foods poses such a risk.

4. **I understand the Blount study also looked for an effect from other compounds that inhibit iodine uptake. The study either found that these other compounds didn't show the effect they should, or that one of them actually worked opposite of the way all other science says it should. Based on these inconsistent outcomes, do you think the Blount study should be used for policy decisions?**

The authors of the CDC biomonitoring study recommended further research to affirm the finding of association between perchlorate exposure and reduced thyroid function in women with sub-optimal low urine iodine levels (less than 100 micrograms per liter (μg/L) that may indicate iodine deficiency. FDA agrees with this recommendation for further clarifying the potential public health significance of such changes in thyroid function.

<u>The Honorable Albert Wynn</u>

1. **In both written and oral testimony, FDA neglected to report what the specific findings were of its Exploratory Data Studies. (Referring to *FDA's Exploratory Data on Perchlorate in Food,* November 2004 at *http://www.cfsan.fda.gov/~dms/clo4data.html*). Is it correct that FDA tested 500 samples of food, including lettuce, milk and bottled water from areas where water was thought to have perchlorate contamination and perchlorate was found in 90 percent of lettuce samples and 101 out of 104 of store bought milk from 14 states?**

Yes. FDA's Exploratory Data on Perchlorate in Food, November 2004, found perchlorate in 90 percent of lettuce samples (116 out of 128), and in 101 out of 104 milk samples (3 raw milk samples from a research facility in Maryland and 101 store bought milk samples from 14 states).

2. **Referring to *FDA's Collection and Analysis of Food for Perchlorate Memorandum, February 23, 2005* which states that "Perchlorate at high doses can interfere with iodide uptake into the thyroid gland, disrupting its functions." Please explain what FDA considers to be "high doses" of perchlorate and the basis for this assertion. Additionally, is the FDA going to revise this statement in view of CDC biomonitoring data finding that levels of perchlorate common in the population were associated with small to medium changes in thyroid hormone levels? If not, why not?**

Human exposure to high dosages (e.g., pharmacological levels) of perchlorate can interfere with iodide uptake into the thyroid gland, disrupting the functions of the thyroid and potentially leading to a reduction in the production of thyroid hormone. In fact, perchlorate has been used as a drug to treat hyperthyroidism (excess thyroid hormone production) and to diagnose disorders related to thyroid or iodine metabolism.

The authors of the CDC biomonitoring study recommended further research to affirm the finding of association between perchlorate exposure and reduced thyroid function in women with sub-optimal low urine iodine levels (less than 100 μg/L that may indicate iodine deficiency). FDA agrees with this recommendation for further clarifying the potential public health significance of such changes in thyroid function.

3. **What levels of contaminant in food, such as perchlorate, warrant the issuance of a "tolerance" or the setting of an "action level?"**

Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) provides that a food is deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. In addition, section 402(a)(2)(A) provides that a food is deemed to be adulterated if it bears or contains any added poisonous or deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406 of the Act.

With respect to perchlorate, insufficient exposure and health effects information for perchlorate in foods exists to support setting action levels above which FDA might take regulatory action based on adulteration under section 402(a)(1) of the Act, or to support setting a tolerance at which a food is deemed to be adulterated under section 402(a)(1) or 402(a)(2)(A) of the Act.

4. ***FDA's Collection and Analysis of Food for Perchlorate Memorandum, February 23, 2005* states that objective of collecting and analyzing food for perchlorate is "to generate information on the incidence and levels of perchlorate contamination in selected food items. The data will be used to determine the need for future monitoring and/or enforcement strategies." Please explain in detail how the "incidence" and the "level" of perchlorate contamination is derived and noted. Also, please explain in detail and**

with examples, how such data is used to determine: 1) the need for monitoring, and 2) enforcement strategies in terms of the levels and incidences that are needed for implementing particular enforcement activity under the Food and Drug Cosmetic Act.

To generate information on the incidence and levels of perchlorate contamination in foods, FDA conducted the following activities during Fiscal Year 2004 and Fiscal Year 2005:

- FDA first developed a rapid, sensitive, and specific ion chromatography-tandem mass spectrometry (IC-MS/MS) method for determining perchlorate levels in foods, such as bottled water, fruits and vegetables, milk, grain products, and seafood.
- During Fiscal Year 2004, FDA conducted an initial exploratory survey in which FDA Field Offices collected samples of domestic origin of seven food products (bottled water, milk, lettuce, tomatoes, carrots, spinach, and cantaloupe). The overall goal of the sampling plan (convenience samples, not necessarily representative of the U.S. food supply) was to gather initial information on occurrence of perchlorate in foods from various locations with a high likelihood of perchlorate contamination.
- During Fiscal Year 2005, FDA conducted a second exploratory survey in which FDA Field Offices collected additional samples of tomatoes, carrots, spinach, cantaloupe, and other high water content foods, including fruits and fruit juices, vegetables, and seafood. In addition, grain products such as wheat flour, cornmeal, and rice were sampled as a follow up to a Texas Tech University study report finding perchlorate in wheat heads. The Fiscal Year 2005 samples collected by FDA consisted of domestic products grown in a broader range of locations, i.e., 14 states within the United States to determine if perchlorate occurs in foods from wider regions of the United States, and not only from regions where water sources are known to be contaminated with perchlorate. In addition, FDA also collected a limited number of imported products commonly entering the U.S. market that were available for sampling during Fiscal Year 2005.
- Food samples collected during Fiscal Year 2004 and Fiscal Year 2005 were sent to FDA Field Laboratories for perchlorate analysis using the FDA's IC-MS/MS analytical method.
- Analytical results were then compiled, showing the incidence (or occurrence) and levels of perchlorate among the food samples collected and analyzed. This information entitled, "2004-2005 Exploratory Survey Data on Perchlorate in Food," is available at *http://www.cfsan.fda.gov/~dms/clo4data.html.*

Based on the 2004-2005 Exploratory Survey Data on Perchlorate in Foods, FDA conducted a preliminary exposure assessment. However, because the preliminary assessment is based on 2004/2005 exploratory survey data for 27 types of foods and beverages that represents only about a third of the total diet for the U.S. population, ages 2 years and older, sources of uncertainty for this preliminary exposure estimate exist. Therefore, sampling of additional food types to increase representation of the total U.S. diet, collection of more samples within a food type, and collection of food types from wider regions of the country would better characterize perchlorate distribution in the U.S. food supply. Additional sampling such as the data expected from FDA's forthcoming Total Diet Study (TDS) will provide a more precise assessment of the scope of perchlorate exposure and the public health implications for food with more reasonable certainty to determine if action is warranted under the FD&C Act to protect the public health.

5. **Has the FDA ever mandated the monitoring and or taken an enforcement action on a contaminant that is present in both the drinking water and food supply, if so, please provide specific information as to the contaminant of concern, the levels and incidence of the contaminant and the type of FDA action taken. Please include citations to guidance and/or regulations where appropriate.**

There is an allowable level of lead in bottled water of 5 ppb (Title 21, *Code of Federal Regulations,* 165.110(b)(4)(iii)(A)). Lead is also present in drinking water regulated by EPA. In November 2006, FDA issued a guidance level for lead in candy of 0.1 part per million (see *http://www.cfsan.fda.gov/~dms/pbguid3.html*). FDA stated that the new guidance level is achievable with the use of good manufacturing practices in the production of candy and candy ingredients and is not harmful to human health. In assessing lead levels in candy products, FDA had found certain chili and high-salt containing Mexican candy products to contain excessive levels of lead that could be avoided by washing the chili peppers prior to grinding and by controlling the sourcing of salt to avoid salt types that have high levels of naturally occurring lead. FDA will continue to monitor lead levels in imported candy.

6. **Please explain in detail the interaction between the FDA, USDA and EPA regarding the assessment of exposure risks presented by perchlorate. This answer should include, but not be limited to, whether EPA discussed how FDA food sampling data will be used by EPA in its decision to whether to regulate perchlorate under the Safe Drinking Water Act.**

In the summer of 2005, FDA participated in a series of teleconferences with EPA and the United States Department of Agriculutre (USDA) to discuss possible approaches EPA can use to estimate perchlorate exposure based on available information in the literature on perchlorate levels in foods, including FDA's Exploratory Data on Perchlorate in Food, November 2004, to better inform EPA for determining the relative source contribution.

In 2006, FDA participated in a series of teleconferences with EPA and USDA to discuss the possibility of sampling and analyzing additional food samples for perchlorate to better inform EPA for determining the relative source contribution. In January 2007, FDA entered into an Interagency Agreement with EPA to analyze approximately 820 food samples collected by USDA for perchlorate during Fiscal Year 2007. FDA plans to use the additional perchlorate data to update its preliminary exposure assessment.

In the summer of 2006, FDA's draft preliminary exposure assessment, based on 2004-2005 exploratory survey data, was peer reviewed by USDA. The peer review charge, peer reviewers' comments, and FDA's response to peer reviewers' comments are contained in a peer review report available at *http://www.cfsan.fda.gov/~dms/clo4ee2.html.*

In early 2007, a revised draft preliminary exposure assessment, based on USDA peer reviewers' comments, was reviewed by the Interagency Working Group (IWG) on Perchlorate, which includes EPA and USDA. Based on comments by the IWG on Perchlorate, FDA finalized the preliminary exposure assessment and posted it on its website at *http://www.cfsan.fda.gov/~dms/clo4ee.html* in May 2007.

7. Does the sampling of perchlorate in baby food and infant formula indicate the presence of perchlorate and if so, at what levels? Will the processing of milk into infant formula concentrate the levels of perchlorate contamination if perchlorate containing water is used to reconstitute the formula?

In Fiscal Year 2005 and Fiscal Year 2006, FDA tested for perchlorate levels in samples of baby foods, infant formulas and adult foods, respectively, collected under FDA's TDS survey. FDA is preparing an exposure assessment based on FDA's Fiscal Year 2005/2006 TDS data for perchlorate which is expected to be released in the fall of 2007. TDS is FDA's ongoing market basket survey in which more than 280 core foods (TDS foods) in the U.S. food supply are collected and analyzed to determine levels of various contaminants and nutrients in those foods. For more information on TDS, see *http://www.cfsan.fda.gov/~comm/tds-toc.html.*

FDA is not aware of any studies to determine whether perchlorate, if present in milk, is concentrated or reduced (e.g., by volatilization) due to processing of that milk into infant formula. If infant formula powder is reconstituted with perchlorate-containing water, the net perchlorate level in the resulting solution would be higher than the perchlorate level that may be present in the infant formula powder.

8. Did FDA consult with EPA about the nature and extent of sampling of food for the presence of perchlorate with EPA? If so, please describe in detail what those consultations entailed.

In the spring of 2005, FDA provided EPA with information on FDA's Fiscal Year 2004 exploratory survey for perchlorate in foods, i.e., the type and number of food samples collected and analyzed, and the results obtained from the survey. FDA also provided EPA with information on FDA's Fiscal Year 2005 exploratory survey for perchlorate in foods, i.e., the type and number of food samples that are being collected and analyzed, and FDA's plan for collecting and analyzing FDA's TDS food samples for perchlorate in Fiscal Year 2006.

9. Please explain the purpose for conducting the Preliminary Exposure Assessment and how this assessment will be used by FDA and/or the EPA in making any regulatory decisions regarding perchlorate.

FDA conducted the preliminary exposure assessment to obtain initial information on exposure based on information available at the time and because of significant public interest in the issue of perchlorate exposure from food. However, this is a "preliminary" assessment based on exploratory survey data for 27 types of foods and beverages that represents only about a third of the total diet for the U.S. population, ages 2 years and older. Sampling of additional food types to increase representation of the total U.S. diet, collection of more samples within a food type, and collection of food types from wider regions of the country would better characterize perchlorate distribution in the U.S. food supply. Additional sampling such as the data expected from FDA's forthcoming TDS will provide a more precise assessment of the scope of perchlorate exposure and the public health implications for food with more reasonable certainty to determine if action is warranted to protect the public health.

10. Various studies have shown that nursing and bottle fed infants could receive doses of perchlorate from breast milk above EPA's RfD of 24 µg/L. Recent studies have determined the existence of perchlorate doses that were above EPA's RfD of 24 µg/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 µg/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.

In Fiscal Year 2005 and Fiscal Year 2006, FDA tested for perchlorate levels in samples of baby (including infant formula) and adult foods, respectively, collected under FDA's TDS survey. FDA is preparing an exposure assessment based on FDA's Fiscal Year 2005/2006 TDS data for perchlorate, which is expected to be released in the fall of 2007, for assessing perchlorate exposure of bottle-fed infants with infant formulas. For breast milk, FDA intends to utilize referenced studies in the literature on assessing perchlorate exposure of nursing infants with breast milk.

11. Referring to FDA's Estimation of Perchlorate Dietary Exposure, May 2007, in which FDA issued a preliminary estimate of the exposure to perchlorate in foods, is it correct that FDA found the presence of perchlorate at varying levels in 27 types of foods and beverages? Is it also correct that FDA's estimate of the total mean population exposure from 27 foods and beverages of 0.053 µg/kg bw/day is similar to geometric mean perchlorate dose of 0.066 µg/kg bw/day found in the CDC Blount et al, 2006 study of *Perchlorate Exposure of US Population*?

Yes. FDA found the presence of perchlorate at varying levels in 27 types of foods and beverages and the total mean population exposure from 27 foods and beverages of 0.053 micrograms per kilogram body weight per day (µg/kg bw/day) is similar to geometric mean perchlorate dose of 0.066 µg/kg bw/day found in the CDC Blount et al, 2006 study of *Perchlorate Exposure of US Population.*

12. Despite the fact that levels of perchlorate were found at varying levels in 27 types of foods tested by the FDA, the Agency concluded that "this exposure assessment suggests that the overall dietary exposure to perchlorate is likely to be below the RfD recommended by the National Academy of Sciences and adopted by the Environmental Protection Agency." Given that 2005 National Academy Report "acknowledges that the RfD may need to be adjusted upward or downward on the basis of future research" and that the CDC studies have found that that levels of perchlorate common in the population, which are significantly less than EPA's RfD of 24.5 ppb., were associated with small to medium changes in thyroid hormone levels, if the RfD were revised downward would that change FDA's assessment regarding overall dietary exposure to perchlorate?

If the Reference Dose (RfD) is revised downward, FDA will use the revised RfD to assess the potential risk of perchlorate exposure from foods in its exposure assessments based on perchlorate data obtained from its surveys, such as the preliminary exposure assessment based on 2004 and 2005 exploratory survey data and any updates of the preliminary exposure assessment.

13. If the results of the health effects on the United States population documented by the CDC studies were applied, rather than ignored, resulting in a lower RfD, would the levels of perchlorate found in the 2004 and 2005 Exploratory Surveys conducted by FDA, result in the Agency utilizing any of its response or enforcement authorities under the Food and Drug Cosmetic Act?

If the RfD is lowered, FDA will use the lower RfD to assess the potential risk of perchlorate exposure from foods in its exposure assessments based on perchlorate data obtained from its surveys, such as the preliminary exposure assessment based on 2004 and 2005 exploratory survey data.

However, because the preliminary exposure assessment is based on 2004/2005 exploratory survey data for 27 types of foods and beverages that represents only about a third of the total diet for the U.S. population, ages 2 years and older, sources of uncertainty for this preliminary exposure estimate exist. Therefore, sampling of additional food types to increase representation of the total U.S. diet, collection of more samples within a food type, and collection of food types from wider regions of the country would better characterize perchlorate distribution in the U.S. food supply. Additional sampling such as the data expected from FDA's forthcoming TDS will provide a more precise assessment of the scope of perchlorate exposure and the public health implications for food with more reasonable certainty to determine if action is warranted under the FD&C Act to protect the public health.

14. Please explain why the FDA has chosen not to conduct its own health assessment for perchlorate, an exercise typically conducted by FDA in determining whether a contaminant may be deleterious to the Nation's food supply, and instead has abdicated its authority, by adopting the 2005 National Academy Report, *Health Implications of Perchlorate Ingestion*? How can the FDA continue to support the proposed National Academy RfD in light of the additional health data that has been published by the CDC and documented existence of perchlorate in food as documented by the Agency's own studies?

EPA, which is responsible for establishing national drinking water standards, conducted a draft risk assessment for perchlorate in 2002. In 2003, EPA, the Department of Defense (DOD), the Department of Energy (DOE), and the National Aeronautics and Space Administration (NASA) asked the National Academy of Sciences (NAS) to review several important questions relating to whether perchlorate is a public health concern. In January 2005, the NAS Committee to Assess the Health Implications of Perchlorate Ingestion released its study report that recommended an RfD of 0.7 μg/kg bw/day. Therefore, FDA did not consider it necessary to duplicate EPA and NAS health assessments by conducting its own health assessment.

FDA is using the NAS recommended RfD that was adopted by EPA to assess potential risk of perchlorate exposure from foods, such as FDA's preliminary exposure assessment based on 2004 and 2005 exploratory survey data on perchlorate levels in 27 types of foods and beverages.

15. Is it correct that FDA sampled carrots of growers in Arvin, California and Moorpark, California and that these samples were found to contain 87.6 ppb. and 81.3 ppb. of perchlorate respectively? Based upon these sampling results, did FDA take any action to prevent these perchlorate contaminated carrots from entering the nation's food supply? If the answer to the prior question is "no," is it possible that these perchlorate containing carrots would have been made available for public purchase and consumption?

Yes, carrot samples that FDA collected from growers in Arvin, California and Moorpark, California were found to contain 87.6 ppb and 81.3 ppb perchlorate, respectively. The collected samples were destroyed during sample preparation for perchlorate analysis and therefore were not marketed. FDA did not take any action to prevent carrots from these growers from entering the nation's food supply because insufficient scientific information exists for FDA to consider carrots containing perchlorate at these levels to present a public health risk. Therefore, it is possible carrots from these growers would have been made available for public purchase and consumption.

16. Is it correct that FDA sampled spinach of growers in Brawley, California and Riverside, California, and that these samples were found to contain 927 ppb. and 80 ppb. of perchlorate respectively? Based upon these sampling results, did FDA take any action to prevent this perchlorate contaminated spinach from entering the nation's food supply? If the answer to the prior question is "no," is it possible that this perchlorate containing spinach would have been made available for public purchase and consumption?

Yes, spinach samples that FDA collected from growers in Brawley, California and Riverside, California were found to contain 927 ppb and 680 ppb perchlorate, respectively. The collected samples were destroyed during sample preparation for perchlorate analysis and therefore were not marketed. FDA did not take any action to prevent spinach from these growers from entering the nation's food supply because insufficient scientific information exists for FDA to consider spinach containing perchlorate at these levels to present a public health risk. Therefore, it is possible spinach from these growers would have been made available for public purchase and consumption.

17. Is it correct that FDA sampled cantaloupes of growers in Goodyear, Arizona and that these samples were found to contain 57.8 ppb., 63.3 ppb., and 66.6 ppb. of perchlorate? Based upon these sampling results, did FDA take any action to prevent these perchlorate contaminated cantaloupes from entering the nation's food supply? If the answer to the prior question is "no," does this mean that it is possible that these perchlorate containing cantaloupes would have been made available for public purchase and consumption?

Yes, cantaloupe samples that FDA collected from growers in Goodyear, Arizona were found to contain 57.8 ppb, 63.3 ppb, and 66.6 ppb perchlorate. The collected samples were destroyed during sample preparation for perchlorate analysis and therefore were not marketed. FDA did not take any action to prevent cantaloupes from these growers from entering the nation's food supply because insufficient scientific information exists for FDA to consider cantaloupes containing perchlorate at these levels to present a public health risk. Therefore, it is possible cantaloupes from these growers would have been made available for public purchase and consumption.

18. Is it correct that FDA sampled broccoli of a grower in Greensburg, Pennsylvania and that this broccoli sample was found to contain 40.2 ppb. of perchlorate? Based upon this sampling result, did FDA take any action to prevent this bunch of perchlorate contaminated broccoli from entering the nation's food supply? If the answer to the prior question is "no," is it possible that these perchlorate containing carrots would have been made available for public purchase and consumption?

Yes, the broccoli sample that FDA collected from a grower in Greensburg, Pennsylvania was found to contain 40.2 ppb perchlorate. The collected sample was destroyed during sample preparation for perchlorate analysis and therefore was not marketed. FDA did not take any action to prevent broccoli from this grower from entering the nation's food supply because insufficient scientific information exists for FDA to consider broccoli containing perchlorate at this level to present a public health risk. Therefore, it is possible broccoli from this grower would have been made available for public purchase and consumption.

19. Is it correct that FDA sampled collard greens of growers in Mount Olive, North Carolina; Newton Grove, North Carolina; Raleigh, North Carolina; and Peleion, South Carolina, and that these samples were found to contain 238 ppb., 47.8 ppb., 39.7 ppb., and 69.1 ppb. of perchlorate respectively? Based upon these sampling results, did FDA take any action to prevent these perchlorate contaminated collard greens from entering the nation's food supply? If the answer to the prior question is "no," is it possible that these perchlorate containing collard greens would have been made available for public purchase and consumption?

Yes, FDA collard greens samples collected from growers in Mount Olive, North Carolina; Newton Grove, North Carolina; Raleigh, North Carolina; and Peleion, South Carolina were found to contain 238 ppb, 47.8 ppb, 39.7 ppb, and 69.1 ppb perchlorate, respectively. The collected samples were destroyed during sample preparation for perchlorate analysis and therefore were not marketed. FDA did not take any action to prevent collard greens from these growers from entering the nation's food supply because insufficient scientific information exists for FDA to consider collard greens containing perchlorate at these levels to present a public health risk. Therefore, it is possible collard greens from these growers would have been made available for public purchase and consumption.

Thank you for your continued interest in these important public health matters. If you have any further questions or concerns, please let us know.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

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

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

The Honorable John Shimkus, Ranking Member
Subcommittee on Environment and Hazardous Materials
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Washington, DC 20515–6115

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July 6, 2007

Mr. Benjamin Grumbles
Assistant Administrator for Water
Office of Water
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Mr. Grumbles:

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 **Friday, 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

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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

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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

Ms. Susan Parker Bodine
Assistant Administrator
Office of Solid Waste and
Emergency Response
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Ms. Bodine:

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.

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Sincerely,

JOHN D. DINGELL
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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

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 hypothyrodism 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?**

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.

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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 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, 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 perchorate is a contaminant that must be addressed. Such discussions are ongoing at two sites:

<u>Navy Boardman Bombing Range, Boardman, OR (non-NPL, Operational Range)</u>
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..

<u>Fairchild Air Force Base, Spokane, WA (NPL)</u>

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 hypothyrodism 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 hypothyrodism 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.

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

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July 6, 2007

Anila Jacob, M.D., M.P.H.
Senior Scientist
Environmental Working Group
1436 U Street, N.W.
Washington, D.C. 20009

Dear Dr. Jacob:

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 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 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

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July 20, 2007

The Honorable John D. Dingell
United States House of Representatives
Committee on Energy and Commerce
Washington, DC 20515

Dear Mr. Chairman:

I am attaching a copy of answers to questions that were directed to me after my testimony before the Subcommittee on Environment and Hazardous Materials on April 25, 2007, at the hearing entitled "Perchlorate: Health and Environmental Impacts of Unregulated Exposure."

I would like to thank you for the opportunity to testify at this hearing. The Environmental Working Group will continue to work on this issue and would be happy to provide any further assistance to the committee regarding this matter.

Sincerely,

Anila Jacob, M.D., M.P.H.
Senior Scientist
Environmental Working Group
1436 U Street, N.W.
Washington, D.C. 20009

Environmental Working Group

Questions from the Honorable Joe Barton and the Honorable John Shimkus

1) I would like to clarify that the Environmental Working Group (EWG) recommended an MCL in drinking water of "no higher than 1 ppb". Current technology exists that allows for clean up to levels below 1 ppb, which is consistent with our recommendation. Based on the most recent study from the CDC, women with lower iodine levels may still have significant changes in their thyroid hormone levels even at this low level of exposure, but our recommendation of an MCL is limited by the available technology.

2) Perchlorate is a competitive inhibitor of iodine uptake by the thyroid gland. Iodine is one of the building blocks of thyroid hormone. Thus, perchlorate exposure can prevent adequate levels of iodine from being taken up by the thyroid gland, resulting in less iodine available for thyroid hormone synthesis. Two other environmental exposures that work by the same mechanism are nitrate and thiocyanate (1). Other factors that may also influence thyroid hormone levels include age, sex, race, pregnancy, body mass index, tobacco smoking, inflammatory conditions, and menopause.

   The CDC scientists who conducted the most recent study (the Blount study) were very careful to take these multiple factors into consideration, as noted in this quote:

   > We selected a broad number of covariates to evaluate the independence of the perchlorate relationship. These covariates were: age, race/ethnicity, body mass index (BMI), serum albumin, serum cotinine (a marker of tobacco smoke exposure), estimated caloric intake, pregnancy status, post-menopausal status, premenarche status, serum C-reactive protein, hours fasting before sample collection, urinary thiocyanate, urinary nitrate, and use of selected medications.

   As a result, these experienced CDC scientists went on to conclude, "These associations of perchlorate with T4 and TSH are coherent in direction and **independent of other variables known to affect thyroid function**..." (2).

   Several states have set an MCL for perchlorate that is far less than the current EPA reference dose of 24.5 ppb, although none has set an MCL lower than 1 ppb. Most states did not have the information from the most recent CDC study available at the time that they were setting their MCLs. While EWG applauds their efforts to protect the public health of their citizens by setting MCLs based on the data available at the time, we encourage them to revisit the issue in light of the new CDC data.

Environmental Working Group

3) It is not accurate to state that roughly one-third of women in the U.S. have a form of hypothyroidism that contributes to decreased iodine uptake. It is accurate to say that a recent epidemiological study from the CDC suggests that the roughly one third of women in the U.S. with lower iodine levels are particularly susceptible to the effects of perchlorate (2).

   Other environmental exposures that may exert similar effects on thyroid hormone levels include nitrate and thiocyanate, both of which were taken into account by the CDC scientists when they conducted their study.

4) While EWG supports all efforts to conduct further studies on the relationship between perchlorate exposure and thyroid hormone levels, there is sufficient scientific evidence to support an MCL of no higher than 1 ppb. In addition, we would like to point out that there have been instances where one particular study was used by a group of scientists to determine the toxic level of a chemical. For example, the National Academy of Sciences and EPA have consistently relied on the Greer study from 2002 to justify the reference dose of 24.5 ppb for perchlorate. This study was conducted on small numbers of people and did not take into account the iodine status of the participants, which we now know is a critically important variable (3). The Blount study provides valuable information that the Greer study did not by including larger numbers of participants (2299 in the Blount study vs. 37 in Greer study) and by identifying a subpopulation of women who are especially vulnerable to perchlorate; EWG supports the principle that all the current scientific literature on perchlorate be taken into consideration when setting a reference level.

5) The Blount study does not definitely show that perchlorate caused the changes in thyroid hormone levels; it shows a strong association between perchlorate exposure and changes in thyroid hormone levels. The CDC scientists who conducted this study took the greatest care in accounting for other factors that may have influenced these findings.

6) The Blount study shows that for a sub-population of women with lower iodine levels, exposure to perchlorate at levels far below the EPA reference dose is associated with changes in TSH levels to the degree that these levels would be considered in the range consistent with sub-clinical hypothyroidism. This is a medical condition that requires treatment if a woman becomes pregnant in order to prevent abnormal brain development in the developing fetus. EWG estimates that based on the Blount study, exposure to perchlorate at just 5 ppb in water could place more than 2 million women of childbearing age at risk for thyroid hormone levels that are lower than optimal for fetal brain development and would require medical intervention to restore thyroid levels to the normal range.

7) With all due respect to Dr. Utiger and his extensive clinical and academic experience, I would like to bring up some points regarding iodine supplementation. Dr. Utiger stated the following in his written testimony:

> One way to minimize the action of perchlorate on the thyroid is to increase iodide intake. Indeed, such an increase would benefit the entire U.S. population, given that iodide intake decreased by approximately 50% between 1971-74 and 2000-2002, and conversely the proportions of people with mild or moderate iodide deficiency increased substantially.

However, the Public Health Committee of the American Thyroid Association noted in a publication from 2006:

> Although the current data do not lead to a recommendation of fortification or supplementation with iodine for the U.S. population as a whole, this may not be the case to meet the increased needs of pregnancy and lactation. Without specific physiologic evidence of iodine deficiency in the United States at this time, and with the most recent U.S. survey reporting a median value of 173 ug/L, which is within that currently recommended for pregnancy, the rational for iodine supplementation during pregnancy is tenuous (4).

These statements from the ATA clearly indicate that it does not believe there would be a benefit from increasing iodine intake by the whole population. In addition, here are a few other points about iodine supplementation:

a. There is no question that iodine deficiency is a serious problem and a major cause of low thyroid hormone levels and goiter in some developing nations. The CDC periodically monitors iodine status in the US and as recently as 2005, scientists from the CDC and University of Kansas Medical Center analyzed CDC data and determined "the current stability of the U.S. iodine intake and **continued adequate iodine nutrition for the country**" (5). This analysis suggests that the vast majority of the US population is not in an iodine deficient state. Therefore, public health measures to encourage increased iodine intake by the general population are not justified by current CDC data or supported by the American Thyroid Association and I would venture to suggest that our population is not iodine deficient but is, in fact, perchlorate overloaded.

b. While it is true that the Blount study suggests that women with lower iodine levels are more susceptible to perchlorate and increasing their iodine intake would potentially mitigate the effects of the chemical in these women, how would one go about identifying these women? According to CDC data, the majority of women in this country are iodine sufficient and able to adequately compensate for effects of perchlorate. In fact, public health interventions aimed at increasing iodine intake in the general population through iodination of food products could expose

millions of people to excess iodine intake because it would not be feasible to identify those with iodine insufficiency. Excess iodine intake is associated with autoimmune thyroiditis and certain types of thyroid cancer. Measures aimed at increasing iodine intake of the US population to counteract the effects of perchlorate are not without risk and increasing iodine intake in an already iodine sufficient population could have clear negative consequences as mentioned above.

c. While it is easy to suggest measures that are aimed at increasing the iodine intake of the general population, public health interventions that are aimed at changing peoples behavior (using iodized salt, eating foods rich in iodine, using prenatal vitamins that contain iodine) can take years to enact and often do not have optimal compliance. For example, although anti-smoking campaigns have been in place for decades, CDC estimates that 20% of adults are still smokers. It is estimated that only 50% to 60% of the population uses iodized salt. In addition, mandatory salt iodization has never been enacted in the US, even in the 1930s when iodine deficiency was a major public health issue. Even the seemingly simple intervention of increasing the use of iodized salt could take years before significant numbers of the population change their behaviors, and as noted above, this might result in excessive iodine intake by a significant portion of the population. Therefore, while EWG agrees that increasing iodine intake among iodine insufficient and pregnant women may mitigate the effects of perchlorate exposure, the practicalities involved in carrying out this public health measure may result in delays that would still put millions of women at risk of the health effects related to perchlorate exposure. The pubic health measures that would reduce the health effects of perchlorate exposure in the shortest amount of time and reach the greatest number of people are to set the MCL for perchlorate in drinking water at no higher than 1 ppb and minimize perchlorate contamination of food.

8) In EWG's testimony, we clearly state that we recommend an MCL for pechlorate in drinking water of no higher than 1 ppb. A level of 0.5 ppb is considered to be no higher than 1 ppb. We fully support efforts to treat drinking water to a level of 0.5 ppb.

9) EWG is concerned about all sources of exposure to perchlorate, and we will continue to work with the committee, the FDA, and the EPA to ensure that health standards for perchlorate in food and water are based on the best available science and provide protections for widely recognized vulnerable sub populations.

Questions from the Honorable Albert Wynn

1) Thyroid function is determined by the status of thyroid hormone levels; levels of T3 and T4 (the biologically active thyroid hormones) that are lower than normal are consistent with an underactive thyroid (hypothyroidism) and levels higher

than normal are consistent with an overactive thyroid (hyperthyroidism). In the CDC study, women with lower iodine levels who were exposed to perchlorate at doses commonly found in the environment were found to have small to medium changes in their thyroid hormone levels. What this study tells us is that for some women who have thyroid hormone levels in the high normal range, exposure to perchlorate at levels commonly found in the environment are associated with changes in thyroid hormone levels from the normal to the abnormal range. This is especially alarming if these women become pregnant because it may result in sub-optimal levels of thyroid hormone being available for their developing fetus and subsequent abnormal brain development.

2) The results from the most recent CDC studies, when extrapolated to the general public, suggest that the one third of American women who have lower iodine levels are especially susceptible to the effects of perchlorate. This is approximately 43 million women nation wide, including 22 million of childbearing age (15-44).
3) EWG strongly encourages the EPA to take action on perchlorate by setting an MCL that takes into account the most recent research from the CDC and breast milk studies. We know that the current EPA RfD of 24.5 is grossly inadequate; the breast milk studies prove that this current RfD is resulting in breast milk levels of perchlorate that are exposing breast feeding infants to levels that exceed the EPA RfD. The longer that EPA delays this action, the more likely the chance that millions of vulnerable members of the population will continues to be exposed to unsafe levels of this thyroid toxin.

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2) Blount BC, Pirkle JL, Oserloh JD, Valentin-Blasini L, Caldwell KL. 2006. Urinary perchlorate and thyroid hormone levels in adolescent and adult men and women living in the Unites States. Environmental Health Perspectives 114(12): 1865-71.

3) Greer MA, Goodman G, Pleus RC, Greer SE. 2002. Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans. Environmental Health Perspectives 110(9): 927-37.

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July 6, 2007

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Deputy Director for Science
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4770 Buford Highway, NE
Atlanta, GA 30341-3724

Dear Dr. Pirkle:

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.

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James L. Pirkle, M.D., Ph.D.
Page 2

Thank you for your prompt attention to this request. If you need additional information or have other questions, please 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

Centers for Disease Control and Prevention's Responses to Questions for the Record From House Committee on Energy and Commerce

The Honorable Joe Barton and the Honorable John Shimkus

1. From what I know of the CDC/Blount study, your findings were much different than what was found in previous animal studies used by EPA and human data evaluated by NAS. In the conclusion of your study -- as well as in your testimony -- you claim that subsequent, confirmatory analysis is necessary to verify the findings of your study. What things do you believe need to be followed up on? Have you begun this process? How long do you expect this process to take? Can you be absolutely certain that further information gaps will not emerge when you conduct these studies?

Response:

The Blount study is the only study to focus on women with lower iodine levels (women with urine iodine levels less than 100 micrograms per liter). Thus, for this group, there were no previous results with which to compare the Blount results. NAS did not have any data to examine for this group of women, who account for about 36% of women in the U.S. population. Additionally, the Blount study has a very large sample size compared to previous work. The Blount results for men did not show an association between perchlorate levels and thyroid hormone levels. This finding for men was consistent with findings of other studies. For women with iodine levels greater than 100 micrograms per liter, perchlorate levels were associated with thyroid stimulating hormone (TSH) but not total thyroxine.

The Blount publication stated that "Further research is recommended to affirm these findings." We do not think confirmatory analysis is necessary to validate Blount's analysis of the NHANES data. Although we understand that conclusions of causality can rarely be drawn based upon a single study, when viewed within the context of the available clinical literature, the findings of the Blount study are consistent with causality. That is, we think that there is sufficient evidence from clinical studies that perchlorate directly causes decreases in thyroxine at high levels. The remaining scientific question is whether the direct effect extends to the levels of perchlorate found in the U.S. population. For that reason, we do think that another enhanced NHANES analysis of the relationship between perchlorate exposure and thyroid hormone levels in additional women and men should afford additional evidence regarding the strength of the association by providing more than twice the number of women and men to analyze, substantially improving statistical power.

This would help in the following analyses:

1) Examination of people who have increased exposure to other environmental factors that could affect thyroid hormone levels. For example, people who have higher thiocyanate exposure (from smoking or dietary sources) are important to examine further for a potential synergistic effect with perchlorate. Smoking, thiocyanate and nitrate were adjusted for in the Blount multiple regression analysis, and increasing the sample size will afford a greater ability to detect potential synergistic effects of these factors with perchlorate. It may also be useful

to examine differences in dietary intake in more detail.

2) Separate analysis for women of childbearing age which is important because of the vulnerability of the fetus.
3) Examination of factors that may account for differences in the observed associations between men and women.

In addition, we plan to examine the relationship of free thyroxine and thyroid autoantibodies to perchlorate levels to supplement and aid in understanding the results of the Blount study on total thyroxine and thyroid stimulating hormone.

A second NHANES study is in the planning stage currently. This study will examine about 50% more men and women than the first study. We hope to be able to combine data from the two studies resulting in about 2.5 times the study sample size we currently have. We cannot with confidence provide a firm finish date for the second study, but a reasonable estimate would be December 2008 to February 2009. We are confident that this additional study will provide more information about relationships between perchlorate exposure and thyroid effects at low population levels.

---

2. Some witnesses claim that your study is definitive and that further study of this issue is not required. Yet, your study was unique in that the results that you observed were unexpected and different from everything else that previous studies have found. Do you believe it is a good scientific principle to do more study if the results from an existing study are new?

Response

The Blount study is the only study to focus on women with lower iodine levels (women with urine iodine levels less than 100 micrograms per liter). Thus, for this group, there were no previous results with which to compare these results. In addition, a notable strength of the Blount study was its very large sample size (1,111 women) compared to previous work, affording more statistical power to detect potential effects than other studies.

The decision to conduct additional research is a case-by-case decision that is based on a number of factors including the significance of the original findings, the strength and statistical power of previous studies, study design methods and their limitations, and the likelihood that new research will advance scientific understanding. In the current case, we believe there is value in additional study, and we have itemized that value in answer to question 1.

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3. You said in your testimony that the CDC/Blount study showed an "association" between urinary perchlorate and increased TSH and decreased total T4 in women 12 and older, who had urine iodine levels < 100 μg/L. It is possible people might assume then that perchlorate actually "caused" the thyroid changes. Was the CDC/Blount study designed to evaluate whether there is a causal relationship between low levels of perchlorate exposure and thyroid function? Can you please clarify the difference between "an association" and "causation?"

Response:

We begin by clarifying the difference between "an association" (referring to a pattern in the data) and "causation" (referring to necessary antecedents to a health outcome). Observational data play an important role in establishing statistically significant associations, evaluating dose response gradients, evaluating the influence of potentially confounding variables, and providing information on coherency and consistency of findings. Causality is difficult to determine and relies on the best scientific assessment of the overall weight of evidence based on multiple important factors. We discuss these factors below. Causality is rarely determined on the basis of a single study, but by the weight of evidence from more than one study.

We find important parallels with the discussion of characterizing causation presented in the recent (2004) Surgeon General's Report on Smoking. That report concludes that inferences, whether about causality or statistical associations, are always uncertain to a degree, thus the goal (of that report) is to explain and communicate scientific judgments.

The design of the Blount study itself, referred to as cross sectional study, allows assessment of association, dose response gradient and some other factors useful in a weight-of-evidence evaluation. The Blount study, by itself, does not establish causation, but its findings are consistent with causation. Below, we discuss our assessment of the body of literature and the role that the Blount study plays.

The Blount study used NHANES data to examine the potential relationship between perchlorate levels and thyroid hormone levels in men and women. Establishing a causal relationship rests on weight of evidence of a 1) statistically significant association that is independent of other known variables that affect thyroid hormone levels, 2) a logical temporal association (i.e., exposure precedes effect), 3) biological plausibility and 4) coherency, specificity, and consistency of findings (including dose response effects). The Blount study provides information on the statistically significant association with variables available for analysis from NHANES data, and coherency and consistency of findings, but does not address a logical temporal association or biologic plausibility. Previous medical use of perchlorate has demonstrated that use of perchlorate as a drug directly causes decreases in levels of thyroxine. This direct causal effect is at a dose much higher than experienced by the general population and the Blount study is aimed at determining whether this effect extends to these lower perchlorate exposure levels.

The Blount study concluded that for women, there were statistically significant associations between perchlorate levels and total thyroxine and TSH that are coherent in direction and independent of other variables known to affect thyroid function. The "statistically significant association" found between perchlorate levels and total thyroxine levels means that, after adjusting for effects of other NHANES variables known to affect thyroid function (but not all variables which may impact thyroid function, e.g. some dietary factors), perchlorate levels independently predicted thyroid hormone levels, and this independent relationship was unlikely to be explained by chance.

After finding a statistically significant association that is independent of available variables known to affect thyroid function, the justification for a causal relationship relies mainly on other established evidence such as temporality, biological plausibility, and coherency and consistency of findings. Temporality requires that exposure takes place prior to the effect, in this case a change in thyroid hormone. The Blount study is cross-sectional, so it measured perchlorate levels and thyroid hormones at the same time and cannot determine if exposure occurred prior to effect. As noted above, concerning biological plausibility, it is known that high doses of perchlorate inhibit the production of thyroxine, leading to lower total thyroxine levels and higher TSH levels. It is important to note that these exposures were far above those experienced by the NHANES cohort analyzed by Blount et al. Concerning coherency and consistency of findings, after adjustment for other variables known to affect thyroid function, increasing perchlorate levels were found in separate analyses to be associated with both decreasing total thyroxine levels *and* increasing TSH levels. This finding is cited in the paper as coherent in direction. By contrast, if increasing perchlorate had been associated with decreasing thyroxine and *decreasing* TSH, such a finding would not be coherent in terms of an effect on thyroid hormones.

Also relevant to coherency and consistency was the finding that women with lower levels of iodine (urine iodine levels of less than 100 micrograms per liter) had a statistically significant and more pronounced association of perchlorate with thyroid hormone levels. This finding is consistent with the mechanism of perchlorate inhibition of iodine uptake.

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4. Did the CDC/Blount study show other known thyroid iodine uptake inhibiting agents as not having any effect or actually in one case showing a reverse effect from the recognized biological normal ranges? How can this be explained?

Response:

In the regression analysis examining TSH levels in women with urinary iodine levels greater than or equal to100 micrograms per liter, urinary levels of thiocyanate were negatively associated with TSH levels in the final regression model. (Note: This is *not* the group of women with lower iodine levels in whom the statistically significant and more pronounced association of perchlorate and thyroid hormone levels was found). As stated in the paper, a physiologic explanation for the sign of this coefficient for this group of women with higher iodine levels is unclear. The expected effect of thiocyanate on TSH would be for TSH to increase as thiocyanate increases because thiocyanate inhibits uptake of iodine into the thyroid. One possibility for the current finding is that smoking sources of thiocyanate may include exposures to other chemicals that have mixed effects on thyroid function.

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5. In the CDC/Blount study, were fluctuations in thyroid hormones among women with low iodine outside normal ranges?

Response:

Most of the women in the Blount study were within the normal range. Many women with levels of thyroid hormones outside the normal range were excluded from analysis because these women were taking thyroid medications or had a known history of thyroid disease. Women taking thyroid medications had to be excluded because the thyroxine measurement would have been measuring the thyroxine they were taking for treatment.

Of the 1,111 women in the final regression analysis in the Blount study, 51 or 4.6% had levels outside the normal range. Of the 356 women with lower iodine levels who were in the final regression analysis, 11 or 3.1% had levels outside the normal range.

Thyroid hormone levels were measured at one point in time, so it was not possible to detect fluctuations in levels of an individual.

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6. Do you believe that the CDC/Blount's thyroid study is sufficiently definitive for EPA Headquarters to rely on in moving forward with a regulatory determination on perchlorate as well as use by EPA Regions in developing site-specific risk assessments and cleanups?

Response:

As we state in CDC (2004), there are differences between both the process and goals of causal inference and decision making. We believe it is more appropriate for EPA to make this determination, based on its own scientific expertise and experience administering the specific statutes at issue.

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7. In commenting on the CDC/Blount study, which you spoke of in your testimony, the American Thyroid Association (ATA) states that "[t]hese findings are intriguing, although several features of the study may limit the immediate application to guidelines for perchlorate exposure standards." The ATA also states that "further laboratory information is necessary before the implications of the findings can be understood." The Blount study itself says "further research is recommended to affirm these findings." Would you agree with the ATA and the Blount study in this regard, specifically that more study is needed and this study alone is not sufficient for setting a regulatory standard, and could you please explain your answer?

Response:
Concerning regulation, as noted above, we defer to EPA on what is sufficient for setting an EPA regulatory standard.

The Blount publication stated "Further research is recommended to affirm these findings." Another enhanced NHANES analysis of the relationship between perchlorate exposure and thyroid hormone levels in additional women and men should provide more than twice the number of women and men to analyze, substantially improving statistical power.

This enhanced statistical power would help in the following analyses:

1) Examination of people who have increased exposure to other environmental factors that could affect thyroid hormone levels. For example, people who have higher thiocyanate exposure (from smoking or dietary sources) are important to examine further for a potential synergistic effect with perchlorate. Smoking, thiocyanate and nitrate were adjusted for in the Blount multiple regression analysis, and increasing the sample size will afford a greater ability to detect potential synergistic effects of these factors with perchlorate. It may also be useful to examine differences in dietary intake in more detail.
2) Separate analysis for women of childbearing age which is important because of the vulnerability of the fetus.
3) Examination of factors that may account for differences in the observed associations between men and women.

In addition, we plan to examine the relationship of free thyroxine and thyroid autoantibodies to perchlorate levels to supplement and aid in understanding the findings of the Blount study on total thyroxine and thyroid stimulating hormone. The ATA also suggested adding free thyroxine to the measurements in the Blount study.

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8. Many of your studies look at the health effects of various things on people of differing socio-economic backgrounds. Did your recent perchlorate study extrapolate that information?

Response:
In the Blount study, race/ethnicity was a variable included in the regression models, but it was not a significant predictor of thyroid hormones. We did not examine a variable that tracked income.

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9. Do you agree with Dr. Utiger that people with hypothyroidism should compensate for potential perchlorate exposures through greater dietary intake of iodine rich foods and vitamins?

Response:

We believe that people with hypothyroidism should be under the care of a physician for appropriate diagnosis and treatment. Adequate intake of iodine has previously been recognized as important for healthy thyroid function. The Blount study results would reinforce that recommendation for women.

The Honorable Albert Wynn

1. Are calculations for median estimated dose of perchlorate for adults about 1/10 of EPA's reference dose of 24.5 ppb.?

Response:
Yes; for adults, the median estimated dose (0.064 μg/kg day) is about 1/10th of the EPA reference dose (RfD) (0.7 μg/kg day).

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2. Is it true that the 2006 NHANES study found measurable amount of perchlorate in all 2,820 survey participants and that the levels of perchlorate found in children were 65 percent higher than those found in adults?

Response:
Yes, all 2820 study participants had measurable perchlorate in urine, with the creatinine-adjusted perchlorate levels in children (6-11 years old) being 65% higher than the creatinine-adjusted perchlorate levels in adults (aged 20 years and older).

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3. The CDC 2006 NHANES study was peer reviewed and tested multiple times and CDC testified that it has a high level of confidence in its findings. Does CDC agree that this study is based on the best available, high quality, peer reviewed science and that the data was collected by accepted methods?

Response: Yes

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4. CDC's second study examined the relationship between urine perchlorate levels and thyroid hormone level, 12 years old and up using perchlorate levels common in the US populations that are much lower than those used therapeutically. This study was also peer reviewed. Is CDC planning a second study to affirm these findings and expand on the study?

Response:

Yes. A second study is in the planning stages and will include at least as many men and women as the first study.

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5. Is it true that CDC NHANES was peer reviewed and is in compliance with the information Quality Act, Pub. L. NO. 106-544?

Response:
The CDC National Health and Nutrition Examination Survey (NHANES) is in compliance with the Information Quality Act. NHANES is conducted by CDC's National Center for Health Statistics (NCHS). Statistical information is subject to quality guidelines requiring federal agencies to adopt a basic standard of quality (including objectivity, utility, and integrity) and to incorporate quality criteria into agency information dissemination practices, issued by the Office of Management and Budget (OMB). Information dissemination practices of CDC's NCHS, including information dissemination associated with NHANES, comply with these OMB guidelines. In addition, the NHANES undergoes extensive review both within the Department and by OMB as a way to ensure the integrity of the data. NCHS is committed to integrating the

principle of information quality into every phase of information development, including creation, collection, maintenance, and dissemination. Detailed information about how NCHS assures the quality of information disseminated to the public is available on the NCHS Web site http://www.cdc.gov/nchs/about/quality.htm. The Information Quality Bulletin for Peer Review issued by OMB enhances the practice of peer review of government science documents. As specified in the Federal Register Notice on this policy (Vol. 70, No. 10, Page 2677), the Bulletin provides an exemption to the peer review requirement for, "Routine statistical information released by federal statistical agencies (e.g., periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends (e.g., unemployment and poverty rates)." As recommended by the Interagency Council on Statistical Policy, OMB considers NHANES to be covered by this exemption.

In the case of the 2006 analysis of the perchlorate data that is the subject of this question, scientists in the National Center for Environmental Health of the CDC analyzed the data and wrote the two publications with the standard disclaimer on the publications that the findings and conclusions in this report are those of the authors and do not necessarily represent the views of CDC. These publications were peer-reviewed by outside experts before being submitted for publication and also peer-reviewed by reviewers of the publishing journals.

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6. 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 at. 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.

Response:
We are actively investigating perchlorate exposure and thyroid function in both breast-fed and bottle-fed infants. We first developed high-quality analytical methods for measuring perchlorate in the following body fluids that are relevant to a baby's exposure: breast milk, amniotic fluid, cord blood, newborn dried blood spots, and newborn urine. Our ongoing collaborative studies of perchlorate exposure in infants are listed below:

- Perchlorate exposure and thyroid function in breast-fed and formula-fed infants. In collaboration with Dr. Water Rogan (National Institute of Environmental Health Sciences), we are assessing perchlorate exposure and thyroid function in infants (ages 1 – 12 months) who are consuming either breast milk or infant formula.

- Perchlorate exposure in lactating women and breast-fed infants in West Texas. In collaboration with Dr. Purnendu Dasgupta (University of Texas, Arlington), we are assessing perchlorate exposure in lactating mothers and their breast-fed infants. Perchlorate exposure may be higher in West Texas compared with the rest of the country because of prevalent consumption of well water with naturally-occurring perchlorate contamination.
- Characterizing perchlorate exposure in the developing fetus. In collaboration with Dr. Mark Robson (Rutgers University), we are measuring perchlorate in maternal urine, maternal serum, amniotic fluid, and cord blood. By measuring perchlorate levels in different fluids from the mother and the infant, we can better understand how a mother's exposure to perchlorate may lead to exposure in the developing fetus.
- Perchlorate exposure assessment in lactating women in San Diego. In collaboration with Dr. Phillip Alexander (University of California, San Diego) we are measuring perchlorate and iodine in breast milk and urine samples collected from women who drink tap water with perchlorate contamination below the California Public Health Goal level of 6 μg/L. Perchlorate levels in their drinking water will also be measured. This study will also examine the impact of a therapeutic dose of iodine on perchlorate clearance from the body.
- Perchlorate exposure assessment in lactating West Coast women. In collaboration with Kim Hooper (California EPA) we are measuring perchlorate in breast milk samples collected from nearly 250 women living in California and Washington. We plan to examine both the magnitude and variability in breast milk perchlorate levels. A dietary questionnaire is being used to identify potential sources of perchlorate from the diet.

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July 6, 2007

Mr. John B. Stephenson
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G. Street, N.W.
Washington, D.C. 20548

Dear Mr. Stephenson:

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 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 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

United States Government Accountability Office
Washington, DC 20548

July 20, 2007

The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives

Dear Mr. Barton:

We appreciate the opportunity to appear before the Subcommittee on Environment and Hazardous Materials on April 25, 2007 to speak about GAO's work related to the health and environmental impacts of exposure to perchlorate.

Enclosed is GAO's response to questions that you submitted for the hearing record in response to our testimony, *Perchlorate: EPA Does Not Systematically Track Incidents of Contamination,* (GAO-07-797T). If you or your staff have any questions about our responses, please contact me at (202) 512-3841 or stephensonj@gao.gov.

Sincerely yours,

John B. Stephenson
Director, Natural Resources
and Environment

Enclosure

cc: The Honorable John Dingell, Chairman
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

Enclosure

GAO Response to Questions

1. Your report on perchlorate mentioned that you reviewed 92 studies that examined the health effects of perchlorate and only 44 offered conclusions or observations about whether perchlorate had an adverse health effect, and 25 of these studies suggested an adverse health effect. What did these other 48 studies conclude then? Why, in your assessment, is there such a wide range of numbers and conclusions?

As we reported in May 2005, GAO identified and summarized 90 peer-reviewed studies published between 1998 and 2005 that examined the health effects of perchlorate exposure.[1] The 90 studies used a variety of methodologies, study populations, and health outcomes, which helps to account for their differing conclusions (or lack thereof) about whether perchlorate has adverse health effects. Of those studies, 44 offered findings or conclusions about the effects of perchlorate on health, and 46 did not.[2] Many of the latter studies focused on particular physiological processes, and did not seek to specifically establish conclusions regarding perchlorate's health effects. For example, one study that did not draw conclusions examined perchlorate's effects on iodide transport across the gut and skin in frogs.

With regard to the wide range of methodologies, some of the studies used experimental design methods that exposed subjects to different amounts of perchlorate; some used field study methods that compared subjects in contaminated areas with subjects in uncontaminated areas; and some analyzed data from previous studies to determine the highest perchlorate exposure level that does not adversely affect humans. With regard to study populations, some studies examined men and/or women, whereas others looked at other mammals, fish, or amphibians. The studies also examined different health outcomes, including enlarged thyroid and cancer.

Of the 44 studies that offered conclusions about health, 26 indicated that perchlorate had an adverse effect on thyroid function and human health. Of those, 18 studies found adverse effects on development resulting from maternal exposure to perchlorate. Most studies on adult populations were unable to determine whether the thyroid was affected because adverse effects of perchlorate on the adult thyroid, such as cancer, may happen over longer time periods than are generally observed in a research study. In contrast, the adverse effects of perchlorate on prenatal development can be more easily studied and measured within typical study time frames.

[1]GAO, *Perchlorate: A System to Track Sampling and Cleanup Results is Needed*, GAO-05-462 (Washington, D.C.: May 20, 2005).

[2]Appendix I of our report provides details of the methodology that we used to review the scientific literature, and appendix III provides details about the studies we reviewed, including their sponsor, the methodologies used by the authors, and the authors' findings or conclusions about the effects of perchlorate, where given.

EPA officials told us, at the time of our review, that the most sensitive population for perchlorate exposure is the fetus of a pregnant woman who is nearly iodine-deficient. About 36 percent of U.S. women have these lower iodine levels. However, none of the studies that we identified had considered this population. The National Academy of Sciences recommended in their 2005 review that additional research be conducted on perchlorate exposure and its effect on children and pregnant women. As we discussed in our April 2007 testimony before the Subcommittee, CDC researchers recently published the results of the first large study to examine the relationship between low-level perchlorate exposure and thyroid function in women with low iodine levels.[3] The study found decreases in a thyroid hormone that helps regulate the body's metabolism and is needed for proper fetal neural development in pregnant women.

One conclusion has become clearer since our 2005 review—perchlorate exposure can reduce iodine uptake in the adult thyroid, and iodide is critical for making thyroid hormones that help control metabolism and development, particularly for fetuses of pregnant women. In part as a result of advances in the scientific understanding of perchlorate's effects on human health, the American Water Works Association—which represents public and private drinking water utilities—and the Association of Metropolitan Water Agencies—which represents drinking water utilities in large cities—recently called on EPA to set a Maximum Contaminant Level (MCL) for perchlorate because they believe EPA now has enough information to make a "positive regulatory determination."

2. In your assessment of perchlorate contamination found by site, you mention that while 28% of contamination stems from DOD and NASA industries, 27% is naturally occurring. Can you further expand on how perchlorate is naturally occurring and what you estimate this means to cleanup efforts?

Of those 395 contaminated sites we identified, 105 (28 percent) were from natural sources in the Texas high plains region.[4] Perchlorate, much like arsenic, is naturally occurring, and human activity can mobilize or concentrate it in the environment. GAO has not evaluated the impacts of naturally-occurring perchlorate on cleanup efforts. However, naturally-occurring perchlorate is widely dispersed and readily dissolves in surface and groundwater sources and may pose a cleanup challenge when those sources are used for drinking water or irrigation. If

[3]GAO, *Perchlorate: EPA Does Not Systematically Track Incidents of Contamination*, GAO-07-797T (Washington, D.C.: April 25, 2007).

[4]Perchlorate contamination was due undetermined sources at 122 sites (31 percent), activities related to defense and aerospace at 110 sites (28 percent), natural sources at 105 sites (27 percent) in the Texas high plains region, and manufacturing and handling, agriculture, or a variety of commercial activities such as fireworks and flare manufacturing at 58 sites (15 percent).

it is not possible to clean up the perchlorate at a given site or water source, the relevant water treatment plant may have to address the problem.

A recent study, published in June 2007 and funded by the DOD's Strategic Environmental Research and Development Program, identified more naturally-occurring sites than the ones we cataloged in northern Texas. The study found naturally-occurring perchlorate in 5 states across the desert southwest United States—Arizona, Nevada, New Mexico, Texas, and Utah.[5] This discovery may increase pressure on EPA to monitor or regulate the chemical in drinking water.

As the 2007 study observed, perchlorate accumulations in dry unsaturated zones such as the desert southwest are relatively stable while undisturbed, even after accumulating for thousands of years. However, it can be readily flushed into groundwater as a result of human activity. For example, irrigation in the southern High Plains of Texas appears to have completely flushed the naturally-occurring perchlorate from soil into groundwater. The authors concluded that any assessment of potential perchlorate exposure should consider these readily mobilized, naturally-occurring reservoirs of perchlorate, and they recommended that future impacts of agriculture, irrigation, desert urbanization, and even climate change—which may bring increased rainfall to certain parts of the U.S.—should be carefully considered when assessing impacts (and cleanup) from anthropogenic (human) sources. Nonetheless, the study estimated that, while the deserts hold 103 million kilograms, U.S. perchlorate production over the past half-century amounts to 5 *billion* kilograms. Therefore, the vast majority of perchlorate in the environment is from anthropogenic sources, including DOD, NASA, and other manufacturing.

3. How would adopting an MCL affect cleanup of hits from unexplained sources? Who would be responsible for such cleanup, and what funding mechanism would EPA suggest for such cleanup?

An MCL's effect on cleanup activities is indirect. The Safe Drinking Water Act regulates contaminants in drinking water, but it is not an environmental cleanup statute. For contaminants that are known or anticipated to occur in public water systems, and that the EPA Administrator determines may have an adverse impact on health, the Safe Drinking

[5]According to DOD, the Strategic Environmental Research and Development Program (SERDP), the DOD's environmental science and technology program, is planned and executed in partnership with the Department of Energy and the Environmental Protection Agency with participation by numerous other federal and non-federal organizations. To address the highest priority issues confronting the Army, Navy, Air Force, and Marines, SERDP focuses on cross-service requirements and pursues high-risk/high-payoff solutions to the DOD's most intractable environmental problems. The development and application of innovative environmental technologies support the long-term sustainability of DOD's training and testing ranges as well as significantly reduce current and future environmental liabilities.

Water Act requires EPA to set a nonenforceable maximum contaminant level goal (MCLG) at which no known or anticipated adverse health effects occur and that allows an adequate margin of safety. Once the MCLG is established, EPA may set an enforceable standard for water as it leaves the treatment plant—the MCL. The MCL generally must be set as close to the MCLG as is feasible, using the best technology or other means available, and taking costs into consideration. Adopting an MCL would help ensure that public drinking water supplies do not exceed a level of perchlorate shown to adversely affect human health, regardless of the perchlorate source.

Cleanups usually occur under the federal Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund), the Resource Conservation and Recovery Act (RCRA), or state cleanup programs. Existing standards, such as MCLs under the Safe Drinking Water Act, often serve as cleanup objectives under these programs. Thus, if EPA were to establish an MCL for perchlorate in drinking water, it would also potentially serve as a cleanup standard under one or more of the cleanup programs discussed above.

Parties potentially responsible for perchlorate cleanup costs could include relevant federal agencies (e.g., DOD and NASA), their contractors (e.g., present and former owners and operators of perchlorate manufacturing facilities), and others. DOD has unsuccessfully sought legislative exemptions from environmental cleanup requirements. A recent Supreme Court case will probably make it easier for DOD and NASA contractors to recover cleanup costs from the federal agencies in the event that perchlorate cleanups occur under CERCLA.[6] Both the agencies and their contractors may be able to limit their CERCLA liability at a given perchlorate-contaminated site by establishing that the perchlorate in question was natural rather than anthropogenic, as discussed above.[7] However, potentially responsible parties under CERCLA bear the burden of establishing that natural contamination absolves them of liability for cleanup costs at a site.[8] Notably, DOD recently developed a new technology to distinguish between anthropogenic and naturally-occurring perchlorate.

As we discussed in the previous question, changes in human activity and rainfall patterns may be mobilizing previously-stable, naturally-occurring perchlorate into groundwater that serves as a drinking water source. For any particular contaminated site, the effect of adopting an MCL and the allocation of cleanup responsibilities are dependent on the facts and circumstances associated with that site. For example, some sites with perchlorate contamination that are not likely to be flushed into drinking water sources may not require

[6] United States v. Atlantic Research Corp., 127 S.Ct. 2331 (2007).

[7] E.g., United States v. Alcan, 315 F.3d 179, 184-85 (2d Cir. 2003).

[8] See id. at 185-87.

the same cleanup as sites with a more direct link to drinking water sources. Our report did not attempt to estimate the aggregate responsibility of various parties for cleanups related to perchlorate contamination, but new methods for determining perchlorate sources will likely be used to help assess such responsibility. We suggest that the question about funding for cleanups be directed to EPA.

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July 6, 2007

Robert David Utiger, M.D.
Senior Physician, Brigham and Women's Hospital
Clinical Professor of Medicine
Harvard Institutes of Medicine
77 Avenue Louis Pasteur
Boston, MA 02115

Dear Dr. Utiger:

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 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 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

July 20, 2007

The Honorable Joe Barton
The Honorable John Shimkus
Subcommittee on Environment and Hazardous Materials
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Office Building
Washington, DC 20515-6115

Dear Mr. Barton and Mr. Shimkus,

I am writing in response to the questions that you addressed to me subsequent to my presentation and responses to questions at the subcommittee's hearing on "Perchlorate: Health and Environmental Impacts of Unregulated Exposure" on April 25, 2007.

I shall first repeat your questions, and then offer my replies.

1. "You testified that people with hypothyroidism should compensate for potential perchlorate exposures through greater dietary intake of iodine rich foods and vitamins. This was also the recommendation of the "National Academy's Committee to Assess the Health Implications of Perchlorate Ingestion." Could you please talk about why you consider this so important? Please also detail what medicinal therapies or protocols are used to treat iodine deficiency, how widely available these are, what their costs are, and whether such treatments can be undergone when a woman is pregnant or breastfeeding."

> Reply. Perchlorate competitively blocks the uptake of iodide by the thyroid by inhibiting the action of the sodium-iodide symporter (transporter) that carries iodine into the thyroid gland, which is the first step in thyroid hormone (thyroxine and triiodothyronine) production. Perchlorate is therefore an antithyroid drug. If the dose of perchlorate is high, little iodide enters the thyroid, and therefore thyroid hormone production falls. Increasing dietary iodide intake overcomes the inhibitory effect of perchlorate, so that the thyroid takes up more iodide and thyroid hormone production does not fall. Given this competitive interaction between iodide and

perchlorate, the effect of perchlorate can be minimized and even overcome completely by an increase in iodide intake. In short, the greater the intake of iodide, the less the effect of perchlorate.

While increasing iodide intake prevents the effect of perchlorate on the thyroid, the National Academy's Committee to Assess the Health Implications of Perchlorate Exposure (hereafter referred to as the NAS Perchlorate Committee) went beyond the issue of perchlorate to note that the iodine intake in the U.S. population as a whole decreased by approximately 50 percent between 1971-1974 (urinary iodide 310 μg/L) and 1988-1994 (urinary iodide 145 μg/L). In 1988-1994 12 percent of adults, 15 percent of women of childbearing age, and 7 percent of pregnant women had values urinary iodide values <50 μg/L, which is the World Health Organization's definition of moderate iodide deficiency (Hollowell JG, et al. Iodide nutrition in the United States. Trends and public health implications: iodine excretion data from the National Health and Nutrition Examination Surveys I and III (1971-1974 and 1988-1994). J Clin Endocrinol Metab 1998;83:3401-8). The results of a survey in 2001-2002 were similar to those of the 1988-1994 survey (Caldwell KL, et al. Urinary iodine concentrations: United States National Health and Nutrition Survey 2001-2002. Thyroid 2005;15:692-9). The reasons for this decrease include less use of salt (and therefore less use of iodized salt) and less use of iodide in processed foods, baking, and animal husbandry. These results led the NAS Perchlorate Committee to recommend that steps be taken to increase iodide intake in all pregnant women, and in particular that all prenatal vitamin preparations contain iodide. When the NAS Perchlorate Committee completed its review in 2005, approximately 50 percent of prenatal vitamins did not contain iodide, and a quick survey of two drug stores recently revealed that many prenatal vitamin products remained iodide-free.

Several national organizations recommend that pregnant women and nursing women consume more iodide than anyone else (for example, the Food and Nutrition Council of the National Research Council recommends an intake of 150 μg daily for adults, 220 μg daily for pregnant women, and 290 μg daily for nursing mothers). Iodide intake can be increased by adding iodide to all multiple vitamin products, by increasing the iodide content of salt, by encouraging or mandating that iodized salt be used in food processing and baking, and by mandating that all salt be iodinated (as is done in many countries). For bottle-fed infants, iodide intake can be increased by increasing the iodide content of infant formulas (most contain less iodine than breast milk).

The cost of these steps is very small (pennies or less per day), and the entire population would benefit. Iodide tablets are available, primarily in areas near nuclear power plants, to be ingested in the event of an explosion that releases radioactive iodine, but the doses are much higher than needed to reverse iodide deficiency. Among foods, those richest in iodide are seafood, eggs, and dairy products.

2. "You starting talking about therapies for thyroid damage, but due to time constraints were not allowed to finish your answer. Could you please expound on the points you wanted to make about thyroid damage, treatment or replacement, and the effects of perchlorate."

Reply. Iodide deficiency, compounds such as perchlorate that inhibit thyroid iodide uptake, and compounds that block other steps in thyroid hormone production (some drugs and some foods consumed in other countries) may result in a decrease in thyroid hormone production. Very small decreases in thyroid hormone production lead to an increase in secretion of thyroid-stimulating hormone (TSH, thyrotropin) from the pituitary gland, which in turn increases thyroid iodide uptake and thyroid hormone production and causes thyroid enlargement. None of these exposures or the compensatory changes cause structural damage to the thyroid, and therefore they are reversible, with two exceptions. One, thyroid enlargement, if very long-standing, may persist. Two, decreased thyroid hormone production during fetal and early postnatal life results in permanent abnormalities in neural and physical development.

Chronic thyroid disease, for example that caused by chronic inflammation (Hashimoto's disease) or radioactive iodide therapy for hyperthyroidism, is usually permanent, and therefore is treated with thyroxine. The fall in thyroid hormone production in these people elicits a similar increase in TSH secretion. This may slow the decline in thyroid hormone production, but does not usually reverse it, in contrast to the effect of TSH to restore thyroid hormone production to normal in people with a fundamentally normal thyroid gland, including those with iodide deficiency or exposed to very high doses of perchlorate.

People with chronic thyroid disease would probably be more sensitive to the antithyroid action of perchlorate than normal people, because their thyroid gland is less sensitive to the increase in TSH secretion. However, I know of no studies in which people with chronic thyroid disease were given perchlorate.

3. "Were there any other human health related topics concerning perchlorate effects or exposures that were discussed or alluded to during the hearing that you believe need to be addressed or clarified? Are there any comments that you would like to make or questions you would like to more fully answer which you did not get a chance to due to time constraints at the hearing?"

Reply. The only known effect of perchlorate is to inhibit competitively thyroid uptake of iodide. The sodium-iodide symporters that facilitate iodide uptake by the thyroid are present in other tissues, including mammary tissue and the placenta, but the extent to which the symporters in these two tissues transport iodide and whether perchlorate inhibits iodide transport into these tissues is uncertain. In one study, high breast-milk concentrations of perchlorate were not associated with low breast-milk concentrations of iodide, suggesting that perchlorate and iodide transfer into milk are unrelated (Pearce EN, et al. Breast milk iodine and perchlorate concentrations in lactating Boston-area women. J Clin Endocrinol Metab 2007;92:1673-7). Perchlorate has no effect on the function of any other organ.

There are two topics that I would like to discuss further. One is the possible effect of perchlorate in pregnant women, fetuses, and infants, and the other is the topic of pituitary-thyroid compensation for perchlorate (see below).

4. "There is much discussion about perchlorate's health effects on pregnant women, fetuses, and young children. When the National Academy's Committee to Assess the

Health Implications of Perchlorate Ingestion was reviewing existing studies on human perchlorate exposures, did you consider work on neo-natal health and breast-feeding impacts from perchlorate? Was any of the information you evaluated compelling in showing an increase in hyperthyroidism?"

Reply. The frequency of hypothyroidism in infants born in regions of high or low water content of perchlorate in the western United States varied little in most but not all studies (see Health implications of perchlorate ingestion. National Research Council. Washington, DC 2005:91-105).

More comprehensive data are available from two studies in three cities in Chile, Taltal (natural water content of perchlorate 100-120 μg/L), Chanaral (5-7 μg/L), and Antofagasta (not detectable). Among newborn infants, the only cases of hypothyroidism were in infants born in Antofagasta. Among children aged 6 to 8 years in the three cities, serum thyroid hormone and TSH concentrations and the frequency of thyroid enlargement were similar (Crump C, et al. Does perchlorate in drinking water affect thyroid function in newborns or school-age children? J Occup Environ Med 2000;42:603-12).

In a second study of pregnant women and their newborn infants in these cities, there were no consistent differences in thyroid function in the mothers during pregnancy or after delivery or in their newborn infants (Tellez RT, et al. Long-term environmental exposure to perchlorate through drinking water and thyroid function during pregnancy and the neonatal period. Thyroid 2005;15:963-75). Breast-milk iodide concentrations were not lower in the women living in Taltal, despite higher breast-milk perchlorate concentrations.

These results, taken together, provide no evidence to support the possibility that substantial quantities of perchlorate have deleterious thyroid effects (hypothyroidism) in pregnant women, their fetuses, and newborn infants. I know of no studies in which thyroid function was measured in infants being nursed for weeks or months by mothers in whom perchlorate intake and breast-milk perchlorate concentrations were high.

5. "The CDC/Blount study showed an "association" between urinary perchlorate and increased TSH and decreased total T_4 in women 12 and older, who had urine iodine levels <100 μg/L. It is possible people might assume then that perchlorate actually "caused" the thyroid changes. Was the CDC/Blount study designed to evaluate whether there is a causal relationship between low levels of perchlorate exposure and thyroid function? Can you please clarify how you view the difference between an association and causation?"

Reply. Some people will assume that the results of the CDC/Blount study (Blount BC, et al. Urinary perchlorate and thyroid hormone levels in adolescent and adult men and women living in the United States. Environ Health Perspect 2006;114:1865-71) indicate that a high perchlorate intake reduces thyroid secretion and raises TSH secretion in women with a relatively low iodide intake. That assumption is incorrect. The results indicate there may be an association between low iodide intake and high perchlorate intake and abnormal thyroid function, but they do not indicate causation (if perchlorate intake is high and if iodide intake is low, and then if thyroid secretion [serum thyroxine] falls, then serum TSH may rise — a lot of

"ifs"). To evaluate causation one must conduct a prospective study to determine if there is time dependence between these variables, and ideally a prospective study in which the key variable is a prolonged increase in perchlorate intake and iodide intake is constant. I think there are some other problems with this study. The authors do not tell us why they subdivided the subjects into two groups with urinary iodide values <100 μg/L and ≥100 μg/L. Was this cut-off value planned in advance or only after the authors had looked at other cut-off values for urinary iodide or some cut-off values for urinary perchlorate? The authors present predicted (not actual) changes in serum thyroxine and TSH values according to urinary perchlorate values (highest 100 μg/L) in the women with urinary iodide values <100 μg/L. These predictions also presume causation, but in fact they are estimates based on statistical analyses of cross-sectional data, not prospective data. Lastly, it is important to note that the calculated decreases in serum thyroxine and increases in serum TSH values at the higher urinary perchlorate values would still be within the normal range for those measurements.

In addition to the Chilean studies, in which the perchlorate exposures were life-long, there have been five prospective studies in which known quanitities of perchlorate were given to small numbers of normal adults. In the longest study (6 months) with a high dose of perchlorate (0.04 mg/kilogram per day; urine perchlorate 2000 μg daily), there was no effect on thyroid uptake of iodide or serum thyroid hormone and TSH values measured repeatedly during the study (Braverman LE, et al. Effects of six months of daily low-dose perchlorate exposure on thyroid function in healthy volunteers. J Clin Endocrinol Metab 2006;91:2721-4).

The NAS Perchlorate Committee chose a no-effect dose of 0.007 mg/kilogram body weight per day because that dose did not inhibit thyroid uptake of iodide when given for 2 weeks (Greer M, et al. Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodine uptake in humans. Environ Health Perspect 2002;110:927-37). The committee then added an uncertainty factor of 10 to take into account the possibility that some people (pregnant women, fetuses, infants) might be more sensitive to the antithyroid action of perchlorate.

6. "As a medical doctor, specializing in thyroid function, what do you make of the split in the CDC/Blount study findings between perchlorate's iodine effects on men and women?"

Reply. Urinary iodide values are usually from 50 to as much as 100 percent higher in men than women, indicating that men ingest considerably more iodide. What iodide-containing foods or beverages account for this difference is not known. That being the case, and given that perchlorate is a competitive inhibitor of iodide uptake into the thyroid, the same amount of perchlorate might be expected to have a greater effect on thyroid function in women. However, this has not been documented in any of the prospective studies of perchlorate administration, and the CDC/Blount paper does not give urinary perchlorate values for men.

To generalize, nearly all thyroid disorders are more common in women than men, although why women are more vulnerable is not known. A lower dietary intake of iodide may contribute to their vulnerability, but it is unlikely to explain much of the difference.

7. "Your testimony talks about the compensatory nature of the thyroid. Do you agree with this statement published by the National Academy's Committee to Assess the Health Implications of Perchlorate Ingestion: "inhibition of iodide uptake by the thyroid is duration-dependent, the effect should decrease rather than increase with time, because compensation would increase the activity of the sodium-iodide symporter and therefore increase iodide transport into the thyroid"?"

> Reply. I definitely do agree with the statement. I would add that other mechanisms contribute to compensation for thyroid deficiency (including that resulting from iodide deficiency and perchlorate excess). One that is particularly relevant to iodide deficiency, as noted above, is the increase in the activity of sodium-iodide symporters in the thyroid, an increase that is not dependent on an increase in TSH secretion. A second is an increase in TSH secretion, which occurs after very small decreases in thyroid hormone production, and which alone may result in full compensation in people with many thyroid disorders. A third is an increase in the conversion of thyroxine to triiodothyronine in many extrathyroidal tissues, including the brain, which is beneficial because triiodothyronine is more potent than thyroxine.
>
> All of these compensatory mechanisms are duration-dependent, in that they are activated by a fall in thyroid iodide uptake or in some other step(s) of thyroid hormone production. Thus, thyroid hormone production will return toward if not to normal with time, rather than decrease more.
>
> With particular respect to perchlorate, if a daily dose is not sufficient to inhibit thyroid uptake of iodide in a few weeks, it never will, and therefore there will be no need for compensation.

I hope that my answers to your questions are clear. Please don't hesitate to let me know if they are not, or if you have additional questions.

Thank you.

Sincerely yours,

Robert D. Utiger, M.D.
Clinical Professor of Medicine
Harvard Medical School
Senior Physician
Brigham and Women's Hospital

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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

Gary L. Ginsberg, Ph.D.
Connecticut Department of Public Health
410 Capitol Avenue
Hartford, CT 06134-0308

Dear Dr. Ginsberg:

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 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 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

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

July 18, 2007

Congressman John Dingell
US House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

Dear Congressman Dingell,

In response to your letter dated July 6, 2007, I have reviewed the questions from the Honorable Joe Barton and the Honorable John Shimkus from the House Committee on Energy and Commerce, Subcommittee on Environment and Hazardous Materials. I appreciate the opportunity to clarify the points that they raise as provided in the attachment. Thank you once again for taking my testimony on this important public health matter. Please let me know if I can be of further assistance.

Sincerely yours,

Gary Ginsberg

Gary Ginsberg, Ph.D.
Toxicologist

Phone:
Telephone Device for the Deaf: (860) 509-7191
410 Capitol Avenue - MS # _____
P.O. Box 340308 Hartford, CT 06134

1. *Congress has traditionally relied upon the guidance, assistance, and recommendations of the National Academy to resolve questions of science, including current efforts on climate change. The National Academy panel was comprised of 15 leading scientists and physicians with the wide ranging expertise necessary to evaluate all aspects of the available science related to perchlorate. Are you suggesting that you are right and the scientists appointed by the National Academy are wrong?*

Response: I appreciate that the committee members in particular and that Congress in general has great respect for the National Academy of Science process, expertise, and quality of reports. As a member of two National Academy committees myself (Human Biomonitoring Committee, report to Congress, July 2006; Improving USEPA Risk Assessment Methods, ongoing, expected report early 2008) I see first hand the high level of scientific deliberation and expert judgement.

However, no one panel can be constructed to answer all questions and that is why it is given a specific charge. The charge to the NAS perchlorate panel was to "assess the current state of the science regarding potential adverse effects of disruption of thyroid function by perchlorate ..." and "to determine whether EPA's findings in its 2002 draft risk assessment, *Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization*, are consistent with the current scientific evidence." Finally, the Committee was to "suggest specific scientific research that could reduce the uncertainty in the understanding of human health effects associated with ingestion of low concentrations of perchlorate." The charge was not to redo the USEPA risk assessment but to provide a scientific assessment of its validity and areas for improvement or new research. To meet the stated charge, the construction of the commitment may have been appropriate – of the 15 members, 10 have academic posts, mostly in clinical or basic research settings. Of the other 5 members, 4 are consultants and only one is in a public health position. The strong emphasis on clinical and research expertise was appropriate for the committee to meet its charge of determining whether USEPA got the science

right. However, this particular NAS panel overstepped the charge and actually provided its own quantitative assessment of potency, dismissing the use of benchmark dose (BMD) analysis, and employing their own set of uncertainty factors to come up with an acceptable level of exposure (0.007 ug/kg/d, which corresponds to 24.5 ug/L in drinking water). The panel was not constructed for this activity as there were no (possibly one) members with expertise in the practice of risk assessment who works in public health. The types of expert judgement required for public health risk assessment requires years of experience with data analysis, statistical approaches to variability and uncertainty and the setting of uncertainty factors. This experience is so important because standards of practice have been developed to foster consistency between chemicals, media (water, soil, air, food), and sites (Superfund, Brownfields, others). Without the proper training and experience, the risk assessment will likely have arbitrary aspects and be out of line with modern practice. That unfortunately is the way that this particular document reads. The problem is not with the Committee's knowledge base to tackle the charge; the problem is that the Committee overstepped the charge. As one might expect, those are the areas in which the NAS perchlorate report are weakest. The dismissal of the BMD approach (which was used by USEPA in its draft assessment and also used by CalEPA in its final assessment) without proper justification and the inadequate application of uncertainty factors are two of the indicators that this report is not an improvement over perchlorate risk assessments that came before or after. Regarding uncertainty factors, the Committee felt comfortable with a rather minimal UF largely on the basis that they considered perchlorate's effect as a precursor effect and not a true adverse effect. However, they did not fully account for the variability between people such that relatively low levels of perchlorate in certain individuals (women with low iodine status) can actually experience decreased thyroid function (Blount, et al, 2006), an effect that would never have been predicted by the Committee. In fact, the recent data from CDC strongly suggest that the study relied upon by the CDC, the Greer study, underappreciated human variability and sensitivity to perchlorate. Obviously if that study had been published before the NAS report was completed, it may have changed their deliberations. However, now that it is published, it is important that EPA scientists and public health officials use it to refine the perchlorate risk assessment.

I don't believe this is a question of my being right and the NAS Committee on perchlorate being wrong. Staying within the charge, the NAS Committee provided useful information that I have no concern over. However, when venturing into the risk assessment arena, the NAS panel did not bring the type of perspective and analysis that is the standard in this field. This difference in perspective is important to public health at large because when dealing with millions of Americans you are more likely to see the small percentage problems. This is less the case for clinicians and academic researchers in university settings who may be studying effects in single individuals or small numbers of experimental groups. And of course, as I am writing this, I have the advantage of having seen the 2006 CDC study which bears out the importance of human variability in response to perchlorate, a study that the NAS Committee did not have at the time.

One additional note is that there was one dissenting opinion on the Committee that made it into the report regarding the size of uncertainty factors:

"The RfD is derived from a study in which a group of only seven healthy adults was given 0.007 mg/kg of perchlorate daily for 14 days (Greer et al. 2002). Although two other studies had similar results, the total number of subjects is still small. In addition to the small number of subjects, no chronic exposure studies have been published. An uncertainty factor of 3 could account for the uncertainty surrounding the small number of subjects and the absence of a long-term study."

2) *Isn't it true that the National Academy, in its recommendation, incorporated a 10-fold intra-species uncertainty factor to account for sensitive populations, including the fetuses of pregnant mothers with iodine deficiency or hypothyroidism?*

Response: Yes, this is true. However, as suggested by the one dissenting opinion on the Committee quoted above, this factor may not be large enough to address all the uncertainties in the perchlorate assessment. The difference between a small group of healthy volunteers tested in the Greer study (or in the occupational studies) vs. the general public in terms of iodine status, physiological status (particularly pregnancy which puts extra demands on the thyroid), medical status (e.g. preexisting thyroid

conditions) and exposure to other thyroid toxicants (PCBs, thiocyanate from cigarette smoke, nitrates in the diet, etc.) can easily span more than 10 fold. This 10 fold factor is of course a common risk assessment default for interindividual variability but should not be seen as highly conservative or a guarantee of protecting everyone. When interindividual variability is combined with the unknowns about human response to perchlorate and the substantial data gaps (e.g., longer-term testing), there is certainly wisdom in a larger than 10 fold total uncertainty factor.

This is especially the case given the uncertainty that the key endpoint from the Greer study chosen by the NAS Committee is in fact no effect level (NOEL). It was considered an effect level (LOAEL) by USEPA in the original risk assessment (2002) and by others (Ginsberg and Rice, 2005; Mass DEP, 2006). Further, CalEPA surpassed the NOEL/LOAEL level of analysis with a benchmark dose approach to show the statistically likely minimal effect level, which is below the dose chosen by the NAS as a NOEL (Ting, et al., 2006).

3) *The National Academy suggested level for perhclorate in drinking water that is based on "no observed effects" rather than the traditional approach using "no adverse effects." For regulatory and public health purposes, is a standard that uses a "no observed effects" level more conservative than a "no adverse effects" level?*

Response: First, it is incorrect to state that risk assessment traditionally only uses frankly toxic or adverse effects as a point of departure. Official USEPA guidance is to use an adverse effect or its precursor to set an RfD (USEPA, 2002). This is because of the recognition that affecting an upstream event in the steps leading towards toxicity (e.g., iodine uptake inhibition) leaves open the possibility that other exposures or events (e.g., co-exposure to anti-thyroid agents with similar mechanism or iodine deficiency) will compound the perchlorate effect and lead to an unpredictably large risk. One of the great

uncertainties in risk assessment is compounding of effect due to multiple chemical exposures. In fact, the public often loses confidence in risk assessment over the glaring "one chemical at a time" approach common to regulatory risk assessment. However, at least if we are starting from a point of no demonstrable biochemical effect that could be part of a toxic process, we are more guaranteed of no significant interactions or unpredictable risk. Therefore, the precursor effect of iodine uptake inhibition should have primacy in this risk assessment just as other precursor effects have in other risk assessments. The fact that the NAS Committee marginalized this effect on this basis again shows a lack of experience with the process. It appears that they were heavily influenced by the large degree of thyroid hormone reserve in typical adults such that a small amount of iodide uptake inhibition from low level perchlorate exposure could not plausibly have an effect on thyroid hormone status. As we learned from the CDC study (Blount, et al., 2006), this assumption is incorrect for at least 31% of US women who evidently have low iodine status and low thyroid hormone reserves. It is clear from the CDC study that the perchlorate effect is much more significant than some precursor finding with only theoretical but implausible connection to human risk.

4) *Dr. Utiger, your co-panelist, who has been a practicing physician specializing in thyroid function for 40 years, suggests that one of the best ways for people with hypothyroidism to compensate for potential perchlorate exposures is through greater dietary intake of iodine rich foods and vitamins. Yet, your testimony seems to reject these notions as inappropriate. What about your scientific background makes you more qualified to reject the health advice of this medical clinician?*

Response: Actually on this account I may not disagree very much with Dr. Utiger. Iodine supplementation is a good way to combat nutritionally-based thyroid insufficiency that is compounded by perchlorate exposure. Perchlorate is an excellent competitor for

thyroid uptake, its uptake being many times higher than iodide's. However, enough iodide can get into the thyroid if the diet is rich in this element. There is a question of how much is enough given the new data from FDA and other sources on the wide range of perchlorate concentrations in common vegetables, fruits and dairy. However, I would agree that iodide sufficiency is an important public health goal during pregnancy and nursing to combat the effects of perchlorate on the thyroid and neurodevelopment. However, equally important is diminishing perchlorate exposure where this is testable and intervention measures are available. A key arena in this regard is water supplies which are known to have substantial perchlorate contamination. Iodine supplementation will not solve the problem of environmental perchlorate because of the difficulty in getting everyone to an adequate level of education, nutrition and if necessary, supplementation. The fact that iodine intake has dropped approximately 30% in the US since the mid-1970s shows the challenge (Hollowell, et al.,1998). A combined approach to perchlorate mitigation via establishment of a health protective MCL in combination with campaigns to increase awareness about iodine during pregnancy and lactation will protect children from the harmful effects of perchlorate on brain development.

Finally, I believe the health advice of the medical clinician and public health toxicologist are both needed to move this issue forward.

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