

US EPA ARCHIVE DOCUMENT

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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

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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 46 National Priorities List (NPL) sites out of 1557 current and deleted sites. Of these 46 sites, 12 are private sites and 34 are Federal Facilities. At approximately 28 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:

- o Is the contaminant likely to cause an adverse effect on the health of persons?
- o Is the contaminant known or likely to occur in public water systems at a frequency and level of public health concern?
- o 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.