

January 22, 2003

MEMORANDUM

SUBJECT: Status of EPA's Interim Assessment Guidance for Perchlorate

FROM: Marianne Lamont Horinko /SIGNED/
Assistant Administrator

TO: Assistant Administrators
Regional Administrators

The purpose of this memorandum is to provide information concerning the status of the interim assessment guidance for perchlorate originally transmitted on June 18, 1999 (the "1999 Interim Guidance"), a copy of which is attached to this memorandum for your information. This memorandum was developed in response to requests from EPA Programs, Regions and individual states for a clarification concerning the Agency's guidance in light of more recent assessment activities. Today, as an interim measure and in the absence of a finalized oral health risk benchmark for perchlorate, we are reaffirming the 1999 interim guidance. The 1999 interim guidance may be replaced upon finalization of the 2002 Draft Assessment referred to below.

Background

The US EPA has been working with states, federal agencies, tribes, water suppliers and the private sector for several years to address perchlorate as an environmental contaminant. Ammonium perchlorate, a component of, among other things, solid rocket fuel, fireworks, air bags and some fertilizers, is a widespread environmental contaminant. In 1998, EPA released an assessment of ammonium perchlorate which was then subject to peer review in 1999. The external review draft of the revised document, entitled, "Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization" (the "2002 Draft Assessment") responds to those recommendations emanating from the peer review.

The development of the 2002 Draft Assessment and the risk characterization activities have been subject to review by the working partnership of the Interagency Perchlorate Steering Committee ("IPSC"), which is co-chaired by the US EPA and the Department of Defense, and comprised of representatives from more than 23 state, federal and tribal agencies. On January 18, 2002, the 2002 Draft Assessment was made available for a 77- day public comment period. An external scientific peer review workshop, open to the public, was held in Sacramento, CA, on March 5 and 6, 2002 to review the 2002 Draft Assessment and provide comments. These comments are in the process of being addressed, and, over the next few months, the revised 2002 Draft Assessment document, including a recommendation for an RfD, will undergo further, focused review to address remaining issues and uncertainties. Once these issues have been

addressed, the document will be finalized and prepared for entry onto the Agency's repository of consensus risk information, the Integrated Risk Information System ("IRIS"). At that time, we will consider the need for further guidance on this issue.

1999 Interim Guidance

On June 18, 1999, because of significant concerns and uncertainties that needed to be addressed in order to finalize a human health oral risk benchmark for perchlorate, the Office of Research and Development ("ORD") released the 1999 Interim Guidance. That guidance recommended that Agency risk assessors and risk managers continue to use the standing provisional reference dose ("RfD") range of 0.0001 to 0.0005 mg/kg-day for perchlorate-related assessment activities. This range was originally issued by ORD's National Center for Environmental Assessment ("NCEA") Superfund Technical Support Center based on assessments completed in 1992 and revised in 1995. In the 1999 Interim Guidance, ORD stated, "If federal, state or local environmental authorities decided to pursue site-specific clean-up or other water management decisions based on this RfD range by applying the standard default body weight (70 kg) and water consumption level (2L/day), the resulting provisional clean-up levels or action levels would range from 4-18 parts per billion ("ppb")."

In the absence of a finalized oral health risk benchmark for perchlorate, but in light of ongoing assessment activities by EPA, states and other interested parties, we are re-affirming this guidance with an added suggestion to carefully consider the low end of the provisional 4-18 ppb range. The 1999 Interim Guidance remains the applicable guidance until supplanted by new guidance based on a finalized risk assessment. ¹

The uptake and elimination kinetics of perchlorate for children are such that traditional adjustment of exposure based on body weight scaling results in exposure estimates equivalent to those for adults. Concern for increased susceptibility of exposures throughout lifetime are addressed by the uncertainty factors used in arriving at the health risk benchmark. For these reasons, with respect to both a new oral health risk benchmark and the existing provisional clean up range of 4-18 ppb set out in the 1999 Interim Guidance no additional adjustment for childhood exposure is necessary.

Because of the complexity of the issues surrounding this assessment, Programs, Regions and states are encouraged to consult with ORD on the status of the emerging science and the progress toward finalizing an oral health benchmark value. Similarly, because of the complexity of the issues surrounding analytical methods and available treatment technologies as outlined below, and because questions may arise as to the application of this guidance for site specific decision-making, Programs, Regions and States are encouraged to consult with Office of Solid Waste and Emergency Response ("OSWER") on these issues.

Regulatory Implications

¹The suggestion to carefully consider the low end of the 4-18 ppb range is based on the fact that recent analyses carried out by EPA and independently by the State of California suggest that a new oral health risk benchmark for perchlorate is likely to suggest provisional clean-up levels within or slightly below the 1999 Interim Guidance range. Because pregnant women and the fetus in utero are the most sensitive populations of concern for perchlorate toxicity in these recent analyses, the standard default adult body weight and water consumption values would be applied in converting a new RfD to provisional clean-up levels in ppb.

The Office of Water ("OW") will use the RfD as a starting point for a rulemaking process under the Safe Drinking Water Act ("SDWA"). Before initiating that process, the statute requires that the Administrator make a determination that the regulation of perchlorate would represent a "meaningful opportunity for health risk reduction". As discussed below, EPA is gathering the necessary data to assess the exposure to perchlorate in public drinking water systems. No later than the spring of 2004, we anticipate data will be available to enable the Administrator to make such a determination. In the interim, prior to a determination whether to proceed with a rulemaking, the Office of Water may issue a Health Advisory (HA), an estimate of acceptable drinking water levels of a contaminant. It is not a legally enforceable standard but serves as guidance to Federal, State and local officials. A Health Advisory may be issued within six months of a final RfD.

By itself, an RfD does not determine the level of the an enforceable standard, but is the foundation for determining the public health target, the maximum contaminant level goal ("MCLG"). The MCLG represents a public health goal specifically set at a level of no known or anticipated adverse health effects with an adequate margin of safety. The SDWA then requires the Maximum Contaminant Level ("MCL") to be set as close to the MCLG as is technically feasible, taking cost and other factors into consideration. By requiring consideration of these additional feasibility factors, Congress specifically recognized that the MCL may not be as stringent as the MCLG. As part of Development of an MCL the Agency will also need to evaluate whether there are other sources of perchlorate exposure in addition to drinking water. The RfD represents a scientific estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to a human population including sensitive subgroups which is likely to be without appreciable risk of adverse health effects. It does not represent a "bright-line" between safety and risk. Because of the use of uncertainty factors in deriving the RfD so as not to underestimate the "safe" level, the specific level at which actual risk from exposure begins above the RfD cannot be precisely calculated.

While an RfD addresses the issue of protection from adverse health impacts, EPA must also gather occurrence data at public water systems, evaluate the availability and cost of treatment technology and, finally, assure that analytical methods are available for a range of different water matrices to measure perchlorate at whatever the ultimate MCL level may be. Simultaneous with development of a revised risk assessment, the Agency has been gathering and developing information to address each of these additional factors.

If the Agency decides to regulate perchlorate, the Agency has 24 months to propose an MCLG and an MCL. Within 18 to 27 months after the proposal, EPA must publish a final rulemaking.

In the area of occurrence, perchlorate is being monitored under the Unregulated Contaminant Monitoring Rule ("UCMR") at all large water systems and a statistical sample of small systems. Data is also being gathered by the USGS, by States, and through several large research projects. The combined results of these efforts together with related data analysis is expected in the Spring of 2004.

With regard to analytical methods, OW is revising the methodology for EPA method 314.0 which will be more definitive for perchlorate and yield results in the sub-ppb range by isolating it from the matrix interferences, and avoiding possible resin contamination which might yield false positives. In addition, OW and ORD are collaborating on a method coupling ion chromatography and mass spectrometry to achieve reliable results, again below 1 ppb. Results are expected in late 2003.

Finally with respect to evaluating available technology, a number of bench and pilot scale research efforts are underway to develop and refine treatment technologies for perchlorate. Ion exchange and biological treatment appear to be the most promising candidates at the moment. There are systems currently operative in California that use an ion exchange technology. Questions remain with respect to the performance of these technologies in different source waters with competing ions, microbial sensitivity, method for waste brine disposal or destruction for IX, and acceptability of using bacterial reduction of perchlorate for drinking water. For more information on available treatment strategies, you can consult <http://clu.in.org/perchlorate>, a web page maintained by OSWER's Technology Innovation Office.

Cleanup Decisions at CERCLA and RCRA Sites

Although EPA's waste programs implement cleanups through several different authorities, they have the goal of operating within a "one-cleanup program" concept. Where different programs face the same environmental problem, we should strive for consistent technical approaches. Thus, as a general matter, we expect the regions, under CERCLA and RCRA, to take similar approaches in assessing risks from perchlorate in groundwater and in determining appropriate cleanup levels. Regardless of the authority under which perchlorate is addressed, the risks are the same. The guidance in this memorandum, therefore, is applicable to all OSWER programs.

Specifically, perchlorate has been found in groundwater at numerous facilities around the country where, for example, rocket propellants and explosives have been handled. Therefore, we encourage the regions to consider during the site assessment and characterization phase, the likelihood that perchlorate may be present at facilities that manufactured, tested, or disposed of solid rocket propellant, fireworks, flares, or other such materials commonly associated with perchlorate. We also recommend that CERCLA five-year reviews and standard RCRA oversight activities (e.g., permit modifications or renewals) at these types of facilities include steps to determine whether previously undetected perchlorate is present at levels that may not be protective. In some cases, this may result in the need for additional followup in terms of monitoring and in some cases response actions to ensure protectiveness.

In determining whether cleanup may be necessary and in setting appropriate cleanup levels, the regions should follow the 1999 Interim Guidance described in the first section of this memorandum. As stated there, when based on the provisional RfD range, the regions should continue to use the provisional cleanup levels for perchlorate in groundwater ranging from 4 to 18 parts per billion ppb with an added suggestion to carefully consider the lower end of the provisional range (as discussed earlier in this memorandum). Also, as noted earlier in this memorandum, the 4 to 18 ppb range is considered to be protective based on recent, ongoing

analyses and taking into account the most sensitive receptors, and therefore no additional adjustment for childhood exposure is needed.

In selecting the appropriate cleanup level at specific sites, the regions should consider the factors that are typically addressed in setting groundwater cleanup levels, such as practicability, the reliability of exposure data, whether the groundwater is used as a source of drinking water, as well as other routes of exposure. Before a region, for site-specific reasons, chooses a cleanup level either below or above the 4 to 18 ppb range, it must consult with OSWER, ORD, and OW.

While this memorandum is intended for EPA regions, we encourage the regions to share its contents with the states. In addition, the regions should continue to honor state standards through the CERCLA ARAR process, and in case of RCRA comply with more stringent state standards.

Conclusion

To restate some of the points raised earlier in this memorandum, in the absence of a finalized oral health risk benchmark for perchlorate, but in light of ongoing assessment activities by EPA, states and other interested parties, we are re-affirming the 1999 interim guidance based on a provisional RfD range. Because an RfD represents a scientific estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to a human population including sensitive subgroups which is likely to be without appreciable risk of adverse health effects, it does not represent a "bright-line" between safety and risk, but provides a starting point for risk management decisions. Because women of childbearing age and the developing fetus are the most sensitive receptors for perchlorate exposures, the standard adult default body weight and water consumption factors apply in developing a range of provisional clean-up levels. Because of the approaches used to derive health risk benchmarks in recent analyses, no additional adjustment for childhood exposure is necessary.

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