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

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OFFICE OF
RESEARCH AND DEVELOPMENT

SUBJECT: Interim Assessment Guidance for Perchlorate

FROM: Norine E. Noonan Norine E. Noonan
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TO: Regional Administrators
Regional Waste Management Division Directors
Regional Water Management Division Directors

The purpose of this memorandum is to transmit the attached interim assessment guidance from the Office of Research and Development (ORD) relevant to Agency activities related to perchlorate. The development of this guidance is in response to requests to ORD from some of the Regional offices, as well as from individual States.

As you know, the Office of Solid Waste and Emergency Response (OSWER) has recently forwarded to you the final report of the February 1999, External Peer Review of the document entitled "Perchlorate Environmental Contamination: Toxicology Review and Risk Characterization." The external review document (ERD), subject of the peer review, was developed by ORD's National Center for Environmental Assessment (NCEA).

The human health and ecological assessment issues related to environmental contamination by perchlorate are complex. The ERD addressed an immediate need to bring more science into the assessment process, but at the time of the February 1999 peer review meeting, several key studies on perchlorate were underway or planned. These studies will provide some critical assessment information. These new data will be incorporated into the revised assessment document that will undergo a second external peer review in January 2000. Because ORD is committed to bringing the latest available science to bear on the human and ecotoxicology estimates, ORD is recommending that until the completion of the second review, EPA risk assessors and risk managers follow the attached interim guidance. This guidance has been reviewed by the Office of Water (OW), Office of Solid Waste and Emergency Response (OSWER), and the Office of General Counsel and is supported by both OW and OSWER.

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We look forward to working with you as we come to closure on this aspect of the perchlorate contamination issues over the next nine months. If there are any questions or if you require additional information, do not hesitate to contact Annie Jarabek at 919-541-4847 (voice); 919-541-1818 (FAX); or jarabek.annie@epa.gov (E-mail).

Attachment

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ORD Interim Guidance for Perchlorate

Because of remaining significant concerns and uncertainties that must be addressed in order to finalize a human health oral risk benchmark for perchlorate, the Office of Research and Development (ORD) recommends that Agency's risk assessors and risk managers continue to use the standing provisional RfD range of 0.0001 to 0.0005 mg/kg-day for perchlorate-related assessment activities. This recommendation is based on the determination that important new emerging data may have an impact on the proposed revised oral human health risk benchmark contained in the February 1999 External Review Document (ERD). Some background information and the reasons for this recommendation are detailed below.

In February 1999, an external peer review meeting was held in San Bernadino, California to review the document entitled "Perchlorate Environmental Contamination: Toxicology Review and Risk Characterization." This ERD was developed by ORD's National Center for Environmental Assessment (NCEA). The ERD, available on the Internet at http://www.epa.gov/ncea/perch.htm, was developed as part of a wider interagency effort to address environmental contamination issues related to perchlorate. More information on this effort is available at http://www.epa.gov/ogwdw/ccl/perchlor/perchlo.html. The external peer review was sponsored by the Office of Solid Waste and Emergency Response (OSWER) and the Office of Water. The final peer review report of the February 1999 meeting has recently been transmitted to you by OSWER.

As explained in the ERD, the current range of a provisional RfD value for perchlorate spans from 0.0001 mg/kg-day to 0.0005 mg/kg-day; this range was issued by the NCEA Superfund Technical Support Center based on assessments in 1992 and revised in 1995. If state or local environmental authorities decide to pursue site-specific clean-up or other water management decisions based on this provisional RfD range by applying the standard default body weight (70 kg) and water consumption level (2 L/day), the resulting provisional clean-up levels or action levels would range from 4-18 parts per billion (ppb). It should be noted that no cancer assessment was performed at this time.

The ERD presented an updated human health risk assessment as well as a screening-level ecological assessment of newly performed studies on the toxicity of perchlorate. The updated health assessment harmonizes noncancer and cancer approaches to derive a single oral risk benchmark based on precursor effects for both neurodevelopmental effects and thyroid neoplasia. Both of these are historically established effects often observed after disturbances in the hypothalamic-pituitary-thyroid feedback system. By their nature, each of these effects is likely to have a biological threshold. The proposed revised oral human health risk benchmark is protective of potential carcinogenic effects based on new perchlorate data on the lack of its genotoxicity and the reversibility of induced thyroid hypertrophy/hyperplasia. The proposed revised oral human health risk benchmark is 0.0009 mg/kg-day. No traditional RfD or cancer slope factor was proposed in the ERD. If state or other local environmental authorities choose to apply the same default values as above to the revised oral benchmark, a site-specific clean-up or action level of 32 ppb would result.

The Agency has committed to another external peer review as part of the process to more completely and accurately characterize the human and ecotoxicological risks associated with perchlorate contamination and to make this information available through the Integrated Risk Information System (IRIS). In the next assessment, NCEA will address comments made in the February 1999 report, as well as review and incorporate data from additional studies that were either nearing completion or recommended at that time. In addition to recommended studies on pharmacokinetics, developmental effects testing in another species and repeat motor activity evaluations are underway. Another important recommended activity underway is a National Toxicology Program-sponsored pathology working group (PWG) review of the thyroid and brain tissue from all previous and pending studies. This PWG review will provide for a common nomenclature of lesions and for a consistent pathology review across studies, with the goal to reduce variability in the data. Further, an interlaboratory validation study of the hormone analyses (T4, T3, and TSH) across participating laboratories will be performed. Additional ecotoxicology studies, including some site-specific and farm gate analyses of food crops, are also either being reviewed or already underway.

The purpose of the next external peer review will be to evaluate these additional data and to review the draft final NCEA assessment. All of the perchlorate testing and study activities, whether underway, in review, or planned, are being timed to support the goal of the next external peer review in January 2000. As mentioned above, this next peer review is intended as part of the IRIS process. After revision to reflect any additional comments or recommendations, the final NCEA assessment will then go to IRIS consensus review.

Because new analyses and data are to be considered, we can predict that the human and ecotoxicology benchmarks are likely to change. The new estimates will reflect greater accuracy and may be either higher or lower than the harmonized benchmark proposed in the February 1999 document (0.0009 mg/kg-day). *Therefore, ORD recommends that Agency risk assessors and risk managers continue to use the standing provisional RfD range of 0.0001 to 0.0005 mg/kg-day because of continued uncertainty with respect to the impact of the pending data and analyses on the final estimate.* This recommendation helps to ensure that the Agency bases its risk management decisions on the best available peer reviewed science and is in keeping with the full and open participatory process embodied by the proposed series of peer review workshops. It should be noted, that due to the uncertainty of whether the final oral human health risk benchmark will increase or decrease based on the new data and analyses, the standing provisional RfD range is the more conservative of the estimates available at this time and, therefore, more likely to be public health protective in the face of this uncertainty. This is also consistent with Agency practice that existing toxicity estimates remain in effect until the review process to revise them is completed.

This document provides guidance to EPA Regions concerning Agency activities related to perchlorate. It also provides guidance to the public and the regulated community on how EPA intends to exercise its discretion in carrying out these activities. The guidance is designed to implement national policy on these issues. The document does not, however, substitute for EPA statutes or regulations; nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA decisionmakers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. EPA may change this guidance in the future.