

Reference

Texas Natural Resource Conservation Commission

INTEROFFICE MEMORANDUM

To: Distribution **Date:** December 11, 2001

Thru: JoAnn Wiersema, Manager
Toxicology & Risk Assessment Section
Office of Permitting, Remediation & Registration

From: Michael Honeycutt, Ph.D.
Toxicology & Risk Assessment Section
Office of Permitting, Remediation & Registration

Subject: Technical Justification for a Revised Interim Action Level for Perchlorate

On October 5, 2001, the Toxicology & Risk Assessment Section (TARA) revised its recommended interim drinking water action level for perchlorate from 22 $\mu\text{g}/\text{L}$ (ppb) to 4 ppb. This memorandum provides the technical justification for this change. Perchlorate presents the TNRCC with some unique challenges in that the Agency is trying to make important regulatory decisions in the midst of rapidly developing science. Further compounding the importance of the decisions and the need for the data is that, based on perchlorate's mechanism of action, short-term exposures to perchlorate can lead to permanent adverse health effects.

Background

Perchlorate gained widespread attention in 1997 when the California Department of Health Services developed an analytical method for perchlorate which lowered the quantitation limit for perchlorate from 400 ppb to 4 ppb. Regulatory agencies and potentially responsible parties then began to detect perchlorate in areas where it had previously either not been detected or not been a concern. The United States Environmental Protection Agency (USEPA) and the United States Department of Defense (DoD) began to conduct toxicological research on perchlorate to generate data to develop toxicity factors, specifically a reference dose (RfD), for perchlorate.

While the toxicity studies were ongoing, USEPA recommended that states and USEPA regions use the provisional reference dose range (0.0001 mg/kg-day to 0.0005 mg/kg-day) developed by USEPA's National Center for Environmental Assessment (NCEA) in 1995. However, in December of 1998, USEPA published an external review draft document containing a new provisional RfD of 0.0009 mg/kg-day for perchlorate using the new toxicological data generated by USEPA and DoD. TARA reviewed this new RfD and considered it appropriate to use as the basis for a drinking water interim action level. Using the child exposure factors prescribed in the Texas Risk Reduction Program (TRRP) rule (0.64 L/day drinking water ingestion rate and 15 kg bodyweight), the acceptable drinking water value derived using the newer provisional RfD was determined to be 22 ppb. This 22 ppb value was selected as the TNRCC interim action level for drinking water as described in the TARA June 28, 1999 memorandum (see attachment 1) and also as a TRRP groundwater ingestion Protective Concentration Level (PCL) and as a Risk Reduction



Rule (RRR) Standard 2 residential groundwater Medium Specific Concentration (MSC).

In June of 1999, USEPA released a memorandum (see attachment 2) indicating that an external scientific peer review panel recommended that the perchlorate toxicity data be re-reviewed using thyroid hyperplasia for the determination of the reference dose rather than thyroid hypertrophy. Additionally, they recommended that more toxicity tests (i.e. immunotoxicity tests) be conducted to reduce some of the uncertainty of the new RfD. In the 1999 memorandum, USEPA also recommended that the 1995 reference dose range of 0.0001 mg/kg·day to 0.0005 mg/kg·day be used until USEPA released a new RfD incorporating the new toxicity test data and the re-evaluation of the thyroid pathology data. TARA decided to continue to use the 22 ppb interim action level since the new provisional RfD was based on the best available toxicity data.

This 22 ppb value was also used as a human health surface water quality criterion. Human health surface water quality criteria generally consider two pathways: 1) ingestion of drinking water and 2) consumption of fish that have bioaccumulated the chemical of concern. The 22 ppb human health surface water quality criterion considered only ingestion of drinking water. Since perchlorate is an anion, bioaccumulation in fish was not considered an issue at the time. The TNRCC considered promulgating the 22 ppb human health surface water quality criterion as a Texas surface water quality standard in the last triennial review of the water quality standards which were adopted July 26, 2000. However, the agency decided to not promulgate a water quality standard, but to address perchlorate issues in surface water on a site-specific basis via a site-specific water quality standard.

It is important to note that surface water quality criteria and standards are generally in-stream values and are not typically applied as discharge criteria. Rather, they are typically used to derive a water-quality based discharge criterion which incorporates a mixing zone. Also, if treatment technology is available which can treat effluent to a level lower than the water-quality based criterion, then the treatment-technology based criterion would apply.

Development of the 4 ppb Interim Action Level

Subsequent to the development of the 1998 provisional RfD and the 1999 USEPA memorandum recommending the use of the 1995 NCEA range of RfD values, newer toxicity and tissue residue data have been developed. This new information, along with several additional considerations, led the TNRCC to develop a new interim action level for perchlorate. The development of the 4 ppb interim action level was based on a weight-of-the-evidence approach (i.e. a number of factors were considered in making the decision). These factors are outlined below:

(1) USEPA is currently recommending use of NCEA's 1995 provisional reference dose range of 0.0001 mg/kg·day to 0.0005 mg/kg·day. Current toxicological studies (subsequent to the 1998 provisional RfD) indicate the potential for developmental and neonatal impacts from perchlorate which could result in an acceptable drinking water value *at the lower end* of the 1995 provisional RfD range (USEPA, 2001). USEPA toxicologists are developing a new RfD for perchlorate incorporating the new toxicology studies and the re-evaluated thyroid pathology data. The new RfD should be available for public review early next year.

(2) USEPA Region 9 in July of 2001 issued a Superfund Record of Decision for the Aerojet Sacramento Site in Rancho Cordova, California in which they established a groundwater cleanup

value and a surface water discharge criterion of 4 ppb for perchlorate. The groundwater cleanup value was derived using a RfD of 0.0001 mg/kg·day and adult exposure factors. The toxicology studies mentioned in point 1 above are part of the rationale behind USEPA Region 9's selection of the 4 ppb cleanup value. The 4 ppb discharge criterion is a treatment-technology based discharge criterion.

(3) USEPA Region 1 in July of 2001 established a perchlorate groundwater cleanup level of 1.5 ppb for Camp Edwards in Massachusetts. This cleanup level was derived using a RfD of 0.0001 mg/kg·day and child exposure factors (1 L/day drinking water ingestion rate and 15 kg body weight). USEPA Region 1's justification for the cleanup level also references the new toxicology data: "...because EPA believes important new studies that were not available in 1999 are either underway or planned and are anticipated to have in [sic] impact on the proposed human health risk benchmark,..." (see attachment 3). However, it is unclear how perchlorate's analytical detection limit will affect this cleanup level as current detection limits are higher than this cleanup level.

(4) Texas Tech University, in cooperation with the Brazos River Authority and the US Army Corps of Engineers, has collected fish samples from waterbodies adjacent to the NWIRP McGregor facility for perchlorate analysis. Perchlorate levels in fillets from bass, sunfish, and catfish ranged from 260 to 690 ppb, which could pose a potential health concern if ingested. Using a RfD of 0.0001 mg/kg·day, a body weight of 70 kg, and a fish ingestion rate of 30 g/d, an acceptable fish tissue concentration that would be protective of human health would be about 200 ppb. In addition, perchlorate levels in the heads of suckers and sunfish were in the 1000 ppb range. The possibility of ecological effects are also a concern. However, the data are variable and are not adequate to derive a bioaccumulation factor (a factor used to predict uptake of a chemical into fish from water). While these data would not necessarily directly impact a drinking water value, they would impact surface water criteria for perchlorate.

(5) Another consideration in setting the interim action level for perchlorate is the current state of analytical capabilities. The only USEPA method currently approved for perchlorate analysis in water is Method 314, which has a reporting limit of 4 ppb. Various research groups have developed new analytical techniques for perchlorate, including an ion chromatographic method which employs a prefilter to remove interfering ions and an ion chromatographic/mass spectrometric method, which will lower the reporting limit even further.

Taking all of the above information into consideration, TARA selected the 1995 NCEA RfD range (0.0001 mg/kg·day to 0.0005 mg/kg·day) as the basis for the TNRCC drinking water interim action level, groundwater cleanup values, and human health surface water quality criterion. Using child exposure factors (0.64 L/day drinking water ingestion rate and 15 kg bodyweight) from the TRRP rule in conjunction with the 1995 NCEA RfD range, a range of acceptable drinking water values of 2.4 to 12 ppb is calculated. Given the weight of the evidence described above and that the analytical method currently approved by USEPA has a reporting limit of 4 ppb, the perchlorate interim action level was set at 4 ppb which is at the lower end of this range. We have consulted with USEPA toxicologists on an ongoing basis regarding perchlorate toxicology issues for several years and they concur with our recommendation of using the lower, more conservative end of the RfD range.

In summary, TARA is now recommending that the TNRCC use 4 ppb as an interim action level

for perchlorate in drinking water, as well as a human health surface water quality criterion. This value is at the lower end of the range of values currently recommended by USEPA and is similar to cleanup values established by USEPA Regional offices. The value is scientifically defensible; it is health protective; and it is consistently and accurately detectable using current analytical techniques.

If you have any questions, please call me at 512-239-1793.

Reference:

USEPA. 2001. Record of Decision for the Western Groundwater Operable Unit OU-3. Aerojet Sacramento Site, Rancho Cordova, California. USEPA Region 9. San Francisco, California.

Distribution

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Attachment 1

Texas Natural Resource Conservation Commission

INTEROFFICE MEMORANDUM

To: Distribution

Thru: JoAnn Wiersema, Manager *JW*
Toxicology & Risk Assessment
Chief Engineer's Office

From: Michael Honeycutt, Ph.D. *MH*
Toxicology & Risk Assessment
Chief Engineer's Office

Date: June 28, 1999

Fax Transmittal Memo

of Pages 8

To: Ralph Fordschuidt	From: Michael Honeycutt
Co.:	Co.: TNRCC
Dept.:	Phone #
Fax #	Fax #

DMFX14

Subject: Interim Action Level for Perchlorate

Concern about perchlorate contamination at two sites in Texas has prompted staff from the Office of Waste and the Office of Water to request that the Toxicology & Risk Assessment Section develop an action level for perchlorate in drinking water. Currently, there is neither an USEPA-promulgated Maximum Contaminant Level nor Advisory Level. After consulting with USEPA Regions 6 and 9, the Agency for Toxic Substances and Disease Registry, the Texas Department of Health, and several states that also have perchlorate contamination, we have developed an interim action level of 22 $\mu\text{g/L}$ (ppb) for perchlorate.

The interim action level of 22 $\mu\text{g/L}$ was derived using the interim provisional reference dose (RfD) of 0.0009 mg/kg-day published on December 31, 1998 by USEPA's National Center for Environmental Assessment. USEPA cautions that this RfD is in an interim status and that a range of older provisional RfDs (0.0001 mg/kg-day to 0.0005 mg/kg-day) should be used until the interim provisional RfD is finalized. However, in reviewing the interim provisional RfD, I have found it to be based on the best scientific information available to date and therefore more scientifically-defensible than the older provisional RfDs. Numerous toxicologists from other agencies I have consulted on the matter concur. Please note that we fully expect that the interim provisional RfD published by USEPA will change once the final review currently ongoing is complete (tentatively at the end of this year). In any event, the general consensus is that the interim provisional RfD is conservative and is not expected to change drastically in either direction. Given the interim status of the RfD, the action level we are deriving should also be considered interim and subject to change when more data become available.

Please note that, based on perchlorate's mechanism of toxicity, we would expect children to be the most susceptible subpopulation. Therefore, we are using child exposure factors (0.64 L/day ingestion rate, 15 kg body weight) rather than adult exposure factors (2 L/day ingestion rate, 70 kg body weight) to calculate the interim action level for perchlorate.

Also note that in developing the interim action level for perchlorate, we considered other perchlorate action levels that are being used in other states. One such value being used in California, 18 $\mu\text{g/L}$, is based on the older provisional RfD of 0.0005 mg/kg-day and uses adult

exposure factors. Another value used in Nevada, 32 $\mu\text{g/L}$, is based on the interim provisional RfD of 0.0009 mg/kg-day and also uses adult exposure factors. Again, we are confident that the interim action level of 22 $\mu\text{g/L}$ which was developed using the interim provisional RfD and child exposure factors is the most appropriate and scientifically-defensible.

If you have any questions, please call me at extension 1793.

Distribution:

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Attachment 2



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

JUN 3 1999

99 JUN 10 AM 9:52
RCRA PERMITS PROGRAM
OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

MEMORANDUM

SUBJECT: Release of Report on Perchlorate Toxicity Peer Review

FROM: Timothy Fields, Jr. *Timothy Fields, Jr.*
Acting Assistant Administrator
Office of Solid Waste and Emergency Response

TO: Interested Parties

Please find the attached final report of the external peer review workshop on the toxicity of perchlorate, held on February 10-11, 1999, in San Bernardino, California. The peer review workshop was conducted by Research Triangle Institute, a contractor to EPA's Office of Solid Waste and Emergency Response. Areas covered by the peer review included the draft toxicological review document for perchlorate, protocols and results of several recently completed and ongoing toxicological and ecological effects studies on perchlorate, and the harmonized human health oral risk benchmark (RfD) proposed for perchlorate in the toxicological review document.

The peer review workshop was sponsored by the EPA Office of Solid Waste and Emergency Response (OSWER) and Office of Water. The draft toxicological review document for perchlorate, entitled "Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization Based on Emerging Information", was prepared by EPA's National Center for Environmental Assessment (NCEA). The draft toxicological review document presented an updated human health risk assessment as well as a screening ecological assessment of newly performed studies on perchlorate. The updated human health assessment harmonizes noncancer and cancer approaches to derive a single proposed oral RfD based on precursor effects for both non-cancer health effects and thyroid cancer.

The panel concluded that the presentation of the data in the toxicological review document was generally well done but that further work is needed before the RfD proposed by EPA can be definitively evaluated. It recommended using thyroid hyperplasia (increase in cell number) rather than thyroid hypertrophy (increase in cell size) for the determination of the reference dose, since it concluded that hypertrophy is an adaptive effect, not an adverse effect. The panel recommended that a pathology working group (PWG) be convened to review 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. In addition, the peer reviewers identified a number of statistical issues that should be addressed by NCEA.

The peer reviewers commended NCEA's use of available biological and toxicological data to move in the direction of a harmonized approach to assessing cancer and noncancer endpoints,

TOTAL P.03
and encouraged further use of the mode of action data in the determination of the RfD. The peer reviewers concluded that the RfD proposed by EPA in the toxicological review document (0.0009 mg/kg/d) is likely to be conservative, based upon the existing toxicological data base.

The panel found that the ecotoxicology studies were well done and support the screening ecological risk assessment. The major weaknesses of the screening ecological risk assessment (SERA) were identified as limited data on the current levels of perchlorate in the environment and the potential for long-term effects. These data limitations resulted in a SERA that was conservative both in terms of the risk-based effects thresholds suggested and the scope of the additional studies recommended. The lack of this information makes it difficult to determine what types of fish, wildlife and plants are at risk from perchlorate.

NCEA is currently working with the National Institute of Environmental Health Sciences on the establishment of a PWG to review the thyroid and brain tissue from all previous and pending studies. In the final toxicological review document, NCEA will address comments made in the peer review workshop report, and will review and incorporate data from additional studies that are currently ongoing, as well as the results of the PWG review.

Several months ago the Agency committed to a second external peer review as part of the process to characterize the potential human and ecotoxicological risks associated with perchlorate contamination. The purpose of the second external peer review will be to evaluate the additional data, the presentation and analyses of these data in the toxicological review document, and the draft final NCEA assessment. It is anticipated that a second peer review workshop will be held early in 2000. The second peer review may use a number of the peer reviewers that participated in the recent workshop. This next peer review is intended as part of the Integrated Risk Information System (IRIS) process. After revision to reflect any additional comments or recommendations, the final NCEA assessment will then go to IRIS consensus review.

EPA's Office of Research and Development will address in a separate memorandum the issue of the appropriate provisional reference dose for perchlorate pending the completion of the final toxicological review document with its associated health benchmark dose. In brief, it will recommend the continued use of the existing provisional reference dose range of 0.0001 to 0.0005 mg/kg-day, until such time as a final benchmark is approved.

Any questions regarding the peer review workshop report should be directed to Peter Grevatt (202-260-3100) or Dorothy Canter (202-260-2230) of my staff.

cc: P. Grevatt
D. Canter
N. Noonan
W. Farland
A. Jarabek

3. Sp26 - 17. Sp22

Attachment 3



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION I
ONE CONGRESS STREET SUITE 1100
BOSTON, MASSACHUSETTS 02114-2023

Memorandum

Date: 26 July 2001

From: Sarah Levinson, Human Health Risk Assessment Support
Technical Support Branch

To: Todd Borci, Project Manager
MMR Project Team

Subj: Recommendations Regarding Human Health Risk Evaluation of Perchlorate: Application to
MMR Project Activities

In response to detections of perchlorate in groundwater samples at MMR, perchlorate has become a chemical of interest at the MMR. Neither EPA nor MA DEP has formally adopted a safe drinking water standard or health advisory for perchlorate in public water supplies. However, the Agencies are aware and are concerned about the potential for perchlorate to cause adverse human health effects (especially on the thyroid) were exposure to occur. As such, the purpose of this letter is to communicate current EPA policy regarding human health risk evaluation of perchlorate in groundwaters. This policy is based upon my communications with the perchlorate chemical manager Annie Jarabek (ORD), Peter Grevatt (OSWER Sr. Scientist HQ), and other EPA Regional toxicologists.

While the issues surrounding risk evaluation of perchlorate are complex and are the subject of review at present, it has been and continues to be the position of EPA that human health risk evaluation of perchlorate should proceed using the provisional oral reference dose (RfD) issued by EPA's NCEA Superfund Technical Support Center of 0.0001 to 0.0005 mg/kg-day. This position was articulated in a guidance of June 18, 1999 from Norine Noonan (ORD) to all Regional Administrators and all Waste and Water Management Division Directors (copy attached). While issued as interim guidance, it was to remain in effect until such time that a final assessment of the hazard to human health posed by exposure to perchlorate was formally adopted and placed on EPA's IRIS database. The range of oral reference doses issued by EPA in 1992 and later revised in 1995 of 0.0001 to 0.0005 mg/kg/day is based on adverse effects of the thyroid gland and has not been superceded by an IRIS value at present.

Since 1995, EPA has attempted to bring the latest available scientific information to bear on a health protective benchmark value for perchlorate and in 1999, EPA released an External Peer Review Draft document ("Perchlorate Environmental Contamination: Toxicology Review and Risk

Characterization"). However, because EPA believes important new studies that were not available in 1999 are either underway or planned and are anticipated to have in impact on the proposed human health risk benchmark, EPA does not recommend use at this time of the 0.0009 mg/kg/day health risk benchmark contained in the 1999 External Review Document. This policy helps to ensure that EPA bases its risk management decisions on the best available peer reviewed science and is consistent with EPA practice that existing toxicity estimates remain in effect until the review process to revise them is completed.

Thus, using the range of provisional oral reference doses (0.0001 to 0.0005 mg/kg-day) suggested be used in this interim period and in keeping with prudent public health measures assuming that a young child (15 kg body weight, 1 l/day water ingestion rate) represents a plausible receptor, the concentration of perchlorate in water that would not exceed the provisional reference dose for a child equates to approximately 2 ppb -8 ppb (1.5 ppb - 7.5 ppb). Were one only concerned about effects on adults (2 l/day ingestion rate, 70 kg body weight), then the concentration of perchlorate in water that would not exceed the provisional reference dose for an adult approximates 4-18 ppb (3.5ppb -17.5 ppb). As the child receptor is consistent with the beneficial use of the aquifer as a public drinking water supply, I strongly advise consideration be given to protecting the young child receptor population for remedial decisions involving perchlorate in groundwater at MMR.

Attachment (EPA Memo from N. Noonan to Regional Administrators 6/18/99)