



**American Water Works
Association**

Government Affairs Office
1401 New York AVE, NW, Suite 640
Washington, DC 20005
(202) 628-8303 Fax: (202) 628-2846

The Authoritative Resource for Safe WaterSM

May 27, 2005

Mr. Benjamin Grumbles
Assistant Administrator for Water
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: Perchlorate Regulatory Determination

Dear Mr. Grumbles:

As noted in our previous letter of January 26th, we recognize the significant challenges the Environmental Protection Agency (EPA) faces in evaluating the need for a national drinking water regulation for perchlorate. Since our earlier letter, EPA has taken significant steps, including incorporating the Reference Dose (RfD) developed by the National Academy of Sciences (NAS) into its Integrated Risk Information System (IRIS) and issuing a Drinking Water Equivalent Level (DWEL) of 24.5 µg/L. Both the completion of the NAS report and EPA's acceptance of its findings mark significant progress on the perchlorate issue.

AWWA believes that perchlorate is a prime candidate for one of the regulatory determinations that EPA will propose this summer under the framework of the Contaminant Candidate List (CCL). We urge EPA to determine under that process, and as soon as possible, whether to regulate perchlorate.

If EPA concludes that limitations in currently available information prevent such a determination, then we ask that you identify the specific knowledge gaps that need to be filled and identify what EPA will do to close those gaps, with a timeline. This will help utilities and the public better understand the reasons for not making a determination at this time, EPA's next steps, and the potential timeframe for a future decision.

I will be glad to meet with you or your staff at any time on this matter, and we look forward to cooperating with the Agency to help in any way possible as you move forward in making a decision on this matter.

Sincerely Yours,

A handwritten signature in black ink that reads "Tom Curtis".

Thomas W. Curtis
Deputy Executive Director

cc: Cynthia Dougherty - USEPA OGWDW
Philip Oshida - USEPA OGWDW
Ephraim King - USEPA OGWDW
Alan Roberson
Kevin Morley



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PERCHLORATE OCCURRENCE MAPPING

Submitted by:

Philip Brandhuber Ph.D
Sarah Clark PE

HDR
Denver, Colorado

Submitted to:

American Water Works Association
Washington, DC

January, 2005

Table of Contents

ABSTRACT.....	1
1.0 INTRODUCTION	1
2.0 RESULTS OF THIS STUDY.....	2
2.1 National Map of Perchlorate Detections in Drinking Water	2
2.2 Impact of Perchlorate Occurrence on Drinking Water Systems.....	2
3.0 STUDY GROUND RULES AND ASSUMPTIONS.....	4
4.0 PREVIOUS STUDIES OF PERCHLORATE OCCURRENCE.....	5
4.1 American Water Works Service Company Survey	5
4.2 National Assessment of Perchlorate Contamination Occurrence	6
4.3 EPA Tracking of Perchlorate Manufacturing and Release.....	6
5.0 PERCHLORATE OCCURRENCE INFORMATION INCLUDED IN THIS STUDY	6
6.0 ANALYSIS OF INDIVIDUAL DATA SOURCES.....	7
6.1 Unregulated Contaminants Monitoring Rule (UCMR)	7
6.1.1 Background.....	7
6.1.2 Completeness of Data Set	8
6.1.3 Analysis of Data Set.....	8
6.1.4 Comparison of UCMR Occurrence to Known Perchlorate Releases	11
6.2 California Department of Health Served Drinking Water Database.....	11
6.2.1 Background.....	12
6.2.2 Completeness of Data Set	12
6.2.3 Analysis of Data Set.....	12
6.3 Massachusetts Department of Environmental Protection Study.....	14
6.3.1 Background.....	14
6.3.2 Completeness of Data Set	14
6.3.3 Analysis of Data Set.....	14
6.4 Arizona Department of Environmental Quality 2004 Study	15
6.4.1 Background.....	15
6.4.2 Completeness of Data Set	16
6.4.3 Analysis of Data Set.....	16
6.5 Texas Commission on Environmental Quality Study (Texas Tech Study)	17
6.5.1 Background.....	17
6.5.2 Completeness of Data Set	18
6.5.3 Analysis of Data Set.....	18
7.0 CONCLUSIONS.....	19
REFERENCES	21

APPENDIX - PERCHLORATE OCCURRENCE MAPS	22
Map 1. National Occurrence of Perchlorate in Drinking Water.	23
Map 2. National Occurrence of Perchlorate in UCMR Systems by Congressional District.....	24
Map 3. UCMR Systems Measuring for Perchlorate.	25
Map 4. UCMR Systems (CWS and NTNCWS) with Perchlorate Detections \geq 4 ug/L – August, 2004 Data.	26
Map 5. Comparison of Known Perchlorate Releases and UCMR perchlorate Detections by System.....	27
Map 6. California Public Water Systems with Perchlorate Detections.	28
Map 7. Massachusetts Systems Measuring for Perchlorate.....	29
Map 8. Massachusetts Systems Detecting Perchlorate in Finished Water.	29
Map 9. Arizona 2004 Study Perchlorate Sample Sites.	30
Map 10. Arizona 2004 Study Perchlorate Detections.....	30
Map 11. Arizona Pre-2004 Perchlorate Sample Sites.....	31
Map 12. Arizona Pre-2004 Perchlorate Detections.	31
Map 13. Texas 2004 Study Perchlorate Sample Sites and Detections.	32

List of Figures

Figure 6.1. Distribution of UCMR Detections.....	8
Figure 6.2. Number of EPTDS and Large CWS Impacted by Potential Perchlorate MCLs – August, 2004 UCMR Data.....	10
Figure 6.3. Percentage of System Entry Points Containing Perchlorate for Systems Which Have Detected Perchlorate– August, 2004 UCMR Data.	11
Figure 6.4. Distribution of CalDHS Perchlorate Detections.....	12
Figure 6.5. Number of Sources and Systems Impacted by Potential Perchlorate MCLs – July 2004 CalDHS Data.....	14
Figure 6.6. Number of Treated Waters and CWS’s in Massachusetts Impacted by Potential Perchlorate MCLs – September, 2004 MDEP Data.	15
Figure 6.7. Distribution of Perchlorate Detections in Arizona Study.....	17

List of Tables

Table 2.1. Impact of Alternative MCL – Includes All System Sizes.	3
Table 2.2. Impact of Alternative MCL – by EPTDS/Source.....	4
Table 5.1. Summary of Data Sources.	7
Table 6.1. Completeness of August 2004 UCMR Perchlorate Data Set	8
Table 6.2. Perchlorate Detection by EPTDS.	9
Table 6.3. UCMR Results as of August, 2004.....	9
Table 6.4. California Perchlorate Detection by Source.	13
Table 6.5. Perchlorate Detections by System Size and Source Water.....	13
Table 6.6. Massachusetts Results as of September, 2004.....	15
Table 6.7. Arizona Perchlorate Sampling Results.	17
Table 6.8. Texas Perchlorate Sampling Results.....	18

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The authors of this report wish to thank all of those who supported its preparation. Particular thanks are given to the AWWA project manager, Kevin Morley. The contributions of the Project Advisory Committee (PAC) were also invaluable in completing this report. The members of the PAC included, Ms. Traci Case of the AWWA Research Foundation, Dr. Michelle Frey, PureSense Environmental Inc., Mr. Kevin Mayer, USEPA Region 9, and Dr. Shane Snyder, Southern Nevada Water Authority.

ABSTRACT

The national occurrence of perchlorate in drinking water was analyzed and geographically mapped by compiling data from existing perchlorate occurrence surveys. The existing surveys included studies by USEPA and by the States of Arizona, California, Massachusetts, and Texas. Perchlorate occurrence was found to be national in scope, with detections in 26 states and Puerto Rico. Perchlorate was detected in at least one entry point to the distribution system of approximately 5% of the nation's large (>10,000 population) Community Water Systems. Geographically, the highest density of perchlorate detection was found to be in Southern California, west central Texas, along the east coast between New Jersey and Long Island and in Massachusetts. At the present time no perchlorate has been detected in drinking water in the northern Great Plains, the central and northern Rocky Mountains, Alaska or Hawaii. If detected, perchlorate was typically present at concentrations of less than 12 ug/L. The frequency of perchlorate detection increased with lower detection limits, indicating that perchlorate will be more frequently detected if analytical methods of greater sensitivity are used. Perchlorate was often detected in drinking water in areas for which there was no documented environmental release of perchlorate. This implies that the environmental release of perchlorate is more wide spread than anticipated or that undocumented mechanisms of perchlorate formation exist. Since two of the occurrence surveys summarized by this study are still in progress, it is likely that the estimates of perchlorate occurrence made by this report represent a lower bound of the actual number of drinking water systems impacted by perchlorate contamination.

1.0 INTRODUCTION

In 1998 perchlorate was added to the USEPA contaminant candidate list (CCL), indicating the agency's potential interest in regulating this contaminant in drinking water.¹ Inclusion of perchlorate on the CCL was primarily based upon the discovery of perchlorate in California drinking water supplies. Of key concern was the environmental release of ammonium perchlorate by two manufacturers located in Nevada. These releases were associated with low levels of perchlorate contamination in found in Lake Mead and the Colorado River. This water is used for drinking water, irrigation and recreation by millions of people in Nevada, California, and Arizona.² Subsequent investigations have identified perchlorate releases to the environment in as many as 26 states.³

Salts of perchlorate (ClO_4^-) are used in a number of applications including as an oxidizer in solid rocket fuel, and as a component of fireworks, pyrotechnics, flares and explosives. It has also been used medicinally as a treatment for hyperthyroidism as well as a analytical chemical reagent. Perchlorate has also been identified in fertilizers.⁴ On a volume basis, more perchlorate is used in the production of solid rocket fuel than for all other uses combined.⁵ While the vast majority of perchlorate occurrence in the environment is anthropogenic in nature, there may be instances of natural perchlorate occurrence.⁶

In preparation for the potential regulation of perchlorate, the American Water Works Association (AWWA) has developed an Action Plan to address issues related to perchlorate which may impact the drinking water industry. Part of this Action Plan is to consolidate and map the national occurrence of perchlorate using information from existing occurrence surveys. The existing surveys included results from the Unregulated Contaminants Monitoring Rule (UCMR) and surveys by the states of Arizona, California, Massachusetts and Texas. This report presents consolidated perchlorate occurrence information from these surveys and maps the known location of perchlorate occurrence as of the fall of 2004.

2.0 RESULTS OF THIS STUDY

2.1 National Map of Perchlorate Detections in Drinking Water

Map 1 (See appendix) presents the national map of perchlorate detections in drinking water. This map is a compilation of all perchlorate detections in drinking water extracted from the August, 2004 UCMR data and from studies performed by the states of California, Massachusetts and Texas. Data from the Arizona study did not distinguish between potable and non-potable sources. For this reason it is not included on the map, but will be analyzed in detail later.

As can be seen in reviewing Map 1, perchlorate occurrence in drinking water is national in scope. Perchlorate has been detected in drinking water in 26 states and Puerto Rico. Geographically, the highest density of perchlorate detection is in Southern California, west central Texas, along the east coast between New Jersey and Long Island and in Massachusetts. At present, no perchlorate has been detected in drinking water in the northern Great Plains, the central and northern Rocky Mountains, Alaska or Hawaii. However, the apparent absence of perchlorate occurrence in these regions may merely be because relatively few sources have been sampled. More intensive sampling, particularly of small systems, may detect perchlorate contaminated drinking water sources in these regions.

While completely mapping the perchlorate detections of the databases which were analyzed, this map is likely to under represent the occurrence of perchlorate in drinking water. This is because small systems are under represented in the UCMR data and the UCMR study is incomplete. In particular, relatively sparse sampling data exists for the northern Great Plains and the central and northern Rocky Mountains.

Map 2 (Appendix) present perchlorate detections by Congressional District. This map is limited to detections in UCMR systems only. It does not include perchlorate detections recorded by state agencies in California, Massachusetts and Texas.

2.2 Impact of Perchlorate Occurrence on Drinking Water Systems

The USEPA has not proposed a MCL for perchlorate. However eight states have established guidance levels or goals for perchlorate in drinking water. Depending upon

the state, the guidance levels range from 1 ug/L to 18 ug/L. Hence it appears that a MCL in the range of 1 ug/L to 20 ug/L¹ is plausible. Using information from this study a preliminary estimate of the percentage of systems which could be impacted by a range of potential MCL's was made. Table 2.1 compares the percentage of systems impacted by alternative MCL's for the UCMR, California and Massachusetts data. The Arizona study again is not included in this comparison since it did not distinguish between potable and non-potable sources. The Texas data is also not included in Table 2.1 since it only identified potable sources and not systems.

Table 2.1. Impact of Alternative MCL – Includes All System Sizes.

Study	Detection Limit ug/L	# Systems Sampled	Number and Percent Systems Exceeding				
			2 ug/L	4 ug/L	6 ug/L	10 ug/L	20 ug/L
UCMR	4	3356	136	88	55	29	7
			4.1%	2.6%	1.6%	0.9%	0.2%
CalDHS	4	1168	123	68	37	18	4
			10.5%	5.8%	3.2%	1.5%	0.3%
MDEP	1	617	7	5	4	2	0
			1.1%	0.8%	0.6%	0.3%	0.0%

At a hypothetical perchlorate MCL of 20 ug/L less than one half percent of all drinking water systems will be impacted by the presence of perchlorate nationally. At this MCL there appears to be little regional impact and the handful of impacted systems would be scattered throughout the nation. The percentage of systems impacted increases with decreasing hypothetical MCL's. If the hypothetical MCL is an order of magnitude lower, 2 ug/L, approximately 4% of all systems will be impacted. At a 2 ug/L MCL clear regional impacts of perchlorate occurrence will be present. For example, at 2 ug/L up to 10% of all systems impacted in California would be impacted.

It should be noted that these estimates are based upon direct extrapolation of the raw occurrence data. As will be discussed later in this report (section 6.1.3), due to the design of the UCMR small system sampling program, adjustments must be made to the data to create a statistically rigorous occurrence estimate.⁷ Insufficient data is available at the present time to perform these adjustments. At present it appears that the impact to small systems is underestimated in the unadjusted data, so the overall impact of perchlorate on all systems sizes is likely to be higher than indicated in Table 2.1. None the less, even after adjustment, it is not expected that the percentage of systems impacted will be substantially greater than indicated in Table 2.1.

¹ In 2002 USEPA completed a Toxicological Review and Risk Characterization⁸ for perchlorate which proposed an oral reference dose (RfD) of 0.00003 mg/kg per day. This corresponds to a drinking water MCL of 1 ug/L using the standard assumption of 2 L/day consumption for a 70 kg individual. In January, 2005 the National Research Council⁹ (NRC) recommended a perchlorate RfD of 0.0007 mg/kg per day as protective of human health. Using similar assumptions, this corresponds to a MCL of 24 ug/L. However the NRC only recommended a RfD, not a MCL. The determination of a MCL will be made by USEPA.

The percentage of sources or entry points to the distribution system (EPTDS) impacted by alternative MCL's is presented in Table 2.2. At a theoretical perchlorate MCL of 20 ug/L, only a fraction of a percent of sources/EPTDS are impacted either nationally (UCMR data) or in California. No EPTDS are impacted in Massachusetts. In the Texas panhandle area slightly more than 1% of the sources are impacted at hypothetical MCL of 20 ug/L. Using this information as a rough guideline, it appears that one percent or less of sources/ EPTDS would be impacted nationally by a perchlorate MCL of 20 ug/L. Excluding the Texas study, if a MCL of 2 ug/L were promulgated by USEPA, between one and seven percent of the sources/EPTDS would be impacted.

Source waters in Texas appear to be a unique case compared to waters in other locations in the country. A potential MCL of 2 ug/L would impact approximately 36% of the sources in the panhandle area. More information regarding regional perchlorate occurrence in Texas will be presented in section 6.5.

Table 2.2. Impact of Alternative MCL – by EPTDS/Source.

Study	Detection Limit ug/L	# EPTDS/ Sources Sampled	Number and Percent EPTDS Exceeding				
			2 ug/L	4 ug/L	6 ug/L	10 ug/L	20 ug/L
UCMR	4	13,357	348	227	141	55	9
			2.6%	1.7%	1.1%	0.4%	0.1%
CalDHS	4	5512	398	175	98	40	6
			7.2%	3.2%	1.8%	0.7%	0.1%
MDEP	1	1140	15	6	5	3	0
			1.3%	0.5%	0.4%	0.3%	0.0%
TCEQ	1	559	201	102	64	27	7
			36.0%	18.2%	11.4%	4.8%	1.3%

In the following sections background information regarding this study will be presented and the individual data sources will be analyzed in greater detail.

3.0 STUDY GROUND RULES AND ASSUMPTIONS

No sampling of perchlorate was performed by this study. Several national and state databases monitoring perchlorate occurrence were used to develop the information presented in this report. Two of the perchlorate monitoring programs were in progress at the time the analysis was performed. For this reason the occurrence information contained in this report represents a “snap shot” of the perchlorate occurrence information available in the second half of 2004.

Several ground rules were established regarding the scope of the mapping effort and the procedures for the analysis of data. These are summarized as follows:

- *Scope:* The scope of this analysis was limited to perchlorate occurrence in drinking water sources or in treated drinking water. This report does not attempt to quantify or map general levels of perchlorate occurrence in all surface or groundwaters.
- *Data sources:* The data sources for this project were limited to surveys of perchlorate performed by or under the direction of the USEPA or State agencies. Department of Defense, local government or private surveys of perchlorate occurrence were not included in this analysis.
- *Acceptable analytical methods:* Only perchlorate concentration data obtained per USEPA method 314.0 or subsequent revisions was used.
- *Determination of detection in a source:* A detection of perchlorate was defined as one or more measurements of perchlorate at or above the detection limit.
- *Averaging of perchlorate values:* Multiple perchlorate measurements at a single source were averaged to provide an estimate of the source's concentration. Non-detects were assigned a value of one half of the detection limit for the sample and included in the average for the source.
- *Data quality:* The information contained in the databases which were evaluated by this study was assumed to be correct. Data was used "as is." If possible, clearly erroneous information was corrected, otherwise it was excluded from the analysis.
- *Mapping:* Occurrence information was mapped to the greatest level of geographic accuracy possible with the available data. The precedence used for mapping the location of perchlorate occurrence was in this order
 - Latitude/longitude of the source
 - Centroid of zip code of the source
 - Centroid of zip code of administrative unit responsible for source
 - Centroid of nearest city

4.0 PREVIOUS STUDIES OF PERCHLORATE OCCURRENCE

Two published studies have been completed which evaluated perchlorate occurrence in surface and groundwater. These were performed by the American Water Works Service Company and AwwaRF. In addition, USEPA has been tracking the manufacturing, use and release of perchlorate to the environment since the late 1990's.

4.1 American Water Works Service Company Survey

This survey was sponsored and performed by the American Water Works Service Company during 1997 and 1998.¹⁰ The survey included both surface and groundwaters. In total, 522 groundwater samples from 367 wells in 17 states were analyzed. These included 329 untreated sources and 38 treated sources. Of the 367 wells tested, 18 wells tested positive ($\text{ClO}_4^- \geq 4 \text{ ug/L}$) at least once. The presence of perchlorate was confirmed by a second detection in 9 of the 18 wells. Of the remaining 9 wells with perchlorate detects, the study concluded that 5 wells were false positives caused by analytical abnormalities. Wells with confirmed perchlorate detections were located in California and New Mexico.

4.2 National Assessment of Perchlorate Contamination Occurrence

The objective of this AwwaRF sponsored study¹¹ was to “assess perchlorate occurrence in US drinking water supplies.” The conclusions of the study were as follows:

- A total of 196 sites in 39 states were identified to have used, manufactured or received shipment of perchlorate compounds.
- Of 160 drinking water samples collected in a targeted sampling, 4 groundwaters and 2 surface waters tested positive for perchlorate. One additional unidentified source tested positive for perchlorate.
- A total of 138 samples were collected from large utilities (> 100,000 population served). No perchlorate was found in any sample.
- Targeted sampling did not detect perchlorate in groundwater sources supplying drinking water utilities located within a 4 mile radius of 12 different fertilizer manufacturing plants.

It should be noted that both studies were performed prior to the approval of EPA method 314.0 for perchlorate detection in water. Consistent with the ground rules of this study, data from the American Water Works Service Company and AwwaRF study have not been included in the occurrence maps presented in this report.

4.3 EPA Tracking of Perchlorate Manufacturing and Release

In a series of updates to the public, USEPA has been tracking known and potential sources of perchlorate releases to the environment. Perchlorate occurrence information collected by Region 9 of the USEPA through April, 2003 is posted on the USEPA Hazardous Waste Cleanup website. According USEPA, in 2003 there were approximately 230 locations in 40 states where perchlorate was manufactured or used. As of April 2004 USEPA estimated there were 98 perchlorate releases from governmental and non governmental sites in 26 states.³

5.0 PERCHLORATE OCCURRENCE INFORMATION INCLUDED IN THIS STUDY

The results presented in this study are a compilation of occurrence surveys performed or sponsored by various governmental agencies. Six sets of data were analyzed. Two sets of data were obtained from USEPA. These included the Unregulated Contaminants Monitoring Rule (UCMR) database, obtained from the Office of Ground Water Drinking Water, and the list of Known Perchlorate Releases was obtained from Office of Solid Waste and Emergency Response. Four data sets were obtained from state agencies. These included perchlorate occurrence surveys performed by the State of Arizona, obtained from the Department of Environmental Quality; California, obtained from the Department of Health Services; Massachusetts, obtained from the Department of Environmental Protection; and Texas, obtained from the Commission on Environmental Quality through Texas Tech University.

Table 5.1 summarizes the data sources used for this study.

Table 5.1. Summary of Data Sources.

Data Set	Sponsoring Agency	Date	Type of Water Tested	Available Locational Information	Reported Detection Limit
UCMR	USEPA OGWDW	Aug 04	Potable	City, Zip, County	4 ug/L
California	CalDHS	Jul 04	Potable Non potable	City, Zip, County	4 ug/L
Massachusetts	MDEP	Sept 04	Potable	Lat/long, County, Zip	1 ug/L
Texas	TCEQ	Sept 04	Potable Non potable	Lat/long, County	1 ug/L
Arizona	ADEQ	Dec 04	Potable Non potable	Lat/long, County	4 ug/l 2 ug/L
Known Perchlorate Releases	USEPA OSWER	Aug 04	--	Facility/site name, Zip	Unknown

6.0 ANALYSIS OF INDIVIDUAL DATA SOURCES

6.1 Unregulated Contaminants Monitoring Rule (UCMR)

6.1.1 Background

Perchlorate was included by USEPA on List 1 of contaminants to be monitored under the UCMR in September 1999.¹² Sampling began in 2001 and was scheduled to be completed by the end of 2003. Approximately 2800 large systems (>10,000 served) and 800 small systems were required to perform perchlorate sampling. The sampling strategy for the UCMR is to perform a census of large systems, and perform a stratified sampling of small systems. Samples were taken at entry points to the distribution system (EPTDS) and analyzed by EPA Method 314.0. The detection level for UCMR reported perchlorate data is 4 ug/L. Sampling frequency depended on source water type. Surface water sources were to be sampled quarterly over a one year period and groundwater sources twice in a one year period.

The UCMR sampling has been completed and data analysis is in progress. Data input by USEPA is expected to be completed in mid 2005 at which time the UCMR database should be fully populated. USEPA periodically posts the most recent update of the UCMR data set on the UCMR website. The results presented in this report are based on the August, 2004 UCMR database release.

6.1.2 Completeness of Data Set

Since the UCMR database is not fully populated, an analysis of the August 2004 release was performed to assess the “completeness” of the data set. Table 6.1 summarizes the completeness of the August 2004 release. The perchlorate data set was complete for approximately 80% of the groundwater entry points and 44% of the surface water entry points. Hence while the August 2004 release provides a fairly complete picture of groundwater perchlorate occurrence, the surface water occurrence information is largely incomplete. Given the inherent variability of water quality in surface waters, it is likely that perchlorate will be detected at least once in some of the remaining samples from surface waters which have yet to detect perchlorate.

Table 6.1. Completeness of August 2004 UCMR Perchlorate Data Set

Water Type	EPTDS Sampled	EPTDS with complete data set	Percentage
GW	8479	6813	80%
SW	4622	2034	44%
Not Defined	256	-	-

GW => Complete is 2 or more measurements

SW => Complete is 4 or more measurements

Does not include EPTDS for which no measurements have been recorded

6.1.3 Analysis of Data Set

Overall, out of 29,870 results recorded in the database, perchlorate was detected 583 times or in 1.9% of the samples. The range of detected values extends from 4 ug/L (the minimum detection limit) to a maximum value of 420 ug/L. The distribution of detections is presented in Figure 6.1.

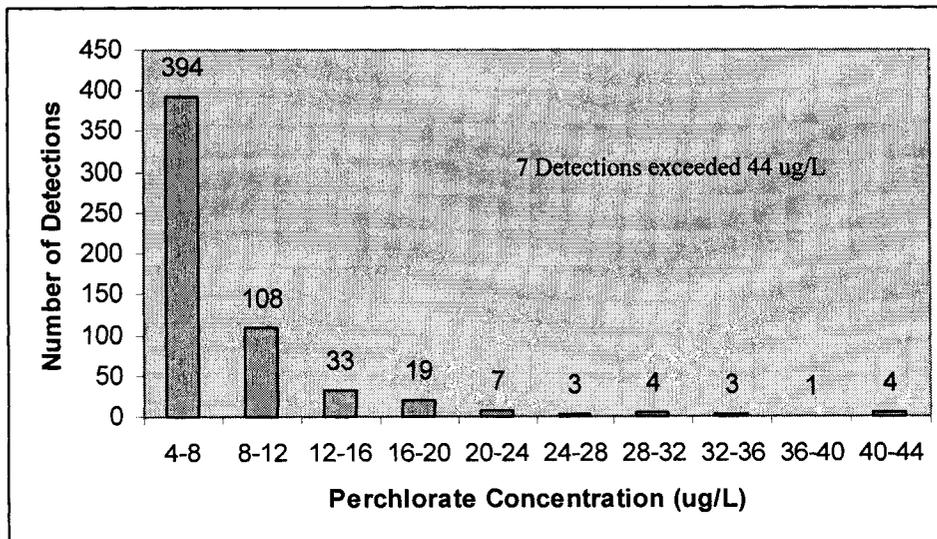


Figure 6.1. Distribution of UCMR Detections.

Table 6.2 consolidates the occurrence information by EPTDS. Perchlorate was detected in 363 of the 13,357 EPTDS or at a rate of 2.7%. Of the 363 perchlorate detections, about half of the detections were unconfirmed (perchlorate only detected once in the EPTDS when there was more than one sampling of the EPTDS). Conversely, approximately about 27% of the EPTDS detected perchlorate in all samples.

Table 6.2. Perchlorate Detection by EPTDS.

Category	Number	% of all EPTDS	% of EPTDS with detections
Total EPTDS	13,357	-	-
EPTDS with detects	363	2.7	-
EPTDS with unconfirmed detection	173	1.3	48
EPTDS with single measurement and detection	56	0.4	15
EPTDS with 2 or more detections	134	1.0	37
EPTDS with all detections	98	0.7	27

Additional analysis of the data set was performed to determine the occurrence of perchlorate by source water type and system size. As presented in Table 6.3, perchlorate was detected at approximately equal rates for surface and groundwater sources. There appears to be a difference in the rate of occurrence between large and small systems, with perchlorate being found more frequently in large systems. However, caution must be applied in interpreting this data. Since small systems were sampled through a stratified sampling strategy,⁷ an unbiased estimate of occurrence for the entire small system population can only be made by an estimator which is weighted by the sampling probability of each sample within the strata. Because the weighting factors use by USEPA were not available and not all small system data has been compiled, the calculation of an occurrence estimate for small systems could not be completed. Hence the information presented in Table 6.3 for small systems ($\leq 10,000$ population) represents the rate of perchlorate occurrence within the subset of small systems sampled, not a projection of perchlorate occurrence in the total population of small systems. Occurrence information for large systems is valid without any adjustment since, as previously mentioned, a census of large systems was performed and the sampled population and total population are one and the same.

Table 6.3. UCMR Results as of August, 2004.

Water	Systems with Population $\leq 10,000$			Systems with Population $> 10,000$		
	Sampled	Detected	Percentage	Sampled	Detected	Percentage
GW	526	4	0.8%	1140	69	6.1%
SW	245	1	0.4%	1359	67	4.9%
Total	771	5	0.6%	2499	136	5.4%

Totals do not include 86 UCMR systems for which population or water type data was unavailable. No perchlorate was detected in these systems.

Limiting the analysis to Community Water Systems (CWS) with populations greater than 10,000, an initial estimate can be made of the number of large systems impacted by alternative perchlorate MCLs. Figure 6.2 illustrates the numbers of EPTDS and the corresponding number of large systems impacted by potential MCLs ranging from 2 ug/L to 20 ug/L.

Note: Based on mean value measured at EPTDS with non-detects calculated at 0.5x detection level.
Systems with multiple EPTDS impacted by perchlorate are classified by the EPTDS with the highest concentration

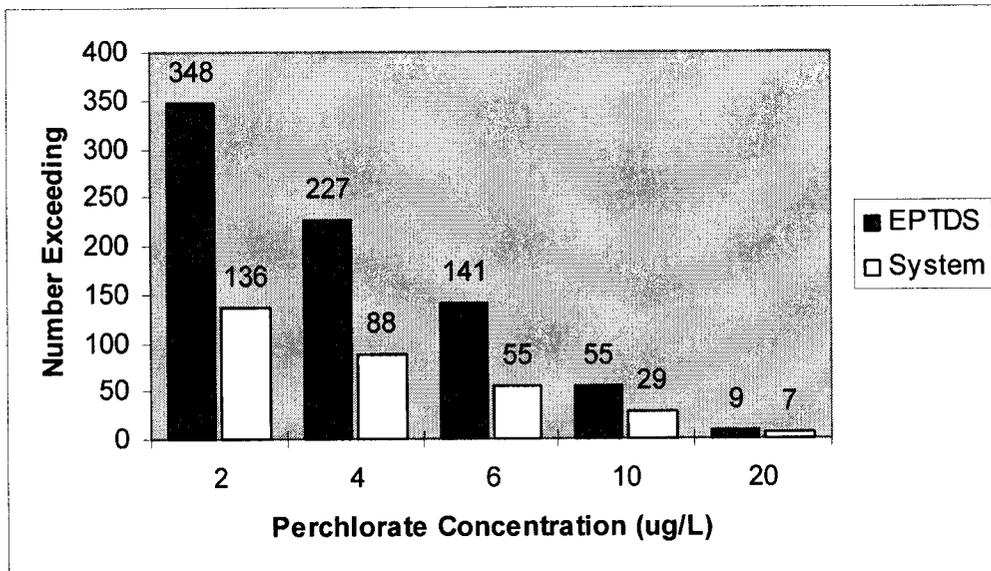


Figure 6.2. Number of EPTDS and Large CWS Impacted by Potential Perchlorate MCLs – August, 2004 UCMR Data.

Most systems have multiple entry points to the distribution system and perchlorate may not be present in all the entry points. A system which has detected perchlorate in only a

portion of its entry points may have the option of eliminating the perchlorate contaminated source. Alternatively, a system detecting perchlorate in most or all of its entry points will probably be forced to treat perchlorate. As illustrated in Figure 6.3, approximately 89% of the systems detecting perchlorate detected it in 50% or less of their entry points. Only 3% of the systems detected perchlorate in more than 75% of their entry points.

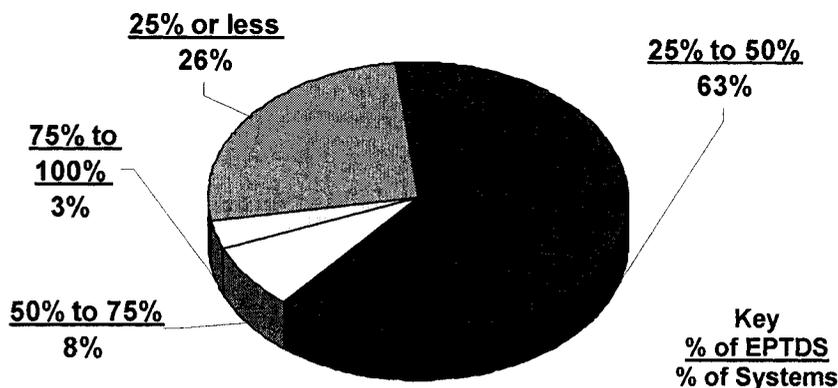


Figure 6.3. Percentage of System Entry Points Containing Perchlorate for Systems Which Have Detected Perchlorate– August, 2004 UCMR Data.

Maps 3 and 4 (Appendix) present the location of UCMR systems measuring for perchlorate and the occurrence of perchlorate respectively.

6.1.4 Comparison of UCMR Occurrence to Known Perchlorate Releases

An attempt was made to determine if there was a correspondence between the locations of perchlorate occurrence in drinking water as determined by UCMR and the locations of known releases of perchlorate into the environment as tracked by USEPA. Little correspondence was found. As can be seen in Map 5, perchlorate is frequently found in areas in for which there is no known source of environmental release. For example perchlorate has been detected by UCMR sampling in the States of North Carolina and Minnesota, yet there is no known release of perchlorate in any of these States. The implication is that sources of perchlorate release to the environment are more widespread and numerous than indicated by the USEPA OSWER list. Other possible sources of perchlorate release could potentially include localized activities, such as blasting or other uses of explosives, residual contamination from firework displays, releases from manufacturing processes or laboratories or the use of perchlorate containing fertilizers. The formation of perchlorate in undocumented natural processes is also possible.

6.2 California Department of Health Serviced Drinking Water Database

6.2.1 Background

In the late 1990's perchlorate was found in California waters. A preliminary sampling of several hundred wells was initiated in 1997 by the California Department of Health Services (CalDHS). The study found perchlorate in both northern and southern California groundwaters. In 1999, CalDHS added perchlorate to the list of unregulated contaminants for which monitoring is required. At the present time CalDHS is collecting perchlorate samples from drinking water sources and analyzing per EPA 314.0 or 314.1. The "official" reporting limit for perchlorate in the database 4.0 ug/L, but lower values are included in the database.

6.2.2 Completeness of Data Set

The dataset used for this analysis was extracted from the California Department of Health Services Drinking Water Database. Perchlorate data from 1999 through July 2004 was analyzed. The database is continuously being updated by the State.

6.2.3 Analysis of Data Set

Out of 36,217 measurements in the data set, perchlorate was detected 7256 times or in approximately 20% of the samples. The highest detection was 820 ug/L. (This well has been abandoned.) The distribution of detections is presented in Figure 6.4.

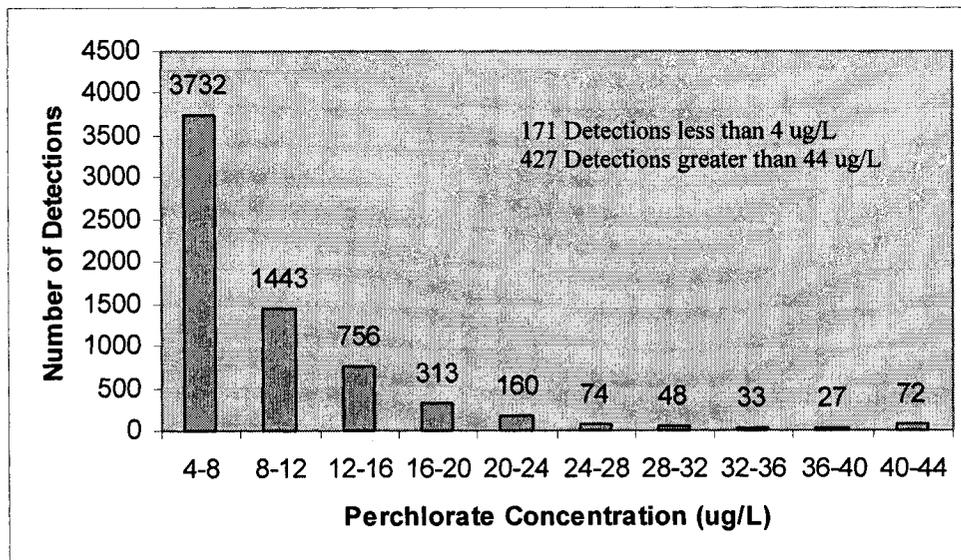


Figure 6.4. Distribution of CalDHS Perchlorate Detections.

The CalDHS database tracks a number of different types of sources, including standby wells, inactive wells and monitoring wells which are not regularly used as drinking water supplies. The results for all wells sampled for perchlorate are included in data presented in Figure 6.4. To provide a more accurate assessment of the impact to potable water sources, subsequent analysis has been limited to active drinking water sources (sources

with an AR or AU status in the CalDHS database). Table 6.4 compares the detection of perchlorate, by source, for all sources in the database and those sources identified as active drinking water sources. If all sources are considered, approximately 9% have detected perchlorate in at least one sample. Of active drinking water sources, approximately 7% have detected perchlorate in at least one sample. Approximately 1% of active drinking water sources have detected perchlorate in all samples.

Table 6.4. California Perchlorate Detection by Source.

Category	All Sources		Active Drinking Water Sources	
	Number	% of Sources	Number	% of Sources
Total Sources	6726	-	5512	-
Sources with detects	613	9.1	398	7.2
Sources with unconfirmed detection	153	2.3	124	2.2
Sources with single measurement and detection	35	0.5	10	0.2
Sources with 2 or more detections	425	6.3	264	4.8
Sources with all detections	152	2.3	59	1.1

The information can be further aggregated to the system level. Table 6.5 summarizes perchlorate occurrence by system size and water type. In California, perchlorate is overwhelmingly found in groundwater. Numerically, it is also found in more large systems than small systems.

Table 6.5. Perchlorate Detections by System Size and Source Water.

Water Type	System Size (Population)	
	≤ 10,000	> 10,000*
Surface Water	3	6 [†]
Groundwater	47	70

* Includes 3 systems with both surface and groundwater perchlorate detections.

[†] Includes Metropolitan Water District of Southern California which has no population estimate in the database.

Figure 6.5 plots the numbers of sources and the corresponding number of systems impacted by potential MCLs ranging from 2 ug/L to 20 ug/L.

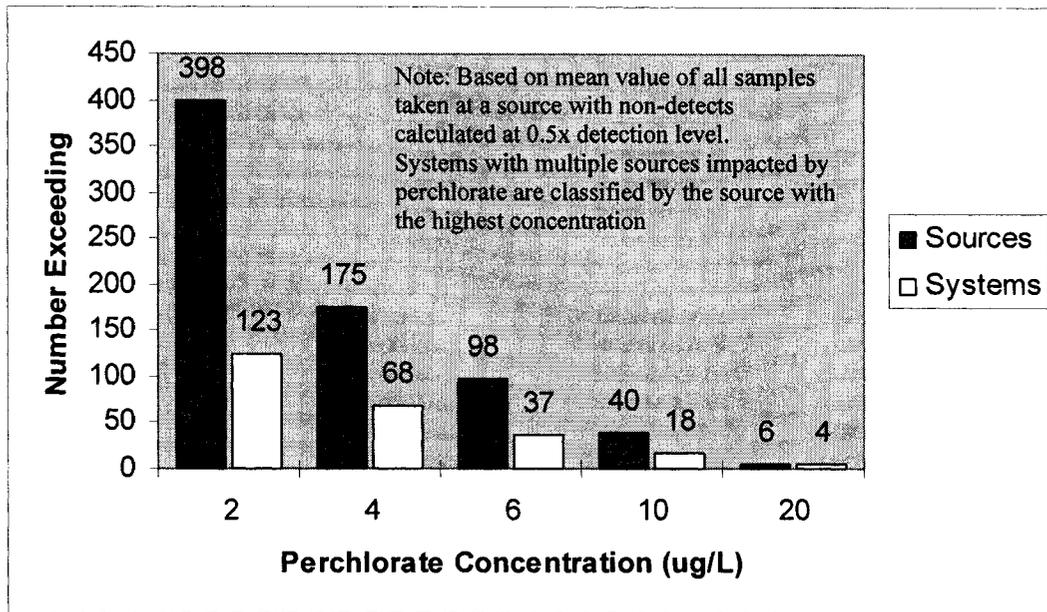


Figure 6.5. Number of Sources and Systems Impacted by Potential Perchlorate MCLs – July 2004 CalDHS Data.

Map 6 (Appendix) presents the location of perchlorate sampling sites and perchlorate detections for the 1999 to July, 2004 CalDHS perchlorate data.

6.3 Massachusetts Department of Environmental Protection Study

6.3.1 Background

The Massachusetts Department of Environmental Protection (MDEP) initiated a perchlorate monitoring program in the spring of 2004. The program applies to all community and non-transient non-community water systems. Groundwater systems were to collect samples in April and September, 2004. Surface water systems were to collect quarterly samples, beginning in March, 2004 and completing by December, 2004. Samples were taken after treatment and prior to the entry to the distribution system. Perchlorate samples were analyzed per EPA Method 314.1, with a method detection level of 1 ug/L. Detections of less than 1 ug/L were recorded as “trace” detections and were not quantified.

6.3.2 Completeness of Data Set

The analyzed data set was obtained from MDEP on September 30, 2004. It contained the first round of groundwater sampling results and the first and some of the second round of surface water sampling results. Overall the data set was approximately 40% to 50% complete as of September, 2004.

6.3.3 Analysis of Data Set

As of September, 2004, a total of 1354 measurements were recorded for 1140 treated waters in 617 systems. Of these measurements, 126 (9.3%) detected perchlorate. Of the 1140 treated waters, 35 (2.4%) contained detectable levels of perchlorate. Table 6.6 presents the rate of occurrence for small and large systems. Figure 6.6 illustrates the numbers of EPTDS and the corresponding number of systems impacted by potential perchlorate MCLs.

Table 6.6. Massachusetts Results as of September, 2004.

Systems with Population ≤ 10,000			Systems with Population > 10,000		
Sampled	Detected	Percentage	Sampled	Detected	Percentage
504	20*	4.0%*	113	9*	8.0%*
	7**	1.4%**		3**	2.7%**

* At trace level or greater

** At quantifiable level or greater (≥1 ug/L)

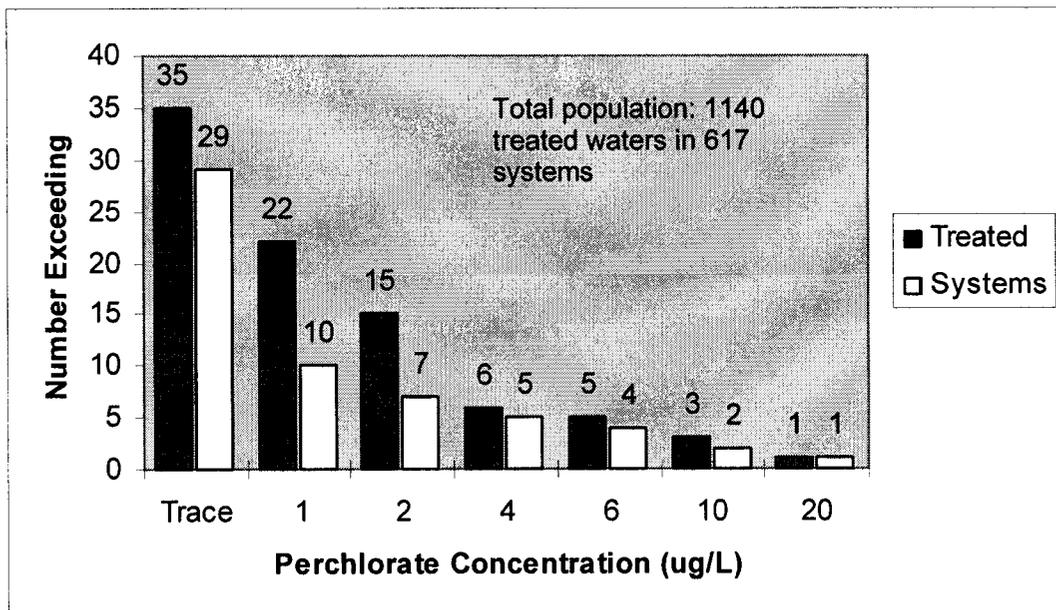


Figure 6.6. Number of Treated Waters and CWS's in Massachusetts Impacted by Potential Perchlorate MCLs – September, 2004 MDEP Data.

Maps 7 and 8 (Appendix) present the location of Massachusetts systems measuring for perchlorate and the occurrence of perchlorate respectively.

6.4 Arizona Department of Environmental Quality 2004 Study

6.4.1 Background

In the spring of 2004 the State of Arizona initiated a statewide perchlorate sampling program. The objective of the program was to conduct a comprehensive assessment of perchlorate concentration in Arizona waters. The program was a collaborative effort between the Arizona Departments of Environmental Quality and Water Resources. Raw water samples were collected between May and July 2004. Sampling focused on three types of sources: surface water, groundwaters and groundwater in aquifers used for storage by recharge. Since the study was a general assessment of perchlorate occurrence, both potable and non-potable sources were sampled. Unfortunately the study did not distinguish potable from non-potable sources. For this reason the Arizona occurrence data was not included in the national perchlorate map (Map 1). Nevertheless, given the limited water resources available in Arizona it is likely most samples, particularly of surface water and recharge water, are of sources used for potable supply. Samples were analyzed per EPA 314.1 with a MDL of 2 ug/L. In addition to the 2004 sampling program, the State has also assembled an ad hoc database of perchlorate occurrence from samples taken prior to 2004. These samples were analyzed by several analytical methods with detection levels of 2 or 4 ug/L.

6.4.2 Completeness of Data Set

Sampling for the 2004 survey is finished and the data set is complete. The final report was released by the State of Arizona in December, 2004.

6.4.3 Analysis of Data Set

The 2004 survey took 88 perchlorate measurements at 85 sites. Perchlorate was detected in 34 measurements and at 33 of the sites. Most sites detecting perchlorate were surface waters on or supplied by the Colorado River at locations downstream of the Kerr-McGee facility near Henderson, NV. Twelve of 17 samples taken from the Colorado River and 10 of 11 samples taken from the Central Arizona Project detected perchlorate. In general, perchlorate concentrations in the 2004 sampling were lower than in samples taken at similar locations prior to 2004. The State attributes the decrease in perchlorate concentrations in Colorado River water and Central Arizona Project water to the initiation of perchlorate treatment at the Kerr-McGee facility.

Groundwater sampling focused on wells potentially impacted by irrigation with Colorado River water or Central Arizona Project water. Of 35 wells tested, 4 detected perchlorate. Twelve perchlorate samples were taken at groundwater recharge facilities. Perchlorate was detected in water supplying the facilities, but no perchlorate was found in any treated recharge facility effluent. Table 6.7 summarizes perchlorate sampling results for the 2004 survey and for the ad hoc samples taken prior to 2004. Figure 6.7 presents the distribution of perchlorate concentrations derived from the Arizona data.

Table 6.7. Arizona Perchlorate Sampling Results.

Category	2004 Survey		Prior 2004 Sampling	
	Measurements	Detections	Measurements	Detections
Surface Water			31 [†]	17
Colorado River	17	12	Not Specified	
Central AZ Project	11*	10		
Salt River Project	2	0		
Other Rivers	5	1		
Impoundments	6 [#]	1		
<i>Surface Water sub total</i>	41	24	31	17
Groundwater	35	4	64	15
Recharge	12	6	4	3
Totals	88	34	99	35

* Includes dual measurement at single site – both measurements at site were detections.

Includes dual measurements at two sites – no measurements at any site were detections.

† Includes dual measurements at four sites – all measurements at all sites were detections.

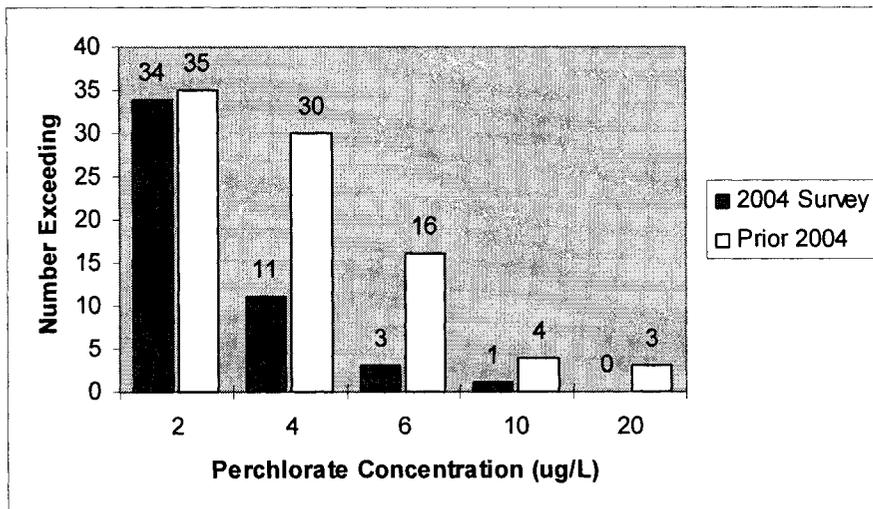


Figure 6.7. Distribution of Perchlorate Detections in Arizona Study.

Maps 9 and 10 (Appendix) present the location of perchlorate sampling sites and perchlorate detections respectively for the 2004 survey. Maps 11 and 12 (Appendix) present similar information for the pre-2004 measurements.

6.5 Texas Commission on Environmental Quality Study (Texas Tech Study)

6.5.1 Background

Initial sampling performed under the UMCR detected perchlorate in potable groundwaters in the vicinity of Midland, Texas. As a result, the Texas Commission on

Environmental Quality (TCEQ) contracted the Texas Tech University Water Resources Center to perform an initial evaluation of the extent of perchlorate contamination in a nine county region near Midland. Samples were collected between July and December, 2002. A total of 254 public and private wells were sampled. Perchlorate was detected in 88 wells (35%) at a detection level of 4 ug/L.

The initial nine county study was expanded to 54 counties in Texas and 3 counties in eastern New Mexico. The expanded study included sampling of irrigation wells, private wells and wells used by public water systems (PWS). Sampling for the expanded study was completed in the summer of 2004. Single samples were taken of each well. Samples were analyzed by Texas Tech using EPA method 314.0 with a detection limit of 1 ug/L.

This study is of particular interest since no credible anthropogenic source of perchlorate has been identified which could be responsible for the consistent detection of perchlorate over such a large geographic area. Researchers at Texas Tech University are investigating the possibility of perchlorate contamination of groundwater by natural sources.⁶ If true, this would be the first detection of natural perchlorate in the United States. Conceivably other locations in the United States with similar meteorological and geological conditions could also have natural sources of perchlorate. However at the present time no evidence exists to indicate that the presence of perchlorate in drinking water in other regions of the United States is due to natural sources.

6.5.2 Completeness of Data Set

The study is complete.

6.5.3 Analysis of Data Set

Overall a total of 734 irrigation, private and PWS wells were sampled. Perchlorate was detected in 325 (44%) of the wells. Of the 734 wells sampled 559 were used by PWS. Two hundred forty seven of the PWS wells contained detectable levels of perchlorate. A summary of sampling results is contained in Table 6.8. The distribution of perchlorate detections for the PWS wells is presented in Figure 6.8.

Table 6.8. Texas Perchlorate Sampling Results.

Description	Irrigation wells	Private wells	PWS Wells
Total sources	99	76	559
Sources with detects	42	36	247
Percentage	42%	47%	44%

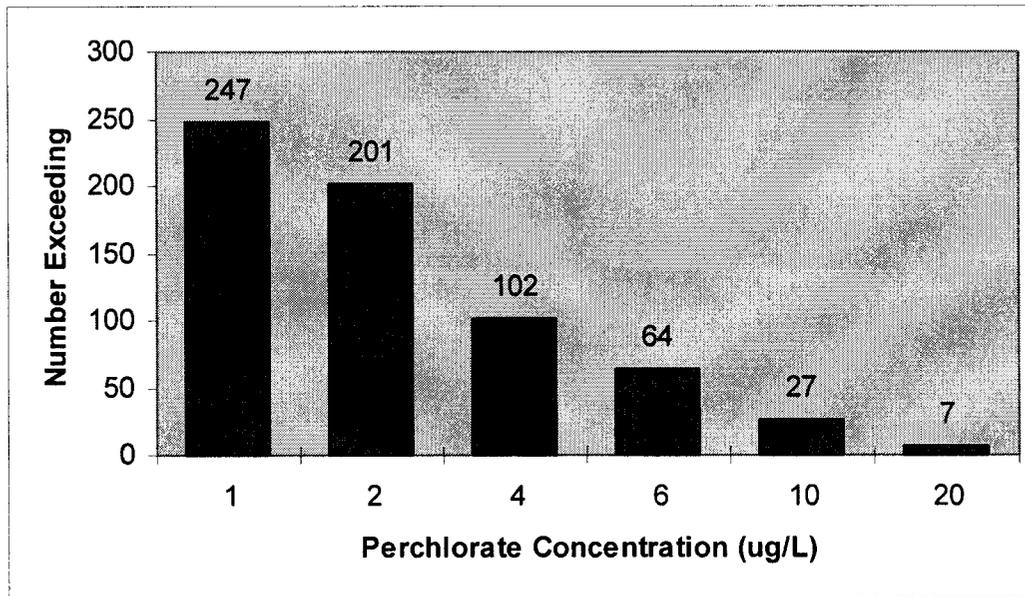


Figure 6.8. Distribution of Perchlorate Detections for PWS Wells in 54 County Texas Study.

Map 13 (Appendix) presents the location of perchlorate sampling sites and perchlorate detections for the 54 county Texas survey.

7.0 CONCLUSIONS

This study consolidated existing potable water perchlorate occurrence information taken from recently completed and ongoing occurrence studies. It mapped the location of known detections of perchlorate in public drinking water systems and provided insights into the level at which perchlorate has been detected in these systems. It also compared the location of detections of perchlorate in drinking water systems to known environmental releases of perchlorate.

The detection of perchlorate in drinking water was determined to be national in scope but at very low concentrations. Perchlorate has been detected in drinking water in at least 26 States and Puerto Rico and in approximately 5% of the nation's large CWS's. Yet when detected, perchlorate was typically present at concentrations of less than 12 ug/L and was generally found in less than one half of the sources for systems which sampled multiple sources. No difference in the rate of perchlorate occurrence between surface and groundwaters was found. However, the available data regarding surface water occurrence in the UCMR was largely incomplete. Extrapolating the results of the occurrence studies reviewed by this report, it appears that nationally less than 1% of all drinking water systems would be impacted if a MCL of 20 ug/L were established. A MCL of 2 ug/L could impact on the order of 4% of public water systems nationally. Regional impacts in California and Texas would be greater. Significantly, there was little

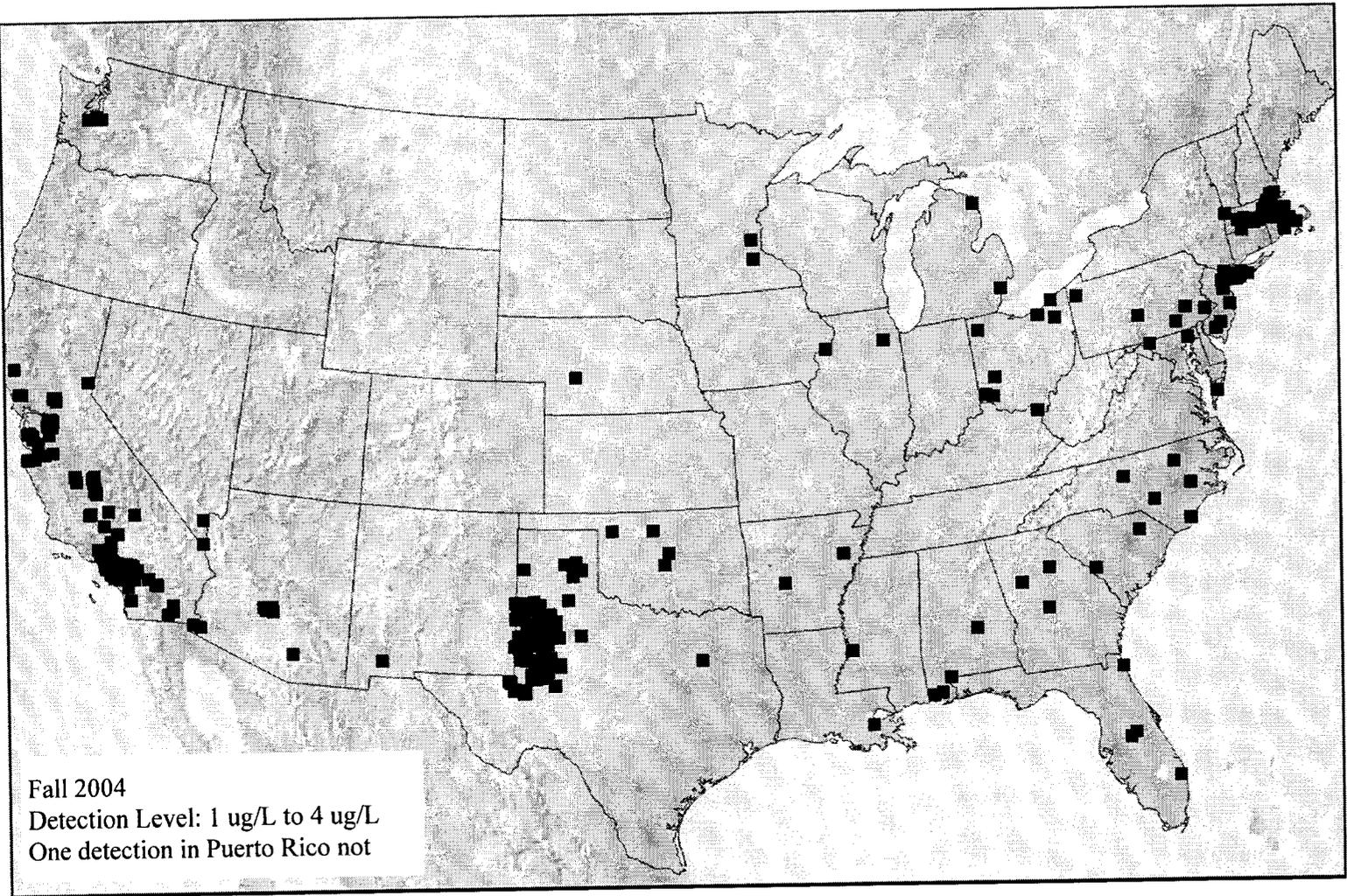
correlation between perchlorate detection in drinking water and known points of perchlorate release to the environment identified by the USEPA.

It should be emphasized that these are initial order of magnitude occurrence estimates based upon extrapolations derived mostly from incomplete UCMR perchlorate data. As more data becomes available, a formal statistically based prediction of perchlorate occurrence in small systems can be made. This information is needed to complete a rigorous prediction of national perchlorate occurrence. It is believed that the estimates made in this report under represent the impact of perchlorate on small systems and surface waters. The actual occurrence of perchlorate is likely to be greater than currently estimated in this report. However, is not anticipated that the percentage of systems impacted by perchlorate will be *significantly* greater than estimated by this report.

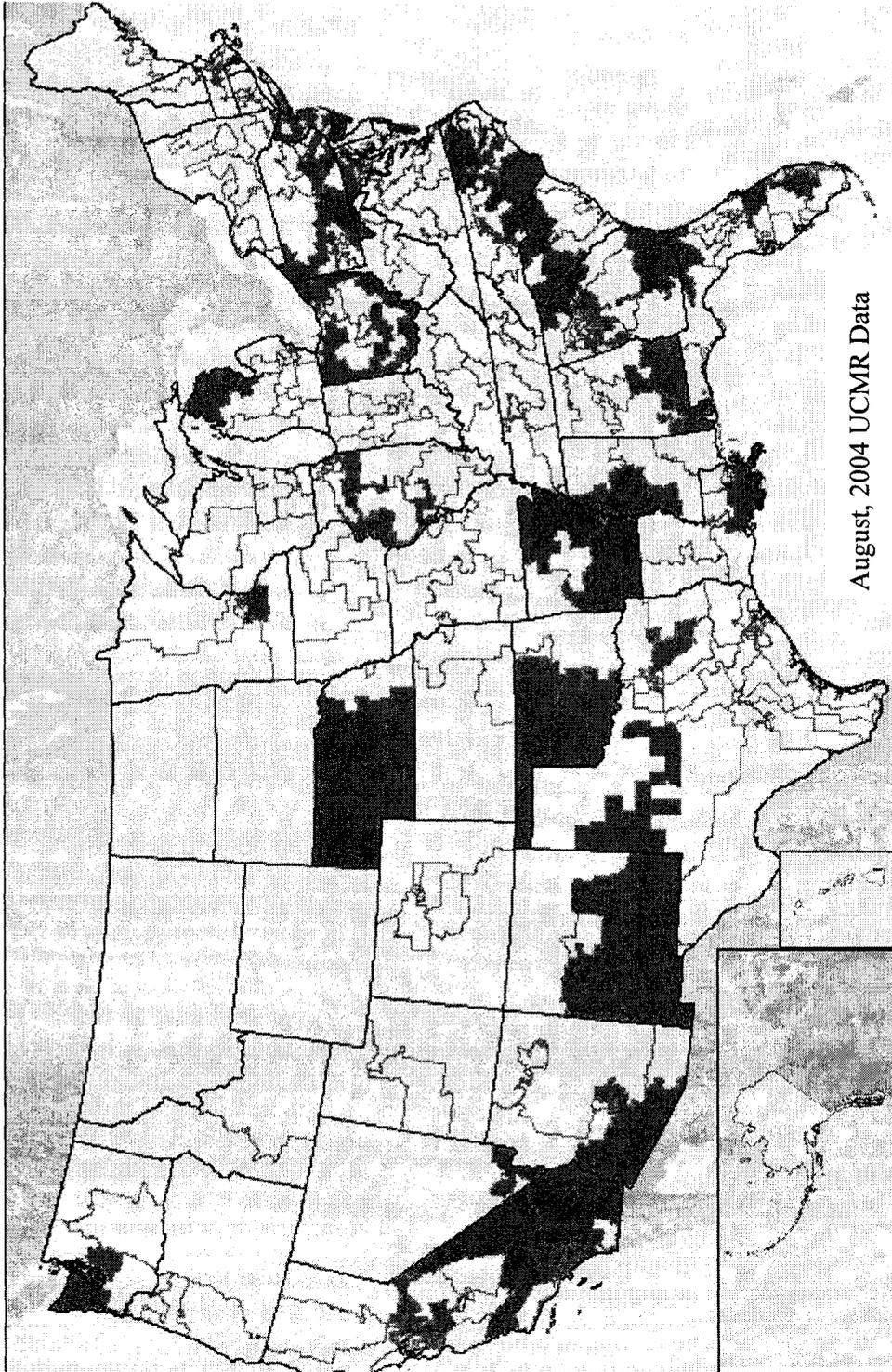
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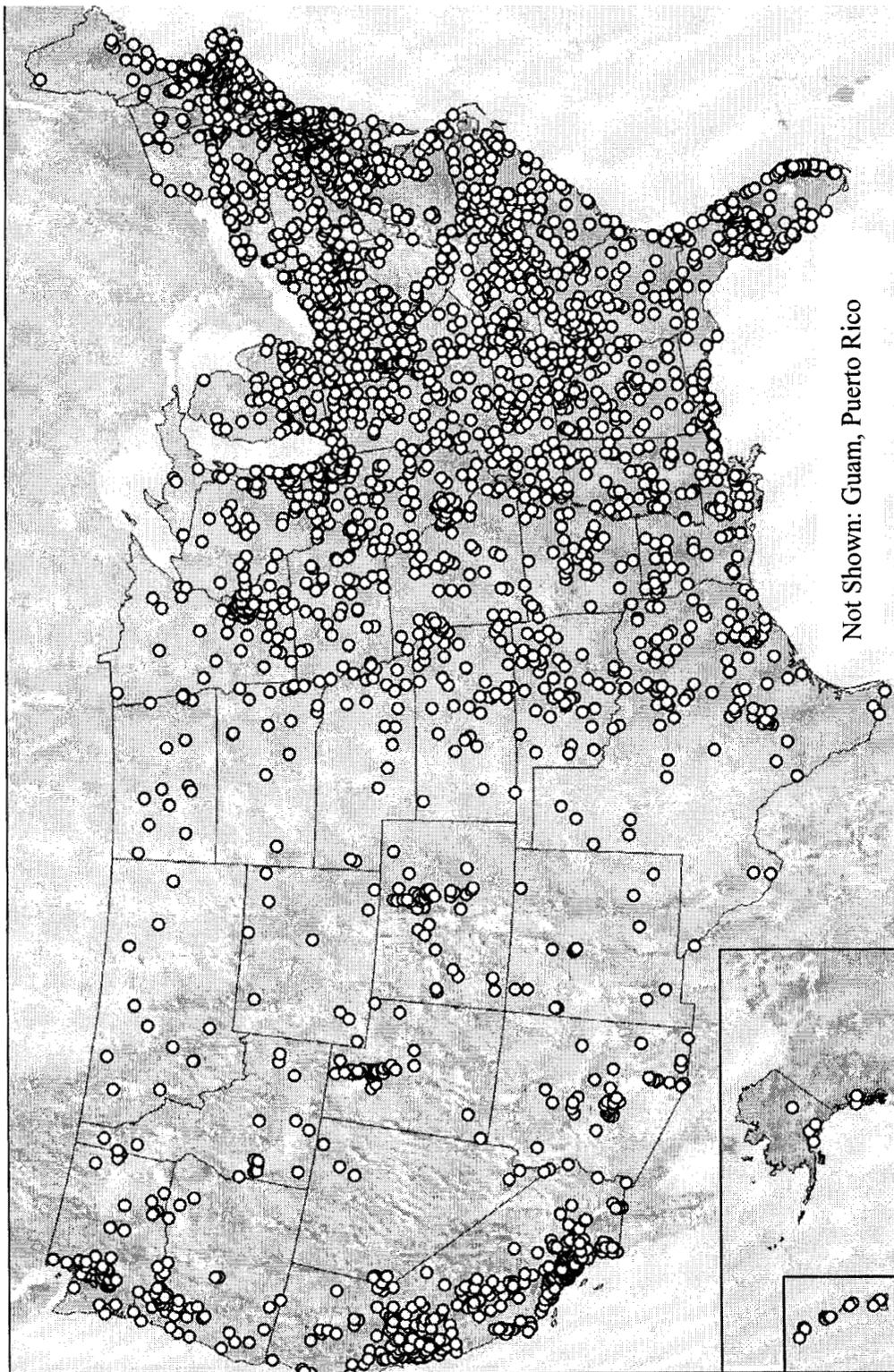
APPENDIX - PERCHLORATE OCCURRENCE MAPS



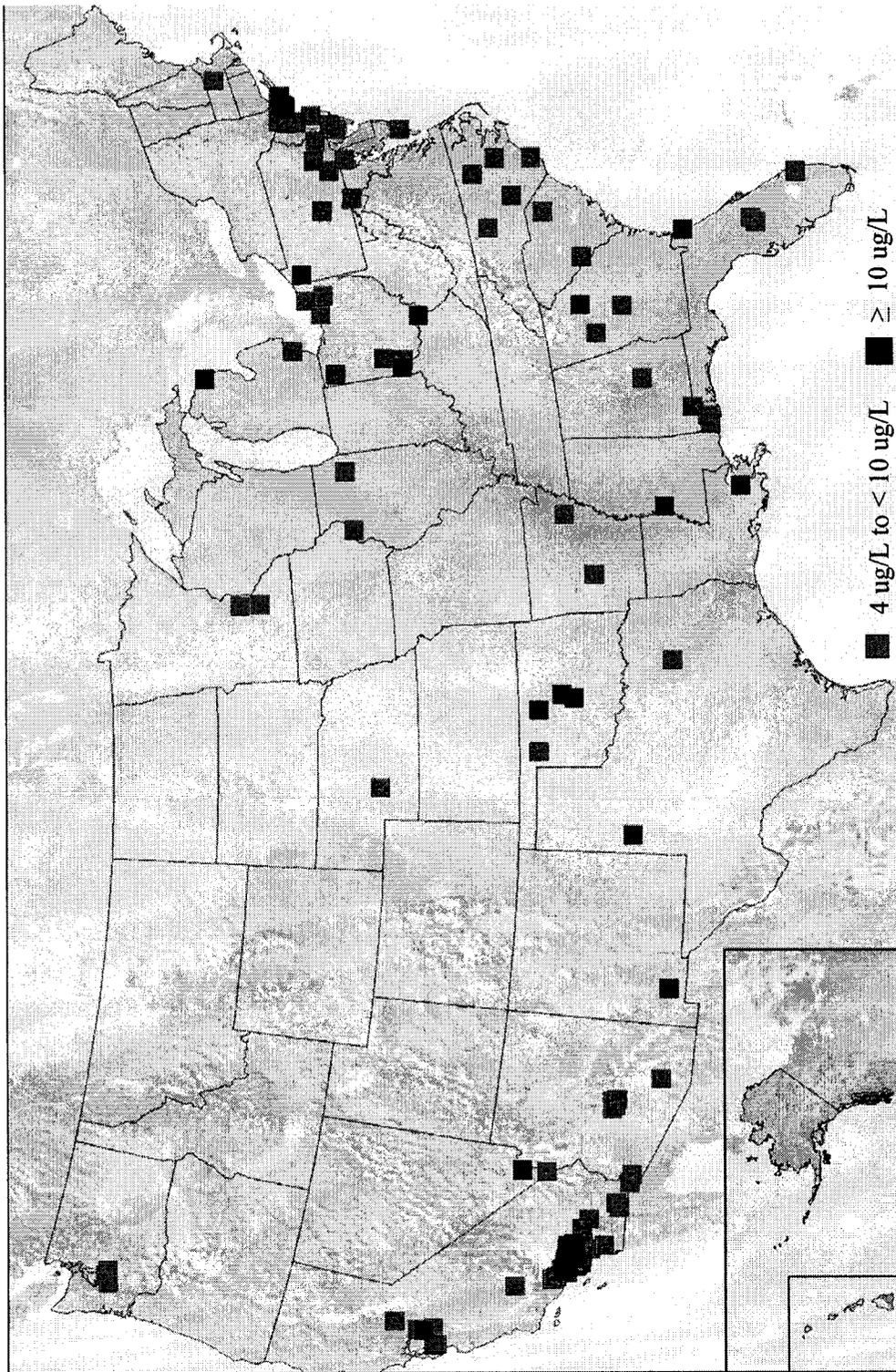
Map 1. National Occurrence of Perchlorate in Drinking Water.



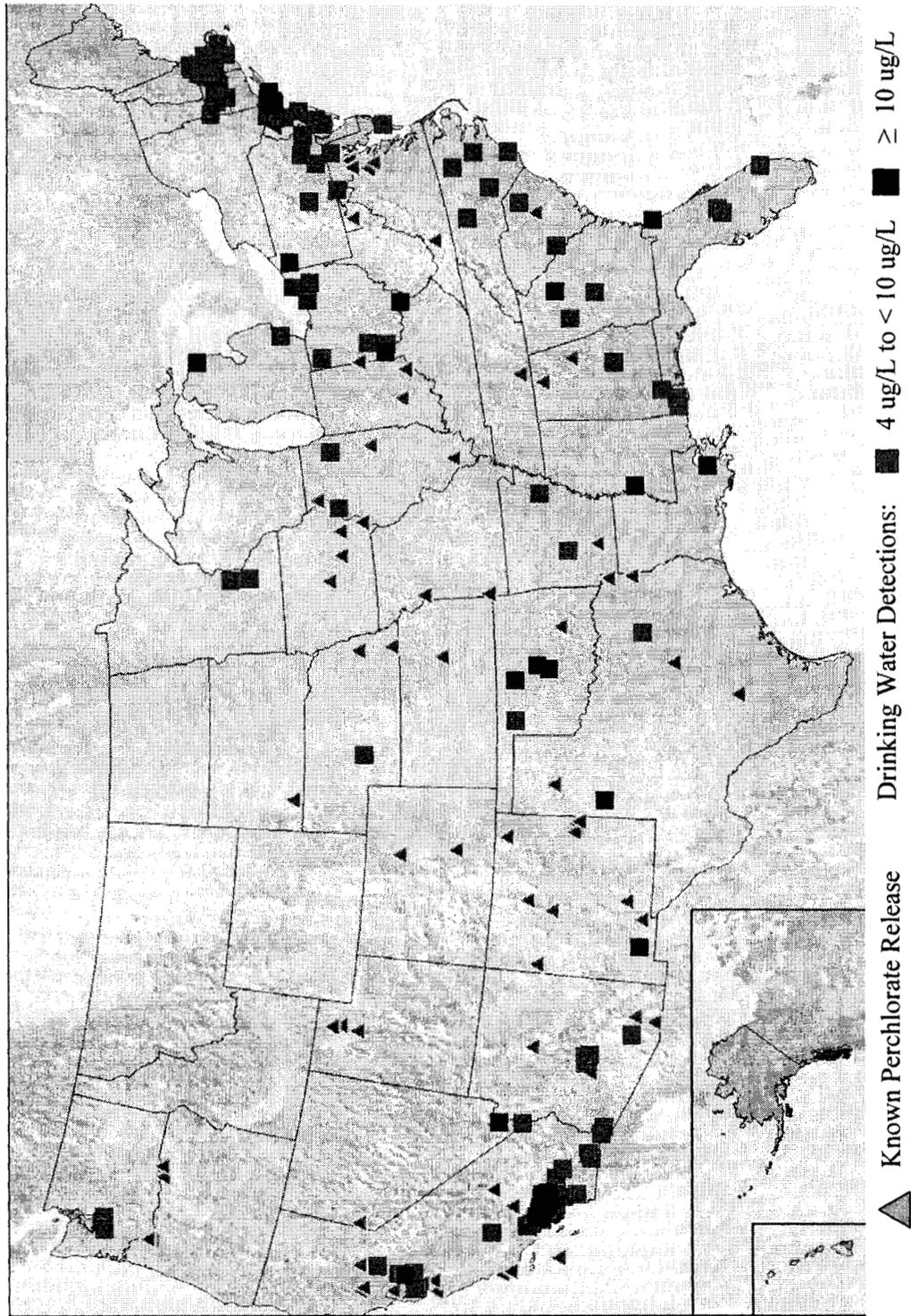
Map 2. National Occurrence of Perchlorate in UCMR Systems by Congressional District



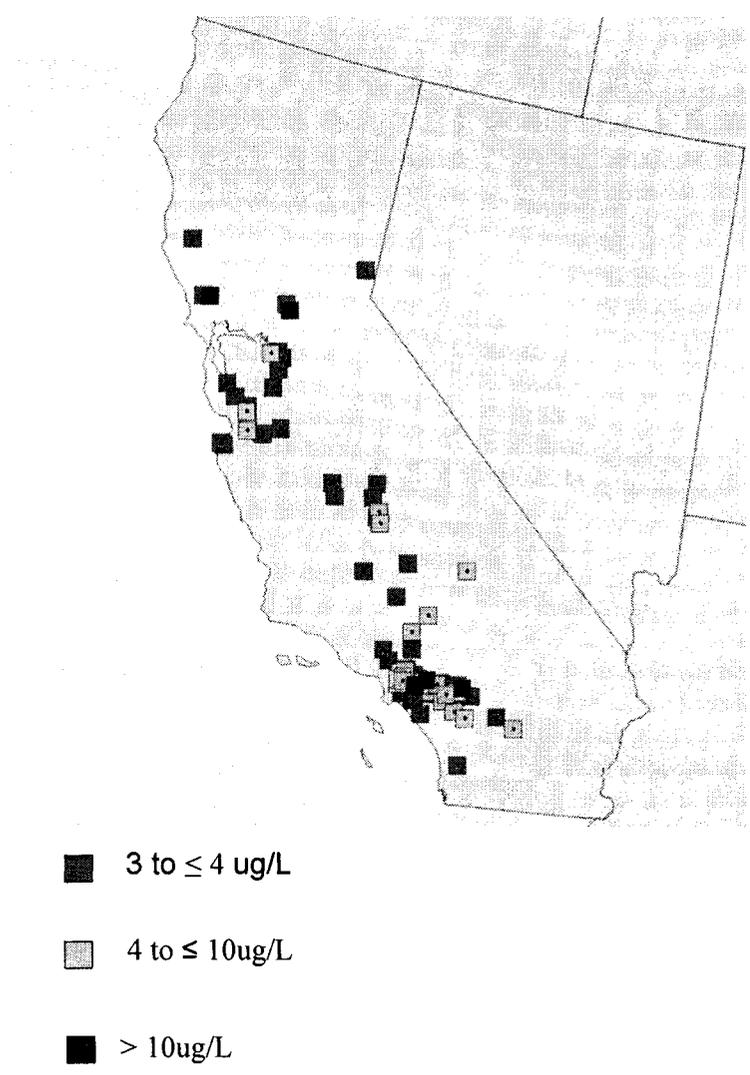
Map 3. UCMR Systems Measuring for Perchlorate.



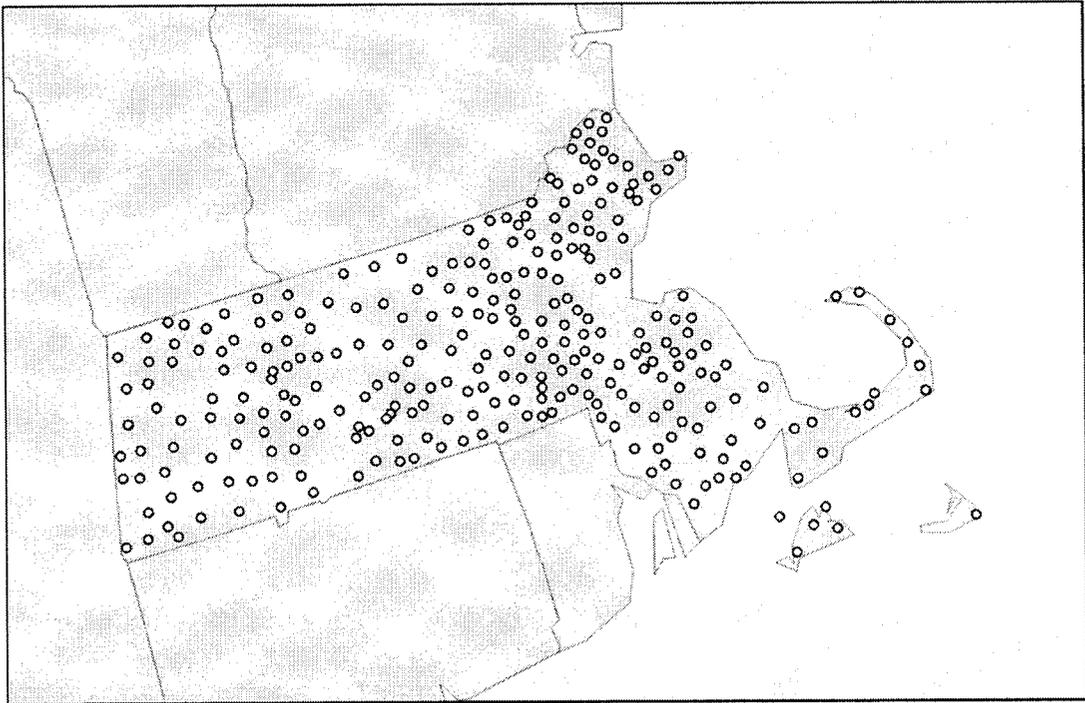
Map 4. UCMR Systems (CWS and NTNCWS) with Perchlorate Detections ≥ 4 ug/L – August, 2004 Data.



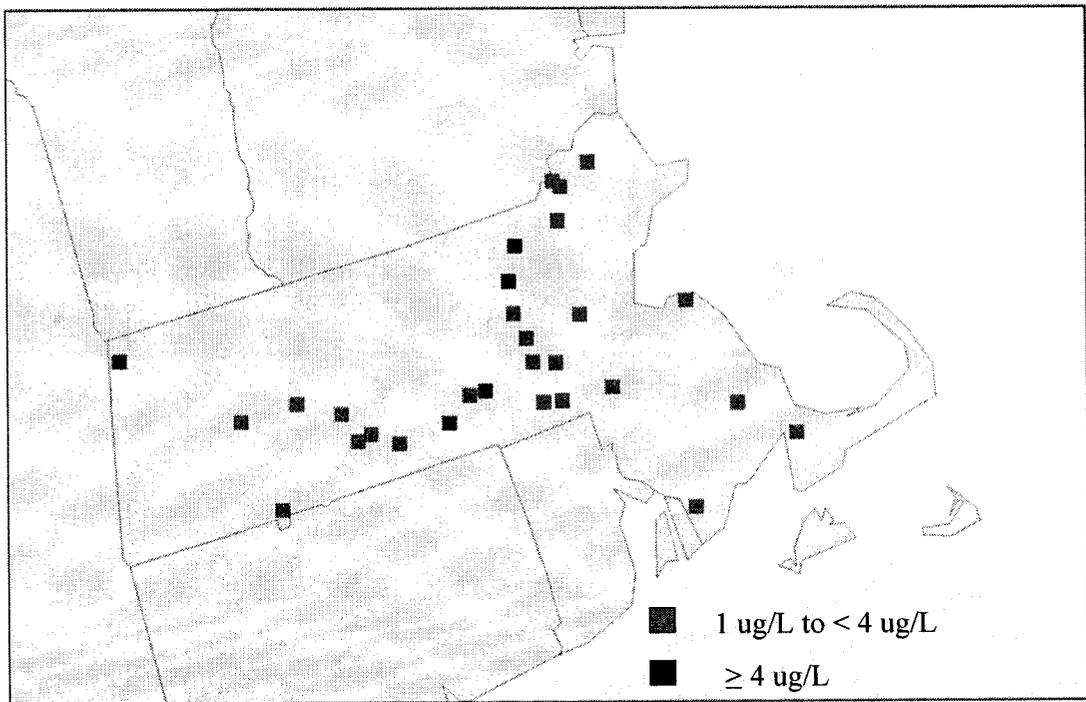
Map 5. Comparison of Known Perchlorate Releases and UCMR perchlorate Detections by System



Map 6. California Public Water Systems with Perchlorate Detections.



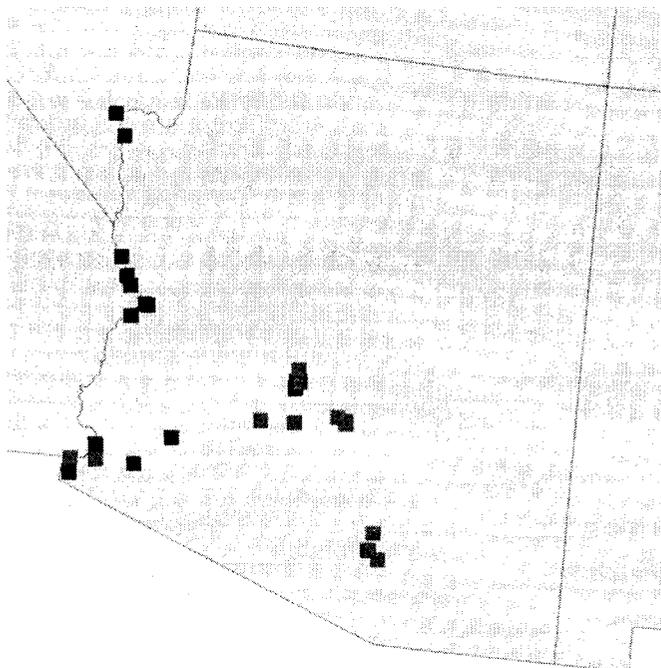
Map 7. Massachusetts Systems Measuring for Perchlorate.



Map 8. Massachusetts Systems Detecting Perchlorate in Finished Water.

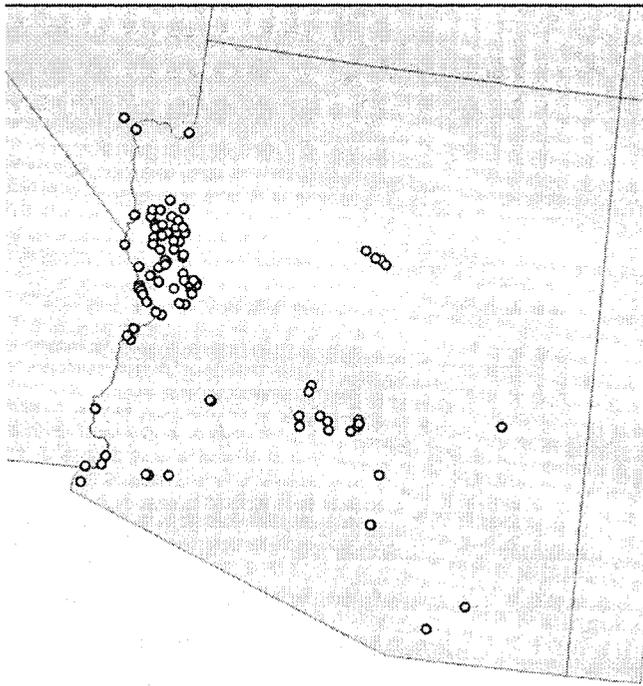


Map 9. Arizona 2004 Study Perchlorate Sample Sites.

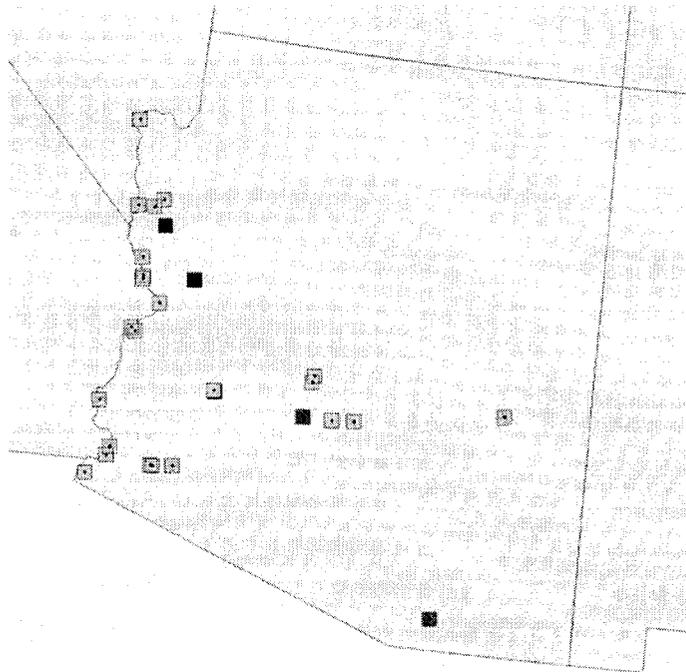


- 2 ug/L to < 4 ug/L
- ≥ 4 ug/L

Map 10. Arizona 2004 Study Perchlorate Detections.

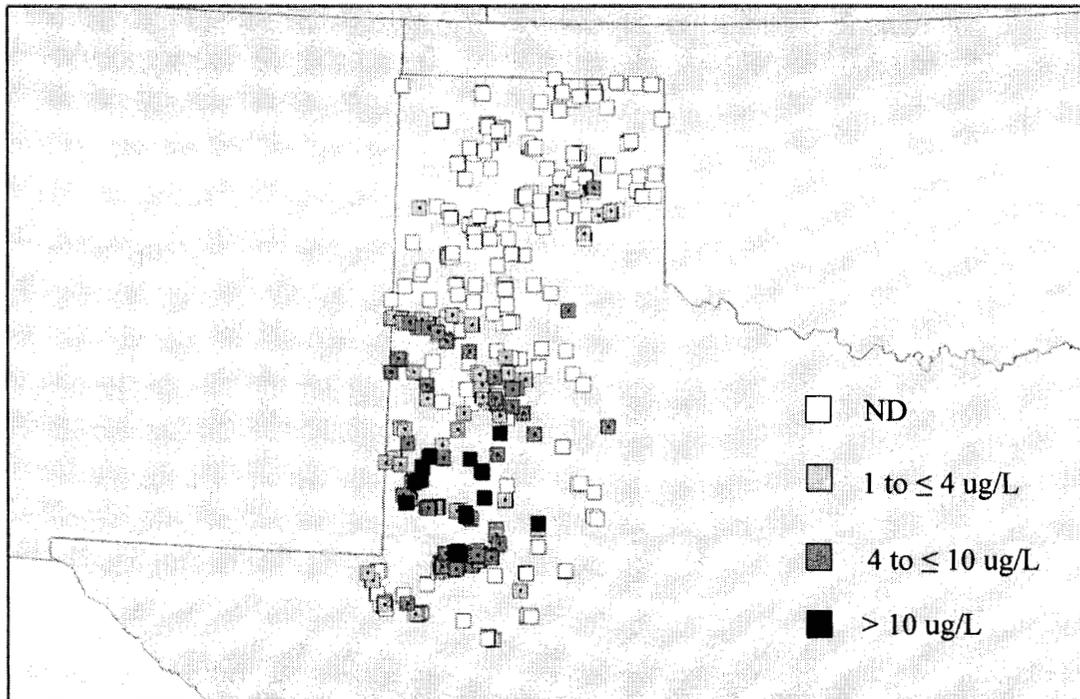


Map 11. Arizona Pre-2004 Perchlorate Sample Sites.



- Detected (< 4 ug/L)
- ◻ 4 to ≤ 10 ug/L
- > 10 ug/L

Map 12. Arizona Pre-2004 Perchlorate Detections.



Map 13. Texas 2004 Study Perchlorate Sample Sites and Detections.

Intersubject Variability of Risk from Perchlorate in Community Water Supplies

Doug Crawford-Brown,¹ Bob Raucher,² and Megan Harrod²

¹Department of Environmental Sciences and Engineering and Carolina Environmental Program, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA; ²Stratus Consulting Inc., Boulder, Colorado, USA

This article is a brief review and summary of the estimated incremental risks (increases in hazard quotient or decreases in thyroid uptake of iodine) to pregnant women (and hence their fetuses) associated with perchlorate exposure in community water supplies (CWSs). The analysis draws on the recent health effects review published in 2005 by the National Research Council (NRC). We focus on the potential level of risk borne by the NRC-identified most sensitive subpopulation (pregnant women and hence their fetuses). Other members of the population should be at a level of risk below that calculated here, and so protection of the sensitive subpopulation would protect the general public health. The analysis examines the intersubject distribution of risks to this sensitive subpopulation at various potential drinking water concentrations of perchlorate and also draws on estimates of the national occurrence of perchlorate in U.S. CWSs to estimate the variability of risks under defined regulatory scenarios. Results suggest that maximum contaminant levels (MCLs) of up to 24.5 µg/L should pose little or no incremental risk to the large majority of individuals in the most sensitive subpopulations exposed in the United States at current levels of perchlorate in water. The protectiveness of an MCL of 24.5 µg/L depends, however, on whether the study subjects in the health effects data used here may be assumed to have been exposed to background (non-drinking water) contributions of perchlorate. *Key words:* Monte Carlo analysis, perchlorate, risk, sensitive subpopulations, water. *Environ Health Perspect* 114:975–979 (2006). doi:10.1289/ehp.8459 available via <http://dx.doi.org/> [Online 16 March 2006]

Perchlorate is an inorganic compound that has been manufactured and used as a solid rocket fuel for several decades. Initial detection of perchlorate in drinking waters was associated with proximity to military and industrial sites where the compound was produced, stored, and/or used. More recent data collection efforts suggest perchlorate is more widespread than initially thought and in some locations may be associated with sources other than military rocket fuels. In some locations, perchlorate may be present from commonly used explosive devices (e.g., fireworks, road blasting materials) and in other locations the compound may be formed naturally under suitable atmospheric and soil conditions. For example, some researchers hypothesize that lightning interactions with desert soils containing certain salt compounds may be responsible for perchlorate levels detected in western Texas (Dasgupta et al. 2005). Similar natural forces may explain the presence of perchlorate in the Atacama Desert region of Chile, and fertilizers mined from the Chilean desert may contribute to perchlorate found in some areas of the United States where those products were applied.

Perchlorate is among a class of goitrogens that inhibit the uptake of iodide by the thyroid and thereby cause goiter and related iodine deficiency disorders (IDDs), including, in extreme cases, cretinism. IDD is no longer considered a public health concern in the United States because the large majority of Americans have ample iodide uptake through their normal diet to prevent IDD. There is, however, a fraction of pregnant women, between 10 and 15%, whose

urinary excretion rates are elevated (Hollowell et al. 1998). If this increased urinary excretion rate is interpreted as indicating a deficit of iodine uptake (this link is not established in the cited report), these women are likely to be the sensitive subpopulation for perchlorate exposures. Iodide intake is sufficient to typically enable the thyroid to compensate and overcome any adverse effects from goitrogen exposure. It is important to note that the effects of perchlorate are therefore dependent on the total pool of goitrogens to which individuals are exposed.

Goitrogen exposure in humans is from a variety of routes, including both water ingestion and consumption of food products found in the diet containing those with relatively high levels of nitrate (fruits, vegetables, grains, drinking water, and smoked meats), thiocyanates (broccoli, cabbage, corn, yams, sorghum, and milk), isoflavones (soy, beans, and peas), bromide (drinking water), and disulfides (onions, garlic, and peas). Goitrogen intake from perchlorate exposure in water must be compared against this background of exposure to other goitrogens, with risks from perchlorate resulting from the incremental effect of iodine uptake inhibition above and beyond the inhibition caused by the intake of other goitrogens. Presently, the relative effectiveness of these different routes of exposure at producing decreases in iodine uptake has not been assessed, so it is not possible to specify the fraction of total decrease due solely to perchlorate exposures.

Overall goitrogen exposure would need to be quite high for iodide uptake to be inhibited to a degree sufficient to elevate IDDs to a

matter of health concern, although again, this level of exposure is not known at present and may be significantly lower for the sensitive subpopulation. The National Research Council (NRC) examined the risks posed by perchlorate ingestion (NRC 2005) and indicated in their executive summary, "To cause declines in thyroid hormone production that would have adverse health effects, iodide uptake would most likely have to be reduced by at least 75% for months or longer." The mode of action for perchlorate exposure and human health risk is summarized here in the Appendix, based on the mode of action described in the NRC (2005) report.

The NRC expert panel developed an oral reference dose (RfD) of 0.0007 mg perchlorate per kilogram of body weight per day (mg/kg/day). This oral RfD is intended to reflect a safe threshold dose at which no risk of adverse health effect is anticipated for an iodide-deficient pregnant woman and any developing fetus she might be carrying. As stated by the NRC (2005): "The committee concludes that an RfD of 0.0007 mg/kg per day should protect the health of even the most sensitive populations." This RfD is based on observing no significant inhibition of thyroid uptake of iodide at a perchlorate dose of 0.007 mg/kg/day in human subjects (Greer et al. 2002). A total uncertainty factor of 10 then was applied to ensure protection of the sensitive subpopulation: iodide-deficient pregnant women (and their fetuses). Such a subpopulation could be exposed to perchlorate levels up to the RfD of 0.0007 mg/kg/day and not be expected to face a significant risk of adverse health effect. Because this is the most sensitive population, this RfD also would be protective of all other exposed individuals (including infants).

Address correspondence to D. Crawford-Brown, CB #1105, University of North Carolina at Chapel Hill, Chapel Hill, NC 27599-1105 USA. Telephone: (919) 966-6026. Fax: (919) 966-9920. E-mail: douglas_crawford-brown@unc.edu

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The need for a larger uncertainty factor was precluded (according to the NRC committee) by the use of a precursor to adverse effect (iodine uptake inhibition) in establishing a threshold for exposure, which was considered by the committee to represent a health-protective assumption causing the recommended RfD to be based on a no observed effect level (NOEL) rather than the more commonly used no observed adverse effects level (NOAEL). A NOAEL is by definition an adverse effect equal to or higher than a NOEL where the effect used to establish the NOEL is a precursor to the adverse effect of interest in establishing a NOAEL.

A possible argument is that a larger uncertainty factor still is warranted because we do not know the precise level at which a decrease in iodine uptake becomes adverse, and so it is possible that even small decreases may be adverse in the sense implied by the NOAEL and the lowest observed adverse effect level (LOAEL). This would be true especially in the case of women who already are iodine deficient. The authors of the present article believe this confuses the concept of an uncertainty factor as originally developed to argue for RfDs based on effects judged adverse. The question is not whether a given decrease in iodine uptake does or does not lead to adverse effects in some percentage of the population but whether such a decrease in and of itself, absent any sequelae, is to be taken as an adverse effect. Our position here is that such a decrease is not adverse in and of itself and so does not warrant the application of uncertainty factors developed originally to reason from NOAELs and LOAELs. The NRC committee appears to agree, whether explicitly or implicitly.

After the NRC report, the U.S. Environmental Protection Agency (U.S. EPA 2005) issued a statement accepting the NRC's RfD and announcing that it had developed a drinking water equivalent level (DWEL). The DWEL converts the RfD (represented in units of mg/kg/day) into an associated concentration in drinking water (in units of micrograms per liter), taking into account the relative source contribution (RSC) from water versus other exposure routes. The DWEL was established by the EPA at 24.5 µg/L (U.S. EPA 2005) and is derived assuming a 70-kg adult consuming 2 L of drinking water per day. This gives an intake rate (of water) per unit body mass of 0.029 L/kg/day, which is slightly above the mean value for women of child-bearing age when both direct and indirect water ingestion are considered (U.S. EPA 2004, table 6.1.A2). Hence, use of this value may be considered conservative (in the sense of being health protective) for the sensitive subpopulation.

The present article places the NRC assessment into the framework of probabilistic risk assessment. The question addressed here is what the distribution of risks is in the sensitive

subpopulation of pregnant women in the United States resulting from exposure to perchlorate in water from community water supplies (CWSs). The term "risk" in this article has two metrics: a hazard quotient (HQ) and a percentage reduction in iodide uptake. These risks then are examined using Monte Carlo analysis to produce intersubject variability distributions under a variety of scenarios of regulatory interest.

Materials and Methods

Exposure assessment. The occurrence of perchlorate in drinking waters has recently been reported in a study sponsored by the American Water Works Association's Water Industry Technical Action Fund (Brandhuber and Clark 2004). The study relied principally on data collected under the U.S. EPA unregulated contaminant monitoring rule (UCMR), supplemented with monitoring data collected by the Massachusetts Department of Environmental Protection (MDEP), by the California Department of Health Services (CalDHS), and in Arizona and Texas (Brandhuber and Clark 2004). The results (summarized in Brandhuber and Clark 2004, table 2.1) provide estimates of the percentage of CWSs exceeding a variety of proposed maximum contaminant levels (MCLs) for perchlorate. For the U.S. EPA sampling, the percentages of CWSs exceeding 2, 4, 6, 10, and 20 µg/L were 4.1, 2.6, 1.6, 0.9, and 0.2%, respectively. For the CalDHS sampling, the percentages of CWSs exceeding 2, 4, 6, 10, and 20 µg/L were 10.5, 5.8, 3.2, 1.5, and 0.3%, respectively. For the MDEP sampling, the percentages of CWSs exceeding 2, 4, 6, 10, and 20 µg/L were 1.1, 0.8, 0.6, 0.3, and 0.0%, respectively. Data from Arizona and Texas are not included here because they did not identify whether a water source was potable or nonpotable or whether it was part of a water system. Unfortunately, the data are insufficient at present to develop a fully probabilistic population-weighted distribution of concentrations in CWSs, and so the present analysis assumes no correlation between system size (and hence size of population served) and perchlorate concentration.

The UCMR used analytic methods with a detection limit of 4 µg/L (micrograms per liter are essentially the same as parts per billion), and drew four quarterly samples from each entry point to the distribution system (EPDS) for every CWS > 10,000 persons served in the United States. Data also were collected for a sample of 771 smaller systems, but this sample may be too small to provide a sound basis for statistical inference. These data suggest a slightly higher concentration in the smallest water supplies, and so the analysis of Brandhuber and Clark (2004) may underestimate exposures (by up to 20%) in the

small percentage of the population using these small systems serving fewer than 10,000 people. The results reported by Brandhuber and Clark (2004) and used here reflect the UCMR database compiled as of August 2004, when the database did not yet contain all the data from all quarters for all EPDSs. Hence, the final UCMR data set may suggest results that differ slightly from those discussed here.

The UCMR data reveal detectable amounts (≥ 4 µg/L) in 1.9% of the samples taken. Because most CWSs have more than one EPDS, and samples were taken for each EPDS, a higher percentage of CWSs (> 1.9%) were found to have at least one EPDS with detectable levels of perchlorate. The UCMR data suggest that perchlorate occurs in detectable amounts in at least one EPDS associated with 5.4% of CWSs. In systems serving > 10,000 people, perchlorate was detected in 6.1% of groundwater-based CWSs and in 4.9% of the surface-water-fed systems.

Although > 5% of large CWSs in the UCMR database had some detectable perchlorate in at least one of the EPDS-finished waters, the levels observed were generally quite low. More than two-thirds (68%) of the measurable perchlorate concentrations were in the 4–8 ppb range, and 86% were < 12 µg/L. Only 2.6% of the detected samples had concentrations > 24 µg/L (Brandhuber and Clark 2004), which is near the U.S. EPA-designated DWE of 24.5 µg/L (U.S. EPA 2005). The highest observed level in the UCMR data was 420 µg/L.

In Massachusetts, samples were analyzed with a more sensitive detection limit that yielded quantifiable results ≥ 1 µg/L and "trace" observations for levels < 1 µg/L. This method revealed that 2.4% of treated drinking water samples contained detectable levels of perchlorate. However, the vast majority of the Massachusetts detections in treated waters were at or near the 1-µg/L limit of detection: 66% of detects in treated drinking water were at trace levels (≤ 1 µg/L), 83% of detects were ≤ 2 µg/L, and 90% were ≤ 4 µg/L (Brandhuber and Clark 2004).

The above data were fit by a lognormal distribution. The resulting distribution is characterized by a median of 0.03 µg/L and a geometric standard deviation (GSD) of 13. The assumption here is that the properties of the distribution identified at the higher levels of exposure (≥ 1 µg/L) continue to apply in water supplies at concentrations below the detection limit.

Based on the NRC review, potential for risk arises only if a person from the sensitive subpopulation ingests perchlorate at an incremental rate (i.e., above background) that exceeds the identified threshold for effect. The average daily rate of intake (ADRI) for any individual is based on how much tap water

they consume, the concentration of perchlorate in their tap water, and their body weight. These three factors vary across the U.S. population of pregnant women. Using available data, the distributions for these variables can be included in a Monte Carlo analysis to develop a combined distribution of ADRI values across this subpopulation. The distribution of water ingestion rates used here is based on total CWS consumption values for adults established by the U.S. EPA (2004), which provides values associated with given percentiles of the variability distribution.

Data on water ingestion for pregnant women were too limited to use reliably in this analysis, but the existing data suggest that using the data for U.S. adults does not underestimate exposures in pregnant women. As demonstrated in the U.S. EPA *Exposure Factors Handbook* (U.S. EPA 1997), the difference in intake rates of tap water for the general population of women of child-bearing age and pregnant women is small (mean of 1.16 vs. 1.19 L/day), and so the former is assumed to approximate the latter intake rates in this analysis. The distribution of body weight for 25-year-old women (representing women 18–40 years of age, who largely make up the child-bearing-age population) is taken from the U.S. EPA *Exposure Factors Handbook* (U.S. EPA 1999). The data on water ingestion rate per unit body weight described above then were fitted by a lognormal distribution, with a best fit showing a median of 0.0182 L/kg/day and a GSD of 1.8. This distribution is consistent with the mean value assumed in regulatory calculations.

The U.S. EPA typically employs an RSC of drinking water, expressed as the percentage of total contaminant dose that is provided by drinking water, to estimate total risk from all routes of exposure (i.e., aggregate risk). These RSCs for drinking water generally are in the range of 20–80%. The relevance of applying an RSC here depends on how one interprets the human subject perchlorate study conducted by Greer et al. (2002) that forms the basis of the risk coefficients. An RSC is appropriate when the study on which risk coefficients are based includes only exposures through one route, whereas exposures through other routes will be present in exposure situations envisioned in regulatory decisions (and so must be factored in when regulating exposures by the first route). If one assumes that the individuals in the study by Greer et al. (2002) were exposed to the same background levels of perchlorate as the rest of the U.S. population (there is nothing in their diets or in the study design to preclude this), then no further RSC adjustment is needed to reflect total exposures via all routes because the risk coefficient from the study already reflects the incremental risk from ingestion of perchlorate in water above

and beyond the contributions to perchlorate exposure via the other routes. Similarly, because the study population presumably was exposed to the complement of goitrogens other than perchlorate, the study by Greer et al. (2002) also reflects the incremental risk from ingestion of the goitrogen perchlorate above and beyond the contributions from these other goitrogens. This is the scenario we employ in our analysis. Unfortunately, adequate data are not available at present to estimate the RSC for water exposures reliably.

Risk characterization. A standard metric of potential health risk for threshold contaminants like perchlorate is the HQ. The HQ is equal to the estimated ADRI (in units of milligrams per kilogram per day) divided by the RfD. An HQ value of 1.0 thus means that a person is receiving an ADRI equal to the RfD. Any HQ value ≥ 1.0 indicates that exposure is at or below the “no risk” threshold (the term “no risk” here meaning a risk judged to be nonsignificant), and thus no significant risk of adverse health effect is anticipated. An HQ value > 1.0 indicates an ADRI above the RfD and suggests that there may be some nonzero risk of adverse health effect (although, because of the uncertainty factors in the RfD, which produce a margin of safety, the risk may be zero even for exposures yielding HQ values < 1.0). In the present article, we use the value of RfD suggested by the NRC (2005): 0.0007 mg/kg/day.

Another measure of effect used in this analysis is the estimated percent decrease in iodide uptake by the thyroid (the critical effect used originally to establish the RfD). This is estimated based on fitting a dose–response curve to the data from Greer et al. (2002), relating the ADRI to the percent decrease in iodide uptake. The resulting curve is shown in Figure 1. The best model fit is as follows:

$$\text{Percent decrease in iodide uptake} = 70 \times \{1 - \exp[-14 \times (\text{ADRI} - 0.005)]\},$$

where ADRI is in units of mg/kg/day. Note that this model suggests a threshold at 0.005 mg/kg/day, which is slightly below the NOEL for the study at 0.007 mg/kg/day. This is because there is a measured decrease in iodide uptake (1.8%) even at the NOEL, although this decrease is not statistically significant. A comparison point for risk here is the NRC (2005) observation that a 75% decrease in iodide uptake would be required to initiate a potential health effect, although again, it must be noted that the percent decrease required in the sensitive subpopulation currently is unknown and is likely to be less than this value. As before, note that our assumption here is that the dose–response data from Greer et al. (2002) reflect the incremental decrease in iodide uptake per unit incremental increase in

exposure to perchlorate through water alone, above and beyond the modifying effects of the background perchlorate exposures through other routes.

Results

The Monte Carlo assessment was conducted for hypothetical MCLs of 1, 2, 5, 6, 10, 20, 24.5, and 50 $\mu\text{g/L}$ (values of 6 and 24.5 were included to reflect potential limits by the California Environmental Protection Agency and the U.S. EPA DWEL, respectively). The analysis was conducted first using the national occurrence distribution to reflect nationwide conditions. In this analysis the actual distribution of perchlorate concentrations in CWSs is assumed (median of 0.03 $\mu\text{g/L}$ and GSD of 13), with systems above the MCL mitigated to exactly the MCL (the nonexceeding systems remain at their current concentrations). From this, the distribution of water concentrations in the United States was established after the MCL is in place, and a value was selected at random. An intake rate per unit body mass for an individual in the sampled population (women of child-bearing age) then was selected at random from the distribution described previously (median of 0.0182 L/kg/day and a GSD of 1.8). The product of the perchlorate concentration in water and the intake rate of water per unit body weight then equals the ADRI for that sampled individual. The sampled ADRI was divided by the RfD (0.007 mg/kg/day) to produce an estimate of the HQ, then the ADRI was placed into the model in Figure 1 to produce an estimate of percentage reduction in iodine uptake. The Monte Carlo process was repeated for 10,000 individuals to generate intersubject variability distributions for these two risk metrics. The value of 10,000 was based on the goal of providing stability in the tails of the distribution.

Then we focused on intersubject variability of doses and risk metrics for people possibly exposed to water mitigated to exactly a potential MCL to reflect risk distributions only within those CWSs that currently have elevated perchlorate concentrations and might therefore be expected to reduce concentrations

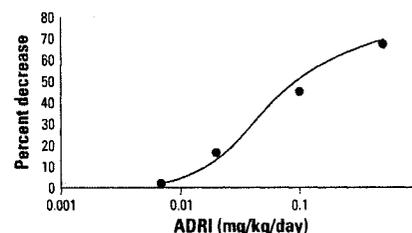


Figure 1. Data (circles) on decrease in iodine uptake in the thyroid versus ADRI for perchlorate in healthy males and females, averaged over the sexes (the difference between sexes is not statistically significant). Data from Greer et al. (2002). The line is the best-fitting model as discussed in the text.

down to the MCL. The Monte Carlo process is the same as described previously (including the focus on the sensitive subpopulation), with the exception that all individuals are exposed at the same concentration of perchlorate in water, equal to the MCL. Both sets of results are described below.

National occurrence results. The HQ results using the national occurrence analysis are summarized in Table 1. For example, at the 95th percentile of the sensitive subpopulation, the HQ value was 0.02 (i.e., dose was 2% of the RfD no risk threshold), even at an MCL of 50 $\mu\text{g/L}$. Note from this same table that the percent decrease in iodine uptake, using the model in Figure 1, is zero for all MCL values and percentiles examined because the ADRI was below the threshold in the model.

Results for systems at the MCL. In this second set of calculations, all individuals in the sensitive subpopulation are assumed exposed at the concentration of a potential MCL. In other words, in this analysis, we examine risks to the highly exposed portion of the sensitive subpopulation after the potential MCL has been established and all CWSs are mitigated down to that MCL.

For the at-the-MCL analysis, some HQ values do exceed 1.0. As shown in Table 2, there were no HQ values > 1.0 at MCLs of ≤ 24.5 $\mu\text{g/L}$ for the percentiles of the cumulative distribution functions examined. In systems with perchlorate concentrations of 50 $\mu\text{g/L}$, however, 28.6% of the sensitive subpopulation had an HQ value exceeding 1.0 (an HQ value of 1.0 was found at approximately the 71st percentile of the variability distribution for this population). At the 90th percentile, the HQ value at 50 $\mu\text{g/L}$ exposure was 1.54, and at the 95th percentile the HQ value was 1.89. There was, however, no reduction in iodide uptake estimated from the model at any MCL because all intake rates were below the threshold for the model in Figure 1.

Sensitivity analyses. The above-described analyses and results are based on several assumptions that can be altered. We conducted several alternate Monte Carlo simulations to reflect a mix of potential differences in selection of underlying data or in how those data are interpreted. The goal here was to determine an upper-bound estimate of the risks, and so more conservative assumptions were used than was the case in Tables 1 and 2. Specifically, in this new analysis, the amount of water consumed was increased to include total water intake (not just intake from CWSs), as obtained from the U.S. EPA *Exposure Factors Handbook* (U.S. EPA 1999). Using the national occurrence data for the concentration of perchlorate in the drinking water (i.e., assuming the non-CWS concentration was the same as that in the CWS for an individual), there is no appreciable difference between the base case results from Table 1

and the "upper-end" values calculated here. Results in Table 1 may therefore be assumed to represent upper-end risks when all water consumption, and not only drinking water, is considered in the exposure assessment.

However, for the at-the-MCL analysis results (as shown in Table 3, and equivalent to Table 2), for those women consuming water with perchlorate at the potential MCLs, there are some elevated HQ values compared with those in the base analysis depicted in Table 2. In particular, there are now HQ values > 1.0 at the 95th percentile even at 20 $\mu\text{g/L}$.

Discussion and Conclusions

Perchlorate in drinking water is more widespread than originally anticipated, with perhaps 2% of sources showing detectable levels

≥ 4 $\mu\text{g/L}$. Combining the newly emerging risk and occurrence information, we have modeled the percentage of the sensitive subpopulation (pregnant women) that may face (or whose infants may face) a risk of adverse health effects due to perchlorate in U.S. drinking waters. The results indicate that for any population using a CWS with a perchlorate concentration of 50 $\mu\text{g/L}$ (i.e., slightly more than twice the proposed U.S. EPA DWEL of 24.5 $\mu\text{g/L}$), there would be an appreciable percentage of pregnant women who face a risk of adverse effects in themselves or their fetuses because they would have an HQ value > 1.0 . When perchlorate concentrations are 50 $\mu\text{g/L}$, between 28.6% (if only ingestion of drinking water is assumed) and 58.1% (if all water ingestion is assumed, with the non-CWS being

Table 1. HQ values for pregnant women (the sensitive subpopulation): base case analysis, using national occurrence data (i.e., existing distribution of perchlorate in water, with only supplies currently above the proposed MCL mitigated down to the proposed MCL).

MCL ($\mu\text{g/L}$)	Median ^a	90th percentile ^b	95th percentile ^b	Percent HQ < 1 ^c	Percent decrease ^d
1	0.01	0.02	0.02	> 99	0
2	0.01	0.02	0.02	> 99	0
5	0.01	0.02	0.02	> 99	0
6	0.01	0.02	0.02	> 99	0
10	0.01	0.02	0.02	> 99	0
20	0.01	0.02	0.02	> 99	0
24.5	0.01	0.02	0.02	> 99	0
50	0.01	0.02	0.02	> 99	0

^aThe median for the variability distribution. ^bThe 90th and 95th percentiles of the variability distribution. ^cThe percentage of the population with an HQ value < 1 . ^dThe percent decrease in iodide uptake for individuals at the 95th percentile. The percent decrease is predicted using the equation in the text; a value of 0% indicates the modeled threshold of 0.005 mg/kg/day has not been exceeded.

Table 2. HQ values for pregnant women (the sensitive subpopulation): base case analysis, for persons using CWSs at the MCL concentration (i.e., considering only supplies currently above a potential MCL, which are mitigated down to the potential MCL).

MCL ($\mu\text{g/L}$)	Median ^a	90th percentile ^b	95th percentile ^b	Percent HQ < 1 ^c	Percent decrease ^d
1	0.01	0.03	0.04	> 99	0
2	0.03	0.06	0.08	> 99	0
5	0.07	0.15	0.19	> 99	0
6	0.08	0.19	0.22	> 99	0
10	0.14	0.30	0.38	> 99	0
20	0.29	0.62	0.76	> 99	0
24.5	0.33	0.70	0.90	> 99	0
50	0.73	1.54	1.89	71.4	0

^aThe median for the variability distribution. ^bThe 90th and 95th percentiles of the variability distribution. ^cThe percentage of the population with an HQ value < 1 . ^dThe percent decrease in iodide uptake for individuals at the 95th percentile. The percent decrease is predicted using the equation in the text; a value of 0% indicates the threshold of 0.005 mg/kg/day has not been exceeded.

Table 3. HQ values for pregnant women (the sensitive subpopulation): sensitivity analysis, high-end exposure scenarios for persons consuming all water, and not only drinking water, at the MCL.

MCL ($\mu\text{g/L}$)	Median ^a	90th percentile ^b	95th percentile ^b	Percent HQ < 1 ^c	Percent decrease ^d
1	0.04	0.07	0.08	> 99	0
2	0.06	0.11	0.13	> 99	0
5	0.13	0.25	0.31	> 99	0
6	0.15	0.28	0.36	> 99	0
10	0.24	0.48	0.60	> 99	0
20	0.45	0.95	1.16	91.2	0
24.5	0.50	1.10	1.35	88.3	0
50	1.10	2.37	2.90	41.9	0

^aThe median for the variability distribution. ^bThe 90th and 95th percentiles of the variability distribution. ^cThe percentage of the population with an HQ value < 1 . ^dThe percent decrease in iodide uptake for individuals at the 95th percentile. The percent decrease is predicted using the equation in the text; a value of 0% indicates the threshold of 0.005 mg/kg-day has not been exceeded.

similarly contaminated by perchlorate) of the sensitive subpopulation might face a dose exceeding the RfD. Values of the HQ > 1.0 at the 95th percentile of the intersubject variability distribution are predicted at 20 µg/L perchlorate if ingestion of all water, and not only drinking water, is included in the exposure assessment. The results suggest that few women in the sensitive subpopulation would face a significant perchlorate risk from drinking water at MCLs ≤ 24.5 µg/L if only drinking water is considered, but that the equivalent MCL would need to be slightly below 20 µg/L if all water ingestion were considered.

We caution the reader on the interpretation of these results. The present analysis falls within a framework of probabilistic risk assessment that differs in significant ways from traditional approaches to determining

regulatory limits on exposure. In those traditional approaches, risks are estimated to maximally exposed individuals within sensitive subpopulations, and the concentration determined that produces an acceptable level of risk in those individuals. This level is independent of any consideration of the fraction of people in that subpopulation. The question being addressed traditionally is to what extent a proposed MCL will reduce the risk to an individual in this maximally exposed, sensitive subpopulation.

Probabilistic risk assessment as conducted here, however, examines the intersubject variability distribution of risks in this subpopulation and asks what fraction of people in an exposed population have a risk (HQ or percentage decrease in iodide uptake) judged to be unacceptable. Such probabilistic

distributions form the basis of cost-risk-benefit calculations, allowing society to determine how a given mode of risk reduction (e.g., controls on perchlorate exposures) compares against other modes of risk reduction. The goal then is to determine the total burden of disease in a population and to use this estimate of burden to determine whether the examined mode of risk reduction (here, control on perchlorate exposures) represents an effective way to allocate limited societal resources in improving the overall health of the public. We have not attempted here to draw any conclusions in that regard, but rather to present the probabilistic information on which such cost-risk-benefit assessments might be based.

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Appendix. Mode of action for perchlorate.

There is broad scientific agreement that the mode of action for perchlorate is as follows:

- Perchlorate binds to, and blocks, receptors for the movement of iodine from the bloodstream into the thyroid. This will reduce the movement of iodine into the thyroid.
- The thyroid responds to this reduction either by producing less triiodothyronine (T₃) and thyroxine (T₄) or by drawing on the pool of iodine stored in the thyroid.
- Perchlorate can therefore reduce the production of T₃ and T₄ initially, although there are feedback mechanisms that can bring these levels in the circulating blood back to normal ranges over time.
- The effect on T₄ is not significant because that molecule is an intermediary, and so the focus should be on changes in T₃.
- For some fraction of the population that has very little iodine stored in the thyroid, there may be reduced ability to compensate for the reduction of iodine crossing from the bloodstream to the thyroid. This may reduce T₃ levels in the circulating blood, leading eventually to

increased production of thyroid-stimulating hormone (TSH) to try to correct the imbalance.

- If the imbalance cannot be corrected, there could be changes in metabolic function at any age of exposure, or abnormal fetal and child growth and development.

The NRC committee (NRC 2005) disagreed as to where the U.S. EPA should draw the line between adverse and nonadverse effects. The agency considered changes in T₃ and TSH levels to be adverse in and of themselves, or at least indications of, or biomarkers of, adverse effects. The NRC committee did not consider changes in T₃ and/or TSH adverse in and of themselves. Instead, the NRC committee claimed that changes in these levels must first produce thyroid hypertrophy or hyperplasia, followed by hypothyroidism, which then will produce the final metabolic and growth/developmental effects mentioned above. The NRC committee considered the first effect that is adverse to be hypothyroidism rather than either the preceding thyroid hypertrophy/hyperplasia or the changes in T₃ and/or TSH.

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