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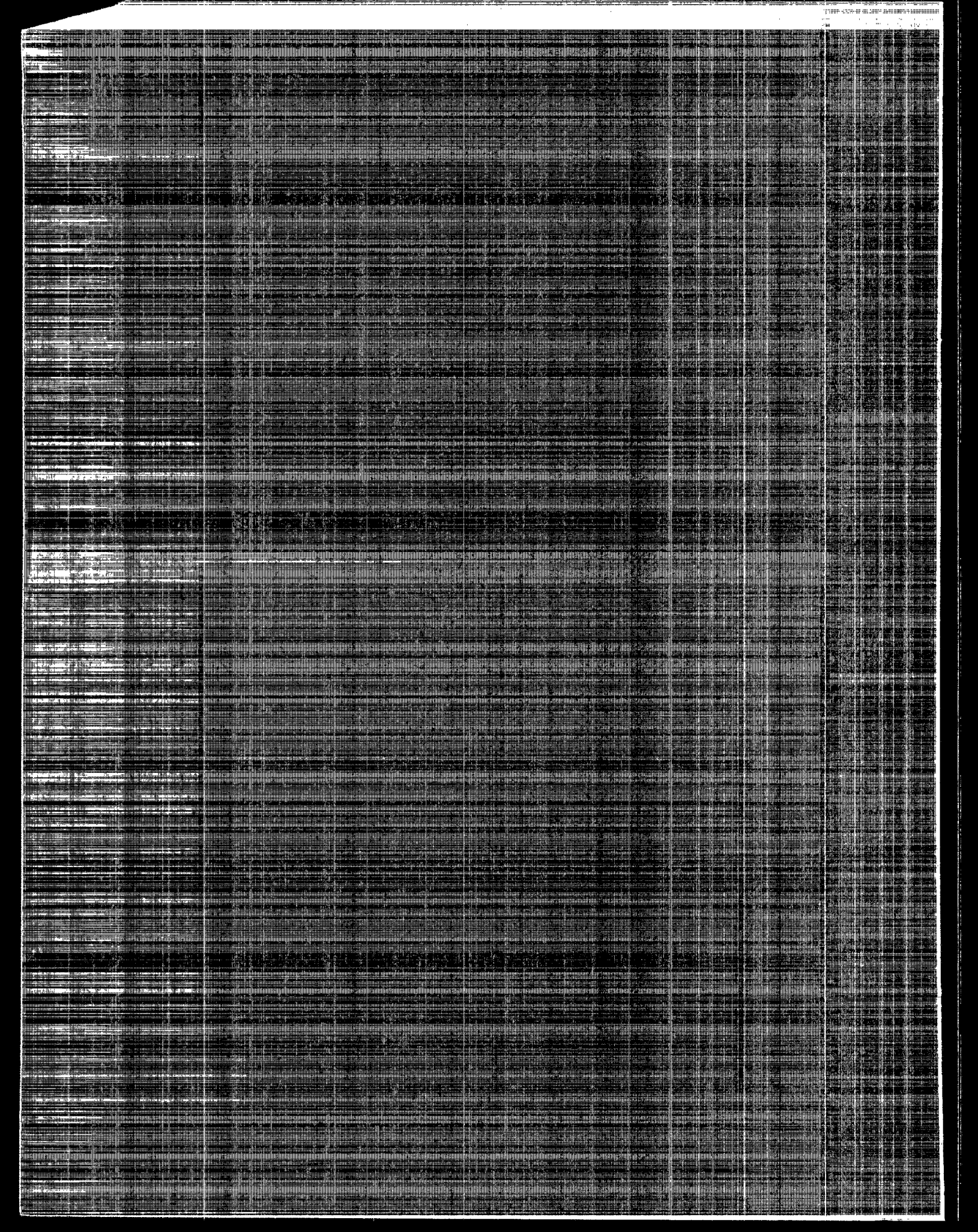
EPA

Contaminant Candidate List Preliminary Regulatory Determination Support Document for Sulfate



Disclaimers

This document is designed to provide supporting information regarding the regulatory determination for sulfate as part of the Contaminant Candidate List (CCL) evaluation process. This document is not a regulation, and it does not substitute for the Safe Drinking Water Act (SDWA) or the Environmental Protection Agency's (EPA's) regulations. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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USEPA, Office of Water Report: EPA 815-R-01-015, November, 2001

CONTAMINANT CANDIDATE LIST
PRELIMINARY REGULATORY DETERMINATION SUPPORT
DOCUMENT FOR SULFATE

Executive Summary

Sulfate is a 1998 Contaminant Candidate List (CCL) regulatory determination priority contaminant. Sulfate is one of the contaminants considered by the U.S. Environmental Protection Agency (EPA) for a regulatory determination. The available data on occurrence, exposure, and other risk considerations suggest that regulating sulfate may not present a meaningful opportunity to reduce health risk. EPA presents preliminary CCL regulatory determinations and further analysis in the *Federal Register* Notice.

To make the preliminary determination for sulfate, EPA used approaches guided by the National Drinking Water Advisory Council's (NDWAC) Work group on CCL and Six-Year Review. The Safe Drinking Water Act (SDWA) requirements for National Primary Drinking Water Regulation (NPDWR) promulgation guided protocol development. The SDWA Section 1412(b)(1)(A) specifies that the determination to regulate a contaminant must be based on a finding that each of the following criteria are met: (i) "the contaminant may have adverse effects on the health of persons"; (ii) "the contaminant is known to occur or there is substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern"; and (iii) "in the sole judgement of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems." Available data were evaluated to address each of the three statutory criteria.

Sulfate, a soluble, divalent anion (SO_4^{2-}), is produced from the oxidation of elemental sulfur, sulfide minerals, or organic sulfur. Sulfate is ubiquitous in the environment because of the abundance of sulfur on earth. Anthropogenic sources of sulfate include the burning of sulfur-containing fossil fuels, household wastes including detergents, and industrial effluents from tanneries, steel mills, sulfate-pulp mills, and textile plants. Sulfate is also used in pickle liquor (sulfuric acid) for steel and metal industries, as a feedstock or reagent in manufacturing processes, in some fertilizers, and exists as an end-product in the form of copper sulfate in its use as a fungicide and algicide.

In 1979, EPA established a secondary maximum contaminant level (SMCL), a non-enforceable guidance level for aesthetic quality, at 250 mg/L for sulfate in drinking water. In 1985, EPA proposed a sulfate health advisory of 400 mg/L that was never finalized. The SDWA amendments of 1986 mandated an NPDWR for sulfate as well as the establishment of a maximum contaminant level goal (MCLG). After a proposal of two alternative MCLGs of 400 and 500 mg/L in 1990, and a reproposal of a 500 mg/L MCLG and Maximum Contaminant Level (MCL) in 1994, a regulatory determination had not been finalized when Congress amended the SDWA in 1996. Sulfate was monitored from 1993 to 1999 under the SDWA Unregulated Contaminant Monitoring (UCM) program.

The SDWA amendments of 1996 required EPA to finalize a sulfate regulatory determination by August, 2001 and to complete a joint study with the Center for Disease Control and Prevention (CDC) before NPDWR promulgation. The joint study was to determine a reliable dose-response relationship for human health effects following exposure to sulfate in drinking water. EPA and CDC jointly concluded it is unlikely that any adverse health effects will result from sulfate concentrations in drinking water below

600 mg/L for adults. An expert panel of scientists convened in September, 1998, to supplement the EPA/CDC study concluded there was insufficient scientific evidence regarding health effects to justify a regulation, and suggested that a health advisory be issued in areas where sulfate concentrations in drinking water exceed 500 mg/L.

Sulfate occurrence is ubiquitous in ambient waters monitored by the United States Geological Survey's (USGS) National Water Quality Assessment (NAWQA) program. The NAWQA monitoring results indicate nearly 100% of all surface and ground water sites have sample analytical detections of sulfate. Although sulfate detection frequencies are high in surface and ground waters, sulfate occurrence at levels of public health concern is low. Less than approximately 1.4% of all surface water sites and about 1.8% of all ground water sites showed detections greater than a Health Reference Level (HRL) of 500 mg/L, a preliminary health effect level used for this analysis. HRL exceedances and 99th percentile concentrations are generally greatest in urban basins, while median sulfate concentrations are similar for urban, mixed land use, and agricultural basins.

Sulfate has also been detected in public water systems (PWS) compliance monitoring samples collected under SDWA. Occurrence estimates are very high by all measures. Approximately 87% of all samples show detections, and the median and 99th percentile concentrations of all samples are 24 mg/L and 560 mg/L, respectively. Approximately 88% of systems, serving 95% of the national PWS population (202 million people), report detections. An estimated 0.9% of PWSs, serving about 2 million people nationally, use water with sulfate levels above an HRL of 500 mg/L. Additional data, including both ground water and surface water PWSs from select States, were examined through independent analyses and also have shown substantial low-level sulfate occurrence.

The available toxicological data indicate that sulfate may cause adverse health effects in humans and animals. Sulfate has a laxative effect in high doses, but adverse health effects are temporary and recovery is rapid. Sub-populations sensitive to sulfate ingested through drinking water include formula-fed infants, the elderly or invalids who use powdered nutritional supplements, and visitors who are not acclimated to high sulfate concentrations in drinking water.

In summary, monitoring data indicate that sulfate is detected in the majority of drinking water supplies, but is infrequently detected above the HRL of 500 mg/L. The risk of adverse health effects to the general population is limited and acute (a short-duration laxative response), and such effects occur only at high drinking water concentrations (>500 mg/L, and in many cases >1,000 mg/L). People can develop a tolerance for high concentrations of sulfate in drinking water. Also, because of the taste of water high in sulfate (the taste threshold for sulfate is 250 mg/L), people tend to decrease the amount of high-sulfate water they drink at one time, thus reducing the likelihood of acute exposure. For these reasons, it is unlikely that regulation of sulfate would present a meaningful opportunity for health risk reduction. EPA is, however, issuing an advisory to provide guidance to communities that may be exposed to drinking water contaminated with high sulfate concentrations.

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1.0 INTRODUCTION

1.1 Purpose and Scope

This document presents scientific data and summaries of technical information prepared for, and used in, the Environmental Protection Agency's (EPA) regulatory determination for sulfate. Information regarding sulfate's physical and chemical properties, environmental fate, occurrence and exposure, and health effects is included. Analytical methods and treatment technologies are also discussed. Furthermore, the regulatory determination process is described to provide the rationale for the decision.

1.2 Statutory Framework/Background

The Safe Drinking Water Act (SDWA), as amended in 1996, requires the EPA to publish a list of contaminants (referred to as the Contaminant Candidate List, or CCL) to assist in priority-setting efforts. The contaminants included on the CCL were not subject to any current or proposed National Primary Drinking Water Regulations (NPDWR), were known or anticipated to occur in public water systems, were known or suspected to adversely affect public health, and therefore may require regulation under SDWA. The first Drinking Water CCL was published on March 2, 1998 (USEPA, 1998; 63 FR 10273), and a new CCL must be published every five years thereafter.

The 1998 CCL contains 60 contaminants, including 50 chemicals or chemical groups, and 10 microbiological contaminants or microbial groups. The SDWA also requires the Agency to select 5 or more contaminants from the current CCL, and determine whether or not to regulate these contaminants with an NPDWR. Regulatory determinations for at least 5 contaminants must be completed 3½ years after each new CCL.

Language in SDWA Section 1412(b)(1)(A) specifies that the determination to regulate a contaminant must be based on a finding that each of the following criteria are met:

Statutory Finding i: ...the contaminant may have adverse effects on the health of persons;

Statutory Finding ii: the contaminant is known to occur or there is substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

Statutory Finding iii: in the sole judgement of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

The geographic distribution of the contaminant is another factor evaluated to determine whether it occurs at the national, regional, or local level. This consideration is important because the Agency is charged with developing national regulations and it may not be appropriate to develop NPDWRs for regional or local contamination problems.

EPA must determine if regulating this CCL contaminant will present a meaningful opportunity to reduce health risk based on contaminant occurrence, exposure, and other risk considerations. The Office of Ground Water and Drinking Water (OGWDW) is charged with gathering and analyzing the occurrence, exposure, and risk information necessary to support this regulatory decision. The OGWDW must evaluate when and where this contaminant occurs, and what would be the exposure and risk to

public health. EPA must evaluate the impact of potential regulations as well as determine the appropriate measure(s) for protecting public health.

For each of the regulatory determinations, EPA must first publish, in the *Federal Register,* the draft determinations for public comment. EPA will respond to the public comments received, and will then finalize regulatory determinations. If the Agency finds that regulations are warranted, the regulations must then be formally proposed within twenty-four months, and promulgated eighteen months later. EPA has determined that there is sufficient information to support a regulatory determination for sulfate.

1.3 Statutory History of Sulfate

Sulfate has been monitored under the SDWA Unregulated Contaminant Monitoring (UCM) program since 1993 (USEPA, 1992a; 57 FR 31776). Monitoring ceased for small public water systems (PWSs) under a direct final rule published January 8, 1999 (USEPA, 1999a; 64 FR 1494), and ended for large PWSs with promulgation of the new Unregulated Contaminant Monitoring Regulation (UCMR) issued September 17, 1999 (USEPA, 1999c; 64 FR 50556) and effective January 1, 2001. At the time the UCMR lists were developed, the Agency concluded there were adequate monitoring data for a regulatory determination. This obviated the need for continued monitoring under the new UCMR list.

EPA established a secondary maximum contaminant level (SMCL) for sulfate in drinking water in 1979 (USEPA, 1979; 44 FR 42195). An SMCL is based on the negative aesthetic effects of a contaminant in drinking water (i.e. taste, smell), and is not a federally enforceable standard. It is estimated that humans detect sulfate in water starting at concentrations of between 250 and 350 mg/L. For sulfate, the recommended SMCL is 250 mg/L (USEPA, 1979; 44 FR 42195). The World Health Organization (WHO) advises that sulfate concentrations in drinking water not exceed 400 mg/L, based on taste (USEPA, 1985; 50 FR 46936).

In 1985, EPA proposed a health advisory for sulfate of 400 mg/L. This advisory was intended as an alternative to a federally enforceable maximum contaminant level (MCL), and was meant to protect infants (USEPA, 1985; 50 FR 46936). The proposed health advisory was never finalized (USEPA, 1999b; 64 FR 7028). As a part of the CCL process, health effects data have been reviewed, and are summarized in Section 4.0 of this document.

The 1986 Safe Drinking Water Act mandated a National Primary Drinking Water Regulation for sulfate, as well as the establishment of a maximum contaminant level goal (MCLG) (USEPA, 1999b; 64 FR 7028). In 1990, EPA proposed two alternative MCLGs of 400 and 500 mg/L (USEPA, 1990; 55 FR 30370). Promulgation of these standards was deferred, however, until EPA could identify proper implementation techniques for target populations (USEPA, 1992a; 57 FR 31776). EPA reproposed an MCLG and MCL for sulfate in drinking water of 500 mg/L in 1994, including in their proposal four compliance options to facilitate implementation (USEPA, 1994; 59 FR 65578). A regulatory determination had not been finalized when Congress amended the SDWA in 1996.

The SDWA amendments of 1996 contained specific regulatory authority for sulfate. The amendments required that EPA finalize a regulatory determination by August, 2001. The amendments also mandated the initiation and completion of a joint study by EPA and the Center for Disease Control and Prevention (CDC) prior to promulgation of an NPDWR for sulfate. The joint study was to determine a reliable dose-response relationship for human health effects in the general population (including at-risk groups like transients and infants) following exposure to sulfate in drinking water (SDWA, § 1412 (b) (12) (B)). Results from this study were published in January, 1999.

EPA and CDC were unable to complete the dose-response study for infants because of an insufficient study population. EPA and CDC concluded that, for adults, it is unlikely that any adverse health effects will result from sulfate concentrations in drinking water below 600 mg/L. There are no significant dose-response associations between sulfate exposure and reports of diarrhea in adults (EPA and CDC, 1999a). An expert panel of scientists was convened in a September, 1998, workshop to supplement the EPA/CDC study. Participating scientists concluded that there was insufficient scientific evidence regarding health effects to justify a regulation. The panel suggested that a health advisory be issued in areas where sulfate concentrations in drinking water exceed 500 mg/L (EPA and CDC, 1999b).

1.4 Regulatory Determination Process

In developing a process for the regulatory determinations, EPA sought input from experts and stakeholders. EPA asked the National Research Council (NRC) for assistance in developing a scientifically sound approach for deciding whether or not to regulate contaminants on the current and future CCLs. The NRC's Committee on Drinking Water Contaminants recommended that EPA: (1) gather and analyze health effects, exposure, treatment, and analytical methods data for each contaminant; (2) conduct a preliminary risk assessment for each contaminant based on the available data; and (3) issue a decision document for each contaminant describing the outcome of the preliminary risk assessment. The NRC noted that in using this decision framework, EPA should keep in mind the importance of involving all interested parties.

One of the formal means by which EPA works with its stakeholders is through the National Drinking Water Advisory Council (NDWAC). The NDWAC comprises members of the general public, State and local agencies, and private groups concerned with safe drinking water, and advises the EPA Administrator on key aspects of the Agency's drinking water program. The NDWAC provided specific recommendations to EPA on a protocol to assist the Agency in making regulatory determinations for current and future CCL contaminants. Separate but similar protocols were developed for chemical and microbial contaminants. These protocols are intended to provide a consistent approach to evaluating contaminants for regulatory determination, and to be a tool that will organize information in a manner that will communicate the rationale for each determination to stakeholders. The possible outcomes of the regulatory determination process are: a decision to regulate, a decision not to regulate, or a decision that some other action is needed (e.g., issuance of guidance).

The NDWAC protocol uses the three statutory requirements of SDWA Section 1412(b)(1)(A)(i)-(iii) (specified in section 1.2) as the foundation for guiding EPA in making regulatory determination decisions. For each statutory requirement, evaluation criteria were developed and are summarized below.

To address whether a contaminant may have adverse effects on the health of persons (statutory requirement (i)), the NDWAC recommended that EPA characterize the health risk and estimate a health reference level for evaluating the occurrence data for each contaminant.

Regarding whether a contaminant is known to occur, or whether there is substantial likelihood that the contaminant will occur, in public water systems with a frequency, and at levels, of public health concern (statutory requirement (ii)), the NDWAC recommended that EPA consider: (1) the actual and estimated national percent of public water systems (PWSs) reporting detections above half the health reference level; (2) the actual and estimated national percent of PWSs with detections above the health reference level; and (3) the geographic distribution of the contaminant.

To address whether regulation of a contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems (statutory requirement (iii)) the NDWAC recommended that EPA consider estimating the national population exposed above half the health reference level and the national population exposed above the health reference level.

The approach EPA used to make preliminary regulatory determinations followed the general format recommended by the NRC and the NDWAC to satisfy the three SDWA requirements under section 1412(b)(1)(A)(i)-(iii). The process was independent of many of the more detailed and comprehensive risk management factors that will influence the ultimate regulatory decision making process. Thus, a decision to regulate is the beginning of the Agency regulatory development process, not the end.

Specifically, EPA characterized the human health effects that may result from exposure to a contaminant found in drinking water. Based on this characterization, the Agency estimated a health reference level (HRL) for each contaminant.

For each contaminant EPA estimated the number of PWSs with detections >½HRL and >HRL, the population served at these benchmark values, and the geographic distribution, using a large number of occurrence data (approximately seven million analytical points) that broadly reflect national coverage. Round 1 and Round 2 UCM data, evaluated for quality, completeness, bias, and representativeness, were the primary data used to develop national occurrence estimates. Use and environmental release information, additional drinking water data sets (e.g., State drinking water data sets, EPA National Pesticide Survey, and Environmental Working Group data reviews), and ambient water quality data (e.g., NAWQA, State and regional studies, and the EPA Pesticides in Ground Water Database) were also consulted.

The findings from these evaluations were used to determine if there was adequate information to evaluate the three SDWA statutory requirements and to make a preliminary determination of whether to regulate a contaminant.

1.5 Determination Outcome

After reviewing the best available public health and occurrence information, EPA has made a preliminary determination not to regulate sulfate with an NPDWR. This preliminary decision is based on the weight of evidence suggesting that regulating sulfate does not present a meaningful opportunity for health risk reduction for persons served by public water systems. EPA is , however, issuing an advisory to provide guidance to communities that may be exposed to drinking water contaminated with high sulfate concentrations. All preliminary CCL regulatory determinations will be presented in the *Federal Register* Notice. The following sections summarize the data used by the Agency to reach this preliminary decision.

2.0 CONTAMINANT DEFINITION

Sulfate, a soluble, divalent anion (SO_4^{2-}) with molecular weight 96.06 g/mol, results from the oxidation of either elemental sulfur, sulfide minerals, or organic sulfur (Alley, 1993; Field, 1972; Wetzel, 1983). The anion is often connected, through ionic bonds, to alkali, alkaline earth, or transition metals (Field, 1972). Living organisms assimilate sulfate and reduce it to organic sulfur (R-SH, where R denotes an alkyl group), an essential constituent of two amino acids (Madigan et al., 1997). Sulfate is also incorporated into the structure of several polysaccharides, and is released to the environment through

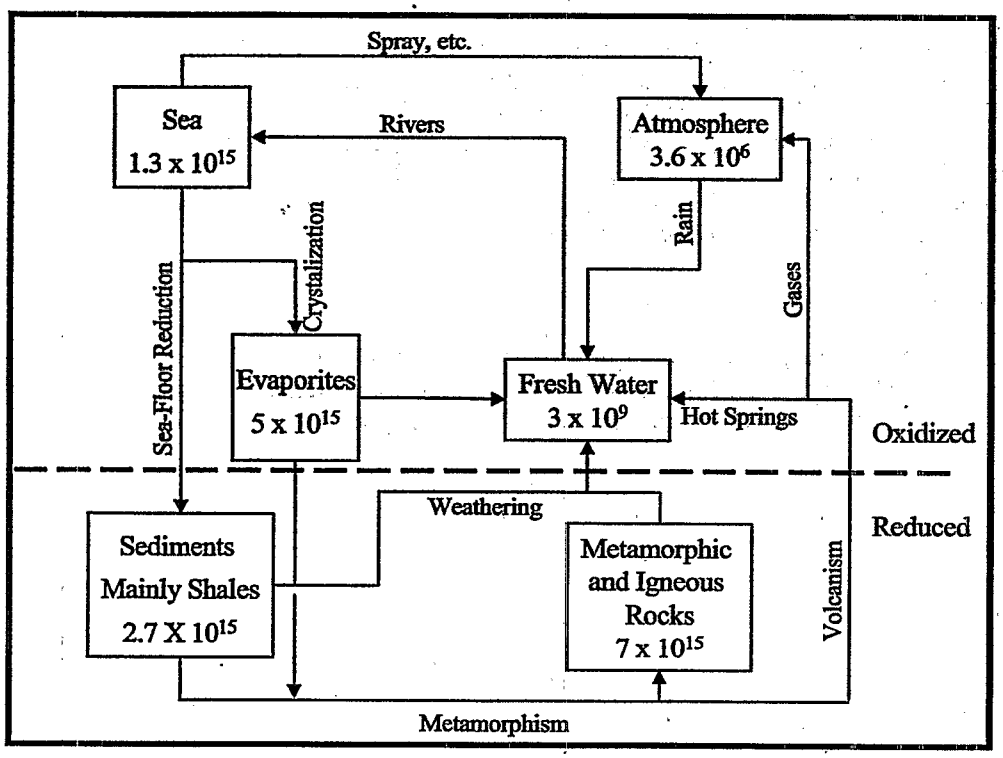
degradation of fecal wastes and organic material. Terrestrial evaporite minerals and the ocean are the largest reservoirs of planetary sulfate (Alley, 1993).

Anthropogenic sources of sulfate include the burning of sulfur-containing fossil fuels, household wastes including detergents, and industrial effluents from tanneries, steel mills, sulfate-pulp mills, and textile plants (USEPA, 1985; 50 FR 46936). Sulfate is also used in pickle liquor (sulfuric acid) for steel and metal industries, as a feedstock or reagent in manufacturing processes, and as an end-product such as copper sulfate, which is used as a fungicide and algicide (USEPA, 1990; 55 FR 30370). Sulfate is constantly replenished by means of the sulfur cycle (explained below), and is ubiquitous in the environment because of the abundance of sulfur on earth.

2.1 Environmental Fate/Behavior

The environmental fate and transport of sulfate are inextricably linked to the physical and chemical processes active in the earth's sulfur cycle (Figure 2-1). Sulfur reservoirs depicted in the upper portion of Figure 2-1 are present in the oxidized sulfate form, whereas those portrayed in the lower part are found as reduced sulfides.

Figure 2-1: The Sulfur Cycle



after Kaplan, 1972; masses in millions of metric tons

Sedimentary sulfur is present mostly in the form of evaporite sulfates, such as gypsum ($CaSO_4 \cdot 2H_2O$), anhydrite ($CaSO_4$), magnesium sulfate, and sodium sulfate. Sulfate can be leached from these evaporites to fresh water (USEPA, 1985; 50 FR 46936; Kaplan, 1972). In general, sulfate salts resulting from lower molecular weight alkali metals like sodium, potassium, and magnesium are extremely soluble, while those salts of higher molecular weight metals like barium, iron, or lead have a low solubility (USEPA, 1990; 55 FR 30370). Although adsorption has been documented in the field, sulfate does not generally adsorb strongly to soils but instead is carried unchanged through soil by percolating water (Drever, 1988). The weathering and oxidation of metallic sulfides, like pyrite (FeS_2), found in shales, limestone, and sandstone, are important sources for sulfate in fresh water (Kaplan, 1972).

Sulfur is oxidized to the sulfate anion in fresh water and is eventually transferred to the ocean by streams or rain. The sulfate anion is very stable, and does not spontaneously reduce under normal environmental conditions. However, the reduction of sulfate by sulfate-reducing bacteria (obligate anaerobes) is extremely important to the sulfur cycle. Once in the ocean, the sulfate anion is either reduced by bacteria and converted to pyrite at the mud-water interface, or is brought into the atmosphere by sea spray. Oceanic sulfate can also be precipitated as gypsum ($CaSO_4 \cdot 2H_2O$) in semi-isolated basins in arid portions of the earth (at which point evaporation has increased sulfate levels to four times the oceanic concentration). The approximate residence time for sulfate in the sea is 21 x 10^6 years (Kaplan, 1972). Sulfate is not expected to bioaccumulate in the aquatic food chain (Moore, 1991).

The concentration of sulfate ions in rain can be highly variable depending on proximity to industrial areas where sulfur-containing fuels are combusted and sulfur dioxide (SO_2) is released (Wehmiller, 1972). SO_2 is converted to sulfate in the atmosphere by photooxidation and heterogenous reactions, with the rate of conversion increasing in polluted areas that have high atmospheric concentrations of oxidizing radicals (like HO, HO_2, and CH_3O_2; Moore, 1991).

3.0 OCCURRENCE AND EXPOSURE

This section examines the occurrence of sulfate in drinking water. While no complete national database exists of unregulated or regulated contaminants in drinking water from public water systems (PWSs) collected under the Safe Drinking Water Act (SDWA), this report aggregates and analyzes existing State data that have been screened for quality, completeness, and representativeness. Populations served by PWSs exposed to sulfate are estimated, and the occurrence data are examined for regional or other special trends. To augment the incomplete national drinking water data and aid in the evaluation of occurrence, information on the use and environmental release, as well as ambient occurrence of sulfate, is also reviewed.

3.1 Use and Environmental Release

3.1.1 Production and Use

Anthropogenic sources of sulfate include: the burning of sulfur-containing fossil fuels, household wastes including detergents, and industrial effluents from tanneries, steel mills, sulfate-pulp mills, and textile plants (USEPA, 1985; 50 FR 46936). Sulfate is also used in pickle liquor (sulfuric acid) for steel and metal industries, as a feedstock or reagent in manufacturing processes, and as an end-product such as copper sulfate, which is used as a fungicide and algicide (USEPA, 1990; 55 FR 30370). Ammonium sulfate is applied to the environment directly as a fertilizer. Sulfate is constantly replenished by means of the sulfur cycle, and is ubiquitous in the environment because of the abundance of sulfur on earth (See Figure 2-1)

Sulfur is the 14th most abundant element in the earth's crust, and the 8th or 9th most abundant in sediments (Kaplan, 1972). See Table 3-1 for sulfur abundances in different environments:

Table 3-1: Abundance of sulfur in different environments

Locale	Sulfur (ppm)
Crustal Average	260
Ultramafic	300
Basalt	250
Granite	270
Shale	2,400
Sandstone	240
Carbonate	1,200
Deep-sea sediment	1,300
Soils	850
Terrestrial plants	500
Seawater	885
Freshwater	5.5

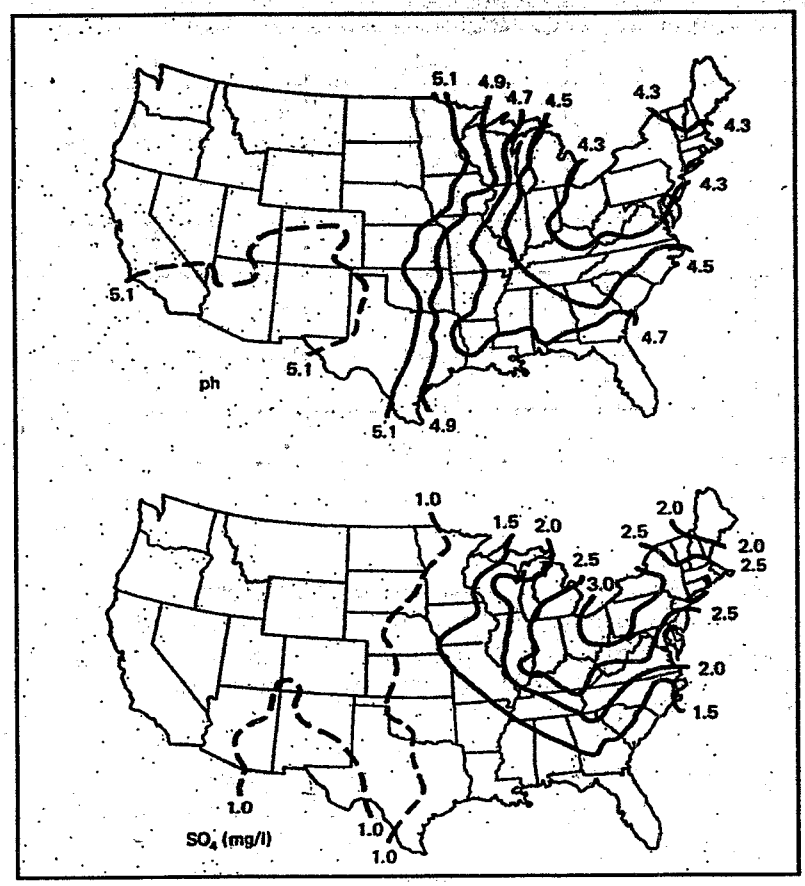
after Field, 1972

Since the sulfate anion is naturally occurring and is readily generated by the oxidation of various sulfur compounds, exact figures for its use and environmental release are unavailable. Production of sulfate compounds is expected to be very high, however (in the thousands of tons per year), as the use of sodium sulfate alone in 1987 was reported to be 792 tons (USEPA, 1990; 55 FR 30370).

3.1.2 Environmental Release

Sulfur dioxide (SO_2) emissions have recently become a major concern for industrialized nations. One of the most pressing of these concerns is related to the interaction of SO_2 with atmospheric water to produce sulfuric acid (H_2SO_4), causing acid rain (Moore, 1991; Wetzel, 1983). In addition, SO_2 can be converted to sulfate in the atmosphere. Elevated SO_4 concentrations in precipitation can lead to the acidification of soil solutions and elevate sulfate concentrations in terrestrial waters (See Figure 3-1; Drever, 1988). Note that in Figure 3-1, precipitation pH is lowest in regions where precipitation SO_4 concentrations are highest.

Figure 3-1: Annual weighted mean pH and sulfate concentration in precipitation in North America in 1985



after Drever, 1988

Anthropogenic sulfur emissions have a significant impact on the sulfur cycle, with at least 80% of global SO_2 emissions and over 45% of riverborne sulfates traceable to man-made sources (Moore, 1991). Table 3-2 indicates that total global sulfur dioxide production continually increased from 1930-1980 (the years when data were available).

Table 3-2: Global production of sulfur dioxide (x 10^6 metric tons Sulfur per year)

Continent	1930	1940	1950	1960	1970	1980	2000
Asia	5	9	12	34	43	57	30-90
Europe	21	25	21	30	30	30	12-30
North America	22	17	25	24	34	29	25
Africa	0.5	0.7	1	2	3	4	6
South America	0.4	0.5	1	2	3	4	6
Oceania	0.4	0.5	1	1	1	2	2
Total	49	53	61	93	114	126	81-159

after Dignon and Hameed, 1989; Hordijk, 1988; Moller, 1984

In addition to acidification through precipitation, terrestrial waters are acidified through a process called acid mine drainage. The process takes place in ground waters proximal to the mining and milling of sulfur-bearing ores, where sulfur compounds, including sulfate, are important mineral components of the hydrogeologic system. Acidified ground water produced through acid mine drainage can also affect surface waters through ground water discharge (Moore, 1991).

The basic reaction taking place in acid mine drainage involves the bacterially-mediated conversion of pyrite (FeS_2) to ferric hydroxide in the presence of percolating ground water, releasing sulfate and acid:

$$FeS_2 + 3.5\ O_2 + H_2O \rightarrow Fe^{2+} + 2\ SO_4^{2-} + 2\ H^+$$
$$Fe^{2+} + 0.25\ O_2 + 2.5\ H_2O \rightarrow Fe(OH)_3 + 2\ H^+$$

If more acid is produced than can be neutralized by the alkalinity of the surrounding aquifer, acid water will result. The bacteria that catalyze the above reactions thrive under acidic conditions, accelerating acidification once it has begun (Drever, 1988).

Sulfate concentrations from ~1,500 mg/L (coal mine in Pennsylvania) to 63,000 mg/L (zinc mine in Idaho; Barton, 1978) have been detected in waste waters near mines. To put this in perspective, the national secondary standard for sulfate is 250 mg/L.

Sulfate is almost always present in drinking water, and is often found in relatively high concentrations. A 1985 survey by the American Water Works Association, conducted in 39 States and 3 territories, detected sulfate concentrations above 250 mg/L in 1,466 cases (Moore, 1991).

3.2 Ambient Occurrence

To understand the presence of a chemical in the environment, an examination of ambient occurrence is useful. In a drinking water context, ambient water potentially (though not necessarily) is source water existing in surface waters and aquifers before treatment. The most comprehensive and nationally consistent data describing ambient water quality in the United States are being produced by the United States Geological Survey (USGS), particularly in their National Water Quality Assessment (NAWQA) program. (NAWQA, however, is a relatively young program and complete national data are not yet available from their entire array of sites across the nation.)

3.2.1 Data Sources and Methods

The USGS instituted the NAWQA program in 1991 to examine water quality status and trends in the United States. NAWQA is designed and implemented in such a manner as to allow consistency and comparison between representative study basins located around the country, facilitating interpretation of natural and anthropogenic factors affecting water quality (Leahy and Thompson, 1994).

The NAWQA program consists of 59 significant watersheds and aquifers referred to as "study units." The study units represent approximately two thirds of the overall water usage in the United States and a similar proportion of the population served by public water systems. Approximately one half of the nation's land area is represented (Leahy and Thompson, 1994).

To facilitate management and make the program cost-effective, approximately one third of the study units at a time engage in intensive assessment for a period of 3 to 5 years. This is followed by a period of less intensive research and monitoring that lasts between 5 and 7 years. This way all 59 study units rotate through intensive assessment over a ten-year period (Leahy and Thompson, 1994). The first round of intensive monitoring (1991-96) targeted 20 study units, and the second round monitored another 16 beginning in 1994.

Sulfate is an analyte for both surface and ground water NAWQA studies, with a Minimum Reporting Level (MRL) of 0.1 mg/L.

Sulfate data from the first two rounds of intensive NAWQA monitoring have undergone USGS quality assurance checks and are available to the public through their NAWQA Data Warehouse (USGS, 2001). EPA has analyzed these data after further data quality review and occurrence results are presented below. The descriptive statistics generated from the sulfate NAWQA data broadly characterize the frequency of sulfate detections by sample and by site. Furthermore, detection frequencies above a Health Reference Level (HRL) of 500 mg/L are also presented for all samples, and by site. The HRL is a preliminary health effect level used for this analysis (see Section 3.3.1.4 for further discussion of the HRL and its development). The median and 99th percentile concentrations are included as well, to characterize the range of sulfate concentration values present in ambient waters sampled by the NAWQA program.

3.2.2 Results

Typical of many inorganic contaminants, sulfate occurrence in ambient surface and ground waters is high (Table 3-3). This is not surprising, considering that the anion occurs naturally and is ubiquitous because of the abundance of sulfur on earth. Anthropogenic sources are also numerous.

Surface and ground water detection frequencies are similar, between 89.9% and 100% across all NAWQA sites, though ground water detections are somewhat lower (Table 3-3). Median sulfate concentrations are also similar between surface and ground water, but HRL exceedances and 99th percentile values are generally much greater in ground water. Locally high concentrations in ground water, higher than most surface water concentrations, are not surprising given the possibility of long contact times between ground water and rocks enriched in sulfide minerals or sulfates at a given location (the natural oxidation of sulfides is an important source for sulfate in fresh water). Contact times between surface waters and naturally occurring sulfides and sulfates are orders of magnitude shorter, hence concentrations are lower. Furthermore, surface waters subject to large anthropogenic inputs of sulfate are more easily diluted by waters integrated from other parts of the watershed where sulfate concentrations may be lower.

Table 3-3 illustrates that low-level sulfate occurrence is ubiquitous. Surface water detection frequencies are greater than 99% for all land use categories. However, detection frequencies greater than the HRL are significantly lower. Forest/rangeland basins did not detect sulfate at levels greater than the HRL, while urban, mixed, and agricultural basins show infrequent HRL exceedances (by site: between 0.4%-3.6%). Median concentrations for sulfate in surface waters are similar for urban, mixed, and agricultural basins, while forest/rangeland basins again show lower sulfate levels. Forest/rangeland basins also have the lowest 99th percentile concentrations. The 99th percentile concentrations are considerably higher for all other land use categories, with the highest concentrations found in urban areas. These concentration percentiles are understandable because sulfate is used widely in both industry and agriculture, is produced in the burning of fossil fuels, and can affect surface waters in urban and agricultural basins. Sulfate occurrence in forest/rangeland basins is low by comparison, given anthropogenic sources are few. Detections exceeding the MRL and HRL, by site, for all sites are approximately 99.6% and 2.7%, respectively. These figures indicate that although sulfate is ubiquitous in surface water, detections at levels of public health concern are low.

For ground water, detections frequencies for all samples, and by site, exceed 89% for all land use categories. Urban and agricultural areas have the greatest median and 99th percentile concentrations, and the highest frequency of HRL exceedances. Forest/rangeland basins report no detections greater than the HRL, and have the lowest median and 99th percentile values. Detection frequencies above the MRL and HRL, by site, for all sites are approximately 98.0% and 3.2%, respectively. Again, sulfate detections at levels of public health concern are low relative to sulfate occurrence.

Table 3-3: Sulfate detections and concentrations in streams and ground water

	Detection frequency > MRL*		Detection frequency > HRL*		Concentrations (all samples; mg/L)	
	% samples	% sites	% samples	% sites	median	99th percentile
surface water						
urban	100 %	100 %	2.6 %	0.4 %	20	2000
mixed	99.9 %	99.4 %	0.8 %	2.2 %	21	440
agricultural	99.8 %	99.7 %	2.9 %	3.6 %	25	670
forest/rangeland	99.9 %	99.5 %	0.0 %	0.0 %	5	160
all sites	99.8 %	99.6 %	1.8 %	2.7 %	20	680
ground water						
urban	91.1 %	98.7 %	5.3 %	6.4 %	20	2600
mixed	89.9 %	96.6 %	2.1 %	2.4 %	12	940
agricultural	93.6 %	99.5 %	4.3 %	4.3 %	24	1200
forest/rangeland	91.8 %	97.5 %	0.0 %	0.0 %	7	71
all sites	91.6 %	98.0 %	2.7 %	3.2 %	17	1300

** The Minimum Reporting Level (MRL) for sulfate in water is 0.1 mg/L and the Health Reference Level (HRL) is 500 mg/L. The HRL is a preliminary health effect level used for this investigation.*

3.3 Drinking Water Occurrence

The Safe Drinking Water Act, as amended in 1986, required PWSs to monitor for specified "unregulated" contaminants, on a five year cycle, and to report the monitoring results to the States. Unregulated contaminants do not have an established or proposed National Primary Drinking Water Regulation, but they are contaminants that were formally listed and required for monitoring under federal regulations. The intent was to gather scientific information on the occurrence of these contaminants in order to enable a decision as to whether or not regulations were needed. All non-purchased community water systems (CWSs) and non-purchased non-transient non-community water systems (NTNCWSs), with greater than 150 service connections, were required to conduct this unregulated contaminant monitoring. Smaller systems were not required to conduct this monitoring under federal regulations, but were required to be available to monitor if the State decided such monitoring was necessary. Many States collected data from smaller systems. Additional contaminants were added to the Unregulated Contaminant Monitoring program in 1991 (USEPA, 1991; 56 FR 3526) for required monitoring that began in 1993 (USEPA, 1992a; 57 FR 31776).

Sulfate has been monitored under the SDWA Unregulated Contaminant Monitoring (UCM) program since 1993 (USEPA, 1992a; 57 FR 31776). Monitoring ceased for small PWSs under a direct final rule published January 8, 1999 (USEPA, 1999a; 64 FR 1494), and ended for large PWSs with promulgation of the new Unregulated Contaminant Monitoring Regulation issued September 17, 1999 (USEPA, 1999c; 64 FR 50556) and effective January 1, 2001. At the time the UCMR lists were developed, the Agency concluded there were adequate monitoring data for a regulatory determination for sulfate. This obviated the need for continued monitoring under the new UCMR list.

EPA established a secondary maximum contaminant level for sulfate in drinking water in 1979 (USEPA, 1979; 44 FR 42195). An SMCL is based on the negative aesthetic effects of a contaminant in drinking water (i.e. taste, smell), and is not a federally enforceable standard. It is estimated that humans detect sulfate in water starting at concentrations of between 250 and 350 mg/L. For sulfate, the recommended SMCL is 250 mg/L (USEPA, 1979; 44 FR 42195).

3.3.1 Data Sources, Data Quality, and Analytical Approach

Currently, there is no complete national record of unregulated or regulated contaminants in drinking water from PWSs collected under SDWA. Many States have submitted unregulated contaminant PWS monitoring data to EPA databases, but there are issues of data quality, completeness, and representativeness. Nonetheless, a significant amount of State data are available for UCM contaminants , and can provide estimates of national occurrence. The contaminant occurrence analyses findings presented in this report are based on a national cross-section of aggregated State data (i.e., a representative subset of available State data) derived from the Safe Drinking Water Information System (Federal version; SDWIS/FED) database.

The National Contaminant Occurrence Database (NCOD) is an interface to the actual occurrence data stored in the SDWIS/FED database and can be queried to provide a summary of the data in SDWIS/FED for a particular contaminant. The drinking water occurrence data for sulfate presented here were derived from monitoring data available in the SDWIS/FED database. Note, however, that the SDWIS/FED data used in this report have undergone significant review, edit, and filtering to meet various data quality objectives for the purposes of this analysis. Hence, not all data from a particular source were used, only data meeting the quality objectives described below were included. The sources of these data, their quality and national aggregation, and the analytical methods used to estimate a given contaminant's national occurrence (from these data) are discussed in this section (for further details see USEPA, 2001a, 2001b).

3.3.1.1 UCM Rounds 1 and 2

The 1987 UCM contaminants included 34 volatile organic compounds (VOCs) (USEPA, 1987; 52 FR 25690). Sulfate, an inorganic compound (IOC), was *not* among these contaminants. The UCM (1987) contaminants were first monitored coincident with the Phase I regulated contaminants, during the 1988-1992 period. This period is often referred to as "Round 1" monitoring. The monitoring data collected by the PWSs were reported to the States (as primacy agents), but there was no protocol in place to report these data to EPA. These data from Round 1 were collected by EPA from many States over time and put into a database called the Unregulated Contaminant Information System, or URCIS.

The 1993 UCM contaminants included 13 synthetic organic contaminants (SOCs) and sulfate, the only IOC (USEPA, 1992a; 57 FR 31776). Monitoring for the UCM (1993) contaminants began coincident with the Phase II/V regulated contaminants in 1993 through 1998. This is often referred to as

"Round 2" monitoring. The UCM (1987) contaminants were also included in the Round 2 monitoring. As with other monitoring data, PWSs reported these results to the States. EPA, during the past several years, requested that the States submit these historic data to EPA and they are now stored in the SDWIS/FED database.

Monitoring and data collection for sulfate, a UCM (1993) contaminant, began in Round 2. Therefore, the following discussion regarding data quality screening, data management, and analytical methods is restricted to SDWIS/FED. Discussion of the URCIS database is included where relevant, but it is worth noting that the various quality screening, data management, and analytical processes were nearly identical for the two databases. For further details on the two monitoring periods as well as the databases, see USEPA (2001a) and USEPA (2001b).

3.3.1.2 Developing a Nationally Representative Perspective

The Round 2 data contain contaminant occurrence data from a total of 35 primacy entities (including 34 States and data for some tribal systems). However, data from some States are incomplete and biased. Furthermore, the national representativeness of the data is problematic because the data were not collected in a systematic or random statistical framework. These State data could be heavily skewed to low-occurrence or high-occurrence settings. Hence, the State data were evaluated based on pollution-potential indicators and the spatial/hydrologic diversity of the nation. This evaluation enabled the construction of a cross-section from the available State data sets that provides a reasonable representation of national occurrence.

A national cross-section comprised of the Round 2 State contaminant occurrence databases was established using the approach developed for the EPA report *A Review of Contaminant Occurrence in Public Water Systems* (USEPA, 1999d). This approach was developed to support occurrence analyses for EPA's Chemical Monitoring Reform (CMR) evaluation, and was supported by peer reviewers and stakeholders. The approach cannot provide a "statistically representative" sample because the original monitoring data were not collected or reported in an appropriate fashion. However, the resultant "national cross-section" of States should provide a clear indication of the central tendency of the national data. The remainder of this section provides a summary description of how the national cross-section from the SDWIS/FED (Round 2) database was developed. The details of the approach are presented in other documents (USEPA, 2001a, 2001b); readers are referred to these for more specific information.

3.3.1.2.1 Cross-Section Development

As a first step in developing the cross-section, the State data contained in the SDWIS/FED database (that contains the Round 2 monitoring results) were evaluated for completeness and quality. Some State data in SDWIS/FED were unusable for a variety of reasons. Some States reported only detections, or the data was recorded with incorrect units. Data sets only including detections are obviously biased, over-representing high-occurrence settings. Other problems included substantially incomplete data sets without all PWSs reporting (USEPA, 2001a Sections II and III).

The balance of the States remaining after the data quality screening were then examined to establish a national cross-section. This step was based on evaluating the States' pollution potential and geographic coverage in relation to all States. Pollution potential is considered to ensure a selection of States that represent the range of likely contaminant occurrence and a balance with regard to likely high and low occurrence. Geographic consideration is included so that the wide range of climatic and hydrogeologic conditions across the United States are represented, again balancing the varied conditions that affect

transport and fate of contaminants, as well as conditions that affect naturally occurring contaminants (USEPA, 2001b Sections III.A. and III.B.).

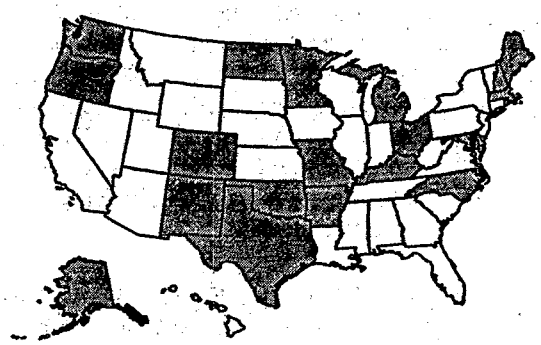
The cross-section States were selected to represent a variety of pollution potential conditions. Two primary pollution potential indicators were used. The first factor selected indicates pollution potential from manufacturing/population density and serves as an indicator of the potential for VOC contamination within a State. Agriculture was selected as the second pollution potential indicator because the majority of SOCs of concern are pesticides (USEPA, 2001b Section III.A.). The 50 individual States were ranked from highest to lowest based on the pollution potential indicator data. For example, the State with the highest ranking for pollution potential from manufacturing received a ranking of 1 for this factor and the State with the lowest value was ranked as number 50. States were ranked for their agricultural chemical use status in a similar fashion.

The States' pollution potential rankings for each factor were subdivided into four quartiles (from highest to lowest pollution potential). The cross-section States were chosen equally from all quartiles for both pollution potential factors to ensure representation, for example, from: States with high agrochemical pollution potential rankings and high manufacturing pollution potential rankings; States with high agrochemical pollution potential rankings and low manufacturing pollution potential rankings; States with low agrochemical pollution potential rankings and high manufacturing pollution potential rankings; and States with low agrochemical pollution potential rankings and low manufacturing pollution potential rankings (USEPA, 2001b Section III.B.). In addition, some secondary pollution potential indicators were considered to further ensure that the cross-section States included the spectrum of pollution potential conditions (high to low). At the same time, States within the specific quartiles were considered collectively across all quartiles to attempt to provide a geographic coverage across all regions of the United States.

The data quality screening, pollution potential rankings, and geographic coverage analysis established a national cross-section of 20 Round 2 (SDWIS/FED) States. The 20 cross-section States provide good representation of the nation's varied climatic and hydrogeologic regimes, and the breadth of pollution potential for the contaminant groups (Figure 3-2).

Figure 3-2: Geographic distribution of cross-section States for Round 2 (SDWIS/FED)

Round 2 (SDWIS/FED) Cross Section States	
Alaska	New Hampshire
Arkansas	New Mexico
Colorado	North Carolina
Kentucky	North Dakota
Maine	Ohio
Maryland	Oklahoma
Massachusetts	Oregon
Michigan	Rhode Island
Minnesota	Texas
Missouri	Washington



3.3.1.2.2 Cross-Section Evaluation

To evaluate and validate the method for creating the national cross-sections, the method was used to create smaller State subsets from the 24-State, Round 1 (URCIS) cross-section. Again, States were chosen to achieve a balance from the quartiles describing pollution potential, and a balanced geographic distribution, to incrementally build subset cross-sections of various sizes. For example, the Round 1 cross-section was tested with subsets of 4, 8 (the first 4 State subset plus 4 more States), and 13 (8 State subset plus 5) States. Two additional cross-sections were included in the analysis for comparison; a cross-section composed of 16 States with biased data sets eliminated from the 24 State cross-section for data quality reasons, and a cross-section composed of all 40 Round 1 States (USEPA, 2001b Section III.B.1).

These Round 1 "incremental cross-sections" were then used to evaluate occurrence for an array of both high and low occurrence contaminants. The comparative results illustrate several points. The results are quite stable and consistent for the 8-, 13- and 24- State cross-sections. They are much less so for the 4-State, 16-State (biased), and 40-State (all Round 1 States) cross-sections. The 4-State cross-section is apparently too small to provide balance both geographically and with pollution potential, a finding that concurs with past work (USEPA, 1999d). The CMR analysis suggested that a minimum of 6-7 States was needed to provide balance both geographically and with pollution potential, and the CMR report used 8 States out of the available data for its nationally representative cross-section (USEPA, 1999d). The 16- and 40-State cross-sections, both including biased States, provided occurrence results that were unstable and inconsistent for a variety of reasons associated with their data quality problems (USEPA, 2001b Section III.B.1).

The 8-, 13-, and 24-State cross-sections provide very comparable results, are consistent, and are usable as national cross-sections to provide estimates of contaminant occurrence. Including greater amounts of data from more States improves the national representation and the confidence in the results, as long as the States are balanced related to pollution potential and spatial coverage. The 20-State cross-section provides the best, nationally representative cross-section for the Round 2 data.

3.3.1.3 Data Management and Analysis

The cross-section analyses focused on occurrence at the water system level; i.e., the summary data presented discuss the percentage of public water *systems* with detections, not the percentage of *samples* with detections. By normalizing the analytical data to the system level, skewness inherent in the sample data is avoided. System level analysis was used since a PWS with a known contaminant problem usually has to sample more frequently than a PWS that has never detected the contaminant. Obviously, the results of a simple computation of the percentage of samples with detections (or other statistics) can be skewed by the more frequent sampling results reported by the contaminated site. The system level of analysis is conservative. For example, a system need only have a single sample with an analytical result greater than the Minimum Reporting Limit (MRL), i.e., a detection, to be counted as a system with a result "greater than the MRL."

Also, the data used in the analyses were limited to only those data with confirmed water source and sampling type information. Only standard SDWA compliance samples were used; "special" samples, or "investigation" samples (investigating a contaminant problem that would bias results), or samples of unknown type were not used in the analyses. Various quality control and review checks were made of the results, including follow-up questions to the States providing the data. Many of the most intractable data quality problems encountered occurred with older data. These problematic data were, in some cases, simply eliminated from the analysis. For example, when the number of problematic data were insignificant relative to the total number of observations, those data were dropped from the analysis (for further details see Cadmus, 2000).

3.3.1.4 Occurrence Analysis

To evaluate national contaminant occurrence, a two-stage analytical approach has been developed. The first stage of analysis provides a straightforward, conservative, non-parametric evaluation of occurrence of the CCL regulatory determination priority contaminants as described above. These Stage 1 descriptive statistics are summarized here. Based in part on the findings of the Stage 1 Analysis, EPA will determine whether more rigorous parametric statistical evaluations, the Stage 2 Analysis, may be warranted to generate national probability estimates of contaminant occurrence and exposure for priority contaminants (for details on this two stage analytical approach see Cadmus, 2000, 2001).

The summary descriptive statistics presented in Table 3-4 for sulfate are a result of the Stage 1 analysis and include data from Round 2 (SDWIS/FED, 1993-1997) cross-section States. Included are the total number of samples, the percent samples with detections, the 99th percentile concentration of all samples, and the median concentration of all samples. The percentages of PWSs and population served indicate the proportion of PWSs (or population served by PWSs) whose analytical results include at least one detection of the contaminant (simple detection, > MRL) at any time during the monitoring period; or a detection(s) greater than half the Health Reference Level (HRL); or a detection(s) greater than the HRL (the HRL is a preliminary estimated health effect level used for this analysis).

The HRL used in evaluating the occurrence information for sulfate is 500 mg/L. This is the value suggested by a panel of experts convened by EPA (USEPA, 1999e) as protective for sulfate-induced diarrhea. The Agency adopted the HRL of 500 mg/L, based on the recommendations of the CDC/EPA Panel (USEPA, 1999e), as a health-related benchmark for evaluating the occurrence data.

The 99th percentile concentration is used here as a summary statistic to indicate the upper bound of occurrence values, because maximum values can be extreme values (outliers) that sometimes result from sampling or reporting error.

As a simplifying assumption, a value of half the MRL is often used as an estimate of the concentration of a contaminant in samples/systems whose results are less than the MRL. However, for these occurrence data this is not straightforward. For Round 2, States have reported a wide range of values for the MRLs. This is in part related to State data management differences as well as real differences in analytical methods, laboratories, and other factors.

The situation can cause confusion when examining descriptive statistics for occurrence. For example, most Round 2 States reported non-detections as zeros resulting in a modal MRL value of zero. By definition the MRL cannot be zero. This is an artifact of State data management systems. Because a simple meaningful summary statistic is not available to describe the various reported MRLs, and to avoid confusion, MRLs are not reported in the summary table (Table 3-4).

In Table 3-4, national occurrence is estimated by extrapolating the summary statistics for the 20-State cross-section to national numbers for systems, and population served by systems, from the *Water Industry Baseline Handbook, Second Edition* (USEPA, 2000). From the handbook, the total national number of community water systems (CWSs) plus non-transient, non-community water systems (NTNCWSs) is 65,030, and the total population served by CWSs plus NTNCWSs is 213,008,182 persons (see Table 3-4). To generate the estimate of national occurrence based on the cross-section occurrence findings, the national number of PWSs (or population served by PWSs) is simply multiplied by the percentage value for the particular cross section occurrence statistic (e.g. the national estimate for the total number of PWSs with detections (57,299) is the product of the total national number of PWSs (65,030) and the percentage of PWSs with detections (88.1%)).

Because the State data used for the cross-section are not a strict statistical sample, national extrapolations of these Stage 1 analytical results can be problematic. For this reason, the nationally extrapolated estimates of occurrence based on Stage 1 results are not presented in the Federal Register Notice. The presentation in the Federal Register Notice of only the actual results of the cross-section analysis maintains a straight-forward presentation, and the integrity of the data, for stakeholder review. The nationally extrapolated Stage 1 occurrence values are presented here, however, to provide additional perspective. A more rigorous statistical modeling effort, the Stage 2 analysis, could be conducted on the cross-section data (Cadmus, 2001). The Stage 2 results would be more statistically robust and more suitable to national extrapolation. This approach would provide a probability estimate and would also allow for better quantification of estimation error.

3.3.1.5 Supplemental CMR State Data

Occurrence data on sulfate submitted directly with other drinking water occurrence data by the States of Alabama, California, Illinois, Montana, New Jersey, and Oregon, for the independent analysis *A Review of Contaminant Occurrence in Public Water Systems* (USEPA, 1999d), was used to augment the SDWIS/FED Round 2 occurrence analysis. These State supplemental CMR data provide additional perspective on sulfate occurrence as five of the six States were not represented in the 20-State cross-section. These CMR State data are also compared to the 20-State SDWIS/FED cross-section. *A Review of Contaminant Occurrence in Public Water Systems* supported occurrence analyses for EPA's Chemical Monitoring Reform (CMR) evaluation, and is therefore referred to in this document as the CMR report.

The occurrence data for sulfate used in the CMR analysis were submitted by States for an independent review of the occurrence of regulated contaminants in PWSs at various times for different programs (USEPA, 1999d). In the USEPA (1999d) review, occurrence data from a total of 14 States were noted. However, because several States contained data that were incomplete or unusable for various reasons, only 12 of the 14 States were used for a general overview analysis. From these 12 States, eight were selected for use in a national analysis because they provided the best data quality and completeness, and a balanced national cross-section of occurrence data. These eight States were Alabama, California, Illinois, Michigan, Montana, New Jersey, New Mexico, and Oregon. The CMR 8-State cross-section was developed in the same manner as, and was the model for, the 20-State Round 2 cross-section (see Sections 3.3.1.2, 3.3.1.3, and 3.3.1.4 for description).

Only the Alabama, California, Illinois, Montana, New Jersey, and Oregon State data sets contained occurrence data for sulfate. These results are presented in Table 3-5 and are described in section 3.3.2.2. The data represent more than 38,000 analytical results from about 5,800 PWSs mostly during the period from 1993 to 1997, though some earlier data are also included. The number of sample results and PWSs vary by State, however, with some States having considerably more data.

3.3.2 Results

3.3.2.1 Occurrence Estimates from SDWIS/FED Round 2 Data

The percentages of SDWIS/FED Round 2 PWSs with detections are high, as should be expected for sulfate (Table 3-4). The cross-section findings indicate that 88% of PWSs (57,299 PWSs nationally) experienced detections of sulfate above the MRL, affecting 95% of the population served (about 202 million people nationally). Occurrence analyses are also provided relative to the Health Reference Level of 500 mg/L; 1.8% of PWSs reported detections above the HRL. These statistics indicate that nationally, about 1,163 PWSs would be affected by sulfate levels greater than the HRL of 500 mg/L (affecting approximately 2 million people).

Surface and ground water PWSs show similar detection frequencies for sulfate for all concentration thresholds evaluated (> MRL, >½ HRL, and > HRL). The median concentration of all samples is 24 mg/L and the 99th percentile concentration of all samples is 560 mg/L.

The Round 2 national cross-section shows a proportionate balance in PWS source waters and population served, compared to the national inventory. Nationally, 91% of PWSs use ground water (and 9% surface waters); the Round 2 cross-section also shows 91% use ground water (and 9% surface waters). The relative populations served are almost as comparable. Nationally, about 40% of the population is served by PWSs using ground water (and 60% by surface water). For the Round 2 cross-section, 39% of the cross-section population is served by ground water PWSs (and 61% by surface water). The resultant national extrapolation is affected by this slight disproportion, so that adding the national extrapolation of an occurrence parameter for just ground water PWSs to the same parameter for just surface water PWSs does not always produce the national extrapolation for *all* PWSs.

3.3.2.2 Occurrence Estimates from the CMR State Data

Drinking water data for sulfate from the CMR States vary among States (Table 3-5). The number of systems with sulfate data for Illinois is far less than the number of PWSs in the State. Hence, it is not clear how representative these data are. Alabama, California, Montana, New Jersey, and Oregon have substantial amounts of data and PWSs represented.

Sulfate detections by PWS range from about 83% in Oregon to 93% in California (Table 3-5). Detection frequencies are relatively evenly distributed between surface water and ground water systems. These figures agree with simple sulfate detection frequencies from the SDWIS/FED Round 2 cross-section where an average of 88% of PWSs experienced detections greater than the MRL with surface water and ground water detections were similar. The variability of SDWIS/FED Round 2 detections, with a range of 4.5% to 100% detections (Table 3-4), is greater than that for the CMR data. However, comparisons made between data for simple detections need to be viewed with caution because of differences in MRLs between the CMR State data sets and the SDWIS/FED Round 2 data set, as well as differences in MRLs between the CMR States and the SDWIS/FED Round 2 States themselves (see Section 3.3.1.4).

Simple sulfate detection frequencies (i.e., >MRL)are significantly higher than detection frequencies of levels greater than the HRL. At the HRL of 500 mg/L, data from the CMR States indicate PWS exceedances from 0% to 6.32%. The SDWIS/FED Round 2 range of PWS detections greater than the HRL of 500 mg/L is quite comparable (0%-5.24%), with an average of 1.79%

Population figures for the CMR States are incomplete, and are only reported for those systems in the database that have reported their population data. For sulfate, approximately 85% of the PWSs reporting occurrence data for these 6 States also reported population data.

3.3.2.3 Cross-Section Comparisons

An important comparison can be made between the two cross-sections analyzed in this report. The 20-State cross-section of SDWIS/FED Round 2 data was used in Table 3-4 to extrapolate national estimates of sulfate occurrence. The cross-section States were chosen based on geographic coverage and relative pollution potential distribution. The 8-State CMR cross-section of States were chosen in the same manner (USEPA, 1999d). Significantly, of the 6 States that reported data for sulfate in the 8-State CMR cross-section, only one (Oregon) was part of the 20-State SDWIS/FED cross-section.

Sulfate detection frequencies from these two cross-sections are very similar (Table 3-6). For PWSs with simple detections (concentrations > MRL), the 20-State cross-section detection frequencies are consistently about two percent less than the corresponding 8-State cross-section detection frequencies, suggesting a possible variation in MRLs. For PWSs with detections greater than the HRL of 500 mg/L, the 20-State cross-section and the 8-State cross-section differ by less than 1% in all instances.

The proportion of ground water PWSs compared to surface water PWSs for the 20-State SDWIS/FED and the 8-State CMR cross-sections are also almost identical; 91% ground water (9% surface water) and 90% ground water (10% surface water), respectively.

Table 3-4: Summary occurrence statistics for sulfate

Frequency Factors	20 State Cross-Section[1] (Round 2)	National System & Population Numbers[2]
Total Number of Samples	40,484	–
Percent of Samples with Detections	87.0%	–
Health Reference Level	500 mg/L	–
Minimum Reporting Level (MRL)	Variable[3]	–
99[th] Percentile Concentration of all Samples	560 mg/L	–
Median Concentration of all Samples	24 mg/L	–
Total Number of PWSs	16,495	65,030
Number of GW PWSs	15,009	59,440
Number of SW PWSs	1,486	5,590
Total Population	50,370,291	213,008,182
Population of GW PWSs	19,649,749	85,681,696
Population of SW PWSs	30,720,542	127,326,486
Occurrence by System		**National Extrapolation[4]**
% PWSs with detections (> MRL)	88.1%	57,299
Range of Cross-Section States	4.5-100%	N/A
GW PWSs with detections	87.8%	52,165
SW PWSs with detections	91.7%	5,124
% PWSs > 1/2 Health Reference Level (HRL) (500 mg/L)	4.97%	3,229
Range of Cross-Section States	0-11.1%	N/A
GW PWSs > 1/2 HRL	4.61%	2,741
SW PWSs > 1/2 HRL	8.55%	478
% PWSs > HRL (500 mg/L)	1.79%	1,163
Range of Cross-Section States	0-5.24%	N/A
GW PWSs > HRL	1.83%	1,085
SW PWSs > HRL	1.41%	79
Occurrence by Population Served		
% PWS Population Served with detections	95.1%	202,468,000
Range of Cross-Section States	4.56 - 100%	N/A
GW PWS Population with detections	94.0%	80,533,000
SW PWS Population with detections	95.7%	121,890,000
% PWS Population Served > 1/2 HRL (500 mg/L)	10.2%	21,791,000
Range of Cross-Section States	0 - 36.1%	N/A
GW PWS Population > 1/2 HRL	5.29%	4,532,000
SW PWS Population > 1/2 HRL	13.4%	17,049,000
% PWS Population Served > HRL (500 mg/L)	0.89%	1,887,000
Range of Cross-Section States	0 - 33.5%	N/A
GW PWS Population > HRL	1.61%	1,383,000
SW PWS Population > HRL	0.42%	535,000

1. Summary Results based on data from 20-State Cross-Section, from SDWIS/FED, UCM (1993) Round 2.
2. Total PWS and population numbers are from EPA March 2000 Water Industry Baseline Handbook (USEPA, 2000).
3. See Section 3.3.1.4 for discussion.
4. National extrapolations are from the 20-State data using the Baseline Handbook system and population numbers.
- PWS = Public Water Systems; GW = Ground Water; SW = Surface Water; MRL = Minimum Reporting Level (for laboratory analyses); HRL = Health Reference Level, an estimated health effect level used for preliminary assessment for this review; N/A = Not Applicable
- Total Number of Samples = the total number of analytical records for sulfate
- 99th Percentile Concentration = the concentration value of the 99th percentile of all analytical results (in mg/L)
- Median Concentration of Detections = the median analytical value of all the analytical results (in mg/L)
- Total Number of PWSs = the total number of public water systems with records for sulfate
- Total Population Served = the total population served by public water systems with records for sulfate
- % PWS with detections, % PWS > ½ Health Reference Level, % PWS > Health Reference Level = percent of the total number of public water systems with at least one analytical result that exceeded the MRL, ½ Health Reference Level, Health Reference Level, respectively

Table 3-5: Occurrence summary by State for sulfate (CMR data)

Frequency Factors	Alabama	California	Illinois	Montana	New Jersey	Oregon
Total Number of Samples	1,545	29,050	280	1,565	5,055	1,346
Number of Ground Water Samples	1,132	26,682	210	1,343	4,446	804
Number of Surface Water Samples	413	2,368	70	222	609	542
Percent of Samples with Detections	90.5%	95.7%	86.4%	86.9%	86.9%	77.0%
Percent of Ground Water Samples with Detections	87.8%	95.6%	81.9%	86.8%	85.7%	79.1%
Percent of Surface Water Samples with Detections	97.8%	96.2%	100.0%	87.4%	96.1%	73.8%
99th Percentile Concentration (all samples)	72 mg/L	523 mg/L	760 mg/L	1,200 mg/L	260 mg/L	79 mg/L
Median Concentration (all samples)	8.1 mg/L	33 mg/L	60 mg/L	22 mg/L	15.9 mg/L	5.13 mg/L
Minimum Reporting Level (MRL)	Variable[1]	Variable[1]	Variable[1]	Variable[1]	Variable[1]	Variable[1]
Total Number of PWSs	547	2,195	195	775	1,443	656
Number of Ground Water PWSs	478	1,977	128	722	1,410	507
Number of Surface Water PWSs	69	218	67	53	33	149
Occurrence by System						
% PWSs with detections (> MRL)	90.9%	93.4%	87.2%	88.4%	88.6%	82.9%
Ground Water PWSs with detections	89.5%	93.4%	80.5%	88.1%	88.4%	81.1%
Surface Water PWSs with detections	100.0%	93.1%	100.0%	92.5%	97.0%	89.3%
Health Reference Level (HRL) = 500 mg/L						
% PWSs > 1/2 HRL	0.18%	10.4%	7.18%	12.5%	1.59%	0.15%
Ground Water PWSs > 1/2 HRL	0.00%	10.9%	10.9%	12.5%	1.42%	0.20%
Surface Water PWSs > 1/2 HRL	1.45%	5.96%	0.00%	13.2%	9.09%	0.00%
% PWSs > HRL	0.00%	2.69%	3.08%	6.32%	0.69%	0.00%
Ground Water PWSs > HRL	0.00%	2.98%	4.69%	6.23%	0.57%	0.00%
Surface Water PWSs > HRL	0.00%	0.00%	0.00%	7.55%	6.06%	0.00%
Occurrence by Population Served						
% PWS Population Served with detections	99.9%	99.9%	95.8%	95.9%	99.2%	93.7%
Ground Water PWS Population with detections	97.2%	99.8%	86.1%	93.8%	98.0%	85.2%
Surface Water PWS Population with detections	100.0%	99.9%	100.0%	97.9%	100.0%	96.8%
Health Reference Level (HRL) = 500 mg/L						
% PWS Population Served > 1/2 HRL	0.23%	50.7%	1.59%	10.2%	12.0%	0.00%
Ground Water PWS Population > 1/2 HRL	0.00%	43.9%	5.19%	15.5%	0.52%	0.01%
Surface Water PWS Population > 1/2 HRL	0.13%	57.0%	0.00%	5.34%	19.4%	0.00%
% PWS Population Served > HRL	0.00%	22.6%	0.67%	4.33%	11.7%	0.00%
Ground Water PWS Population > HRL	0.00%	34.4%	2.11%	5.41%	0.11%	0.00%
Surface Water PWS Population > HRL	0.00%	0.00%	0.00%	3.33%	19.2%	0.00%

[1] *See Section 3.3.1.4 for details*

- PWS = Public Water Systems; GW = Ground Water; SW = Surface Water; MRL = Minimum Reporting Level (for laboratory analyses); HRL = Health Reference Level, an estimated health effect level used for preliminary assessment for this review; N/A = Not Applicable

- Total Number of Samples = the total number of analytical records for sulfate

- 99th Percentile Concentration = the concentration value of the 99th percentile of all analytical results (in mg/L)

- Median Concentration of Detections = the median analytical value of all the analytical results (in mg/L)

- Total Number of PWSs = the total number of public water systems with records for sulfate

- Total Population Served = the total population served by public water systems with records for sulfate

- % PWS with detections, % PWS > ½ Health Reference Level, % PWS > Health Reference Level = percent of the total number of public water systems with at least one analytical result that exceeded the MRL, ½ Health Reference Level, Health Reference Level, respectively

Table 3-6: 20-State SDWIS/FED Round 2 cross-section compared to the 8-State CMR cross-section for sulfate[1]

	20-State Cross-Section[2]	8-State Cross-Section[3]
Total Number of PWSs	16,495	5,973
Number of GW PWSs	15,009	5,381
Number of SW PWSs	1,486	592
% PWSs with detections (> MRL)	88.1%	90.3%
GW PWSs with detections	87.8%	89.9%
SW PWSs with detections	91.7%	93.9%
% PWSs with detections > 500 mg/L	1.8%	2.1%
GW PWSs > 500 mg/L	1.8%	2.2%
SW PWSs > 500 mg/L	1.4%	1.0%

[1] Only six States reported data for sulfate in the 8-State cross-section.
[2] Summary Results based on data from 20-State Cross-Section, from SDWIS/FED, UCM (1993) Round 2; see Table 3-4 and Section 3.3.1.1.
[3] after USEPA, 1999d; see Table 3-5 and Section 3.3.1.5.

3.4 Conclusion

Low-level sulfate occurrence in ambient waters monitored by the USGS NAWQA program is ubiquitous, with detections approaching 100% of all surface and ground water sites. The percent samples with detections are similarly high for all surface and ground water sites. Forest/rangeland basins show the lowest frequency of HRL exceedances, median concentrations, and 99th percentile concentrations across all land use categories, for both surface and ground waters. HRL exceedances and 99th percentile concentrations are generally greatest in urban basins, while median concentrations are similar for urban, mixed, and agricultural basins. Although sulfate detection frequencies are high in surface and ground waters, sulfate occurrence at levels of public health concern is low.

Sulfate has been detected in a high percentage of PWS samples collected under SDWA. Occurrence estimates from SDWIS/FED Round 2 data are very high, with 87% of all samples showing detections. The median concentration of all samples is 24 mg/L and the 99th percentile concentration of all samples is 560 mg/L. Systems with detections constitute 88% of Round 2 cross-section systems. National estimates for the population served by PWSs with detections are very high: about 202 million people (95% of the national PWS population). At the HRL of 500 mg/L, approximately 2% of PWSs, serving about 2 million people nationally, use water with sulfate levels above the HRL.

Additional CMR data from the States of Alabama, California, Illinois, Montana, New Jersey, and Oregon were examined through independent analyses and also show high levels of sulfate occurrence. Systems with detections constitute between 83%-93% of systems from the six CMR States with sulfate data. Approximately 0%-23% of the CMR populations are served by systems with sulfate detections greater than the HRL of 500 mg/L. A comparison between the 20-State SDWIS/FED national cross-

section and the CMR 8-State national cross-section shows very similar results for sulfate detection frequencies in public water systems.

4.0 HEALTH EFFECTS

A description of the health effects and the available dose-response information associated with exposure to sulfate is summarized below. For more detailed information, please see *Drinking Water Advisory: Consumer Acceptability Advice and Health Effects Analysis on Sulfate* (USEPA, 2001c).

4.1 Hazard Characterization and Mode of Action Implications

Most data on human responses to sulfate are based on short-term exposure that are obtained from controlled settings (i.e., studies and experimental trials). Reports on long-term exposure are based on responses to questionnaires in North Dakota and South Dakota, States with high sulfate concentrations in their drinking water supply. Data from animal studies on the reproductive, developmental, and carcinogenic effects are available for both short-term and long-term exposures to sulfate.

The data from human studies demonstrate that sulfate induces a laxative effect following acute exposures of concentrations greater than 500 mg/L (Anderson and Stothers, 1978; Fingl, 1980; Schofield and Hsieh, 1983; Stephen et al., 1991; Cochetto and Levy, 1981; Gomez et al., 1995; Heizer et al., 1997; USEPA, 1999f). However, the severity of the laxative effect that occurs from acute sulfate exposures may be dependent on the sulfate salt, as well as how the dose is administered. For instance, magnesium sulfate exerts a stronger laxative effect than sodium sulfate because magnesium sulfate is absorbed less completely, and therefore has a more pronounced effect on the osmolality of the intestinal contents (Morris and Levy, 1983b). Additionally, a single dose of sulfate that produces a laxative effect does not have the same effect as when divided and administered in intervals (Cochetto and Levy, 1981).

Since humans appear to develop a tolerance to drinking water with high sulfate concentrations, chronic exposures do not appear to produce the same laxative effect as seen in acute exposures (Schofield and Hsieh, 1983). While it is not known when this acclimation occurs in adults, researchers believe that acclimation occurs within 7 to 10 days. In a 90-day study, rats who were administered mineral waters containing up to 1,595 mg/L of sulfate showed no soft feces or diarrhea, indicating rapid acclimation (Wurzner 1979). However, earlier reports have shown that chronic exposure to high sulfate concentrations in drinking water does have laxative effects in humans (Peterson, 1951; Moore, 1952; Cass, 1953). These reports are subject to response bias, however, since the data used was based on questionnaires. For example, an inquiry on the questionnaire about the laxative effect (that requested a YES or NO response) is subject to a respondent's interpretation of a laxative effect. Furthermore, sulfate was probably not the only contaminant found in the drinking water.

High sulfate concentrations do not appear to exert adverse reproductive or developmental effects. Following the ingestion of drinking water containing up to 5,000 mg/L of sulfates by mice and pigs, no reproductive effects were observed (Andres and Cline, 1989). Furthermore, no adverse developmental effects were observed following the administration of 2,800 mg/kg/day of sulfate to pregnant mice (Seidenberg et al., 1986).

No tumor development was observed in a limited-duration study done on rats injected intramuscularly with sodium every other day for 4 weeks (Kasprazak et al., 1980). Because of the short-term experimental protocol and the injection route of exposure, it is impossible to draw conclusions on the

potential carcinogenicity of sulfate. Because of the limited data, EPA has classified sulfate in Group D, or not classified as to human carcinogenicity (1993). This category is reserved for contaminants with inadequate evidence to support a determination on carcinogenicity.

4.2 Dose-Response Characterization and Implications in Risk Assessment

Although several studies have been conducted on the long-term exposure of humans to sulfate in drinking water, none of them can be used to derive a dose-response characterization (Peterson, 1951; Moore, 1952; Cass, 1953). These studies utilized data collected from the North Dakota Department of Health Survey, which was administered over a period of several years to determine the mineral content of the drinking water and any correlated health effects (Moore, 1952). An increasing trend was observed in the number of persons reporting laxative effects as sulfate concentrations increased (i.e., 22, 24, 33 and 69 percent for sulfate concentrations 0–200, 200–500, 500–1,000 and >1,000 mg/L, respectively). However, the results of these studies cannot be used to derive a dose-response characterization for the following reasons: (1) the results are based on recall with little scientific weight (i.e., sulfate may have induced the laxative effects, but it cannot be proven), and (2) the water samples had varying concentrations of magnesium and total dissolved solids in addition to sulfate. No laxative effects were observed in rats or heifers following long-term exposure to sulfate in drinking water (Wurzner, 1979; Digesti and Weeth, 1976).

Because sulfate appears to exert its laxative effect with short-term as opposed to long-term exposures, several short exposure studies were reviewed. Two short-term studies were identified that evaluated the effect of various sulfate concentrations on bowel function in a controlled environment, one in humans and one in animals. In the multiple dose study, sulfate concentrations of 0, 400, 600, 800, 1,000 and 1,200 mg/L were given to four subjects (2 men and 2 women) for six consecutive 2-day periods (Heizer et al., 1997). A significant trend was only observed for a decreasing mouth-to-anus appearance time for chemical markers with increasing sulfate concentration. For a single dose study by the same researchers, 6 adults (3 men and 3 women) received drinking water with sulfate concentrations of 0 or 1,200 mg/L for two consecutive 6-day periods. A statistically significant increase in mean stool mass per 6-day pool and in mean stool mass per hour were observed with the higher dose. However, none of the subjects reported diarrhea.

In a study where neonatal piglets were exposed to various concentrations of sulfate to simulate the effect of inorganic sulfate on the bowel function in infants, no diarrhea was observed in any of the piglets at 0 and 1,200 mg/L concentrations (Gomez et al., 1995). However, concentrations greater than 1,200 mg/L resulted in an increased prevalence of diarrhea, while concentrations greater than 1,800 mg/L resulted in persistent, nonpathogenic diarrhea.

The studies discussed above suggest that there is a risk for a laxative-related response to sulfate in drinking water at concentrations greater than 1,000 mg/L (USEPA, 1999f; Heizer et al., 1997; Moore, 1952). The observed effect is a response to changes in the net osmolality of the intestinal contents, and thus is influenced not only by sulfate intake, but also by the presence of other osmotically active materials in the drinking water or diet, and the temporal pattern of sulfate ingestion. The laxative effect of sulfate can be manifest as an increase in stool mass, increased stool moisture, and decreased intestinal transit time, and/or frank diarrhea. The tendency for a frank diarrheal response increases with increased osmolality of the intestinal contents, and therefore, with the amount of sulfate ingested.

At this time, it is not possible to characterize a dose-response relationship for laxative effects of short-term or long-term exposure to sulfate based on the available data. A Centers for Disease Control and

Prevention (CDC) panel favored a Health Advisory for sulfate drinking water levels of 500 mg/L or greater (USEPA, 1999e). The Advisory was designed to prevent osmotic diarrhea in infants. The panelists referred to the study by Chien et al. (1968) which found that sulfate levels greater than 630 mg/L caused diarrhea in infants. It should be noted that this effect was observed after the infants had ingested formula made with water containing sulfate and other osmotically active agents: the total dissolved solid concentration of the water used to prepare infant formulas was high, from 2,424 to 3,123 mg/L. The CDC further stated that 500 mg/L seemed to be a safe sulfate level because 500 mg/L was shown to be safe in all reviewed studies.

4.3 Relative Source Contribution

There is limited data on dietary exposure to inorganic sulfate. A study of per capita sulfate exposure, from data on the use of sulfate additives by the food industry, estimates an average of 453 mg/day (FASEB, 1975). The median exposure to sulfates in drinking water is 48 mg/day for an adult drinking 2 L of water per day. Abernathy (2000) estimates that sulfate exposure from ambient air averages 0.4 mg/day given high end median air concentration. Under these conditions, food is the major source of sulfate exposure, comprising 90% of the total. However, under conditions where the water concentration is at the 99th percentile level of all samples, or 560 mg/L, and where the dietary and inhalation exposures remain constant, drinking water is the major source of sulfate exposure, contributing 70% of the total.

Sulfate has little tendency to bioaccumulate through the food chain. Biologically, sulfate is incorporated into complex carbohydrates by animal systems or reduced and used for the synthesis of the sulfur-containing amino acids by microbial, plant and animal systems. Mammalian systems also conjugate a number of xenobiotics with sulfate for excretion. Dissolved sulfate ion is removed by the excretion in urine.

4.4 Sensitive Populations

Anecdotal data suggest that visitors to an area with high sulfate concentrations in the water may be more sensitive than the local population. Acclimatization appears to occur approximately one week after first water use. However, even permanent residents would experience an increase in their risk for diarrhea if the water were used to prepare a beverage that contained additional osmotically active materials. Thus, formula fed infants and invalids or elderly patients who use nutritional supplements prepared with tap water could be more likely to experience laxative effects from the sulfate in the drinking water than other individuals. In high sulfate areas, the use of bottled water for preparation of formula or nutritional supplements could significantly reduce the risk of osmotic diarrhea.

4.5 Exposure and Risk Information

Estimates of the total exposed population, as well as the population exposed above the Health Reference Level (HRL) receive the highest consideration in determining whether a regulation would provide a meaningful opportunity to reduce risk. The HRL for sulfate is 500 mg/L (see Section 3.3.1.4). Estimates of the populations exposed and the levels to which they are exposed are derived from the monitoring results, presented in Section 3.3.2, and are summarized below.

Approximately 95% of the population served by public water systems (PWSs), about 202 million people nationally, are exposed to sulfate concentrations above the minimum reporting level. However, only 1.8% of the PWS-served population, about 2 million people nationally, are exposed to levels greater than 500 mg/L. The median concentration of all samples is 24 mg/L and the 99th percentile concentration

of all samples is 560 mg/L. One of the six States (Montana) that provided supplemental (CMR) data for the independent analysis, *A Review of Contaminant Occurrence in Public Water Systems*, had a 99th percentile level of 1,200 mg/L. However, Montana's median concentration was 22 mg/L, well below the health and taste threshold.

The EPA is required to consider both the general public and sensitive populations, including the fetus, infants, and children, in making its regulatory determination. Thus, identification and characterization of sensitive populations are an important component of the regulatory determination. Then, the EPA must carefully consider whether a national drinking water regulation can achieve any risk reduction for such populations. There are some instances where the therapeutic course of treatment for a genetic or physiological disorder renders the risk from exposure through drinking water inconsequential. For example, in cases where individuals undergoing dialysis for renal disorders are identified as a sensitive population, the risk would not be significantly reduced by regulation since the primary control of risk would be by way of the dialysis process.

4.6 Conclusion

The estimated population exposed at concentrations of possible health concern is relatively small. Furthermore, the critical health effect of sulfate, a laxative effect, is generally temporary and reversible. Persons exposed repeatedly to water from affected systems seem to adjust to the sulfate in the drinking water within a week or so of initial exposure. Effective, low-cost risk management options, such as use of bottled water or minimization of the amount of water consumed at one time, is available for transient visitors to an affected area. For these reasons, it is unlikely that the regulation of sulfate represents a meaningful opportunity for health risk reduction for persons served by public water systems. All preliminary CCL regulatory determinations and further analysis will be presented in the *Federal Register* Notice.

5.0 TECHNOLOGY ASSESSMENT

If a determination has been made to regulate a contaminant, SDWA requires development of proposed regulations within 2 years of making the decision. It is critical to have suitable monitoring methods and treatment technologies to support regulation development according to the schedules defined in the SDWA.

5.1 Analytical Methods

The availability of analytical methods does not influence EPA's determination of whether or not a CCL contaminant *should* be regulated. However, before EPA actually regulates a contaminant and establishes a Maximum Contaminant Level (MCL), there must be an analytical method suitable for routine monitoring. Therefore, EPA needs to have approved methods available for any CCL regulatory determination contaminant before it is regulated with an NPDWR. These methods must be suitable for compliance monitoring, and should be cost effective, rapid, and easy to use.

Sulfate is an unregulated contaminant for which monitoring was required under the Unregulated Contaminant Monitoring Program (USEPA, 1987; 52 FR 25690). Monitoring for sulfate was initiated through rulemaking in 1992 (USEPA, 1992a; 57 FR 31776), and began in 1993. Sulfate has well-documented analytical methods developed specifically for low-level drinking water analyses (see Table 5-1).

Table 5-1: Analytical methods for sulfate

Method	Type	Method Detection Limit (µg/L)
EPA 300.0	Ion Chromatography	20
ASTM D4327-91	Ion Chromatography	Test Range of method 2,850-95,000
SM 4110 B	Ion Chromatography	Minimum detectable conc. 100
EPA 375.2	Automated Colorimetry	500
SM 4500-SO_4^{2-} C	Automated Methylthymol Blue Method	Conc. ranges from 10,000 to 30,000
SM 4500-SO_4^{2-} C	Gravimetric Method with Ignition of Residue	Suitable for conc. >10,000
SM 4500-SO_4^{2-} C	Gravimetric Method with Drying of Residue	Suitable for conc. >10,000

5.2 Treatment Technology

Treatment technologies also do not influence the determination decision. But before a contaminant can be regulated with an NPDWR, treatment technologies must be readily available. Sulfate is one of three inorganic contaminants listed as Regulatory Determination Priorities on the CCL. The treatment data for these inorganic compounds was obtained from technology and cost documents, Office for Research and Development's National Risk Management Research Laboratory (NRMRL) Treatability Database, and published studies. The technologies reviewed include conventional treatment, ion exchange, reverse osmosis, lime softening, and chemical precipitation.

Conventional treatment usually includes pre-treatment steps of chemical coagulation, rapid mixing, and flocculation, followed by floc removal via sedimentation or flotation. After clarification, the water is then filtered. Common filter media include sand, dual- and tri-media (e.g. silica sand, garnet sand, or anthracitic coal).

Ion exchange involves the selective removal of charged inorganic species from water using an ion-specific resin. The surface of the ion exchange resin contains charged functional groups that hold ionic species by electrostatic attraction. As water containing contaminant ions passes through a column of resin beds, charged ions on the resin surface are exchanged for the contaminant species in the water.

Reverse osmosis (RO) is similar to other membrane processes, such as ultrafiltration and nanofiltration, since water passes through a semi-permeable membrane. However, in the case of RO, the principle involved is not filtration. Instead, it involves the use of applied hydraulic pressure to oppose the

osmotic pressure across a non-porous membrane, forcing the water from the concentrated solution side to the dilute solution side. The water does not travel through pores, but rather dissolves into the membrane, diffuses across, then dissolves out into the permeate. Most inorganic and many organic contaminants are rejected by the membrane and will be retained in the concentrate.

In the lime-softening process, the pH of the water being treated is raised sufficiently to precipitate calcium carbonate and, if necessary, magnesium hydroxide. Calcium and magnesium ions in water cause hardness. After mixing, flocculation, sedimentation, and pH readjustment, the softened water is filtered.

Results of a preliminary technology assessment and review indicate that ion exchange and reverse osmosis are the most successful techniques for removing sulfate from water, though chemical precipitation is also effective. No data are available for the efficacy of using conventional treatment or lime softening to remove sulfate from water.

6.0 SUMMARY AND CONCLUSIONS - DETERMINATION OUTCOME

Three statutory criteria are used to guide the preliminary determination of whether regulation of a CCL contaminant is warranted: 1) the contaminant may adversely affect the health of persons; 2) the contaminant is known or is likely to occur in public water systems with a frequency, and at levels, of public health concern; and 3) regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems. As required by SDWA, a decision to regulate a contaminant commits the EPA to propose a Maximum Contaminant Level Goal (MCLG) and promulgate a National Primary Drinking Water Regulation (NPDWR) for the contaminant. A decision not to regulate a contaminant is considered a final Agency action and is subject to judicial review. The Agency can choose to publish a Health Advisory (a nonregulatory action) or other guidance for any contaminant on the CCL that does not meet the criteria for regulation.

Sulfate in drinking water at concentrations greater than 500 mg/L appears to have a short-term laxative effect. If other osmotically active materials are not present, the effect is usually not seen unless sulfate concentration exceeds 1000 mg/L. The laxative effect can be manifested as an increase in stool mass, increased stool moisture, decreased intestinal transit time, and/or frank diarrhea. Recovery from laxative effects is rapid and complete, and acclimation to high levels of sulfates seems to occur within one week. Available data do not indicate developmental or reproductive effects from long-term exposure. Carcinogenicity of sulfate cannot be determined from available health effects data.

Available occurrence data show that sulfate is occasionally present in potable water supplies at concentrations that can produce a laxative effect. Nationwide, the 99th percentile concentration of sulfate was 560 mg/L, greater than the Health Reference level (HRL) of 500 mg/L. Although such concentrations are not likely to produce a laxative effect alone, they may be combined with other osmotically active materials such as in infant formula preparation, creating a stronger laxative effect. Therefore, the contaminant is known to occur in public water systems and at levels of public health concern. However, the population exposed at concentrations of possible health concern is relatively small.

To make its regulatory evaluation, the EPA looks at total exposed population, as well as population exposed to levels above the estimated HRL. To evaluate risk from exposure through drinking water, the EPA compares net environmental exposure to drinking water exposure. EPA also considers exposure to both the general public and sensitive populations, including fetuses, infants, and children. Approximately

202,464,000 people are served by systems with detections greater than the minimum reporting level, but only 1,887,000 are exposed to concentrations above the HRL, and 490,000 above the concentrations that are most likely to have a laxative effect when other osmotically active materials are not present (>1000 mg/L). At median water concentrations, food comprises 90% of sulfate exposure, but at the 99th percentile level of 560 mg/L, water contributes 70% of total exposure. Sensitive populations include visitors, formula-fed infants, and those who consume nutritional supplement drinks from powdered preparations. In high sulfate areas, use of bottled water for sensitive populations could significantly reduce the risk of laxative effects.

Available data indicate that regulation of sulfate would not present a meaningful opportunity for health risk reduction. The population exposed at concentrations of possible health concern is relatively small. The critical health effect is generally temporary and reversible. Those exposed chronically to water high in sulfate tend to adjust within a week of initial exposure, or reduce their intake because of taste in the water. To manage risk, sensitive populations can use bottled water during visits or to prepare formula and supplement drinks. EPA is issuing an advisory to provide guidance to communities that may be exposed to drinking water contaminated with high sulfate concentrations. All preliminary CCL regulatory determinations and further analysis are presented in the *Federal Register* Notice.

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Appendix A: Abbreviations and Acronyms

CCL	- Contaminant Candidate List
CDC	- Center for Disease Control and Prevention
CMR	- Chemical Monitoring Reform
CWS	- Community Water System
EPA	- Environmental Protection Agency
FR	- Federal Register
g/mol	- grams per mole
GW	- ground water
HA	- Health Advisory
HAL	- Health Advisory Level
HRL	- Health Reference Level
IOC	- inorganic compound
L	- liters
mg	- milligrams
MCL	- Maximum Contaminant Level
MCLG	- Maximum Contaminant Level Goal
MDL	- Method Detection Limit
MRL	- Minimum Reporting Level
NAWQA	- National Water Quality Assessment Program
NCOD	- National Drinking Water Contaminant Occurrence Database
NDWAC	- National Drinking Water Advisory Council
NIRS	- National Inorganic and Radionuclide Survey
nm	- nanometer
NPDWR	- National Primary Drinking Water Regulation
NRMRL	- National Risk Management Research Laboratory
NTNCWS	- Non-Transient Non-Community Water System
OGWDW	- Office of Ground Water and Drinking Water
ORD	- Office of Research and Development
PGWD	- Pesticides in Ground Water Database
pH	- the negative log of the concentration of H^+ ions
ppm	- part per million
PWS	- Public Water System
RO	- reverse osmosis
SDWA	- Safe Drinking Water Act
SDWIS/FED	- the Federal Safe Drinking Water Information System
SMCL	- Secondary Maximum Contaminant Level
SOC	- synthetic organic compound
SW	- surface water
SWP	- surface water - purchased
UCM	- Unregulated Contaminant Monitoring
UCMR	- Unregulated Contaminant Monitoring Regulation/Rule
URCIS	- Unregulated Contaminant Monitoring Information System
USEPA	- United States Environmental Protection Agency
USGS	- United States Geological Survey
VOC	- volatile organic compound
WHO	- World Health Organization
µg	- micrograms

>MCL - percentage of systems with exceedances
>MRL - percentage of systems with detections