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Part II

Environmental Protection Agency

40 CFR Parts 141, 142, and 143

National Primary Drinking Water Regulations—Sulfate; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141, 142 and 143

[WH-FRL-5120-7]

RIN 2040-AC07

Drinking Water; National Primary Drinking Water Regulations—Sulfate; National Primary Drinking Water Regulation Implementation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: By this action, EPA is reproposing a maximum contaminant level goal (MCLG), and a National Primary Drinking Water Regulation (NPDWR) including a maximum contaminant level (MCL) for sulfate. There is a potential for an adverse health effect for infants, travelers, and new residents in areas that have high sulfate levels in their drinking water. The objective of this rule is to ensure that sulfate levels in drinking water provided by public water systems are reduced below levels of concern. The proposal contains alternatives that allow public water systems the flexibility to select compliance options appropriate to protect the population served.

DATES: Comments must be received on or before March 21, 1995. Comments received after this date may not be considered. A public hearing on the proposal will be held in Washington, DC on February 2, 1995 at the address listed below under **ADDRESSES.**

ADDRESSES: The Agency will hold a public hearing on the proposal at the following location: EPA Education Center Auditorium, 401 M Street SW., Washington, DC 20460, on February 2, 1995.

The hearing will begin at 9:30 am, with registration at 9 am. The hearing will end at 4 pm, unless concluded earlier. Anyone planning to attend the public hearing (especially those who plan to make statements) may register in advance by writing the Sulfate Public Hearing Officer, Office of Ground Water and Drinking Water (4603), USEPA, 401 M Street SW., Washington, DC 20460; or by calling Tina Mazzocchetti, (703) 931-4600. Oral and written comments may be submitted at the public hearing. Persons who wish to make oral presentations are encouraged to have written copies (preferably three) of their complete comments for inclusion in the official record.

Send written comments to the Sulfate Docket Clerk, Water Docket (MC-4101), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. Please submit any references cited in your comments. EPA would appreciate an original and three copies of your comments and enclosures (including references). Commenters who want EPA to acknowledge receipt of their comments should include a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted because EPA cannot ensure that they will be submitted to the Water Docket.

The proposed rule with supporting documents, including public comments and EPA responses to the Phase V rulemaking and this proposed rule, are available for review at the Water Docket at the address above. For access to Docket materials, call (202) 260-3027 between 9 am and 3:30 pm for an appointment.

FOR FURTHER INFORMATION CONTACT: The Safe Drinking Water Hotline, telephone 800-426-4791. The Hotline is open Monday through Friday, excluding Federal holidays, from 9 am to 5:30 pm Eastern Standard Time. For technical inquiries, contact Jude Andreasen, Drinking Water Standards Division, Office of Ground Water and Drinking Water (4603), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, 202-260-5555, or one of the EPA Regional Office contacts listed under Supplementary Information.

SUPPLEMENTARY INFORMATION: The Agency prefers that commenters type or print comments in ink, and cite, where possible, the paragraph(s) in this proposed regulation (e.g., § 141.32(b)) to which each comment refers. Commenters should use a separate paragraph for each issue discussed. Technical inquiries can be directed to the contacts in regional offices as follows:

I. JFK Federal Bldg., Room 2203, One Congress Street, 11th floor, Boston, MA 02203, Phone: (617) 565-3484, Jerome Healey
II. 26 Federal Plaza, Room 824, New York, NY 10278, Phone: (212) 264-1800, Walter Andrews
III. 841 Chestnut Street, Philadelphia, PA 19107, Phone: (215) 597-8826, Stuart Kerzner
IV. 345 Courtland Street, NE., Atlanta, GA 30365, Phone: (404) 347-2207, Wayne Aronson
V. 77 West Jackson Boulevard, Chicago, IL 60604, Phone: (312) 353-2151, Ed Watters
VI. 1445 Ross Avenue, Dallas, TX 75202, Phone: (214) 655-7150, Tom Love
VII. 726 Minnesota Ave., Kansas City, KS 66101, Phone: (913) 551-7032, Ralph Langemeier
VIII. One Denver Place, 999 18th Street, Suite 500, Denver, CO 80202-2466, Phone: (303) 293-1652, Patrick Crotty
IX. 75 Hawthorne Street, San Francisco, CA 94105, Phone: (415) 744-1817, Loretta Barsamian
X. 1200 Sixth Avenue, Seattle, WA 98101, Phone: (206) 553-4092, Kenneth Feigner

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Abbreviations Used in This Document

ASDWA: Association of State Drinking Water Administrators
BAT: Best Available Technology
BTGA: Best Technology Generally Available
CRAVE: Cancer Risk Assessment Verification Endeavor
CWS: Community Water System
DWEL: Drinking Water Equivalent Level
ED: Electrodialysis
EIA: Economic Impact Analysis
EPA: Environmental Protection Agency
FDA: Food and Drug Administration
FR: Federal Register
FRDS: Federal Reporting Data System
ICR: Information Collection Request
IE: Ion Exchange
IOC: Inorganic Chemical
IRIS: Integrated Risk Information System
LCP: Laboratory Certification Program
LOAEL: Lowest-Observed-Adverse-Effect Level
MCL: Maximum Contaminant Level (expressed as mg/L) (1,000 micrograms (μg) = 1 milligram (mg))
MCLG: Maximum Contaminant Level Goal
MDL: Method Detection Limit
NAS: National Academy of Science
NCWS: Non-Community Water System
NIRS: National Inorganics and Radionuclides Survey
NOA: Notice of Availability
NOAEL: No-Observed-Adverse-Effect Level
NOEL: No-Observed-Effect Level
NPDWR: National Primary Drinking Water Regulation
NTIS: National Technical Information Service
NTNCWS: Non-Transient Non-Community Water System
O&M: Operations & Maintenance
OMB: Office of Management and Budget
PE: Performance Evaluation
POE: Point-of-Entry Device
POU: Point-of-Use Device
PQL: Practical Quantitation Level
PWS: Public Water System
RFA: Regulatory Flexibility Analysis
RfD: Reference Dose
RIA: Regulatory Impact Analysis
RMCL: Recommended Maximum Contaminant Level
RO: Reverse Osmosis
RSC: Relative Source Contribution
RWS: Rural Water Survey
SDWA: Safe Drinking Water Act, or the "Act," as amended in 1986
SMCL: Secondary Maximum Contaminant Level
SMF: Standardized Monitoring Framework
SOC: Synthetic Organic Chemical
T&C: Technology & Costs
TWS: Transient Non-Community Water System
URTH: Unreasonable Risk To Health
VOC: Volatile Organic Chemical
WS: Water Supply

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I. Summary of Today's Action

Today the Agency is proposing an MCLG of 500 mg/L, an MCL of 500 mg/L, and other NPDWR requirements for sulfate. Sulfate is a unique contaminant for several reasons. The health effect associated with the ingestion of relatively high levels of sulfate in drinking water (i.e., ranging from loose stools to diarrhea) is acute and temporary, and is expected to last approximately two weeks. In addition, the health risk only applies to persons not already acclimated to high sulfate-containing water: infants, travelers, and new residents. (For the purposes of this rule, infants are defined as children up to the age of 12 months.) Today's proposed rule is also unique because it affects all public water systems, that is, community water systems, traveler non-community water systems, and non-transient, non-community water systems. In the past, only regulations on microbial contaminants and nitrate have affected transient, non-community systems.

EPA decided to defer promulgation of a sulfate standard, originally proposed July 25, 1990 (55 FR 30370) in order to identify an implementation approach which was tailored to the target populations. The approach EPA developed, working in cooperation with several States at a 1992 meeting, is innovative, and was designed specifically to provide flexibility to smaller systems. This approach could reduce compliance costs while still providing adequate protection of public health. It provides public water systems a means of compliance which is less expensive than central treatment, and it affords States flexibility in implementing the rule. Under this approach, the State would have the authority to allow the public water system (PWS), as one means of compliance with the sulfate MCL, to provide "Alternative Water" and public education/notification to the targeted, sensitive population. A PWS authorized to comply under this option would choose to supply customers with "Alternative Water", defined as either bottled water which has been monitored or certified to be in compliance with all EPA MCLs, or water treated by point-of-use (POU) or point-of-entry (POE) devices.

In the interest of reducing costs and maximizing flexibility, the proposal allows for unique means of compliance. Four options are being proposed for public comment. The lead option requires provision of alternative water to both transient adults (travelers and new residents) and infants. Two variations of the lead option require provision of alternative water to infants only. These two options differ only in the content of the public notification. In one case, only infants are considered at risk, and temporary diarrhea is considered as only an inconvenience for adults. In the other, both adults and infants are considered at risk, but public notification is deemed sufficient protection for adults. Because the lead option and its two variations represent a significant change in regulatory approach, EPA considered another, more conventional option. This fourth option would enable systems to seek a variance from the sulfate MCL. As a condition of receiving a variance, systems would be required to provide alternative water to their target populations, just as in the lead option. The only difference is that the relief for small systems would be provided through a different statutory mechanism. The Agency also considered limiting compliance to central treatment, which would be consistent with the approach for other contaminants, but which would not provide flexibility for smaller systems.

The Agency expects that approximately 1,500 of the 2,000 affected systems would choose the lead option (Option 1) if it were available to them. The annual cost to those systems is estimated to be $7 million. The Agency has conservatively assumed that the remaining 500 systems would choose central treatment or regionalization in spite of the availability of Option 1. The cost to those systems is estimated to be $71 million. Total national cost of Option 1, including $8 million for State implementation and monitoring costs, is $86 million. If central treatment were the only means of compliance with the sulfate rule, the annual national cost would be $147 million (household costs ranging from $244 to $811). Household costs for Option 1 range from $106 to

$287 per year, but this is an average of all households in all systems, including those choosing central treatment.

In an effort to reduce the cost of this rule even further, the Agency is giving serious consideration to variations of Option 1. These variations, described as Options 2 and 3, would require public notification/education, but would only require the provision of bottled water which complies with EPA MCLs to infants. The difference between Options 2 and 3 is that Option 2 would target only infants as being at risk from an adverse effect, and Option 3 would target both adults and infants, but would propose that public notification/education is sufficient protection for adults. The Agency sees advantages and disadvantages to these alternative options, which are discussed later in this notice. The cost for either option would be $16 million, which includes $8 million for State implementation and monitoring costs. Household costs for these two options would be from $2 to $145 per year.

EPA also considered Option 4, which would achieve the same result as Option 1, but with different administrative procedures involving a variance from the sulfate MCL. Under Option 4, the regulation would specify that the conditions for States to grant a variance from the sulfate MCL would include the same elements described for Option 1, namely public notification/education and Alternative Water provisions. These elements would be defined as BAT only for the purposes of Section 1415 of the SDWA. The Agency believes that the unique nature of the sulfate health effect warrants a more flexible perspective on the implementation of the Act. The Agency recognizes that while the transitory nature of the diarrhetic effect of high-sulfate water may be uncomfortable and inconvenient for healthy adults, the potential risk to infants of diarrhea, as well as the dehydration and electrolyte imbalance which may be associated with it, are significant and potentially fatal if untreated.

TABLE 1.—PROPOSED MCLG AND MCL FOR SULFATE

Inorganic Contaminant.	Sulfate
Proposed MCLG	500 mg/L [1]
Proposed MCL	500 mg/L
Best Available Technologies.	Reverse Osmosis (RO) Ion Exchange[2] (IE) Electrodialysis (ED)
Analytical Methods[3]	Colorimetry Gravimetry Ion Chromatography

[1] An alternative MCLG/MCL option of 400 mg/L was proposed in the July 25, 1990 notice but is not proposed here.

[2] For those systems with other anions that need to be removed (such as nitrate), the removal efficiency will decrease for those anions since sulfate binds more strongly to the exchange resin than other anions.

[3] Acceptance limits=±15% at ≥10 mg/L.

TABLE 2.—COMPLIANCE MONITORING REQUIREMENTS[1] FOR SYSTEMS BELOW THE MCL, OR WITH BAT INSTALLED

Contaminant	Base requirement		Trigger that increases monitoring	Waivers
	Ground water	Surface water		
Sulfate	1 Sample/3 yr	Annual sample	> MCL	Yes[2]

[1] The compliance monitoring requirements apply to community water systems, transient non- community and non-transient non-community water systems.

[2] Sample/9 Years After 3 Samples < MCL.

The options in today's proposal would override the general prohibition in 40 CFR 141.101 on using bottled water which complies with EPA MCLs and point-of-use devices to achieve compliance with an MCL. This override would apply only to sulfate because of its unique characteristics.

II. Background

A. Statutory Authority

The Safe Drinking Water Act (SDWA or "the Act"), as amended in 1986 (Pub. L. No. 99–339, 100 Stat. 642), requires EPA to publish "maximum contaminant level goals" (MCLGs) for contaminants which, in the judgment of the Administrator, "may have any adverse effect on the health of persons and which (are) known or anticipated to occur in public water systems" (Section 1412(b)(3)(A)). MCLGs are to be set at a level at which "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety" (Section 1412(b)(4)).

Concurrent with EPA publishing an MCLG, which is a non-enforceable health goal, it must promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either:

(1) an MCL, or (2) a required treatment technique (Section 1401(1), 1412(a)(3), and 1412(b)(7)(A)).

An MCL must be set as close to the MCLG as feasible (Section 1412(b)(4)). Under the Act, "feasible" means "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions (taking cost into consideration)" (Section 1412(b)(5)). In setting MCLs, EPA considers the cost of treatment technology to large public water systems (i.e., >1,000,000 people) with relatively clean source water supplies (132 Cong. Rec. S6287 (daily ed., May 21, 1986)).[1] Each NPDWR that establishes an MCL must list the best available technology, treatment techniques, and other means that are feasible for meeting the MCL (Section 1412(b)(6)). NPDWRs include monitoring, analytical and quality assurance requirements, specifically, "criteria and procedures, to assure a supply of drinking water which dependably complies with such maximum contaminant levels * * *." (Section 1401(1)(D)). Section 1445 also authorizes EPA to promulgate monitoring requirements.

A treatment technique may be required if it is not "economically or technologically feasible" to ascertain the level of a contaminant (Sections 1401(1) and 1412(b)(7)(A)).

Section 1414(c) requires each owner or operator of a PWS to give notice to persons served by it of (1) any failure to comply with a maximum contaminant level, treatment technique, or testing procedure required by a NPDWR; (2) any failure to comply with any monitoring required pursuant to section 1445 of the Act;

(3) the existence of a variance or exemption; and

(4) any failure to comply with the requirements of any schedule prescribed pursuant to a variance or exemption.

Under the 1986 Amendments to the SDWA, EPA was to complete the promulgation of NPDWRs for 83 listed contaminants, including sulfate, by June 19, 1989. After 1989, an additional 25

[1] EPA also evaluates the costs to smaller systems in its analysis of economic impacts.

contaminants must be regulated every three years (section 1412(b)).

In the 1986 Amendments to the SDWA, Congress required that MCLGs and MCLs be proposed and promulgated simultaneously (section 1412(a)(3)). This change streamlined development of drinking water standards by combining two steps in the regulation development process. Section 1412(a)(2) renamed recommended maximum contaminant levels (RMCLs) as maximum contaminant level goals (MCLGs).

B. Regulatory History

EPA is required by the 1986 amendments to the SDWA to issue a proposed and final standard for sulfate. EPA grouped sulfate with 23 other organic and inorganic compounds in the "Phase V" regulatory package proposal. The 24 contaminants were among the last of the original list of 83 to be regulated by the SDWA. On June 25, 1990 EPA proposed the Phase V regulation, including sulfate (published at 55 FR 30370, July 25, 1990). In the notice, EPA described the health effects associated with sulfate (see 55 FR 30382–83). The notice stated that the available scientific information suggests that an adverse health effect from ingesting high levels of sulfate is diarrhea and associated dehydration. Because local populations usually acclimate to high sulfate levels, the impact is primarily on infants, transient populations (e.g., business travelers, visitors and vacationers), and new residents. In the 1990 notice, EPA proposed alternative levels of 400 mg/L and 500 mg/L for the MCLG for sulfate.

In the Fall of 1991, as EPA was nearing publication of regulations for the 24 Phase V contaminants, it became apparent that the Agency had not reached a consensus on how to proceed with the sulfate regulation in light of concerns raised by the commenters. Given the high cost of the rule, the relatively low risk, and the need to explore alternative regulatory approaches targeted at the transient consumer, EPA decided to seek a deferral of a final regulatory decision on sulfate. The Agency needed more time to resolve issues that included: (1) Whether additional research is needed on how long it takes infants to acclimate to water with high sulfate content, (2) whether new regulatory approaches were needed for regulating a contaminant whose health effect is confined largely to transient populations, and (3) whether the Agency should revise its definition of BAT for small systems (i.e., what should be considered affordable for the small, transient non-community water systems). For the above reasons, the regulation on sulfate was deferred. A new schedule has been established in connection with litigation brought over the schedule for regulating sulfate. This schedule requires EPA to finalize its regulatory action for sulfate by May 1996.

The secondary maximum contaminant level (SMCL) for sulfate is 250 mg/L and is based on aesthetic effects (i.e., taste and odor). EPA is not proposing changes in the SMCL for sulfate, but is requesting public comment on the correlation between sulfate concentrations, palatability, and consumption of high-sulfate water by the public.

C. Sulfate General Information

Sulfate is the divalent anion (SO_4^{-2}). It exists in a variety of inorganic compounds and salts formed with metal cations. Sulfate salts with lower molecular weight alkali metals such as sodium, potassium, and magnesium are very water soluble and are often found in natural waters. Salts of higher molecular weight metals such as barium, iron or lead have very low water solubility.

Sulfate is found in soil sediments and rocks, and occurs in the environment as a result of both natural processes and human activities. Specific data on the total production of all sulfates are not available, but production is expected to be thousands of tons per year; the use of sodium sulfate alone in 1987 was reported to be 792 tons. Sulfate is used for a variety of commercial purposes, including pickle liquor (sulfuric acid) for steel and metal industries, and as a reagent in manufacturing of products such as copper sulfate (a fungicide/algicide).

Sulfate may enter surface and ground water as a result of discharge or disposal of sulfate-containing wastes. In addition, sulfur oxides produced during the combustion of fossil fuels are transformed to sulfuric acid in the atmosphere. Through precipitation (i.e., acid rain), sulfuric acid can enter surface waters, lowering the pH and raising sulfate levels.

III. Explanation of Today's Action

A. Establishment of MCLG for Sulfate

The MCLG for sulfate is reproposed today at a level of 500 mg/L. In this notice, EPA is responding to the public comments submitted in reference to the MCLG options contained in the July 1990 proposal. EPA's complete responses to the public comments on the previously proposed MCLGs appear in the Comment/Response Document that is included in the docket for this rulemaking.

MCLGs are set at concentration levels at which no known or anticipated adverse health effects occur, allowing for an adequate margin of safety. The process for establishing an MCLG for a contaminant has been described in many documents, including the final Phase V rule issued in July 1992 (57 FR 31781–31783).

1. Health Effects

The available information on the health effects of sulfate was fully described in the July 25, 1990 (55 FR 30370) Phase V proposal. Studies mentioned in that notice are summarized in the Health Criteria Document for Sulfate (US EPA, 1992), which is available for review and comment in the docket for this rulemaking. Since that time, EPA has funded additional studies on humans and piglets which are currently under review.

In the July 25, 1990 notice, EPA stated that there was no evidence of adverse health effects in animals or humans from chronic exposure to sulfate in drinking water. The available health data indicate that chronic exposure to sulfate is not harmful to health.

The acute effects noted from exposure to high levels of sulfate range from soft stools to diarrhea. Infants may be more sensitive to sulfate than healthy adults. Infants consume more water and food on a body weight basis than adults, and consequently ingest a higher dose of sulfate (per body weight) in drinking high-sulfate water than do adults. In infants, the greatest risk is from dehydration and electrolyte imbalance that may result from diarrhea. This effect can be fatal if untreated.

It has been questioned whether the concentration of sulfate found in drinking water would cause significant dehydration in infants or adults. Schild (1980) reported that eight grams of sulfate retain 120 milliliters of water in the intestine. In this case, an adult drinking two liters of water containing 1500 milligrams of sulfate per liter would ingest three grams of sulfate and retain 45 milliliters of water in the intestine. The Agency is requesting any scientific data which would support or refute the hypothesis that this decrease in available water is likely to cause dehydration and electrolyte imbalance in adults or infants.

There are three documented case histories of infants, 5 to 12 months old, who were given formulas prepared with water containing 630 to 1,150 mg/L of sulfate (Chien, et al., 1968). These

infants developed diarrhea shortly after they ingested the formula, but the effect subsided after use of the high sulfate water was discontinued. Cole (1992) evaluated this study and concluded that neither the potential effects of osmolarity, specifically hyperosmolarity, nor viral gastroenteritis had been considered as possible causes of the observed diarrhea. Thus, Cole suggested and the Agency agrees that the Chien study provides qualitative evidence of the effects of sulfate but should not be used quantitatively in a sulfate risk assessment.

Similar effects have been observed in adults, but individuals seem to become acclimated to high sulfate levels in a short period of time, with a cessation of all ill effects.

The laxative effect of sulfate is well-known. Peterson (1951) compiled the results of questionnaires sent to North Dakota residents and concluded that "waters with 600 to 750 ppm sulfates should be looked upon with suspicion as they may or may not be laxative. Over 750 ppm sulfates is generally a laxative water and below 600 ppm sulfates should be considered safe." Moore (1952) replotted the Peterson data and found that as sulfate concentrations increased from 500 to 1000 mg/L, the number of adults reporting laxative effects also increased. At concentrations of sulfate above 1,000 mg/L, the majority of respondents noted a laxative effect. While it is not known how long is needed to achieve acclimation in adults or infants, EPA scientists believe the time to be approximately two weeks, based on mucosal cell turnover rate in the intestines.

The Agency is using these studies to support the MCLG, although each has limitations. For example, in the Peterson (1951) study, there is no information available on the chemical composition or the microbiological quality of the water, nor on the length of time that people drank the water.

There are insufficient data to calculate a precise and reliable quantification of the exact dose which will cause diarrhea in a given percentage of the susceptible population. Some sulfate salts are used as laxative agents. Their mechanism of action is known, and there is apparently little interest in the medical community in additional research on the subject. Acclimation to sulfate is assumed due to the fact that people living in regions with high-sulfate drinking water seem to have no adverse effect, whereas newcomers drinking that region's water will initially experience the laxative effect.

In developing the MCLG for sulfate, issues were raised concerning the ability of infants to acclimate to sulfate in drinking water. In 1992, EPA convened an expert panel to discuss the sulfate data base (US EPA, 1992). The panel (D.E.C. Cole, Children's Hospital, Halifax, Nova Scotia; M. Cassidy, George Washington University, Washington, DC; and M. Morris, State University of New York, Amherst, NY) concluded that the lack of data on the sulfate content and the osmolarity of the formulas used in the Chien et al. (1968) study prevents it from being a reliable estimate of the level of sulfate that would induce diarrhea in infants. They concluded that: (1) Additional studies on sulfate are desirable, (2) the Chien et al. (1968) study cannot be used quantitatively, (3) the 500 mg/L value for sulfate is conservative for adults, and there are no differences between sulfate levels of 400 and 500 mg/L, (4) the three cases of diarrhea reported in the Chien study may or may not be attributable to sulfate, and (5) acute short-term effects are the appropriate focus for risk assessment and further research.

The panel members recommended additional research with piglets and humans. EPA agreed and initiated studies in collaboration with the University of North Carolina School of Medicine and the North Carolina State University Department of Animal Science. These studies have been completed and are undergoing internal and external peer review.

2. Occurrence and Human Exposure

The available information on the occurrence and human exposure to sulfate was fully described in the July 25, 1990 proposal. Since that time, additional State data have been gathered and used to update the information in Table 8.

Review of data sources for estimating national occurrence levels of sulfate included: The Community Water Supply Study (CWSS) released in 1969; the Rural Water Survey (RWS) from the late 1970s; new State survey data from Utah, North and South Dakota, and Texas: The Federal Reporting Data System (FRDS) and STORET, EPA's computerized water quality data base. In the CWSS, 106 surface water supplies sampled had an apparent detection limit of 1 mg/L. For the ground water supplies the mean of the positive sulfate detections was approximately 43 mg/L (range of 1 to 480 mg/L), and for surface water it was approximately 49 mg/L (range of 2 to 358 mg/L). The Rural Water Survey (RWS) reported a lower frequency of positives and a higher mean of the positive values, but this lower frequency probably reflects the higher detection limit of 15 mg/L. In the RWS, sulfate was reported to be present in 271 of 494 ground water supplies with a mean of about 98 mg/L (range of 10 to 1,000 mg/L) for the positives (some laboratories can achieve accuracy at levels lower than the published detection limit of 15 mg/L). In surface water, it was found in 101 of 154 supplies, with a mean of 53 mg/L (range of 15 to 321 mg/L) for the positives.

As noted above, sulfate can be formed in the atmosphere, and EPA has reported ambient levels during the period of 1980–1986 to range from 0.2 to 199.4 $\mu g/m^3$. Since the amounts of sulfate that could be transferred from the atmosphere through the pulmonary system to the gastrointestinal tract are minuscule compared to what could be ingested in drinking water, atmospheric levels are not of concern for the purposes of this rule.

No information is available on the occurrence of sulfate in foods, nor are there any estimates on dietary intake. The Agency did not follow its usual practice of determining a relative source contribution (RSC) factor. As with certain other inorganic contaminants (nitrate, fluoride, barium, manganese), calculation of RSC is not appropriate for sulfate because the MCLG is derived directly from human exposure to the contaminant in drinking water.

3. Previously Proposed MCLG

In July 1990, EPA proposed two alternative options for the sulfate MCLG based on the available health information. The first option was to set the MCLG at 400 mg/L, based on a Science Advisory Board (SAB) conclusion that sulfate's mode of action is well known and some human data are available indicating that ill effects occur only at concentrations above 600 mg/L (Peterson, 1951). SAB applied a small uncertainty factor of 1.5 to the 600 mg/L level to give a recommended MCLG of 400 mg/L. Their recommendation corresponded to the World Health Organization (WHO) sulfate standard of 400 mg/L, which is based on aesthetic considerations.

The second option was to set the MCLG at 500 mg/L. As a basis for choosing this option, EPA referred to the survey conducted by Peterson (1951) and evaluated by Moore (1952). Combining the questionnaire respondents into discrete groups, Moore indicated that the number of adults reporting laxative effects increased at sulfate concentrations above 500 mg/L.

The Health Protection Branch of Health and Welfare/Canada has indicated to EPA (Canadian Guidelines,

1991) that the maximum acceptable concentration of sulfate in water is 500 mg/L, considered an aesthetic objective, since "at this level sulfate gives an objectionable taste, but is still below the level at which we would expect to see deleterious health effects". The Agency notes that the Canadian sulfate guideline of 500 mg/L and the lack of health problems reported at that level lends support to the proposed MCLG. Canada does not yet have national drinking water regulations. Their guidelines are offered to the provinces, which may choose to adopt them as provincial regulations.

Public Comments

There were 15 separate comments concerning sulfate on the 1990 proposed rule. Several commenters believed that EPA should not regulate sulfate due to a lack of adequate health data, lack of chronic effects and because people acclimate to the laxative effects of sulfate. Eleven commenters stated that if it were necessary to regulate sulfate, that the MCLG should be higher than 500 mg/L (between 600 and 1,000 mg/L). The remaining four commenters stated that 500 mg/L was protective. One commenter stated that the usual approach for deriving the MCLG—an RfD calculation—should be used for sulfate. Another commenter cited a July 17, 1989 letter from the Metals Subcommittee of the Science Advisory Board's Environmental Health Committee to the Administrator stating that the Subcommittee could not support the setting of an acute MCLG, and recommending additional study before regulation. Several commenters urged EPA not to regulate sulfate, stating that a secondary MCL is sufficient. They noted that infants as well as adults acclimate to sulfate, sulfate is present in food, and the WHO guidelines are based on taste considerations and not health effects. Several commenters noted that systems which do not serve the target population, infants in particular, should be excused from complying with the sulfate regulation. Several commenters questioned EPA's cost analysis.

EPA Response

Some commenters noted that no chronic health effects have been associated with long-term exposure to high levels of sulfate. However, sulfate can have acute adverse effects on non-acclimated persons. The population at risk is readily identified and targeted for protective measures. While the laxative effect eases and disappears as the person acclimates to the high sulfate concentration, the individual is subject to debilitation during the acclimation period.

Diarrhea and/or laxative effects have been reported in infants ingesting water with high levels of sulfate and in adults at concentrations in the 500 to 1000 mg/L range. EPA believes an MCL level of 500 mg/L will be sufficiently protective of infants and adults. An RfD for sulfate has not been determined.

SMCLs for aesthetic qualities relating to the public acceptance of drinking water are not federally enforceable, and intended only as guidance for the States. SMCLs do not meet the statutory requirement to set an NPDWR for sulfate.

The requirements for transient and non-transient, non-community water systems which do not serve the target population frequently would be minimal. They could achieve compliance by placing permanent signs at drinking fountains and having bottled water which complies with EPA MCLs available for visitors.

The Agency has updated the occurrence data and the cost analysis since the Phase V proposal.

4. Today's Proposed MCLG

Today EPA is proposing an MCLG of 500 mg/L which represents the level at which no known or anticipated adverse effects on human health occur, and which allows for an adequate margin of safety based on current data. As a basis for choosing this level, EPA notes that the survey conducted by Peterson (1951) and evaluated by Moore (1952) indicated that the number of people reporting laxative effects greatly increased at sulfate concentrations above 500 mg/L. This concentration is considered protective of infants based on the information reported by Chien et al. (1968).

EPA believes that the MCLG for sulfate should be based on the potential for causing loose stools and diarrhea. Infants are at risk from diarrhea regardless of the cause, and unacclimated adults may also be at risk. A standard to limit the intake of sulfate will protect the infant population and unacclimated adults from potential adverse effects.

EPA requests comment on this proposed MCLG. EPA particularly requests any new data or any other new information that may be submitted in support of or opposing the reproposed sulfate MCLG of 500 mg/L. In light of comments opposing the regulation of sulfate, the Agency is also requesting any new data or information that would support a higher level for the MCLG. The Agency is particularly interested in comments that raise issues other than those that EPA has already considered and responded to above and in the record for today's proposal.

B. Establishment of NPDWR for Sulfate

1. Methodology for Determination of MCLs

The SDWA directs EPA to set the MCL "as close to" the MCLG "as is feasible." The term "feasible" means "feasible with the use of the best technology, treatment techniques, and other means, which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking costs into consideration)", (SDWA section 1412(b)(5)). Each NPDWR that establishes an MCL lists the technology, treatment techniques, and other means which the Administrator finds to be feasible for meeting the MCL (SDWA section 1412(b)(6)).

The present statutory standard for BAT under 1412(b)(5) represents a change from the provision prior to 1986, which required EPA to judge feasibility on the basis of "best technologies generally available" (BTGA). The 1986 Amendments to the SDWA changed BTGA to BAT and added the requirement that BAT must be tested for efficacy under field conditions, not just under laboratory conditions. The legislative history explains that Congress removed the term "generally" to assure that MCLs "reflect the full extent of current technology capability" (S. Rep. No. 56, 99th Cong., 1st Session at 6 (1985)). EPA has concluded that the statutory term "best available technology" is a broader standard than "best technology generally available" and that this standard allows EPA to select a technology that is not necessarily in widespread use, as long as its performance has been validated in a reliable manner. In addition, EPA believes that the technology selected need not necessarily have been field tested for each specific contaminant but, rather, that the operating conditions may be projected for a specific contaminant using a field tested technology from laboratory or pilot systems data.

Based on the statutory directive for setting the MCLs, EPA derives the MCLs based on an evaluation of (1) the availability and performance of various technologies for removing the contaminant, and (2) the costs of applying those technologies. Other technology factors considered in determining the MCL include the ability of laboratories to measure accurately and consistently the level of the

contaminant with available analytical methods.

EPA's initial step in deriving the MCL is to make an engineering assessment of technologies that are capable of removing a contaminant from drinking water. EPA reviews the available data to determine technologies that have the highest removal efficiencies, are compatible with other water treatment processes, and are not limited to a particular geographic region.

Based on the removal capabilities of the various technologies, EPA calculates the level of each contaminant that is achievable by their application to large systems with relatively clean raw water sources. (See H.R. Rep. 1185, 93rd Cong., 2nd Sess. at 13 (1974); 132 Cong. Rec. S6287, May 21, 1986, statement of Sen. Durenberger.)

When considering costs to control contaminants, EPA analyzes whether the technology is reasonably affordable by regional and large metropolitan PWSs (See H.R. Rep. No. 93–1185 at 18 (1974) and 132 Cong. Rec. S6287 (May 21, 1986) (statement of Sen. Durenberger)). EPA also evaluates the total national compliance costs, considering the number of systems that will have to install treatment in order to comply with the MCL. The resulting total national costs vary depending upon the concentration level chosen as the MCL. The more stringent the MCL, the greater the number of systems that may have to install BAT to achieve compliance and the higher the national cost.

The feasibility of setting the MCL at a precise level is also influenced by laboratory ability to measure the contaminant reliably. Because compliance with the MCL is determined by analysis with approved analytical techniques, the ability to analyze consistently and accurately for a contaminant at the MCL is important for enforcing a regulatory standard. Thus, the feasibility of meeting a particular level is affected by the ability of analytical methods to determine with sufficient precision and accuracy whether such a level is actually being achieved.

2. Treatment Technologies and Costs

In the July 25, 1990 proposal, EPA identified two technologies as BATs under Section 1412 of the SDWA for sulfate: Reverse osmosis (RO) and ion exchange (IE). EPA believes that the costs of these technologies to large systems are reasonable, and that these technologies are compatible with other water treatment processes in different regions of the U.S. These technologies and the costs of using them are described as follows:

Reverse Osmosis. RO uses semi-permeable membranes to remove a high percentage of almost all inorganic ions. The technology is relatively insensitive to flow and total dissolved solids (TDS). The effectiveness of RO is adversely affected by the presence of turbidity, iron, manganese, silica, or scale-producing constituents in the source water. If pretreatment is not already in place to remove these constituents, additional costs may be incurred to install other technologies (e.g., pH adjustment, filtration, or scale-prevention additives). The cost generated by the model includes the cost of a scale inhibitor. On the other hand, in situations where high dissolved solids and/or several contaminants may have to be removed simultaneously, the RO process may offer an especially desirable and cost-effective approach to their removal. Less chlorine may be needed due to removal of many bacteria and viruses during the RO process.

Disadvantages to RO include fouling of membranes either from scaling or from water with high organic content and a reject stream of 20% to 50% of the water flow. It is also possible that corrosion control chemicals will be needed after RO, and a more qualified operator may be needed.

Full scale tests indicate that RO is capable of removing between 86 and 97 percent of the sulfate, and is effectively used for the reduction of contaminants other than sulfate. Estimated cost for reducing sulfate by RO range from $3.50/1,000 gallons for systems serving between 500 and 1,000 persons to $1.00/1,000 gallons for systems serving more than 1,000,000 persons. High sulfate levels are typically associated with high levels of TDS, which can indicate the presence of other inorganics; in such cases, RO becomes a cost effective treatment technology because it removes those other inorganics as well. Since the removal efficiency required for sulfate will typically be less than 86 percent, a portion of the water can be treated and blended with an untreated portion to reduce the cost of this process.

Commenters to the Phase V proposed rule expressed concerns regarding the potential costs associated with disposal of wastes generated by treatment processes such as RO, particularly in water-scarce regions. The Agency believes that wastewater would be minimized, since only a portion of source water containing elevated sulfate levels would need to be treated, and would then be blended with source water. With an MCL of 500 mg/L, EPA believes blending treated water and source water would greatly reduce the reject stream.

Ion Exchange. IE reduces sulfate concentrations to levels below the MCLG of 500 mg/L at reasonable costs to large systems. Typical sulfate anion removals using IE are greater than 75 percent in full-scale studies that evaluated influent concentrations close to drinking water levels. Estimated costs for IE to reduce sulfate concentrations range from $2.90/1,000 gallons for systems serving between 500 and 1,000 persons to $1.40/1,000 gallons for systems serving more than 1,000,000 people. When the removal efficiency required for sulfate is less than 75 percent, a portion of the water can be treated and blended with an untreated portion to reduce cost. For those systems with other anions that need to be removed (such as nitrate), the removal efficiency will decrease for those anions since sulfate binds more strongly to the exchange resin than other anions. A disadvantage of IE is that it may not be feasible at high levels of TDS.

EPA received a number of public comments on the proposal to select RO and IE as BATs for the Phase V inorganic contaminants in general and for sulfate in particular. EPA's responses are in the comment-response document for the Phase V rulemaking and in the preamble to the final rule (57 FR 31809–12). In the preamble, EPA responded to comments on sulfate in particular concerning the disposal of wash brines from IE and RO treatments in water-scarce areas and on the costs of using RO and IE to treat for sulfate. EPA is not aware of any new information on these two technologies or costs since the proposal. Interested parties are invited to submit any new public comments or new information on the selection of RO and IE as BAT for sulfate.

Electrodialysis. Since the Phase V proposal, EPA has identified electrodialysis (ED) as an additional proposed BAT. EPA requests comment on its conclusion that electrodialysis should also be considered BAT for sulfate.

ED was the first membrane process developed for desalting brackish waters, and was commercially available in the 1950's. In the early 1970's, a major technological improvement was made, called electrodialysis reversal. Recovery ratios increased from the 50% to 60% range to 80% to 90% recovery.

In ED, feed water containing dissolved ions is pumped across electrified membranes. The positive ions migrate to the negative electrode,

and the negative ions migrate to the positive electrode, and are effectively trapped in alternating compartments. The partially deionized/dilute stream is circulated through additional stages until the desired purity is obtained. Since this is a unidirectional process, membrane fouling and mineral scale formation tend to degrade system performance. Some pretreatment may be required, such as clarification, presoftening, or treatment with acid or anti-scaling agents.

Electrodialysis reversal (EDR) is the same process but with the polarity of the current automatically reversed at regular 15 to 30-minute intervals. This changes the direction of ion movement within the membrane stack. As a result, foulants and scale tend to be removed from the membrane surfaces and carried away during the purge period. EDR requires minimum pretreatment and is very tolerant of system upsets, shock chlorination, and long-term operation at temperatures up to 45 C. Sulfate removal of 84% was achieved in a 1990 pilot study in Virginia, in which efficiency and costs for RO and EDR were compared (AWWA, 1991).

Operating costs for EDR are comparable to those for RO. All reference to ED as BAT for sulfate removal in this notice will refer to electrodialysis reversal, rather than unidirectional electrodialysis. Table 3 summarizes the efficiency and cost of the treatment technologies proposed as BATs for sulfate, and indicates that each can reduce the contaminant level from the maximum expected occurrence level to below the proposed MCLG. The costs in Table 3 are representative of annual operation and maintenance (O & M) costs plus annualized capital costs, and may differ depending on local conditions. Costs may be lower if sulfate concentration levels encountered in the raw water are lower than those used for the calculations, or higher if additional system-specific treatment or storage requirements are needed. The general assumptions used to develop the treatment costs include: Capital costs amortized over 20 years at a 7 percent interest rate; engineering fees; contractor overhead and profit; late 1991 power, fuel, labor and chemical costs. The removal efficiencies cited in Table 3 are what is possible, and are not directly linked with the cited costs. These costs are linked with the efficiency needed to achieve the sulfate MCL.

TABLE 3. ANNUAL COSTS OF PROPOSED 1412 BAT FOR SULFATE (1991 DOLLARS)

BAT	Percent removal	Cost per 1,000 gallons 500–1000 population	Cost per 1,000 gallons 3,300–10,000 population	Cost per 1,000 gallons 1,000,000 population
Reverse osmosis	86–97	$3.50	$2.20	$1.00
Ion Exchange	>75	2.90	1.90	1.40
Electrodialysis	80–90	3.50	2.20	1.00

3. Sulfate Analytical Methods

a. *Choice of analytical method.* The reliability of analytical methods used for compliance monitoring is critical at the MCL. EPA evaluated the availability, costs and the performance of analytical methods for measuring sulfate, and considered the ability of laboratories to measure consistently and accurately for sulfate at the level of the proposed MCL.

In selecting analytical methods, EPA considers five factors:

(a) Reliability (i.e., precision/accuracy) of the analytical results;

(b) Specificity in the presence of interferences;

(c) Availability of enough equipment and trained personnel to implement a national monitoring program;

(d) Simplicity of analysis to permit routine use; and

(e) Cost of analysis to water supply systems.

Sulfate has an SMCL of 250 mg/L for which EPA recommends measurements be made with an EPA method or a Standard Method (SM) method (40 CFR 143.4(b)), each of which uses a turbidimetric analytical technique. The July 1990 proposal listed analytical methods for sulfate that use one of four analytical techniques: turbidimetry, colorimetry, ion chromatography, and gravimetry. The July 1992 regulations did not regulate sulfate, but specified a colorimetric analytical technique to measure sulfate as an unregulated contaminant (40 CFR 141.409(n)(12)). However, the regulations did not list specific colorimetric methods. In an analytical methods proposal (58 FR 60622, December 15, 1993) EPA removed this ambiguity by identifying several colorimetric methods. The December 1993 proposal also proposed methods that use other analytical techniques, and improved laboratory efficiency by allowing all sulfate methods to be used for both secondary and unregulated contaminant monitoring.

Today EPA is proposing methods that use colorimetric, gravimetric or ion chromatographic analytical techniques. The methods are proposed for analysis of sulfate as regulated and as a secondary contaminant. For information on the precision and accuracy of these methods, EPA refers readers to the references in Table 4.

TABLE 4.—PROPOSED ANALYTICAL METHODS FOR SULFATE

Contaminant	Method	EPA (1)	ASTM (2)	SM (3)
Sulfate	Colorimetry	375.2		4500–SO_4–F.
	Gravimetry			4500–SO_4–C,D.
	Ion chromatography	300.0	4327–91	4110

(1) "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA/600/R/93/100. NTIS, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161, PB 94–121811, August 1993.
(2) Annual Book of ASTM Standards, Vol. 11.01, 1993, American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.
(3) 18th edition of *Standard Methods for the Examination of Water and Wastewater,* American Public Health Association, American Water Works Association, Water Environment Federation, 1992.

EPA is not proposing turbidimetric methods because the methods are inadequate. The operating range of turbidimetric methods is 0 to 40 mg/L, which requires excessive dilution of the sample to cover the range between the SMCL (250 mg/L) and the proposed MCL (500 mg/L). EPA recommends that compliance samples not be diluted more than four or five-fold to obtain reliable and reproducible results. The gravimetric and colorimetric chromatographic methods require acceptable dilution of the sample to measure samples containing more than 350 mg/L of sulfate.

Colorimetric and gravimetric methods have been used for many years to measure sulfate in water, and were described in the July 1990 proposal. As stated in the July 1992 rule, EPA agrees with comments that only methylthymol blue, not chloranilate, colorimetric methods are suitable for sulfate analysis. Therefore, EPA is only proposing methylthymol blue colorimetric methods for sulfate analysis.

Ion chromatographic methods have been approved for measurement of nitrate and nitrite (40 CFR 141.23) in drinking water. These methods have been described or discussed in the July 1990 and the December 1993 proposals, and in 54 FR 22097 (May 22, 1989). EPA is proposing ion chromatographic methods for sulfate analysis only with the suppressed column option. EPA has no data to support use of a "non-suppressed" column (57 FR 31800), and the Agency is not proposing to approve this option in any ion chromatographic method.

EPA believes the proposed analytical methods are technologically and economically feasible for sulfate monitoring. The analytical cost for sulfate is $10 to $30 per sample. EPA believes these costs are affordable. Actual analytical costs may vary with the laboratory, analytical technique selected, the total number of samples and other factors. The number of laboratories that routinely participate in EPA's Water Supply and Water Pollution performance evaluation studies indicates that many laboratories have the capability to conduct analysis for sulfate.

Sulfate has a long history as a water quality parameter. There is a large body of performance data available for water pollution studies. The proposed analytical methods have detection limits much lower than the proposed MCLG for sulfate. The detection limit for a given contaminant varies with the analytical method (Table 5).

b. *Method detection limits and practical quantitation levels.* EPA determines practical quantitation levels (PQLs) for each substance for the purpose of integrating analytical chemistry data into regulation development. The PQL yields a limit on measurement and identifies specific precision and accuracy requirements which EPA uses to develop regulatory requirements. As such, PQLs are a regulatory device rather than a standard that labs must specifically demonstrate they can meet. The PQLs for inorganic compounds are determined based on the method detection limits (MDLs) and the results from performance evaluation data.

TABLE 5.—PROPOSED METHODOLOGY AND DETECTION LIMITS FOR SULFATE

Contaminant	Method	Detection limit (mg/L)
Sulfate	Colorimetry	3
	Gravimetry	1
	Ion chromatography.	0.02

The PQL for sulfate was determined using the MCL as well as EPA and State laboratory data from Water Pollution PE studies using the procedure described in 54 FR 22100 (May 22, 1989). A PQL of 10 mg/L was proposed for sulfate in the Phase V proposed rule (55 FR 30411, July 25, 1990). Since the detection limit using the colorimetric method is 3 mg/L, EPA is soliciting comment on whether a higher PQL of 30 mg/L should be set in order to retain the colorimetric method.

c. *Sulfate sample preservation, container and holding times.* Requirements for sample preservation, containers and holding times listed in Table 6 were proposed for sulfate in the 1990 proposal. No comments were received on these specifications. The Agency is reproposing these requirements today.

TABLE 6.—SULFATE SAMPLE PRESERVATION CONTAINER, AND HOLDING TIME REQUIREMENTS

Contaminant	Preservative	Container [1]	Maximum holding time [2]
Sulfate ..	Cool, 4 °C.	Plastic or glass.	28 days.

[1] Container may be a hard or soft, plastic or glass material.

[2] Samples should always be analyzed as soon after collection as possible.

d. *Laboratory certification.* Today EPA is proposing that only certified laboratories be allowed to analyze samples for compliance with the proposed MCL for sulfate. EPA recognizes that the effectiveness of today's proposed regulations depends on the ability of laboratories to reliably analyze contaminants at low levels. EPA has a drinking water laboratory certification program that States must adopt as a part of primacy. (40 CFR 142.10(b)) EPA's Manual for the Certification of Laboratories Analyzing Drinking Water, EPA/570/9-90/008, April, 1990, specifies minimum criteria which States must use to implement their drinking water laboratory certification program.

Performance evaluation (PE) samples are an important tool in EPA's laboratory certification program. The samples are provided by EPA or the States to laboratories seeking certification. To obtain and maintain certification a laboratory must use an approved method, and at least once a year successfully analyze an appropriate PE sample. Successful analysis requires that a laboratory report a concentration of sulfate in the PE-sample that is within the acceptance limits. Specification of these proposed limits, which are listed in drinking water regulations at § 141.23(k), is discussed below.

e. *Setting PE sample acceptance limits for sulfate.* Acceptable performance has historically been set by EPA using two different approaches: (1) Regressions from performance of preselected laboratories (using 95 percent confidence limits), or (2) specified accuracy requirements. Acceptance limits based on specified accuracy requirements are developed from existing PE study data. When there are insufficient PE data to determine expected laboratory performance, EPA determines acceptance limits from individual study statistics based upon 95 percent confidence limits. After sufficient performance data are generated from PE studies, EPA will develop fixed acceptance limits using a "plus or minus of the true value approach." The true value approach requires each laboratory to demonstrate its ability to perform within pre-defined limits. Laboratory performance is evaluated using a constant yardstick independent of performance achieved by other laboratories participating in the same study. A fixed criterion based on a percent error around the "true" value reflects the experience obtained from numerous laboratories and includes relationships of the accuracy and precision of the measurement to the concentration of the analyte. It also assumes little or no bias in the analytical methods that may result in average reporting values different from

the reference "true" value. This concept assures that reported results can be related to the percentage variance from the PQL.

Performance data are available for sulfate at concentrations proposed for regulation. The data are sufficient to set fixed acceptance limits of ± 15% for sulfate PE samples. The acceptance limits are estimated using the approach described in 54 FR 22132.

4. Establishment of a NPDWR

a. Today's Proposed MCL. Today EPA is proposing an MCL for sulfate of 500 mg/L, which is equal to the proposed MCLG. EPA believes that costs for large systems are reasonable and affordable, and that it is technologically feasible for PWSs to achieve this level for sulfate. EPA also believes that the flexibility afforded by Option 1 allows small systems to comply with the MCL in a way that is reasonable and affordable.

Examination of the BATs identified above (RO, IE, and ED) indicates that each can reduce the levels of sulfate from the maximum expected occurrence levels to levels below the proposed MCLG of 500 mg/L (minimum removal efficiencies of 86%, 75%, and 80%, respectively). The maximum reported occurrence level for sulfate in a national study (RWS) is 1,000 mg/L, although individual State data have shown levels twice as high. Each of these technologies is currently available, has been installed in PWSs, is compatible with other water treatment processes, and can remove sulfate from the maximum occurrence level to below the proposed MCLG. EPA is proposing an MCL for sulfate based upon an analysis of several factors, including:

(1) The effectiveness of BAT in reducing sulfate levels from influent concentrations to the MCLG.

(2) The feasibility (including costs) of applying BAT. EPA considered the availability of the technology and the costs of installation and operation for large systems.

(3) The performance of available analytical methods.

b. Lead option for implementing the MCL requirement. As described in the Regulatory Background section, EPA determined that sulfate is found primarily in small PWSs in the western part of the U.S., and that compliance with the sulfate MCL would place a significant burden on these systems. EPA decided that a requirement for PWSs to comply with the sulfate MCL by treating all of their source water might be excessive since high sulfate levels affect only persons who are not acclimated to the water. Therefore, the Agency decided in 1992 to defer the regulation for sulfate in order to consider ways of allowing PWSs to comply with the MCL that would not require central treatment.

To develop alternative options for complying with the MCL, EPA held a meeting with interested States and the Association of State Drinking Water Administrators (ASDWA). In November 1992, officials from Texas, South Dakota, Colorado, and New Mexico, ASDWA staff, EPA Regional staff, and EPA Headquarters staff met to explore regulatory options for sulfate. They discussed the regulatory process, a toxicological profile of sulfate, and State perspectives on sulfate regulation, health effects and implementation options. Neither the issue of whether or not to regulate sulfate nor the MCL/MCLG levels were topics of discussion. The participants felt that the sulfate regulation should give the States flexibility. After the discussions at this meeting, most of the States present supported the conclusion that PWSs should be allowed to protect their customers from the risk of sulfate levels exceeding the MCL either by centralized treatment or through public education/notification and provision of Alternative Water. The outline of a regulatory option that included all of these elements was formulated. Each of the components was directed at a certain population and the majority agreed that those components, together, would be adequately protective. The option developed at that meeting is essentially Option 1, being proposed today. In the past, EPA has not generally set restrictions or conditions on the means of compliance with the MCL. Traditionally, EPA simply identifies the central treatment technologies that are considered BAT and then sets the MCL based on the capabilities of those technologies to remove the contaminant. PWSs are not required to use the identified BATs but must achieve compliance with the MCL. EPA regulations prohibit PWSs from using bottled water or POU devices to achieve compliance with the MCL. In addition, the regulations prohibit PWSs from using POE devices to achieve compliance with the MCL unless the PWS meets certain conditions for ensuring effective protection of all consumers. See 40 CFR 141.100 and 141.101. In Option 1, EPA proposes to override the general prohibition on the use of bottled water and POU/POE devices and to allow States to authorize PWSs to use these methods to achieve compliance with the MCL.

c. Method of compliance. The State would have the authority under Option 1 to allow PWSs to achieve compliance with the sulfate MCL by one of two methods. The PWS could comply either by using conventional central treatment or by providing Alternative Water. With the State's authorization, PWSs would have the choice of supplying bottled water which complies with EPA MCLs, POU or POE devices to target populations. Under Option 1, PWSs that provide Alternative Water would also need to meet certain public education/notification requirements. Transient systems would also have to provide Alternative Water, but their public notification requirement would be posting of signs, unless POE/POU devices brought all taps into compliance. This approach directly focuses protection on the sensitive populations: Infants, travelers and new residents. Under Option 1, any program developed by a PWS would need to contain the following provisions or others which it can demonstrate are at least as stringent and protective:

(1) Community Water Systems

(i) Bottled water.

PWSs would need to provide and deliver two liters of bottled water per person per day (unless the customer requests less), on request, to households with infants, new residents, or transients (visitors). The bottled water would have to have been monitored or certified to be in compliance with all EPA MCLs. PWSs would be allowed to deliver enough water for several weeks, or the entire time period, at once, and would not be required to provide daily delivery. Infants, up to one year old, would receive bottled water for a maximum of 20 weeks from the date of request. Since a mother may nurse her infant during the first year, it would be her decision as to when to begin giving the infant tap water. Each new resident (person moving to the high-sulfate community from another location) would receive bottled water for a maximum of six weeks. New residents with infants up to one year old would receive bottled water for their infant for 20 weeks. New residents with infants older than one year would receive bottled water for themselves and their infant for six weeks. Since new residents would be informed about the Alternative Water by the PWS at the time of starting water service to their residence, the six weeks would begin at that time. Travelers (guests visiting residents and hotel guests) would receive bottled water for the period requested, not to exceed six weeks. In resident households with infants, the public water system would only need to supply bottled water for the infant in the household. EPA is not proposing to require that bottled water be provided to

resident pregnant women prior to childbirth, since there seems to be no transfer of sulfate through the placenta.

The rule would require PWSs supplying Alternative Water to determine an equitable way of recouping their expenses in providing that service without charging a premium to the recipients of the Alternative Water. EPA believes that an additional charge for Alternative Water (above and beyond what would normally be charged for the water if it had been delivered through the distribution system) would be a disincentive to a consumer's decision to request Alternative Water and receive protection from high levels of sulfate. Therefore, the proposed rule would prohibit PWSs from charging a premium. The Agency believes this is necessary in order to "assure a supply of drinking water which dependably complies with" the sulfate MCL (see SDWA Section 1401(1)(D)). Each utility would need to determine the best way to meet its operating expenses without imposing a premium on the subpopulation of customers that is receiving Alternative Water under the sulfate rule. For example, a PWS could charge the same unit cost for each liter of bottled water as it charges for centrally-distributed water. The number of liters of bottled water delivered to a household would simply be added to the number of liters of centrally-distributed water that appears on the meter, and the same unit cost would apply to the entire volume. EPA requests comment on whether it is appropriate to restrict the PWS's fee structure in this way. In particular, the Agency is interested in whether there are State or local ratemaking laws or other laws that bear on this issue.

Two liters per day is the amount of water selected to be provided since that is the consumption level used by EPA in calculating risk estimates, and is the 85th percentile consumption level of water for the U.S. population. Infants are considered to consume one liter per day, but since they comprise a small portion of the target population, two liters per day for all members of the target population is retained for simplicity of implementation. Twenty weeks was chosen as the period for providing bottled water to infants since EPA staff scientists believe that this is a sufficiently lengthy period for infants to become gradually acclimated to high sulfate-containing water. Similarly, six weeks was chosen as the period for providing bottled water to new residents and travelers (guests) to allow gradual acclimation. Although two weeks is the period necessary to acclimate to high sulfate levels if a person is exposed continually to high-sulfate water, this rapid time frame would require the person to experience the adverse effect. In addition, new residents and travelers are likely to have many activities occupying their attention which may prevent them from accomplishing the acclimation in a shorter time period. EPA is requesting comment on these allotted time periods.

The notice provided to customers by the PWS would advise that during the period when bottled water is provided, there should be mixing of bottled water with tap water to allow gradual acclimation of the digestive system to the high-sulfate water. If gradual introduction of tap water is not done, there could still be adverse health effects when use of bottled water ceases.

The PWS would be responsible for providing bottled water which complies with EPA MCLs on request to any household which has an infant or travelers (guests), and to any household with new residents who have moved to the community from outside the service area.

Monitoring requirements to ensure that the bottled water meets the sulfate MCL and other MCLs are explained in the section below on Compliance Monitoring Requirements.

PWSs would need to maintain a record of public requests for bottled water, either by a telephone log or other means, by which the date of the request and the date of delivery are recorded and maintained for State verification.

If the public notification is done effectively, it is not anticipated that emergency delivery of bottled water will be necessary. Customers should have the time to notify the PWS well in advance of the desired delivery date. In the event that a customer has not had access to the public notification and is unable to procure bottled water prior to the normal delivery by the PWS, the PWS should have the ability to provide an emergency delivery within 24 hours of receiving the request.

(ii) Public Education/Notification.

Public education and public notification are important in making people aware of the potential adverse health effects of high levels of sulfate and educating them about how to protect themselves if they are within the targeted population. For CWSs, there are four components to the proposed public education and public notification requirement: Notices in bills, pamphlets, signs and notices to the media. In communities where a significant portion of the population speaks a language other than English, the text would need to be in the appropriate language(s), in addition to English.

Notices in Bills. PWSs would be required to use their bill notices to inform residents of the sulfate content in their water and its potential impact on non-acclimated persons. The compliance requirements for mail delivery would be the same as those for the general public notification mail delivery requirements in § 141.32(a) (2) and (3), except that the interval for sulfate notification is proposed to be every six months rather than three months. EPA is proposing to specify a six-month interval to assure that a pregnant woman would receive at least one notice during the term of her pregnancy. The notice would have to be typed in bold lettering on the bill itself. There would also need to be an additional page with more information on the potential health effect from ingesting high levels of sulfate in drinking water. That page would include information about how expectant mothers and residents can request and receive bottled water for infants and guests, how to mix tap water with bottled water over time to gradually acclimate the person to sulfate, as well as a section reassuring the consumer that there are no ill effects from high sulfate-containing water for residents.

The PWS would also need to provide the same notice to new customers or billing units prior to or at the time service begins.

Pamphlets. PWSs would be required to provide pamphlets to all medical facilities, which includes, but is not limited to city, county and State health departments, pharmacies, public and private hospitals and clinics, family planning clinics and local welfare agencies. The PWS would need to request that the operators of those facilities make the pamphlets available to pregnant women. The pamphlets would contain the information listed above for notices in bills.

Signs. PWSs would be required to post permanent, prominent and visible signs in all public areas where not all taps will have treated water.

Notices to the Media. PWSs would be required to submit copies of the notice described above to radio and television stations that broadcast to the community served by the water system when sulfate in excess of the MCL has been detected in the water, and once every six months while the water delivered into the distribution system exceeds the sulfate MCL. The geographical service area in question would have to be indicated and clearly defined in the notice.

(2) Transient Systems and Non-Transient, Non-Community Systems

(i) Bottled Water and POU/POE Devices

Transient systems, which comprise most of the affected systems (1,200 of 1,950), and non-transient, non-community systems would be required to make either bottled water which complies with EPA MCLs or water treated with a POU/POE device available for travelers at establishments in the service area. Where the target population is affected on a relatively continual basis, PWSs may find it more cost-effective to provide POU or POE devices. Where the system rarely serves members of the target population, it might choose to have a supply of bottled water on hand. Non-transient, non-community water systems, such as schools, factories and hospitals, might choose to install POEs in their cafeterias. PWSs would be responsible for maintaining POU/POE devices to ensure their continuing effectiveness.

(ii) Public Education/Notification

Public notification for transient systems and non-transient, non-community systems would be posting of signs. Such systems have no customers to "bill", and notices to the media and pamphlets would not be effective or necessary. PWSs would be required to post permanent, prominent and visible signs, made of durable material such as plastic, in places such as rest areas, campgrounds, gas stations and public areas. The signs would target travelers and newcomers, and would alert the public to the health effects of sulfate and the nearest location of drinking water for individuals not acclimated to high sulfate levels. The signs would have to be placed in any location where all taps (i.e., faucets, fountains, or other source of water that could be used for drinking) are not providing water in compliance with the sulfate MCL. If the location has a POE device, posting would not be necessary, since all taps would provide water that complies with the MCL. In the case of campgrounds, sources such as hand pumps or trailer hook-ups would be posted with signs, and bottled water could be available at the entrance gate or registration area. The Agency recognizes that there are unmanned, remote campgrounds in the national parks system, and requests comment on the means of compliance for those systems.

(3) Rationale

The sanctioning of Alternative Water as a means of compliance is an innovative approach that EPA has developed in recognition of the special circumstances and concerns surrounding the sulfate regulation. The proposed option would provide Alternative Water to sensitive populations only for the period of time needed for acclimation. The Alternative Water approach is appropriate in this case because the target populations are readily identifiable and because their need is short-term. Option 1 provides PWSs flexibility and seeks to alleviate the financial burden that central treatment might entail for small PWSs, and as such is in accordance with the objectives of the Regulatory Flexibility Act.

EPA believes that the requirements of Option 1 for PWSs to provide bottled water which complies with EPA MCLs or POU/POE devices and to provide public notice and education, taken together, will assure a supply of drinking water to the Target Population which dependably complies with the MCL for sulfate (see SDWA Section 1401(1)(D).

As detailed below in the section on costs, EPA finds that this Alternative Water approach would result in an annual national cost of $86 million annually, as compared to an annual cost for central treatment by all affected systems of $147 million. The $86 million estimate would be substantially lower except that EPA assumed conservatively that about 25% of affected systems would choose central treatment or regionalization even with Option 1 available to them. Of the $86 million, $7 million would be the cost to the 1,500 systems choosing the public notification/Alternative Water method of compliance, and $71 million would be the cost to the 500 systems choosing central treatment.

To understand how the logistics of the option would work, the Agency chose two system sizes: A PWS serving a town of 500 people, and another serving a town of 3,300 people. As very few systems (approximately 40) serving 3,300 people or more are expected to exceed the sulfate MCL, this system size was chosen to illustrate that it would be more cost-effective for a system of that size to centrally treat. Costs were calculated by using national averages.

In a population of 500, the Agency assumed (based on analysis of U.S. Census Bureau and Current Population Reports data) that there would be eight households (500 times 1.68%) with infants and 30 households with new residents (500 times 16.4% divided by 2.6 persons per household) at any given time. (EPA assumed that an average household contains 2.6 people. New residents and infants would require Alternative Water for 6 weeks and 20 weeks, respectively. A system serving this population of 500 would be required to deliver a maximum of approximately 8,800 liters of bottled water annually, or 24 liters per day, as illustrated by the calculations below.

30 households×2.6 persons×2 liters×42 days=6,552 liters

8 infants×2 liters×140 days=2,240 liters

Total Annual Bottled Water Needs=8,792 liters

Average Daily Bottled Water Needs 8,792/365 days=24 liters

The above calculation is given as an example only, and the 24-liter figure is a high estimate. The required mixing of tap water with bottled water over time for infants and new residents would reduce their consumption of bottled water. The cost analysis in the RIA for this rulemaking assumes that bottled water will represent, on average, half the water consumption for infants and new residents, and that customers will exercise their option to have less than 2 liters per day delivered over the entire period.

Although it is up to the water system to decide how to deliver the water, the Agency finds that the system could contract the delivery service out to a bottled water supplier or could procure and distribute bottled water itself. For the sake of simplifying the model, EPA assumed that a town with a population of 500 would not have to install any POUs or POEs, and would rely entirely on bottled water for the target population. The Agency recognizes that, in actuality, some percentage of such towns may have a restaurant and/or gas station, and could use a POU/POE device. However, these towns would be few in number, and the simplified model is retained for costing purposes only. If such a town had very few travelers passing through, for example, a restaurant or gas station might find it more cost-effective to use permanent signs and have bottled water available for those few travelers. EPA assumes that systems which rarely serve the target population would comply by posting signs and having bottled water available for visitors, rather than install POE/POU devices. The Agency solicits comment on the types of Alternative Water that PWSs would choose.

For a town with a population of 3300, the logistics become more complicated. The estimated number of households with infants increases from 8 to 55. The number of households with new residents becomes 210, and the number of liters of bottled water to be delivered per day is approximately 170. It is also estimated that there will be 3 POU units per town. The Agency thinks that few PWSs serving populations this large will

choose Option 1, and will choose instead to centrally treat.

There are several disadvantages to Option 1. First, it requires persons to learn about sulfate and take action to protect themselves. Second, because high-sulfate water is still available at the tap, Option 1 does not guarantee that all target audiences will be protected. The Agency requests comment on the feasibility, equity, enforceability, and attractiveness of the option.

Although EPA believes that allowing compliance with the MCL through the use of POUs, POEs, and bottled water is acceptable in the case of sulfate, the Agency continues to believe that it should not be allowed in the case of other drinking water contaminants, for which the general prohibitions in 40 CFR 141.100 and 141.101 still would apply. Option 1 proposes to override the prohibition in these sections against using bottled water and POU devices as a means of compliance with the sulfate MCL because of its unique characteristics. The susceptible population is limited, and the health effects are short-lived, so the logistics of Option 1 are feasible for smaller systems. The effects are immediate, so the cause/effect relationship of drinking water containing high levels of sulfate can be easily demonstrated, and the affected population can be readily convinced of the need for precautions. EPA is unaware of any other drinking water contaminant having these unique features. Therefore, EPA considers Alternative Water and public notification/education to be acceptable means for compliance with the MCL for sulfate, but not for other contaminants, given current information on health risk and treatment costs.

Because of the burden of administering Alternative Water in larger systems, noncompliance and the difficulties of enforcement become larger concerns. Therefore, EPA considered, but decided against, limiting the availability of Option 1 to smaller systems (e.g., systems serving fewer than 3,300 persons). Such a limitation would be unlikely to have any practical effect since, for cost efficiency reasons, systems above this size would probably choose central treatment. Also, EPA's occurrence projections indicate that few if any systems above 3,300 are likely to exceed a sulfate MCL of 500 mg/L.

d. *Other options being considered.* Option 1 above is EPA's preferred approach to regulating sulfate in drinking water and is being proposed by EPA today. EPA believes that Option 1 fully complies with SDWA's scheme for establishing drinking water regulations and is the best approach for regulating sulfate. However, there has been considerable discussion as to the necessity for federal regulatory action in protecting the public from the real, yet temporary laxative effect of sulfate. Various commentors on the 1990 proposal argued that sulfate should not be regulated at all because diarrhea does not present a significant risk to health, but rather is only an inconvenience.

The Agency has a statutory requirement to regulate sulfate. In light of the above comments, EPA is seriously considering the following additional options for regulating sulfate. EPA solicits public comment and scientific evidence on all of the options being considered.

Option 2 Under this option, the sulfate MCL and MCLG would be set at 500 mg/L. However, the target population would be limited to only infants, that is, only infants would need to be provided drinking water that meets the MCL for sulfate. The rationale for this option is that infants are the only population subgroup potentially subject to a significant risk to health, not due to the initial effect (diarrhea), but due to their inability to modify their environment or fluid intake, and the possibility that dehydration could occur if no action is taken. Under this Option, EPA would be taking the position that the laxative effect is more of an inconvenience than an adverse health effect in adults, and that no protection of adults is necessary.

The implementation of Option 2 would require the same public notification/education activities outlined in Option 1, with modifications in the text to limit the target population to infants. The text would state that only infants are exposed to significant risk from sulfate ingestion. Just as in Option 1, CWSs in excess of the sulfate MCL would be required to provide notices in bills, signs, pamphlets and media notices to their customers in the service area. These CWSs would be required to deliver Alternative Water upon request to households with infants for a maximum of 20 weeks during their first year of life. Transient systems and non-transient, non-community systems would be required to post signs and assure a supply of bottled water for infants if there is any possibility of an infant being present at the facility. Since the target population is comprised only of infants, the allocation of bottled water would be 1 liter per day, rather than the 2 liters per day proposed under Option 1 for adults and infants. For costing purposes, the Agency assumes that under Option 2, no PWS would choose central treatment as a means of compliance. This assumption is based on the relatively small number of infants (less than 2% of a given population) and the option's relatively low administrative and logistical costs. The cost of arranging delivery of bottled water and providing public notification in the service area would be lower than the cost of installing central treatment. However, it is possible that a large PWS, in anticipation of future regulations for other contaminants, or to comply with other existing regulations for contaminants that can be removed by the same treatment technologies as sulfate (e.g., RO), might, in reality, choose central treatment. Such a system may find the permanent requirement to provide public notification and bottled water to the target population to be a long-term administrative burden that is ultimately less cost-effective than central treatment. A disadvantage to this option is the possible precedent that would be set by an EPA statement that diarrhea is not considered an adverse effect for adults.

Option 3 Option 3 differs from Option 2 in the definition of the targetpopulation. The target population would be composed, as in Option 1, of infants and transient adults (including new residents), all of whom are subject to the adverse effect. However, unlike Option 1, there would be two different strategies under Option 3 to protect the two target population subgroups, infants and adults. As in Option 2, Alternative Water would have to be provided for infants. Unlike Option 2 however, PWSs would be required to notify transient adults of their risk, even though not required to provide them with Alternative Water. Public education/notification requirements would be identical to those described for Option 1 for both subgroups, except that the text of the notices would state that Alternative Water is only provided for infants upon request of the parent. Just as in Option 2, CWSs exceeding the sulfate MCL would be required to provide notices in bills, signs, pamphlets and media notices to their customers in the service area, and deliver bottled water upon request to households with infants for a maximum of 20 weeks. Similarly, transient and non-transient, non-community systems would be required to post signs and maintain a supply of bottled water.

The rationale for Option 3 is that it is necessary to set the MCL at a protective level, but sufficient for compliance purposes to provide notification/education to the affected adult population. This option is based on the theory that adequate protection for

adults can be achieved through proper education and notification. Informed adults would be able to reduce or avoid the effect by taking the initiative to purchase bottled water or otherwise abstain from drinking tap water. Infants, on the other hand, depend on adults for their survival, and the minimization of diarrhea's effects depends on the adult's gradual mixing of the infant's tap water with water that complies with the sulfate MCL. Consequently, more stringent requirements (provision of Alternative Water) would be imposed to ensure protection of infants. The disadvantage of this option is that it requires members of the affected public to protect themselves after being notified of a potential risk.

e. *Implications of Options 1, 2 and 3.* Options 1, 2 and 3 represent a significant change from the Agency's approach in other drinking water regulations. The principal advantage to these options is the reduced cost to systems. However, there are potential disadvantages in terms of policy implications to adopting any of these options which should be addressed and debated with public participation. EPA recognizes that there may be concern over the decision not to require PWSs to treat their water centrally but to allow them to supply water at levels that may exceed the sulfate MCL, and to rely on the provision of Alternative Water at the consumer's end to ensure ultimate compliance. A disadvantage of these three options is that it is possible that some members of sensitive subpopulations may still drink untreated tap water from the distribution system and thus, not be protected. Consumers may be unaware of the need to request Alternative Water, or may find it too burdensome to do so. While EPA believes that this strategy conforms with the requirements and intent of the Safe Drinking Water Act, EPA requests comment on this issue.

Options 1, 2 and 3 also require more assertive action by the public to ensure protection, especially those served by a CWS. This is true for Option 1, where adults in the target population would be required to contact the CWS for Alternative Water, which would then be delivered. Even more assertive action is needed for Option 3, since informed adults would have to obtain Alternative Water themselves. For Options 2 and 3, in transient systems, an adult wishing Alternative Water might not readily find it, as there would be no requirement to have it available, except for infants. The Agency is requesting comment on whether this need for assertive action would be appropriate, or whether such a strategy is reasonable, given the unique aspects of sulfate.

Option 2 is based on the premise that diarrhea is not an adverse effect in adults. Until now, the Agency has considered some effects as adverse which, by themselves, are not harmful, but are precursors of adverse effects. Examples are (a) developmental effects, such as an extra embryonic rib which is later resorbed; (b) benign tumors; (c) reduction in maternal weight gain, even with no observable fetal effect; and (d) marginal cholinesterase inhibition. In comparison to these effects, the long-term effects of sulfate ingestion appear to be nil, and acclimation occurs in a short period of time. The other effects mentioned are only detected with scientific measurement, while diarrhea or loose stools are readily observed by the person ingesting sulfate. EPA requests comment on whether transient bouts of diarrhea should be considered an adverse health effect or simply an inconvenience in adults.

In addition, EPA requests comment on whether, given the available information, a conclusion can be made that experiencing transient bouts of diarrhea resulting from ingestion of sulfate in drinking water is not an adverse effect in any segment of the population (adults or infants) within the meaning of the Safe Drinking Water Act.

EPA also recognizes that the provisions of this regulation are more difficult to enforce than central treatment. Indeed, it is for similar reasons that EPA has always prohibited Alternative Water as a means of compliance. While PWSs already have the legal option to use a POE device to comply with any MCL if certain requirements are followed, the requirements for using bottled water or POU devices have been applicable only to temporary situations to prevent unreasonable risk to health. Adoption of any of the proposed options would also mean that individuals in the target population would drink bottled water on a temporary basis. However, the extent to which bottled water quality (i.e., compliance with all MCLs) can be assured varies from State to State. The Food and Drug Administration (FDA), which is responsible for overseeing bottled water quality, is continuing to adopt standards which ensure truthful labeling. However, production and sales of bottled water have increased dramatically in recent years, and FDA does not have a complete inventory of domestic bottled water plants. FDA inspects the known plants, on average, every three to four years, or more frequently if problems arise (GAO, 1992). A few States have stricter standards than FDA (NY, CA, PA, CT) and require all bottled water plants to register with the State and conform to State requirements.

Similarly, POU devices are not subject to EPA certification. Since the proposed rule gives the States full authority to decide whether or not an alternative option would be allowed, each State would presumably base its decision on the extent to which it believes implementation is practicable. EPA requests comment on whether it is appropriate to allow use of bottled water and POU devices for sulfate MCL compliance.

f. *Option 4.* Because the proposed option (1) and its variations (2) and (3) represent a significant change in regulatory approach, and in order to fully consider the issues raised, EPA considered another, more conventional option. Option 4 was considered in the event EPA determines that Alternative Water may not be as effective as central treatment in enabling small systems to comply with the sulfate MCL. Option 4 would not directly allow the use of Alternative Water as a means of compliance with the MCL.

In Option 4, systems would need to obtain a variance from the sulfate MCL under the provisions of SDWA section 1415. As a condition of receiving a variance, systems would be required to provide Alternative Water to their target populations, just as in Option 1. Therefore, the relief under Option 4 would be similar to the relief under Option 1 but would be provided through a different statutory mechanism.

In Option 4, central treatment would be designated as section 1412 BAT. Central treatment would be considered economically feasible despite the financial difficulties presented to small systems, because the SDWA legislative history indicates Congress' desire that economic feasibility be determined by reference to large metropolitan water systems.

Section 1415 (and corresponding State laws) provide that systems may obtain a variance only after they have applied the designated BAT technology. However, section 1415 also states that the EPA Administrator may vary the technologies identified as BAT for purposes of section 1415 variances "depending on the number of persons served by the system or for other physical conditions related to engineering feasibility and costs of compliance with [MCLs] as considered appropriate by the Administrator." As a key component of Option 4, EPA would designate Alternative Water along with central treatment as BAT for purposes of

section 1415 variances only. A PWS that is granted a variance would also be required to meet all of the requirements of Option 1 for public education/notification and provision of Alternative Water.

Alternative Water would be designated as a section 1415 BAT because of the special need to provide bottled water which complies with EPA MCLs only to targeted populations for a limited time, which represents a special "physical condition related to engineering feasibility" under section 1415. To protect public health from the adverse effects of sulfate, it is necessary to protect only these specific subpopulations (infants, travelers, and new residents). It is technically infeasible to direct treated water only to those households containing these subpopulations, particularly when various households contain sensitive subpopulations at different times. However, it is technically feasible to direct public education and notification and Alternative Water only to those homes which require it. To treat water going to households with sensitive subpopulations would require a PWS to treat all water. The cost of providing treated water to everyone could be much higher than the PWS would otherwise have to incur.

Option 4 would require administrative involvement by the State in reviewing variance applications. The additional administrative burden is a clear disadvantage of this option, especially because many State agencies administering the drinking water program currently have significant funding and resource problems. On the other hand, a scheme based on individually granted variances might be considered more desirable in that each PWS would need to justify to the State its individual plan for providing Alternative Water.

States may also choose to grant variances in a block to many PWSs at a time, thus reducing their own administrative burden. However, the burden would remain on each system to make an application and present the details of its program to the State.

For the reasons stated above with respect to Option 1, EPA has decided not to limit the availability of variances based on Alternative Water under Option 4 to smaller systems. The public education/notification requirements discussed under Option 1 would apply to those systems receiving a variance under Option 4.

Making relief available to small systems only through variances presents some additional statutory constraints compared to Option 1. First, variances are only available at the discretion of the State. The State is free not to grant variances or to issue them under more stringent conditions than set by EPA. For sulfate, based on the prior State comments and input, States are seeking flexibility and relief for small systems and, therefore, might generally be expected not to be more stringent on variances than EPA. On the other hand, it is unclear whether States will be dissuaded from providing many variances by the administrative burdens presented by Option 4.

Second, under section 1415, variances are available only where the State finds that they will not result in an unreasonable risk to health ("URTH"). However, EPA does not believe that this constraint will present any problems since, as a condition of receiving the variance, PWSs will be required to supply Alternative Water that complies with the sulfate MCL.

Third, section 1415 requires the State to prescribe with the variance a schedule for compliance with the MCL. In this case, by providing Alternative Water to qualify for the variance, the PWS would in fact be supplying water that meets the MCL. Therefore, EPA believes it is not necessary or appropriate to prescribe any further schedules for achieving compliance with the sulfate MCL.

Finally, EPA also notes that SDWA section 1415 provides for variances where a system cannot meet the MCL because of characteristics of the raw water source. Here, the raw water source is not the issue; application of Alternative Water as section 1415 BAT would achieve the MCL but would be considered not as effective as central treatment in ensuring a consistent and reliable supply of water at the MCL. EPA nevertheless believes that Option 4 is consistent with the purposes and intent of SDWA section 1415, but requests comment on this issue.

As an additional option, EPA considered whether relief to small systems could be provided through exemptions under SDWA section 1416. This does not appear to be a viable approach, however. Unlike section 1415, section 1416 does not authorize EPA to vary its designation of BAT for purposes of exemptions. Instead, to qualify for indefinite exemptions, section 1415 envisions that small systems will be continuously working toward obtaining the financing necessary to install the BAT technologies identified under section 1412 (i.e., central treatment). Therefore, exemptions do not appear to be an appropriate mechanism for providing relief from the sulfate MCL to small systems. EPA solicits comment on whether exemptions do provide a mechanism for relief.

g. *Additional option*. The Agency requests comment on the feasibility and appropriateness of the Options discussed above. The Agency is also considering an additional option, namely the traditional approach of simply relying on central treatment as BAT for all systems, with no special provisions for relief for small systems. The advantages to central treatment are that it is the easiest approach to enforce, and it is consistent with the Agency's regulatory approach for other contaminants. The disadvantages are that it is costly and would not provide flexibility or relief for small systems. In particular, under this option, drinking water that meets the sulfate MCL would need to be provided to all consumers even though only a small percentage of the population would experience adverse health effects from ingesting sulfate. Also, the Agency has concerns that this option would not be economically feasible for small systems, as discussed in section IV below. Accordingly, this option is not being offered as the preferred option in today's notice, but EPA is still considering it, and it has the potential to be adopted in the final rule. This option would be adopted, for example, if it appears that the other options would be inadequate to assure a supply of drinking water that dependably complies with the sulfate MCL (see § 1401(1)(D) because members of the target population would fail to take appropriate action to protect themselves from an acute but temporary adverse health effect. The total national cost of this option would be identical to that for Option 4 ($147 million, see Table 8), since the economic analysis assumed that all systems would choose central treatment under Option 4. Similarly, the household cost for this option would be identical to those for Option 4 (Table 9). The Agency requests comment on whether this option, which would effectively limit methods of compliance to central treatment, should be adopted.

5. Compliance Monitoring Requirements

a. *Introduction*. The proposed compliance monitoring requirements for sulfate would apply to all systems (community, non-transient non-community, and transient non-community water systems).

The occurrence of sulfate in drinking water may be predictable based on several factors including geological conditions, use patterns (e.g., pesticides), presence of industrial

activity in the area, and type of source or historic record.

PWSs would need to monitor for sulfate in accordance with EPA's Standard Monitoring Framework (SMF), published Jan. 30, 1991 (56 FR 3564). Monitoring is done for three, three-year compliance periods in a nine-year cycle. The Phase II regulations established a nine-year cycle for those contaminants in that **Federal Register** notice. By agreement between States and EPA at a Denver work group meeting in 1992, subsequent rules will begin their individual nine-year cycles in the first January after the effective date (18 months after promulgation).

The monitoring requirements described in the next section are proposed to apply to systems which exceed the MCL and are authorized by the State to select the preferred option (Option 1) to achieve compliance with the sulfate MCL. For systems which select central treatment, or which do not exceed the MCL, the SMF is proposed to apply. If either Option 2 or Option 3 becomes the final regulation for sulfate and the State allows that method of compliance, the monitoring requirements described for Option 1 regarding Alternative Water and the reporting/record keeping requirements for public notification would apply for systems exceeding the sulfate MCL. Initial monitoring to determine MCL exceedence would be required of all systems, that is, community, transient and non-transient, non-community systems.

b. *Proposed monitoring requirements for sulfate.* The monitoring requirements for those systems selecting Option 1, with State authorization, would be as follows, and are consistent with the provisions of § 142.62 (g) and (h).

(1) Bottled water.

There are regulations in effect (§ 142.62) which state that a PWS can be required or permitted by the State to supply its customers with bottled water as a condition for receiving a variance or exemption. These regulations indicate that the State shall require and approve a monitoring program for bottled water and that the PWS shall develop and put in place a monitoring program that provides reasonable assurances that the bottled water meets all MCLs. These same monitoring requirements are proposed to apply here. The PWS monitors a representative sample of the bottled water for all contaminants regulated under §§ 141.61 (a) and (c) and 141.62 during the first three-month period that it supplies the bottled water to the public, and annually thereafter. Results of the monitoring are provided to the State annually.

The State, in lieu of the above requirements, could accept certification from the bottled water company that the bottled water supplied has come from an approved source as defined in 21 CFR 129.3(a); and that the bottled water company has conducted monitoring in accordance with 21 CFR 129.80(g) (1) through (3); and that the bottled water does not exceed any EPA MCLs. The PWS would have to provide certification to the State the first quarter after it supplies bottled water and annually thereafter. At the State's option a PWS may satisfy the requirements of this subsection by citing an approved monitoring program which is already in place in another State.

The existing regulations regarding interim use of bottled water to avoid an unreasonable risk to health state that the PWS is fully responsible for the provision of sufficient quantities of bottled water to every customer via door-to-door delivery. The Option being proposed today (Option 1) would similarly require door-to-door delivery by the PWS to persons in the target population when the sulfate MCL is exceeded. EPA requests comment on whether this door-to-door delivery requirement is appropriate for the sulfate rulemaking, or whether the requirements should be more flexible. For example, several possible means of delivery might be allowed. Distribution points could be authorized to stock and supply bottled water to the target population, with coupons issued to consumers in the target population redeemable at the distribution point. PWSs supplying bottled water to households would deliver that water upon request and free of charge, except as discussed under III.B.4.c. above. EPA requests comment on the degree of flexibility needed in the mechanism for delivery of bottled water that meets the sulfate MCL.

(2) POU/POE devices.

The existing regulations for variance and exemption conditions (§ 142.62) also describe the requirements for allowing a PWS to use POU or POE devices. These regulations state that it is the responsibility of the PWS to operate and maintain the POU and/or POE treatment system. Before POU or POE devices are installed, the PWS obtains the primacy agent's approval of a monitoring plan which ensures that the devices provide health protection to the target population equivalent to that provided by central treatment. The PWS must apply effective technology under a State-approved plan. The microbiological safety of the water must be maintained at all times. The State must require certification of adequate performance, field testing, and if not included in the certification process, an engineering design review of the POU/POE devices. Under § 142.62(h), the design and application of the POU/POE devices must consider the potential for increasing concentrations of heterotrophic bacteria in water treated with activated carbon. The State must be assured that buildings connected to the system have sufficient POU or POE devices that are properly installed, maintained, and monitored such that all consumers will be protected.

The existing regulations described above would be applied in both Options 1 and 4. EPA assumes that only Options 1 and 4 would entail the use of POU/POE devices, since in Options 2 and 3, bottled water would likely be more cost-effective, given the reduced target population. The Agency seeks comment on whether all of these existing requirements should be proposed in the case of sulfate MCL exceedence, or whether more flexible requirements would be appropriate. For example, if recordkeeping could demonstrate that an effective maintenance program was in place to ensure the proper functioning of the treatment equipment and compliance with the MCL, some reduction in monitoring might be foreseen. The efficiency or longevity of certain types of POU or POE devices might also be considered.

(3) Effective Dates for Initial Monitoring.

Initial monitoring for all systems would begin in the first January after the effective date of the rule. EPA's issuance of the final sulfate rule is scheduled for May 1996. The effective date will be 18 months after the promulgation of the final rule, or November of 1997. If this schedule is maintained, the initial monitoring for sulfate would begin in January 1998 for all systems.

(4) Sampling Location.

Under the proposed regulation, both ground water and surface water systems would take a minimum of one sample at every entry point to the distribution system which is representative of each well or source after treatment. The number of samples a system must take will be determined by the number of entry points. This will make it easier to pinpoint possible contaminated sources (wells) within a system. In both surface and ground water systems, the system shall take each sample at the same sampling point unless conditions make another sampling point more representative of each source or treatment plant.

(5) Monitoring Frequency.

Surface water systems would be required to monitor annually and ground water systems would sample every three years. Systems which comply by Option 1 would not be required to continue monitoring the water in the distribution system for sulfate. That water may continue to exceed the sulfate MCL, but the PWS would be in compliance by providing Alternative Water and public notification to target populations. However, the water would still have to be monitored for and meet MCLs for other contaminants.

(6) Public Notice Requirements.

EPA proposes that PWSs who use central treatment and who are nevertheless not in compliance with the sulfate MCL would be subject to the public notification requirements in § 141.32. However, the Agency recognizes that having different public education/notification requirements for those systems choosing central treatment and those choosing Option 1 may create confusion, and seeks comment on this issue.

For PWSs authorized by the State to use whichever option (1 through 4) is promulgated in the final sulfate rule, public notification requirements are proposed to be those described in section III.B.4.b.3 of this Notice.

c. *State Implementation.* The Act provides that States may assume primary implementation and enforcement responsibilities for the PWS program (primacy). 40 CFR part 142 contains EPA's primacy regulations. In States or tribal governments where EPA has direct implementation, resource constraints make it unlikely that the Agency would offer the alternative options (1 through 4, whichever is promulgated) to systems. EPA Regional Offices will, however, have the discretion to consider particular circumstances in their decision about whether or not to offer and implement the alternative option. The Agency assumes that most States with primacy would offer the alternative option, but requests comment on this issue.

Fifty-five out of 57 jurisdictions have applied for and received primacy under the Act. To implement the federal regulations for drinking water contaminants, States must have legal authorities which are at least as stringent as the federal regulations. To update their programs, States must comply with the requirements in 40 CFR 142.12 on revising approved primacy programs. This proposal describes the regulations and other procedures and policies States would need to adopt or have in place to implement the new regulations for sulfate.

Under this proposal, States would be required to adopt the following requirements: Modifications to § 141.23, Inorganic Chemical Sampling and Analytical Requirements, § 141.32, Public Notification Requirements (i.e., mandatory health effects language to be included in public notification or violations), and § 141.62(b), Maximum Contaminant Levels for Inorganic Contaminants, where sulfate has been added to the list.

In addition to adopting drinking water provisions no less stringent than the federal regulations listed above, EPA is proposing to allow States to adopt certain requirements related to this regulation in order to have their program revision application approved by EPA. This rule proposes to provide flexibility to the State with regard to implementation of the monitoring requirements for sulfate depending on whether a system chooses central treatment or the alternative method of compliance promulgated in the final rule. In all cases, States would decide and inform PWSs as to whether the alternative method of compliance (referred to as Option 1 for simplicity) promulgated in the final sulfate rule will be allowed. Specifically, States would be authorized to offer Option 1 as a means of compliance to PWSs who exceed the sulfate MCL. Under Option 1, the State would need to approve the monitoring plan of a PWS that chooses the Alternative Water and public education/notification as a means of compliance. The requirements would be as follows:

(1) State Primacy Requirements.

To ensure that the State program includes all the elements necessary for an effective and enforceable program, the State's request for approval must include a plan that each system monitor for sulfate by the end of each compliance period. If the State is planning to authorize PWSs to use Option 1, it would need to submit the text of State laws requiring the Alternative Water and public notification/education program, and a description of the State's plan to oversee compliance of the program. States planning to issue monitoring waivers would do so according to the requirements of § 142.16.

(2) State Recordkeeping Requirements.

The State shall keep a record of PWSs choosing to use Option 1 to comply. If the State has authorized Option 1, PWSs would be required to notify the State within 30 days of reporting a sulfate MCL exceedence, of its decision on whether to use Option 1 or other means of achieving compliance.

(3) State Reporting Requirements.

The quarterly report shall include all systems that have violated the sulfate MCL, and those which the State has authorized to use Option 1.

d. *Variances and Exemptions.* Option 4 offers relief to small systems in the form of an alternative to centralized treatment. If a system in violation of the sulfate MCL chooses centralized treatment but for some reason cannot achieve compliance, the system would apply to the Primacy Agent for a variance, and the conditions of the variance would be the same elements described for Option 1.

(1) Variances

Under section 1415(a)(1)(A) of the SDWA, EPA or a State with primacy may grant variances from MCLs to those public water systems that cannot comply with the MCLs because of characteristics of their water sources. At the time a variance is granted, the State must prescribe a compliance schedule and may require the system to implement additional control measures. The SDWA requires that variances may only be granted to those systems that have installed BAT (as identified by EPA). However, in limited situations a system may receive a variance if it demonstrates that the BAT would only achieve a *de minimis* reduction in contamination (see § 142.62(d)). Before EPA or a State issues a variance, it must find that the variance will not result in an unreasonable risk to health (URTH). In general, the URTH level would reflect acute and subchronic toxicity for short-term exposures and high carcinogenic risks for long-term exposures. For sulfate EPA's guidance regarding what is an URTH level is set at the MCL because sulfate has an acute adverse health effect. For the sulfate variance, if the PWS provides public education/notification and Alternative Water, EPA believes that the State should be able to conclude that the PWS will not be considered to exceed an URTH because those actions are considered protective of public health.

Under section 1413(a)(4) of the Act, States with primacy that choose to issue variances must do so under conditions and in a manner that is no less stringent than EPA allows under section 1415.

The Act permits EPA to vary the BAT established under section 1415 from that established under section 1412 based on a number of findings such as system size, physical conditions related to engineering feasibility, and the cost of compliance. Paragraph 142.62 of this proposed rule lists the BAT that EPA

has specified under section 1415 of the Act for the purposes of issuing variances. The variance BAT is Alternative Water and public education/notification.

(2) Exemptions

Under section 1416(a), a State or EPA may grant an exemption extending deadlines for compliance with a treatment technique or MCL if it finds that:

(a) Due to compelling factors (which may include economic factors), the PWS is unable to comply with the requirement;

(b) The exemption will not result in an URTH; and

(c) The system was in operation on the effective date of the NPDWR, or, for a system not in operation on that date, that no reasonable alternative source of drinking water is available to the new system.

In determining whether to grant an exemption, EPA expects the State to determine whether the facility could be consolidated with another system or whether an alternative source could be developed. Another compelling factor is the affordability of the required treatments. It is possible that very small systems may not be able to consolidate or find a low-cost treatment. EPA's analysis of cost for the proposed sulfate rule shows that, for very small systems, the cost is lower to provide public education/notification, and Alternative Water than to provide central treatment. Thus, EPA believes this alternative BAT is affordable for these systems.

As discussed above, granting exemptions under SDWA section 1416 does not appear to be a viable approach to providing relief from the sulfate MCL for smaller systems. Unlike section 1415 for variances, section 1416 does not authorize EPA to vary its designation of BAT for purposes of exemptions.

IV. Economic Analysis

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735 (October 4, 1993)), the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact on entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" because it proposes a means of MCL compliance that is unique in its attempt to limit protection only to the affected populations. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

EPA prepared a Regulatory Impact Analysis (RIA) for this rule, titled the Regulatory Impact Analysis of Sulfate (August 30, 1994). The analysis used the following data, where available, for sulfate:

- Occurrence data to determine the number of systems exceeding the MCL;
- Treatment and waste disposal cost data and corresponding selection probabilities to estimate the system level and aggregate costs of achieving the proposed MCL; and
- Monitoring costs to estimate aggregate costs of the monitoring requirements.

Occurrence data adequate to determine the number of systems exceeding the proposed MCL are available for sulfate. Table 7 indicates the number of systems in several system size categories expected to be out of compliance with the proposed MCL of 500 mg/L.

TABLE 7.—NUMBER OF SYSTEMS EXPECTED TO EXCEED 500 MG/L SULFATE [1]

Water system type	Serving less than 500 people	Serving less than 3300 people	Total of all systems
Community Water Systems	350 (356)	500 (477)	500 (511)
Non-Transient, Non-Community Systems	250 (235)	250 (264)	250 (266)
Transient, Non-Community Systems	1150 (1144)	1200 (1187)	1200 (1189)
Total Number of Systems	1750 (1735)	1950 (1929)	1950 (1966)

[1] Numbers are rounded; actual numbers are in parentheses.

B. National Costs of the Proposed Rule

Under Option 1, annualized national treatment and waste disposal cost is projected to total $86 million for the proposed MCL of 500 mg/L, of which $8 million is estimated for monitoring and State implementation.

With State authorization, the 1,500 systems assumed to choose public notification/education and Alternative Water account for $7 million of the total, or about $5,000 per system. The Agency assumes that, despite the availability of Option 1, 25% of the systems (approximately 500) exceeding the sulfate MCL would choose either central treatment or regionalization, for a total cost of $71 million. Possible reasons for choosing central treatment would be to avoid a permanent requirement for public notification/Alternative Water provision and its associated administrative and logistical costs and activities, or to comply with other existing or future regulations on other contaminants. The difference in cost to large systems choosing central treatment rather than Option 1 is a factor of approximately 3 to 5. EPA assumes that this additional cost would not dissuade large systems from choosing central treatment. For costing purposes, it was assumed that all transient systems not choosing central treatment would install a POE device, and all CWS and NTNC systems not choosing central treatment would use bottled water or POU devices. In reality, the Agency recognizes that there would be a mixture of choices among system types, and that the choice of a POE by a small system constitutes "central treatment" for that system, since all water is treated and the technology used for the POE would be a BAT technology such as RO. Small transient systems could legally choose a POE device under any of the proposed options, and

since their cost cannot be counted under both centralized treatment and Option 1, their costs have been included under the heading "non-centralized treatment".

Under Options 2 and 3, the total cost of the rule is approximately $16 million, which also includes $8 million for State implementation and monitoring costs. The implementation of Options 2/3 would be much less costly than Option 1, but would involve all 2,000 systems, compared to the 1,500 systems which would choose public notification/education and Alternative Water in Option 1. Consequently, the cost of implementation would be $8 million rather than the $7 million for Option 1. The target population would be reduced to infants and the water allocated reduced to 1 liter per day. Although more infants would be included by large systems choosing this option, infants comprise less than 2% of the population at any given time. The difference in cost to large systems choosing central treatment rather than Options 2/3 would be at least an order of magnitude. EPA assumes that this additional cost would dissuade large systems from choosing central treatment, and therefore that all systems would choose Option 1. Implementation of Options 2 and 3 would be identical, except for the content of the public education/notification.

Under Option 4, the total national cost of the rule is $147 million. For costing purposes, it was assumed that all systems would install central treatment, rather than request a variance. For some of the smallest systems, the central treatment installed consists of a POE device, which functions on the same principles as a treatment plant (e.g., reverse osmosis). Since some percentage of systems would, in reality, request a variance and comply by public notification/education and Alternative Water provision, the cost for Option 4 is somewhat of an overestimate. At the same time the cost for Option 4 is an accurate estimate of what the cost would be for central treatment for all affected systems.

Under all options, approximately 2,000 systems, most serving populations less than 500, are expected to exceed the sulfate MCL.

1. Assumptions Used To Estimate Costs

For each system size category, for both ground and surface water systems, the projected number of systems with contamination above the sulfate proposed MCL was determined from the occurrence data. The number of systems exceeding the MCL was then merged with a compliance decision matrix, which gave the relative likelihood that a given system would choose various treatment, compliance and waste disposal options.

For systems choosing central treatment, the resulting estimates were then multiplied by the unit engineering costs, which include both capital and O&M costs. Although pre-treatment costs were included in the estimates, the operation of reverse osmosis by some systems with very high influent sulfate levels may contribute to the need for additional post-treatment corrosion control to comply with the lead and copper rule. This would likely affect only systems with influent sulfate concentrations above 750 mg/L because more than one-third of the influent stream would be treated. These costs would be added to the costs of the BAT, but would not affect EPA's conclusions on affordability because they would be insignificant compared to the overall costs of the central treatment technology.

For the purposes of cost estimation, the Agency assumed that the cost of either POU or POE is the same. Each system is assumed to install POE, since the cost of one POE is generally less than the cost of multiple POU units. For example, in a gas station, a POU unit would be needed at the men's restroom, the women's restroom and the water fountain in the public area. In this scenario, it might be cost-effective to install one POE unit versus three POU devices. Several sources were used to estimate the capital and O&M costs for POU/POE units, including (1) "Point-Of-Use Treatment of Drinking Water in San Ysidro, New Mexico;" March, 1990; (2) National Network for Environmental Management Studies Research Report on Affordable Drinking Water Treatment for PWSs Contaminated by Excess Levels of Natural Fluoride;" December, 1991; and (3) "Very Small Systems Best Available Technology Document;" First Draft; September, 1993. The calculations included some of the following assumptions:

(1) Laboratory costs including four bacteriological analyses and two sulfate analyses per year.

(2) The replacement frequency for both the particulate filter and the carbon post filter is assumed to be twice per year.

(3) The purchase price for the POU devices ranges from $329 to $665 depending on the number purchased at one time.

(4) The cost for installation is assumed to be $79.

(5) The cost for a one year maintenance service contract is assumed to be $508 per unit.

Bottled water costs are based on data provided by the International Bottled Water Association. The cost includes cost of water, delivery, and labor. Water is estimated at $1.06 per gallon. People are assumed to consume 0.53 gallons per day. The Agency estimated 1 delivery per week with a round trip distance of 25 miles costing $0.28 cents per mile. The Agency also estimated one hour for each delivery at a labor rate of $14.70 per hour. For Options 2 and 3, where bottled water is provided only to infants, the water allocation is one liter per day.

The Agency used Federal Reporting Data System (FRDS) data to determine how many people lived in an average system in each system size category. EPA used U.S. Census Bureau population and fertility data to estimate that 1.68% of the people were infants and 16.4% of the people were new residents. Recent census data put the average number of people per household at 2.6. The number of travelers needing Alternative Water was derived from information from the National Travel Data Center that there are approximately 1.27 billion person-trips made nationally each year. The number of traveling persons exposed is calculated by multiplying the estimated 250 million people served by all water systems with the probability that a traveler will visit a system with water containing sulfate levels exceeding the MCL. The probability that a traveler will visit such a system is calculated by dividing the resident population in a given system size category by the total resident population of all systems. This value is then multiplied by the number of person trips and divided by five (the number of person trips per year per traveler) to get the population of exposed travelers in that size category. The resulting estimate is that approximately 1 million travelers are exposed to sulfate in excess of 500 mg/L.

For the public education and notification requirements, the PWS is responsible for producing and delivering pamphlets according to EPA's public notification guidelines. The number of pamphlets needed per size category is calculated based on the population served by the PWS. Larger population centers will contain more medical facilities. For example, if size category 1 (25–100 people) serves 0.03% of the total population, it is also assumed to serve 0.03% of the nation's 6,634 hospitals, 83,425 schools, and so on. The number of permanent signs per system is calculated by taking the number of hotels, campgrounds, interstate rest areas, rest rooms in

restaurants and gas stations in the nation and multiplying by the percent of population served by each size category.

The national annualized cost of the rule for the four options is shown in Table 8.

TABLE 8.—NATIONAL ANNUAL SULFATE COSTS FOR OPTIONS 1–4 (DOLLARS IN MILLIONS)

	Option 1	Options 2/3	Option 4
Central Treatment	$71	.....	$139
Public Not./Ed./Alt. Water	7	$8	.....
State Implementation	7	7	7
Monitoring	0.5	0.5	0.5
Total	86	16	147

2. Costs to Households

Table 9 illustrates estimated household costs for the options being considered. For costing purposes, it was assumed that all systems were community water systems, since transient systems do not have households. For Option 1, costs increase for systems serving populations greater than 3,300 due to the fact that most of those systems would choose central treatment. Costs level off and decrease for systems serving populations greater than 10,000 due to economies of scale.

TABLE 9.—AVERAGE ANNUALIZED COSTS FOR HOUSEHOLDS (DOLLARS IN MILLIONS) IN COMMUNITY WATER SYSTEMS

System size	No. of systems	Option 1	Options 2/3	Option 4
25–100	1244	$250	$145	$811
101–500	491	138	56	534
501–3.3K	194	106	24	376
3.3K–10K	26	287	4	287
10K–100K	10	244	2	244
>100K	0	NA	NA	NA

[1]NA—no systems that size affected by high-sulfate water.

On the basis of these estimated costs, EPA concludes that the options being considered would be economically feasible, and requests comment on this conclusion.

3. Assumptions Used to Estimate Benefits

The Agency made assumptions for estimating the benefits of diarrhea cases avoided which included affected population, costs of medical care, and value of days lost to care givers, business travelers and vacationers.

It is estimated that approximately 1.2 million people will have reduced exposure to sulfates as a result of PWSs' compliance with the sulfate MCL. The low and high estimates of reduced population exposure, based on uncertainty in occurrence data, are 0.9 million and 1.7 million people, respectively.

Evaluating benefits is limited to estimating reduced population exposure because there are inadequate dose-response data to estimate cases of adverse health effects avoided. Consequently, potential benefits per case of diarrhea avoided are estimated rather than total benefits. Exposed population is usually calculated by multiplying the number of systems failing the MCL by the average population served by each system. A different approach was used for sulfate, since only unacclimated persons and infants are affected. The affected population is in areas served by systems with sulfate levels of 500 mg/L or more, and includes resident infants under one year of age, travellers, including infants, of all ages visiting the area, new residents and houseguests that stay with residents. Infants were assumed to accompany parents on pleasure trips but not on business trips. Sources of population data were the National Travel Data Center and the U.S. Census Bureau Current Population Reports and fertility statistics. The Agency used the 1991 census data for the number of infants born in a year. The number of persons exposed is calculated by multiplying the estimated 250 million people served by all water systems with the probability that the average traveler will visit a system with elevated sulfate levels. The Agency used the National Travel Data Center estimate of approximately 1.27 billion person-trips made nationally each year for travelers. The number of diarrhea cases avoided is based on the estimate of person-trips because each un-acclimatized individual is assumed to face multiple exposures to sulfate and potentially contract diarrhea more than once a year.

This estimate of people exposed has uncertainty based on two variables: the number of systems with elevated sulfate levels, and the data used to model the traveling population. The best estimate of the number of travellers and resident infants with reduced exposure to sulfate at an MCL of 500 mg/L is 1.2 million people (including 27,000 infants). A logistic response function was used to characterize the statistical relationship between sulfate levels in drinking water and the probability of an exposed individual experiencing a laxative effect. One weakness of this approach is that it assumes that consumption of either sodium sulfate or magnesium sulfate results in equivalent laxative effects. It has been reported that magnesium sulfate is a better purgative than sodium sulfate.

Uncertainty is also associated with the lack of toxicological data on the relationship between various sulfate levels and the resulting laxative effect. There are insufficient data to plot a

dose-response function. As a result, the Agency is limiting its estimate of benefits to an individual case basis.

The assumptions made in estimating benefits on a case by case basis are shown in Table 10. The value of an outpatient case in Table 10 is between $218–$273. For example, the value of a case of diarrhea in a resident infant who is not hospitalized would be $55+$11 for the doctor and medication, plus 8 hours of the care giver's time ($19×8=$152), since it is assumed the caretaker would miss work. The total value for the case is $66+$152=$218. An additional $55 would be added in the case of a traveling infant for hotel and travel expenses lost. The range accounts for the difference between residents and travelers. The infant hospitalization cases cost between $3,608 and $3,828 per case. The Agency is requesting comment on the assumptions used in the analysis of the benefits of the proposed rule.

TABLE 10.—ASSUMPTIONS MADE IN ESTIMATING BENEFITS

	Resident infants	Travelling infants	Travelling adults	New resident adults
Out-Patient Cases:				
Doctor Charges	$55	$55	$55	$55
Medication Charges	$11	$11	$11	$11
Days Lost Per Case	1	1	1	1
Value of Each Day Lost [1]	(NA)	$55	$55	(NA)
Hours Lost Per Case	8	8	8	8
Value of Each Hour Lost	$19	$19	$19	$19
Value Per Case:	$218	$273	$273	$218
Hospitalized Cases: [2]				
Number of Days	4	4	0	0
Hospital Cost Per Day	$750	$750	0	0
Value of Each Trip Day Lost [3]	(NA)	$55	0	0
Hours Lost Per Case	32	32	0	0
Value of Each Hour Lost	$19	$19	0	0
Value Per Case	$3,608	$3,828	0	0

[1] Out of pocket hotel and travel expenses, not applicable to infants or new residents, only to business travelers.
[2] NA—Older travellers are not hospitalized.
[3] No value assigned to trip days lost for infants.

C. Comparison to Earlier Proposed Rule

The 1990 proposed rule estimated the cost for central treatment to be $65 million (excluding monitoring costs). There were assumed to be 1350 systems which would need to treat for sulfate. For this reproposal EPA updated the cost to $139 million (excluding State and monitoring costs). The increase in cost is due to: (1) The increase in projected number of systems that would exceed the sulfate MCL from 1350 to 1950, (2) change in the interest rate from 3% to 7%, and (3) updating for 1991 dollars.

Although the new occurrence information was taken primarily from the National Inorganics and Radionuclides Survey (NIRS), EPA complemented that information with sampling data from New York, Utah, South Dakota, North Dakota and New Jersey. Because of the new occurrence information, the number of systems has gone up from 1350 to 1950. Another reason for the increase is EPA's modification, as a result of research for the upcoming regulation concerning the control of radionuclides in drinking water, of the number of treatment sites per ground water system. Ground water systems frequently contain more than one site requiring treatment because wells are typically not piped to a central source. EPA has incorporated this estimation method for all systems served by ground water.

D. Annual Burden to PWSS and States

EPA estimates that the cost of sulfate regulation to State programs will be $7 million per year. Table 11 illustrates the 18-year average annual national burden hours, responses and costs to PWSs and States. Sulfate testing does not require special laboratory equipment. Therefore, it is assumed that laboratory expansion undertaken to implement the Phase II and Phase V regulations will largely satisfy the monitoring needs of this rule. On the other hand, EPA recognizes that States are likely to provide more technical assistance to systems than for an average contaminant because of the unique nature of Option 1. Total annual costs are estimated to be $10.6 million. The additional public reporting burden on PWSs for this collection of information is estimated to average 8.6 hours per response.

TABLE 11.—ANNUAL BURDEN HOURS

	PWSs	States	Total
Annual Burden (Hours)	66,581	300,000	366,581
Annual Cost ($)	$3,577,613	$7,000,000	$10,577,613
Annual Responses	42,615	57	42,672

Source: Sulfate ICR, August 31, 1994.

V. Summary of Selected Issues

EPA is soliciting public comment and scientific information on all issues presented in or pertaining to this proposed sulfate regulation. In particular, EPA requests comments on the following:

(1) Is there a correlation between sulfate concentrations, palatability and consumption of high-sulfate water by the public?

(2) Are there new data in support of or opposing the reproposed MCLG of 500 mg/L? Are there new data in support of a higher MCLG?

(3) Are there data to support or refute the hypothesis that the decrease in available water resulting from sulfate ingestion may result in dehydration in adults or infants?

(4) Are reverse osmosis, ion exchange and electrodialysis reversal appropriate technologies for sulfate removal?

(5) Should a higher PQL of 30 mg/L be set in order to retain the colorimetric method of analysis?

(6) Are the allotted time periods for provision of Alternative Water, i.e., 20 weeks for infants within the first year of life and 6 weeks for new residents and travelers, appropriate and protective?

(7) What should be the means of compliance for unmanned, remote campgrounds in the national parks system, particularly in regard to the provision of Alternative Water?

(8) What types of Alternative Water would be likely to be chosen by public water systems of various types and sizes?

(9) Are the compliance requirements, that is, Alternative Water and public notification, sufficiently protective of the sensitive population?

(10) Should the target population be limited just to infants, or should there be different requirements for protecting infants and adults?

(11) Are the proposed options consistent with the purposes and intent of SDWA, and are they feasible?

(12) Is a provision to allow the water supply to exceed the sulfate MCL while relying on public notification and self-protection appropriate under SDWA?

(13) Is the need for assertive action on the part of the public for self-protection appropriate?

(14) Should temporary diarrhea be considered an adverse health effect in adults or infants?

(15) Would exemptions provide a mechanism for relief to smaller systems?

(16) Should compliance be limited to central treatment?

(17) Is it appropriate under SDWA to allow the use of bottled water and POU devices for sulfate MCL compliance?

(18) What degree of flexibility is appropriate in the bottled water monitoring requirements and delivery mechanism?

(19) In Options 1 and 4, should all the existing regulations regarding use of POU and POE devices be imposed in the case of sulfate levels higher than the MCL, or are more flexible requirements appropriate?

(20) Should the generic public notice requirements applicable to variances under § 141.32 apply under Option 4 to systems who choose central treatment, in lieu of the public notice requirements proposed in Option 1?

(21) Are the assumptions used in the analysis of the costs and benefits of the proposed rule reasonable?

(22) What flexibility is appropriate or practical in regard to the maintenance of POU/POE devices installed to comply with the sulfate MCL? What flexibility is appropriate regarding a reduction in monitoring if certain types of POU/POE devices were installed?

(23) Would most States offer the alternative option to PWS as a means of compliance?

VI. Other Requirements

A. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) calls for the Agency to consider the potential impacts of proposed regulations on small businesses, organizations and government jurisdictions. If an analysis shows that regulations would have a significant impact on a substantial number (usually taken as at least 20 percent) of small entities, then a regulatory flexibility analysis (RFA) must be prepared. In an RFA, an agency examines "any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities" (Regulatory Flexibility Act section 603).

Today's proposed regulation would affect less than 2,000, or one percent, of the total of 200,000 public water systems (including all community and non-community systems). Nevertheless, EPA's analysis shows that regulating sulfate through standard approaches that assume the need for central treatment would have significant economic impacts that would fall largely on smaller public water systems. Therefore, EPA has conducted a regulatory flexibility analysis by investigating alternative, less burdensome regulatory approaches for those small systems. From these investigations, EPA developed and is considering the innovative options for regulating sulfate described earlier in this notice. These innovative options accomplish the Regulatory Flexibility Act's goal of minimizing the impacts of this regulation on small public water systems while meeting the objectives of the Safe Drinking Water Act by ensuring that drinking water that meets the sulfate MCL will be provided to all persons within the target population.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act* (44 U.S.C. 3501 et seq.). An Information Collection Request (ICR) document has been prepared by EPA(ICR No. 270.34) and a copy may be obtained from Sandy Farmer, Information Policy Branch; EPA; 401 M Street, SW. (Mail Code 2136); Washington, DC 20460 or by calling (202) 260–2740.

This collection of information has an estimated annual reporting and recordkeeping burden averaging 9.3 hours per respondent. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. National annual burden and cost estimates for PWSs and States are presented in Table 11.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch; EPA; 401 M Street, SW. (Mail Code 2136); Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget; Washington, DC 20503, marked "Attention: Desk Officer for EPA". The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Enhancing the Intergovernmental Partnership

Executive Order 12875, Enhancing Intergovernmental Partnerships explicitly requires Federal agencies to consult with State, local, and tribal entities in the development of rules and policies that will affect them. EPA has complied with the Order in proposing the sulfate rule in the following ways.

First, the Agency met with interested parties, including representatives from four States, Region 8, and the Association of State Drinking Water Administrators in Denver, Colorado in November, 1992.

Secondly, the Agency plans to meet with the National Drinking Water Advisory Council (NDWAC), a group composed of representatives from State, local and tribal governments in addition to water suppliers and environmentalists.

Thirdly, the Agency is developing generic contacts with State, Tribal and

local fiscal and program officials which will enable various programs to consult with affected parties in a coordinated fashion. Identification of appropriate contacts was not accomplished in a time frame which enabled EPA's Office of Water to have extensive consultation with affected parties in compliance with the E.O. before proposal. However, a contact person has now been designated from ASDWA, and the Agency will be meeting with this designee and other interested State officials. EPA is committed to expanded dialogue and collaboration with State, Tribal and local governments. EPA will schedule a work group or public meeting to solicit comments of fiscal and program officials or State, Tribal and local governments. The intent of such a meeting is to allow for the maximum input from the regulated community for the drafting of the final rule. EPA will also send copies of this proposed rule to these governmental bodies, as well as to national and local associations (e.g., the Association of State Drinking Water Administrators, the National League of Cities, the National Association of Towns and Townships, the National Association of County Health Officers, etc.)

VII. References

The following references are referred to in this notice and are included in the public docket together with other correspondence and information. The public docket is available as described at the beginning of this notice. All public comments received on the proposal are included in the public docket.

American Water Works Association (AWWA) Conference Proceedings (March 1991): Suffolk Introduces Electrodialysis Reversal to Virginia. M. Thompson and M. Robinson.

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List of Subjects in 40 CFR Parts 141, 142 and 143

Chemicals, Reporting and recordkeeping requirements, Water supply, Administrative practice and procedure.

Dated: November 30, 1994.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, 40 CFR parts 141, 142 and 143 are proposed to be amended as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4 and 300j–9.

§ 141.23 Inorganic chemical sampling and analytical requirements.

2. Section 141.23 is amended by revising the last sentence of the introductory text to read as follows:

Transient, non-community water systems shall conduct monitoring to determine compliance with the nitrate, nitrite and sulfate maximum contaminant levels in § 141.11 and § 141.62 (as appropriate) in accordance with this section.

* * * * *

§ 141.23 [Amended]

3. In § 141.23(a)(4)(i), the table is amended by adding in alphabetical order an entry for sulfate to read as follows:

* * * * *

(a) * * *

(4) * * *

(i) * * *

Contaminant	MCL (mg/l)	Methodology	Detection limit (mg/l)
* * *	*	* *	*
Sulfate	500	Colorimetry	3
		Gravimetry	1
		Ion Chromatography	0.02

* * * * *

§ 141.23 [Amended]

4. In § 141.23(c) introductory text, "sulfate" is added in alphabetical order to the list of contaminants.

§ 141.23 [Amended]

5. In § 141.23(d) introductory text, "and sulfate" is added after the word "nitrate".

§ 141.23 [Amended]

6. In § 141.23(f)(1), "sulfate" is added in alphabetical order to the list of contaminants.

§ 141.23 [Amended]

7. In § 141.23(i)(1) and § 141.23(i)(2), "sulfate" is added in alphabetical order to the list of contaminants.

§ 141.23 [Amended]

8. The table in § 141.23(k)(1) is amended by adding an entry for "Sulfate" in alphabetical order as follows:

* * * * *

(k) * * *

(l) * * *

Contaminant	Methodology	EPA[1 5 12]	ASTM[2]	SM[3]	USGS[4]	Other
*	*	*	*	*	*	*
Sulfate	Ion chromotography	[8]300.0	D4327–91	4110		
	Colorimetry	[8]375.2		4500–SO_4–C,D		
	Gravimetry			4500–SO_4–F		

* * * * *

§ 141.23 [Amended]

9. In § 141.23(k)(4), "Sulfate" is added in alphabetical order to the list of contaminants, and the table is amended as follows:

* * * * *

(k) * * *

(4) * * *

Contaminant	Preservative[1]	Container[2]	Time[3]
*	*	*	*
Sulfate	Cool, 4 °C.	P or G	28 days

* * * * *

§ 141.23 [Amended]

10. In § 141.23(k)(5), introductory text, "sulfate" is added in alphabetical order to the list of contaminants.

§ 141.23 [Amended]

11. In § 141.23(k)(5)(ii), the table is amended by adding an entry for sulfate as follows:

(k) * * *

(5) * * *

(ii) * * *

Contaminant	Acceptance limit
Sulfate	±15% at ≥ 10 mg/l

* * * * *

§ 141.23 [Amended]

12. Section 141.23 is amended by adding paragraph (r) to read as follows:

* * * * *

(r)(1) *Compliance with the MCL for Sulfate.* (i) PWSs subject to the sulfate MCL established under § 141.62(b) shall demonstrate compliance with the sulfate MCL. If authorized by the State to do so, PWSs may choose to comply in one of the following two ways:

(A) The PWS shall demonstrate compliance by achieving the MCL in samples taken at each entry point to the distribution system; or

(B) The PWS shall demonstrate compliance by meeting the requirements of §§ 141.23(r)(2) and (3) (program for providing Alternative Water to Target Populations and providing public notification and education). The requirements of §§ 141.23(r)(2) and (3), taken together, are termed the "Alternative Method of Compliance." However, the availability of the Alternative Method of Compliance is limited by paragraph (r)(1)(ii) of this section.

(ii) The State has the option of whether or not to allow PWSs to demonstrate compliance through the Alternative Method of Compliance. Where the State has chosen not to allow the Alternative Method of Compliance, PWSs shall demonstrate compliance by achieving the MCL in samples taken at each entry point to the distribution system.

(iii) Where EPA is the primacy agent, the Regional Administrator may authorize PWSs to demonstrate compliance through the Alternative Method of Compliance. In determining whether to authorize the use of the Alternative Method of Compliance, the Regional Administration in its sole discretion may consider the availability of regional resources, and whether it is reasonable and practical for the Regional Office to oversee implementation of the Alternative Method of Compliance. If the Regional Administrator authorizes the Alternative Method of Compliance, each PWS shall have the option to comply either by achieving the MCL in samples taken at each entry point to the distribution system or through the Alternative Method of Compliance.

(iv) Until such time as notified by the State or Primacy Agency that the Alternative Method of Compliance will be authorized, PWSs shall be required to achieve the MCL at each entry point to the distribution system.

(v) The general prohibition on the use of bottled water and point-of-use devices in 40 CFR 141.101 shall not apply to PWSs that choose to achieve compliance with the MCL for sulfate by meeting the requirements of the Alternative Method of Compliance.

(vi) A PWS must report failure to comply with a NPDWR to the State under the requirements of 40 CFR 141.31. Within 30 days of notifying the State of failure to comply with the sulfate MCL, the PWS shall notify the State as to which of the two methods of compliance, § 141.23(r)(1)(i) (A) or (B), the PWS intends to use to return to compliance with the sulfate MCL.

(2) *Alternative Water Supplied to Target Populations.* The requirements of this subsection apply only to a PWS that has chosen to comply with the MCL for sulfate through the Alternative Method of Compliance instead of by achieving the MCL in samples taken at each entry point to the distribution system.

(i) *Definitions.* (A) *Alternative water:* For purposes of this section, a PWS supplies Alternative Water when it supplies either bottled water or water that has been treated with a POU or POE device (as defined in § 141.2).

(B) *Target population,* for purposes of this section, means all infants, travelers and new residents within the PWS's service area, according to the following:

(1) For the purposes of this rule, *infant* is defined as persons under the age of 12 months.

(2) *Transients* means visitors from outside the service area, vacation travelers and business travelers.

(3) *New residents* means persons who have resided in the service area for no more than six weeks.

(ii) Community water systems shall maintain a record of all requests for Alternative Water. Records shall include the name and address of the person requesting the water, date of request, date of delivery requested, date of delivery and quantity of water delivered (or date of installation in the case of a POU/POE device). This record shall be maintained for five years from the time of recording.

(iii) Community water systems shall supply Alternative Water in compliance with this subsection to the Target Population for the time periods described under paragraph (r)(2)(vii) of this section. Transient water systems and non-transient, non-community systems shall have alternative water available for infants, travelers, newcomers and visitors.

(iv) Community water systems shall provide door-to-door delivery of the bottled water or installation of POU or POE devices upon request to customers who are within the Target Population. The PWS shall have the option of deciding whether to provide a customer with bottled water or POU/POE devices.

(v) *Bottled water requirements.* (A) *Quality.* Bottled water provided by the PWS shall meet the requirements of § 142.62 (g)(1) or (g)(2) of this chapter.

(B) *Quantity.* Community water systems shall have bottled water available and delivered at the level of two liters per day for each person within the Target Population for whom bottled water is requested (unless the customer requests a lesser amount). Transient water systems and non-transient, non-community systems shall have sufficient bottled water to serve the transient population, unless POE or POU devices are installed.

(C) *Time of delivery.* Community water systems shall deliver the bottled water within 24 hours of the request, or on the date requested, whichever is later.

(vi) *POU and POE device requirements.* PWSs that choose POU or POE devices as a method of compliance shall meet the following requirements:

(A) PWSs that choose POE devices as a method of compliance shall meet the requirements of § 141.100 (a) through (d).

(B) If the PWS decides to provide a POE/POU device and is unable to install such equipment within 24 hours of the request, or on the date requested, the PWS shall provide bottled water to the target population during the interim time period between the time of the request and the time of installation of the POU/POE device.

(C) PWSs that choose POU devices as a method of compliance shall obtain the approval of a monitoring plan which ensures that the devices provide water that complies with the sulfate MCL. It is the responsibility of the public water system to operate and maintain the POU system. The microbiological safety of the water must be maintained at all times. The State shall require adequate certification of performance and a rigorous engineering design review. The design and application of the POU must consider the potential for increasing concentrations of heterotrophic bacteria in water treated with activated carbon.

(D) The State must be assured that the POU and POE devices are properly installed, maintained and monitored.

(vii) *Period of delivery.* The PWS shall provide Alternative Water for the following time periods:

(A) Alternative Water shall be provided to each infant for the period requested, which may not exceed twenty weeks from the date of initial delivery. Alternative Water delivery shall be provided for the full twenty weeks if requested, even if the infant becomes one year of age during the delivery period.

(B) Alternative Water shall be provided to each traveler and new resident for the period requested, not to exceed six weeks from the date of initial delivery.

(3) *Public Notification/Education Program.* The requirements of this section apply only in States which have authorized the Alternative Method of Compliance. The requirements apply only to those PWSs in such States which have chosen to comply with the sulfate MCL through the Alternative Method of Compliance rather than by achieving the MCL in samples taken at each entry point to the distribution system. The PWS shall implement the public notification/education program described in this subsection in lieu of § 141.32, and shall provide the State with copies of all public notification and education materials at the same time. There are four components to the program: Notices in bills, pamphlets, signs, and notices to the media. Transient systems (e.g., campgrounds and gas stations) and non-transient, non-community systems (e.g. schools, factories) shall be required to post signs in accordance with paragraphs (r)(3)(v) of this section, but shall not be required to comply with the requirements for notices in bills, notices to the media, or pamphlets in paragraphs (r)(3) (i)–(iv) and (vi) of this section. Community water systems which are non-transient systems shall comply with all four components set forth in paragraphs (r)(3) (i)–(vi) of this section, i.e., notices in bills, pamphlets, signs, and notices to the media.

(i) *Newspaper, mail, hand delivery, of notices.* PWSs shall give notice by publication in a daily newspaper of general circulation in the area served by the system as soon as possible, but in no case later than 14 days after sulfate in excess of the MCL has been detected in the water. The notice shall be repeated at intervals of 6 months while the sulfate concentration of the water in the distribution system continues to exceed the MCL. If the area served by a public water system is not served by a daily newspaper of general circulation, notice shall instead be given by publication in a weekly newspaper of general circulation. The notice shall define and describe the geographic location served by the system. In communities where a significant portion of the population speaks a language other than English, the text shall be published in the appropriate language(s), in addition to English. A telephone number(s) and an office location for requesting Alternative Water delivery shall be provided. The notice shall be provided at least once every six months by mail delivery (by direct mail or with the water bill), or by hand delivery, not later than 45 days after the sulfate MCL has been exceeded.

(ii) *Text of the Notice.* The PWS shall, within 60 days of confirmed detection of sulfate in the distribution system, insert notices in each customer's water utility bill containing the following mandatory paragraph on the water bill itself in large bold print.

Warning: The water being supplied to you has high levels of sulfate which can cause diarrhea in people who are not used to it. If you have visitors in your home from outside the area, or if you are expecting a baby, please read the enclosed notice for further information.

The notices included in the water utility bill and those provided to the media shall also contain the following mandatory language. Any additional information presented shall be consistent with the information in these paragraphs, and in plain English that can be understood by laypersons. In communities where a significant portion of the population speaks a language other than English, the text shall be published in the appropriate language(s), in addition to English. The text shall be as follows: "Introduction. The United States Environmental Protection Agency (EPA), the [insert name of State primacy agency], and [insert name of water supplier] are

concerned about sulfate in your drinking water. Sulfate salts are found naturally in soil and rock in certain areas of the country, including ours. With the exception of infants, residents of the area should be accustomed to the sulfate in our drinking water, and should not experience ill effects. However, people who are not accustomed to high levels of sulfate in their drinking water may experience diarrhea. Under Federal law, we are required to provide sensitive populations with alternative water until their bodies adapt to the sulfate concentrations in our water. This brochure explains the simple steps you can take to protect the sensitive populations: infants, visitors from outside the area, and new residents.

Health Effects of Sulfate

Ingestion of sulfate in high concentrations is known to cause diarrhea. The greatest risk is to infants, for whom prolonged diarrhea can be dangerous. New residents and travelers may also experience diarrhea when they first drink water with high levels of sulfate. After approximately two weeks, adult's bodies become accustomed to the sulfate, and the diarrhea stops. Available studies have not shown any long-term or chronic adverse effects from consuming sulfate in drinking water. Boiling the water will not reduce the sulfate content, and in fact, will concentrate it through evaporation of the water.

The Alternative Water Program

If you are expecting a baby, if you are a new resident, or expecting visitors from outside the area, please call [insert phone number of water system] to request delivery of alternative water to your home. We will provide you with sufficient water for the cooking and drinking needs for each sensitive person. We will provide you with two liters per day of bottled water for your infant for up to 20 weeks, during which time you should gradually add tap water to the bottled water. In this way, your baby will become gradually accustomed to the sulfate in the water. We will provide your out-of-town guests with two liters of bottled water per day for the period needed, up to a maximum of six weeks. We will provide new residents with two liters per person per day for up to six weeks. During that time, tap water should be gradually mixed with the bottled water. Restaurants and other establishments who are likely to serve at least some members of the target population on a continual basis may be provided individual treatment devices, depending on our evaluation of the size of the target population and other circumstances.

(iii) *New customers.* The PWS shall provide notice of the following to new customers or billing units prior to or on the date service begins: Sulfate MCL exceedence in the water entering the distribution system, the health effect of sulfate for target populations, and the need to mix bottled water and tap water for gradual acclimation to sulfate.

(iv) *Pamphlets.* PWSs shall deliver pamphlets to all physicians and all medical facilities within the PWS service area, including, but not limited to, city, county and State health departments, pharmacies, public and private hospitals and clinics, family planning clinics and local welfare agencies. The PWS shall request the operators of such facilities to make the pamphlets available, in particular, to pregnant women. The pamphlets shall contain the information in paragraph (r)(3)(ii) of this section. The pamphlet shall define the extent of the geographical service area in question.

(v) *Signs.* A prominent, permanent sign in a durable material, such as plastic, shall be placed at each faucet, fountain or source of water which could be used for drinking water in places such as restaurants, hotels/motels, rest areas, campgrounds, gas stations and public areas where not all taps will have treated water. If such facilities are equipped with a POE device or with POU devices such that all taps deliver water in compliance with the sulfate MCL, sign posting is not required. The signs must state the location of the nearest source of water which complies with the sulfate MCL and why precautions should be taken by non-acclimated persons. The text of the sign, in multiple languages where appropriate, shall be as follows:

This water contains high levels of sulfates. This mineral can cause diarrhea in persons not accustomed to drinking water with high sulfate content. Persistent diarrhea can cause dehydration. Special care should be taken for infants. Bottled water is available nearby at_____.

(vi) *Notices to the media.* PWSs shall submit copies of the notice described in paragraph (r)(3)(ii) of this section to radio and television stations that broadcast to the community served by the water system as soon as possible, but in no case later than 14 days after sulfate in excess of the MCL has been detected in the water, and once every six months while the water delivered into the distribution system exceeds the sulfate MCL. The geographical service area in question shall be indicated and clearly defined in the notice.

13. Section 141.33 is amended by adding paragraph (e) to read as follows:

§ 141.33 Record maintenance.

* * * * *

(e) Record maintenance requirements concerning a PWS's delivery of Alternative Water as a means of compliance with the MCL for sulfate are contained in § 141.23(r)(2)(ii).

§ 141.51 Maximum contaminant level goals for inorganic contaminants. [Amended]

14. The table in § 141.51(b) is amended by adding "Sulfate" in alphabetical order under the column heading "Contaminant", and next to it, under the column heading "MCL(mg/l)" adding "500".

§ 141.62 Maximum contaminant levels for inorganic contaminants. [Amended]

15. In the last sentence in paragraph § 141.62(b), the word "and" between "(b)(8)" and "(b)(9)" is removed, and "and (b)(16)" is added after "(b)(9)".

§ 141.62 [Amended]

16. The table in § 141.62(b) is amended by adding "sulfate" in alphabetical order under the column heading "Contaminant" and next to it, under the column heading "MCL" adding "500".

§ 141.62 [Amended]

17. The table in § 141.62(c) is amended by adding "Sulfate" in alphabetical order under the column heading "Chemical Name", and next to it, under the column heading "BAT" adding "5, 7, 9".

18. Section 141.101 is amended by adding two sentences to the end to read as follows:

§ 141.101 Use of other non-centralized treatment devices.

* * * The requirements of this section do not apply to the control of sulfate in drinking water by public water systems in States authorizing the Alternative Method of Compliance with the sulfate MCL. Instead, a public water system that chooses to use bottled water or point-of-use devices to achieve compliance with the MCL for sulfate must meet the requirements of § 141.23(r).

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS—IMPLEMENTATION

19. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4 and 300j–9.

20. Section 142.14 is amended by adding paragraph (d)(12) to read as follows:

§ 142.14 Records kept by States.

* * * * *

(d) * * *

(12) Records of notification received pursuant to § 141.23(r)(1)(vi) of this chapter of the method of compliance chosen by PWSs which exceed the sulfate MCL.

* * * * *

21. Section 142.15 is amended by adding paragraph (a)(4) to read as follows:

§ 142.15 Reports by States.

* * * * *

(a) * * *

(4) Notification of public water systems authorized to implement the Alternative Method of Compliance for sulfate.

* * * * *

22. Section 142.16 is amended by adding paragraph (f) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

(f) *Sulfate requirements.* The national primary drinking water regulation for sulfate in part 141 gives States the option to allow PWSs to use the Alternative Method of Compliance with the sulfate MCL contained in §§ 141.23(r)(2) and (3) (see 141.23(r)(1)(ii)). If a State chooses to allow PWSs to use the Alternative Method of Compliance, its application for approval of a State program revision must include the text of State laws and regulations that are no less stringent than §§ 141.23(r)(2) and (3) of this chapter. In addition, the State's application must include a description of the State's method for overseeing implementation by PWSs of the Alternative Method of Compliance. Such a description must include actions the State will take to assure compliance with bottled water requirements (§ 141.23(r)(2)(v) of this chapter), POU and POE device requirements (§ 141.23(r)(2)(vi) of this chapter), and public notification/education program requirements (§ 141.23(r)(3) of this chapter).

23. Section 142.62 is amended by adding one sentence to the end of paragraph (f) to read as follows:

§ 142.62 Variances and exemptions from the maximum contaminant levels for organic and inorganic chemicals.

* * * * *

(f) * * * The State may authorize a public water system to use bottled water, point-of-use or point-of entry devices to comply with the sulfate MCL, pursuant to §§ 141.23(r)(1) through (3) of this chapter.

* * * * *

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