ENVIRONMENTAL PROTECTION AGENCY

[FRL–6232–5]

Health Effects from Exposure to High Levels of Sulfate in Drinking Water Study and Sulfate Workshop

AGENCY: Environmental Protection Agency.

ACTION: Notice of data availability and request for comments.

SUMMARY: The Safe Drinking Water Act (SDWA), as amended in 1996, directs the U.S. Environmental Protection Agency (EPA) and the Centers for Disease Control and Prevention (CDC) to jointly conduct a study to establish a reliable dose-response relationship for the adverse human health effects from exposure to sulfate in drinking water, including the health effects that may be experienced by sensitive subpopulations (infants and travelers). EPA and CDC are to complete the study by February 1999.

The purpose of this notice is to inform the public of the completion of the ''Health Effects from Exposure to High Levels of Sulfate in Drinking Water Study'' (''Sulfate Study'') and announce the availability of both the Sulfate Study report and the September 28, 1998 Sulfate Workshop summary. This notice provides a summary of these two documents and discusses EPA's next steps on sulfate in drinking water regulatory activities. Comments are requested on the two documents being made available. Today's notice does not include any decisions regarding the determination of whether or not to regulate sulfate.

DATES: Submit comments on or before May 12, 1999.

ADDRESSES: Send written comments to the Comment Clerk, docket number W–99–01, Water Docket (MC4101), USEPA, 401 M St, SW, Washington 20460. Please submit an original and three copies of your comments and enclosures (including references). Comments must be received or postmarked by midnight May 12, 1999.

Commenters who want EPA to acknowledge receipt of their comments should enclose a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted. Comments may also be submitted electronically to ow-docket@epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and form of encryption or in WordPerfect 5.1 or 6.1. Electronic comments must be identified by the docket number W–99–01. Comments and data will also be accepted on disks in WordPerfect 5.1, 6.1 or ASCII file format. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

Documents discussed in the notice and supporting documentation (i.e., sulfate literature review and relevant literature provided to participants at the Sulfate Workshop), as well as public comments are in docket number W–99–01. The record is available for inspection from 9 to 4 p.m. Monday through Friday, excluding legal holidays at the Water Docket, EB 57, USEPA Headquarters, 401 M. St., S.W., Washington, D.C. For access to the docket materials, please call 202–260–3027 to schedule an appointment.

FOR FURTHER INFORMATION CONTACT: For general information and for copies of the Sulfate Study report and Sulfate Workshop summary, please contact the Safe Drinking Water Hotline at 1–800–426–4791 or 703–285–1093 between 9:00 a.m. and 5:30 p.m. Eastern Time. The documents can also be accessed on the internet at http://www.epa.gov/safewater/sulfate.html.
For specific information and technical inquiries, contact Jennifer Wu at 202–260–0425 or wu.jennifer@epa.gov.

Abbreviations Used in This Document

CCL: Contaminant Candidate List
CDC: Centers for Disease Control and Prevention
EPA: U.S. Environmental Protection Agency
MCL: Maximum Contaminant Level
MCLG: Maximum Contaminant Level Goal
NPDWR: National Primary Drinking Water Regulation
SAQ: self-administered questionnaire
SDWA: Safe Drinking Water Act, as amended
SMCL: secondary maximum contaminant level
WHO: World Health Organization
WIC: Women, Infants and Children

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I. Introduction

The Safe Drinking Water Act (SDWA), as amended in 1996, directs the U.S. Environmental Protection Agency (EPA) and the Centers for Disease Control and Prevention (CDC) to ''jointly conduct an additional study to establish a reliable dose-response relationship for the adverse human health effects that may result from exposure to sulfate in drinking water, including the health effects that may be experienced by groups within the general population (including infants and travelers) that are potentially at greater risk.'' Section 1412 (b)(12)(B). SDWA specifies that the study be based on the best available peer-reviewed science and supporting studies, conducted in consultation with interested States, and completed in February 1999.

The purpose of this notice is to inform the public of the completion of the ''Health Effects from Exposure to High Levels of Sulfate in Drinking Water Study'' (''Sulfate Study'') and to announce the availability of both the Sulfate Study report and the September 28, 1998 Sulfate Workshop summary. This notice provides a summary of the Sulfate Study report and the Sulfate Workshop summary, as well as discusses EPA's next steps on sulfate in drinking water regulatory activities. Today's notice does not include any decisions regarding the determination of whether or not to regulate sulfate.

II. Sulfate Background Information

Sulfate is a substance that occurs naturally in drinking water. Health concerns regarding sulfate in drinking water have been raised because of reports that diarrhea may be associated with the ingestion of water containing high levels of sulfate. Of particular concern are groups within the general population that may be at greater risk from the laxative effects of sulfate when they experience an abrupt change from drinking water with low sulfate concentrations to drinking water with high sulfate concentrations. One potentially sensitive population is infants receiving their first bottles containing tap water, either as water alone or as formula mixed with water. Other groups of people who could potentially be adversely affected by water with high sulfate concentrations include transient populations (i.e., tourists, hunters, students, and other temporary visitors) and people moving from areas with low sulfate concentrations in drinking water into areas with high concentrations.

III. Statutory Authority and Regulatory History

On July 19, 1979 (44 FR 42195) EPA published a secondary maximum contaminant level (SMCL) for sulfate in drinking water of 250 milligrams per liter (mg/L), based on aesthetic effects

(i.e., taste and odor). This regulation is not a Federally enforceable standard, but is provided as a guideline for States. States are encouraged to implement SMCLs so that the public will drink water provided by public water systems. The World Health Organization's (WHO) recommended sulfate guideline is 400 mg/L, which is based on taste.

In an advance notice of proposed rule making published in the **Federal Register** on October 5, 1983 (48 FR 45502), EPA recommended developing a health advisory for sulfate instead of establishing an enforceable level. On November 13, 1985, EPA proposed a health advisory at 400 mg/L to protect infants (50 FR 46936). However, the proposed health advisory was never finalized.

Under Section 1412 of the 1986 SDWA, EPA was required to establish maximum contaminant level goals (MCLGs) and promulgate National Primary Drinking Water Regulations (NPDWRs) for 83 contaminants, including sulfate. EPA proposed alternative levels of 400 mg/L and 500 mg/L for the MCLG for sulfate on July 25, 1990 (55 FR 30370). However, EPA deferred promulgation of an enforceable sulfate standard in order to identify an implementation approach which was tailored to the target populations. The SMCL guideline of 250 mg/L remains in place. 40 CFR 143.3.

On December 20, 1994 (59 FR 65578), EPA reproposed an MCLG and MCL for sulfate of 500 mg/L. The proposal contained four alternate compliance options designed to allow flexible implementation. EPA had not issued a final enforceable MCL for sulfate when Congress amended the SDWA in 1996.

The SDWA, as amended in 1996, provides specific authority as to sulfate. The statute directs EPA and CDC to jointly conduct a study to establish a reliable dose-response relationship for the adverse health effects from exposure to sulfate in drinking water, including effects on sensitive subpopulations. The SDWA also directs EPA to include sulfate among the five or more contaminants for which the Agency will determine by August, 2001 whether or not to regulate. Sulfate is one of the 50 chemical and 10 microbiological contaminants/contaminant groups included on the Drinking Water Contaminant Candidate List (CCL) published on March 2, 1998 (63 FR 10273). The CCL list is the primary source of priority contaminants for the Agency's drinking water program. Contaminants for priority drinking water research, occurrence monitoring, and guidance development, including health advisories, will also be drawn from the CCL.

IV. Health Effects From Exposure to High Levels of Sulfate in Drinking Water Study

Through an interagency agreement, EPA and CDC jointly conducted a study to establish a reliable dose-response relationship for health effects from exposure to sulfate and to examine the effects in sensitive subpopulations of infants and transients (i.e., tourists, hunters, students, and other temporary visitors). EPA's role in the ''Health Effects from Exposure to High Levels of Sulfate in Drinking Water Study'' (''Sulfate Study'') included participation in planning sessions on study design and execution and in meetings to discuss progress and preliminary results, as well as review of draft documents and the draft Sulfate Study report. This section provides a brief summary of the Sulfate Study report. (For a copy of the report, see section **FOR FURTHER INFORMATION** above.)

The objective of the study was to provide additional information regarding whether sensitive populations (infants and travelers) may be adversely affected by sudden exposure to drinking water containing high levels of sulfate. Specifically, CDC researchers designed a field investigation to recruit 880 infants naturally exposed to high levels of sulfate in the drinking water provided by public water systems and an experimental trial of exposure in adults.

CDC researchers planned a prospective cohort study of infants born in geographic areas with naturally occurring high levels of sulfate in the drinking water provided by public water systems in New Mexico, South Dakota, and Texas. Infants were to be enrolled at birth and followed for four weeks to determine if there was an association between exposure to drinking water containing varying levels of sulfate and reported cases of diarrhea.

CDC researchers conducted a pilot study of the planned recruitment methods and study instruments in four counties in South Dakota with high levels of sulfate in the drinking water provided by the public water systems. Because the CDC researchers experienced recruiting problems during the pilot study, they developed a self-administered questionnaire (SAQ) to examine tap water use. The questionnaires were provided to all women who received care during a two-week period from one of 32 Women, Infants and Children (WIC) clinics in New Mexico, South Dakota, and Texas. The clinics were located in geographic areas with a range of sulfate levels (from less than 100 mg/L to greater than 1000 mg/L) in the drinking water provided by public water systems. The SAQ asked questions about the source of the women's home tap water, what mothers of infants less than or equal to 3 months old were currently feeding their babies, and how pregnant women planned to feed their new infants.

To determine how many of the 1388 women who completed the SAQ would have been eligible to participate in the study based on the drinking water source and use criteria, the CDC researchers examined the responses of the 1164 women (84%) who received their tap water from public water systems and who did not have filters on their home taps. Of the women who use or planned to use infant formula mixed with water, most (80%) used or planned to use water other than tap water, leaving only 74 infants who were or would be exposed to tap water with equal to or greater than 250 mg/L of sulfate. These results are consistent with the findings during the pilot study and indicate that only a very small number of women who live in areas with high levels of sulfate in the tap water provided by public water systems plan to give this water to their infants.

The other population potentially sensitive to abrupt exposure to high levels of sulfate in drinking water is transient adults (students, visitors, hunters, etc.). To study the effects in adults of suddenly changing drinking water sources from one that has little or no sulfate to one that is high in sulfate, CDC researchers conducted an experimental study involving volunteers from Atlanta, Georgia, including CDC employees and employees at the EPA Region IV office. Volunteers were randomly assigned to one of five sulfate exposure groups (i.e., 0, 250, 500, 800, or 1200 mg/L sulfate from sodium sulfate in bottled drinking water) and were provided with bottled drinking water for six days. The bottled water for days 1, 2, and 6 contained plain water, while the bottles for days 3 through 5 contained water with added sulfate. Volunteers were blinded to the level of sulfate in their drinking water.

One hundred and five study participants were divided among the dose groups as follows: 24 received 0 mg/L sulfate; 10 received 250 mg/L sulfate; 10 received 500 mg/L sulfate; 33 received 800 mg/L sulfate; and 28 received 1200 mg/L sulfate. CDC researchers analyzed the number, consistency, and volume of bowel movements recorded each day by study participants. There were no statistically significant differences in the bowel movements among the groups on days 3,

4, 5, or 6. There were also no statistically significant differences in the bowel movements reported when comparing days 1 and 2 (the days when there was no sulfate in the water) with days 3, 4, and 5 within each dose group.

To examine the data for a trend toward increased frequency of reports of diarrhea with increased dose of sulfate, CDC researchers included the dose as an ordinal variable in a logistic regression model of osmotic diarrhea. There was no statistically significant increase in reports of diarrhea with increasing dose (one-sided $p = 0.099$).

The overall purpose of these studies was to examine the association between consumption of tap water containing high levels of sulfate and reports of osmotic diarrhea in susceptible populations (infants and transients). EPA and CDC were unable to conduct a study of infants because the researchers could not identify enough exposed individuals from which to draw a study population. The results of the SAQ indicated that more than half of the pregnant women who completed the survey planned to breast-feed their infants. Of those who planned to use formula mixed with water, most did not plan to use tap water to mix the formula. In the experimental trials with adult volunteers, CDC researchers did not find an association between acute exposure to sodium sulfate in tap water (up to 1200 mg/L) and reports of diarrhea.

V. Sulfate Workshop

As a supplement to the Sulfate Study and literature review, CDC, in coordination with EPA, convened an expert workshop, open to the public, in Atlanta, Georgia on September 28, 1998, whose members reviewed the available literature and the Sulfate Study results, and provided their expert opinions in response to a series of questions about the health effects from exposure to sulfate in drinking water. The following are the questions and summaries of the discussion (for the complete Sulfate Workshop summary, see section **FOR FURTHER INFORMATION** above.):

(1) Do reported studies suggest that a certain sulfate level would not be likely to cause adverse effects? Existing data do not identify the level of sulfate in drinking water that would be unlikely to cause adverse human health effects. The panel members noted that the available published literature included reports that piglets in experimental feeding trials and some people experience a laxative effect when consuming tap water containing from 1,000 to 1,200 mg/L of sulfate (as sodium sulfate). However, none of the studies found an increase in diarrhea, dehydration, or weight loss.

(2) Does the literature support acclimatization or adaptation (what process and time frame does it take)? Based on biologic plausibility and anecdotal reports, evidence indicates that people acclimate to the presence of sulfate in drinking water. In addition, serum sulfate levels are high (compared to adults) in human fetuses and neonates (to support rapid growth and development). However, data describing acclimation and the changes in sulfate metabolism during growth and development are limited.

(3) Can an infant study be done for dose-response anywhere in the U.S. or Canada? The difficulty of locating a population of women feeding their infants formula mixed with unfiltered tap water containing high levels of sulfate hinders the completion of a dose-response study in infants. A study using neonatal pigs could assess a dose response for both magnesium and sodium sulfates.

(4) Is there enough scientific evidence of adverse health effects from sulfate in drinking water to support regulation? [Congress directed EPA to use the best available science to set drinking water goals and regulations.] There is not enough scientific evidence on which to base a regulation, but panelists favored a health advisory in places where drinking water has sulfate levels of 500 mg/L or higher.

VI. Next Steps on Sulfate in Drinking Water Regulatory Activities

EPA is very interested in receiving written comments on the two documents being made available with today's notice. EPA will be further evaluating the two documents referenced in today's notice, analyzing all public comments on the present documents, reviewing all comments on its previously proposed National Primary Drinking Water Regulation (NPDWR) for sulfate (December 20, 1994; 59 FR 65578), and reviewing any other pertinent information that could have a bearing on its decision of whether or not to regulate sulfate as a NPDWR. In so doing, EPA will be evaluating whether or not the statutory tests provided at Section 1412(b)(1)(A) of SDWA for proceeding with such regulation are met:

(1) ''* * * the contaminant may have an adverse effect on the health of persons;

(2) The contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

(3) In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for person served by public water systems.''

In making this determination, EPA will review, in addition to the dose-response data and information described in today's notice, a host of applicable risk management factors, including, but not limited to: occurrence data on concentrations of sulfate in public water systems; information relative to treatment technologies (particularly, technologies applicable to small public water systems); availability and costs of analytical methods for sulfate; and overall costs and benefits attributable to any likely rule.

Two principal outcomes of this evaluation are possible. The Agency could decide to proceed with a NPDWR for sulfate. In this case, EPA would be required, in accordance with Section 1412(b)(1)(E), to propose a regulation within 24 months after the determination to regulate and issue a final regulation within 18 months after proposal. Alternatively, the Agency could decide not to regulate sulfate as a NPDWR. Such a finding would be considered final Agency action and would be subject to judicial review. Section 1412(b)(1)(B)(ii)(IV). In either case, EPA's rationale for making a determination relative to sulfate would need to be documented and available for public comment. Section1412(b)(1)(B)(iii). It is important to recognize that a decision not to regulate does not prohibit other control actions short of a NPDWR. These other actions could include a National Health Advisory or Consumer Advisory, that would indicate the Agency's view of safe levels of sulfate in drinking water and provide guidance to public water systems and to States that might want to develop drinking water regulations for sulfate.

The Agency will continue to use a variety of means to conduct outreach relative to sulfate and to communicate information about sulfate including the Office of Ground Water and Drinking Water's (OGWDW) web site (http://www.epa.gov/safewater), possible additional **Federal Register** notices, and possible future stakeholder meetings.

Dated: February 5, 1999.

Dana D. Minerva,

Acting Assistant Administrator for Water.

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