EPA 811-Z-94-003

federal register

Friday
July 29, 1994

Part III

Environmental Protection Agency

40 CFR Parts 141 and 142
National Primary Drinking Water Regulations: Enhanced Surface Water Treatment Requirements; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[WH–FRL–4998–1]

National Primary Drinking Water Regulations: Enhanced Surface Water Treatment Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the Surface Water Treatment Rule to provide additional protection against disease-causing organisms (pathogens) in drinking water. This action would primarily focus on treatment requirements for the waterborne pathogens *Giardia, Cryptosporidium,* and viruses. With the exception of one requirement (sanitary surveys), this action would apply to all public water systems that use surface water or ground water under the influence of surface water, and serve 10,000 people or more. Among the features of the rule would be a stricter watershed control requirement for systems using surface water that wish to avoid filtration; a change in the definition of ground water under the influence of surface water to include the presence of *Cryptosporidium;* a periodic sanitary survey requirement for all systems using surface water or ground water under the influence of surface water, including those that serve fewer than 10,000 people; a health goal (maximum contaminant level goal) of zero for *Cryptosporidium;* and several alternative requirements for augmenting treatment control of *Giardia, Cryptosporidium,* and viruses.

DATES: Comments should be postmarked or delivered by hand on or before May 30, 1996. Comments received after this date may not be considered. Public hearings will be held at the addresses indicated below under **ADDRESSES** on August 30, 1996 (and 31, if necessary) in Denver, CO and on September 13, 1994 (and 14, if necessary) in Washington, DC.

ADDRESSES: Send written comments to ESWTR 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 Agency requests commenters to follow the instructions regarding format provided in Section IX of the Preamble, immediately before the list of references.

The Agency will hold public hearings on the proposal at two different locations indicated below:

1. Denver Federal Center, 6th and Kipling Streets, Building 25, Lecture Halls A and B (3d Street), Denver, CO 80225 on August 30 (and 31, if necessary), 1994.
2. EPA Education Center Auditorium, 401 M Street SW., Washington, D.C. 20460, on September 13 (and 14, if necessary), 1994.

The hearings will begin at 1:00 p.m., with registration at 12:30 p.m., on the first day. The hearings will begin at 9:30 a.m., with registration at 9:00 a.m., on the second day. The Hearings will end at 4:00 p.m., unless concluded earlier. Anyone planning to attend the public hearings (especially those who plan to make statements) may register in advance by writing the ESWTR Public Hearing Officer, Office of Ground Water and Drinking Water (4603), USEPA, 401 M Street, S.W., Washington, D.C. 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.

The proposed rule with supporting documents and all comments received 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 Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9 a.m. to 5:30 p.m. Eastern Time. For technical inquiries, contact Stig Regli or Paul S. Berger, Ph.D., Office of Ground Water and Drinking Water (MC 4603), U.S. Environmental Protection Agency, 401 M Street SW., Washington DC 20460; telephone (202) 260–7379 (Regli) or (202) 260–3039 (Berger); or Bruce A. Macler, Ph.D., Water Management Division, Region 9, U.S. Environmental Protection Agency, 75 Hawthorne Street (W–6–1), San Francisco, CA 94105–3901; telephone (415) 744–1884.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Statutory Authority

The Safe Drinking Water Act (SDWA or the Act), as amended in 1986, requires EPA to publish a "maximum contaminant level goal" (MCLG) for each contaminant which, in the judgment of the EPA 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)).

At the same time EPA publishes an MCLG, which is a non-enforceable health goal, it also must publish a National Primary Drinking Water Regulation (NPDWR) that specifies either a maximum contaminant level (MCL) or treatment technique (Section 1401(1), 1412(a)(3), and 1412(b)(7)(A)). A treatment technique may be set in lieu

of an MCL if it is not "economically or technologically feasible" to determine the level of a contaminant.

Section 1412(b)(3) of the Act requires EPA to publish regulations for at least 25 contaminants at three year intervals. Section 1412(b)(9) requires EPA to review each NPDWR every three years and revise it if appropriate.

Section 1412(b)(7)(C) requires the EPA Administrator to publish a NPDWR "specifying criteria under which filtration (including coagulation and sedimentation, as appropriate) is required as a treatment technique for public water systems supplied by surface water sources". In establishing these criteria, EPA is required to consider "the quality of source waters, protection afforded by watershed management, treatment practices (such as disinfection and length of water storage) and other factors relevant to protection of health". This section of the Act also requires EPA to promulgate a NPDWR requiring disinfection as a treatment technique for all public water systems and a rule specifying criteria by which variances to this requirement may be granted.

Section 1445(a)(1) of the Act requires a public water system to "establish and maintain such records, make such reports, conduct such monitoring, and provide such information as the Administrator may reasonably require by regulation . . .".

Section 1414(c) requires each owner or operator of a public water system to give notice to persons served by it of any failure to comply with an MCL, treatment technique, or testing procedure required by a NPDWR and any failure to comply with any monitoring required pursuant to section 1445 of the Act.

II. Regulatory Background

Two NPDWRs control disease-causing microorganisms (pathogens) in public water supplies—the Total Coliform Rule (TCR)(54 FR 27544; June 29, 1989) and the Surface Water Treatment Rule (SWTR)(54 FR 27486; June 29, 1989). A third regulation, the Groundwater Disinfection Rule (GWDR), which is currently under development, will add further protection for systems using ground water.

The SWTR met the requirements of Section 1412(b)(7)(C) and, for surface waters, Section 1412(b)(8) of the SDWA, as amended in 1986. The SWTR requires all systems using surface water, or ground water under the direct influence of surface water, to disinfect. In addition, all such systems are required to filter their water unless they demonstrate that they have an effective watershed protection program and meet other EPA-specified requirements (§ 141.71). The watershed control program must minimize the potential for source water contamination by *Giardia* cysts and viruses, and typically includes characterization of watershed hydrology, land ownership by the system, and activities on the watershed that might have an adverse effect on source water quality. The rule also requires an annual on-site inspection of all systems that wish to avoid filtration. This inspection must demonstrate that the required watershed control program and disinfection treatment processes are adequately designed and maintained. The SWTR also established MCLGs of zero for *Giardia lamblia,* viruses and *Legionella.*

The SWTR requires all systems to achieve at least 99.9% (3-log) removal/inactivation of *Giardia lamblia* cysts, and 99.99% (4-log) removal/inactivation of enteric viruses. The intention of these provisions was to provide appropriate multiple barriers of treatment to control pathogen occurrence in finished drinking water. This rule was promulgated as a treatment technique rather than an MCL, because EPA believed that routine monitoring for the pathogens was not economically or technologically feasible. Another pathogen, *Cryptosporidium,* was considered for regulation under the SWTR, but was not addressed, because EPA lacked sufficient health, occurrence, and water treatment control data regarding this organism at that time.

The TCR established MCLGs of zero for total coliforms, which includes fecal coliforms and *E. coli.* MCLs, monitoring requirements, and analytical requirements were promulgated for these organisms. The TCR requires all public water systems that collect fewer than five samples per month to have an on-site sanitary survey every five years (ten years for some systems). The purpose of this requirement is to help ensure the long-term quality and safety of drinking water in small systems that cannot be accomplished by infrequent coliform monitoring.

The TCR and SWTR were promulgated to minimize both epidemic and endemic waterborne microbial illness. The public health goal, as described in the preamble to the SWTR, was to provide treatment to ensure an acceptable risk of less than one waterborne microbial illness per year per 10,000 people.

In addition to the SWTR, TCR, and GWDR, EPA is also developing a rule that would limit concentration levels of disinfectants and the chemical disinfection byproducts (DBPs) resulting from their use. The use of chemical disinfectants in water treatment results in a substantial decrease in waterborne microbial illness and is an integral part of a multiple-barrier removal/inactivation approach. However, disinfectants and DBPs may present potential health risks themselves. DBPs form when disinfectants used for microbial control in drinking water react with various organic chemicals in the source water. Some of these are known to be toxic to humans or are considered to be probable human carcinogens. As such, a number of disinfectants and DBPs were included on the 1991 Drinking Water Priority List (56 FR 1470, January 14, 1991) as candidates for future regulations. To address these health issues, EPA is proposing elsewhere in today's **Federal Register** the disinfectants/disinfection byproducts (D/DBP) rule, which includes NPDWRs for several disinfectants and disinfectant byproducts.

To develop the D/DBP Rule, EPA instituted a formal regulation negotiation process in 1992 with potentially affected parties (57 FR 53866; Nov. 13, 1992). The committee established to negotiate the regulation included representatives from water utilities, State and local health and regulatory agencies, environmental groups, consumer groups, and EPA (hereafter the Negotiating Committee or the Committee). One of the major goals addressed by the Committee was to develop an approach that would reduce the level of exposure from disinfectants and DBPs without undermining the control of pathogens. The intention was to ensure that drinking water is microbiologically safe at the limits set for disinfectants and DBPs and that these chemicals do not pose an unacceptable risk at these limits. The approach in developing this rule considered the constraints of simultaneously treating water for these different concerns. As part of this effort, the Negotiating Committee decided that the SWTR may need to be revised to address health risk from high densities of pathogens in poor quality source waters and from the protozoan, *Cryptosporidium.* If such requirements were deemed necessary, and could be promulgated concurrently with new D/DBP regulations (the regulations proposed elsewhere in today's **Federal Register** and termed "Stage 1 D/DBPR"), a system could comply with both regulations and meet the intended public health goals.

The Negotiating Committee also decided that to develop a reasonable set

of rules, including today's proposed rule, and to understand more fully the limitations of the current SWTR, additional field data were critical. Thus, the Committee agreed to the development of an information collection rule (ICR) that would require, in part, systems serving a population of 10,000 or greater to determine the density of specific pathogens in their source water and to characterize their treatment processes. Under the ICR, systems serving populations greater than 100,000 would also be required to monitor for pathogens in their finished water (depending upon the pathogen density in the source water), and the concentration of DBPs and parameters related to their formation at various steps in the treatment process. To this end, EPA proposed the ICR on February 10, 1994 (59 FR 6332) that would require this additional information. The Committee agreed to the requirements in the proposed ICR as necessary and reasonable.

According to the regulatory strategy developed by the Committee, systems serving a population of 10,000 or greater would use the monitoring and treatment data collected under the ICR to decide what additional treatment measures, if any, would be necessary to protect the public from pathogens while controlling for DBPs. This decision would be based on criteria specified either in amendments to the SWTR or by guidance. Today's proposed rule includes a variety of regulatory options, from requiring systems to provide minimum levels of treatment based upon the density of pathogens in the source water to maintaining the existing requirements of the SWTR.

According to the Committee's strategy, amendments to the SWTR would be developed under two rules. The first of these rules, which is today's proposed rule, would be an interim enhanced SWTR (ESWTR) that would only pertain to systems serving 10,000 people or greater. Data collected under the ICR would be used to determine the appropriate regulatory option(s) under this rule, and then to implement it at the time systems are required to comply with the Stage 1 D/DBP regulations. Following the full compilation and analysis of all data collected under the ICR rule and from other research findings, EPA would propose a long-term ESWTR with which systems serving fewer than 10,000 people would comply while also complying with the Stage 1 D/DBP rule. The long-term ESWTR might also include additional refinements for systems serving 10,000 people or greater. Today's proposal also satisfies the provision in section 1412(b)(9) of the SDWA for review of NPDWRs every three years; the SWTR was promulgated on June 29, 1989, and became effective in stages, beginning December 31, 1990.

III. Discussion of Proposed Rule

A. Basis for Amending Existing SWTR: Limitations of SWTR

As discussed above, the SWTR requires all systems using surface water, or ground water under the direct influence of surface water, to disinfect. It also requires all such systems to filter their water unless they can demonstrate that they have an effective watershed control program, meet source water quality criteria, achieve minimum disinfection requirements, and have no evidence of reported waterborne disease among the served population. The SWTR also specifies that systems using surface water must treat water to remove/inactivate at least 99.9% of the *Giardia lamblia* cysts and at least 99.99% of the enteric viruses, regardless of their densities in the source waters. The SWTR does not require a system to monitor its source water or drinking water for these pathogens. At the time of promulgation, EPA recognized a variety of uncertainties and unknowns regarding potential health risks, but these were not possible to address at that time. Subsequently, additional information has become available that indicated possible deficiencies in the SWTR. Some of these deficiencies are described below.

SWTR Did Not Address Cryptosporidium

During the development of the SWTR, the United States experienced its first recognized waterborne disease outbreak of cryptosporidiosis, caused by the protozoan, *Cryptosporidium* (D'Antonio et al., 1985). Other outbreaks caused by this pathogen have since been reported both in the United States and other countries (Smith et al., 1988; Hayes et al., 1989; Levine and Craun, 1990; Moore et al., 1993; Craun, 1993). Because of the lack of data before 1989 on *Cryptosporidium* oocyst occurrence and removal by treatment, EPA decided to regulate this pathogen in a future rulemaking, rather than to delay publication of the SWTR until this data was available. Thus, the SWTR does not now specifically address *Cryptosporidium* treatment removal/inactivation requirements, watershed control requirements for *Cryptosporidium* for systems that wish to avoid filtration, or a definition of ground water under the influence of surface water that includes *Cryptosporidium*. Moreover, the assumptions about *Giardia* reduction under the SWTR may not be applicable to *Cryptosporidium*, which, based on laboratory studies, is much more resistant to common disinfection practices than is *Giardia* (Korich et al., 1990; Korich et al., 1992). Since publication of the SWTR in 1989, some information on *Cryptosporidium* occurrence and control measures has been published. EPA will have new data available shortly from systems that monitor for this organism under the ICR and from research currently being carried out by the Agency and the water industry. As a result, EPA believes that it will soon be in a better position to develop a suitable regulation for *Cryptosporidium*.

Specified Pathogen Reductions May Be Inadequate

The 3-log removal/inactivation of *Giardia* and 4-log removal/inactivation of enteric viruses required by the SWTR were developed to provide adequate protection from pathogens in average quality source water, and thus may be inadequate when a system is supplied by poorer quality source water with high levels of these or other pathogens. In developing the SWTR, EPA assumed, on the basis of data available at that time, that this level of treatment was adequate for the vast majority of systems.

Additionally, risk assessments for the pathogens of concern had high degrees of uncertainty, such that the risks associated with a given level of pathogen contamination were unclear. Moreover, methods for quantifying these organisms were not generally available. Therefore, the Agency believed that a simple, yet conservative treatment requirement was most appropriate. However, it was apparent during the development of the SWTR that the level of treatment being specified might not always be adequate. Therefore, the Agency published associated guidance recommending greater treatment for systems supplied by poorer quality source waters (EPA, 1991a).

Subsequent data on *Giardia* and virus densities in source water and drinking water, however, bring into question the assumption that the treatment specified in the SWTR was adequate for most systems. These new data suggest that the concentrations of *Giardia* cysts and viruses in the source waters of many systems may be too great for the specified level of treatment to adequately control waterborne pathogens. For example, LeChevallier et al. (1991a,b) examined *Giardia* and *Cryptosporidium* levels in the source

waters and filtered drinking waters of 66 surface water systems in 14 States and one Canadian province. They detected at least one of these two organisms in 97% of the raw water samples. *Giardia* densities ranged from 0.04 to 66 cysts/L (geometric mean of 2.77 cysts/L), while *Cryptosporidium* densities ranged from 0.07 to 484 oocysts/L (geometric mean of 2.70 oocysts/L).

These investigators also detected at least one of the two organisms in the drinking water of 39% of the systems. For those drinking waters that were positive, *Giardia* densities ranged from 0.29–64 cysts/100L (geometric mean 4.45 cysts/100L), while *Cryptosporidium* densities ranged from 0.13 to 48 oocysts/100L (geometric mean 1.52 oocysts/100L). According to the investigators, 78% of the systems that were positive for *Giardia* or *Cryptosporidium* met the turbidity standards specified by the SWTR. Based on a risk assessment model developed for *Giardia*, 24% of the 66 systems might not meet the health goal in the SWTR of no more than the one *Giardia* infection annually per 10,000 people per year (LeChavallier et al., 1991b). (This incidence of infection is a conservative estimate of illness, since not all infected people become ill.) This study suggests that the SWTR may need to be revised if an annual 10^{-4} risk level, or some other desired risk level, is to be achieved by all systems in the United States.

EPA used the data in LeChevallier et al. (1991a,b) to calculate the percentage of systems that use source waters containing various densities of *Giardia* cysts. The Agency calculated that about 85% of the source waters in the study contained 10 cysts/100L or more, while about 45% contained 100 cysts/100L or more. Many of these systems currently provide four, five, or even six or more logs of removal/inactivation and therefore are able to achieve EPA's 10^{-4} annual risk goal. However, if such systems were to reduce existing levels of disinfection to more easily meet new D/DBP regulations, and only marginally meet the three-log removal/inactivation requirement for *Giardia* specified in the current SWTR, they could experience significant increases in microbial risk (Regli et al., 1993; Grubbs et al., 1992; EPA, 1994)).

An epidemiology study by Payment et al. (1991) also suggests that the pathogen density reductions specified by the SWTR may not be sufficient for adequate protection. The goal of this study was to determine the extent to which drinking water caused gastrointestinal disease in a community served by poor quality source water that was subjected to full conventional treatment. In this study, the investigators carried out a trial where 299 households in a community drank water from a reverse-osmosis water filter, while 307 households used the usual tapwater. According to the data, 35% of the reported gastrointestinal illness was associated with the drinking water. The etiologic agent(s) were not identified, but a plausible explanation is that pathogens were in the finished water. A recent analysis by Haas et al. (1993) also suggests that high levels of microbial risk far above the health goal of the existing SWTR may be occurring in systems with highly contaminated source waters that may only minimally comply with the SWTR.

Several other recent studies have shown that *Giardia* and *Cryptosporidium* cysts/oocysts can be found in filtered drinking waters in systems served by highly contaminated source waters (Clancy, 1993; EPA, 1993). If treatment is inadequate in reducing pathogens to an acceptable level, EPA must consider revising and strengthening treatment requirements. A mitigating factor is that, based upon a microscopic examination of the cysts/oocysts detected by LeChevallier et al. (1991b), most of the cysts/oocysts in the drinking water may not be viable. This observation, however, has not yet been confirmed.

Virus CT Values May Be Greater Than Assumed by SWTR

The SWTR assumes that disinfection more readily controls viruses than may actually be the case. The Guidance Manual to the SWTR (EPA, 1991a) identifies the disinfection CT values (disinfectant concentration times the contact time) for viruses. These data are based on laboratory studies in which a dispersed suspension (i.e., non-cell associated, non-aggregated) of hepatitis A virus was used. These CT values relative to the much higher CT values needed for *Giardia* inactivation for systems to comply with the SWTR have led to the assumption by some that systems which satisfactorily control for *Giardia* cysts will adequately control for pathogenic viruses. (The CT values to comply with the level of disinfection inactivation requirements for viruses in the Guidance Manual to the SWTR are one to two orders of magnitude below the CT values necessary to achieve the inactivation requirements for *Giardia*.)

However this assumption may not always be valid. In environmental waters, viruses are usually aggregated or associated with cell debris, some of which may not be removed entirely by filtration processes. Such cell-associated aggregates are considerably more resistant to disinfection than free viruses (Williams, 1985; Sobsey, 1991). Moreover, some pathogenic enteric viruses may be substantially more resistant to disinfection than hepatitis A (Keswick et al., 1985). In addition, laboratory studies to determine CT values for viruses, even with applied uncertainty factors, may underestimate the actual CT values necessary to achieve the desired level of inactivation, since viruses in the environment may be hardier and less susceptible to disinfection.

The detection of viruses in fully treated waters (i.e., after coagulation, sedimentation, filtration, and disinfection) (Gerba and Rose, 1990; Payment, 1985; Hurst, 1991) also suggests that viruses in environmental sources have greater CT values than those published in the Guidance Manual. Hurst (1991), for example, summarized the published data on viruses in drinking water, and found that the percentage of samples positive for viruses ranged from 0 to 100%. In one study, Payment et al. (1985) detected enteroviruses in 7% of finished water samples (1,000 L samples from 7 systems), with an average density of 0.0006 most probable number of cytopathogenic units. In another study, Payment (1981) detected 1–10 enteroviruses/100L in most drinking water samples in a system using poor quality source water.

The above data also suggests that EPA needs to reassess the 4-log level of treatment required for viruses under the SWTR. Under this requirement, a system may only provide a 2-log inactivation of viruses by disinfection and still meet the 4-log overall treatment requirement (under current EPA guidance, systems using conventional treatment are assumed to achieve a 2-log removal of viruses by clarification processes alone). For some systems, virus densities in surface waters may be sufficiently high to warrant at least a 4-log or greater level of inactivation by disinfection alone (and a 6-log or greater removal of viruses with clarification and disinfection) to achieve desired risk levels (Regli et al., 1991). The Agency would like to determine what minimum level of disinfection inactivation is necessary for surface water supplies to ensure adequate virus control, regardless of *Giardia* densities. EPA intends to use data from the ICR to: (1) Help clarify the adequacy of using *Giardia* as a target organism to control for viruses in systems with different source water qualities, (2) determine what assumptions can be made regarding quantification of virus

removal for different treatment processes and disinfection conditions, and (3) determine what, if any, changes to the SWTR are needed to control pathogenic viruses.

DBP Rule May Undermine Pathogen Control

Some systems currently exceed the required *Giardia* and virus reductions specified by the SWTR. The DBP Rule may potentially undermine pathogen control in these systems by prompting them to reduce DBP concentrations at the expense of pathogen control (e.g., by shifting point of disinfection to later in the treatment chain, reducing disinfection dose, or switching to a weaker disinfectant such as chloramines). These systems would still have to comply with the removal/inactivation criteria in the current SWTR, but would do so with a lower margin of safety. This situation might result in a substantial increase in waterborne illness for systems using a poor quality source water. For example, according to a model developed by EPA (Regli et al., 1993), a reduction of the MCL for total trihalomethanes (TTHMs) (one of the toxic byproducts) from 100μg/L to 75μg/L could increase the incidence of waterborne giardiasis in some systems by as many as 10,000 per million people per year, if the existing SWTR is not amended to require higher levels of treatment for poor quality source waters.

This situation is further evidence that EPA may need to revise the SWTR to ensure that measures taken by systems to comply with the forthcoming DBP Rule do not increase the health risk from pathogens.

B. General Approach for Revising SWTR

Under the negotiated rulemaking, the Negotiating Committee agreed to propose three rules: (1) ICR, proposed on February 10, 1994 (59 FR 6332), (2) D/DBP regulations (proposed in today's **Federal Register**), and (3) ESWTR. EPA is planning to remedy the shortcomings of the SWTR indicated above through two sequential stages—an interim ESWTR and a long-term ESWTR. Today's rule proposes the interim ESWTR. The Agency and the Negotiating Committee decided that this phased approach was appropriate because of the uncertainties associated with lack of data. EPA needs much more data on the concentrations of *Giardia, Cryptosporidium*, and enteric viruses for various qualities of source waters, with variations over time and season, to determine the need for additional treatment. Some members of the Negotiating Committee believed that health effects information, especially dose response data for pathogens of concern, is also important to ensure that EPA selects the most appropriate control option. In addition, EPA needs more field data on the effectiveness of different types of water treatment for controlling these pathogens. Data from the ICR and various research studies would provide much of this information, sufficient in EPA's view to refine the present proposed interim rule. Additional work would culminate in a long-term ESWTR that would be protective for all surface water system sizes (including those that serve fewer than 10,000 people) and would also include possible refinements to any interim requirements for larger systems. EPA believes that the interim and long-term ESWTR rules are essential for providing adequate human health protection; however, some members of the Negotiating Committee believed that the most appropriate regulatory criteria to provide this protection are not yet apparent.

Schedule of Regulations

Table I–1 indicates the schedule agreed to by the Negotiating Committee for proposing, promulgating, and implementing these rules. Implementation dates for the ICR are indicated under the columns of the Stage 2 D/DBP rule and ESWTR to reflect the relationship between these rules. Although the schedule for proposing these rules has slipped slightly, EPA believes the scheduled promulgation dates for the ESWTR and D/DBP Rule can still be met.

The Negotiating Committee believes that the December 1996 scheduled date for promulgating the Stage 1 D/DBP Rule reflects the shortest time possible by which the interim ESWTR, if necessary, could also be promulgated. EPA is proposing that the Stage 1 D/DBP regulations and the interim ESWTR become effective on the same date of June 30, 1998, for those surface water systems, or ground water systems under the direct influence of surface water, serving 10,000 people or more. This strategy is necessary so that systems do not degrade pathogen control in attempting to comply with the Stage 1 D/DBP regulations.

TABLE I–1.—PROPOSED D/DBP, ESWTR, ICR RULE DEVELOPMENT SCHEDULE

Time line	State 1 DBP rule	Stage 2 DBP rule	ESWTR
12/93	.....	Propose information collection requirements for systems>100k.	Propose information collection requirements for systems >10k.
3/94	Propose required enhanced coagulation for systems with conventional treatment. MCLs–TTHMs (80μg/l), HAA5 (60ug/l), bromate, chlorite. Disinfectant limits	Propose Stage 2. MCLs for TTHMs (40 μg/l), HAA5 (30 μg/l), BAT is precursor removal with chlorination.	Propose interim ESWTR for systems>10k.
6/94	.....	Promulgate ICR	Promulgate ICR.
8/94	Close of public comment period	.....	Public comment period for proposed ESWTR closes.
10/94	.....	Systems>100k begin ICR monitoring	Systems>100k begin ICR monitoring.
1/95	.....	.....	Systems 10–100k begin source water monitoring.
10/95	.....	SW systems>100k, GW systems>50k begin bench/pilot studies unless source water quality criteria met.	
11/95	.....	.....	NOA for monitoring data, direction of interim ESWTR.
1/96	.....	.....	Systems>10k complete ICR monitoring. End NOA public comment period.

TABLE I–1.—PROPOSED D/DBP, ESWTR, ICR RULE DEVELOPMENT SCHEDULE—Continued

Time line	State 1 DBP rule	Stage 2 DBP rule	ESWTR
3/96	.....	Systems complete ICR monitoring	Systems>100k complete ICR monitoring.
12/96	Promulgate Stage 1	.....	Promulgate interim ESWTR for systems>10k.
6/97	.....	Notice of availability for Stage 2 reproposal	Propose long-term ESWTR for systems<10k, possible changes for systems>10k.
10/97	.....	Complete and submit results of bench/pilot studies.	
12/97	.....	Initiate reproposal—begin with 3/94 proposal.	
6/98	Effective. Effective for SW systems serving greater>10k, extended compliance date for GAC or membrane technology	Close of public comment period	Interim ESWTR effective for systems>10k. 1994–6 monitoring data used to determine treatment level.
12/98	.....	Propose for CWSs, NTNCWSs	Publish long-term ESWTR.
6/00	Stage 1 limits effective for surface water systems<10k, GW systems>10k	Promulgate Stage 2 for all CWSs, NTNCWSs.	Long-term ESWTR effective for all system sizes.
1/02	Stage 1 limits effective for GW systems<10k unless Stage 2 criteria supersede	Stage 2 effective, compliance for GAC/membranes by 2004.	

EPA is proposing to delay the effective date of the Stage 1 D/DBP regulations for systems serving less than 10,000 people until June 30, 2000, to allow such systems time to comply with the long-term ESWTR. EPA believes that this date reflects the shortest time possible that would allow the long-term ESWTR to be proposed, promulgated, and become effective, thereby providing the necessary protection from any downside microbial risk that might otherwise result when systems of this size achieve compliance with the Stage 1 D/DBP rule.

Since EPA is proposing the interim ESWTR before systems begin collecting the monitoring data specified by the ICR, the Agency's final direction for the interim ESWTR is not yet clear. For this reason, the Agency is proposing a number of regulatory alternatives, including one that would not revise the existing SWTR. After EPA receives and processes pertinent monitoring data generated under the ICR, the Agency will prepare a **Federal Register** notice (referred to as a Notice of Availability) that will present the processed data to the public, the Agency's interpretation of that data, and the specific regulatory strategy the Agency is considering. Public comments on this **Federal Register** package will influence the direction the Agency ultimately takes in developing the interim ESWTR.

EPA is extending the comment period to the proposed interim ESWTR to May 30, 1996, which is beyond the original date indicated in Table I–1 (August 1994). The Agency believes this adjustment is necessary to take into account the slippage in the anticipated ICR promulgation date, which will necessarily also result in a slippage in the NOA publication date to early Spring 1996. The Agency believes that it would be more reasonable and efficient for EPA not to close the comment period for the ESWTR before the comment period ends for the NOA.

Unlike the interim ESWTR, the long-term ESWTR will cover all surface water systems, including those serving fewer than 10,000 people. The anticipated primary thrust of these final regulations will be to cover these smaller systems, rather than to make major changes in the treatment requirements for larger systems, although some refinements are possible. EPA expects the criteria for defining the specified treatment needed for smaller systems will be simpler than that for the larger systems and may, for example, only require monitoring of easily measured indicators rather than pathogens, especially if an adequate correlation is observed between indicator and pathogen densities under the ICR and other related research. Pathogen monitoring in small systems may be possible, if inexpensive, simple analytical tests for viruses and/or protozoa can be developed, evaluated, and approved. EPA may also cover small systems by using the ICR data to develop national occurrence patterns that would allow the Agency to establish more appropriate treatment criteria for small systems. The Agency anticipates that by characterizing source water quality using any one or a combination of these approaches, a small system could evaluate the adequacy of its existing level of treatment for pathogen control and determine the need for treatment modifications.

Data Collection and Monitoring

If EPA decides to revise the SWTR to require higher levels of treatment for poorer quality source waters, information on microbial densities in these sources gathered under the ICR can be used by utilities, States and EPA to determine required levels of treatment for individual systems. If such information is not available for a system (e.g., if a system that had not performed ICR monitoring serves a community which grows in population from less than to greater than 10,000 people), EPA would require such a system to collect sufficient information on microbial densities of its source water and treatment practices to allow the State to make this determination. The ESWTR may also require systems serving 10,000 people or greater to monitor their source waters periodically to determine whether changes have occurred in the quality of that water since the ICR monitoring. Any deterioration in source water quality may necessitate additional pathogen control measures.

For monitoring subsequent to the ICR for *Giardia* and *Cryptosporidium*, EPA intends to require the use of the immunofluorescence method specified by the ICR. If performance data support their use, newer assays currently under development may be considered. One of

these assays is based on the observation that particles in a rotating electric field also rotate if the frequency is right. Investigators using this principle have developed a novel assay, referred to as the electrorotation assay, that can apparently easily distinguish between the target organism (e.g., *Cryptosporidium*) and other organisms and particle debris if the field frequency is adjusted properly. At this frequency, the target organism rotates and other particles do not, an observation easily visualized under the microscope. Preliminary data reported by the developer for sterile natural water samples spiked with *Cryptosporidium* are similar to those obtained with an immunofluorescence method. If these data are confirmed, the assay would be far less expensive, simpler, and more rapid than the standard method.

In addition to this assay, other potential assays for *Giardia* and *Cryptosporidium* include polymerase chain reaction (PCR) and flow cytometry. The PCR is a powerful and rapid tool for detecting genetic material that is initially present in very low concentrations. It involves the amplification of genetic material in a laboratory instrument until sufficient quantities are available for analysis. Recent publications have described the use of PCR in detecting *Giardia* and its potential for differentiating between live and dead cysts (Mahbubani, et al. 1991). Flow cytometry is a process that measures physical or chemical characteristics of cells passing single file through the measuring apparatus in a fluid stream (Shapiro, 1992). This process is rapid and may be useful for distinguishing between and quantifying *Giardia* and *Cryptosporidium.*

C. Proposed Maximum Contaminant Level Goal and Treatment

Technique for *Cryptosporidium*

As stated above, the protozoan *Cryptosporidium parvum* has recently been implicated in a number of large waterborne disease outbreaks in the United States. The disease cryptosporidiosis is caused by ingestion of the environmentally-resistant oocysts of *Cryptosporidium,* which are readily carried by the waterborne route. Both human and other animals may excrete these oocysts. Transmission of this disease often occurs through ingestion of the infective oocysts from contaminated water or food, but may also result from direct or indirect contact with infected persons or animals. Symptoms of cryptosporidiosis include diarrhea, abdominal discomfort, nausea, vomiting, dehydration, weight loss, and other gastrointestinal symptoms (Current et al., 1983). These may persist for several days to several months. Young children and immunocompromised persons are most susceptible to infection (Wittenberg et al., 1989; De Mol et al., 1984), but people of all ages may become infected. While cryptosporidiosis is generally a self-limiting disease with a complete recovery in otherwise healthy persons, it can be very serious in immunosuppressed persons, such as persons with AIDS, those receiving treatment for certain types of cancer, and organ-transplant recipients (De Mol et al., 1984; CDC, 1982). Several studies in Great Britain have documented a waterborne route for cryptosporidiosis in AIDS patients and in persons receiving immunosuppressive transplant therapy (Casemore, 1990). There appears to be an immune response to *Cryptosporidium,* but it is not known if this results in protection (Fayer and Ungar, 1986). Data suggest that a person, once infected, can transmit this infection by direct contact to other susceptible persons (Casemore and Jackson, 1984).

Between 1984–1993, there were a number of reported outbreaks of significant waterborne cryptosporidiosis in the U.S. and Great Britain, totaling many tens of thousands of cases (D'Antonio et al., 1985; Smith et al., 1988; Hayes et al., 1989; Herwaldt et al., 1991; Levine and Craun, 1990; Moore et al., 1993). The trend in numbers of outbreaks has been on the increase, probably due to greater recognition and subsequent reporting of *Cryptosporidium* in outbreaks during recent years. Prevalence data for human cryptosporidiosis in all age groups ranged from 1 to 2 percent in Europe, 0.6 to 4.3 percent for North America, and 3 to 20 percent for Asia, Australia, Africa, and South America (EPA, 1993). The role of water in the transmission of cryptosporidiosis has been proven. However, the known percentages of cases from water compared to other routes may substantially under-represent the water route. The route of transmission for many cases of cryptosporidiosis was not determined, but may have been waterborne.

During the spring of 1993, there was a severe waterborne disease outbreak of cryptosporidiosis in Milwaukee, Wisconsin, with an estimated 400,000 cases of diarrhea and apparently several deaths associated with the disease in severely immunocompromised persons. Another recent outbreak of waterborne cryptosporidiosis occurred in Jackson County, Oregon, during the winter and spring of 1992, where as many as 15,000 people (10% of the population) displayed cryptosporidiosis-like symptoms (AWWA, 1992).

It is estimated that over 162 million people are served by public water systems using surface water, most of which are filtered and disinfected. Of these, as of June 1989, an estimated 21 million people were receiving unfiltered surface water that is only disinfected. EPA anticipates that, as a result of the SWTR, more than 80 percent of the unfiltered systems will install filtration. Nevertheless, in spite of filtration and disinfection, *Cryptosporidium* oocysts have been found in filtered drinking water (LeChevallier et al., 1991b; EPA, 1993) and most waterborne outbreaks of cryptosporidiosis have been associated with filtered surface water systems. Therefore, it appears that surface water systems that filter and disinfect may still be vulnerable to *Cryptosporidium,* depending on source water quality and treatment effectiveness. In addition, some surface water systems that were able to avoid filtration under the SWTR may need to filter to provide adequate protection against *Cryptosporidium.*

EPA is proposing an MCLG for *Cryptosporidium* because *Cryptosporidium* oocysts have been demonstrated to be a significant health threat for all persons consuming untreated or inadequately treated surface waters and ground waters under the influence of surface waters. The proposed MCLG is based upon animal studies and the human epidemiology of waterborne outbreaks of cryptosporidiosis.

While it is clear that *Cryptosporidium* can infect humans, dose-response data for infection and illness rates are lacking. Therefore, risk assessments for this organism based on human data are not currently possible. However, the results of several animal studies have been published on the infectious dose of *Cryptosporidium* oocysts. Korich et al. (1990) examined neonatal mice inoculated with 600, 6,000, or 60,000 oocysts. In this study, the mean infectious dose (ID50) was determined by initial experiments to be 60 oocysts. Mice receiving 60 or more oocysts were typically infected while those receiving less than 60 oocysts often did not demonstrate any infection. The work of Miller et al. (1990), while limited because of the small number of animals tested, was conducted on Macaque monkeys. Ten oocysts via oral intubation were capable of causing infection and the signs and symptoms resembled the effects seen in children and immunocompromised humans with cryptosporidiosis. Feeding studies in mice described by Ernest et al. (1986)

indicated that inoculation with 100, 500, or 1,000 oocysts caused infection in 22, 66, and 78 percent, respectively, of the mice in each dose group. Studies to date strongly suggest that there are strain differences or virulence factors that may greatly influence the ability of *Cryptosporidium* to infect humans and animals via the oral route. The comparative infectivity of specific strains for humans and various animal models has not been accurately established.

The use of animal models for determining infectious dose may overestimate the number of oocysts required for human infection. Also, technical questions remain that affect EPA's consideration of the reliability and meaning of the available data. For example, the length of time and procedures used in storage of oocysts in the laboratory before infectivity studies begin may influence infectivity determinations. There are currently no proven *in-vitro* methods to determine whether oocysts used in testing are all viable.

Because some strains of *Cryptosporidium parvum* appear to be highly infectious, and because there is no current generally accepted practical means for distinguishing whether detected oocysts are viable or for determining the infectious dose of any particular strain, EPA believes this organism should be assumed to be without an infectivity threshold for purposes of this rule. That is, consumption of one *Cryptosporidium* oocyst would be considered sufficient to initiate human infection as a possible consequence. Also, direct person-to-person spread of infection may readily occur, thus magnifying the significance of the original waterborne infection. Therefore, the presence of this organism at any level in consumed drinking water cannot be considered safe for human consumption. For these reasons and to be consistent with EPA drinking water standards for *Giardia*, enteric viruses, *Legionella*, *E. coli* and coliform bacteria, EPA proposes that the MCLG for *Cryptosporidium* oocysts in water be zero. Public comments are requested on this rationale for setting an MCLG of zero and a treatment technique for *Cryptosporidium*.

D. Proposed Revisions to SWTR Under all Treatment Alternatives

This section proposes three revisions of the SWTR that would apply regardless of which of the four treatment alternatives in Section E that EPA selects. This section also requests public comment on several additional measures (Section 4, below).

1. Inclusion of Cryptosporidium in Definition of "Groundwater Under the Direct Influence of Surface Water"

The SWTR at 40 CFR 141.2 defines "groundwater under the direct influence of surface water" as "any water beneath the surface of the ground with (1) significant occurrence of insects or other macroorganisms, algae, or large-diameter pathogens such as *Giardia lamblia*, or (2) significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity, or pH which closely correlate to climatological or surface water conditions * * *". Systems using such ground waters as a source for drinking water are subject to the provisions of the SWTR. Determination of whether a ground water is under the direct influence of surface water requires careful evaluation of site-specific information on water quality, well construction characteristics, and hydrogeology.

EPA defined groundwater under the direct influence of surface water in the SWTR to ensure that public water supply systems using this type of source water would provide appropriate treatment to minimize health risks from pathogens. Since viruses and bacteria are known to contaminate true ground waters, EPA focused attention on those contaminants that do not normally occur in true ground waters and whose presence suggests direct surface water contamination.

Among those contaminants are certain pathogenic protozoa, such as *Cryptosporidium parvum* and *Giardia lamblia*. These protozoa are common in surface waters. At the time of promulgation of the SWTR, routine methods for detection of *Cryptosporidium* were not generally available and, therefore, *Cryptosporidium* was not specifically addressed under the definition of "groundwater under the direct influence of surface water". EPA is currently revising its existing guidance (EPA, 1991a; EPA, 1992) to address this issue.

EPA proposes to amend the SWTR by including *Cryptosporidium* in the definition of a "ground water under the direct influence of surface water". Under the rule, a system using ground water considered vulnerable to *Cryptosporidium* contamination would be subject to the provisions of the SWTR. The Agency proposes that this determination be made by the State for individual sources using State-established criteria for requirements and documentation. The Agency believes that this would allow States sufficient flexibility to accommodate local and regional hydrogeological conditions and maintain consistency with State well construction requirements, watershed management policies, and wellhead protection plans.

Because *Cryptosporidium* can occur episodically, the inability to detect this organism in a ground water at any given time would not necessarily suggest that ground water is not under the direct influence of surface water. The presence of *Cryptosporidium*, however, would indicate fecal contamination and direct influence of surface water.

The SWTR does not necessarily require a system that uses ground water to filter if it detects *Cryptosporidium*, *Giardia*, or other contaminants associated with surface water in the ground water, or if the groundwater is categorized as being under the direct influence of surface water. The presence of these organisms may be the result of faulty well construction that can be remedied by inexpensive measures. Also, the rule allows States to grant removal/inactivation credit for the "natural disinfection" achieved during flow from the surface water source to a well; such natural disinfection could mitigate the treatment level that might otherwise be required. For the State to grant removal/inactivation credit for a system, that system would have to demonstrate the extent to which *Giardia* and *Cryptosporidium* are removed by site-specific natural removal processes before the water enters the well.

However, strategies for granting such credits are currently limited because accurate pathogen removal/inactivation rates during transport through the ground cannot yet be easily predicted.

EPA solicits comment on the inclusion of *Cryptosporidium* in the determination of ground water under the influence of surface water, on the larger consideration of revisions to guidance on this issue, and on the most appropriate procedures for determining removal/inactivation credits and treatment requirements for systems using ground waters under the direct influence of surface water.

2. Inclusion of *Cryptosporidium* in Watershed Control Requirements

The SWTR at § 141.71 specifies the conditions under which a public water system using a surface water source can avoid filtration. Among the conditions is a requirement that the system maintain a watershed control program that minimizes the potential for source water contamination by *Giardia lamblia* and viruses (§ 141.71(b)(2)). This program must include a characterization of the watershed hydrology characteristics, land ownership, and

activities which may have an adverse effect on source water quality.

EPA is proposing to extend the watershed control requirements to include the control of *Cryptosporidium* in the source water in a manner analogous to the existing requirements in § 141.71(b)(2) for *Giardia* cysts and viruses. The rationale is that *Cryptosporidium* is a pathogen that cannot be easily controlled with conventional disinfection practices, and therefore its presence in source water serving unfiltered surface water systems must be limited. Specifically, *Cryptosporidium* would be included in the watershed protection control provisions wherever *Giardia* is mentioned.

3. Sanitary Surveys for all Surface Water Systems

The SWTR at § 141.71(b)(3) requires that systems wishing to avoid filtration must be subject to an annual on-site inspection performed by the State or a party approved by the State. The results of this system inspection must indicate to the State's satisfaction that the disinfection treatment process and the watershed control program are adequately designed and maintained.

EPA proposes to amend the SWTR to require all systems that use surface water, or ground water under the direct influence of surface water, to have a periodic sanitary survey, regardless of whether they filter or not. States would be required to review the results of each sanitary survey to determine whether the existing monitoring and treatment practices for that system are adequate, and if not, what corrective measures are needed to provide adequate drinking water quality. If EPA publishes a regulation that requires systems to treat their water on the basis of pathogen densities in the source water (see Section E below), the Agency would require systems, as part of the sanitary survey, to assess quantitatively whether the source water quality has changed sufficiently since the previous sanitary survey to warrant changes in treatment practice.

Under this rule, the system would be responsible for insuring that the sanitary survey is accomplished. Only the State or an agent approved by the State would be able to conduct this sanitary survey, except in the unusual case where a State has not yet implemented this requirement, i.e., the State has neither performed a sanitary survey nor generated a list of approved agents. For these unusual cases, the Agency solicits comment on what EPA prerequisites, if any, should be specified in the rule or guidance for individuals performing sanitary surveys (e.g., BS degree in environmental engineering, professional engineer certificate, sanitarians, etc.).

Sanitary surveys are defined in § 141.2 as "an on-site review of the water source, facilities, equipment, operation and maintenance of a public water system for the purpose of evaluating the adequacy of such sources, facilities, equipment, operation and maintenance for producing and distributing safe drinking water." Guidance for conducting a sanitary survey for unfiltered systems appears in the SWTR Guidance Manual (EPA, 1991), even though such a survey is not specifically required by the SWTR. EPA solicits comment on how this Guidance Manual should be revised to address concerns for filtered systems, and for *Cryptosporidium*.

The requirement for a sanitary survey under this rule would be similar to that in the TCR, which requires periodic sanitary surveys for some systems. Specifically, the TCR at § 141.21(d) requires periodic sanitary surveys for systems that collect fewer than five routine samples per month. These surveys are performed by the State or a party approved by the State. The results of the sanitary surveys are to be used by the State to determine whether the monitoring frequency is appropriate, and if not, what the new frequency should be and whether the system needs to undertake any specific measures to improve water quality. These surveys are to be performed every five years or ten years, depending on circumstances. These surveys are somewhat more extensive than the on-site inspection required under the existing SWTR and include an evaluation of the distribution system.

In addition to the sanitary survey in the TCR and the proposed requirement for surface water systems, EPA intends to propose a sanitary survey requirement in the forthcoming Groundwater Disinfection Rule for all public water supply systems using groundwater that wish to avoid disinfection.

The Agency believes that periodic sanitary surveys, along with appropriate corrective measures, are indispensable for assuring the long-term quality and safety of drinking water. Many States already perform sanitary surveys on most or all systems. By taking steps to correct deficiencies exposed by a sanitary survey, the system provides an additional barrier to microbial contamination of drinking water.

Compliance with this requirement would not eliminate the requirement for unfiltered systems to conduct annual on-site inspections, although applicable information from these on-site inspections could be used to satisfy some elements of the sanitary survey. During the years when the sanitary survey is conducted, the sanitary survey would fulfill the on-site inspection requirement.

With promulgation of these rules, EPA hopes to focus more attention on watersheds and watershed protection activities to enhance and maintain the quality of both surface waters and ground waters as sources for drinking water. The Agency recognizes that in many areas of the United States, watersheds that serve as drinking water sources are increasingly vulnerable to degradation. Moreover, the current status of technology and scarce funding may limit the levels of water treatment reasonably possible. Therefore, the Agency wishes to minimize the contamination of source waters to maintain or improve the health benefits from drinking water treatment. While the rule proposed here derives from provisions of the SDWA, protection of watersheds is also consistent with provisions of the Clean Water Act.

One issue that the Negotiating Committee considered throughout the negotiation process was the relationship and role of watershed protection to these regulations. The committee sought to promote watershed protection and to provide incentives to establish new watershed protection programs and to improve existing ones. This goal was prompted by the benefits that watershed protection provides not only for disinfectant byproduct control, but for the control of a wide range of potential drinking water contaminants.

Watershed protection minimizes pathogen contamination in water sources, and hence the amount of physical treatment and/or disinfectant needed to achieve a specified level of microbial risk in a finished water supply. It also may reduce the level of turbidity, pesticides, volatile organic compounds, and other synthetic organic drinking water contaminants found in some water sources. Watershed protection results in benefits for water supply systems by minimizing reservoir sedimentation and eutrophication and by reducing water treatment operation and maintenance costs. Watershed protection also provides other environmental benefits through improvements in fisheries and ecosystem protection.

The types of watershed programs that the committee wished to encourage are those that consider agricultural controls, silvicultural controls, urban non-point controls, point discharge controls, and land use protection that are tailored to

the environmental and human characteristics of the individual watershed. These characteristics include the hydrology and geology of the watershed; the nature of human sources of contaminants; and the legal, financial and political constraints of entities that affect the watershed.

Sanitary survey frequency. EPA is considering requiring sanitary surveys either every three years or every five years, and requests public comment on this issue. There is a major concern that changes over time in watershed characteristics, such as those resulting from development or other changes in land use, may degrade surface source water quality significantly. Treatment facilities and distribution systems likewise may deteriorate over time. It is important to address such adverse changes as soon as possible. Consequently, more frequent sanitary surveys should result in safer and more reliable drinking water. This is the advantage of a three-year survey over a five-year survey.

Yet a survey every five years is less expensive and is more consistent with the provisions of the TCR. EPA considers a five-year frequency to be minimal for assessing watershed and system conditions associated with surface waters. To provide adequate lead time to the State for implementing any sanitary survey requirement, EPA would not require systems to complete the initial sanitary survey until five years after the effective date of this rule. This lead time would not apply to systems that collect fewer than five samples per month under the TCR, since they should already have had their initial survey.

EPA does not believe this sanitary survey requirement would be onerous to systems, since systems collecting fewer than five samples/month (i.e., serving fewer than 4101 people) are already required to conduct sanitary surveys under the TCR, and larger systems should have greater financial resources than these smaller ones.

4. Possible Supplemental Requirements

a. Uncovered Finished Water Reservoirs. EPA guidelines recommend that all finished water reservoirs and storage tanks be covered (EPA, 1991a,b). The American Water Works Association (AWWA) also has issued a policy statement strongly supporting the covering of reservoirs that store potable water (AWWA, 1993). In addition, a workshop in 1981 convened by EPA, in conjunction with the American Society for Microbiology, to advise EPA on a variety of drinking water issues recommended that EPA require systems to cover all new finished water reservoirs (EPA, 1983). By covering reservoirs and storage tanks, systems would reduce the potential for contamination of the finished water by pathogens and hazardous chemicals. It would also limit the potential for taste and odor problems and increased operation and maintenance costs resulting from environmental factors such as sunlight (Bailey and Lippy, 1978).

Potential sources of contamination to uncovered reservoirs and tanks include airborne chemicals, surface water runoff, animal carcasses, animal or bird droppings, growth of algae and other aquatic organisms due to sunlight that results in biomass, and violations of reservoir security (Bailey and Lippy, 1978).

Because of these adverse consequences, EPA is considering whether to issue regulations that require systems to cover finished water reservoirs and storage tanks. The Agency solicits public comment on whether such a national regulation is appropriate, whether such a requirement should be at State discretion only, what costs would be incurred by systems under such a regulation, and under what conditions a waiver from this rule would be appropriate.

Cross-Connection Control Program. Plumbing cross-connections are actual or potential connections between a potable and non-potable water supply (EPA, 1989b). According to Craun (1991), 24% of the waterborne disease outbreaks that occurred during 1981–1990 were caused by water contamination in the distribution system, primarily as the result of cross-connections and main repairs. During this period, 11 reported outbreaks with 1350 associated cases were blamed on cross-connection problems in community water systems (Craun, 1994). While the vast majority of outbreaks associated with cross connections are caused by pathogens, a few are caused by chemicals.

EPA does not have a regulation mandating a cross-connection control program, but does address the issue in the TCR. Section 141.63(d)(3), for example, identifies proper maintenance of the distribution system as one of the best technologies, treatment techniques, and other means for achieving compliance with the MCL for total coliforms. In a subsequent clarification, EPA explained that this statement in the rule includes a cross-connection control program. In addition, in a rule that stayed the no variances provision of the TCR, i.e., allows States to grant variances, EPA recommended that one of the criteria that States could use to identify systems that could operate under a variance without posing an unreasonable risk to health was that the system has a cross-connection control program acceptable to the State and performs an audit of its effectiveness (56 FR 1556, January 15, 1991). The AWWA also has a policy statement on cross connections urging systems to set up a program for their control (AWWA, 1993).

EPA is seeking public comment on whether EPA should require States and/or systems to have a cross-connection control program; what specific criteria, if any, should be included therein; and how often such a program should be evaluated. Should EPA require that only those connections identified as a cross connection by the public water system or the State be subject to a cross connection program? EPA also seeks comment on what conditions would a waiver from this rule be appropriate. In addition, the Agency requests commenters to identify other regulatory measures EPA should consider to prevent the contamination of drinking water already in the distribution system (e.g., minimum pressure requirements in the distribution system).

State notification of high turbidity levels. The SWTR requires filtered systems to report turbidity measurements to the State within ten days after the end of each month the system serves water to the public (§ 141.75(b)(1)). If at any time the turbidity exceeds 5 NTU, however, the system must notify the State as soon as possible, but no later than the end of the next business day (§ 141.75(b)(3)(ii)). In addition, the system must notify the public as soon as possible, but in no case later than 14 days after the violation (non-acute violation, § 141.32(a) and § 141.32(b)(10)).

EPA is considering broadening the requirement for systems to notify the State as soon as possible. The Agency might, for example, require systems to notify the State as soon as possible if at any point during the month it becomes apparent that a system will exceed the monthly turbidity performance standard in § 141.73 (0.5 NTU for conventional filtration or direct filtration, 1 NTU for slow sand filtration or diatomaceous earth) for an extended period of time (e.g., more than 12 consecutive hours), regardless of whether the system will violate the monthly standard. In addition, the Agency might require systems to notify the State as soon as possible if at any point during the month it becomes apparent that a system will violate the monthly

turbidity performance standard in § 141.73, rather than await the end of the month, as specified in the existing SWTR.

There are sound public health reasons for requiring swift State notification for persistent turbidity levels above the performance standards in § 141.73. Pathogens may accompany the turbidity particles that exit the filters, especially with poor quality source waters. High turbidity levels in the filtered water, even for a limited time, may represent a significant risk to the public. Increasing the disinfection residual in such cases is essential, but some pathogens (e.g., *Giardia* and *Cryptosporidium*) are relatively resistant to disinfection. Early notification would allow the states to require the system to issue an immediate public notice of the turbidity violation if the nature of the violation is considered to be an immediate health concern.

EPA solicits comment on whether the Agency should require systems to notify the State as soon as possible for persistent turbidity levels above the performance standards or for any other situation that is not now a violation of the turbidity standards.

E. Alternative Treatment Requirements

This section proposes five alternative treatment requirements for removing *Giardia*, *Cryptosporidium*, and/or viruses. The final rule might include one or some combination of these alternatives. These regulatory alternatives would require systems to remove a specified level of pathogen based upon its density in the raw water, as measured either under the ICR or another comparable approach. The greater the pathogen density in raw water, the greater would be the pathogen reduction required by treatment. This section also examines several statistical options for defining pathogen densities in source waters.

The Regulatory Impact Analysis for this proposal includes preliminary estimates of the incremental costs for several of these options and discusses what incremental risk reductions would be needed to offset these costs from a cost benefit perspective. As the ICR data become available, EPA intends to develop the risk reduction and cost estimates of these different options for defining pathogen densities in source waters, for different treatment alternatives, and to publish this analysis in a Notice of Availability. After reviewing public comments and additional information and data, EPA intends to select one or more options that provides the greatest improvement in public health taking into account any adverse health effects associated with treatment strategies required and the costs of these improvements.

1. Options for Defining Pathogen Densities in Source Waters

EPA is considering several options for defining the raw water pathogen density that systems would use to determine their needed level of treatment. As part of this, EPA is considering both the technical and public health implications of these options.

The public health risk from waterborne microorganisms depends on their density in source water and their infectious dose levels. Since the calculated infectious dose levels for *Giardia* and other pathogens do not address high-risk populations, e.g., the very young and old and immunocompromised individuals, they may not be conservative with respect to protecting public health. Therefore, EPA could provide a margin of safety for such populations by requiring a system to define the pathogen density used for determining the required treatment level in terms of a conservative statistical method, i.e., one that would provide a higher pathogen density than an arithmetic mean. Such analysis would also need to consider various assumptions regarding the likelihood of a detected organism being viable and infectious. Currently it is not yet possible to determine whether a protozoan cyst in water is viable or, if viable, infectious. EPA and other groups, however, are conducting research in this area.

The approach EPA selects for calculating pathogen density should consider the wide temporal and spatial variations in densities that occur in raw water and should be appropriate for the calculation of the attendant health risks. Among the approaches being considered by the Agency are the arithmetic mean, geometric mean, 90th percentile, and maximum measured value. These are discussed below.

EPA expects that systems subject to this rule will use their data collected under the ICR as a basis for determining source water pathogen densities and selection of appropriate treatment levels. The Negotiating Committee recommended this approach so that systems would have sufficient time to determine the need for, design, and install any necessary treatment to comply with both the ESWTR and D/DBPR requirements in a consistent, integrated manner. This approach would require States, as part of their primacy applications for the ESWTR, to include provisions for acquiring ICR data from EPA's ICR data base when it becomes available, directly from the system or a database.

EPA recognizes that some systems that currently serve fewer than 10,000 people, and thus not subject to ICR monitoring, may eventually, as a result of their growth, become subject to the interim ESWTR. Once such a system serves 10,000 people or more, the rule would require it to collect data sufficient to determine the source water pathogen densities in a manner analogous to that specified in the ICR. The system would then use these data to determine the level of treatment needed. EPA solicits comment on this approach.

a. Use of arithmetic mean of data. The arithmetic mean is the sum of the pathogen densities from all collected samples divided by the number of samples. An arithmetic mean would be calculated for each pathogen. The arithmetic mean is most appropriate when the densities are relatively uniform, both spatially and temporally, and symmetrical about the mean.

Use of the arithmetic mean is most useful when the distribution of measured values approximates a normal distribution. Relative to the geometric mean, the arithmetic mean allows an easier calculation of confidence intervals and may be more conservative. When considering the multiple exposures associated with drinking water ingestion at the low microbial risk levels associated with treated water, risks can be considered as additive and linearly related. Under these circumstances, the arithmetic mean is superior to the geometric mean in the estimation of central tendency (Regli et al., 1991).

b. Use of geometric mean of data. The geometric mean is defined by the equation:

$G_m = \log^{-1}(1/n \times [\log X_1 + \log X_2 + \ldots \log X_n])$,

Where n = number of samples and X_i is the measured density for each sample. For example, the geometric mean of the values 1, 10, and 100 would be 10. The geometric mean is more appropriate than the arithmetic mean for representing the central tendency for data that have a skewed distribution. However, the geometric mean is less conservative, i.e., it would generally estimate a lower mean density and therefore lower risk for pathogens than the arithmetic mean (for example, the arithmetic mean of 1, 10, and 100 is 37, versus the geometric mean of 10). Nevertheless, depending upon the assumptions made in the risk

assessment calculation (e.g., percentage of cysts/oocysts viable), use of the geometric mean may be adequately conservative for estimating exposures and consequently appropriate levels of treatment (Regli et al., 1991).

c. Use of the 90th percentile value. Another alternative for defining pathogen density is to base this value on the 90th percentile of all data for a particular pathogen. This is the value below which fall 90% of the data points and above which fall 10% of the data points. This approach is more conservative in terms of risk than the arithmetic mean and geometric mean, because for sources where pathogen density varies significantly throughout the year, use of this value will be more representative of the elevated risk associated with peak contamination periods.

Use of the 90th percentile measured value, however, has the obvious drawback that it requires a sufficient number of samples to provide a good 90th percentile estimate without interpolation. In many cases, particularly for small water systems, cost considerations will prevent extensive sampling. For example, the proposed ICR would require only six raw water samples over the period of a year for systems from 10,000 to 100,000 people served. The 90th percentile value could be interpolated from the two highest values.

d. Use of the maximum measured value. This approach would dictate the use of the highest density measured under the ICR for raw water. Since few systems have the resources for routine, frequent, and long-term sampling for pathogens such as *Giardia*, *Cryptosporidium* and viruses, it is clear that episodic periods of microbial contamination may escape detection. EPA is particularly concerned with the risks from unusually high level contamination events that might exceed the removal/inactivation capacity of a treatment system. While the maximum measured value may not be representative of the normal pathogen density in a source water, it would be more indicative of potential short-term risks.

Additionally, since the published dose-response values for *Giardia* and other pathogens were developed in healthy adult populations and therefore are not conservative with respect to protecting public health, EPA might select use of the maximum value, which is the most conservative statistical option, to offset this problem. Alternatively, it may be more appropriate to use a less conservative method for estimating microbial densities but to use more conservative criteria for deriving the actual level of treatment requirements as they relate to pathogen densities. For example, if EPA assumes that all *Giardia* cysts detected are viable and infectious to humans in specifying the level of treatment needed, this approach may be sufficiently conservative to warrant the density calculation by one of the other above described methods.

A major problem with basing the density calculation on the maximum value is that if a utility collects more than the minimum number of samples required in the interest of better defining potential exposures, it has a greater likelihood of collecting a sample with a higher pathogen density than would occur with the minimum required number of samples. In this case, the system may face a more stringent (and thus more expensive) standard.

Use of the maximum measured density may be more appropriate than other statistical methods for systems that have not collected sufficient data to allow calculation of an adequately representative mean value or 90th percentile value. With such limited data, the maximum value might be suitable for determining level of treatment.

EPA is soliciting comment on which approach is most appropriate for defining pathogen density. The Agency is also requesting comment on whether the approach used should be based on the number of pathogen samples collected, i.e., the maximum measured value would be required for systems taking only six samples under the ICR (systems serving between 10,000 and 100,000 people) and 90th percentile value for systems that collect at least 10 samples.

2. Treatment alternatives for controlling pathogens. To determine what regulatory controls are most appropriate for controlling pathogens in drinking water, EPA must decide what constitutes acceptably safe drinking water. The SDWA frames this discussion in determining MCLGs and MCLs. MCLG levels, which are not legally enforceable, are based solely on health concerns. As required by the SDWA, they are set "at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety". The corresponding enforceable regulation consists of either an MCL set as close to the MCLG as feasible, taking cost and availability of treatment into account; or, when it is not technologically or economically feasible to monitor for the contaminants, a treatment technique(s) to achieve an acceptable risk.

The SWTR promulgated an MCLG for *Giardia* of zero, i.e., no *Giardia* cysts should be allowed in drinking water. A system using surface water cannot usually attain this goal in any practical sense. Therefore, the SWTR preamble suggested a more practical health goal for *Giardia*: drinking water should not cause more than one *Giardia lamblia* infection annually per 10,000 exposed persons (10^{-4} risk). In contrast to this goal, EPA policy for specific chemical carcinogens is for theoretical lifetime upper bound risks to be no greater than within a range of 10^{-4} to 10^{-6}. For non-carcinogenic chemical contaminants, EPA policy is to base the MCLG on the reference dose (RfD) for the given chemical. The RfD is calculated to be below any known level of exposure resulting in adverse health effects, so that drinking water at the resulting MCLG over a lifetime should be without known risk.

In developing the D/DBP rule (proposed elsewhere in today's **Federal Register**), EPA is attempting to ensure that drinking water remains microbiologically safe at the limits set for disinfectants and byproducts, and that the disinfectants and byproducts themselves do not pose an unacceptable risk at these limits.

Based on data on microbial illness and death in the U.S. compiled by Bennett et al. (1987), the estimated annual risk of waterborne illness during 1985 was about 4×10^{-3} and the estimated lifetime risk of death was about 3×10^{-4}. As stated above, the goal of the SWTR was for systems to achieve a risk of less than 10^{-4} infections per year for *Giardia*. Because *Giardia* is relatively difficult to inactivate compared to virus and bacterial pathogens, the SWTR assumed that water treatment adequate to achieve a 10^{-4} risk for *Giardia* would provide an even higher level of protection against pathogenic viruses and bacteria in untreated surface waters. Applying the Bennett et al. (1987) data regarding the ratio of mortality to waterborne illness (0.1 percent = 10^{-3}), if a system achieves an incidence of 10^{-4} waterborne infections per year or less, the associated lifetime risk of death would be less than 7×10^{-6}. This is a 40-fold decrease in risk relative to those estimated by Bennett et al. (1987), who used 1985 data.

The above calculations refer to the average individual and an average pathogenic organism. Available dose-response data show that the risk of infection for a given pathogen density in

the consumed water ranges over several orders of magnitude for different organisms (Regli et al., 1991). Setting a generic microbiological drinking water standard based on one dose-response curve will either overestimate or underestimate risks from other organisms. The risk of death from infection likewise varies widely with the organism (Bennett et al., 1987). Therefore, the severity of the illness associated with a given organism must be considered.

Additional considerations in assessing acceptable waterborne microbial risks involve the human subpopulations sensitive to infection, illness and death. Infection does not always result in illness; many infections are asymptomatic (Rendtorff, 1954; Lopez et al., 1980). The progression and severity of illness following microbial infection are more a function of individual physiology than the magnitude of dose, as is true for many toxic chemicals. Acute gastrointestinal illness, the most common microbial illness, is generally considered non-life threatening in normally healthy adults. However, this is not necessarily true for those subpopulations that are more sensitive to microbial infection or illness. Some studies (Glass et al., 1991; Lew et al., 1991) indicate that infants and those over 70 years old have mortalities of 3–5 percent from diarrhea requiring hospitalization. As discussed above, *Cryptosporidium* infections, mild in healthy persons, are sometimes fatal to the immuno-compromised. Other identified sensitive human subpopulations include pregnant women and those with cardiovascular disease. EPA estimates that about 15% of the U.S. population is in these higher risk groups.

Prudent health policy would be to protect these groups from their higher risks of waterborne microbial infection. Use of a one percent mortality-to-illness rate (instead of a 0.1 percent) to represent more deadly organisms and a 10-fold uncertainty factor (as used in EPA's RfD calculations) to account for these sensitive subpopulations may be appropriate for estimating potential risks resulting from systems achieving regulatory goals. A risk calculation based on this approach, assuming that the system achieves the risk goal of 10^{-4} annual infections for the average population, might result in a 7×10^{-5} (i.e., $10^{-4}\times10^{-2}\times70$ years) lifetime risk of death for certain subpopulations. The 7×10^{-5} lifetime risk of death (which is a more severe endpoint than cancer) is barely within the 10^{-4}–10^{-6} guideline for excess lifetime cancer risk that EPA uses for regulating chemical carcinogens in drinking water.

These calculations, while based on estimates and approximations and having large uncertainties, suggest that the risk level of 10^{-4} annual infections may be acceptable, albeit barely so. If EPA were to accept a more stringent annual risk level of 10^{-5} or 10^{-6} infections to achieve a greater consistency between lifetime mortality risks from waterborne pathogens and most regulated drinking water chemicals, substantial increases in treatment might be required. EPA solicits comment on the appropriateness and magnitude of specific acceptable risk levels for microbial infection and illness.

To counter waterborne illness, EPA is proposing five treatment alternatives for controlling *Giardia*, *Cryptosporidium*, and/or viruses. Within each alternative, several options are addressed. The Agency may promulgate one or more of these alternatives. Alternative A addresses enhanced treatment for *Giardia* only. Alternatives B and C address treatment for *Cryptosporidium* only. Alternative D addresses enhanced treatment for viruses only. Alternative E maintains existing level of treatment requirements for *Giardia* and viruses. EPA requests comment on what alternative(s) is most suitable.

a. Alternative A. Enhanced treatment for Giardia. This alternative bases the extent of treatment required on the *Giardia* density in the source water. The SWTR currently requires a 99.9 percent (3–log) removal/inactivation of *Giardia* for all surface waters, regardless of *Giardia* cyst concentration in the source water. As discussed above and in the SWTR, EPA believes that for source waters of high quality (low pathogen densities), this level of treatment should result in less than one case of giardiasis (and most other waterborne disease) per 10,000 people per year. This risk level for *Giardia* is associated with an infectious *Giardia* cyst density in the source water of less than one cyst/100 liters and assumes that 3 logs of removal/inactivation is consistently achieved on such source water. For more information about *Giardia* risk calculations and associated uncertainties and assumptions, refer to Rose et al. (1991), Regli et al. (1991), and Macler and Regli (1993).

Under Alternative A, systems using source waters with higher *Giardia* densities would be required to meet higher levels of treatment to satisfy the desired acceptable risk level, e.g., the annual 10^{-4} risk or perhaps a more stringent goal. Specifically, under one option of alternative A, EPA is proposing that systems meet the level of treatment for *Giardia* associated with the following *Giardia* concentrations in the source water to achieve a 10^{-4} annual risk level:

No. of giardia/100L	Required treatment level (percent)
<1	99.9 (3-log).
1–9	99.99 (4-log).
10–99	99.999 (5-log).
>99	99.9999 (6-log).

The determination by utilities and States of removal and inactivation efficiencies for specific treatment strategies would be based on EPA guidance and information, as is currently done under the existing SWTR. EPA would revise the existing SWTR Guidance Manual based on data collected under the ICR and research to complement any criteria promulgated under the ESWTR. The Agency expects that data collected under the ICR will be used by States and utilities to define the source water concentration and consequently the appropriate level of treatment for individual systems. If a utility has not collected data on pathogen densities in source water under the ICR, it would be required to do so to define the appropriate level of treatment.

Depending on the method used for calculating pathogen density, assumptions used for estimating risk (e.g., whether to assume that all or only a portion of the detected cysts in the source water are viable and infectious to humans), the desired acceptable risk level, concern about DBP risk, and the technical and economic feasibility of achieving different levels of treatment, it may be appropriate to specify treatment requirements that address higher source water pathogen concentrations than described above. EPA is not aware to what extent physical removal greater than 2.5 logs can reasonably be achieved by systems using conventional water treatment approaches commonly practiced in the United States. The Agency believes that systems that optimize their treatment may be able to achieve substantially higher levels of removal. Membrane filtration techniques, although promising for much higher levels of removal, may not yet be technologically or economically feasible for large numbers of systems. The balance of the removal/inactivation requirement may have to rely on the use of chemical disinfectants. However, while EPA has confidence in the use of disinfectants to achieve current SWTR requirements, it has not been demonstrated that CT values

extrapolated from tables in the SWTR or other sources are valid for higher levels of disinfection (e.g., to achieve a 4- or 5-log reduction of *Giardia*). EPA requests comment on approaches to achieve higher levels of treatment by physical means and on the use of existing CT values in the EPA guidance (EPA, 1991) to predict, by extrapolation, higher levels of inactivation that could be achieved by disinfection.

EPA is considering an alternative version of the above described treatment requirements that would instead require greater *Giardia* reductions for source waters beginning with *Giardia* concentrations of 10 or more cysts/100 liters, as indicated below:

No. giardia/100L	Required treatment level (percent)
10–99	99.99 (4-log).
100–999	99.999 (5-log).
>1000	99.9999 (6-log).

EPA solicits comment on the two treatment options described above and on associated variations.

b. Alternative B. Specific treatment for Cryptosporidium. EPA is proposing a treatment technique rather than an MCL for *Cryptosporidium*, because EPA believes that it is not currently economically or technologically feasible for a system to monitor for this organism in the finished water to determine whether it meets an acceptable risk level. The Agency bases its belief on three factors: (1) The variability of *Cryptosporidium* spatially and temporally may be considerable, and consequently systems would have to collect frequent samples and inordinately large sample volumes to properly characterize the density of this organism, (2) current methods for *Cryptosporidium* analysis are difficult and expensive, (3) it is not yet possible to predict the risk resulting from a specific level of exposure to *Cryptosporidium*, and (4) even if *Cryptosporidium* could be detected at the lowest concentrations of concern in the finished water, the exposure and associated risk would have already occurred, thereby reducing the significance of monitoring non-compliance.

Under this rule, all community and non-community public water systems using any surface water source, or groundwater under the direct influence of surface water, would be required to treat these sources as described below. EPA anticipates that human dose-response data for *Cryptosporidium* will be available within the next year and will include these data in a Notice of Availability, probably in March 1996. Because they are not yet available, basing the treatment level on a specific acceptable risk level, as proposed by EPA for *Giardia*, cannot be used for *Cryptosporidium* in the present notice. Data collected to date suggest that the dose-response for *Cryptosporidium* may be similar to that for *Giardia*. If this is true, then the required reduction level for *Cryptosporidium* may be the same as for *Giardia* to achieve an equivalent risk level for similar source water densities.

In the absence of dose-response data, EPA is proposing a wide variety of options. One sub-alternative would be to base the level of treatment on the *Cryptosporidium* densities found in the source water, as presented in the Table below.

No. cryptosporidium/100L	Required treatment level (percent)
<1	99.9 (3-log).
1–9	99.99 (4-log).
10–99	99.999 (5-log).
>99	99.9999 (6-log).

EPA is concerned, however, that it may not be technologically or economically feasible to achieve the treatment levels above, given that *Cryptosporidium* is much more resistant to disinfection than is *Giardia*. Conventional treatment of coagulation, sedimentation and filtration may not reliably achieve more than 2.5-log or 3-log *Cryptosporidium* oocyst reduction under typical operating conditions. While membrane filtration technologies (ultrafiltration, nanofiltration), possibly following conventional treatment processes, appear to promise considerably greater reductions in *Cryptosporidium* densities, their widespread use for this purpose raises other concerns such as waste disposal of the concentrate, water wastage, potential failure of the membrane, and significant costs. Unless systems can feasibly achieve higher removal levels for *Cryptosporidium* by physical means, they would have to achieve this additional reduction by the use of disinfectants. However, uncertainties exist with respect to disinfection of *Cryptosporidium*. Current data suggests that chlorine and chlorine-based disinfectants are relatively ineffective in inactivating *Cryptosporidium*, and the Agency is not certain if alternative disinfectants, such as ozone, are more effective than chlorine to allow systems to comply with the removal/inactivation levels above.

With this in mind, EPA is also considering two other treatment sub-alternatives for *Cryptosporidium*, as follows:

No. cryptosporidium/100L	Required treatment level (percent)
<1	99 (2-log).
1–9	99.9 (3-log).
10–99	99.99 (4-log).
>99	99.999 (5-log).

No. cryptosporidium/100L	Required treatment level (percent)
<10	99 (2-log).
10–99	99.9 (3-log).
>99	99.99 (4-log).

EPA requests comment on all treatment alternatives discussed above for *Cryptosporidium*.

c. Alternative C. 99% (2-log) removal of Cryptosporidium. Under this alternative, EPA would require systems to achieve at least 99% (2-log) removal of *Cryptosporidium* by filtration (with pretreatment) alone. This alternative is based on the premise that the 3-log removal/inactivation requirement specified for *Giardia* is not economically or technologically feasible for *Cryptosporidium*, since laboratory data suggests that *Cryptosporidium* is considerably more resistant to disinfection than is *Giardia*. In addition, it may not be practical to remove more than two logs of *Cryptosporidium* consistently by clarification and filtration processes. EPA believes, however, that a two-log removal of *Cryptosporidium* is feasible using current conventional treatment methods of coagulation, sedimentation and filtration, as specified under the SWTR.

Under this treatment option, EPA would continue to assess new field and laboratory data to control *Cryptosporidium* by physical removal and disinfection. If these data indicate that proportionally higher levels of *Cryptosporidium* removal/inactivation can be achieved at a reasonable cost, then EPA would revise the ESWTR accordingly as part of the long-term ESWTR regulatory development. The Agency would also revise the SWTR Guidance Manual to suggest approaches for improving system design and operations for controlling *Cryptosporidium*. When sufficient human dose-response information for *Cryptosporidium* becomes available to allow calculation of drinking water health risks from this organism, EPA will consider a risk-based approach to establishing adequate treatment levels.

EPA solicits comment on whether a higher minimum removal requirement than two logs should be specified for

Cryptosporidium under this alternative. The Agency also requests comment on whether the removal requirement should be increased if treatment were to include disinfection.

d. Alternative D. Specific disinfection treatment for viruses. The SWTR required systems to achieve a four-log reduction/ inactivation of viruses. This is to be achieved through a combination of filtration and disinfection or, for systems not required to filter their source waters, by disinfection alone. Viruses are of particular concern, given that one or several virus particles may be infectious (Regli et al., 1991) and that several enteric viruses are associated with relatively high mortality rates (Bennett et al., 1987). Failure or impairment of filtration performance could allow substantial pathogen contamination of drinking water, particularly if the disinfection barrier following filtration is minimal.

The SWTR considered *Giardia* to be a surrogate for viruses, and assumed that if viruses were present in the source water, treatment requirements adequate to reduce *Giardia* by three logs would also reduce viruses to safe levels. This assumption may not be appropriate if a system were to achieve a 3-log removal of *Giardia* by physical means and provide little disinfection inactivation. Viruses may be present in substantial numbers even in the absence of detectable *Giardia* cysts.

Treatment designed to minimize *Giardia* may not be optimal for viruses. Viruses are substantially smaller than *Giardia* cysts or *Cryptosporidium* oocysts and may pass through certain filter media that will remove the larger protozoa. Therefore, use of data on *Giardia, Cryptosporidium,* or even coliform bacteria (intermediate in size between viruses and protozoa) in assessing treatment efficacy may not be adequate for virus control. Studies by Payment et al. (1991) showed that conventionally treated water meeting current Canadian microbial drinking water advisory levels still led to substantial illness in the studied population. These authors suggested that much of this illness could have resulted from viral infection.

For the above reasons, particularly for strengthening the treatment barrier by disinfection, EPA is proposing to require that systems provide sufficient disinfection such that by disinfection alone it would achieve at least a 0.5-log inactivation of *Giardia* or, alternatively, a 4-log inactivation of viruses. This requirement would be independent of the level of physical removal, e.g., if filtration was able to remove three logs of *Giardia*, the system would still have to provide at least an additional 0.5-log inactivation of *Giardia* or 4-log inactivation of viruses by disinfection. Therefore, this would mean that the system would provide 6 logs of virus removal/inactivation, assuming it is removing 2-logs of viruses by filtration alone. EPA would provide guidance to indicate the appropriate CT values to use with these two alternatives.

The SWTR assumed that a 0.5-log inactivation of *Giardia* would result in a 4-log inactivation of viruses. This assumption was based on a study where the effect of free chlorine on the hepatitis A virus was examined (Sobsey, 1991). Subsequent investigations, however, have suggested that some viruses, such as the Norwalk agent, are substantially more resistant to disinfection by chlorine than is the hepatitis A agent. Additionally, use of disinfectants other than free chlorine to achieve the 0.5-log inactivation of *Giardia* may not yield a 4-log inactivation of viruses. Therefore, a requirement to provide sufficient disinfection to inactivate 4 logs of viruses may be more conservative than the alternative requirement of providing sufficient disinfection to inactivate 0.5 logs of *Giardia*.

Either of these two approaches could result in several additional logs of pathogen removal/inactivation for systems that practice conventional treatment. For example, where the system can remove by physical means at least 2-logs of viruses, the disinfection requirement would yield a total 6-log removal/inactivation of viruses (i.e, 2 logs by physical means and 4 logs by disinfection).

e. Alternative E. No change to existing SWTR treatment requirements for Giardia and viruses. Under this alternative, the existing SWTR requirements for treatment for *Giardia* and viruses would not change. For *Cryptosporidium* control, EPA could either regulate this organism directly (e.g., Alternative C above) or make a finding that *Cryptosporidium* is adequately controlled by filtration and disinfection requirements in the existing SWTR. The Agency may choose this alternative to allow the Agency time to fully develop analyses of the ICR data and accumulate additional data on pathogen occurrence, treatment performance, and health effects, given the view that the current SWTR has not been in effect long enough to evaluate the projected improvements in drinking water quality and resulting public health benefits. EPA would consider additional regulatory alternatives while developing the long-term ESWTR, based on this new data. The Agency requests comment on this alternative, as well.

IV. State Implementation

This section describes the regulations and other procedures and policies States would have to adopt, or have in place, to implement the rule proposed today. States must continue to meet all other conditions of primacy in 40 CFR Part 142.

Section 1413 of the SDWA establishes requirements that a State must meet to maintain primary enforcement responsibility (primacy) for its public water systems. These include (1) adopting drinking water regulations that are no less stringent than Federal NPDWRs in effect under sections 1412(a) and 1412(b) of the Act, (2) adopting and implementing adequate procedures for enforcement, (3) keeping records and making reports available on its activities that EPA requires by regulation, (4) issuing variances and exemptions (if allowed by the State) under conditions no less stringent than allowed by sections 1415 and 1416, and (5) adopting and being capable of implementing an adequate plan for the provision of safe drinking water under emergency situations.

40 CFR Part 142 sets out the specific program implementation requirements for States to obtain primacy for the public water supply supervision (PWSS) program, as authorized under section 1413 of the Act. In addition to adopting the basic primacy requirements, States may be required to adopt special primacy provisions pertaining to a specific regulation. These regulation-specific provisions may be necessary where implementation of the NPDWR involves activities beyond those in the generic rule. States are required by 40 CFR 142.12 to include these regulation-specific provisions in an application for approval of their program revisions. These State primacy requirements would apply to the rule proposed today, along with the special primacy requirements discussed below.

To implement today's proposed rule, States would be required to adopt revisions to § 141.2, Definitions; § 141.52, Maximum contaminant level goals for microbiological contaminants; § 141.70, General requirements; § 141.71, Criteria for avoiding filtration; and § 141.74, Analytical and monitoring requirements.

A. Special State Primacy Requirements

In addition to adopting drinking water regulations at least as stringent as the Federal regulations listed above, EPA would require that States adopt certain additional provisions related to this

regulation to have their program revision application approved by EPA. Because this rule would provide considerable State latitude on implementation, today's rule would require a State to include, as part of its State program submission, its implementation policies and procedures. This information would advise the regulated community of State requirements and help EPA in its oversight of State programs. In concert with promulgating the interim ESWTR, EPA would revise the SWTR Guidance Manual (EPA, 1991). This guidance would assist States in developing appropriate criteria in the regulations they adopted.

To ensure that the State program includes all the elements necessary for a complete enforcement program, today's notice proposes that to obtain EPA approval for implementing this rule, the State's application would be required to include the following:

(1) Adoption of the promulgated ESWTR.

(2) Description of the protocol the State will use to judge the adequacy of watershed protection programs for minimizing the potential for contamination by *Giardia* cysts, *Cryptosporidium* oocysts, and viruses in the source water. The SWTR required States to specify the methodology they would use to judge the adequacy of a watershed control program to control the presence of waterborne *Giardia*. This rule would add *Cryptosporidium*. The addition of *Cryptosporidium* is significant because it may prohibit or substantially limit certain watershed uses such as cattle farming and feedlots. The location of cattle feedlots on a watershed would require additional control measures.

(3) Description of the criteria and methods the State will use for the conduct and review of sanitary surveys. If the State elects to allow non-State personnel to conduct the surveys, the State must specify the criteria for approval and oversight of these personnel and of the surveys.

(4) Description of the procedures for determining the level of treatment required of systems to meet removal and/or inactivation requirements under the rule. If Alternative A described in Section IIIE above is promulgated, demonstration by the State that it has in place enforceable design and operating criteria for achieving the levels of *Giardia* removal and/or inactivation required. If either Alternative B or C described in Section IIIE above is promulgated, demonstration by the State that it has in place enforceable design and operating criteria for achieving the levels of *Cryptosporidium* removal and/or inactivation required. Compliance with the design and operating criteria would be judged on a system-by-system basis.

B. State Recordkeeping Requirements

Changes to the existing recordkeeping requirements to implement the provisions proposed in this notice would require, under general recordkeeping requirements, States to maintain records on the level of treatment necessary to achieve the required levels of removal and/or inactivation of *Giardia*, *Cryptosporidium* and/or viruses. States would also be required to maintain a record of any decisions made as a result of sanitary surveys. These records must be kept for 40 years (as currently required by § 142.14 for other State decision records) or until a subsequent determination is made, whichever is shorter. If the final rule requires systems to base level of treatment on source water pathogen densities, then the State must maintain record of these densities.

C. State Reporting Requirements

Currently States must report to EPA information under 40 CFR 142.15 regarding violations, variances and exemptions, enforcement actions and general operations of State public water supply programs. Today's rule would require States to provide additional information to EPA within the context of the existing special report requirements for the SWTR (§ 142.15(c)(1)) on microbial densities in the source water and the resulting required levels of treatment for each public water system supplied by a surface water source or by ground water under the direct influence of surface water.

V. Public Notice Language

The SDWA (section 1414(c)) requires that notices of violation of the MCL or treatment requirement for a specific contaminant include EPA-specified language on the adverse health effects of that contaminant. Requirements for public notification are found in 40 CFR 141.32. In this notice, EPA is proposing that the existing language for violating the treatment technique requirements in Subpart H of the SWTR, found in 40 CFR 141.32(e)(10), not be changed. This decision is based on EPA's belief that language is sufficiently broad to include the adverse health effects from *Cryptosporidium* exposure.

VI. Economic Analysis

A. Cost of Proposed Rule

This proposed rule would result in treatment costs, monitoring costs, and State implementation costs. These costs are difficult to estimate because of uncertainty in the number of systems that would have to improve treatment and the extent of that improved treatment. This information would depend primarily on the results of future monitoring under the ICR. Under the ICR, systems using surface water and serving 10,000 people or more would determine raw water pathogen densities and, in some cases, the efficiency of treatment for reducing pathogen concentrations. Given the above uncertainties, the cost estimates can now only be addressed in the most general way, across a wide range of possibilities.

With regard to treatment costs, if ICR results indicate that the existing SWTR ensures adequate levels of treatment for most systems, then minimal additional treatment costs would be necessary. Regardless of whether the SWTR is amended to require higher levels of treatment, at least some systems would be expected to upgrade existing levels of treatment based on EPA guidance and ICR monitoring results. Similarly, some systems might reduce existing levels of disinfection upon a finding that their source water is of better quality than expected. Also, some costs will be incurred by systems correcting for deficiencies identified through the sanitary survey requirement.

If ICR monitoring indicates that many source waters contain considerably higher pathogen concentrations than anticipated under the SWTR, then substantial national treatment costs would result in mitigating the associated health risk. These costs could involve increasing disinfection contact time or dosage, switching to stronger disinfectants, or improving filtration efficiencies through upgrades or installation of new technologies.

In estimating possible costs resulting from an ESWTR EPA assumed that (1) national *Giardia* density in source waters are represented by the survey results of LeChevallier et al. (1991a), (2) all systems are at least meeting the treatment requirements of the existing SWTR, (3) some systems, as indicated by the survey results of LeChevallier et al (1991), are providing higher levels of treatment than required by the SWTR, (4) systems would be required to provide sufficient treatment of their source water to achieve no greater than a 10^{-4} annual risk level for *Giardia*, based on the dose-response data and

risk assessment methodology developed by Rose et al. (1991) and Grubbs et al. (1992), (5) additional *Giardia* reduction beyond the requirements of the SWTR to achieve the 10^{-4} risk level would be achieved solely by using chlorine as the disinfectant and providing additional disinfectant contact time (i.e., increasing the CT value by increasing the contact basin size), (6) when all ancillary construction costs including site-specific factors are taken into account, the average total capital cost per system is twice the capital cost of increasing the size of the contact basin alone. Based on the assumptions of Rose et al. (1991) and Grubbs et al. (1992), EPA calculates that systems would need a *Giardia* removal/inactivation level of 3, 4, 5, or 6 logs for *Giardia* concentrations in the source water of <1 cysts/100 L, 1–9 cysts/100 L, 10–99 cysts/100 L, and 100 cysts/100 L or greater, respectively.

National cost estimates for systems to comply with an interim ESWTR as described above are provided in Table VI–1. As discussed in Section III.B of this preamble, depending upon the criteria that are promulgated under the interim ESWTR, EPA also intends to propose requirements for systems serving less than 10,000 people, under a long-term ESWTR, to prevent any undue downside microbial risks that might otherwise result while systems of this size achieve compliance with the Stage 1 D/DBP rule. Therefore, Table VI–1 also includes cost estimates for systems serving less than 10,000 people, even though these costs are not attributed to the interim ESWTR.

Table VI–1 presents the additional contact basin costs needed for twelve system size categories (population served); for each size category, the number and type of systems affected (filtered without softening or filtered with softening), the associated total capital costs, and the associated total annualized costs. In this calculation, operation and maintenance costs are assumed to be negligible since systems are already disinfecting and most of the additional inactivation could be achieved by additional disinfectant contact time. Details of this analysis and other assumptions are described in the Regulatory Impact Analysis for the ESWTR (EPA, 1994). Under this approach, EPA estimates that the capital and annualized costs nationwide for systems serving at least 10,000 people would be $3661 million and $391 million, respectively. Using the same assumptions for systems serving fewer than 10,000 people would result in an additional $820 million capital costs and $114 million annualized costs nationwide, or a total for all system sizes of $4481 million in capital costs and $504 million in annualized costs.

The 10^{-4} annual risk level target was used as an example; costs for achieving different acceptable risk levels, of course, will differ considerably. Although other treatment measures could be used to reduce *Giardia* levels, EPA believed that the national cost based on providing additional disinfectant contact time is probably representative, on average, of other modifications that systems might implement. The Agency chose this methodology for estimating costs because it was the most simple. Moreover, insufficient data prevents the Agency from predicting with any reliability the mix of different technologies systems would use to comply. EPA recognizes that in lieu of expanding contact basin size, some systems may achieve the required *Giardia* reductions through increased disinfectant dosages, improved sedimentation and filtration efficiencies, or use of a stronger disinfectant such as ozone. Smaller systems, especially those serving fewer than 1,000 people, might use cartridge filters, or membrane technology rather than additional contact time to achieve compliance with the long-term ESWTR and other drinking water regulations at lower cost. In addition, the costs for utilities to meet the D/DBP regulations (proposed elsewhere in today's **Federal Register**) are not necessarily additive with the costs for utilities to meet either the interim or long-term ESWTR. For example, systems installing membrane technology to comply with the D/DBP rule would also be expected through use of this technology to comply with the ESWTR. Use of technologies other than increasing contact basin time might be more feasible and less expensive for some systems, depending on site-specific factors (e.g., limited availability of land) and overall treatment objectives (e.g., meeting other regulatory requirements such as the D/DBR rule).

EPA solicits comment on how many systems might use these alternative approaches for meeting ESWTR requirements and whether the use of such technologies would lead to substantially different cost estimates. EPA does not believe there are sufficient data to predict the costs for reducing *Cryptosporidium* to a desired risk level as has been done for *Giardia*. EPA solicits comment on what approaches might be taken for estimating national treatment costs for systems to provide different levels of *Cryptosporidium* removal depending on *Cryptosporidium* densities in the source water. Also, EPA requests comment on whether it is reasonable to assume that any treatment changes that are made to remove *Cryptosporidium* would also remove *Giardia*, thereby not duplicating costs for compliance.

Table VI–2 indicates a range of estimated increases in household costs by system size category for systems needing to achieve an additional 0.5 log to 3 log reduction of *Giardia* to comply with the ESWTR option described above. By this analysis 35 percent of the systems would not be required to make any changes in treatment and would incur no costs. For the interim ESWTR, estimated increases in household costs for systems required to make changes in treatment would range from $11 to $49 per household per year in the smallest size category (serving a median population of 15,000 people) to $3.1 to $24 per household per year in the largest size category (serving a median population of 1,550,000 people).

If the analyzed criteria for the interim ESWTR were extended to smaller systems under the long-term ESWTR, and systems used additional disinfectant contact time to meet such criteria, increases in annualized household costs would range from $360 to $1100 per household per year in the smallest size category (serving a median population of 57 people) to $27 to $85 per household per year in systems with a median population of 5,500. As stated above, EPA believes that smaller systems should be able to use a more economic treatment alternative than additional disinfectant contact time.

EPA solicits comment on whether the system level costs to achieve the different log reductions indicated in Table VI–2 by disinfection, or other means, are reasonable and accurate.

Table VI–3 indicates the estimated labor effort by the number of full time employees (FTEs), hours, and dollar costs for States to implement the interim ESWTR. If systems, rather than the State, were to fund some or all sanitary surveys, then State costs would be reduced accordingly. Further details of this analysis are available in the Regulatory Impact Analysis (EPA, 1994).

TABLE VI–1—ESTIMATED NATIONAL CONTACT BASIN COSTS FOR ENHANCED SWTR

System size category	Population per system	Cost estimates based on additional disinfectant contact basin size[1]								
		Number of affected systems			Total capital cost (M$)			Total annualized cost (M$)		
		Filtering systems			Filtering systems			Filtering systems		
		W/out soft	W/soft	Total	W/out soft	W/soft	Total	W/out soft	W/soft	Total
1	25–100	493	8	501	22	0.5	23	4	0.09	4
2	101–500	454	13	467	42	1.4	43	8	0.3	8
3	501–1K	415	47	462	86	12	98	16	2	18
4	1K–3.3K	586	61	647	200	24	224	25	3	28
5	3.3K–10K	627	104	731	360	72	432	45	9	54
6	10K–25K	291	67	358	330	94	424	34	10	44
7	25K–50K	167	42	209	340	110	450	36	12	47
8	50K–75K	77	24	101	230	92	322	24	10	34
9	75K–100K	63	7	70	250	37	287	26	4	30
10	100K–500K	88	24	112	620	230	850	67	25	92
11	500K–1M	22	5	27	600	170	770	64	18	83
12	1M+	9	1	10	460	97	557	50	11	60
Totals:										
Interim Rule (Systems > 10K).		716	170	887	2830	831	3661	302	88	391
Long-Term Rule (All Systems).		3,290	404	3,694	3,540	941	4,481	401	103	504

Notes:

[1] Cost estimates were developed on the basis of the following assumptions: 1) 35 percent of surface water systems currently meet ESWTR inactivation requirements (based on LeChevallier et al., 1991); 2) the amount of additional inactivation required by systems that do not currently meet ESWTR requirements is based on the distribution of source water *Giardia* concentrations in the LeChevallier data; and 3) the additional basin volume is based upon CT requirements of the SWTR guidance document with: pH = 8 (non-softening) or 9 (softening), $t_{10} : t_{theoretical} = 0.7$, temperature = 5 °C, and Cl_2 residual = 1 mg/l.

TABLE VI–2—ESTIMATED INCREASES IN ANNUAL HOUSHOLD COSTS FOR SYSTEMS EXPANDING CONTACT BASIN SIZE TO MEET AN ENHANCED SWTR[2]

Cat. #	Median pop.	Total household costs, $/hh/yr[3]					
		Filter[4]			Filter and Soften[4]		
		Min	Avg[1]	Max	Min	Avg[1]	Max
1	57	360	420	960	430	500	1,100
2	225	170	200	450	200	240	540
3	750	88	120	310	110	150	350
4	1,910	36	52	110	43	59	130
5	5,500	27	28	67	30	34	85
6	15,000	11	15	40	13	19	49
7	35,000	7.9	12	30	10	15	39
8	60,000	6.6	10	26	8.8	13	34
9	88,100	6.1	8.8	24	7.5	12	32
10	175,000	5.1	8.5	24	6.6	11	33
11	730,000	3.5	6.7	20	4.7	9.1	27
12	1,550,000	3.1	6.0	18	4.2	8.2	24

Notes:

[1] Costs assume that 35 percent of systems currently meet ESWTR requirements (LeChevallier et al., 1991) and therefore do not require contact basin modifications.

[2] Assumes *Giardia* and level of treatment distributions per LeChevallier et al, 1991 are nationally representative of arithmetic averages, and that systems under ESWTR are required to provide additional disinfection inactivation to meet a less than 1/10,000 annual infection rate at the first customer calculated according to the *Giardia* infectivity dose response curve of Rose et al. (1991).

[3] Household costs represent costs for affected systems. Minimum costs are based on costs for systems requiring additional 0.5 log inactivation while maximum costs are based on requiring an additional 3-log inactivation. Average costs are based on distribution of costs for achieving different inactivations based on data by LeChevallier et al. (1991).

[4] Contact basin size dependent upon chlorine residual, pH and temperature. Contact basin costs will increase if chlorine residual or temperature decrease or if pH increases. For non-softening systems ("Filter" and "Unfilt") pH=8, temperature=5 °C, and chlorine residual=1 mg/L. For softening systems ("Soften"), pH=9, temperature=5 °C, and chlorine residual=1 mg/L.

TABLE VI–3.—INTERIM ENHANCED SURFACE WATER TREATMENT RULE STATE PROGRAM COSTS MODEL

Variable	Default assumptions		National burden		Cost
			In FTEs	In hours	
Regulation Adoption and Program Development.	0.5 FTE per State	1	28.0	47,040	$1,540,000
Review Plans and Specs	10 days/large system	112	[1] N/A	[1] N/A	[1] N/A
Log Removal Determination	3 days per surface water system	19	19.0	31,958	1,046,250
Subtotal (x)			47	78,998	2,586,250
Staff Training (Rule Specific)	10 days per technical FTE=f(x)	0	2.1	3,591	117,557
Sanitary Surveys[3]	5 days/lg. sys./survey; 2 days/sm. sys./survey.	79	78.7	132,147	4,326,250
Total			128	214,736	7,030,057
Average Annual Cost over 3.5 years[2]			37	61,353	2,008,588

[1] Costs for reviewing plans and specifications for the ESWTR are counted as a joint activity undertaken with the same step of implementing the Stage 1 DBP Rule and are included in the DBP Rule RIA.
[2] Total cost and burden are divided by 3.5 years, the time between promulgation of this rule and the final ESWTR.
[3] Recordkeeping burden is assumed to equal approximately 2% of the burden shown (i.e. approximately 1.6 FTEs, 2,640 hours, $86,000).

B. Benefits of Proposed Rule

The level of reduction of waterborne illness resulting from implementation of this rule will largely depend on the particular option(s) promulgated. Even if EPA could predict the most suitable option(s), the Agency cannot yet predict the number of illnesses avoided until more data become available. EPA anticipates that much of such data, particularly on national pathogen occurrence and existing treatment levels, will become available under the forthcoming ICR.

With the limited available data, EPA has used a disinfection byproducts risk assessment model (DBPRAM) to estimate potential risks from *Giardia* that might result from systems complying with different DBP standards both with the existing SWTR and an ESWTR (Grubbs et al 1992; Regli et al 1993; Cromwell et al 1992). In this analysis, EPA assumed that the ESWTR would require systems to remove/inactivate *Giardia* by 3, 4, 5, or 6 logs if the *Giardia* concentrations in the source water were <1 cysts/100 L, 1–9 cysts/100 L, 10–99 cysts/100 L, and 100 cysts/100 L or more, respectively. This assumption is consistent with current EPA guidance (EPA, 1991a).

Because of the limited data, EPA used the DBPRAM only for the category of surface water systems that serve at least 10,000 people and practice coagulation, sedimentation, and filtration, but do not soften the water. Collectively this group of systems provides water to about 103 million people.

EPA assumed as part of the modeling effort that (1) *Giardia* densities in source waters in the U.S. are represented by the survey data of LeChevallier et al. (1991a), (2) systems are using, or will use, the least expensive technologies to comply with the SWTR and existing TTHM standard, and (3) systems comply only minimally with both the SWTR (i.e., provide a 3-log removal/inactivation of *Giardia* cysts and maintain a disinfectant residual throughout the distribution system) and the existing TTHM standard. Using these assumptions, the model predicts that, without revising the SWTR, several hundred thousand people would become infected by *Giardia* each year. These predicted risks may be significantly overstated because many systems currently appear to provide more treatment than is minimally required under the SWTR (LeChevallier et al., 1991b). Also, concentrations of *Giardia* cysts in source waters in the U.S. may be significantly less than those indicated by the survey results of LeChevallier et al. (1991a), which did not cover all geographical locations.

The DBPRAM also predicted that, in the absence of any revision to the SWTR, as the hypothetical MCL for DBPs decreases (i.e., either for TTHMs or the sum of five haloacetic acids), the incidence of *Giardia* infection significantly increases. One reason for this result is that lower MCLs would lead systems to use more efficient precursor removal technologies, resulting in a lower disinfectant demand in the water. Therefore, since less disinfectant is necessary, a lower CT value may result at the first customer. Without the removal of DBP precursors (or associated disinfectant demand), systems would need to maintain a higher CT value at the first customer to maintain a disinfectant residual throughout the distribution system.

A second reason why the predicted incidence of *Giardia* infection increases as the MCL for DBPs is lowered is that the model assumes that many systems would switch to chloramine as a residual disinfectant, or to ozone followed by chloramine, to limit the formation of chlorinated DBPs. Chloramine is a weaker disinfectant than chlorine and consequently would result in less *Giardia* inactivation. Similarly, the model also assumes that if a system were to switch to ozone for primary disinfection, followed by chloramine, the system would provide only enough disinfection to inactivate 0.5 logs of *Giardia* to minimally meet the SWTR (assuming that 2.5 log of *Giardia* removal is achieved by physical means). This latter assumption may underestimate the actual level of *Giardia* inactivation that a system would likely provide, since for a relatively small increase in cost compared to that for ozone installation, the system could achieve (by increasing the ozone dose or contact time) a significantly greater level of inactivation than the 3-log reduction specified by the SWTR for *Giardia*.

The DBPRAM also predicts that under more stringent DBP standards, if such systems were to only minimally meet the SWTR, the incidence of waterborne disease outbreaks would significantly increase in systems with the worst quality source waters (but apparently not in those with good quality source waters) (Grubbs et al., 1992; Regli et al., 1993). In its modeling effort, EPA defined waterborne disease outbreaks (epidemic disease) as one in which at least 1% of the population became infected (conservatively used as an indicator for illness) within a 30-day period; this definition was used because EPA believes that at incidence lower than 1% health authorities are generally not aware that an outbreak is in progress, unless the disease is typically very debilitating or life-threatening. According to Harrington et al. (1985),

the total cost of disease avoidance behavior, such as boiling or purchase of bottled water by the entire community, during an outbreak far exceeds the total cost of treating the illness.

The DBPRAM predicts that ESWTR compliance, as described above, would result in no more than a few hundred infections caused by waterborne *Giardia* per year per 100 million people. This is several hundred thousand cases fewer than predicted in the absence of an ESWTR. In the absence of more data and for the purpose of simplicity, the model assumes that systems would use the arithmetic mean (based on LeChevallier et al., 1991a) to calculate pathogen densities, and use the coldest water temperature and maximum flow rate (design rate) to determine disinfection conditions at which plants would operate. Use of the arithmetic mean may underestimate the predicted risk since values above the mean may result in a greater number of infections than values below the mean.

In contrast, using the design flow rate throughout the year for model predictions overestimates the predicted risk, because the flow rate should be significantly less during colder weather, which would result in longer contact times and greater CT values, and therefore greater inactivation of *Giardia* than if the system operated under design flow conditions during this period. In addition, use of the coldest water temperature throughout the year for model predictions also overestimates the predicted risk, because disinfectants are more effective at warmer water temperatures for a given CT. In the absence of more data, EPA cannot determine whether the model assumptions, collectively, may significantly bias the model predictions. EPA solicits comment on this issue and requests suggestions on how EPA can improve the assumptions in the model, based upon data collected under the ICR (59 FR 6332; proposed February 10, 1994).

The model also predicts that if systems complied with an ESWTR, no waterborne disease outbreaks (as defined above) attributed to *Giardia* would occur. Since *Giardia* is more resistant to disinfection than most other pathogens (*Cryptosporidium* being a notable exception), EPA assumes that the incidence of waterborne disease caused by other pathogens would also be substantially reduced.

The disease, giardiasis, causes a gastrointestinal disorder that may be mild or severe and incapacitating, and that generally lasts from one to four weeks. Although mortality is very low (0.0001%), some patients, including otherwise healthy individuals, require hospitalization (about 4600 annually) (Bennett et al., 1987; Addiss and Lengerich, 1994). An individual with giardiasis typically has one or more of the following symptoms: diarrhea, cramps, abdominal distress, flatulence, fatigue, vomiting, chills, fever, and marked weight loss. In one study of 105 stool-positive cases of travelers returning to the U.S., 39 percent had mild symptoms, 41 percent had moderate symptoms, 6.7 percent had incapacitating or severe symptoms, and 13.3 percent had no symptoms (Wolfe, 1990). All age groups are affected. The average time between infection and the onset of disease is about two weeks, although this may vary considerably. Chronic cases that persist for months or longer are not uncommon.

In the original SWTR Regulatory Impact Analysis (EPA, 1989a), the estimated economic cost associated with waterborne giardiasis was based on a study of costs incurred during an outbreak of waterborne giardiasis in 1983 that occurred in Scranton, Pennsylvania (Harrington, et al., 1985). In this study, the investigators estimated that the medical cost and the cost of time lost from work associated with the outbreak was in the range of $1245 to $1878 per case (1984 dollars). The lower cost values the time loss for homemakers, retired persons, and unemployed persons as zero, while the higher cost values the time loss for these people at the average wage rate.

The above estimate was based on the results of a survey of 370 people who had "confirmed" cases of giardiasis, i.e., a positive stool sample. EPA assumed in the analysis that the costs associated with confirmed cases are representative of the costs associated with those who had symptoms of giardiasis, but where no stool sample was examined, since medical costs (minus the cost for a stool specimen examination) and cost for time lost from work should be similar when symptoms are similar.

The $1245-$1878 estimate above does not take into account fatalities associated with waterborne disease. According to Bennett et al. (1987), about 0.1 percent of cases of waterborne disease are fatal. Although these investigators estimate that the mortality rate for giardiasis is much lower than 0.1 percent, EPA believes that control of *Giardia* will also control other waterborne disease agents that have a higher mortality rate than *Giardia*. Therefore, by omitting the risk of mortality associated with waterborne disease, EPA's analysis may represent a significant underestimate of the benefits. In addition, EPA's analysis did not consider benefits associated with avoiding the economic and psychological costs to the affected community (including businesses and government) associated with a waterborne disease outbreak, nor did it consider the benefits of additional public confidence in an enhanced water supply. These benefits were not considered in the analysis because of the difficulty of quantifying them.

Adjusting the $1878/case value for inflation (through 1993), and including a factor for willingness-to-pay, EPA estimates the benefit would be $3,000 per *Giardia* infection avoided. Using this estimate, the 400,000 to 500,000 *Giardia* infections per year that could be avoided in large surface water systems would have an economic value of $1.2 to $1.5 billion per year. This suggests that the benefit nationwide of avoiding *Giardia* infections in large systems is as much as three or four times greater than the estimated $391 million national cost per year to provide additional disinfectant contact time.

At a household level, the Interim ESWTR would impose costs ranging from $11– $49/household/year in systems serving 15,000 people to $3–$24/household/year in systems serving 1,550,000. Household costs are a useful guide for examining cost-benefit tradeoffs, because they are easier to understand in assessing the public's willingness to pay for a more stringent rule. EPA does not believe that the household costs predicted by this analysis represents an unreasonable premium for the systems affected by the Interim ESWTR, considering the nature of microbial risk.

There are at least three approaches for examining the tradeoff between costs and benefits. One approach is to determine the cost of the ESWTR alone. In a second approach, EPA could use the combined cost of the SWTR and ESWTR, since customers of many water systems are already paying, or will soon be paying, an extra premium for microbial protection as a result of the original SWTR. If this second approach is used (the most expensive estimate of ESWTR cost), and if the cost of the original SWTR is adjusted for inflation and factored into the above analysis, the overall ratio of benefits to costs would still be about a break-even proposition. Household costs would be significantly higher for previously unfiltered systems and modestly higher for previously filtered systems. In the third approach, EPA could assume that a large share of the cost of an ESWTR should be borne by the DBP rule, since the treatment changes needed to meet more stringent DBP regulations may increase the

pathogen risk that the ESWTR must address.

The accounting difficulty of sorting between microbial and DBP costs will become even more complicated later in developing the Long-Term ESWTR, which will cover small systems. Household costs for providing additional disinfectant contact time in small systems are significantly greater than those for the larger systems. However, it is not clear that small systems will choose to meet the Long-Term ESWTR by increasing the contact time. Such options as small scale membrane treatment systems may provide a more economical means of meeting both microbial and DBP treatment requirements simultaneously. In that case, the microbial and DBP-related control costs would be truly indistinguishable from each other.

A similar analysis to the one described above for *Giardia* is not yet feasible for *Cryptosporidium* because of much greater data deficiencies. The analysis of national benefits for the different ESWTR options must remain highly speculative, even for *Giardia*, until more data become available. EPA intends to develop a more complete cost and benefit analysis for the different ESWTR options based on data generated under the ICR and complementary research. This analysis would examine the costs of the various treatment options indicated in Section IIIE above, using various statistical approaches to calculate pathogen densities (e.g., mean value versus 90th percentile value), acceptable risk levels, pathogen infectivities, and various assumptions about the analytical methods (e.g., cyst/oocyst viability, percent recovery) and include a broader discussion of the benefits. EPA intends to present such analysis in a Notice of Availability in the **Federal Register** by November 1995. This Notice will indicate the basis for EPA's preferred ESWTR option(s) and solicit comment on the appropriateness for promulgating this option(s) as part of the interim ESWTR. EPA solicits comment on approaches that can be used for this analysis.

VII. Other Statutory Requirements

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 of entitlement, 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 will have an annual effect on the economy of $100 million or more. 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.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 602 *et seq.*, requires EPA to explicitly consider the effect of proposed regulation on small entities. By policy, EPA has decided to consider regulatory alternatives if there is any economic impact on any number of small entities. The Small Business Administration defines a "small water utility" as one which serves fewer than 3,300 people.

The proposed rule is consistent with the objectives of the Regulatory Flexibility Act because it will not have any economic impact on any small entities. Except for the sanitary survey requirement, which EPA believes will be conducted by States, the rule would only apply to systems serving at least 10,000 people. Therefore, the Agency believes that this notice would have no adverse effect on any number of small entities.

C. 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 document has been prepared by EPA (ICR No. 270.32) and a copy may be obtained from Sandy Farmer, Information Policy Branch (MC:2136), EPA, 401 M Street, SW, Washington, DC 20460, or by calling (202) 260–2740.

The reporting and recordkeeping burden for this proposed collection of information will be phased in starting in 1997. The specific burden anticipated for each category of respondent, by year, is shown below:

1997

Public Water Systems—monitoring and reporting
Hours per respondent: 0
Total hours: 0
Public Water Systems—recordkeeping
Hours per respondent: 0
Total hours: 0
State Program Costs—reporting
Hours per respondent: 1,599
Total hours: 89,518
State Program Costs—recordkeeping
Hours per respondent: 16
Total hours: 904

1998

Public Water Systems—monitoring and reporting
Hours per respondent: 0
Total hours: 0
Public Water Systems—recordkeeping
Hours per respondent: 0
Total hours: 0
State Program Costs—reporting
Hours per respondent: 1,149
Total hours: 64,337
State Program Costs—recordkeeping
Hours per respondent: 12
Total hours: 650

1999

Public Water Systems—monitoring and reporting
Hours per respondent: 0
Total hours: 0
Public Water Systems—recordkeeping
Hours per respondent: 0
Total hours: 0
State Program Costs—reporting
Hours per respondent: 699
Total hours: 39,157
State Program Costs—recordkeeping
Hours per respondent: 7
Total hours: 396

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 (MC:2136), EPA, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, OPM, 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.

D. Science Advisory Board, National Drinking Water Advisory Council, and Secretary of Health and Human Services

In accordance with section 1412 (d) and (e) of the SDWA, EPA consulted

with the Science Advisory Board, National Drinking Water Advisory Council, and Secretary of Health and Human Services and requested their comments in developing this rule.

E. Consultation With State, Local, and Tribal Governments

Two Executive Orders (E.O. 12875, Enhancing Intergovernmental Partnerships, and E.O. 12866, Regulatory Planning and Review) explicitly require Federal agencies to consult with State, local, and tribal entities in the development of rules and policies that will affect them, and to document what they did, the issues that were raised, and how the issues were addressed.

As described in Section I of today's rule, SDWA Section 1412 requires EPA to promulgate NPDWRs, to review each NPDWR every three years, and to revise it as appropriate. In 1989, EPA issued the SWTR, in accordance with SDWA Section 1412(b)(7)(C). That rule went into effect in 1991. That rule has since been reviewed and is being reproposed today.

This proposal, which pertains only to systems serving more than 10,000 persons, contains several options for final promulgation. Depending on the option selected, PWSs with poorer quality source waters may need to remove microbiological contaminants above levels currently required under the SWTR. PWSs may also be required to treat for *Cryptosporidium*. There are currently insufficient data to develop an annual cost estimate of compliance with this rule.

In 1992, EPA considered entering into a negotiated rulemaking on a related Disinfectant/Disinfection By-Products rule primarily because no clear path for addressing all the major issues associated with the D/DBP rule was apparent. EPA hired a facilitator to explore this option with external stakeholders and, in November 1992, decided to proceed with the negotiation. The 18 negotiators, including EPA, met from November 1992 until June 1993 at which time agreement was reached on the content of the D/DBP proposed rule. That rule is proposed elsewhere in today's **Federal Register**. During the negotiations, the negotiators identified the possible need for a companion rule on surface water treatment. The purpose of the companion rule was to guard against the possibility of increasing microbial risk while controlling for disinfectant/disinfection byproduct risk. The contents of today's proposed regulatory and preamble language for enhanced surface water treatment have been agreed to by the 17 negotiators who remained at the table through June 1993. A summary of those negotiations is contained in Section II.

The negotiators included persons representing State and local governments. At the table were:

(1) Association of State Drinking Water Administrators, a group representing state government officials responsible for implementing the regulations,

(2) Association of State and Territorial Health Officials, a group representing statewide public health interests and the need to balance spending on a variety of health priorities,

(3) National Association of Regulated Utilities Commissioners, a group representing funding concerns at the state level,

(4) National Association of County Health Officials, a group representing local government general public health interests,

(5) National League of Cities, a group representing local elected and appointed officials responsible for balancing spending needs across all government services,

(6) National Association of State Utility Consumer Advocates, a group representing consumer interests at the state level, and

(7) National Consumer Law Center, a group representing consumer interests at the local level.

In addition, several associations representing public municipal and investor-owned water systems also served on the committee.

As part of the negotiation process, each of these representatives was responsible for obtaining endorsement from their respective organization on the positions they took at the negotiations and on the final signed agreement. During the negotiations, the group heard from many other parties who attended the public negotiations and were invited to express their views. As is true with any negotiation, all sides presented initial positions which were ultimately modified to obtain consensus from all sides. However, all parties mentioned above signed the final agreement on behalf of their associations. This agreement reflected basic consensus that the possible cost of the rule would be offset by its public health benefits and its promotion of responsible drinking water treatment practices.

The only original negotiator who did not sign the agreement left the negotiations in March 1993. That negotiator represented the National Rural Water Association (NRWA), a group representing primarily small public and private water systems. At the time that group left the negotiations, they were objecting to the cost of the D/DBP rule, which applies to all system sizes. Except for a sanitary survey requirement that EPA believes will be conducted by States, the interim ESWTR would only apply to systems serving greater than 10,000 persons and thus does not affect NRWA members. Earlier in the negotiations, NRWA accepted the position that any control of disinfectants and disinfection by-products should not come at the expense of decreased protection from microbial contamination. The NRWA position that small systems should meet a less stringent trihalomethane standard than larger systems was rejected by the remaining negotiators, several of whom also represent small water systems.

The contents of today's proposed rule has been available to the public for several months as part of the regulatory negotiation signature process. EPA has briefed numerous groups, including government organizations, on its contents. The Agency has received several letters from public water systems objecting to the cost of the proposed rule and questioning its potential health benefit. These letters are contained in the public docket supporting today's rule. The Agency recognizes that many persons are concerned whether the proposed rule is warranted. The technical issues are complex. The process needed to develop a common level of understanding among the negotiators as to what was known and unknown and what are reasonable estimates of potential costs and benefits was time-consuming. It is unreasonable to expect persons not at the negotiating table to have that same level of understanding and to all share the same view. However, the discussions throughout the negotiated rulemaking process were informed by a broad spectrum of opinions. The Agency believes this consensus proposal is not only the preferred approach but one which will generate informed debate and comment.

VIII. Request for Public Comment

EPA solicited public comments on specific issues earlier in the preamble and welcomes comments on any other issue the public may wish to address. For ease in referring to requests for comments we are listing them below. In addition, at the end of this section, the Agency is requesting comment on other issues not addressed earlier in the preamble.

- (III.C) Rationale for setting MCLG of zero and a treatment technique for *Cryptosporidium*

• (III.D.1) Ground water under the direct influence of surface water
—Including *Cryptosporidium* in rule language in definition of ground water under the direct influence of surface water
—Revising guidance defining ground water under the influence of surface water
—Most appropriate procedure for determining credits for removal/inactivation and treatment requirements for systems using ground waters under the direct influence of surface water
• (III.D.3) Sanitary surveys
—Prerequisites for individuals performing sanitary survey (academic degree, etc.)
—Revisions needed in SWTR Guidance Manual for conducting sanitary survey for filtered systems and for evaluating vulnerability to *Cryptosporidium*
—Frequency of sanitary surveys (three vs. five years)
• (III.D.4) Possible supplemental requirements
—Whether to publish national rule to require systems to cover finished water reservoirs and storage tanks, or whether this should be left to State discretion. What would the cost be for such a rule, and what waiver provisions would be appropriate.
—Whether EPA should require States and/or systems to have a cross-connection control program; what specific criteria, if any, should be included therein; how often such a program should be evaluated; under what conditions a waiver could be granted; and whether only those connections identified as a cross-connection by the public water system or the State should be subject to a cross-connection program.
—Identification of measures other than cross-connection control program to prevent the contamination of drinking water already in the distribution system (e.g., minimum pressure requirements in the distribution system).
—Whether to require systems to notify the State for persistent turbidity levels above the performance standard (but not in violation of this standard)
• (III.E) Alternative Treatment Requirements
1. Options for defining pathogen densities
—Appropriateness of requiring systems whose population served grows to over 10,000 to perform ICR monitoring.
—Appropriateness of the four approaches for calculating pathogen densities, and whether approach selected should be based on number of pathogen samples collected
2. Treatment alternative for controlling pathogens
—Appropriateness and magnitude of specific acceptable risk levels for microbes
—Which treatment approach(es) is most appropriate
—Identification of approaches for achieving levels of pathogen removal greater than 2.5 logs by physical means
—Utility of extrapolating CT values in SWTR Guidance Manual to predict the effect on pathogens of higher levels of disinfection
—Appropriateness of two treatment alternatives, with possible variations, for removal of *Giardia*
—Appropriateness of indicated treatment alternatives for *Cryptosporidium*
—Feasibility of removing more than two logs of *Cryptosporidium* (with and without disinfection being considered). -
Appropriateness of not
—Changing treatment specifications in SWTR
• (VI) Economic Analysis
—What approaches are reasonable for estimating the national treatment costs of requiring systems to remove a level of *Cryptosporidium* that would depend on *Cryptosporidium* densities in the source water
—Are the system level costs in Table VI–2 for increasing the disinfectant contact time reasonable and accurate
—The number of systems that might use control measures other than increasing contact basin time requirements and whether the use of such technologies would lead to substantially different cost estimates
—Assumption in estimating economic impact that treatment changes to control *Cryptosporidium* will also control *Giardia*
—Soundness of assumptions made in disinfection byproducts risk assessment model (DBPRAM) used to estimate potential risks from *Giardia* that might result from systems complying with different DBP standards both with the existing SWTR and an ESWTR, and how these assumptions could be improved

Other Issues

• How should EPA decide, in developing a forthcoming Notice of Availability, what treatment approach(es) is most suitable for additional public comment?
• What criteria, if any, should the ESWTR include to ensure that systems optimize treatment plant performance?
• Should any turbidity performance criteria in the SWTR be modified? For example, should the ESWTR require systems to base compliance with the turbidity standards on monitoring the turbidity at the effluent of each filter separately, in lieu of (or in addition to) the confluence of all filters? Should any performance standard value be changed?
• To what extent should the ESWTR address the issue of recycling filter backwash, given its potential for increasing the densities of *Giardia* and *Cryptosporidium* on the filter?
• Should the ESWTR define minimum certification criteria for surface water treatment plant operators? Currently, the SWTR (§ 141.70) requires such systems to be operated by "qualified personnel who meet the requirements specified by the State."
• Should the ESWTR include a performance standard(s) for particle removal?
• Under what conditions could systems be allowed different log removal credits than is currently recommended in the SWTR Guidance Manual?

IX. Instructions to Commenters

To ensure that EPA can read, understand and therefore properly respond to comments, the Agency would prefer that commenters type or print comments in ink, and cite, where possible, the paragraph(s) in this proposed regulation (e.g. 141.76(b)) to which each comment refers. Commenters should use a separate paragraph for each method or issue discussed.

X. References

Addiss, DG, and EJ Lengerich (1994). Hypokalemic myopathy induced by *Giardia lamblia*. N. Engl. J. Med. 330(1):66.

AWWA. American Water Works Association (1992). Jackson County Oregon cryptosporidiosis outbreaks: January–June 1992. Summary, Expert Meeting, August 3, 4, 1992.

AWWA. American Water Works Association (1993). Officers & Committee Directory. AWWA, Denver.

Bailey SW, and EC Lippy (1978). Should all finished water reservoirs be covered. Public Works for April 1978. P. 66–70.

Bennett JV, SD Holmberg, MF Rogers and SL Solomon (1987). Infectious and parasitic diseases. Am J Prev Med 3: 102–114. *In*: RW Amler and HB Dull (eds), Closing the gap: the burden of unnecessary illness. Oxford University Press, Oxford.

Berger PS, S Regli and L Almodovar (1992). *Cryptosporidium* control in drinking water. Am Water Works Assoc Proceedings, 1992

Annual Conf, Mgmt and Regs, pp 845–864. American Water Works Association, Denver.
Casemore DP and FB Jackson (1984). Hypothesis: cryptosporidiosis in human beings is not primarily a zoonosis. J Infect 9: 153–156.
Casemore DP (1990). Epidemiological aspects of human cryptosporidiosis. Epid Infec 104: 1–28.
CDC. Centers for Disease Control (1982). Cryptosporidiosis: assessment of chemotherapy of males with acquired immune deficiency syndrome (AIDS). Morbidity and Mortality Weekly Report 31: 589–592.
Clancy JL (1993). Interpretation of microscopic particulate analysis data—a water quality approach. Water Quality Technology Conference Proceedings, 1992, II: 1831–1844. American Water Works Association, Denver.
Craun G (1991). Causes of waterborne outbreaks in the United States. Wat Sci Technol 24:17–20.
Craun GF (1993). Conference conclusions. *In*: (GF Craun, ed.) Safety of Water Disinfection: Balancing Chemical and Microbial Risks. International Life Sciences Inst. Press, Washington.
Craun G (1994). Memorandum from G. Craun to U.S. Environmental Protection Agency (P. Berger), dated 1/19/94. Waterborne outbreak data 1981–90, community water systems.
Cromwell JE, Zhang X, Letkiewicz FJ, et al. Analysis of potential tradeoffs in regulation of disinfection by-products. Office of Water Resource Center. Washington D.C. EPA–811–R–92–008. 1992.
Current WL, NC Reese, JV Ernst, WS Bailey, MB Heyman and WM Weinstein (1983). Human cryptosporidiosis in immunocompetent and immunodeficient persons. New Eng J Med 308(21): 1252–1257.
D'Antonio RG, RE Winn, JP Taylor, et al. (1985). A waterborne outbreak of cryptosporidiosis in normal hosts. Ann. Intern. Med. 103:886–888.
De Mol P, S Mukashema, J Bogaerts, W Hemelhof and J-P Butzler (1984). *Cryptosporidium* related to measles diarrhoea in Rwanda. Lancet 2(8393): 42–43.
EPA. Environmental Protection Agency (1983). Assessment of Microbiology and Turbidity Standards for Drinking Water. EPA 570–9–83–001. Washington, DC.
EPA. Environmental Protection Agency (1989a). Regulatory Impact Analysis: Benefits and Costs of Final Surface Water Treatment Rule, prepared by Wade Miller Associates, Inc., February 17, 1989, Washington, DC.
EPA. Environmental Protection Agency (1989b). Cross-Connection Control Manual. EPA 570/9–89–007. Washington, DC.
EPA. Environmental Protection Agency (1991a). Guidance Manual for Compliance With the Filtration and Disinfection Requirements for Public Water Systems Using Surface Water Sources. Washington, DC.
EPA. Environmental Protection Agency (1991b). Manual of Small Public Water Supply Systems. EPA 570/9–91–003. Washington, DC.
EPA. Environmental Protection Agency (1991c). Manual of Individual and Non-Public Water Supply Systems. EPA 570/9–91–004. Washington, DC.
EPA. Environmental Protection Agency (1992). Consensus method for determining groundwaters under the direct influence of surface water using microscopic particulate analysis (MPA). EPA 910/9–92–029.
EPA. Environmental Protection Agency (1993). Drinking Water Criteria Document for *Cryptosporidium* (Draft). Office of Science and Technology (Office of Water), EPA, Washington, DC.
EPA. Environmental Protection Agency (1994). Regulatory Impact Analysis of Proposed Interim Enhanced Surface Water Treatment Rule (Draft). Office of Ground Water and Drinking Water.
Ernest J, B Blagburn, D Lindsay and W Current (1986). Infection dynamics of *Cryptosporidium parvum* (Apicomplexa: Cryptosporidiidae) in neonatal mice (*Mus musculus*). J Parasitology 72(5):796–798.
Fayer R, and BLP Ungar (1986). *Cryptosporidium* spp. and cryptosporidiosis. Microbiol. Rev. 50:458–483.
Gerba, C, and J. Rose. (1990). Viruses in source and drinking water. Chap.18, pp 380–396. *In*: G. McFeters (ed), Drinking Water Microbiology. Springer-Verlag, New York.
Glass RI, JF Lew, RE Gangarosa, CW LeBaron and M-S Ho (1991). Estimates of morbidity and mortality rates for diarrheal diseases in American children. J Pediatrics 118: 27–33.
Grubbs WD, Macler B. Regli S. (1992). Modelling *Giardia* occurrence and risk. EPA–811–B–92–005. Office of Water Resource Center. Washington D.C.
Haas CN, JB Rose, C Gerba, S Regli (1993). Risk assessment of virus in drinking water. Risk Analysis 13: 545–552.
Harrington, W.A., Krupnick, A.J., and Spofford, W.O.,Jr.. The Benefits of Preventing an Outbreak of Giardiasis Due to Drinking Water Contamination. Resources for the Future, 1616P Street, NW., Washington, DC. September, 1985.
Hayes EB, TD Matte, TR O'Brien, TW McKinley, GS Logsdon, JB Rose, BLP Ungar, DM Word, PF Pinsky, ML Cummings, MA Wilson, EG Long, ES Hurwitz and DD Juranek (1989). Large community outbreak of cryptosporidiosis due to contamination of a filtered public water supply. New Eng J Med 320: 1372–1376.
Herwaldt BL, GF Craun, SL Stokes and DD Juranek (1991). Waterborne disease outbreaks, 1989–1990. In: CDC Surveillance Summaries, Morbidity and Mortality Weekly Report: 40(SS–3): 1–21.
Hurst C (1991). Presence of enteric viruses in freshwater and their removal by conventional drinking water treatment process. Bull World Health Org. 69 (1): 113–119.
Keswick, BH, et al (1985). Inactivation of Norwalk virus in drinking water by chlorine. Appl. Environ. Microbiol. 50: 261–264.
Korich DG, JR Mead, MS Madore, NA Sinclair and CR Sterling (1990). Effects of ozone, chlorine dioxide and monochloramine on *Cryptosporidium parvum* oocyst viability. Appl Environ Microbiol 56: 1423–1428.
Korich D, M Yozwiak, M Marshall, M Arrowood, N Sinclair, and C Sterling (1992). *Cryptosporidium* viability: assessment and correlation with infectivity. Water Quality Technology Conference Proceedings, 1991, I: 65–74. American Water Works Assoc, Denver.
LeChevallier MW, DN Norton and RG Lee (1991a). Occurrence of *Giardia* and *Cryptosporidium* spp. in surface water supplies. Appl Environ Microbiol 57: 2610–2616.
LeChevallier MW, DN Norton and RG Lee (1991b). *Giardia* and *Cryptosporidium* spp. in filtered drinking water supplies. Appl Environ Microbiol 57:2617–2621.
Levine WC and GF Craun (1990). Waterborne disease outbreaks, 1986–1988. In: *CDC Surveillance Summaries*, Morbidity and Mortality Weekly Report 39(SS–1): 1–13.
Lew JF, RI Glass, RE Gangarosa, IP Cohen, C Bern and CL Moe (1991). Diarrheal deaths in the United States, 1979 through 1987. A special problem for the elderly. J Am Med Assoc 265: 3280–3284.
Lopez et al. (1980). Waterborne giardiasis: a communitywide outbreak of disease and a high rate of asymptomatic infection. Am J Epid 112: 495–507.
Macler BA and S Regli (1993). Use of microbial risk assessment in setting US drinking water standards. Int J Food Microbiol 18: 245–256.
Miller RA, MA Bronsdon and WR Morton (1990). Experimental cryptosporidiosis in a primate model. J Infect Dis 161: 312–315.
Moore AC, BL Herwaldt, GF Craun, RL Calderon, AK Highsmith, and DD Juranek (1993). Surveillance for waterborne disease outbreaks—United States, 1991–1992. Morbidity and Mortality Weekly Report: 42(SS–5): 1–22.
Payment, 1981. Isolation of viruses from drinking water at the Point-Viau water treatment plant. Can. J. Microbiol. 27:417.
Payment P, M Trudel, et al., (1985). Elimination of viruses and indicator bacteria at each step of treatment during preparation of drinking water at seven water treatment plants. Appl. Environ. Microbiol. 49:1418–1428.
Payment P, L Richardson, J Siemiatychi, R Dewar, M Edwardes and E Franco (1991). A randomized trial to evaluate the risk of gastrointestinal disease due to consumption of drinking water meeting current microbiological standards. Am J Publ Health 81: 703–708.
Regli S, JB Rose, CN Haas and CP Gerba (1991). Modeling the risk from *Giardia* and viruses in drinking water. J Am Water Works Assoc 83 (11): 76–84.
Regli S, JE Cromwell, X Zhang, AB Gelderloos, WD Grubbs, F Letkiewicz and BA Macler (1993). Framework for decision making: EPA perspective. In: (GF Craun, ed.) Safety of water disinfection: Balancing chemical and microbial risk. pp 487–538. International Life Sciences Institute Press, Washington, DC.
Rendtorff RC (1954). The experimental transmission of human intestinal

protozoan parasites. II. *Giardia lamblia* cysts given in capsules. Am J Hyg 59: 209–220.
Rose JB, CN Haas and S Regli (1991). Risk assessment and control of waterborne giardiasis. Am J Publ Health 81: 709–713.
Smith HV, RWA Girdwood, WJ Patterson, et al. (1988). Waterborne outbreak of cryptosporidiosis. Lancet 2: 1484.
Sobsey MD, F Takashi, and RM Hall (1991). Inactivation of cell-associated and dispersed Hepatitis A virus in water. J Am Water Works Assoc 83 (11): 64–67.
Williams, F (1985). Membrane-associated viral complexes observed in stools and cell culture. Appl. Environ. Microbiol. 50:523-526.
Wittenberg DF, NM Miller and J van den Ende (1989). Spiramycin is not effective in treating *Cryptosporidium* diarrhea in infants: results of a double-blind randomized trial. J Infect Dis 159(1): 131–132.
Wolfe, MS (1990). Clinical symptoms and diagnosis by traditional methods. Pp. 175–185, In: Giardiasis (EA Meyer, ed.), Elsevier, New York.

List of Subjects

40 CFR Part 141

Intergovernmental relations, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

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

Dated: June 7, 1994.

Carol M. Browner,

Administrator.

For the reasons set forth in the preamble, Title 40 of the Code of Federal Regulations is 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, 300j–9.

2. Section 141.2 is amended by revising the definition of "Ground water under the direct influence of surface water" to read as follows:

§ 141.2 Definitions.

* * * * *

Ground water under the direct influence of surface water means any water beneath the surface of the ground with:

(1) Significant occurrence of insects or other macroorganisms, algae, or large-diameter pathogens such as *Giardia lamblia* or *Cryptosporidium*, or

(2) Significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity, or pH which closely correlate to climatological or surface water conditions. Direct influence must be determined for individual sources in accordance with criteria established by the State. The State determination of direct influence may be based on site-specific measurements of water quality and/or documentation of well construction characteristics and geology with field evaluation.

* * * * *

3. In § 141.52, the Table is amended by adding a new entry, in numerical order, to read as follows:

§ 141.52 Maximum contaminant level goals for microbiological contaminants.

* * * * *

Contaminant	MCLG
* * * * *	
(5) *Cryptosporidium*	zero

4. Section 141.71 is amended by revising the first three sentences of paragraph (b)(2) introductory text to read as follows:

§ 141.71 Criteria for avoiding filtration.

* * * * *

(b) * * *

(2) The public water system must maintain a watershed control program which minimizes the potential for contamination by *Giardia lamblia* cysts, *Cryptosporidium* oocysts, and viruses in the source water. The State must determine whether the watershed control program is adequate to meet this goal. The adequacy of a program to limit potential contamination by *Giardia lamblia* cysts, *Cryptosporidium* oocysts, and viruses must be based on: * * *

5. Section 141.73 is amended by revising paragraph (d) to read as follows:

§ 141.73 Filtration.

* * * * *

(d) *Other filtration technologies.* A public water system may use a filtration technology not listed in paragraphs (a) through (c) of this section if it demonstrates to the State, using pilot plant studies or other means, that the alternative filtration technology, in combination with disinfection treatment that meets the requirements of § 141.72(b), consistently achieves 99.9 percent removal and/or inactivation of *Giardia lamblia* cysts and 99.99 percent removal and/or inactivation of viruses and 99 percent removal of *Cryptosporidium* oocysts between the source water and the first customer. For a system that makes this demonstration the requirements of paragraph (b) of this section apply.

6. Section 141.74 is amended by adding a new paragraph (d) to read as follows:

§ 141.74 Analytical and monitoring requirements.

* * * * *

(d) Sanitary surveys for all systems. (1) A public water system that uses a surface water source or a ground water source under the influence of surface water shall be subject to an initial sanitary survey by [insert date 5 years after publication of the final rule] and a subsequent sanitary survey every five years [ALTERNATIVE: every three years] thereafter.

(2) The sanitary survey shall be performed by either the State, or an agent approved by the State. An agent approved by the State shall be paid by the system. In exceptional circumstances, the State may approve the public water system to conduct its own sanitary survey. In this case, the public water system shall certify that the system conducted the sanitary survey is in accordance with § 141.2 and that the sanitary survey report is true and accurate.

(3) If the State or an agent approved by the State is not available to conduct the sanitary survey within the time frame specified in this section, the system must conduct the sanitary survey. If an agent approved by the State or the system itself conducts the sanitary survey, the system must submit the sanitary survey report to the State within 90 days of completing the survey and before the end of the five year period.

Alternative A

7. Section 141.70 is amended by revising paragraph (a)(1) to read as follows:

§ 141.70 General requirements.

(a) * * *

(1)(i) At least 99.9 percent (3-log) removal and/or inactivation of *Giardia lamblia* cysts for systems serving fewer than 10,000 people. A system serving 10,000 people or more must achieve a *Giardia* removal/inactivation level by [insert date 18 months after publication of the final rule in the **Federal Register** that depends on the concentration of *Giardia* in the source water(s), as follows:

(A) If the source water(s) contains less than 1 cyst/100 liters, the system must achieve at least 99.9 percent (3-log) reduction;

(B) If the source water(s) contains 1 to 9 cysts/100 liters, the system must

achieve at least 99.99 percent (4-log) reduction [OPTION: 99.9 percent (3-log) reduction];

(C) If the source water(s) contains 10 to 99 cysts/100 liters, the system must achieve at least 99.999 percent (5-log) reduction [OPTION: 99.99 percent (4-log) reduction];

(D) If the source water(s) contains more than 99 cysts/ 100 liters, the system must achieve at least 99.9999 percent (6-log) reduction [OPTION: 99.999 percent (5-log) reduction].

(ii) Systems must achieve the required *Giardia* removal/inactivation level, as specified above, between the source water and the first customer. To calculate the *Giardia* density in source water from monitoring data obtained during the sampling period specified by § 141.140 of this part, use the:

Option 1: Arithmetic mean of measured values.

Option 2: Geometric mean of measured values.

Option 3: 90th percentile value of measured values.

Option 4: Highest measured value.

* * * * *

Alternative B

8. Section 141.70 is amended by adding new paragraph (a)(3) to read as follows:

§ 141.70 General requirements.

(a) * * *

(3) Beginning 18 months after promulgation of this rule, a system serving 10,000 people or more must achieve a *Cryptosporidium* removal/ inactivation level between the source water and first customer that depends on the concentration of *Cryptosporidium* in the source water(s), as follows:

(i) If the source water(s) contains less than 1 oocyst/100 liters, the system must achieve at least 99.9 percent (3-log) reduction [OPTION: 99 percent (2-log) reduction];

(ii) If the source water(s) contains 1 to 9 oocysts/100 liters, the system must achieve at least 99.99 percent (4-log) reduction [OPTION 1: 99.9 percent (3-log) reduction; OPTION 2: 99 percent (2-log) reduction];

(iii) If the source water(s) contains 10 to 99 oocysts/100 liters, the system must achieve at least 99.999 percent (5-log) reduction [OPTION 1: 99.99 percent (4-log) reduction; OPTION 2: 99.9 percent (3-log) reduction];

(iv) If the source water(s) contains more than 99 oocysts/ 100 liters, the system must achieve at least 99.9999 percent (6-log) reduction [OPTION 1: 99.999 percent (5-log) reduction; OPTION 2: 99.99 percent (4-log) reduction];

Systems must achieve the required *Cryptosporidium* removal/inactivation level, as specified above, between the source water and the first customer. To calculate the *Cryptosporidium* density in source water from monitoring data obtained during the sampling period specified by section 141.140 of this part, use the:

Option 1: Arithmetic mean of measured values.

Option 2: Geometric mean of measured values.

Option 3: 90th percentile value of measured values.

Option 4: Highest measured value.

* * * * *

Alternative C

9. Section 141.73 is amended by adding a new paragraph (e) to read as follows:

§ 141.73 Filtration.

* * * * *

(e) Public water systems that filter their source water must achieve at least 99 percent (2-log) removal of *Cryptosporidium* between the source water and the first customer.

Alternative D

10. Section 141.72 is amended by adding a new paragraph (c) to read as follows:

§ 141.72 Disinfection.

* * * * *

(c) Public water systems that serve 10,000 people or more and use either surface water or ground water under the direct influence of surface water must achieve, by disinfection alone, at least a 0.5-log inactivation of *Giardia* [ALTERNATIVE 1: 4-log inactivation of viruses].

Alternative E

11. No change in existing SWTR regarding level of removal/inactivation requirements.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

1. The authority citation for part 142 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, 300j–9.

2. Section 142.16 is amended by adding paragraph (g) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

(g) An application for approval of a State program revision that adopts the requirement specified below must contain the following:

(1) The State must designate the method it will use to judge the adequacy of watershed protection programs in minimizing the potential for contamination by *Giardia lamblia* cysts, Cryptosporidium oocysts, and viruses in the source water.

(2) The State must describe its criteria for the conduct of sanitary surveys and the method it will use to judge the adequacy of each sanitary survey. If the State elects to allow non-State personnel to conduct the surveys, the State must specify the criteria to be used to approve the non-State personnel. If the State intends to allow public water systems to conduct sanitary surveys, the State must specify procedures it will use for oversight and review of the surveys.

Alternative A

3. The following special primacy requirements are associated with Alternative A from item 7, above.

(3) Section 141.70(a)(1). The State must demonstrate that it has in place enforceable design and operating criteria for achieving the levels of *Giardia lamblia* removal/inactivation required. Alternatively, the State may institute a procedure for establishing design and operating conditions on a system-by-system basis (e.g., a permit system).

Alternative B

4. The following special primacy requirements are associated with Alternative B from item 8, above.

(3) Section 141.70(a)(3). The State must demonstrate that it has in place enforceable design and operating criteria for achieving the levels of *Cryptosporidium* removal/inactivation required. Alternatively, the State may institute a procedure for establishing design and operating conditions on a system-by-system basis (e.g., a permit system).

Alternative C

5. The following special primacy requirements are associated with Alternative C from item 9, above.

(3) Section 141.73(e). The State must demonstrate that it has in place enforceable design and operating criteria for achieving 2-log removal of *Cryptosporidium* between the source water and the first customer. Alternatively, the State may institute a procedure for establishing design and operating conditions on a system-by-system basis. (e.g., a permit system)

Alternative D

6. The following special primacy requirements are associated with Alternative D from item 10, above.

(4) Section 141.72(c). The State must demonstrate that it has in place enforceable design and operating criteria for achieving the level of *Giardia* (virus) inactivation required. Alternatively, the State may institute a procedure for establishing design and operating conditions on a system-by-system basis (e.g., a permit system).

[FR Doc. 94–17650 Filed 7–28–94; 8:45 am]

BILLING CODE 6560–50–P