COMPILATION OF REQUESTS FOR COMMENT IN LONG TERM 2 ENHANCED SURFACE WATER TREATMENT RULE PROPOSAL

Section III.C Cryptosporidium Occurrence

Request for comment on Information Collection Rule and ICRSS data sets

EPA notes that there are significant differences in the Information Collection Rule and ICRSS medium and large system data sets. The median values for these data sets are 0.048, 0.050, and 0.045 oocysts/L, respectively, while the 90th percentile values are 1.3, 0.33, and 0.24 oocysts/L. The reasons for these differences are not readily apparent. The ICRSS used a newer method with better quality control that yields significantly higher recovery, and this suggests that these data are more reliable for estimating concentrations at individual plants. However, the Information Collection Rule included a much larger number of plants (350 v. 40 each for the ICRSS medium and large system surveys) and a similar number of samples per plant (18 v. 24 in the ICRSS). The two surveys cover different time periods (7/97 - 12/98 for the Information Collection Rule and 3/99 - 2/00 for the ICRSS).

In order to better understand the factors that may account for the differences in the three data sets, EPA conducted several additional analyses. First, EPA compared results for the subset of 40 plants that were in both the Information Collection Rule and ICRSS large system surveys. The medians for the two data sets were 0.13 and 0.045 oocysts/L, respectively, while the 90th percentiles were 1.5 and 0.24 oocysts/L. Clearly, the discrepancy between the two surveys persists for the subsample of data from plants that participated in both surveys. This suggests that the different sample groups in the full data sets are not the primary factor that accounts for the different results.

Next, EPA looked at the six month period (July through December) that was sampled in two consecutive years (1997 and 1998) during the Information Collection Rule survey to investigate year-to-year variations at the same plants. Estimated medians for 1997 and 1998

were 0.062 and 0.040 oocysts/L, respectively, while the 90th percentiles were 1.1 and 1.3 oocysts/L. While these comparisons show some interyear variability, it is less than the variability observed between the Information Collection Rule and ICRSS data sets. EPA has no data comparing the same plants using the same methods for the time periods in question (1997-98 and 1999-2000) so it is not known if the variation between these time periods was larger than the apparent variation between 1997 and 1998 in the Information Collection Rule data set.

The choice of data set has a significant effect on exposure, cost, and benefit estimates for the LT2ESWTR. Due to the lack of any clear criterion for favoring one data set over the other, EPA has conducted the analyses for this proposed rule separately for each, and presents a range of estimates based on the three data sets. EPA requests comment on this approach. EPA will continue to evaluate the relative strengths and limitations of the three data sets, as well as any new data that may become available for the final rule.

Section IV.A Additional Cryptosporidium Treatment Technique Requirements for Filtered Systems

EPA requests comments on all aspects of the monitoring and treatment requirements proposed in this section. In addition, EPA requests comment on the following issues:

Requirements for systems that use surface water for only part of the year

Bin classification for the LT2ESWTR is based on the mean annual source water *Cryptosporidium* level. Consequently, today's proposal requires *E. coli* and *Cryptosporidium* monitoring to be conducted over the full year. However, EPA recognizes that some systems use surface water for only part of the year. This occurs with systems that use surface water for part of the year (e.g., during the summer) to supplement ground water sources and with systems like campgrounds that are in operation for only part of the year. Year round monitoring for these systems may present both logistic and economic difficulties. EPA is requesting

comment on how to apply LT2ESWTR monitoring requirements to surface water systems that operate or use surface water for only part of the year. Possible approaches that may be considered for comment include the following:

Small public water systems that operate or use surface water for only part of the year could be required to collect *E. coli* samples at least bi-weekly during the period when they use surface water. If the mean *E. coli* concentration did not exceed the trigger level (e.g., 10/100 mL for reservoirs/lakes or 50/100mL for flowing streams), systems could apply to the State to waive any additional *E. coli* monitoring. The State could grant the waiver, require additional *E. coli* monitoring, or require monitoring of an alternate indicator. If the mean *E. coli* concentration exceeded the trigger level, the State could require the system to provide additional treatment for *Cryptosporidium* consistent with Bin 4 requirements, or require monitoring of *Cryptosporidium* or an indicator, with the results potentially leading to additional *Cryptosporidium* treatment requirements.

Large public water systems that operate or use surface water for only part of the year could be required to collect *Cryptosporidium* samples (along with *E. coli* and turbidity) either twice-per-month during the period when they use surface water or 12 samples per year, whichever is smaller. Samples would be collected during the two years of the required monitoring period, and bin classification would be based on the highest average of the two years.

EPA requests comment on these and other approaches for both small and large systems.

Previously collected monitoring data that do not meet QC requirements

EPA is proposing requirements for acceptance of previously collected monitoring data that are equivalent to requirements for data generated under the LT2ESWTR. The Agency is aware that systems will have previously collected *Cryptosporidium* data that do not meet all

sampling and analysis requirements (e.g., quality control, sample frequency, sample volume) proposed for data collected under the LT2ESWTR. However, the Agency has been unable to develop an approach for allowing systems to use such data for LT2ESWTR bin classification. This is due to uncertainty regarding the impact of deviations from proposed sampling and analysis requirements on data quality and reliability. For example, Methods 1622 and 1623 have been validated within the limits of the QC criteria specified in these methods. While very minor deviations from required QA/QC criteria may have only a minor impact on data quality, the Agency has not identified a basis for establishing alternative standards for data acceptability.

EPA requests comment on whether or under what conditions previously collected data that do not meet the proposed criteria for LT2ESWTR monitoring data should be accepted for use in bin determination. Specifically, EPA requests comment on the sampling frequency requirement for previously collected data, and whether EPA should allow samples collected at lower or varying frequencies to be used as long as the data are representative of seasonal variation and include the required number of samples. If so, how should EPA determine whether such a data set is unbiased and representative of seasonal variation? How should data collected at varying frequency be averaged?

Monitoring for systems that recycle filter backwash

Plants that recycle filter backwash water may, in effect, increase the concentration of *Cryptosporidium* in the water that enters the filtration treatment train. Under the LT2ESWTR proposal, microbial sampling may be conducted on source water prior to the addition of filter backwash water. EPA requests comment how the effect of recycling filter backwash should be considered in LT2ESWTR monitoring.

Bin assignment for systems that fail to complete required monitoring

Today's proposal classifies systems that fail to complete required monitoring in Bin 4, the highest treatment bin. EPA requests comment on alternative approaches for systems that fail to

complete required monitoring, such as classifying the system in a bin based on data the system has collected, or classifying the system in a bin one level higher than the bin indicated by the data the system has collected. The shortcoming to these alternative approaches is that bin classification becomes more uncertain, and the likelihood of bin misclassification increases, as systems collect fewer than the required 24 *Cryptosporidium* samples. Consequently, the proposed approach is for systems to collect all required samples.

Note that under today's proposal, systems may provide 5.5 log of treatment for *Cryptosporidium* (i.e., comply with Bin 4 requirements) as an alternative to monitoring. Where systems notify the State that they will provide treatment instead of monitoring, they will not incur monitoring violations.

Monitoring requirements for new plants and sources

The proposed LT2ESWTR would establish calendar dates when the initial and second round of source water monitoring must be conducted to determine bin classification. EPA recognizes that new plants will begin operation, and that existing plants will access new sources, after these dates. EPA believes that new plants and plants switching sources should conduct monitoring equivalent to that required of existing plants to determine the required level of *Cryptosporidium* treatment. The monitoring could be conducted before a new plant or source is brought on-line, or initiated within some time period afterward. EPA requests comment on monitoring and treatment requirements for new plants and sources.

Determination of LT2ESWTR bin classification

In today's proposal, EPA expects that systems will be assigned to LT2ESWTR risk bins based on their reported *Cryptosporidium* monitoring results and the calculations proposed for bin assignment described in this section. EPA requests comment on whether bin classifications should formally be made or reviewed by States.

Source water type classification for systems that use multiple sources

In today's proposal, the *E. coli* concentrations that trigger small system *Cryptosporidium* monitoring are different for systems using lake/reservoir and flowing stream sources. However, EPA recognizes that some systems use multiple sources, potentially including both lake/reservoir and flowing stream sources, and that the use of different sources may vary during the year. Further, some systems use sources that are ground water under the direct influence (GWUDI) of surface water. EPA requests comment on how to apply the *E. coli* criteria for triggering *Cryptosporidium* monitoring to systems using multiple sources and GWUDI sources.

Section IV.B Unfiltered System Treatment Technique Requirements for Cryptosporidium

EPA solicits comment on the proposed monitoring and treatment technique requirements for unfiltered systems. Specifically, the Agency seeks comment on the following issues:

Use of two disinfectants

EPA requests comment on the proposed requirement for unfiltered systems to use two disinfectants and for each disinfectant to meet by itself the inactivation requirement for at least one regulated pathogen. The requirement for unfiltered systems to use two disinfectants was recommended by the Advisory Committee because different disinfectants tend to be more effective against different pathogens and to provide multiple barriers of protection. An alternate approach would be to allow systems to meet the inactivation requirements using any combination of one or more disinfectants that achieved the required inactivation level for all pathogens. This would give systems greater flexibility and could spur the development of new disinfection techniques that would be applicable to a wide range of pathogens. However, this approach might be less protective against unregulated pathogens.

A related question is whether the proposed requirements for use of two disinfectants

establish an adequate level of multiple barriers in the treatment provided by unfiltered systems.

Treatment requirements for unfiltered systems with higher Cryptosporidium levels

Under the proposed LT2ESWTR, a filtered system that measures a mean source water *Cryptosporidium* level of 0.075 oocysts/L or higher is required to provide a total of 4 log or more reduction of *Cryptosporidium*. However, if an unfiltered system, meeting the criteria for avoiding filtration were to measure *Cryptosporidium* at this level, it would be required to provide only 3 log treatment. Available occurrence data indicate that very few, if any, unfiltered systems will measure mean source water *Cryptosporidium* concentrations above 0.075 oocysts/L. However, EPA requests comment on whether or how this possibility should be addressed.

Section IV.C Options for Systems to Meet Cryptosporidium Treatment Requirements

1. Microbial toolbox overview

For each microbial toolbox component, EPA is requesting comment on: (1) whether available data support the proposed presumptive credits, including the design and implementation conditions under which the credit would be awarded, (2) whether available data are consistent with the decision not to award presumptive credit for roughing filters and raw water off-stream storage, and (3) whether additional data are available on treatment effectiveness of toolbox components for reducing *Cryptosporidium* levels. EPA will consider modifying today's proposal for microbial toolbox components based on new information that may be provided.

EPA particularly solicits comment on the performance of alternative filtration technologies that are currently being used, as well as ones that systems are considering for use in the future, specifically including bag filters, cartridge filters, and bank filtration, in removing *Cryptosporidium*. The Agency requests both laboratory and field data that will support a determination of the appropriate level of *Cryptosporidium* removal credit to award to these

technologies. In addition, the Agency requests information on the applicability of these technologies to different source water types and treatment scenarios. Data submitted in response to this request for comment should include, where available, associated quality assurance and cost information. This preamble discusses bank filtration in section IV.C.6 and bag and cartridge filters in section IV.C.12.

2. Watershed control program

EPA requests comment on the proposed watershed control program credit and associated program components.

- Should the State be allowed to reduce the frequency of the annual watershed survey requirement for certain systems if systems engage in alternative activities like public outreach?
- The effectiveness of a watershed control program may be difficult to assess because of uncertainty in the efficacy of control measures under site-specific conditions. In order to provide constructive guidance, EPA welcomes reports on scientific case studies and research that evaluated methods for reducing *Cryptosporidium* contamination of source waters.
- Are there confidential business information (CBI) concerns associated with making information on the watershed control program available to the public? If so, what are these concerns and how should they be addressed?
- How should the “area of influence” (the area to be considered in future watershed surveys) be delineated, considering the persistence of *Cryptosporidium*?

3. Alternative source

EPA requests comment on the following issues:

- What are intake management strategies by which systems could reduce levels of *Cryptosporidium* in the plant influent?
- Can representative *Cryptosporidium* monitoring to demonstrate a reduction in oocyst levels be accomplished prior to implementation of a new intake strategy (e.g., monitoring a new source prior to constructing a new intake structure)?
- How should this option be applied to plants that use multiple sources which enter a plant through a common conduit, or which use separate sources which enter the plant at different points?

4. Off-stream raw water storage

EPA requests comment on the finding that the available data are not adequate to support a presumptive *Cryptosporidium* treatment credit for off-stream storage, and that systems using off-stream storage should conduct LT2ESWTR monitoring at the reservoir outlet. This monitoring approach would account for reductions in oocyst concentrations due to settling, but would not provide credit for die-off, since non-viable oocysts could still be counted during monitoring. In addition, EPA would also appreciate comment on the following specific issues:

- Is additional information available that either supports or suggests modifications to this proposal concerning off-stream storage?
- How should a system address the concern that water in off-stream storage reservoirs may become contaminated through processes like algal growth, run-off, roosting birds, and activities on the watershed?

5. Pre-sedimentation with coagulant

EPA requests comment on the proposed criteria for awarding credit to presedimentation. EPA would particularly appreciate comment on the following issues:

- Whether the information cited in this proposal supports the proposed credit for presedimentation and the operating conditions under which the credit will be awarded;
- Additional information that either supports or suggest modifications to the proposed performance criteria and presumptive credit;
- Today's proposal requires systems using presedimentation to sample after the presedimentation basin, and these systems are not eligible to receive additional presumptive *Cryptosporidium* removal credit for presedimentation. However, systems are also required to collect samples prior to chemical treatment, and EPA recognizes that some plants provide chemical treatment to water prior to, or during, presedimentation. EPA requests comment on how this situation should be handled under the LT2ESWTR.
- Whether and under what conditions factors like low turbidity raw water, infrequent sludge removal, and wind would make compliance with the 0.5 log turbidity removal requirement infeasible.

6. Bank filtration

The Agency requests comment on the following issues concerning bank filtration:

- The performance of bank filtration in removing *Cryptosporidium* or surrogates to date at sites currently using this technology (e.g. sites with horizontal wells)
- The use of other methods (e.g., geophysical methods such as ground penetrating radar) to complement or supplant core drilling to determine site suitability for bank filtration credit
- The number of GWUDI systems in each State (i.e., the number of systems having at least one GWUDI source) where bank filtration has been utilized as the primary filtration barrier (e.g., no other physical removal technologies follow); also, the method that was

used by the State to determine that each system was achieving 2 log removal of *Cryptosporidium*

- For GWUDI systems where natural or alternative filtration (e.g. bank filtration or artificial recharge) is used in combination with a subsequent filtration barrier (e.g., bag or cartridge filters) to meet the 2 log *Cryptosporidium* removal requirement of the IESWTR or LT1ESWTR, how much *Cryptosporidium* removal credit has the State awarded (or is the State willing to grant if the bags/cartridges were found to be achieving < 2.0 logs) for the natural or alternative filtration process and how did the State determine this value?
- The proposed *Cryptosporidium* removal credit and associated design criteria, including any additional information related to this topic
- Suitable separation distance(s) to be required between vertical or horizontal wells and adjacent surface water
- Testing protocols and procedures for making site specific determinations of the appropriate level of *Cryptosporidium* removal credit to award to bank filtration processes
- Information on the data and methods suitable for predicting *Cryptosporidium* removal based on the available data from surrogate and indicator measurements in water collection devices
- The applicability of turbidity monitoring or other process monitoring procedures to indicate the ongoing performance of bank filtration processes.

7. Lime softening

EPA requests comment on the proposed criteria for awarding credit to lime softening plants. EPA would particularly appreciate comment on the following issues:

- Whether the information and analyses presented in this proposal supports an additional 0.5 log credit for two-stage softening, and the associated criteria necessary for credit.

- Additional information that either support or suggest modifications to the proposed criteria and credit.

8. Combined filter performance

EPA invites comment on the following issues regarding the proposed *Cryptosporidium* treatment credit for combined filter performance:

- Do the studies cited here support awarding 0.5 log credit for CFE ▾ 0.15 NTU 95% of the time?
- Does currently available turbidity monitoring technology accurately distinguish differences between values measured near 0.15 NTU?

9. Roughing filter

The Agency requests comment on the information that has been presented about roughing filters, and specifically the question of whether and under what conditions roughing filters should be awarded a 0.5 log credit for removal of *Cryptosporidium.* EPA also requests information on specific studies of *Cryptosporidium* oocyst removal by roughing filters, or from studies of the removal of surrogate parameters that have been shown to correlate with oocyst removal in roughing filters.

10. Slow sand filtration

The Agency requests comment on whether the available data are adequate to support awarding a 2.5 log *Cryptosporidium* removal credit for slow sand filtration applied as a secondary filtration step, along with any additional information related to this application.

11. Membrane Filtration

EPA requests comment on the following issues:

- EPA is proposing to include membrane cartridge filters that can be direct integrity tested under the definition of a membrane filtration process since one of the key differences between membrane filtration processes and bag and cartridge filters, within the context of this regulation, is the applicability of direct integrity test methods to the filtration process. EPA requests comment on the inclusion of membrane cartridge filters that can be direct integrity tested under the definition of a membrane filtration process in this rule.
- The applicability of the proposed *Cryptosporidium* removal credits and performance criteria to *Giardia lamblia*
- Appropriate surrogates, or the characteristics of appropriate surrogates, for use in challenge testing. EPA requests data or information demonstrating the correlation between removal of a proposed surrogate and removal of *Cryptosporidium* oocysts
- The use of a nondestructive performance test and associated quality control release values for demonstrating the *Cryptosporidium* removal capability of membrane modules that are not directly challenge tested
- The appropriateness of the minimum direct integrity test frequency of once per 24 hours
- The proposed minimum reporting frequency for direct integrity testing results above the control limit and indirect integrity monitoring results that trigger direct integrity monitoring.

12. Bag and cartridge filtration

EPA requests comment on the following issues concerning bag and cartridge filters:

- The performance of bag and cartridge filters in removing *Cryptosporidium* through all differential pressure ranges in a filter run— EPA requests laboratory and field data, along with associated quality assurance and quality control information, that will support a determination of the appropriate level of *Cryptosporidium* removal credit to award to

these technologies.

- The performance of bag and cartridge filters in removing *Cryptosporidium* when used in series with other bag or cartridge filters—EPA requests laboratory and field data, along with associated quality assurance and quality control information, that will support a determination of the appropriate level of *Cryptosporidium* removal credit to award to these technologies when used in series.
- Appropriate surrogates, or the characteristics of appropriate surrogates, for use in challenge testing bag and cartridge filters—EPA requests data or information demonstrating the correlation between removal of a proposed surrogate and removal of *Cryptosporidium* oocysts.
- The availability of non-destructive tests that can be applied to bag and cartridge filters to verify the removal efficiency of production filters that are not directly challenge tested—EPA requests data or information demonstrating the correlation between a proposed non-destructive test and the removal of *Cryptosporidium* oocysts.
- The applicability of pressure drop monitoring, filtrate turbidity monitoring, or other process monitoring and process control procedures to verify the integrity of bag and cartridge filters—EPA requests data or information demonstrating the correlation between a proposed process monitoring tool and the removal of *Cryptosporidium* oocysts.
- The applicability of bag and cartridge filters to different source water types and treatment scenarios
- The applicability of the proposed *Cryptosporidium* removal credits and testing criteria to *Giardia lamblia*
- The use of a 1 log factor of safety for awarding credit to bag and cartridge filters—EPA requests comment on whether this is an appropriate factor of safety to account for the inability to conduct integrity monitoring of these devices, as well as the variability in

removal efficiency observed over the course of a filtration cycle for some filtration devices. This inability creates uncertainty regarding both changes in the performance of a given filter during use and variability in performance among filters in a given product line. If the 1 log factor of safety is higher than necessary to account for these factors, should the Agency establish a lower value, such as a 0.5 log factor of safety?

13. Secondary filtration

The Agency requests comment on awarding a 0.5 log *Cryptosporidium* removal credit for systems using secondary filtration, including the design and operational criteria required to receive the log removal credit. EPA specifically requests comment on the following issues:

- Should there be a minimum required depth for the secondary filter (e.g., 24 inches) in order for the system to receive credit?
- Should systems be eligible to receive additional *Cryptosporidium* treatment credit within the microbial toolbox for both a second clarification stage (e.g., secondary filtration, second stage sedimentation) and lower finished water turbidity, given that additional particle removal achieved by the second clarification stage will reduce finished water turbidity?

14. Ozone and chlorine dioxide

EPA requests comment on the proposed approach to awarding credit for inactivation of *Cryptosporidium* by chlorine dioxide and ozone, including the following specific issues:

- Determination of CT and the confidence bounds used for estimating log inactivation of *Cryptosporidium*;
- The ability of systems to apply these CT tables in consideration of the MCLs for bromate and chlorite; and

- Any additional data that may be used to confirm or refine the proposed CT tables.

15. Ultraviolet light

The Agency requests comment on whether the criteria described in this section for awarding treatment credit for UV disinfection are appropriate, and whether additional criteria, or more specific criteria, should be included.

16. Individual filter performance

The agency invites comment on the following issues related to the proposed credit for individual filter performance.

- Are there different or additional performance measures that a utility should be required to meet for the 1 log additional credit?
- Are there existing peer review programs for which treatment credit should be awarded under the LT2ESWTR? If so, what role should primacy agencies play in establishing and managing any such peer review program?
- The individual filter effluent turbidity criterion of 0.1 NTU is proposed because it is consistent with Phase IV Partnership standards, as based on CCP goals. However, with allowable rounding, turbidity levels less than 0.15 NTU are in compliance with a standard of 0.1. Consequently, EPA requests comment on whether 0.15 NTU should be the standard for individual filter performance credit, as this would be consistent with the standard of 0.15 NTU that is proposed for combined filter performance credit in section IV.C.8.

17. Other demonstration of performance

The Agency requests comment on today's proposal for systems to demonstrate higher

Cryptosporidium removal levels. EPA specifically requests comment on the following issues:

- Approaches that should be considered or excluded for demonstration of performance testing;
- Whether EPA should propose minimum elements that demonstration of performance testing must include;
- Whether a factor of safety should be applied to the results of demonstration of performance testing to account for potential differences in removal of an indicator and removal of *Cryptosporidium*, or uncertainty in the application of pilot-scale results to full-scale plants;
- Whether or under what conditions a demonstration of performance credit should be allowed for a unit process within a plant — a potential concern is that certain unit processes, such as a sedimentation basin, can be operated in a manner that will increase removal in the unit process but decrease removal in subsequent treatment processes and, therefore, lead to no overall increase in removal through the plant. An approach to address this concern is to limit demonstration of performance credit to removal demonstrated across the entire treatment plant.

Section IV.D Disinfection Benchmarks for Giardia lamblia and Viruses

EPA requests comment on the proposed provisions of the inactivation profiling and benchmarking requirement.

Section IV.E Additional Treatment Technique Requirements for Systems with Uncovered Finished Water Storage Facilities

EPA requests comment on the proposed requirements pertaining to uncovered finished water storage facilities. Specifically, the Agency would like comment on the following issues,

and requests that comments include available supporting data or other technical information:

- Is it appropriate to allow systems with uncovered finished water storage facilities to implement a risk management plan or treat the effluent to inactivate viruses instead of covering the facility?
- If systems treat the effluent of an uncovered finished water storage facility instead of covering it, should systems be required to inactivate *Cryptosporidium* and *Giardia lamblia*, since these protozoa have been found to increase in uncovered storage facilities?
- Additional information on contamination or health risks that may be associated with uncovered finished water storage facilities.
- Additional data on how climatological conditions affect water quality, including daily fluctuations in the stability of the water related to corrosion control.
- The definition of an uncovered finished water storage facility in 40 CFR 141.2 is a tank, reservoir, or other facility used to store water that will undergo no further treatment except residual disinfection and is open to the atmosphere. There is a concern that this definition may not include certain systems using what would generally be considered an uncovered finished water storage facility. An example is a system that applies a corrosion inhibitor compound to the effluent of an uncovered storage facility where water is stored after filtration and primary disinfection. In this case, the system may claim that the corrosion inhibitor constitutes additional treatment and, consequently, the reservoir does not meet EPA's definition of an uncovered finished water storage facility. EPA requests comment on whether the definition of an uncovered finished water storage facility should be revised to specifically include systems that apply a treatment such as corrosion control to water stored in an uncovered reservoir after the water has undergone filtration, where required, and primary disinfection.

Section IV.F Compliance Schedules

EPA requests comments on the treatment technique compliance schedules for large and small systems in today's proposal. Specifically, EPA requests comment on the following issues:

Alternative implementation schedules

EPA requests comment on the implementation schedule for the LT2ESWTR. Under today's proposal, all large systems (serving 10,000 or more) begin monitoring six months after rule promulgation. This is followed by small system monitoring, which begins at the conclusion of large system monitoring 2.5 years after promulgation. A potential alternative approach to the implementation schedule is the following:

Alternative approach: Systems serving 100,000 people or more would begin monitoring 6 months after promulgation (i.e., same as proposed schedule), but systems serving 10,000 - 100,000 people would not begin monitoring until 12 months after promulgation (i.e., 6 month delay relative to proposed schedule). There would be an equivalent 6 month delay relative to the proposal for treatment implementation by systems serving 10,000-100,000 and in the implementation schedule small systems. Under this alternative scenario, EPA would still expect to play a significant role in directly implementing large system monitoring.

Potential advantages of this alternative are that it would provide additional time after rule promulgation for systems serving 10,000-100,000 people to become familiar with *Cryptosporidium* sampling procedures and establish a contract with an analytical laboratory. Note that systems serving 100,000 or more people were required to monitor for *Cryptosporidium* under the Information Collection Rule and, consequently, are expected to be more familiar with the associated procedures. In addition, this staggered implementation schedule would provide additional time for laboratories to build capacity by training new personnel and purchasing

equipment in order to accommodate the full demand of LT2ESWTR monitoring.

Disadvantages of this alternative are that delaying monitoring would delay the implementation of additional public health protection by systems with higher source water *Cryptosporidium* levels. Also, the staggered implementation schedule would be more complex, which would make it more difficult for systems to ascertain the compliance deadlines that apply them and for States to track these deadlines. Any modification to the implementation schedule for the LT2ESWTR would also raise issues related to simultaneous implementation with the Stage 2 DBPR.

Time window between large and small system monitoring

Under the current proposal, small filtered system *E. coli* monitoring begins in the month following the end of large system *Cryptosporidium*, *E. coli*, and turbidity monitoring. EPA plans to evaluate large system monitoring results on an ongoing basis as the data are reported to determine if any refinements to the *E. coli* levels that trigger small system *Cryptosporidium* monitoring are necessary. If such refinements were deemed appropriate, EPA would issue guidance to States, which can establish alternative trigger values for small system monitoring under the LT2ESWTR.

This implementation schedule does not leave any time between the end of large system monitoring and the initiation of small system monitoring. Consequently, if it is necessary to provide guidance on alternative trigger values prior to when small system monitoring begins, such guidance would be based on less than the full set of large system results (e.g., first 18 months of large system data). EPA requests comment on whether an additional time window between the end of large system monitoring and the beginning of small system monitoring is appropriate and, if so, how long such a window should be.

Implementation schedule for consecutive systems

The Stage 2 M-DBP Agreement in Principle (65 FR 83015, December 29, 2000) (USEPA

2000a) continues the principle of simultaneous compliance to address microbial pathogens and disinfection byproducts. Systems are generally expected to address LT2ESTWR requirements concurrently with those of the Stage 2 DBPR (as noted earlier, the Stage 2 DBPR is scheduled to be proposed later this year and to be promulgated at the same time as the LT2ESWTR).

As with the LT2ESWTR, small water systems (< 10,0000 served) generally begin monitoring and must be in compliance with the Stage 2 DBPR at a date later than that for large systems. However, the Advisory Committee recommended that small systems that buy/receive from or sell/deliver finished water to a large system (that is, they are part of the same "combined distribution system") comply with Stage 2 DBPR requirements on the same schedule as the largest system in the combined distribution system. This approach is intended to ensure that systems consider impacts throughout the combined distribution system when making compliance decisions (i.e, selecting new technology or making operational modifications) and to facilitate all systems meeting the compliance deadlines for the rule.

The issue of combined distribution systems associated with systems buying and selling water is expected to be of less significance for the LT2ESWTR. The requirements of the LT2ESWTR apply to systems treating raw surface water and generally will not involve compliance steps when systems purchase treated water. Consequently, the compliance schedule for today's proposal does not address combined distribution systems. However, this proposed approach raises the possibility that a small system treating surface water and selling it to a large system could be required to take compliance steps at an earlier date under the Stage 2 DBPR than under the LT2ESWTR. While a small system in this situation could chose to comply with the LT2ESWTR on an earlier schedule, the two rules would not require simultaneous compliance. EPA requests comment on how this scenario should be addressed in the LT2ESWTR.

Section IV.G Public Notice Requirements

EPA requests comment on whether the violations of additional treatment requirements for *Cryptosporidium* under the LT2ESWTR should require a Tier 2 public notice and whether the proposed health effects language is appropriate.

Section IV.H Variances and Exemptions

1. Variances

In theory it would be possible for an unfiltered system to demonstrate raw water *Cryptosporidium* levels that were 3 log lower than the cutoff for bin 1 for filtered systems and, thus, that it is providing comparable public health protection without additional inactivation. However, EPA has determined that in practice it is not currently economically of technologically feasible for systems to ascertain the level of *Cryptosporidium* at this concentration. This is due to the extremely large number and volume of samples that would necessary to make this demonstration with sufficient confidence. Based on this determination and the *Cryptosporidium* occurrence data described in section III.C, EPA is not proposing to allow unfiltered systems to demonstrate raw water *Cryptosporidium* levels low enough to avoid inactivation requirements. EPA requests comment on this approach.

2. Exemptions

EPA believes that granting an exemption to the *Cryptosporidium* treatment requirements of the LT2ESWTR would result in an unreasonable health risk. As described in section II.C, *Cryptosporidium* causes acute health effects, which may be severe in sensitive subpopulations and include risk of mortality. Moreover, the additional *Cryptosporidium* treatment requirements of the LT2ESWTR are targeted to systems with the highest degree of risk. Due to these factors, EPA is not proposing to allow exemptions under the LT2ESWTR. EPA requests comment on

this approach.

Section IV.J System Reporting and Recordkeeping Requirements

EPA requests comment on the reporting and recordkeeping requirements proposed for the LT2ESWTR.

Section IV.K Analytical Methods

1. Cryptosporidium

EPA requests comment on the proposed method requirements for *Cryptosporidium* analysis, including the following specific issues:

Minimum sample volume

It is the intent of EPA that LT2ESWTR sampling provide representative annual mean source water concentrations. If systems were unable to analyze an entire sample volume during certain periods of the year due to elevated turbidity or other water quality factors, this could result in systems analyzing different volumes in different samples. Today's proposal requires systems to analyze at least 10 L of sample or the maximum amount of sample that can be filtered through two filters, up to a packed pellet volume of 2 mL. EPA requests comment on whether these requirements are appropriate for systems with source waters that are difficult to filter or that generate a large packed pellet volume. Alternatively, systems could be required to filter and analyze at least 10 L of sample with no exceptions.

Frequency of matrix spike sample analyses

EPA Methods 1622 and 1623, which are proposed for *Cryptosporidium* analyses under the LT2ESWTR, require analysis of one MS sample to be performed per 20 monitoring samples. MS sample analyses indicate analytical method recovery on a particular water of interest.

As proposed, the LT2ESWTR requires systems to follow EPA Method 1622 or 1623

quality control procedures, including the analysis of one MS sample per 20 monitoring samples. This will typically result in systems analyzing one to two MS samples per year, depending on sampling frequency. Consistent with the Agreement in Principle, EPA is proposing that systems not adjust *Cryptosporidium* analysis results for analytical method recovery when determining their LT2ESWTR bin classification. The proposed *Cryptosporidium* concentrations that bound LT2ESWTR bins account for an expected mean analytical method recovery of 40%, based on recoveries reported during the ICRSS (see section IV.A.2.c).

EPA is requesting comment on whether systems should be required to analyze MS samples at a higher frequency under the LT2ESWTR. Specifically, should systems analyze one MS sample with every field sample or at some other, alternative higher frequency? As discussed in section 3.C, the recovery of Methods 1622 and 1623 has been observed to be highly variable. Analyzing a MS sample with every field sample would provide information on method recovery on a sample-by-sample basis. This would potentially allow for more accurate classification of systems in LT2ESWTR bins.

In addition, EPA is in the process of evaluating a commercially available, attenuated, colored *Cryptosporidium* that potentially could be added as an internal surrogate to all samples analyzed by Methods 1622 and 1623. The colored *Cryptosporidium* is intended to allow differentiation from uncolored, native species. If the colored *Cryptosporidium* is approved as a spiking reagent, should EPA require that all samples be spiked to determine recovery?

Approval of updated versions of EPA Methods 1622 and 1623

EPA has developed draft revised versions of EPA Methods 1622 and 1623 in order to consolidate several method-related changes EPA believes may be necessary to address LT2ESWTR monitoring requirements (see USEPA 2003j and USEPA 2003k). EPA is requesting comment on whether these revised versions should be approved for monitoring under the LT2ESWTR, rather than the April 2001 versions proposed in today's rule. If the

revised versions were approved, previously collected data generated using the earlier versions of the methods would still be acceptable for grandfathering, provided the other criteria described in section IV.A.1.d were met. Drafts of the updated methods are provided in the docket for today's rule, and differences between these versions and the April 2001 versions of the methods are clearly indicated for evaluation and comment. Changes to the methods include the following:

(1) Increased flexibility in matrix spike (MS) and initial precision and recovery (IPR) requirements — the requirement that the laboratory must analyze an MS sample on the first sampling event for a new PWS would be changed to a recommendation; the revised method would allow the IPR test to be performed across four different days, rather than restrict analyses to 1 day;

(2) Clarification of some method procedures, including the spiking suspension vortexing procedure and the buffer volumes used during immunomagnetic separation (IMS); requiring (rather than recommending) that laboratories purchase HCl and NaOH standards at the normality specified in the method; and clarification that the use of methanol during slide staining in Section 14.2 is as per manufacturer's instructions;

(3) Additional recommendations for minimizing carry-over of debris onto microscope slides after IMS and add information on microscope cleaning;

(4) Clarification of the actions to take in the event of QC failures, such as that any positive sample in a batch associated with an unacceptable method blank is unacceptable and that any sample in a batch associated with an unacceptable ongoing precision and recovery (OPR) sample is unacceptable;

(5) Changing the sample storage and shipping temperature to < 8°C, and not frozen, and providing additional guidance on sample storage and shipping procedures based on time of day of collection and would include suggested options for monitoring sample temperature during shipment and/or upon receipt at the laboratory.

(6) Additional analyst verification procedures— adding examination using differential interference contrast (DIC) microscopy to the analyst verification requirements.

(7) Addition of an approved method modification using the Pall Gelman Envirochek HV filter. This approval was based on an interlaboratory validation study demonstrating that three laboratories, each analyzing reagent water and a different source water, met all method acceptance criteria for *Cryptosporidium*. EPA issued a letter (dated March 21, 2002) under the Alternative Test Procedures program approving the procedure as an acceptable version of Method 1623 for *Cryptosporidium* (but not for Giardia). EPA also noted in the letter that the procedure was considered to be an acceptable modification of EPA Method 1622.

The changes in the June 2003 draft revisions of EPA Methods 1622 and 1623 reflect method-related clarifications, modifications, and additions that EPA believes should be addressed for LT2ESWTR *Cryptosporidium* monitoring. Alternatively, these issues could be addressed through regulatory requirements in the final LT2ESWTR (for required changes and additions) and through guidance (for recommended changes and clarifications). However, EPA believes that addressing these issues through a single source in updated versions of EPA Methods 1622 and 1623 (which could be approved in the final LT2ESWTR) may be more straightforward and easier for systems and laboratories to follow than addressing them in multiple sources (i.e., existing methods, the final rule, and laboratory guidance).

2. E. coli

EPA requests comment on whether the *E. coli* methods proposed for approval under the LT2ESWTR are appropriate, and whether there are additional methods not proposed that should be considered. Comments concerning method approval should be accompanied by supporting data where possible.

EPA also requests comment on the proposal to extend the holding time for *E. coli* source water sample analyses to 24 hours, including any data or other information that would support, modify, or repudiate such an extension. Should EPA limit the extended holding time to only those *E. coli* analytical methods that were evaluated in the holding time studies noted in this section? The results in Pope et al. (2003) indicate that most *E. coli* samples analyzed using ONPG-MUG (see methods in Table IV-37) incurred no significant degradation after a 30 to 48 hour holding time. As a result, should EPA increase the source water *E. coli* holding time to 30 or 48 hours for samples evaluated by ONPG-MUG and retain a 24-hour holding time for samples analyzed by other methods? EPA also requests comment on the cost and availability of overnight delivery services for *E. coli* samples, especially in rural areas.

3. Turbidity

EPA requests comment on whether the turbidity methods proposed today for the LT2ESWTR should be approved, and whether there are additional methods not proposed that should be approved.

Section IV.L Laboratory Approval

EPA requests comment on the laboratory approval requirements proposed today, including the following specific issues:

Analyst experience criteria

The Lab QA Program, which EPA will use to approve laboratories for *Cryptosporidium* analyses under the LT2ESWTR, includes criteria for analyst experience. Principal analyst/supervisors (minimum of one per laboratory) should have a minimum of one year of continuous bench experience with *Cryptosporidium* and immunofluorescent assay (IFA)

microscopy, a minimum of six months experience using EPA Method 1622 and/or 1623, and a minimum of 100 samples analyzed using EPA Method 1622 and/or 1623 (minimum 50 samples if the person was an analyst approved to conduct analysis for the Information Collection Rule Protozoan Method) for the specific analytical procedure they will be using.

Under the Lab QA Program, other analysts (no minimum number of analysts per laboratory) should have a minimum of six months of continuous bench experience with *Cryptosporidium* and IFA microscopy, a minimum of three months experience using EPA Method 1622 and/or 1623, and a minimum of 50 samples analyzed using EPA Method 1622 and/or 1623 (minimum 25 samples if the person was an analyst approved to conduct analysis for the Information Collection Rule Protozoan Method) for the specific analytical procedures they will be using.

The Lab QA Program criteria for principal analyst/supervisor experience are more rigorous that those in Methods 1622 and 1623, which are as follows: the analyst must have at least 2 years of college lecture and laboratory course work in microbiology or a closely related field. The analyst also must have at least 6 months of continuous bench experience with environmental protozoa detection techniques and IFA microscopy, and must have successfully analyzed at least 50 water and/or wastewater samples for *Cryptosporidium*. Six months of additional experience in the above areas may be substituted for two years of college.

In seeking approval for an Information Collection Request, EPA requested comment on the Lab QA Program (67 FR 9731, March 4, 2002) (USEPA 2002c). A number of commenters stated that the analyst qualification criteria are restrictive and could make it difficult for laboratories to maintain adequate analyst staffing (and, hence, sample analysis capacity) in the event of staff turnover or competing priorities. Some commenters suggested that laboratories and analysts should be evaluated based on proficiency testing, and that analyst experience standards should be reduced or eliminated. (Comments are available in Office of Water docket,

number W-01-17).

Another aspect of the analyst experience criteria is that systems may generate *Cryptosporidium* data for grandfathering under the LT2ESWTR using laboratories that meet the analyst experience requirement of Methods 1622 or 1623 but not the more rigorous principal analyst/supervisor experience requirement of the Lab QA Program. EPA requests comment on whether the criteria for analyst experience in the Lab QA Program are necessary, whether systems are experiencing difficulty in finding laboratories that have passed the Lab QA Program to conduct *Cryptosporidium* analysis, and whether any of the Lab QA Program criteria should be revised to improve the LT2ESWTR lab approval process.

State programs to approve laboratories for Cryptosporidium analysis

Under today's proposal, systems must have *Cryptosporidium* samples analyzed by a laboratory approved under EPA's Lab QA Program or an equivalent Sate laboratory approval program. Because States do not currently approve laboratories for *Cryptosporidium* analyses, EPA will initially assume responsibility for *Cryptosporidium* laboratory approval. EPA expects, however, that some States may wish to adopt equivalent approval programs for *Cryptosporidium* analysis under State laboratory certification programs. EPA requests comment on how to establish that a State approval program for *Cryptosporidium* analysis is equivalent to the Lab QA Program.

Specifically, should EPA evaluate State Approval programs to determine if they are equivalent to the Lab QA Program? EPA also requests comment on the elements that would constitute an equivalent State approval program for *Cryptosporidium* analyses, including the following: (1) successful analysis of initial and ongoing blind proficiency testing samples prepared using flow cytometry, including a matrix and meeting EPA's pass/fail criteria (described in USEPA 2002c); (2) an on-site evaluation of the laboratory's sample processing and analysis procedures, including microscopic examination skills, by auditors who meet the

qualifications of a principal analyst as set forth in the Lab QA Program (described in USEPA 2002c); (3) an on-site evaluation of the laboratory's personnel qualifications, quality assurance/quality control program, equipment, and recordkeeping procedures; (4) a data audit of laboratories' QC data and monitoring data; and (5) use of the audit checklist used in the Lab QA Program or equivalent.

Section IV.M Requirements for Sanitary Surveys Conducted by EPA

In order to ensure that systems for which EPA has direct implementation authority address significant deficiencies identified during sanitary surveys, EPA requests comment on establishing either or both of the following requirements under 40 CFR 141 as part of the NPDWR established in the final LT2ESWTR:

(1) For sanitary surveys conducted by EPA under SDWA section 1445, systems would be required to respond in writing to significant deficiencies outlined in sanitary survey reports no later than 45 days after receipt of the report, indicating how and on what schedule the system will address significant deficiencies noted in the survey.

(2) Systems would be required to correct significant deficiencies identified in sanitary survey reports if such deficiencies are within the control of the system and its governing body.

For the purposes of these requirements, a sanitary survey, as conducted by EPA, is an onsite review of the water source (identifying sources of contamination by using results of source water assessments where available), facilities, equipment, operation, maintenance, and monitoring compliance of a public water system to evaluate the adequacy of the system, its sources and operations, and the distribution of safe drinking water. A significant deficiency includes a defect in design, operation, or maintenance, or a failure or malfunction of the sources, treatment, storage, or distribution system that EPA determines to be causing, or has the

potential for causing the introduction of contamination into the water delivered to consumers.

Section VI. Economic Analysis

EPA requests comment on both of the methodologies for valuing non-fatal cryptosporidiosis and on the use of a real income growth factor to adjust these estimates for the years 2008 through 2027.

The Agency requests comment on all aspects of the proposed rule's economic impact analysis. Specifically, EPA seeks input into the following issues: (1) How can the Agency fully incorporate all toolbox options into the economic analysis?; and (2) How can the Agency estimate the potential benefits from reduced epidemic outbreaks of cryptosporidiosis?

Section VII.B Paperwork Reduction Act

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques.

Section VII.E Executive Order 13132: Federalism

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

Section IV.F Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

In the spirit of Executive Order 13175, and consistent with EPA policy to promote

communications between EPA and tribal governments, EPA specifically solicits additional comment on this proposed rule from tribal officials.