

monthly). The allowances for deviations from a sampling schedule specified under IV.A.1.b for LT2ESWTR monitoring apply to grandfathered data.

- Samples were collected at the correct location as specified for LT2ESWTR monitoring. Systems must report the use of bank filtration, presedimentation, and raw water off-stream storage during sampling.

- For each sample, the laboratory analyzed at least 10 L of sample or at least 2 mL of packet pellet volume or as much volume as two filters could accommodate before clogging (applies only to filters that have been approved by EPA for use with Methods 1622 and 1623).

- The system must certify that it is reporting all *Cryptosporidium* monitoring results generated by the system during the time period covered by the previously collected data. This applies to samples that were (a) collected from the sampling location used for LT2ESWTR monitoring, (b) not spiked, and (c) analyzed using the laboratory's routine process for Method 1622 or 1623 analyses.

- The system must also certify that the samples were representative of a plant's source water(s) and the source water(s) have not changed.

If a system has at least two years of *Cryptosporidium* data collected before promulgation of the LT2ESWTR and the system does not intend to conduct new monitoring under the rule, the system must submit the data and the required supporting documentation to EPA no later than two months following promulgation of the rule. EPA will notify the system within four months following LT2ESWTR promulgation as to whether the data are sufficient for bin determination. Unless EPA notifies the system in writing that the previously collected data are sufficient for bin determination, the system must conduct source water *Cryptosporidium* monitoring as described in section IV.A.1.b of this preamble.

If a system intends to grandfather fewer than two years of *Cryptosporidium* data, or if a system intends to grandfather 2 or more years of previously collected data and also to conduct new monitoring under the rule, the system must submit the data and the required supporting documentation to EPA no later than eight months following promulgation of the rule. Systems must conduct monitoring as described in section IV.A.1.b until EPA notifies the system in writing that it has at least 2 years of acceptable data. See section IV.J for additional information on reporting requirements associated with previously collected data.

2. How Was This Proposal Developed?

The monitoring and treatment requirements for filtered systems proposed under the LT2ESWTR stem from the data and analyses described in this section and reflect recommendations made by the Stage 2 M-DBP Federal Advisory Committee (65 FR 83015) (USEPA 2000a).

a. *Basis for targeted treatment requirements.* Under the IESWTR, EPA established an MCLG of zero for *Cryptosporidium* at the genus level based on the public health risk associated with this pathogen. The IESWTR included a 2 log treatment technique requirement for medium and large filtered systems that controlled for *Cryptosporidium* as close to the MCLG as was then deemed technologically feasible, taking costs into consideration. The LT1ESWTR extended this requirement to small systems. Given the advances that have occurred subsequent to the IESWTR in available technology to measure and treat for *Cryptosporidium*, a key question for the LT2ESWTR was the extent to which *Cryptosporidium* should be further controlled to approach the MCLG of zero, considering technical feasibility, costs, and potential risks from DBPs.

The data and analysis presented in Section III of this preamble suggest wide variability in possible risk from *Cryptosporidium* among public water systems. This variability is largely due to three factors: (1) The broad distribution of *Cryptosporidium* occurrence levels among source waters, (2) disparities in the efficacy of treatment provided by plants, and (3) differences in the infectivity among *Cryptosporidium* isolates. EPA and the Advisory Committee considered this wide range of possible risks and the desire to address systems where the 2 log removal requirement established by the IESWTR and LT1ESWTR may not provide adequate public health protection.

A number of approaches were evaluated for furthering control of *Cryptosporidium*. One approach was to require all systems to provide the same degree of additional treatment for *Cryptosporidium* (i.e., beyond that required by the IESWTR and LT1ESWTR). This approach could ensure that most systems, including those with poor quality source water, would be adequately protective. The uniformity of this approach has the advantage of minimizing transactional costs for determining what must be done by a particular system to comply. However, a significant downside is that it may require more treatment, with

consequent costs, than is needed by many systems with low source water *Cryptosporidium* levels. In addition, there were concerns with the feasibility of requiring almost all surface water treatment plants to install additional treatment processes for *Cryptosporidium*.

A second approach was to base additional treatment requirements on a plant's source water *Cryptosporidium* level. Under this approach, systems monitor their source water for *Cryptosporidium*, and additional treatment is required only from those systems that exceed specified oocyst concentrations. This has the advantage of targeting additional public health protection to those systems with higher vulnerability to *Cryptosporidium*, while avoiding the imposition of higher treatment costs on systems with the least contaminated source water. In consideration of these advantages, the Advisory Committee recommended and EPA is proposing this second approach for filtered systems under the LT2ESWTR.

b. *Basis for bin concentration ranges and treatment requirements.* The proposed LT2ESWTR will classify plants into different risk bins based on the source water *Cryptosporidium* level, and the bin classification will determine the extent to which additional treatment beyond IESWTR and LT1ESWTR is required. Two questions were central in developing the proposed bin concentration ranges and additional treatment requirements:

- What is the risk associated with a given level of *Cryptosporidium* in a drinking water source?
- What degree of additional treatment should be required for a given source water *Cryptosporidium* level?

This section addresses these two questions by first summarizing how EPA assessed the risk associated with *Cryptosporidium* in drinking water, followed by a description of how EPA and the Advisory Committee used this type of information in identifying LT2ESWTR bin concentration ranges and treatment requirements. For additional information on these topics, see Economic Analysis for the LT2ESWTR (USEPA 2003a).

i. What is the risk associated with a given level of *Cryptosporidium* in a drinking water source? The risk of infection from *Cryptosporidium* in drinking water is a function of infectivity (i.e., dose-response associated with ingestion) and exposure. Section III.B summarizes available data on *Cryptosporidium* infectivity. EPA conducted a meta-analysis of reported infection rates from human feeding