

BILLING CODE 6560-50-C

Cryptosporidium Monitoring

Small systems that exceed the *E. coli* trigger must conduct *Cryptosporidium* monitoring, beginning 6 months after completion of *E. coli* monitoring. As recommended by the Advisory Committee, EPA is proposing that small systems collect 24 *Cryptosporidium* samples over a period of one year. This number of samples is the same as required for large systems, but the monitoring burden is targeted only on those plants that *E. coli* monitoring indicates to have elevated levels of fecal matter in the source water. By completing *Cryptosporidium* monitoring in one year, small systems will conduct a total of 2 years of monitoring to determine LT2ESWTR bin classification (including the one year of *E. coli* monitoring). This time frame is equivalent to the requirement for large systems, which monitor for *Cryptosporidium*, *E. coli*, and turbidity for 2 years.

The Stage 2 M-DBP Agreement in Principle recommended that EPA explore the feasibility of alternative, lower frequency, *Cryptosporidium* monitoring criteria for providing a conservative mean estimate in small systems. As described earlier, EPA has evaluated smaller sample sizes, such as systems taking 12 or 8 samples instead of 24 (see Table IV-6). However, EPA has concluded that these smaller sample sizes result in unacceptably high misclassification rates. For example, bin classification based on the second highest of 12 samples produces an estimated false positive rate of 47% for systems with a mean *Cryptosporidium* concentration 0.5 log below the Bin 1 boundary of 0.075/L. In comparison, bin classification based on the mean of 24 samples achieves a false positive rate of 2.8% for systems at this *Cryptosporidium* concentration. Consequently, EPA is proposing no alternatives to the requirement that small systems take at least 24 samples.

Small system bin classification will be determined by the arithmetic mean of the 24 samples collected over one year. Because the bin structure in the LT2ESWTR is based on annual mean *Cryptosporidium* levels, it is necessary that bin classification involve averaging samples over at least one year. Consequently, small systems will determine their bin classification by averaging results from all *Cryptosporidium* samples collected during their one year of monitoring.

iii. Future monitoring and reassessment. EPA is proposing that beginning 6 years after the initial bin

classification, large and small systems conduct another round of monitoring to determine if source water conditions have changed to a degree that may warrant a revised bin classification. The Advisory Committee recommended that EPA convene a stakeholder process within 4 years after the initial bin classification to develop recommendations on how best to proceed with implementing this second round of monitoring. Unless EPA modifies the LT2ESWTR to allow for an improved analytical method or a revised bin structure based on new risk information, the second round of monitoring will be conducted under the same requirements that apply to the initial round of monitoring.

In addition, EPA is proposing to use the required assessment of the water source during sanitary surveys as an ongoing measure of whether significant changes in watersheds have occurred that may lead to increased contamination. Where the potential for increased contamination is identified, States must determine what follow-up actions by the system are necessary, including the possibility of the system providing additional treatment from the microbial toolbox.

d. *Basis for accepting previously collected data.* Members of the Advisory Committee had multiple objectives in recommending that EPA allow the use of previously collected (grandfathered) *Cryptosporidium* data. These include (1) giving credit for data collected by proactive utilities, (2) facilitating early determination of LT2ESWTR compliance needs and, thereby, allowing for early planning of appropriate treatment selection, (3) increasing laboratory capacity to meet demand for *Cryptosporidium* analysis under the LT2ESWTR, and (4) allowing utilities to improve their data set for bin determination by considering more than 2 years of data (*i.e.*, include data collected prior to effective date of LT2ESWTR). The latter objective incorporates the assumption that occurrence can vary from year to year, so that if more years of data are used in the bin determination, the source water concentration estimate will be a more accurate representation of the overall mean.

A significant issue with accepting previously collected data for making bin determinations is ensuring that the data are of equivalent quality to data that will be collected following LT2ESWTR promulgation. As noted previously, EPA is establishing requirements so that data collected under the LT2ESWTR will be similar in quality to data that were generated under the ICRSS. These

requirements include the use of approved analytical methods and compliance with method quality control (QC) criteria, use of approved laboratories, minimum sample volume, and a sampling schedule with minimum frequency. For example, under the ICRSS, laboratories analyzed 10 L samples and (considered collectively) achieved a mean *Cryptosporidium* recovery of approximately 43% in spiked source water with a relative standard deviation (RSD) of 50%. EPA anticipates that laboratories conducting *Cryptosporidium* analysis for the LT2ESWTR will collectively achieve similar analytical method performance. Consequently, EPA expects previously collected data sets used under the LT2ESWTR to meet these standards and has established criteria for accepting previously collected data accordingly (see section IV.A.1.d).

Systems are requested, but not required, to notify EPA prior to promulgation of the LT2ESWTR of their intent to submit previously collected data. This will help EPA allocate the resources that will be needed to evaluate these data in order to make a decision on adequacy for bin determination. Systems that have at least 2 years of previously collected data to grandfather when the LT2ESWTR is promulgated and do not intend to conduct new monitoring under the rule are required to submit the previously collected data to EPA within 2 months following promulgation. This will enable EPA to evaluate the data and report back to the utility in sufficient time to allow, if needed, the utility to contract with a laboratory to conduct monitoring under the LT2ESWTR.

Systems that have fewer than 2 years of previously collected data to grandfather when the LT2ESWTR is promulgated, or that intend to grandfather 2 or more years of previously collected data and also conduct new monitoring under the rule, are required to submit the previously collected data to EPA within 8 months following promulgation. This will allow these utilities to continue to collect previously collected data in the 6 month period between promulgation and the date when monitoring under the LT2ESWTR must begin, plus a 2 month period for systems to compile the data and supporting documentation. Utilities may submit the data earlier than 8 months after promulgation if they acquire 2 years of previously collected data before this date.

Submitted grandfathered data sets must include all routine source water monitoring results for samples collected during the time period covered by the