

thereby, achieving the public health protection intended for the rule. More costly designs, involving more frequent sampling and analysis, provide only marginally improved performance. Less frequent sampling, though lower in cost, creates unacceptably high misclassification rates and would not provide for the targeted risk reduction goals of the rule.

No Adjustments for Method Recovery or Percent of Oocysts That Are Infectious

Two considerations in using *Cryptosporidium* monitoring data to project risk are (1) Fewer than 100% of oocysts in a sample are recovered and counted by the analyst and (2) not all the oocysts measured with Methods 1622/23 are viable and capable of causing infection. These two factors are offsetting in sign, in that oocyst counts not adjusted for recovery tend to underestimate the true concentration, while the total oocyst count may overestimate the infectious concentration that presents a health risk. Based on information described in this section, EPA is proposing that *Cryptosporidium* monitoring results be used directly to assign systems to LT2ESWTR risk bins and not be adjusted for either factor.

As described in section III.C, ICRSS matrix spike data indicate that average recovery of *Cryptosporidium* oocysts with Methods 1622/23 in a national monitoring program will be about 40%. There is no similar direct measure of the fraction of environmental oocysts that are infectious, but information related to this value can be derived from two sources: (1) A study where samples were analyzed with both Method 1623 and a cell culture-polymerase chain reaction (CC-PCR) test for oocyst infectivity, and (2) the structure of oocysts counted with Methods 1622 and 1623.

LeChevallier *et al.* (2003) conducted a study in which six natural waters were frequently tested for *Cryptosporidium* using both Method 1623 and a CC-PCR method to test for infectivity. *Cryptosporidium* oocysts were detected in 60 of 593 samples (10.1%) by Method 1623 and infectious oocysts were detected in 22 of 560 samples (3.9%) by the CC-PCR procedure. Recovery efficiencies for the two methods were similar. According to the authors, these results suggest that approximately 37% (22/60) of the *Cryptosporidium* oocysts detected by Method 1623 were viable and infectious.

In regard to oocyst structure, *Cryptosporidium* oocysts counted with Methods 1622/23 are characterized in one of three ways: (1) Internal

structures, (2) amorphous structures, or (3) empty. Oocysts with internal structures are considered to have the highest likelihood of being infectious, while empty oocysts are believed to be non-viable (LeChevallier *et al.* 1997). During the ICRSS, 37% of the oocysts counted were characterized as having internal structures, 47% had amorphous structures, and 16% were empty. If it is assumed that empty oocysts could not be infectious, the mid-point value within the percentage range of counted oocysts that could have been infectious is 42%.

After considering this type of information, the Advisory Committee recommended that monitoring results not be adjusted upward for percent recovery, nor adjusted downward to account for the fraction of oocysts that are not infectious. While it is not possible to establish a precise value for either factor in individual samples, the data suggest that they may be of similar magnitude. EPA concurs with this recommendation and is proposing that systems be classified in bins under the LT2ESWTR using the total *Cryptosporidium* oocyst count, uncorrected for recovery, as measured using EPA Method 1622/23. The proposed LT2ESWTR risk bins are constructed to reflect this approach.

Data Collection To Support Use of a Microbial Indicator by Small Systems

As described in the next section, small systems will monitor for an indicator, currently proposed to be *E. coli*, to determine if they are required to sample for *Cryptosporidium*. The proposed *E. coli* levels that will trigger *Cryptosporidium* monitoring are based on Information Collection Rule and ICRSS data. However, to provide for a more extensive evaluation of *Cryptosporidium* indicator criteria, EPA is proposing that large systems measure *E. coli* and turbidity in their source water when they sample for *Cryptosporidium*. This was recommended by the Advisory Committee and will allow for possible development of alternative indicator levels or parameters (e.g., turbidity in combination with *E. coli*) to serve as triggers for small system *Cryptosporidium* monitoring.

Time Frame for Monitoring

In recommending a time frame for LT2ESWTR monitoring, the Agency considered the trade-off between monitoring over a long period to better capture year-to-year fluctuations, and the desire to prescribe additional treatment quickly to systems identified as having high source water pathogen

levels. Reflecting Advisory Committee recommendations, EPA is proposing that large systems evaluate their source water *Cryptosporidium* levels using 2 years of monitoring. This will account for some degree of yearly variability, without significantly delaying additional public health protection where needed.

ii. Systems serving fewer than 10,000 people.

Indicator Monitoring

In recognition of the relatively high cost of analyzing samples for *Cryptosporidium*, EPA and the Advisory Committee explored the use of indicator criteria to identify drinking water sources that may have high levels of *Cryptosporidium* occurrence. The goal was to find one or more parameters that could be analyzed at low cost and identify those systems likely to exceed the Bin 1 boundary of 0.075 oocysts/L. Data from the Information Collection Rule and ICRSS were evaluated for possible indicator parameters, including fecal coliforms, total coliforms, *E. coli*, viruses (Information Collection Rule only), and turbidity. Based on available data, *E. coli* was found to provide the best performance as a *Cryptosporidium* indicator, and the inclusion of other parameters like turbidity was not found to improve accuracy.

The next part of this section presents data that support *E. coli* mean concentrations of 10/100 mL and 50/100 mL as proposed screening levels that will trigger *Cryptosporidium* monitoring in reservoir/lake and flowing stream systems, respectively. It describes how *E. coli* and *Cryptosporidium* data from the Information Collection Rule and ICRSS were analyzed and shows the performance of different concentrations of *E. coli* as an indicator for systems that will exceed the Bin 1 boundary of 0.075 oocysts/L.

Information Collection Rule data were evaluated as maximum running annual averages (Information Collection Rule samples were collected once per month for 18 months) while ICRSS data were evaluated using an annual mean (ICRSS samples were collected twice per month for 12 months). In addition, as indicators were being evaluated it became apparent that it was necessary to analyze plants separately based on source water type, due to a significantly different relationship between *E. coli* and *Cryptosporidium* in reservoir/lake systems compared to flowing stream systems.

Analyzing the performance of an *E. coli* level as a screen to trigger *Cryptosporidium* monitoring under the proposed LT2ESWTR involved