

studies with 3 *Cryptosporidium* isolates. This analysis produced an estimate for the mean probability of infection given a dose of one oocyst near 0.09 (9%), with 10th and 90th percentile confidence values of 0.011 and 0.22, respectively.

Exposure to *Cryptosporidium* depends on the concentration of oocysts in the source water, the efficiency of treatment plants in removing oocysts, and the volume of water ingested (exposure can also occur through interactions with infected individuals). Based on data presented in section III.D, EPA has estimated that filtration plants in compliance with the IESWTR or LT1ESWTR reduce source water *Cryptosporidium* levels by 2 to 5 log (99% to 99.999%), with an average

reduction near 3 log. For drinking water consumption, EPA uses a distribution, derived from the United States Department of Agriculture's (USDA) 1994–96 Continuing Survey of Food Intakes by Individuals, with a mean value of 1.2 L/day. Average annual days of exposure to drinking water in CWS, non-transient non-community water systems (NTNCWS), and transient non-community water systems (TNCWS) are estimated at 350 days, 250 days, and 10 days, respectively. (The Economic Analysis for the LT2ESWTR (USEPA 2003a) provides details on all parameters listed here, as well as morbidity, mortality, and other risk factors.)

Using an estimate of 1.2 L/day consumption and a mean probability of

infection of 0.09 for one oocyst ingested, the daily risk of infection (DR) is as follows:

$$DR = (\text{oocysts/L in source water}) \times (\text{percent remaining after treatment}) \times (1.2 \text{ L/day}) \times (0.09).$$

The annual risk (AR) of infection for a CWS is

$$AR = 1 - (1 - DR)^{350}$$

where 350 represents days of exposure in a CWS.

Table IV–5 presents estimates of the mean annual risk of infection by *Cryptosporidium* in CWSs for selected source water infectious oocyst concentrations and filtration plant removal efficiencies.

TABLE IV–5.—ANNUAL RISK OF *Cryptosporidium* INFECTION IN CWSs THAT FILTER, AS A FUNCTION OF SOURCE WATER INFECTIOUS OOCYST CONCENTRATION AND TREATMENT EFFICIENCY

Source water concentration (infectious oocysts per liter)	Mean annual risk of infection for different levels of treatment efficiency (log removal) <sup>1</sup>			
	2 log	3 log	4 log	5 log
0.0001	3.8E–05	3.8E–06	3.8E–07	3.8E–08
0.001	3.7E–04	3.8E–05	3.8E–06	3.8E–07
0.01	3.7E–03	3.7E–04	3.8E–05	3.8E–06
0.1	3.7E–02	3.7E–03	3.7E–04	3.8E–05
1	0.31	3.7E–02	3.7E–03	3.7E–04
10	0.89	0.31	3.7E–02	3.7E–03

<sup>1</sup> Scientific notation (E<sup>–x</sup>) designates 10<sup>–x</sup>

For example, Table IV–5 shows that if a filtration plant had a mean concentration of infectious *Cryptosporidium* in the source water of 0.01 oocysts/L, and the filtration plant averaged 3 log removal, the mean annual risk of infection by *Cryptosporidium* is estimated as  $3.7 \times 10^{-4}$  (3.7 infections per 10,000 consumers).

ii. What degree of additional treatment should be required for a given source water *Cryptosporidium* level? In order to develop targeted treatment requirements for the LT2ESWTR, it was necessary to identify a source water *Cryptosporidium* level above which additional treatment by filtered systems would be required. Based on the type of risk information shown in Table IV–5, EPA and Advisory Committee deliberations focused on mean source water *Cryptosporidium* concentrations in the range of 0.01 to 0.1 oocysts/L as appropriate threshold values for prescribing additional treatment.

Analytical method and sampling constraints were a significant factor in setting the specific *Cryptosporidium* level that triggers additional treatment by filtered systems. The number of samples that systems can be required to

analyze for *Cryptosporidium* is limited. Consequently, if the bin threshold concentration for additional treatment was set near 0.01 oocysts/L, systems could exceed this level due to a very low number of oocysts being detected. For example, if systems took monthly 10 L samples and bin classification was based on a maximum running annual average, then a system would exceed a mean concentration of 0.01 oocysts/L by counting only 2 oocysts in 12 samples. Given the variability associated with *Cryptosporidium* analytical methods, the Advisory Committee did not support requiring additional treatment for filtered systems based on so few counts.

Another concern related to analytical method limitations was systems being misclassified in a lower bin. For example, if a system had a true mean concentration at or just above 0.1 oocysts/L, the mean that the system would determine through monitoring might be less than 0.1 oocyst/L. Thus, if the bin threshold for additional treatment was set at 0.1 oocysts/L, a number of systems with true mean concentrations above this level would be misclassified in the lower bin with no additional treatment required. This type of error, described in more detail

in the next section, is a function of the number of samples collected and variability in method performance.

In consideration of the available information on *Cryptosporidium* risk, as well as the performance and feasibility of analytical methods, EPA is proposing that the source water threshold concentration for requiring additional *Cryptosporidium* treatment by filtered systems be established at a mean level of 0.075 oocysts/L. This is the level recommended by the Advisory Committee, and it affords a high likelihood that systems with true mean *Cryptosporidium* concentrations of 0.1 oocysts/L or higher will provide additional treatment under the rule.

Beyond identifying this first threshold, it was also necessary to determine *Cryptosporidium* concentrations that would demarcate higher risk bins. With respect to the concentration range that each bin should comprise, EPA and the Advisory Committee dealt with two opposing factors: bin misclassification and equitable risk reduction.

As described in the next section, a monthly monitoring program involving EPA Methods 1622 or 1623 can characterize a system's mean *Cryptosporidium* concentration within a