

The results in Table III–2 show that the mean probability of infection from ingesting a single infectious oocyst ranges from 7% to 10% depending on the assumptions used. In comparison, the best estimate in the IESWTR of this probability was 0.4%, based on the IOWA isolate alone, and using the earlier definition of infection. Thus, these data suggest that both the range and magnitude of *Cryptosporidium* infectivity is higher than was estimated in the final IESWTR.

It should be noted that although significantly more data on *Cryptosporidium* infectivity are available now than when EPA established the IESWTR, there remains uncertainty about this parameter in several areas. It is unknown how well the oocysts used in the feeding studies represent *Cryptosporidium* naturally occurring in the environment, and the analyses do not fully account for variability in host susceptibility and the effect of previous infections. Furthermore, the sample sizes are relatively small, and the confidence bands on the estimates span more than an order of magnitude. Another limitation is that none of the studies included doses below 10 oocysts, while when people ingest oocysts in drinking water it is usually a single oocyst.

3. Significance of New Infectivity Data

The new infectivity data reveal that oocysts vary greatly in their ability to infect human hosts. Moreover, due to this variability and the finding of a highly infectious isolate, TAMU, the overall population of oocysts appears to be more infective than assumed for the IESWTR. The meta-analysis described earlier indicates the probability of infection at low *Cryptosporidium* concentrations may be about 20 times as great as previously estimated (which was based on the IOWA isolate alone and using the earlier definition of infection (stool-confirmed infections)).

C. *Cryptosporidium* Occurrence

This section presents information on the occurrence of *Cryptosporidium* oocysts in drinking water sources. Occurrence information is important because it is used in assessing the risk associated with *Cryptosporidium* in both filtered and unfiltered systems, as well as in estimating the costs and benefits of the proposed LT2ESWTR.

For the IESWTR, EPA had no national survey data and relied instead on several studies that were local or regional. Those data suggested that a typical (median) filtered surface water source had approximately 2 *Cryptosporidium* oocysts per liter, while

a typical unfiltered surface water source had about 0.01 oocysts per liter, a difference of two orders of magnitude.

Subsequent to promulgating the IESWTR, EPA obtained data from two national surveys: the Information Collection Rule and the Information Collection Rule Supplemental Surveys (ICRSS). These surveys were designed to provide improved estimates of occurrence on a national basis. As described in more detail later in this section, the Information Collection Rule and ICRSS results show three main differences in comparison to *Cryptosporidium* occurrence data used for the IESWTR:

(1) Average *Cryptosporidium* occurrence is lower. Median oocyst levels for the Information Collection Rule and ICRSS data are approximately 0.05/L, which is more than an order of magnitude lower than IESWTR estimates.

(2) *Cryptosporidium* occurrence is more variable from location to location than was shown by the data considered for the IESWTR. This indicates that although median occurrence levels are below those assumed for the IESWTR, there is a subset of systems whose levels are considerably greater than the median.

(3) There is a smaller difference in *Cryptosporidium* levels between typical filtered and unfiltered system water sources. The Information Collection Rule data do not support the IESWTR finding that unfiltered water systems have a risk of cryptosporidiosis equivalent to that of a filter plant with average quality source water.

This section begins with a summary of occurrence data that were used to assess risk under the IESWTR (these data were also used in the main risk assessment for the LT1ESWTR). This is followed by a discussion of the Information Collection Rule and ICRSS that covers the scope of the surveys, analytical methods, results, and a characterization of how these new data impact current understanding of *Cryptosporidium* exposure. A more detailed description of occurrence data is available in Occurrence and Exposure Assessment for the Long Term 2 Enhanced Surface Water Treatment Rule (USEPA 2003b).

1. Occurrence Data Evaluated for IESWTR

Occurrence information evaluated for the IESWTR is detailed in Occurrence and Exposure Assessment for The Interim Enhanced Surface Water Treatment Rule (USEPA 1998c). This information is summarized in the next two paragraphs.

a. *Filtered systems.* In developing the IESWTR, EPA evaluated *Cryptosporidium* occurrence data from a number of studies. Among these studies,

LeChevallier and Norton (1995) produced the largest data set and data from this study were used for the IESWTR risk assessment. This study provided estimates of mean occurrence at 69 locations from the eastern and central U.S. Although limited by the small number of samples per site (one to sixteen samples; most sites were sampled five times), variation within and between sites appeared to be lognormal. The study's median measured source water concentration was 2.31 oocysts/L and the interquartile range (i.e., 25th and 75th percentile) was 1.03 to 5.15 oocysts/L.

b. *Unfiltered systems.* To assess *Cryptosporidium* occurrence in unfiltered systems under the IESWTR, EPA evaluated *Cryptosporidium* monitoring results from several unfiltered water systems that had been summarized by the Seattle Water Department (Montgomery Watson, 1995). The median (central tendency) of these data was approximately 0.01 oocysts/L. Thus, the median concentration in these data set was about 2 orders of magnitude less than the median concentration in the data set used for filtered systems. These data, coupled with the assumption that filtered systems will remove at least 2 log of *Cryptosporidium* as required by the IESWTR, suggested that unfiltered systems that comply with the source water requirements of the SWTR may have a risk of cryptosporidiosis equivalent to that of a filter plant using a water source of average quality (62 FR 59507, November 3, 1997) (USEPA 1997a).

2. Overview of the Information Collection Rule and Information Collection Rule Supplemental Surveys (ICRSS)

The Information Collection Rule and the Information Collection Rule Supplemental Surveys (ICRSS) were national monitoring studies. They were designed to provide EPA with a more comprehensive understanding of the occurrence of microbial pathogens in drinking water sources in order to support regulatory decision making. The surveys attempted to control protozoa measurement error through requiring that (1) laboratories meet certain qualification criteria, (2) standardized methods be used to collect data, and (3) laboratories analyze performance evaluation samples throughout the duration of the study to ensure adequate analytical performance. Information Collection Rule monitoring took place from July 1997 to December 1998; ICRSS *Cryptosporidium* monitoring