

Cryptosporidiosis symptoms in immunocompromised subpopulations are much more severe, including debilitating voluminous diarrhea that may be accompanied by severe abdominal cramps, weight loss, and low grade fever (Juranek 1995). Mortality is a significant threat to the immunocompromised infected with *Cryptosporidium*:

the duration and severity of the disease are significant: whereas 1 percent of the immunocompetent population may be hospitalized with very little risk of mortality, *Cryptosporidium* infections are associated with a high rate of mortality in the immunocompromised (Rose 1997)

A follow-up study of the 1993 Milwaukee, WI outbreak reported that at least 50 *Cryptosporidium*-associated deaths occurred among the severely immunocompromised (Hoxie *et al.* 1997).

b. *Waterborne cryptosporidiosis outbreaks.* *Cryptosporidium* has caused a number of waterborne disease outbreaks since 1984 when the first one was reported in the U.S. Table II-1 lists reported outbreaks in community water systems (CWS) and non-community water systems (NCWS). Between 1984–1998, nine outbreaks caused by *Cryptosporidium* were reported in the U.S. with approximately 421,000 cases associated cases of illness (CDC 1993, 1996, 1998, 2000, and 2001). Solo-Gabriele and Neumeister (1996) characterized water supplies associated with U.S. outbreaks of cryptosporidiosis. They determined that almost half of the outbreaks were associated with ground water (untreated or chlorinated springs and wells), but that the majority of affected individuals were served by filtered surface water supplies (rivers and lakes). They found

that during outbreaks involving treated spring or well water, the chlorination systems were apparently operating satisfactorily, with a measurable chlorine residual.

Although the occurrence of *Cryptosporidium* in U.S. drinking water supplies has been substantiated by data collected during outbreak investigations, the source and density of oocysts associated with the outbreak have not always been detected or reported. Furthermore, because of limitations and uncertainties of the immunofluorescence assay (IFA) method used in earlier studies, negative results in source or finished water during these outbreaks do not necessarily mean that there were no oocysts in the water at the time of sampling.

TABLE II-1.—OUTBREAKS CAUSED BY *Cryptosporidium* IN PUBLIC WATER SYSTEMS: 1984–1998

Year	State	Cases	System	Deficiency	Source
1984	TX	117	CWS	3	Well.
1987	GA	13,000	CWS	3	River.
1991	PA	551	NCWS	3	Well.
1992	OR	††	CWS	3	Spring.
1992	OR	††	CWS	3	River.
1993	NV	103	CWS	5	Lake.
1993	WI	403,000	CWS	3	Lake.
1994	WA	134	CWS	2	Well.
1998	TX	1,400	CWS	3	Well.

††=Total estimated cases were 3,000. The locations were nearby and cases overlapped in time Definitions of deficiencies = (1) untreated surface water; (2) untreated ground water; (3) treatment deficiency (e.g., temporary interruption of disinfection, chronically inadequate disinfection, and inadequate or no filtration); (4) distribution system deficiency (e.g., cross connection, contamination of water mains during construction or repair, and contamination of a storage facility); and (5) unknown or miscellaneous deficiency.

3. Remaining Public Health Concerns Following the IESWTR and LT1ESWTR

This section presents the areas of remaining public health concern following implementation of the IESWTR and LT1ESWTR that EPA proposes to address in the LT2ESWTR. These are as follows: (a) Adequacy of physical removal to control *Cryptosporidium* and the need for risk based treatment requirements; (b) control of *Cryptosporidium* in unfiltered systems; and (c) uncovered finished water storage facilities.

EPA recognized each of these issues as a potential public health concern during development of the IESWTR, but could not address them at that time due to the absence of key data. Accordingly, this section begins with a description of how EPA considered these issues during development of the IESWTR, including the data gaps that were identified at that time. This is followed by a statement of the extent to which new information has filled these data gaps, thereby allowing

EPA to address these public health concerns in the LT2ESWTR proposal.

a. *Adequacy of physical removal to control Cryptosporidium and the need for risk based treatment requirements.* A question that received significant consideration during development of the IESWTR is whether physical removal by filtration plants provides adequate protection against *Cryptosporidium* in drinking water, or whether certain systems should be required to provide inactivation of *Cryptosporidium* based on source water pathogen levels. As discussed in the proposal, notice of data availability (NODA), and final IESWTR, EPA and stakeholders concluded that data available during IESWTR development were not adequate to support risk based inactivation requirements for *Cryptosporidium*. However, the Agency maintained that a risk based approach to *Cryptosporidium* control would be considered for the LT2ESWTR when data collected under the Information Collection Rule were available and other

critical information needs had been addressed.

The IESWTR proposal (59 FR 38832, July 29, 1994) (USEPA 1994) included two treatment alternatives, labeled B and C, that specifically addressed *Cryptosporidium*. Under Alternative B, the level of required treatment would be based on the density of *Cryptosporidium* in the source water. The proposal noted concerns with this approach, though, due to uncertainty in the risk associated with *Cryptosporidium* and the feasibility of achieving higher treatment levels through disinfection. Consequently, EPA also proposed Alternative C, which would require 2 log (99%) removal of *Cryptosporidium* by filtration. This was based on the determination that 2 log *Cryptosporidium* removal is feasible using conventional treatment.

In the 1996 Information Collection Rule (61 FR 24354, May 14, 1996) (USEPA 1996a), EPA concluded that the analytical method prescribed for measuring *Cryptosporidium* was