

LT2ESWTR is summarized in Section III of this proposal.

In September 2000, the Committee signed an Agreement in Principle reflecting the consensus recommendations of the group. The Agreement was published in a December 29, 2000 **Federal Register** notice (65 FR 83015, December 29, 2000) (USEPA 2000a). The Agreement is divided into Parts A & B. The entire Committee reached consensus on Part A, which contains provisions that directly apply to the Stage 2 DBPR and LT2ESWTR. The full Committee, with the exception of one member, agreed to Part B, which has recommendations for future activities by EPA in the areas of distribution systems and microbial water quality criteria.

The Committee reached agreement on the following major issues discussed in this notice and the proposed Stage 2 DBPR:

LT2ESWTR: (1) Additional *Cryptosporidium* treatment based on source water monitoring results; (2) Filtered systems that must comply with additional *Cryptosporidium* treatment requirements may choose from a "toolbox" of treatment and control options; (3) Reduced monitoring burden for small systems; (4) Future monitoring to confirm source water quality assessments; (5) *Cryptosporidium* inactivation by all unfiltered systems; (6) Unfiltered systems meet overall inactivation requirements using a minimum of 2 disinfectants; (7) Development of criteria and guidance for UV disinfection and other toolbox options; (8) Cover or treat existing uncovered finished water reservoirs (*i.e.*, storage facilities) or implement risk mitigation plans.

Stage 2 DBPR: (1) Compliance calculation for total trihalomethanes (TTHM) and five haloacetic acids (HAA5) revised from a running annual average (RAA) to a locational running annual average (LRAA); (2) Compliance carried out in two phases of the rule; (3) Performance of an Initial Distribution System Evaluation; (4) Continued importance of simultaneous compliance with DBP and microbial regulations; (5) Unchanged MCL for bromate.

III. New Information on *Cryptosporidium* Health Risks and Treatment

The purpose of this section is to describe information related to health risks and treatment of *Cryptosporidium* in drinking water that has become available since EPA developed the IESWTR. Much of this information was evaluated by the Stage 2 M-DBP Federal Advisory Committee when considering

whether and to what degree existing microbial standards should be revised to protect public health. It serves as a basis for the recommendations made by the Advisory Committee and for provisions in today's proposed rule. This section begins with an overview of critical factors that EPA considers when evaluating regulation of microbial pathogens. New information is then presented on three key topics: *Cryptosporidium* infectivity, occurrence, and treatment.

A. Overview of Critical Factors for Evaluating Regulation of Microbial Pathogens

When proposing a national primary drinking water regulation that includes a maximum contaminant level or treatment technique, SDWA requires EPA to analyze the health risk reduction benefits and costs likely to result from alternative regulatory levels that are being considered. For assessing risk, EPA follows the paradigm described by the National Academy of Science (NRC, 1983) which involves four steps: (1) Hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization. The application of these steps to microbial pathogens is briefly described in this section, followed by a summary of how EPA estimates the health benefits and costs of regulatory alternatives.

Hazard identification for microbial pathogens is a description of the nature, severity, and duration of the health effects stemming from infection. Under SDWA, EPA must consider health effects on the general population and on subpopulations that are at greater risk of adverse health effects. See section II.C.2 of this preamble for health effects associated with *Cryptosporidium*.

Dose-response assessment with microorganisms is commonly termed infectivity and is a description of the relationship between the number of pathogens ingested and the probability of infection. Information on *Cryptosporidium* infectivity is presented in section III.B of this preamble.

Exposure to microbial pathogens in drinking water is generally a function of the concentration of the pathogen in finished water and the volume of water ingested (exposure also occurs through secondary routes involving infected individuals). Because it is difficult to directly measure pathogens at the low levels typically present in finished water, EPA's information on pathogen exposure is primarily derived from surveys of source water occurrence. EPA estimates the concentration of pathogens in treated water by combining source water pathogen

occurrence data with information on the performance of treatment plants in reducing pathogen levels. Data on the occurrence of *Cryptosporidium* are described in section III.C of this preamble and in Occurrence and Exposure Assessment for the LT2ESWTR (USEPA 2003b). *Cryptosporidium* treatment studies are described in section III.D of this preamble.

Risk characterization is the culminating step of the risk assessment process. It is a description of the nature and magnitude of risk, and characterizes strengths, weaknesses, and attendant uncertainties of the assessment. EPA's risk characterization for *Cryptosporidium* is described in Economic Analysis for the LT2ESWTR (USEPA 2003a).

Estimating the health benefits and costs that would result from a new regulatory requirement involves a number of steps, including evaluating the efficacy and cost of treatment strategies to reduce exposure to the contaminant, forecasting the number of systems that would implement different treatment strategies to comply with the regulatory standard, and projecting the reduction in exposure to the contaminant and consequent health risk reduction benefits stemming from regulatory compliance. EPA's estimates of health benefits and costs associated with the proposed LT2ESWTR are presented in Economic Analysis for the LT2ESWTR (USEPA 2003a) and are summarized in section VI of this preamble.

B. *Cryptosporidium* Infectivity

This section presents information on the infectivity of *Cryptosporidium* oocysts. Infectivity relates the probability of infection by *Cryptosporidium* with the number of oocysts that a person ingests, and it is used to predict the disease burden associated with different *Cryptosporidium* levels in drinking water. Information on *Cryptosporidium* infectivity comes from dose-response studies where healthy human subjects ingest different numbers of oocysts and are subsequently evaluated for signs of infection and illness.

Data from a human dose-response study of one *Cryptosporidium* isolate (the IOWA study, conducted at the University of Texas-Houston Health Science Center) had been published prior to the IESWTR (DuPont *et al.* 1995). Following IESWTR promulgation, a study of two additional isolates (TAMU and UCP) was completed and published (Okhuysen *et al.* 1999). This study also presented a