

to develop “an accountable process to ensure meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications.” “Policies that have Tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.”

Under Executive Order 13175, EPA may not issue a regulation that has Tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by Tribal governments, or EPA consults with Tribal officials early in the process of developing the proposed regulation and develops a Tribal summary impact statement.

EPA has concluded that this proposed rule may have Tribal implications, because it may impose substantial direct compliance costs on Tribal governments, and the Federal government will not provide the funds necessary to pay those costs. EPA has identified 67 Tribal water systems serving a total population of 78,956 that may be subject to the LT2ESWTR. They will bear an estimated total annualized cost of \$135,974 at a 3 percent discount rate (\$138,910 at 7 percent) to implement this rule as proposed. Estimated mean annualized cost per system ranges from \$792 to \$23,979 at a 3 percent discount rate (\$844 to \$26,194 at 7 percent) depending on system size (see section 7 of the LT2ESWTR Economic Analysis (USEPA 2003a) for details). Accordingly, EPA provides the following Tribal summary impact statement as required by section 5(b) of Executive Order 13175.

EPA consulted with representatives of Tribal officials early in the process of developing this regulation to permit them to have meaningful and timely input into its development. Section VII.D.2.e describes EPA's outreach and consultation with Tribes, which included presentations on the LT2ESWTR at four Tribal conferences and meetings, mailing fact sheets and presentation materials regarding the proposal to Tribes on several occasions, and a teleconference with representatives of Tribal officials to comment on the proposed rule.

As discussed in section VII.D.2.e, Tribal representatives stated that protection of public health is important

regardless of the number of people a system is serving, and they recognized that the LT2ESWTR would provide a public health benefit. However, Tribal representatives were concerned about the availability of funding to implement the regulation and asked about the projected impact on Tribes (e.g., number of Tribal surface water systems that would be affected). Also, the Tribal representative to the Federal Advisory Committee was concerned that risk mitigation plans for uncovered finished water storage facilities account for cultural uses by Tribes.

EPA has concluded that the proposed LT2ESWTR is needed to reduce the risk associated with *Cryptosporidium* in public water systems using surface water sources. Projected benefits for today's proposal are substantially greater than costs. Moreover, as described in this section and in section VII.D.2.e, today's proposal addresses many of the concerns stated by Tribal representatives.

The LT2ESWTR will provide equivalent public health protection to all system sizes, including Tribal systems. By targeting additional treatment requirements to higher risk systems, the LT2ESWTR will minimize overall burden in comparison with requiring additional treatment by all systems. In addition, the provision in the proposal allowing *E. coli* screening to determine if *Cryptosporidium* monitoring is necessary will reduce monitoring costs for many small Tribal systems. (EPA notes that 66 of the 67 Tribal systems identified by the Agency as subject to the LT2ESWTR are small systems.) Due to the health risks associated with *Cryptosporidium*, capital expenditures needed for compliance with the rule will be eligible for Federal funding sources, specifically the Drinking Water State Revolving Fund. EPA is developing guidance that will address consideration of Tribal cultural uses of uncovered finished water storage facilities.

In the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and Tribal governments, EPA specifically solicits additional comment on this proposed rule from Tribal officials.

G. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks

Executive Order 13045: “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be “economically significant” as defined under Executive

Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule is subject to the Executive Order because it is an economically significant regulatory action as defined in Executive Order 12866, and we believe that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Accordingly, we have evaluated the environmental health or safety effects of *Cryptosporidium* on children. The results of this evaluation are contained in *Cryptosporidium: Risk for Infants and Children* (USEPA 2001d) and described in this section of this preamble. Further, while available information is not adequate to conduct a quantitative risk assessment specifically on children, EPA has assessed the risk associated with *Cryptosporidium* in drinking water for the general population, including children. This assessment is described in the Economic Analysis for the LT2ESWTR (USEPA 2003a) and is summarized in section VI of this preamble. Copies of these documents and supporting information are available in the public docket for today's proposal.

Cryptosporidiosis in children is similar to adult disease (USEPA 2001d). Diarrhea is the most common symptom. Other common symptoms in otherwise healthy (*i.e.*, immunocompetent) children include anorexia, vomiting, abdominal pain, fever, dehydration and weight loss.

The risk of illness and death due to cryptosporidiosis depends on several factors, including age, nutrition, exposure, genetic variability, disease and the immune status of the individual. Mortality resulting from diarrhea generally occurs at a greater rate among the very young and elderly (Gerba *et al.*, 1996). During the 1993 Milwaukee drinking water outbreak, associated mortalities in children were reported. Also, children with laboratory-confirmed cryptosporidiosis were more likely to have an underlying disease that altered their immune status (Cicirello *et al.*, 1997). In that study, the observed association between increasing age of children and increased numbers of laboratory-confirmed cryptosporidiosis suggested to the authors that the data