

benefits calculations, and both options still yield positive net benefits. The choice of the discount rate or time period before onset does not affect the relative ranking of options 1 and 2.

The range of uncertainty between costs and benefits overlaps, but many of the determinants of the range of uncertainty affect both costs and benefits equally, so low costs are associated with low benefits and high costs are associated with high benefits. The exception to this is the uncertainty in the cancer risk coefficient; since this interval is not probabilistic, FDA cannot estimate a probability that this rule will have negative net or positive net benefits for any of these options. However, FDA does consider our central estimates the most likely outcomes. Also note the potentially large benefits from a reduction in kidney toxicity and cocontaminants that we were not able to quantify, which could also affect the size and range of the net benefits.

Finally, our cost-best analysis reaches a different result than EPA's 2000 radionuclide analysis, which concluded that testing for uranium in water destined for human consumption has negative net quantifiable benefits (65 FR 76708). The reason for the difference between our results and EPA's results is that most of the costs of the EPA rule are applied to water that will not be consumed. People do not drink the vast majority of water treated by municipal facilities. Most of that water is used for cleaning, waste disposal, and outdoor uses. In contrast, almost all bottled water is used for human consumption. In fact, a typical bottled water facility processes as much water for drinking as a much larger municipal water facility. Consequently, fewer bottled water facilities would have to incur compliance costs to afford the same level of protection for water consumed as assumed in the EPA analysis.

B. Initial Small Entity Analysis

Under section 603(a) of the Regulatory Flexibility Act, for any proposed rule for which the agency is required by section 553 of the Administrative Procedure Act or any other law to publish a general notice of proposed rulemaking, the agency is required to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this companion proposed rule is a proposed rule for which a general notice of proposed rulemaking is required, and therefore, is subject to the Regulatory Flexibility Act, the agency will consider any comments it receives on the initial regulatory flexibility analysis in this companion

proposed rule when deciding whether to withdraw the direct final rule.

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this rule would have a significant economic impact on a substantial number of small entities.

FDA feels that the flexibility allowed in source testing requirements under option 2 in the impact analysis is the maximum amount of flexibility possible in this regulation. FDA is not establishing exemptions for final product testing since there is a need to test for naturally occurring uranium, which could be present in all source water.

According to the latest database search across the bottled water industry mentioned above, approximately 72 percent of firms qualify as small by the Small Business Administration (SBA) standard of having less than 500 full-time-equivalent employees. We assume that all SBA small firms operate a single facility for the purposes of this analysis. Since all facilities must adopt uranium testing, between 658 and 1,116 small firm facilities will incur a testing burden. Assuming the same distribution of size among out of compliance plants means that between 6 and 16 small facilities will incur the more costly burden of devoting resources to bring their water into compliance with the uranium standard issued in this rule. Table 6 of this document presents the average and maximum annual costs attributable to this rule for each small firm.

TABLE 6.—ANNUAL AVERAGE AND MAXIMUM COSTS PER FIRM

Category	Average (\$)	Maximum (\$)
Monitoring	125	179
Compliance	5,246	13,383
Total	5,400	13,600

Most small firms will only incur a \$125 (1.19 tests per year at an average cost of \$105 per test) uranium testing cost, although a few may incur up to \$179 (1.19 tests per year at an average cost of \$150 per test) in annual testing costs, which is 0.03 percent of the \$580,000 annual revenue of the median small bottled water firm. If a small firm operates more than one facility, testing

costs would be multiplied by the number of facilities they operate. However, between 6 and 16 small firms will incur an average of \$5,400 in total costs, and may incur as much as \$13,600 in total costs if for some reason they need to adopt the most expensive treatment option, although FDA considers this unlikely. The average treatment cost estimates represent .9 percent of median annual small firm sales, but could be as much as 2.3 percent of annual sales. However, 75 percent of the total reduction in cancer incidence of this rule is due to these small firms lowering the amount of uranium in their water, so it is essential that they adopt some sort of treatment technology.

C. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4), requiring cost-benefit and other analyses, in section 1531(a) defines a significant rule as “a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation) in any 1 year.” FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VII. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive Order requires agencies to “construe * * * a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a)(1) provides that “no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce (1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such