

Therefore, even if option 3 were permissible, the statute does not preclude the option with the highest net benefits.

Assumptions and Estimations Applicable to all Options

For the purposes of this analysis, FDA makes the following assumptions:

- Option 3, which has zero costs and benefits, will be considered the baseline for this analysis.

- The regulatory options we consider will have no organoleptic effect on the final bottled water product, and thus no impact on sales due to product quality. The cost of the regulation will be limited to the direct cost of testing, recordkeeping, and possible treatment technology investment or other compliance activity.

- Bottled water producers market their products based on meeting government safety testing requirements. However, any change in sales resulting from successful marketing either transfers revenue from one producer to another with no net loss to society, or causes increased sales of bottled water, which would mitigate the cost of this regulatory effort.

- Both the EPA NPDWR and the FDA standard of quality regulations will compel facilities to comply with the new uranium standard. Therefore, FDA assumes that options 1 or 2 will not differ in terms of the number of illnesses avoided or the burden placed on facilities compelled to adopt treatment technology. However, EPA and FDA do have differing monitoring requirements.

• The number of facilities:

Approximately 1,550 plants produced bottled water in 1998 (63 FR 25764, May 11, 1998). According to another database search conducted in 2002, the industry contains only 914 plants that would be subject to these rules. The 2002 count may not include bottled water services to business, but the decrease in facilities may also be a result of industry consolidation (Ref. 1). Because of this uncertainty, we use both totals to define our uncertainty interval.

- *Facilities out of compliance:* As in the EPA NPDWR analysis, we estimate the baseline incidence of facilities out of compliance by using the EPA's National Inorganics and Radionuclides Survey (NIRS). EPA took the results of the concentration of radionuclides found in the NIRS and extrapolated to the expected percent of municipal water facilities that would be out of compliance—by type and population served—for various uranium levels. Since most bottled water facilities that do not use a public water source use ground water, and are relatively small when compared to municipal water

plants, we assume that the percent of bottled water plants out of compliance with the uranium standard is approximately the same percent as the number of ground water municipal plants that serve less than 500 people. EPA used two methods to extrapolate the NIRS results to all facilities. Using both approaches, small ground water facilities have by far the largest estimated out of compliance percentages, so this is a conservative assumption. Table 1 of this document presents the four possible numbers of facilities out of compliance, using our two bottled water facility counts and EPA's two percentage estimates for groundwater facilities.¹ The lowest and the highest number of facilities identified here (8–22 facilities) will be used as the out of compliance uncertainty interval for cost calculations.

TABLE 1.—NUMBER OF FACILITIES POTENTIALLY OUT OF COMPLIANCE WITH THE URANIUM STANDARD

Total Number of Facilities	EPA Method 1 (1.4% out of compliance)	EPA Method 2 (0.9% out of compliance)
1550	22	14
914	13	8

Cost Calculations under Options 1 and 2

This cost analysis is separated into two sections: Possible compliance activity that firms may have to undertake to meet the uranium standard, and monitoring requirement for all facilities. Between 914 and 1,550 facilities may have to adopt a test for the uranium standard, and between 8 and 22 facilities may also have to take measures to come into compliance with the uranium standard. Uranium testing is a standard procedure that is available in many labs around the country. Firms can choose among many types of treatment options to come into compliance, including water softening/iron removal, point-of-use reverse osmosis, point-of-use anion exchange/activate alumina, blending, or finding an alternative source.

Compliance costs. FDA assumes that all facilities will come into compliance

¹ This is actually a percentage out of compliance for all facilities, but the percentage is dominated by small groundwater facilities. Above an MCL of 40 µg/L, no facilities other than groundwater facilities serving less than 500 people were predicted to be out of compliance. Since EPA did not directly estimate compliance percentages for the EPA MCL of 30 µg/L, we must assume that the number of facilities that are not small groundwater and are out of compliance would be negligible.

under options 1 and 2, so the relative ranking of options 1 and 2 is not affected by compliance cost calculations. In their 2000 NPDWR analysis, EPA estimated compliance investment needed per volume of water treated (here presented as per 83,000 gallons, which is the annual per household water use estimate used by EPA) for each of their extrapolation methods mentioned above, for each facility size category, and for several different uranium standards. However, they did not directly estimate the compliance cost of the 30 µg/L standard considered here. We use an average of the compliance costs per gallon between the 40 and 20 µg/L standard levels for which costs were estimated directly tested by EPA. We also assume that each facility out of compliance is of average size. According to EPA's per capita total water use estimates applied to bottled water, an average bottled water facility processes as much water as a municipal system serving between 42 and 72 households, so we use the compliance cost estimated for groundwater facilities serving between 100 and 500 people, which is the closest category EPA presents.

The extrapolation methods used to construct the uncertainty intervals explained above affect both the percent of facilities out of compliance and the total amount of uranium that would need to be removed to come into compliance. Therefore, the per volume costs will be different under EPA's different estimation methods even for identically sized facilities. As mentioned previously, firms can choose among many types of treatment options. Our central value of uncertain compliance cost estimates is based on EPA's study of technology adoption for previous standards and their decision tree analysis, and our uncertainty interval is defined by the least (alternative sourcing) and most (point-of-use methods) expensive options being adopted by every one of the 8–22 facilities assumed to be affected.

Table 2 of this document summarizes these calculations. Considerable economies of scale exist in water treatment, but EPA only estimates the effect of economies of scale between their grouped size categories. Therefore, within the EPA size category we are assuming applies to bottled water, total treatment cost depends only on the amount of water treated, even though it is probable that larger facilities within this class have a lower per volume cost of treating their water. Also, for these options we base estimates of the amount of bottled water treated per facility not on our uncertain number of facilities but