

TABLE 30.—PRESENT VALUE AND MARGINAL SAVINGS WITH RESPECT TO OPTION 4—Continued

Option	Present Value of Total Cost	Marginal Savings With Respect to Option 4	Description of Option Requirements
3	\$5,534,165,000	\$0	Exclude outer packagers
4	\$5,534,165,000	\$0	Exclude outer packagers and recordkeeping on outer packaging
5	\$4,818,810,000	\$715,355,000	Same as option 4 except records-access requirement is relaxed to 24 hours
6	\$5,087,535,000	\$446,630,000	Same as option 4 except intrastate facilities are excluded
7	\$5,332,584,000	\$201,581,000	Same as option 4 except mixed-type facilities that engage in farming are excluded
8	\$5,534,165,000	\$0	Same as option 4 except universal records retention of 1 year
9	\$5,534,165,000	\$0	Same as option 4 except universal records retention of 2 years
10	\$3,660,808,000	\$1,873,357,000	Proposed. Same as option 4 but limit foreign coverage to be the same as registration.
11	\$2,995,041,000	\$2,539,124,000	Same as option 4 but limit foreign coverage to the final holders prior to export.
12	\$2,657,566,000	\$2,876,599,000	Same as option 4 except all foreign facilities are excluded.
13	\$93,137,167,000	(\$87,603,002,000) <sup>1</sup>	Comprehensive coverage. Precise input to output record-keeping requirement.

<sup>1</sup> Numbers in parentheses are negative.

*Sensitivity of cost estimates to assumptions:* For all the options, FDA attempted to quantify the uncertainty associated with redesign costs and the number firms and facilities exclusively dedicated to imports, but we had no basis for assigning distributions to other uncertain components. By far the largest source of uncertainty is the premium on products that would be subject to new identity preservation under option 13. FDA also tested the sensitivity of other sources of uncertainty under option 10, in order for the reader to compare various sources of uncertainty and submit comments regarding our assumptions. Although the dollar sensitivities to the assumptions specified in Table 31 of this document should be similar across the options, many of the percentage sensitivities would—because of different base costs—differ under other options. FDA believes that the ranking of the costs of these options is not affected by any uncertainty in our estimates.

There is significant uncertainty in the estimate of the number of mixed-type

facilities that engage in farming. Based on research described earlier, our estimate of the number of mixed-type facilities that engage in farming that would be covered by this proposed rule is 30,497. To determine the sensitivity of the cost estimates to changes in the numbers of mixed-type facilities that engage in farming, a sensitivity analysis was performed in which the number of these types of facilities was increased by 10 percent.

Table 31 of this document presents the results of the sensitivity analyses that we conducted. For option 13, Table 31 reports the effect of an increase in crop premium for identity preservation of 1 percent for all crops. For option 10, Table 31 reports the effect of a 10 percent increase in the estimate of the number of mixed-type facilities that engage in farming, and 10 percent cost increases for each component cost on the mean first-year total cost estimates. For redesign costs, we assumed a 10 percent increase in the medium cost estimate.

Finally, to be consistent with the analysis conducted for the Registration proposed rule, a sensitivity analysis was conducted that accounted for the possibility that a number of foreign firms would cease to export to the United States because of the burden imposed by these regulations. This is particularly relevant when considering the burden imposed on foreign firms by the Registration proposed rule. In the analysis of the registration proposed rule, it was estimated that approximately 16 percent of small manufacturers and processors (defined in that analysis as those exporting 10 or fewer line items to the United States) would cease exporting to the United States because of the increase in costs due to that proposed rule. Consistent with the analysis of the Registration proposed rule, we analyzed the cost sensitivity of a 16 percent reduction in the number of foreign firms. FDA requests comments on other desired sensitivity analyses.