

Year 1	\$412,474,000
Year 2	\$689,341,000
Year 3	\$298,427,000
Year 4	\$278,904,000
Year 5	\$260,658,000
Year 6	\$243,605,000
:	:
:	:
Year 15	\$132,505,000
:	:
:	:
Year 30	\$48,026,000
:	:
:	:
Present Value	\$5,663,484,000

¹ Each cell that contains only the symbol “:” is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 3: Require all elements of option 2 (comprehensive coverage, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) except persons who manufacture, process, pack, hold, receive, distribute, transport, or import outer food packaging are excluded.

FDA identifies the option excluding outer packaging facilities separately because the fundamental risk to the public from contaminated packaging is probably different from the risk associated with contaminated food, including inner materials that are food contact substances.

FDA was unable to find any data that discriminated between outer packaging manufacturers and distributors and those that manufacture or distribute materials that FDA currently regulates as food contact substances, including plastic beverage bottles and inner cereal box liners. The possibility exists that some of these data describe manufacturers and distributors of outer packaging materials only, and the remainder describe manufacturers and distributors of both outer packaging materials and food contact substances. To distinguish between manufacturers and distributors of outer packaging materials and food contact substances, we assume that the data is distributed uniformly over the interval between 0 and 1, and each packaging facility has an equal probability (0.5) of being either one or both types of facilities. Based on this distributional assumption, the expected number of manufacturers and distributors of outer packaging materials exclusive of food contact substances is 36,906.5 (or 73,813 divided by 2). We request comments on this distributional assumption.

The range and discounted costs for option 3 are estimated to be the same as for option 4, as explained in the following paragraphs, and are reported in tables 9 and 10. The discount computations are made using mean costs. Although the recurring costs reported for year 3 and later years are the same in nominal terms (i.e., \$334,682,000 reported in table 9), they are reported in discounted terms for each year in table 10. As previously discussed, costs incurred in year 1 are learning costs for all firms and redesign and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms, and learning costs and records access costs for new firms.

The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

Option 4: Require all components of option 3 (no outer packagers, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) but do not require persons that are required to establish and maintain records on food to establish and maintain records on the food’s outer packaging.

FDA is unable to distinguish between the costs incurred when these persons are required to keep records on the food’s outer packaging and when they are not required to keep such records. Persons required to establish and maintain records on foods will also keep records on the food contact substances they use because these substances meet the definition of food. Moreover, we believe that a large portion of outer packaging materials used by persons required to establish records is shipped to that person along with food contact substances. Consequently, persons keeping records on food contact substances are also likely to keep records on the food’s outer packaging under current recordkeeping practices. As a result, the cost savings from exempting recordkeeping on outer packaging are assumed to be negligible and the costs of this option are assumed to be the same as option 3. We request comments on this assumption.

Tables 9 and 10 present the range and discounted cost estimates for options 3 and 4.

TABLE 9: TOTAL ANNUAL COSTS, OPTIONS 3 AND 4

	Mean	Low	High	Average Mean Cost per Firm
Year 1	\$400,491,000	\$318,274,000	\$404,529,000	\$417
Year 2	\$711,860,000	\$566,254,000	\$738,803,000	\$741
Year 3 and later years	\$334,682,000	\$279,074,000	\$334,079,000	\$348