

TABLE 4.—REDESIGN COSTS, OPTION 2—Continued

	Firm Count	Middle Estimate	Low Estimate	High Estimate	Average Middle Cost per Firm
Other Facility Types	124,714	\$151,170,000	\$103,532,000	\$265,500,000	\$1,212
Total Foreign	182,191	\$220,838,000	\$151,246,000	\$387,859,000	\$1,212

¹ Includes both outer packaging and food contact substances.

Additional records maintenance: Table 5 of this document presents the calculations for additional records maintenance costs. Based on the previous discussion, the annual burden per facility that is assumed in the computation of the cost of additional records maintenance is: 13 hours for most facilities, 2.5 hours for convenience stores, and 6.5 hours for packaging facilities. A \$25.10 hourly wage is also assumed in the computation. For example, the

additional records maintenance costs for manufacturers reported in the top row of Table 5 is calculated by multiplying the number of facilities (43,376) by the number of hours required (13) and the hourly wage (\$25.10).

In Table 5, variation in the number of importers reflects the range of uncertainty in the data on the number of these facilities. Additional records maintenance costs are assumed to be incurred by facility. The estimated average cost per firm for additional

records maintenance is also reported in table 5 and is computed using the facilities-to-firm adjustment factor reported in table 1. FDA assumes that facilities will begin to incur the additional records maintenance burden in the second year following the enactment of the final rule. There is considerable nonquantified uncertainty surrounding these estimates; FDA requests comments.

TABLE 5.—ADDITIONAL RECORDS MAINTENANCE COSTS, OPTION 2

	Facility Count	Cost	Average Cost per Firm
Manufacturers	43,376	\$14,154,000	\$383
Wholesalers/Warehouses	95,745	\$31,242,000	\$406
Packaging ¹	73,813	\$12,043,000	\$174
Transporters/Packers	16,773	\$5,473,000	\$361
Retail Grocery and Specialty Food	207,657	\$67,759,000	\$442
Convenience Stores	128,985	\$8,094,000	\$118
Mixed-Type Facilities that Engage in Farming	30,497	\$9,951,000	\$408
Importers	5,036	\$1,643,000	\$408
Total Domestic	601,883	\$150,359,000	\$335
Foreign			
Final Holders	52,728	\$17,205,000	\$278
Manufacturers	85,431	\$27,876,000	\$261
Other Facility Types	311,786	\$101,736,000	\$278
Total Foreign	449,945	\$146,817,000	\$274

¹ Includes both outer packaging and food contact substances.

Access costs: For the purposes of this analysis, as mentioned above, FDA assumes that the 4-hour or 8-hour records access times in option 2 imply extra planning and may imply a change in record retention practices for many firms. FDA has little information on the

possible impact of this requirement, and requests comments. As previously discussed, the computation of the access costs reported in Table 6 of this document assumes a 6-hour burden per firm for developing an access plan and a \$25.10 hourly wage. FDA assumes that

all access planning costs will be incurred in the first year following the final rule for large and small firms, and in the second year following the final rule for very small firms. Table 6 presents the calculations.