

Option 12: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) except all foreign food facilities are excluded.

This option excludes all foreign firms from recordkeeping requirements and has even less coverage than under option 11. Tables 24 and 25 of this document present the cost estimates. As previously discussed, discount computations are made using mean

costs and assume no increase in real labor cost and a 7 percent real discount rate. Although the recurring costs reported for year 3 and later years are the same in nominal terms (i.e., \$162,228,000 reported in Table 24), they are reported in discounted terms for each year in Table 25 of this document. 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.

TABLE 24.—TOTAL ANNUAL COSTS, OPTION 12

	Mean	Low	High	Average Mean Cost per Firm
Year 1	\$139,947,000	\$125,857,000	\$152,775,000	\$329
Year 2	\$376,310,000	\$334,230,000	\$421,832,000	\$885
Year 3 and later years	\$162,228,000	\$155,337,000	\$169,446,000	\$381

TABLE 25.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS: OPTION 12

	Discounted Annual Costs: Option 12	Marginal Savings of Option 12 With Respect to Option 4
Year 1	\$139,947,000	\$260,544,000
Year 2	\$351,692,000	\$313,598,000
Year 3	\$141,696,000	\$150,628,000
Year 4	\$132,426,000	\$140,774,000
Year 5	\$123,763,000	\$131,564,000
Year 6	\$115,666,000	\$122,958,000
: ¹	:	:
:	:	:
Year 15	\$62,915,000	\$66,880,000
:	:	:
:	:	:
Year 30	\$22,803,000	\$24,241,000
:	:	:
:	:	:
Present Value as of Year 1	\$2,657,566,000	\$2,876,599,000

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 13: Facilities must be able to tie specific input ingredients to specific products.

Most comments FDA received during its early outreach efforts for this proposed rule stated that tying specific raw input ingredients to specific finished products would significantly increase the burden on industry, which

would translate into large social costs. Some comments suggested that some facilities have systems in place that can link each lot of raw ingredient to each lot of finished product, but such systems are rare for bulk agricultural commodities. For example, it is common practice in handling agricultural commodities to commingle

raw ingredients from several suppliers in a large silo or storage tank. While this business practice would not be required to change under options 2–12, option 13 would add the significant new burden of requiring firms that traditionally commingle raw ingredients from several suppliers to redesign a production or storage strategy that would allow them