

**4. Option Four: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Interstate and Intrastate Commerce, Not Including Mixed-Type Facilities**

Option four has the same registration and U.S. agent requirements as option two, but does not require mixed-type facilities to register. Tables 21, 22, 23, 24, and 25 provide a summary of the data for cost estimates under option 4 for domestic facilities, foreign facilities, and FDA, respectively.

FDA does not believe this option is legally viable, since some mixed-type facilities engage in activities (such as manufacturing/processing for commercial distribution) that are clearly within the scope of the registration requirement as enacted by Congress. Nevertheless, we are including a discussion of this option for comparison purposes.

Excluding mixed-type facilities lowers the number of affected domestic facilities, from 207,324 affected facilities under option 2 to 171,549. This would lower the first year cost for domestic facilities from \$13.6 to \$11.2 million dollars. The annual cost for domestic facilities would be lowered from \$3.4 to \$2.8 million. Total first year costs would be lowered from \$344.5 to \$342.0 million dollars.

**TABLE 21.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 4**

2000 CBP	103,125
1999 Nonemployer statistics	68,424
Total domestic	171,549

**TABLE 22.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 4**

Administrative worker wage (includes overhead)	25.1
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**TABLE 22.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 4—Continued**

Manager wage (includes overhead)	56.74
Percent with Internet access US	71%
Research time with Internet (hours)	1
Research time without Internet (hours)	2
Research cost with Internet	\$3,057,000
Research cost without Internet	\$2,497,000
Administrative time for form (hours)	0.75
Manager time for form (hours)	0.25
Form costs	\$5,663,000
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
Annual facility costs	\$2,821,000
Total domestic costs	\$11,217,000

**TABLE 23.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 4**

Foreign holders and packagers	100,027
Foreign manufacturers/processors	125,450
Stops exporting	16%
Total facilities	205,405

**TABLE 24.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 4**

Speaks English	16%
Has Internet access	31%
Has U.S. agent	10%
Cost of U.S. agent (annual)	\$1,000
Hourly wage rate	\$25
Time to find agent (hours)	5
Additional time language (hours)	5
Additional time Internet (hours)	5
First year agent cost	\$67,340,000
Agent fee (annual cost)	\$194,868,000
Administrative time (hours)	1
Additional time language (hours)	5
Additional time Internet (hours)	5
First year administrative costs	\$44,418,929
Time to fill out form (hours)	1
Additional time language (hours)	1
Additional time Internet (hours)	1
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
First year form cost	\$12,992,000
Total first year costs	\$319,619,000
Total annual costs	\$228,370,000

**TABLE 25.—COSTS INCURRED BY FDA UNDER OPTION 4**

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	\$8,200,000	\$3,000,000	\$3,300,000	\$2,300,000	\$2,300,000
Maintenance/steady state	\$1,560,000	\$3,500,000	\$4,300,000	\$4,300,000	\$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	\$110,588	\$110,588	\$110,588	\$110,588	\$110,588
Cost per paper submission	\$10	\$10	\$10	\$10	\$10
Number of domestic paper submissions	49,749	19,900	19,900	19,900	19,900