

registrants reminding them to keep their registrations up-to-date and verifying the mailing addresses of the registrants.

FDA presents costs for the first 5 years in table 15 of this document. Wage rates and paper submission costs are

increased by 3 percent each year to account for inflation. Annual costs are discounted at 7 percent.

TABLE 15.—YEARLY COST ESTIMATE FOR FDA UNDER OPTION 2

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	\$10.00	\$10.00	\$10.00	\$10.00
Number of domestic paper submissions	60,124	24,050	24,050	24,050	24,050
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	207,324	207,324	207,324	207,324	207,324
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	\$1	\$1.00	\$1.00	\$1.00	\$1.00
Mailings to foreign facilities	\$1	\$1.00	\$1.00	\$1.00	\$1.00
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	8,280	3,312	3,312	3,312	3,312
Cost per error	\$15	\$15.00	\$15.00	\$15.00	\$15.00
Total costs	\$11,279,000	\$7,398,000	\$8,498,000	\$7,276,000	\$7,276,000
Discounted total costs	\$11,279,000	\$6,914,000	\$7,422,000	\$5,939,000	\$5,551,000

3. Option Three: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Interstate Commerce, Including Mixed-Type Facilities

Option three has the same requirements as option two, but does not require domestic facilities that participate only in intrastate commerce to register. FDA tentatively concludes that this option is not legally viable. The Bioterrorism Act does not seem to limit the scope of the statute to facilities that engage only in interstate commerce. Tables 16, 17, 18, 19, and 20 of this document provide a summary of the data for cost estimates under option 3 for domestic facilities, foreign facilities, and FDA, respectively.

Excluding intrastate facilities would lower the number of affected, domestic facilities from 207,324 affected facilities under option two to 107,646. This would lower the first year cost for domestic facilities from \$13.6 to \$7.0 million dollars. The annual cost would be lowered from \$3.4 to \$1.8 million dollars. Total first year costs would be

lowered from \$344.5 to \$337.6 million dollars.

TABLE 16.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 3

FACTS data	71,871
Mixed-type farms	25,365
Retail processors	10,410
Total domestic	107,646

TABLE 17.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 3

Administrative worker wage (includes overhead)	25.1
Manager wage (includes overhead)	56.74
Percent with Internet access US	71%
Research time with Internet (hours)	1

TABLE 17.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 3—Continued

Research time without Internet (hours)	2
Research cost with Internet	\$1,918,000
Research cost without Internet	\$1,567,000
Administrative time for form (hours)	0.75
Manager time for form (hours)	0.25
Form costs	\$3,553,000
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
Annual facility costs	\$1,770,000
Total domestic costs	\$7,038,000