

8. Option Eight: Issue No New Regulation and Allow the Bioterrorism Act's Default Registration Requirements to Take Effect

The Bioterrorism Act requires facilities to register with FDA by December 12, 2003, even if FDA has not issued final regulations by this date. Failure to do so for both foreign and domestic facilities is a prohibited act, and FDA must hold food from unregistered foreign facilities at the port of entry until they are registered. Thus,

facilities have an incentive to register with FDA. Failure to issue a final regulation would result in an unworkable, chaotic system. The Bioterrorism Act also requires facilities that register in the absence of a final rule to re-register with FDA as specified in the final rule once it is issued.

It is not possible to predict the costs or benefits of this option because the statute is not specific enough to predict how it would be implemented. It seems likely that many facilities will attempt to register, given the penalties for failure

to register. However, if FDA receives all paper, non-standardized registrations, it will be extremely difficult for FDA to process the registrations and to use the information provided. It would also be a slow process for FDA to issue registration numbers.

9. Summary of Costs

Table 42 of this document presents a summary of costs for options 2 through 7 for domestic facilities, foreign facilities, and FDA. Costs in future years are discounted at 7 percent.

TABLE 42.—TOTAL COST OF OPTIONS 2 THROUGH 7 FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND FDA.

	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7
Domestic first year costs	\$13,557,000	\$7,038,000	\$11,217,000	\$12,256,000	\$13,212,000	\$13,212,000
Foreign first year costs	\$319,619,000	\$319,619,000	\$319,619,000	\$318,335,000	\$319,619,000	\$311,762,000
FDA first year costs	\$11,279,000	\$10,907,000	\$11,145,000	\$11,279,000	\$11,225,000	\$11,225,000
Total first year costs	\$344,455,000	\$337,564,000	\$341,981,000	\$341,870,000	\$344,056,000	\$336,199,000
Domestic second year costs	\$3,186,000	\$1,654,000	\$2,636,000	\$2,181,000	\$3,105,000	\$3,105,000
Foreign second year costs	\$213,430,000	\$213,430,000	\$213,430,000	\$212,831,000	\$213,430,000	\$212,696,000
FDA second year costs	\$6,914,000	\$6,769,000	\$6,862,000	\$6,817,000	\$6,893,000	\$6,893,000
Total second year costs	\$223,530,000	\$221,853,000	\$222,928,000	\$221,829,000	\$223,428,000	\$222,694,000
Domestic third year costs	\$2,978,000	\$1,546,000	\$2,464,000	\$2,039,000	\$2,902,000	\$2,902,000
Foreign third year costs	\$199,467,000	\$199,467,000	\$199,467,000	\$198,907,000	\$199,467,000	\$198,782,000
FDA third year costs	\$7,422,000	\$7,287,000	\$7,374,000	\$7,332,000	\$7,403,000	\$7,403,000
Total third year costs	\$209,867,000	\$208,300,000	\$209,305,000	\$208,278,000	\$209,772,000	\$209,087,000
Domestic fourth year costs	\$2,783,000	\$1,445,000	\$2,303,000	\$1,905,000	\$2,712,000	\$2,712,000
Foreign fourth year costs	\$186,418,000	\$186,418,000	\$186,418,000	\$185,895,000	\$186,418,000	\$185,777,000
FDA fourth year costs	\$5,939,000	\$5,814,000	\$5,894,000	\$5,855,000	\$5,922,000	\$5,922,000
Total fourth year costs	\$195,140,000	\$193,677,000	\$194,615,000	\$193,655,000	\$195,052,000	\$194,411,000

a. *Sensitivity to assumptions.* A number of assumptions in the analysis significantly affect the cost estimates. To understand how these assumptions affect the cost estimates, FDA re-estimates the total costs under

alternative assumptions. FDA uses option 7, the proposed option, to compare across assumptions. Table 43 summarizes the results of the sensitivity analysis.

FDA looked at the number of mixed-type facilities. In option 6, FDA estimated that there are approximately 30,497 mixed-type facilities that manufacture/process food for distribution to nonconsumers or pack or