

hold food received from off the facility based on data from the Census of Agriculture and information from CES (Ref. 7). Because there are over 2 million farms in the United States, small changes in assumptions about the percentage of farms that are mixed-type facilities would result in a large change in the total number of affected farms. If the total number of farms that are mixed-type facilities were 100,000, the total, first year, domestic costs increase from \$13.2 to \$17.8 million.

Another significant source of uncertainty is the amount of time it would take facility employees to read and understand the requirements and for foreign facilities to find a U.S. agent. To test the time assumptions, FDA estimated the costs assuming all the time estimates for administrative activities were doubled. This increases the cost estimates for domestic facilities from \$13.2 to \$19.8 million and increases the cost estimates for foreign facilities from \$311.8 to \$423.5 million.

Hiring and retaining a U.S. agent is a significant cost for foreign facilities. FDA tested how this affects total cost estimates by doubling the percent of foreign manufacturers that have U.S.

agents from 10 percent to 20 percent. This lowers the first year cost for foreign facilities from \$311.8 to \$297.3 million.

Also subject to a great deal of uncertainty is the number of foreign manufacturers/processors who can read and write in English. Research on the topic shows widely ranging estimates of the number of English speakers in countries where English is not the primary language. Even in countries where English is a primary or secondary language, many inhabitants may not be fluent in English (Ref. 14). However, more than one individual may work in a facility in an appropriate position to fill out the registration form. This increases the probability that an individual with English skills sufficient to fill out the registration form may be available. FDA estimated that 16 percent of foreign facilities had employees that were fluent in English. To test our assumption about the percentage of foreign facilities with employees who are fluent in English, FDA looked at the alternate assumption that 32 percent of foreign facilities would have a worker with the capability to research and fill out the form in English. This change

decreases the total cost to foreign facilities from \$311.8 to \$303.4 million.

FDA assumed that the number of foreign facilities that hold food products before exporting them to the United States is equal to the number of domestic brokers and consignees, because of the lack of data about foreign facilities holding and doing de minimis processing of food. To test this assumption, FDA looked at the costs if the number of foreign holders and de minimis processors is 160,000. Changing this assumption has a large effect on the foreign and total cost, increasing the foreign cost from \$311.8 to \$405.2 million and the total cost from \$336.2 to \$429.7 million.

FDA tested the effect of changing the annual U.S. agent fee. If the average U.S. agent fee is \$1,500, instead of \$1,000, the costs to foreign facilities will be increased from \$311.8 to \$409.2 million.

Finally, FDA tested the assumption that the foreign wage rate is the same as the domestic wage rate and re-estimated the costs for a foreign wage rate of \$15 per hour. The total cost to foreign facilities was reduced from \$311.8 to \$265.0 million under this assumption.

TABLE 43.—SENSITIVITY ANALYSIS (RELATIVE TO OPTION 7)

First Year Costs	Total Domestic Cost (dollars)	Total Foreign Cost (dollars)	Total FDA Cost (dollars)	Total Cost (dollars)
Under current assumptions ¹	13,212,000	311,762,000	11,225,000	336,199,000
Percentage change from baseline	0%	0%	0%	0%
100,000 mixed-type facilities that engage in farming	17,756,000	311,762,000	11,484,000	341,002,000
Percentage change from baseline	34%	0%	2%	1%
Time costs are doubled	19,754,000	423,521,000	11,225,000	454,500,000
Percentage change from baseline	50%	36%	0%	35%
20 percent of foreign manufacturers have U.S. agents	13,212,000	297,257,000	11,225,000	\$321,694,000
Percentage change from baseline	0%	-5%	0%	-4%
32 percent of foreign facilities are fluent in English	13,212,000	303,395,000	11,474,000	\$328,081,000
Percentage change from baseline	0%	-3%	2%	-2%
160,000 foreign holders	13,212,000	405,168,000	11,304,000	429,684,000
Percentage change from baseline	0%	30%	1%	28%
U.S. agent fee \$1,500	13,212,000	409,195,000	11,225,000	433,632,000
Percentage change from baseline	0%	31%	0%	29%
Foreign wage rate \$15	13,212,000	265,004,000	11,225,000	289,441,000