

FDA estimates the number of new facilities entering each year would be equal to 10 percent of the total current number of facilities. Thus, the annual cost for registration of new foreign facilities would equal 10 percent of the first year cost to facilities.

Facilities that go out of business would need to notify FDA of the cancellation of their registration. The cost to the facility of canceling the registration would be the wage rate times 1 hour to cancel the registration. FDA estimates that 10 percent of the total, current number of facilities would go out of business each year. Table 13 presents a summary of the data used to estimate the cost to foreign facilities to comply with option 2.

TABLE 13.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 2

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

TABLE 14.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 2

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

TABLE 14.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 2—Continued

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

viii. *Cost due to port delays.* FDA anticipates that some foreign facilities would not learn of the requirements before shipping their products to the United States. The administrative costs of learning about the registration requirements for these foreign facilities would be the cost of finding out at the port of entry. FDA requests comment on the percentage of foreign facilities that would become aware of the registration requirement at the U.S. port of entry. For these facilities, the cost of complying would be the possible one-time loss of value of their shipment and other costs of delay, in addition to the cost of registering and finding and hiring a U.S. agent. FDA estimates the cost to foreign facilities of becoming informed about the regulatory requirement is the number of foreign facilities multiplied by either the cost of information, re-exporting the shipment, or a delayed shipment at the U.S. port, whichever is lower.

FDA must hold shipments at the U.S. port for as long as it takes the foreign facility to register with FDA. To register, a foreign facility first must be informed of the delay at the port by the importer, consignee, owner, or transporter. This may happen very quickly via a phone call or e-mail message, or take hours if there is a large difference in time zones. Next, the foreign facility must find and hire a U.S. agent, if it does not already have one. If the foreign facility is open during U.S. business hours and has access to the Internet and a fax machine to find an agent and sign a contract, it may find an agent quickly. If the foreign facility is not in a time zone compatible with customary business hours in the United States or does not have easy access to the Internet or fax machine, finding and hiring an agent may take

longer. The cost of the delay to the foreign facility is the cost of storing the shipment and loss of value of the shipment due to the delay. For perishable products, a delay may reduce the value of the shipment significantly, perhaps even to zero. For nonperishable products, there may be transaction costs due to cancellation of a contract and finding a new buyer. FDA expects that to the extent there are significant port delays, they typically will occur with food manufactured/processed, packed or held at facilities that ship infrequently to the United States. Delays also will be longer and more likely for shipments from facilities that are more distant from the United States or have difficulty communicating with the United States. Perishables, due to their short shelf life, are more likely to be shipped from countries that are geographically close to the United States. For these reasons, FDA expects that costs arising from delays for nonperishable products may be as high or higher than costs arising from perishable products. FDA requests comments on the length of delay for shipments held while waiting for the foreign facility to register and on the costs of the delay, such as loss of product value, storage costs, and transaction costs.

ix. *FDA costs.* FDA's costs include creating and maintaining a database, processing paper submissions, and sending annual mailings to registrants. Developing and maintaining a database includes automatically entering registrations into the database that arrive electronically and sending an electronic receipt and facility registration number back to the registrant. FDA estimates that four full time employees (FTEs) would be needed to oversee the database. An employee's wage is estimated to be equal to a GS-12, step one, in the Washington, DC metro area, which is \$55,924 per year (Ref. 10). To get the cost of the labor to FDA, FDA doubles the wage rate to include overhead costs, such as health insurance, office space, and retirement benefits. Additionally, paper submissions would have to be entered manually, at an estimated cost of \$10 per submission. FDA estimates that facilities that do not have access to the Internet would submit paper registrations. FDA also estimates a 10 percent error rate for paper submissions based on estimates of error rates for another FDA database (Ref. 18). Each paper submission with an error will result in an additional cost for mailing and re-processing. FDA intends to send an annual e-mail or mailing to all