

the costs undertaken by trade organizations, but discusses these costs in the qualitative costs section.

Second, once a representative of the facility becomes aware of the regulations, he or she would need to research the requirements of the regulation. This would require finding a copy of the requirements and reading and understanding them.

Representatives of the facility may find a copy of these requirements on the Internet, in the **Federal Register**, in trade association meetings or mailings, or at a library. Several comments stated that many businesses might not have access to the Internet. Administrative costs would be higher for facilities that do not have access to the Internet, and would have to write to FDA or find other sources of information. In the United States, 59.10 percent of the population has accessed the Internet at least once in the three months prior to being surveyed (Ref. 11). An SBA report (Ref. 12) cites two studies that report 40 and 47 percent of small businesses had Internet access in 1998. An updated report from Dun and Bradstreet in 2002 reports 71 percent of small businesses have Internet access (Ref. 13).

Electronic registration will allow facilities an immediate confirmation and registration number. FDA believes that most domestic facilities with Internet access will register electronically. However, some may register on paper forms they receive from trade organizations, newsletters, or other sources. However, FDA believes that this number of paper submissions will be offset by registrants that choose to register electronically who do not have Internet access at their place of business. These registrants may use computers with Internet access belonging to libraries, friends, or in an Internet café. Therefore, FDA assumes that 71 percent of domestic registrants will research and register electronically. FDA estimates it would take facilities with Internet access 1 hour to research the requirements and facilities without Internet access 2 hours. FDA requests comments on this assumption.

Third, once the requirements are understood, the form has to be filled out and sent to FDA, either by mail or electronically. FDA estimates it would take 45 minutes of an administrative worker's time to find the correct information and fill out the form.

Fourth, the owner, operator, or agent in charge must verify the form. This cost would be 15 minutes of the owner, operator, or agent in charge's time.

iv. Domestic facilities updates, cancellations, and new registrations (annual costs). Facilities are required to

update their registration when a change occurs in any information previously submitted on the registration form. Several comments suggested the requirement to update registrations might be burdensome because some information such as product lines and facility names change frequently and, therefore, could require frequent changes to registrations. FDA does not have any data on how often changes in product lines or other information included in the registration submission would occur. However, given that 10 percent of facilities go out of business each year, FDA estimates that a higher percentage, 20 percent, of all facilities will have to update their registration each year. FDA requests comments on this assumption. FDA also considers an alternative option (option 5) where product codes are not included on the registration form.

To update a registration, a worker at the facility will have to find a copy of the form, look up the facility's registration number, fill out the form, and the owner, operator, or agent in charge will have to verify the form to update a submission. The cost to the facility of updating would be 45 minutes of an administrative worker's time and 15 minutes of a manager's time to certify the changed registration.

New facilities would incur the same costs to learn about the regulation and fill out the registration form in future years as existing facilities experience in the first year. 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 registering new facilities would equal 10 percent of the first year costs to existing facilities.

Facilities that go out of business would need to notify FDA of the cancellation of their registration. Similar to updating registration, a worker at the facility will have to find a copy of the form, look up their registration number, fill out the form, and the owner, operator, or agent in charge will have to verify the form to cancel a registration. The cost to the facility of canceling the registration would be 45 minutes of an administrative worker's time to find and fill out the form and 15 minutes of a manager's time to cancel the registration. FDA estimates that 10 percent of the total, current number of facilities would go out of business each year. Table 9 presents a summary of domestic facilities covered under option 2, and table 10 summarizes the data used to estimate the cost of complying with option 2.

TABLE 9.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 2

2000 CBP	103,125
1999 Nonemployer statistics	68,424
Mixed-type facilities that engage in farming	25,365
Retail processors	10,410
Total domestic	207,324

TABLE 10.—SUMMARY OF COSTS FOR DOMESTIC FACILITIES UNDER OPTION 2

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
Research time without Internet (hours)	2
Research cost with Internet	\$3,695,000
Research cost without Internet	\$3,018,000
Administrative time for form (hours)	0.75
Manager time for form (hours)	0.25
Form costs	\$6,844,000
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
Annual facility costs	\$3,409,000
Total domestic costs	\$13,557,000

v. Foreign facility first year costs. FDA expects foreign facilities to go through the same four steps to comply with the regulation as domestic facilities: a worker must become aware of the regulation, learn the requirements, and fill out the form; the owner, operator, or agent in charge then must verify the form. There are additional fifth and sixth steps for foreign facilities to find, and then hire a U.S. agent. To estimate the cost of registration for foreign facilities, FDA assumes that they would incur the same per facility costs as