

TABLE 7.—NO. OF AFFECTED FACILITIES—Continued

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|---|---------|
| Other sources | 77,150 |
| Total domestic | 216,271 |
| Foreign facilities: | |
| Foreign manufacturers/processors | 125,450 |
| Percent that will stop exporting | 16% |
| Adjusted number of manufacturers/processors | 105,378 |
| Foreign packers and holders | 100,027 |
| Total foreign | 205,405 |
| Total | 421,676 |

4. Costs

a. Time estimates.

In the PRIA, FDA anticipated that it would take four steps for a domestic facility to comply with the regulation: (1) The facility becomes aware of the regulation; (2) the facility learns what the requirements are; (3) an administrative worker fills out the form; and (4) the owner, operator, or agent in charge of the facility confirms the submission is correct. FDA also anticipated that facilities with Internet access that research and register online will have lower registration costs than facilities without Internet access. The interim final rule permits the owner, operator, agent in charge, or an individual authorized by the owner, operator, or agent in charge to submit the registration. Although the owner, operator, or agent in charge is not required to make the actual submission, the owner, operator, or agent in charge is still legally responsible for the registration. Therefore, FDA expects that in cases in which the owner, operator, or agent in charge authorizes an individual to submit the registration on its behalf, the owner, operator, or agent in charge will still take time to confirm that the information on the form is correct before it is submitted to FDA by the authorized individual.

FDA anticipated that foreign facilities would follow the same four steps to comply with the regulation as domestic facilities: (1) The facility must become aware of the regulation, (2) the facility learns the requirements, (3) an administrative worker fills out the form, and (4) the owner, operator, or agent in charge of the facility or the U.S. agent authorized by a foreign facility confirms the submission is correct. In addition, foreign facilities could have fifth and sixth steps to find and then hire a U.S. agent. To estimate the cost of registration for foreign facilities, FDA assumed that they would incur the same per facility costs as domestic facilities, plus additional costs. Similar to

domestic facilities, FDA estimated that facilities that research and register electronically would incur lower costs than facilities that do not. Tables 9 through 13 of this document summarize the costs in the PRIA and the revised costs for the interim final rule. Similar to domestic facilities, the interim final rule permits the owner, operator, agent in charge of a foreign facility, or an individual authorized by the owner, operator, or agent in charge to submit the registration. While the owner, operator, or agent in charge is not required to make the actual submission, the owner, operator, or agent in charge is still legally responsible for the registration. Therefore, FDA expects that in cases in which the owner, operator, or agent in charge authorizes an individual to submit the registration on its behalf, the owner, operator, or agent in charge will still take time to confirm that the information in the form is correct before it is submitted to FDA by the authorized individual.

(Comment 173) A number of comments stated that FDA underestimated the time necessary to comply with the proposed rule. One comment provided an estimate of 40 hours to read the proposed rule, submit comments to FDA, implement any final rule internally, and verify registrations of business partners. With 40 percent of these hours managerial time and 60 percent administrative time, the approximate cost was \$1,500. The commenter also estimated that additional research for any final rule would require another 4 hours. Another comment estimated that the initial registration would take 3 hours, that managerial expertise would be necessary to gather the information for the registration, and that it would take a manager more than 15 minutes to fill out the form.

Another comment stated that a manager or lead counsel would be responsible for reviewing any final rule and formulating a plan for

implementation. This comment estimated that this process would take 10 hours of a manager's time at a cost of \$567.40, in addition to 1 hour of an administrative assistant's time. This comment also suggested legal counsel may review the regulation for 5 hours at a total cost of \$1,500. Finally, another comment stated it would take 20 hours of staff time to read, comprehend, gather the necessary data, and complete the form. All of the estimates provided in these comments were for facilities with Internet access and workers fluent in English. Several of the comments suggested that FDA increase the time estimates for facilities without Internet access and without staff fluent in English.

(Response) FDA estimated that domestic facilities with Internet access and fluent in English would need, on average, 2 hours to research the regulation and complete and certify the form; domestic facilities without Internet access would need 3 hours. A facility would require approximately 1 or 2 hours, depending on the availability of the Internet, to find the requirements and determine if the facility is required to register, 15 minutes to categorize products and enter them in the appropriate food product categories, 30 minutes to find the remaining registration information and enter it onto the form, and 15 minutes for confirming all the registration information is correct. This estimate is on a per facility, not a per firm, basis. Also, this estimate is approximate; some facilities may require more or less time. FDA anticipates and estimated in the PRIA that firms with multiple facilities will spend 2 hours per facility, if Internet is available, researching and submitting registration information. The facility, or the firm on behalf of the facility, is required to enter the registration data; however, the facility, firm, or an industry or trade group may research the regulation. Firms with many