

facilities or industry groups representing hundreds or thousands of facilities submitted all of the comments listed previously.

In the PRIA, a large firm composed of 1,000 facilities would spend 2,000 hours researching and registering all its facilities. Given the estimates provided by the comments, this estimate is likely an overestimate. FDA expects that firms composed of many facilities will have lower per facility registration costs than single-facility firms. Multifacility firms will learn from their experience gained while registering their first facility and will be more efficient at registering additional facilities. Also, the registration system has built-in features that will allow common information to be transferred easily from one facility to another within the same firm. FDA was not able to estimate the reduction in time to register for these multifacility firms on a per facility basis, and so retains its original estimates. However, for this reason, FDA's time estimates are likely overestimates for multifacility firms.

FDA does not anticipate that small facilities will read the **Federal Register**. Instead, they will learn of their obligation to register from trade groups, the press, or FDA outreach efforts, then go to the registration Web site and using the information provided at the Web site, including the interactive features of the registration system, complete and submit their registration. The time estimates included in the economic analysis represent an average facility time estimate across small, medium, and large facilities, and thus, for some individual facilities, the average time estimate will be too high and for some it will be too low. Therefore, FDA did not alter its estimates of the time to complete the registration process.

FDA was persuaded by the comments that managerial staff, rather than administrative staff, would do any necessary research. FDA has re-estimated the analysis using managerial time for researching and administrative time for entering the registration data. Several comments suggested that FDA underestimated the managerial wage, one giving an alternative wage rate of \$75 per hour. In the PRIA, FDA used the Bureau of Labor Statistics estimate from the National Compensation Survey (Ref. 16), doubled to include overhead costs. This estimate is an average across many facilities. The higher wage estimate provided was from a very large firm with over 1,000 facilities that FDA would anticipate would have higher wages than most facilities. Therefore FDA did not change its estimate of the average managerial wage.

FDA did not receive any specific estimates of the additional time to register for facilities that lack Internet access and staff who do not speak English. Therefore, because FDA has not increased the base time for registration and has no new information to increase the additional time for foreign language translation or mail submissions, FDA has not increased its estimate of time costs for facilities without Internet access and staff who do not speak English.

(Comment 174) One comment suggested that FDA ignores the effort that will be required of large companies to identify all of the manufacturing and holding facilities covered by the registration requirement. The comment stated that one large supplier might have as many as 1,000 facilities that would have to register.

(Response) FDA included in its cost estimate one hour of research time for each facility to learn about the registration requirements, including whether it needs to be registered. This time may not be used by each facility, but by the firm that registers all its facilities. Multifacility firms are likely to require less time on a per-facility basis than FDA estimates. For a firm with 1,000 facilities, the PRIA estimated the firm would spend 1,000 hours to learn about the registration requirements, which is probably an overestimate of the time required by the firm, as a large, multifacility firm should learn from experience and become more efficient at registering additional facilities.

b. Other costs.

(Comment 175) Many commenters were concerned about potential port delays arising from FDA's failure to process registrations in a timely manner, facilities not being aware of the registration requirements prior to shipping food to the United States, or the receiver of the shipment not being aware that the foreign facility is not registered. Commenters mentioned costs associated with port delays including the lost value of perishable goods, storage costs, and the need for larger inventories for domestic facilities that receive imports.

(Response) FDA considered qualitatively in the PRIA potential costs associated with port delays due to foreign facilities not being aware of the registration requirement until their shipment reaches the port. This included costs such as lost value of perishables, storage costs, and transaction costs. Commenters did not provide any quantitative data about the size of these costs. Therefore, FDA has not changed its estimate of port delay costs.

(Comment 176) FDA received a number of comments that FDA underestimated the cost of the proposed rule, because it failed to include time for facilities to write and submit comments.

(Response) The function of the Regulatory Impact Analysis is to measure the costs and benefits of the requirements of the rule. Submitting comments is part of the rulemaking process, not a requirement of the rule. Therefore, FDA did not include in the PRIA costs associated with commenting on the proposed rule.

(Comment 177) FDA received comments stating that registration would require changes in business activities to prevent comingling of product or coding on product to reflect where it was manufactured/processed, packed and held.

(Response) FDA disagrees with this comment. The interim final rule requires all facilities that manufacture/process, pack, or hold food for consumption in the United States to register with FDA. However, the interim final rule does not require any additional labeling of food or restriction of comingling of product.

(Comment 178) FDA received comments that FDA failed to include the cost to facilities of confirming that trading partners are registered.

(Response) FDA did not explicitly include this cost because confirming registrations of trading partners is not a requirement of the interim final rule. However, FDA did include higher costs for foreign facilities to learn about the interim final rule and comply with the requirements, and this includes the higher transaction costs for foreign trading partners. These costs may be borne in part by domestic facilities that inform foreign facilities of the requirement to register.

5. Alternative Options

In the PRIA, FDA considered eight different regulatory options. FDA received many comments that suggested additional options. Suggestions included accepting multiple submissions on a CD-ROM, deleting the requirement to include product categories, different requirements for time allowed to update registrations, different requirements for the U.S. agent, and using other registration systems to gather information for the FDA facility database.

a. Accept CD-ROM submissions.

(Comment 179) A number of comments requested that FDA accept multiple registrations on a single submission, such as a specially formatted CD-ROM with the registrations for all the facilities of a