

(Response) FDA does not require a legal agreement between the U.S. agent and the foreign facility, but the estimated total cost for foreign facilities does include the costs of finding and hiring a U.S. agent.

FDA agrees that many facilities do not already have a U.S. agent. In the PRIA, FDA estimated that more than 90 percent of foreign facilities do not currently have a U.S. agent. Again, if more than 10 percent of foreign food facilities already have a relationship to a domestic entity that could serve as an equivalent to the role of the U.S. agent as required in this interim final rule, the impact of this rulemaking would be lower. FDA tests the sensitivity of this estimate in the following paragraphs.

In the PRIA, FDA estimated that foreign facilities currently without a U.S. agent would require 5 to 15 hours to find an agent and would pay an annual fee of \$1,000. FDA's estimate of the U.S. agent fee was based on the fees charged by U.S. agents for other FDA regulated products with similar responsibilities to those required in the proposed rule. Therefore, given the foundation for the fees cited in the PRIA and the lack of evidence for higher fees, FDA does not increase its estimate of the U.S. agent fee.

No comments suggested that FDA overestimated the fee that would be charged by a U.S. agent. The \$1,000 fee estimated in the proposed rule was an estimate of an average fee for a U.S. agent under other FDA regulations, based on fees quoted over the phone and Internet advertisements. However, since publication of the proposed rule, a number of companies have begun Internet advertising of their services as a U.S. agent for foreign food facilities that are required to register with FDA. These companies specify a range of costs, some with discounts for multiple facilities under the same ownership or fees that are a function of the number of shipments each year or additional fees for registration updates. Based on the requirements in the proposed rule, the lowest fee quoted was \$399 for representation by a U.S. agent for 1 year; other U.S. agents charged initial fees between \$599 and \$1,400 (Ref. 18). Many of the U.S. agents intend to charge fees for additional registration-related services, such as registration updates or cancellations. Based on these new estimates of fees, FDA believes that \$1,000 still represents a reasonable estimate of a U.S. agent fee. Ultimately, the fee that a foreign facility will pay to hire and retain a U.S. agent will be a function of several factors; whether the facility has Internet access, whether its

employees are fluent in English, whether it has existing relationships with potential U.S. agents, and individual facility preferences.

#### Sensitivity Analyses

Many facilities will choose lower-priced U.S. agents; therefore, FDA presents an estimate of the cost of the rule with a U.S. agent fee of \$700. In this situation, the total first year cost for foreign facilities would be \$247.6 million and annual costs would be \$164.5 million. In addition, the assumed number of entities that would no longer export to the United States would fall under this scenario; if U.S. agent costs are lower, it would continue to make economic sense for a larger number of foreign facilities to continue importing into the United States. FDA does not provide an estimate of the decrease in the number of facilities that will cease exporting to the United States.

FDA also considers a higher U.S. agent cost of \$1,200. This represents the higher range of Internet estimates; however, fees offered by facilities over the Internet may not represent the full range of U.S. agent fees. Also, foreign facilities that do not have Internet access or are not fluent in the languages commonly used in trade may face higher fees. This gives a first year cost of \$345.0 million and annual costs of \$271.7 million.

As discussed previously, the assumption that 10 percent of foreign facilities have an existing relationship that is equivalent to a U.S. agent is uncertain. FDA considers as an alternative assumption that those facilities that export 40 or more line entries per year, or 26 percent of facilities, already have a business partner in the United States that serves the function of a U.S. agent and the foreign facility will only incur the costs of registering. This lowers that cost to foreign facilities to \$283.9 million in the first year and \$209.7 in future years.

Alternatively, FDA considers that only facilities that export more than 120 line entries per year, or 8 percent of facilities have a U.S. business partner that will fulfill role of the U.S. agent. This will increase the cost to foreign facilities to \$308.8 million in the first year and \$231.2 million, annually.

Given the uncertainty surrounding the percent of facilities that will stop exporting to the United States, FDA also considers two alternative options. Eight percent stop exporting and 24 percent stop exporting. If eight percent of foreign facilities that ship very small numbers of line entries to the United States each year stop exporting to the

United States, then the quantified cost of the interim final rule will increase to \$320.4 million per year and \$239.4 million in subsequent years. However, this estimate does not account for a decrease in the nonquantified costs. Foreign facilities that stop exporting to the United States due to the Bioterrorism Act regulations will earn lower returns on their product because they will shift to a market with a lower return. Additionally, domestic facilities that receive product from these facilities will not incur costs to find new suppliers. Alternatively, if facilities that ship 20 or fewer line entries per year to the United States, or 24 percent of facilities, stop exporting, the quantified costs will decrease to \$291.7 million in the first year and \$218.2 million in subsequent years. However, the increase in nonquantified costs will offset these cost savings.

FDA considers the total cost for foreign facilities under the combination of lowest and highest cost alternatives. The lowest cost combination gives a total cost of \$220.5 million for the first year and \$144.6 million in subsequent years. The highest cost combination gives a total cost of \$364.6 million in the first year and \$267.4 million annually.

#### Distribution of Costs

FDA has chosen to use the facility as its unit of analysis for two reasons: (1) The Bioterrorism Act requires registration on a facility basis, and (2) most information available to FDA is at the facility level. For these reasons, costs are reported as average per facility costs and total costs for facilities. However, FDA expects that all of the costs will not be borne by the facilities. Economic theory shows that, in the case of new costs, a portion of the costs will be borne by the producer and a portion by the consumer. In this case, the costs may be spread among the foreign facility, importers, exporters, domestic food producers and distributors, and consumers. However the costs are distributed, the total social cost of the rule will be unchanged. Although the distribution of these costs is uncertain, the total cost of submitting a facility's registration and U.S. agent services are both costs of the requirements of this interim final rule for foreign facilities. FDA requests comments on the distribution of costs between submitting registrations and other services offered by the U.S. agent and comments on the overall cost of hiring and retaining a U.S. agent and the assumptions underlying FDA's estimates of these costs.