

manufacturers, because it removes the variation in number of line entries exported from countries with a large number of manufacturers exporting to the United States.

To estimate the number of foreign facilities that would have to hire a U.S. agent, FDA assumed that foreign facilities that export more than 80 line entries each year into the United States, or 10 percent of foreign manufacturers, already have a U.S. representative who can function as a U.S. agent. FDA acknowledges that this is an uncertain estimate; the true number of facilities that have an existing business representative that would be willing to serve as their U.S. agent may be much higher. FDA will test the impact of overall U.S. agent costs under different assumptions.

For foreign facilities that do not have an existing business representative willing to act as their U.S. agent for little or no extra cost to the U.S. agent or facility, FDA estimated it would take between 5 and 15 hours to hire a U.S. agent, depending on whether the facility had Internet access and its personnel were fluent in English. Additionally, FDA estimated an annual U.S. agent fee of \$1,000 per year, based on estimates of agent fees provided by U.S. agents for other FDA-regulated products. This estimate of the U.S. agent fee contemplates that the U.S. agent will register the foreign facility. If the foreign facility chooses to register on its own behalf, the U.S. agent fee may be lower; however, the facility itself will have higher costs associated with registering. These costs include time to enter the registration information, translate the registration information if the facility is not fluent in English, and additional time for mailing a postal registration if the facility does not have Internet access.

FDA acknowledges that these assumptions are uncertain. Accordingly,

as explained more fully in the following paragraphs, FDA provides alternative assumptions regarding U.S. agent fees, based on U.S. agents currently proffering their services as U.S. agents for the purposes of the Bioterrorism Act. In general, current prices for other U.S. agent activities (such as serving as a U.S. agent for drug or device foreign establishments) and published prices for an emerging market may not be precise predictors of the actual prices charged for this service.

FDA also assumed that the 16 percent of manufacturers that are exporting 10 or fewer line entries to the United States would stop exporting to the United States, rather than incur the expense of registering, hiring a U.S. agent, and providing prior notice under 21 CFR part 1, subpart I. FDA includes the effect of prior notice on foreign facilities ceasing trade with the United States, because both will represent an increase in the cost of importing to the United States. FDA is unable to separate the effects on foreign facilities ceasing to export to the United States and so considers them both here. These estimates are also uncertain as the value of and the return on food shipments are variable and the cost for an individual food facility to comply with the Bioterrorism Act regulations is uncertain. Some facilities may ship very few shipments to the United States each year, but may earn a very high return; these facilities will likely continue to export to the United States. Conversely, some facilities may ship many, low value, low return shipments to the United States and may stop exporting to the United States as a result of the regulations under the Bioterrorism Act. Foreign facilities may also have existing business relationships with facilities in the United States. If a domestic facility is willing to absorb the cost of registering and providing U.S. agent

services to a foreign facility, the facility may continue to export to the United States. In the proposed rule, FDA requested comments on these assumptions. No comments provided quantitative estimates of the number of facilities that would stop exporting or that already have U.S. agents. These estimates are uncertain, as the value of and the return on food shipments are variable and the cost for an individual facility to comply with the Bioterrorism Act regulations is uncertain. Some facilities may ship very few shipments to the United States each year, but may earn a very high return; these facilities will likely continue to export to the United States. Conversely, some facilities may ship many, low value, low return shipments to the United States and stop exporting to the United States as a result of the regulations under the Bioterrorism Act. In the proposed rule, FDA requested comments on these assumptions. No comments provided quantitative estimates of the number of facilities that would stop exporting or that already have U.S. agents. Table 8 presents average numbers of line entries and the percent of foreign manufacturers that export that number.

If 16 percent of foreign manufacturers/processors do choose to cease exporting to the United States, the total effect on trade will be much smaller than 16 percent. The facilities projected to cease exporting to the United States represent a small fraction of total trade. The 16 percent of facilities represents approximately 20,000 facilities exporting between 1 and 10 line entries to the United States each year. If, on average, each would have exported 5 line entries, the total number of line entries affected would be approximately 100,000, which is less than 2 percent of all lines.

**BILLING CODE 4160-01-P**