

months or annually. However, some comments suggest that to allow update periods longer than 30 days would reduce the usefulness of the database.

(Response) As stated in the definitions section of this rule, trade names mean the terms under which the facility conducts business, or additional names by which the facility is known. Trade names are terms associated with the facility, as opposed to brand names, which are terms associated with products. Therefore, comments that stated that names associated with products change frequently, which would result in the need for frequent updates, overestimate the frequency with which facilities will have to update their registrations because brand names are not included as an element of registration. FDA has also removed the requirement that an individual be identified as the emergency contact, another registration element that commenters mentioned was likely to change frequently.

FDA does not agree that the cost of updates resulting from changes in product lines will require facilities to submit monthly updates. Some types of facilities, such as warehouses or wholesalers, are likely to select the most/all human food category due to the large variety of products handled at the facility. Manufacturers/processors are the most likely facilities to have frequent changes in product lines. However, the majority of these facilities are small. The 18,259 manufacturers in the Nonemployer Statistics have only 1 employee, and due to their small size, should not have frequent changes in product lines. In the CBP data, 80 percent of the 29,149 manufacturers have fewer than 50 employees. It is unlikely facilities of this size will produce many different product lines and that these product lines will change frequently. This leaves a small number, approximately 3,700 large manufacturers, that may have more frequent changes in product lines. Also, the product categories included in the registration form include many individual products; thus, a product line change may not change the food product category. For example, a facility may change pudding flavors or the level of fat in the pudding without changing food product categories.

FDA does agree with the comments that the frequency of updates will be greater than estimated in the PRIA. FDA has re-estimated the frequency with which updates will occur for 60-day updates by using the suggested frequency of updates in the comments for the 30-day update period. For large manufacturing/processing facilities,

FDA has used the estimate provided by some commenters that one in four facilities would have to submit an update each month with a 30-day update period. Large manufacturing/processing facilities would then submit two updates per year with a 60-day update period, rather than 3 times per year with a 30-day update period. For other facilities, FDA has used the estimate that 50 percent of facilities would have to update each year (or facilities would update once every 2 years) with a 30-day update. FDA assumes that the number of updates will still be once every 2 years with a 60-day requirement for updates. A weighted average of the two estimates gives 55 percent of facilities updating each year. FDA has also applied this estimate for domestic facilities to foreign facilities.

FDA has also considered an alternative option in which facilities are required to update their registration within a year of a change. FDA assumes that for facilities that are not large manufacturers/processors, updates by 50 percent of facilities per year is equivalent to one change every 2 years. Under this approach, the frequency of updates for facilities that are not large manufacturers/processors would still be 50 percent of facilities each year, but no updates would occur in the first year. Large manufacturers/processors would have to update once a year, with no updates the first year. Without incorporating zero updates in the first year, adopting this option would give a weighted average of 51 percent of facilities updating each year. To incorporate the lack of updates for the first year, we included zero updates for 1 year in 20 years of the registration system. This lowers the average for percent of facilities submitting updates each year to 48 percent. See tables 11 and 12 of this document for cost estimates for these options.

FDA also considers an option in which facilities are not required to include food product categories in their registrations. FDA estimates that it would take only 45 minutes to fill out and certify the registration form and that 50 percent of all facilities would have changes in their registration information each year.

Comments received in response to the proposed rule assumed that changes in optional elements would result in updates. In the interim final rule, FDA does not require a facility to update its registration when changes occur in optional items. FDA does not have information to adjust the estimates of frequency of update in response to changes in optional information. However, FDA does believe that the

estimate of frequency of updates is an overestimate, as it is based on changes in both optional and required information.

d. *U.S. agent.*

The Bioterrorism Act and the interim final rule require that all foreign facilities required to register have a U.S. agent. The interim final rule requires the U.S. agent to be a person residing or maintaining a place of business in the United States, whom the owner, operator, or agent in charge of a foreign facility designates as its agent. FDA will recognize only one U.S. agent for purposes of registration per foreign facility. The U.S. agent acts as a communications link between FDA and the facility and FDA considers providing information to the U.S. agent the same as providing information directly to the foreign facility. A U.S. agent may submit a registration to FDA, if the owner, operator, or agent in charge of the foreign facility authorizes the U.S. agent (if an individual) to register on behalf of the owner, operator, or agent in charge of the facility.

U.S. Agent Assumptions

In the PRIA, FDA assumed, based on preliminary comments, that some foreign facilities already have a U.S. representative that can function as a U.S. agent. The U.S. representative may be a business partner, broker, U.S. lawyer, or parent company. FDA assumes that the likelihood that a foreign facility has an existing U.S. agent is related directly to the quantity of product the foreign facility exports to the United States.

FDA used data from OASIS on the average number of line entries and the average number of manufacturers by country and product code to estimate the number of line entries for foreign manufacturers (Ref. 2). A shortcoming of these data is that entries are by product code, thus, manufacturers that are exporting products in more than one product code are in the count of manufacturers for every product code in which they export. The OASIS data consequently have approximately twice as many manufacturers as actually exist. To adjust for this double-counting, FDA assumed the average foreign manufacturer exports in two product categories. To find an approximate number of line entries per manufacturer, FDA divided the total number of manufacturers into the total number of line entries for each country and applied the average number of line entries per manufacturer to all the manufacturers from that country. This method will underestimate the number of very small and very large