

single firm. Comments stated that this would lower the burden of registration, particularly for firms with many facilities, and would improve the accuracy of the registrations.

(Response) The interim final rule allows the submission of multiple registrations on a single CD-ROM. The registrant must use a specially formatted CD-ROM with a PDF version of the registration form. The registrant then enters the facilities' registration information on the CD-ROM and mails the CD-ROM to FDA. FDA will process CD-ROM submission, along with paper submissions, in the order received. CD-ROM submissions will be entered electronically into the registration system. This option will result in additional costs to FDA for processing submissions and training staff to process the submissions. FDA estimates it will take an additional 100–150 hours to develop the automated workflow process for CD-ROM submissions, integrate the process into the existing process, and include the process in the testing phases. At a labor cost of \$100 per hour, the total cost for the process control would be approximately \$10,000 to \$15,000. Additional training costs for staff processing the CD-ROM submissions would be about \$8,000 to \$10,500. These costs are incorporated into the total FDA cost estimate.

FDA anticipates that this option will lower costs for some large, multifacility firms. Only firms that can lower their costs by using this option will do so. However, FDA does not quantitatively estimate the cost savings.

*b. Food product categories.*

FDA proposed to require the inclusion of food product categories in the registration information. Food product categories are necessary for FDA to communicate directly with subgroups of facilities and to help verify prior notices from facilities that are subject to both registration and the prior notice requirements. FDA estimated that including food product category information in the registration would increase the time to complete each facility's registration by 15 minutes. Including food product categories in the registration form also increases the number of updates facilities will have to submit to FDA.

(Comment 180) FDA received numerous comments stating that including the food product categories as a registration requirement would add to the costs of the rule, without providing any benefits. Some comments stated that the additional 15 minutes for facilities to include food product categories underestimated the time needed to provide this information.

Also, large facilities may manufacture/process, pack, or hold thousands of products and determining the food product categories for all these products would be very difficult.

(Response) In responding to these comments, FDA breaks the comments into three categories: (1) The time to research the food product categories for the initial registration, (2) the effect of including food product categories on the frequency of updates, and (3) the benefits of including food product categories. FDA addresses the impact on updates in the section on frequency of updates, and addresses the last category of comments in the benefits section.

FDA does not agree with the comments that suggested FDA underestimated the time to include food product categories as a registration element. For facilities that handle many different types of food, such as warehouses the registration form includes a "most/all human food categories" to alleviate the burden of providing information on each specific category of food at the facility. This will allow facilities that handle a large variety of foods to fill out the food product category section of the form very quickly. Also, the electronic registration form includes extensive online help, with descriptions of the food product categories and a link to the FDA product code builder, which will interactively categorize foods. This will simplify identification of the appropriate food product category. For example, pudding is a product that some may believe may be relatively difficult to categorize. On the registration form, it may be unclear to a registrant whether pudding should be characterized as a bakery product/dough/mix/icing or a gelatin/rennet/pudding mix/pie filling. The online registration provides a link to the FDA product code builder, which has a search function. Searching on "pudding" gives three possible categories, the two categories already given and baby food, all with drop down menus. By using the drop down menu, a list of products in those categories is provided. The registrant can then find its product in the drop down menu. Moreover, most products, such as alcoholic drinks, fruits, vegetables, and eggs, can simply be characterized by reading the food product categories.

As previously mentioned, most facilities are small and do not produce a large number of products. Therefore, FDA has not altered its 15 minute estimate of the time to fill in the food product categories.

*c. Frequency of updates.*

The proposed rule would have required registered facilities to submit updates or cancellations of their registration information within 30 days of a change in information previously submitted to FDA. The interim final rule changes this requirement to 60 days. Facilities that close or transfer ownership are required to cancel their registrations. New facilities and facilities that change ownership must register. Based on data from the Small Business Administration (Ref. 17), FDA estimated that 10 percent of facilities will cancel registrations and 10 percent of facilities have to submit a new registration each year. FDA also estimated that 20 percent of facilities would have to update their registrations each year. Updates and cancellations were estimated to take 1 hour. First-time registrations in subsequent years were estimated to be as costly as first-time registrations in the first year.

(Comment 181) FDA received many comments about how often facilities will have to update their registrations. As noted, FDA estimated 20 percent of facilities would have to update their registrations each year. Comments provided a number of other estimates of how frequently updates would be required. Multiple comments estimated that 50 percent of facilities would have to update their registrations each year. Other comments did not provide an estimate of how often updates would be required, but suggested that FDA require annual updates. Others commented that facilities would have to update registration information many times a year. Another comment did not provide an alternative estimate of the frequency of updates, but disagreed with the 20 percent per year estimate provided by FDA. Various comments suggested that the most frequently changing components of the registration would be the name of the emergency contact and, if "trade name" were defined broadly, it would be the most frequently changing registration information element.

Some comments suggested including food product categories in the registration would lead to monthly registration updates. Comments stated that there is constant fluctuation in the nature of products produced at large facilities, which would require frequent updates. One comment suggested that one in four large facilities that manufacture/process food would have to submit updates each month. Comments stated that the cost of maintaining the food product categories would exceed the cost of the initial registration.

Comments most frequently suggested that FDA require updates every 6 to 12