

convenience stores is the same in the 2000 CBP and the 1999 Nonemployer Statistics and reduce the number of grocery and convenience stores from the 1999 Nonemployer Statistics by the percentage in the 2000 CBP. FDA then assumes that 10 percent of these retail facilities manufacture/process, in addition to direct selling to consumers. This gives a total of 10,410 affected mixed-type retail facilities. Because the number of retail facilities is large, the number of facilities covered is highly sensitive to the percentage assumed to be in mixed-type facilities. FDA requests comments on the number of attached retail facilities under Option 2.

iii. *Foreign manufacturers.* FDA estimates the number of foreign manufacturers that would be affected by the regulation from a count in FDA's OASIS database (Ref. 4). OASIS is an automated FDA system for processing and making admissibility determinations for shipments of foreign-origin FDA-regulated products seeking to enter domestic commerce. There are 125,450 foreign manufacturers in the OASIS database. Table 8 presents the number of foreign manufacturers by the type of food they manufacture/process.

TABLE 8.—NUMBER OF FOREIGN FACILITIES EXPORTING FOOD TO THE UNITED STATES IN FISCAL YEAR 1999

Foods	110,392
Food additives	2,979
Color additives	378
Infant formula	235
Vitamins	7,986
Animal feeds	3,330
Medicated animal foods	150
Total	125,450

iv. *Foreign holders.* Also covered under this regulatory option are the final food holders in the foreign country prior to export of the product. FDA does not have any information on how many foreign facilities hold foods that are to be exported to the United States. FDA, therefore, assumed that the number of foreign final holders is equal to the number of consignees, brokers, and importers of food products in the United States. The OASIS data has a count of 77,427 U.S. importers, brokers, and consignees, so FDA assumed that there are also 77,427 foreign final holders (Ref. 4). FDA requests comments on this estimate.

v. *Foreign facilities that do de minimis processing or packaging.* Facilities that do de minimis processing or packaging of the food, such as affixing a label, are also required to register. Because their processing is

minimal, these facilities are not included in the OASIS count of foreign manufacturers. To estimate the number of affected foreign facilities, FDA takes the number of packers/repackers in the FACTS database, 6,204, and adjusts it by the ratio of domestic manufacturers in FACTS to the number of foreign manufacturers in OASIS. This adjustment of 3.64, (125,450 foreign facilities divided by 34,437 domestic facilities), gives the total number of de minimis processing foreign facilities as 22,600. FDA requests comments on this estimate.

vi. *New and closing facilities.* In addition to the facilities currently in existence, in future years, new businesses will open and some existing businesses will close. These new businesses would have to register and closing businesses would have to notify FDA to cancel their registration. According to the Small Business Administration (SBA) Office of Advocacy, in 2001, about 10 percent of all businesses were new and 10 percent of businesses closed (Ref. 8). FDA assumes that the rate of new and closing businesses is the same in other countries as in the United States. Thus, in future years 10 percent of the total count of facilities will be new facilities and 10 percent of the total count of food facilities will go out of business and will need to cancel their registration.

b. *Costs—i. Market reaction.* It is expected that most firms will register correctly and on time. If most facilities do not register correctly and on time, then the costs will be higher than estimated. It is also likely that some manufacturers/processors will not register prior to attempting to introduce their products into U.S. interstate commerce, which would increase the amount of time their products are held at the port. In addition, some foreign facilities may determine that registration, in conjunction with prior notice, would make it no longer profitable to continue to manufacture/process and ship food to the United States. That is, if the expected profit from exports is projected to be less than the cost of a U.S. agent, the cost of registration, and the cost of prior notification, they would cease to export to the United States. The marginal costs and benefits that would result from these changes in manufacturer/processor behavior are estimated in the following paragraphs.

ii. *Wage rates.* FDA uses two hourly wage rates from the Bureau of Labor Statistics' National Compensation Survey (Ref. 9). These wage rates then are doubled to include overhead costs, such as office space, health insurance,

and retirement benefits. For an administrative worker, the cost per hour is \$25.10, and for a manager, who would be the owner, operator, or agent in charge, \$56.74. FDA lacks wage data specific to food industry workers in each of the foreign countries that export to the United States and thus used the wage rate for an administrative worker in the United States for the foreign wage rate. We assume that the nature of the worker and the worker's wage would be about the same in foreign countries as in the United States. In open markets where trade takes place, real wage rates tend to be equal for similar work and productivity across countries. However, FDA tests this assumption in the sensitivity analysis and re-calculates the costs if the foreign wage rate is lower than the domestic wage rate.

iii. *First year costs incurred by domestic facilities.* Domestic facilities would incur administrative and form-associated costs to comply with the regulation. The administrative costs would be partially shared between the registration and recordkeeping rules. FDA estimates administrative costs for the recordkeeping regulation and this proposed rule separately, but this probably gives an overestimate of administrative costs. Although recordkeeping has different requirements than registration, it would affect many of the same facilities and FDA expects that the recordkeeping final rule will be published soon after the registration final rule. Individuals from facilities affected by both regulations would most likely search for information for both regulations at the same time and find information in the same places.

There are four steps associated with a domestic facility complying with the regulation. One, the facility becomes aware of the regulation; two, the facility learns what the requirements are; three, an administrative worker fills out the form; and four, the owner, operator, or agent in charge certifies the form.

First, the facility becomes aware of the regulation through normal business activities; reading trade press or industry news; FDA outreach; or conversations with other business operators. Because facility owners, operators, or agents-in-charge must be aware of the requirement to change their activity, FDA assumes that becoming aware of the regulations would occur as part of normal business practice and we thus have included no economic costs for the facility. There may be costs incurred, however, by FDA or trade organizations to undertake the outreach. FDA costs will be considered in a separate section. FDA does not quantify