

TABLE 24.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Part 1, Subpart I	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Capital Costs	Operating and Maintenance Costs	Total Hours
1.285–1.290, 1.294 ¹	77,427	23.3	1,807,692	1–2	\$6,194,000	\$743,280	1,888,216
1.278(d) ¹	90,385	1	90,385	0.5	\$0	\$0	45,193
1.278(d), 1.285–1.290, 1.294 ²	77,427	23.8	1,844,116	0.5–1	\$620,000	\$817,680	1,833,822
Total hours for first year							1,888,216
Total recurring hours							1,833,822

¹ First year burden.² Recurring burden.

Burden Estimate

Number of Establishments Affected

Using 2001 FY information from FDA's OASIS system (industry codes 02 through 52, 54, and 70 through 72), FDA has determined that there are approximately 77,427 importers and consignees who receive shipments of food for human and animal consumption into the United States. It is these 77,427 U.S. importers or U.S. purchasers (or their agents) that will be primarily responsible for submitting the prior notice information.

New and Closing Importers

In addition to the U.S. importers currently in existence, in future years, new import businesses will open and some existing import businesses will close. These new importers would have to become familiar with the FDA prior notice system and possibly obtain computer equipment and Internet access to comply with prior notice requirements.

According to the Small Business Administration Office of Advocacy, in 2001, about 10 percent of all businesses were new and 10 percent of businesses closed. Using the 10 percent opening and closing business statistic, and given that there are currently 77,427 U.S. importers, FDA will assume, then, that on a yearly basis 7,743 importers will leave the market and 7,743 importers will enter the market.

Hour Burden Estimate Researching the Prior Notice Requirement

To become familiar with the requirements for this rule, FDA estimates it will initially take responsible parties with Internet access (74,330 importers) about one hour to research the prior notice requirements and responsible parties without readily available Internet access (3,097 importers) about 2 hours to research the requirements. This one-time search

burden for the existing importers is 80,524 hours.

In the years that follow the start-up year for prior notice, it is reasonable to expect a certain percentage of importing firms to enter and leave the market. Thus, in addition to the first year burden to research prior notice, it is expected that 8,053 hours will be spent annually researching the prior notice requirement by the anticipated 7,743 new importers entering the market annually that must learn about prior notice, 7,433 of whom are estimated to have Internet access and 310 of whom do not.

Submitting Prior Notice

To estimate the repetitive effort of submitting a prior notice, and updating and amending the information, as needed, FDA will assume the activity takes one hour each time an entry (based on an average of 2.6 lines, and therefore notices, per entry) must be submitted. This includes 45 minutes of an administrative worker's time to fill out the screen, including updating, and then 15 minutes of the manager's time to verify the information. FDA does not have information on how many prior notices will come from each of the 77,427 importers. However, we assume that 1,807,692 prior notices will be submitted annually (based on FY 2001 OASIS information); we can take this number and divide by the 77,427 importers to get an average response frequency per importer of 23.3 notices.

Secure Storage and Notifying FDA

If an article of food is imported or offered for import with no prior notice or inadequate (e.g. untimely, inaccurate, or incomplete) prior notice, the food must be held at the port of entry or in a secure facility. In these cases, the submitter or carrier must promptly notify FDA of the location where the goods are held.

It is quite likely that more imported products will be held during the first year that the prior notice is required than in subsequent years as importers will learn from experience. Therefore, FDA estimates that imported products with insufficient prior notice will be held or sent to secure storage about 5 percent of the time during the first year and 2 percent of the time thereafter. This means that of the 1,807,692 prior notice entries received annually, in the first year prior notice is in effect we would expect 90,385 of the entries to be held or sent to secure storage; 36,154 entries would be held or sent to secure storage in subsequent years.

Most port storage facilities and secure storage facilities located at or near ports are probably familiar to submitters or carriers; therefore it should only take one-half hour per entry to notify FDA of the shipment's location. Thus, in the first year of the regulation, submitters or carriers will spend 45,193 hours notifying FDA of secure storage locations; 18,077 hours in subsequent years.

Capital Cost and Operating and Maintenance Cost Burden

Since all prior notices must be submitted electronically, we will assume that the 3,097 responsible parties without Internet access will have to purchase the appropriate IT equipment and gain Internet access to actually transmit the information. Assuming computer equipment costs each firm \$2,000 and yearly Internet access costs each firm \$240 (\$20 per month for 12 months), this results in a one-time computer cost for these facilities of \$6,194,000 and a recurring Internet access cost of \$743,280. For the 7,743 new firms that enter the import market each year, we can expect 310 of them to need to purchase computer equipment and obtain Internet access. Thus, on an annual basis we can expect