

produce food-packaging material. The OASIS line count also included the codes for beer and wine, but not distilled spirits (*e.g.*, bourbon, whiskey, gin, etc.).

The OASIS entry line totals do not include informal entries for mail or express carrier shipments, or for food brought into the United States as personal baggage, not for personal use, but intended for sale or other distribution use. Persons bringing food into the United States by these means, however, are required to submit prior notice to the FDA. Therefore, even though food contact substances, including food packaging, pesticide chemicals, and pesticide chemical residues are no longer subject to the interim final rule, we do not reduce the estimate of imported food entry lines in order to capture informal food lines and other imported food items that are not currently included in the OASIS line estimates. Rather than adjust the total line estimate downward to account for the exclusion of food packaging, pesticide chemicals, and pesticide chemical residues we adjust the estimate of lines upwards to capture food lines not in OASIS. The upward adjustment should be regarded as net of food contact substances and food packaging.

For the prior notice interim final rule, then, FDA has re-estimated the number of entry lines expected to be filed yearly for prior notice. The FDA PN System Interface and ABI/ACS are estimated to handle up to 25,000 prior notice submissions on a usual business day, for a projected yearly total of 6.5 million submissions. (FDA's prior notice system will operate 24 hours a day, 7 days a week; however, since most shipments enter the United States during a normal business work week, Monday through Friday, we estimate the projected prior notice line total as 25,000 daily submissions \times 260 days = 6.5 million lines per year.) This updated total includes estimates for informal and other entries not currently captured by OASIS.

According to OASIS data, the average import entry contains 2.6 lines, which means that there are typically more than two different articles of food per import entry: *e.g.*, 100 cases of canned tuna and 50 cases of canned peaches in the same shipment. A prior notice must be filed for each of the lines in an entry.

FDA estimates that it will take, on average, 1 hour to submit an import entry of 2.6 lines. This time is an average; some entries will take longer than 1 hour to complete and other entries will take less than 1 hour to complete.

This 1-hour estimate includes 45 minutes of an administrative worker's time to gather information to initially complete the prior notice, and then 15 minutes of a manager's time to verify that the information is correct.

Assuming that there is an average of 2.6 lines per entry, and each line requires a prior notice, then each line actually takes about 23 minutes to complete.

Comments on the prior notice proposed rule agreed with the FDA estimation for time to fill out the notice. Comments also agreed that once prior notice submitters were familiar with the information required, an hour was a reasonable time estimate. Some comments, however, suggested that the time to make amendments and updates to the prior notice had not been included or was not sufficient in the proposed rule. FDA believes the 1 hour estimate is appropriate for the following reasons: (1) The interim final rule does not contain update or amendment provisions as the reduced time for submitting a prior notice negated the need for them; (2) CBP Form 3461, (the entry document upon which information is provided to CBP) carries an estimated burden of 15.5 minutes and FDA Importer Entry Notice (as required by section 801 of the FD&C Act) carries an estimated burden of 8.5 minutes (Paperwork Reduction Act estimates); and (3) many comments agree with the hour estimate for submitting prior notice (23 minutes per line).

Comments were also concerned that FDA had not included costs to have a licensed customs broker file prior notice submissions in the costs estimated for the proposed rule. FDA specifically made no assumptions in its analysis of the proposed rule about who would file the prior notice. Our estimate covered anyone who was authorized to file a prior notice based on the anticipated number of entry lines. The analysis implicitly assumed that if an importer, owner, or consignee hired a customs broker to submit their prior notices, the broker would do so at the marginal cost. In the competitive market for broker services, this assumption is reasonable.

However, FDA prior notice may now be submitted through ABI/ACS for most importations, so the burden of prior notice submission will most likely be on the customs brokers that normally file with CBP. Some comments said that the current customs broker cost to file an entry with CBP is \$110, with the additional filing of prior notice increasing these costs by up to 70 percent. Other comments also indicated that the additional costs to file prior notice would be between \$50 or \$100 or more for an entry.

Based on comments and FDA's own research on the broker costs, FDA agrees that the average costs to submit prior notice will be higher than the \$33 per entry estimated in the proposed rule. For this interim final rule, FDA used information provided by commenters to estimate \$75 as the cost to file prior notice. FDA believes that using a midrange estimate is appropriate for this cost since filing prior notice through ABI/ACS should efficiently combine transactions costs for brokers submitting information to both CBP and FDA.

Using the OASIS data indicating that the average imported entry contains 2.6 lines, we can then divide the expected yearly 6.5 million total lines by 2.6, which results in 2.5 million expected import entries. Table 3 of this document shows that the annual cost of prior notice submissions based on 2.5 million entries will be about \$187.5 million.

TABLE 3.—COST TO FILL OUT PRIOR NOTICE SCREENS BY IMPORT ENTRY
[Must Be Electronic]

Broker cost per entry to submit prior notice	\$75
OASIS entry total based on 6.5 million lines	2,500,000
Total Annual Costs (of all prior notice screens based on 2.6 lines per entry, including updates and amendments to the information)	\$187,500,000

(4) *Information coordination costs.* As previously stated, FDA received numerous comments on the time it takes to file a prior notice for each line, with

some comments agreeing that an entry will take an hour to complete once firms learn how to submit the information. However, comments were concerned

that the preparation cost to coordinate the information needed for each prior notice had not been calculated.