

TABLE 1.—COST TO RESEARCH PRIOR NOTICE—Continued

Cost to Research Prior Notice	With Internet Access	No Internet Access
Total time to research regulation	1 hour	2 hours
First year one-time research costs	\$1,865,683	\$155,469
Annual one time research costs for new firms entering industry in subsequent years	\$186,568	\$15,547
Present value of cost of firms entering the industry	\$2,665,257	\$222,100
Total research cost burden	\$4,530,940	\$377,569

All prior notices must be submitted electronically, so we will assume that the 3,097 responsible parties without Internet access will have to purchase a computer and gain Internet access to actually transmit the information via a prior notice screen. This one-time computer cost and a recurring Internet access cost for these facilities of \$7,559,777 are shown in table 2.

Again, given a 10 percent turnover rate for businesses in the import industry, we expect there to be new businesses in the future that may need to purchase electronic transmitting capabilities. However, it becomes more unlikely with the passage of time that persons will be purchasing this computer equipment solely to comply with prior notice. Therefore, a present value of this cost is not calculated.

TABLE 2.—FACILITIES AND RESPONSIBLE PARTIES WITHOUT INITIAL INTERNET ACCESS

Number of Facilities	3,097
Computer equipment cost per facility	\$2,000
Annual cost of Internet access (\$20 per month x 12)	\$240
Search costs for equipment and access (\$25.10 x 8 hours)	\$201
Total first year one time cost of electronic transmitting capacity	\$7,559,777

TABLE 2.—FACILITIES AND RESPONSIBLE PARTIES WITHOUT INITIAL INTERNET ACCESS—Continued

Annual one time cost of electronic transmitting capacity for firms entering industry in subsequent years	\$755,978
Total electronic transmitting costs	\$8,315,755

FDA used OASIS information to find out that 4.7 million entry lines for food were imported into the United States in FY 2001. An "entry line" is an FDA term used by the OASIS reporting system, which refers to a line on an invoice that reflects a certain article specific to manufacturer or packaging: e.g., 100 cases containing 48 six-ounce cans of tuna. This 4.7 million entry line total includes the 2.2 million entry lines for food that came into the United States in 2001 via ground transportation (trucks and trains) and the 2.5 million entry lines for food that came into the United States in 2001 via airplane and vessel.

The entry line totals for FY 2001 do not include food brought into the United States as personal baggage with the food intended for sale or other distribution, not for personal use. Under the proposed rule, persons bringing food into the United States in this manner, however, are required to submit prior notice to the FDA. FDA does not know how common the practice is of importing food for non-personal use as part of personal baggage. For FY 2002, there were only 18 entry lines associated with food imported as U.S. mail and 486 food entry lines imported by courier. FDA believes that entries of food imported as part of personal baggage but not for personal use will fall somewhere between mail and courier entries. Since any number of entries in this range is minimal as compared with the 4.7 million total OASIS entries, FDA likewise believes the costs associated with prior notice for food in personal baggage entries will be minimal and thus these costs are not included in this analysis. FDA requests comment on this assumption.

According to OASIS data, the average imported 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 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.

U.S. Customs Form 3461, Entry and Immediate Delivery Application, OMB No. 1515-0069, is the entry document upon which information is provided to

U.S. Customs by which it makes its decision to release the merchandise. The burden estimate on U.S. Customs Form 3461 for purposes of the Paperwork Reduction Act is 15.5 minutes. The FDA calculation of average time for completion of the prior notice includes verification of accuracy of the data and supervision time.

FDA estimates that it will take, on average, 1 hour to prepare a prior notice each time an import entry of 2.6 lines is submitted, including the time it takes to update or amend information for each entry line as necessary. This time is an average; some prior notices will take longer than 1 hour to complete and other prior notices will take less than 1 hour to complete. FDA requests comment on the time it will take to complete a prior notice form, including the time it will take for amendments and updates to the information.

This hour includes 45 minutes of an administrative worker's time to gather information to initially complete the screen and then update the information as necessary, and then 15 minutes of the 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 is estimated to take about 23 minutes to complete.

Using the OASIS information that the average imported entry contains 2.6 lines; we can then divide the 4.7 million OASIS lines by 2.6, which results in 1,807,692 expected import entries. Table 3 shows that the annual cost of prior notice submissions based on 1,807,692 entries would be \$59,689,990.

TABLE 3.—COST TO FILL OUT PRIOR NOTICE SCREENS BY IMPORT ENTRY (MUST BE ELECTRONIC)

Administrative worker time at \$25.10 wage rate	45 minutes
Manager time at \$56.74 wage rate	15 minutes
Administrative worker costs per entry	\$18.83
Manager costs per entry	\$14.19
Total Cost per import entry	\$33.02
FY 2001 OASIS entry total based on 4.7 million lines	1,807,692
Total Annual Costs of all prior notice screens based in lines, and including updates and amendments to the information	\$59,689,990

FDA Costs: We assume that FDA's information technology (IT) costs for