

Users who have limited ability to read English may take longer to read and comprehend the requirements. Comments suggest that many foreign manufacturers are limited in their ability to read and write English. Estimates of the number of people outside of countries where English is the primary language who are able to speak English fluently vary widely, ranging from 300 million to 750 million (Ref. 11). To estimate the number of English speakers outside of the United States, FDA adds the number of English speakers in countries where English is the primary language, excluding the United States (151 million), the number of English speakers in countries where English is a secondary language (300

million), and the midpoint (525 million) of the range of the estimate of the number of speakers of English as a foreign language. FDA then divides this total number of English speakers by 5.9 billion—the world population minus the U.S. population (Ref. 11) to tentatively conclude that 16 percent of foreign manufacturers read and write English well enough to research the recordkeeping requirement directly. FDA requests comments on this calculation. Facilities without the capacity to read and write English would have to hire a translator to aid them in comprehending the regulatory requirements. Alternatively, trade groups, distributors, or the government may provide translation services.

Regardless of whether the translation is paid for directly by the registrant or a third party, for ease of computation we assume there is a cost for translation for 84 percent of foreign facilities. FDA assumes it would take foreign facility operators who do not understand English 5 additional hours to read and comprehend the recordkeeping requirements. FDA requests comments on these assumptions.

Table 3 summarizes these cost estimates, which do not differ across any of the options that do not grant exemptions. These include costs for searching, reading, and comprehending the requirements of the rule for English and non-English speaking users, and for users with and without Internet access.

TABLE 3.—LEARNING COSTS

	Firm Count	Cost (at labor rate of \$25.10)	Average Learning Costs per Firm
<b>Domestic</b>			
Manufacturers	43,376	\$5,215,000	\$120
Wholesalers/Warehouses	95,745	\$11,511,000	\$120
Packaging <sup>1</sup>	73,813	\$8,875,000	\$120
Transporter/Packer	16,773	\$2,017,000	\$120
Retail Grocery and Specialty Food	207,657	\$24,966,000	\$120
Convenience Stores	128,985	\$15,508,000	\$120
Mixed-Type Facilities that Engage in Farming	30,497	\$3,667,000	\$120
Importer	5,036	\$605,000	\$120
<b>Total Domestic</b>	<b>601,883</b>	<b>\$72,364,000</b>	<b>\$120</b>
<b>Foreign</b>			
Final Holders	77,427	\$23,613,000	\$305
Manufacturers	125,450	\$38,258,000	\$305
Other Facility Types	457,836	\$139,624,000	\$305
<b>Total Foreign</b>	<b>660,713</b>	<b>\$201,495,000</b>	<b>\$305</b>

<sup>1</sup> Includes both outer packaging material and food contact substances.

*New and closing facilities:* In future years new businesses will open and existing businesses will close. Since the total number of firms in the food industry remains stable from year to year, we assume that the rate at which new firms enter the industry is the same as the rate at which existing firms leave the industry. The Small Business Administration estimates that in 2000 approximately 10 percent of all businesses were new businesses and 10 percent of all businesses closed (Ref.

31). FDA estimates that new businesses will also have to incur learning costs.

*New information collection costs:* These costs include the burden of redesigning records to accommodate new information specified in possible options, and the burden of collecting and maintaining that new information within the recordkeeping system.

*Records redesign:* In order to estimate the cost of adding additional information to a firm's records, we used the Label Cost Model developed for FDA by RTI International (Ref. 13). We

modified this model to estimate the graphic design and printing cost for adding information onto existing records such as Bills of Lading, Invoices, and Purchase Orders. We also used the model to estimate the cost of designing an entirely new input-to-output ingredient record for part of option 13.

Based on a sample of bills of lading collected through FDA's early outreach efforts and through the Web sites of companies and trade associations, FDA assumes that firms already collect most