

apply to foreign entities. It is clear from Table 39 of this document that any

provision in this regulation that takes the size of the facility into account

would cover a significant percent of food businesses.

TABLE 39.—PERCENTAGE OF SMALL AND VERY SMALL FIRMS

Type	< 500 Employees	< 20 Employees	< 10 Employees
Manufacturers	98.0%	85.3%	77.0%
Wholesalers/Warehouses	99.3%	89.4%	82.2%
Packaging ¹	98.6%	87.0%	78.7%
Transporter/Packers	99.5%	94.8%	89.5%
Grocery and other Retail	99.7%	93.9%	87.8%
Convenience Stores	99.6%	88.9%	73.1%
Mixed-Type Facilities that Have Farms	—	—	—
Importers	—	—	—

¹ Includes both outer packaging and food contact substances.

In Tables 40 and 41 of this document, FDA presents the average and maximum possible burden placed on each small and very small firm following the adoption of the final rule. We explain these costs in detail in the preliminary regulatory impact analysis. Costs fall into four categories: learning about the regulation, redesigning records to accommodate new information, collecting and maintaining new information, and planning for a rapid response in the event of a records request from FDA under this authority. The average mean startup costs reported in the table are approximately \$888, and the average mean recurring costs

reported in the table are approximately \$222. Based on our assumptions, average maximum startup costs are approximately \$2569 and the average maximum recurring costs reported in the table are \$521. We also acknowledge considerable nonquantifiable uncertainty in these estimates, so the true burden of the regulation on small businesses could be higher or lower.

The estimated burden on convenience stores is lower since: (1) We assume that most convenience stores will depend on either a corporate parent or other facility in the supply chain for document redesign, and (2) only a small percentage of convenience stores sales (11.4 percent according to a comment

received through FDA's early outreach) is for food products, so the volume of food products for which they would have to collect information and prepare access is relatively small. Transporters and Packing firm costs are larger since we assume that transporting firms would not be able to share records redesign costs with firms up or down the supply chain. We also assumed that packaging producers and distributors would have to maintain relatively less additional information since not all of their products will be used to pack food. In subsequent years, all firms will only incur the additional records maintenance burden.

TABLE 40.—AVERAGE STARTUP AND RECURRING COSTS PER FIRM

Cost	Transporter/ Packer	Convenience Store	Packaging ¹	Other
Startup				
Learning	\$120	\$120	\$120	\$120
Redesign	\$1,211	\$121	\$606	\$606
Access Preparation	\$151	\$75	\$151	\$151
Total Startup	\$1,482	\$317	\$876	\$876
Recurring				
Additional Records Maintenance	\$326	\$63	\$163	\$326

¹ Includes both outer packaging and food contact substances.

The maximum first year costs per firm are calculated using the following assumptions: First, a firm may not have Internet access, so it may have a 5 1/2 hour learning burden. Next, a firm may incur the largest value in the

distribution of redesign costs, and may not be able to share the redesign burden with other facilities. Finally, the firm may not receive records with any additional information previously collected that is required in this

proposed rule. Thus they may incur the entire burden of additional records maintenance. We assume access preparation costs do not vary.