

TABLE 41.—MAXIMUM STARTUP AND RECURRING COSTS PER FIRM

Cost	Transporter/ Packer	Convenience Store	Packaging <sup>1</sup>	Other
<b>Startup</b>				
Learning	\$138	\$138	\$138	\$138
Redesign	\$2,299	\$2,299	\$2,299	\$2,299
Access Preparation	\$151	\$75	\$151	\$151
Total Startup	\$2,588	\$2,512	\$2,588	\$2,588
<b>Recurring</b>				
Additional Records Maintenance	\$653	\$126	\$653	\$653

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

In order to get a rough estimate of the impact of higher recordkeeping costs on small businesses, we ran the small business simulation model that was developed by FDA's contractor, RTI International (Ref. 31), for the candy and ready-to-eat food sectors. In the simulation, we used the high annual costs of the second year per-firm recordkeeping costs (about \$850) to see the impact on revenues and cash flow. The results from the simulation indicate that when firm size (by number of employees) is assumed to be normally distributed, the recordkeeping costs in the second year would result in pre-tax costs being greater than cash flow for 0.1 percent of firms with fewer than 20 employees in the candy industry. For the ready-to-eat sector, the results indicate that the high second year per-firm recordkeeping costs would not result in pre-tax costs being greater than cash flow for any firms.

*Additional flexibility considered:* Agencies can consider three basic small business regulatory options: First, if the implementing statute allows, an agency could exempt small businesses from all regulatory requirements. In addition, an agency could modify the regulatory requirements for small businesses, including offering an exemption from part of the regulation. Finally, an agency could specify a longer effective compliance date for small businesses. In this proposed rule, FDA considers each of these possibilities. We designed several provisions to lower the impact on small firms, some of which apply to small firms exclusively, and some of which apply to all firms.

First, FDA proposes a staggered effective compliance date for this regulation. The compliance dates are the following: 6 months for large firms, 12 months for small firms, defined as having less than 500 but more than 10 full-time equivalent employees, and 18

months for very small firms, defined as having 10 or fewer full-time equivalent employees. Only one of the cost estimates we explained in detail in the preliminary regulatory impact analysis directly depends on the compliance date; records redesign cost. We estimated using the FDA Label Cost Model that very small firms would save an average of 10 percent in their redesign costs by having longer than a year to comply. The medium 1-year redesign cost estimate is \$1,309 per redesign. We assume this cost is shared between two firms, since a single set of records can serve as source, recipient, and transport records. The average redesign cost per firm is \$655 for firm types other than transporters and convenience stores. The median 18-month redesign cost estimate is \$1,190 per redesign, for an average cost of \$595 per firm. The estimated medium redesign burden would drop by \$60 per firm, or 8 percent of the estimated average first startup burden of the regulation. Also, present value considerations will result in reduced future cost estimates. Thus, the later compliance dates specified in the proposed rule will reduce the total cost for all small firms. FDA requests comments regarding these assumptions.

In addition, FDA is proposing to describe the specific information a covered entity must keep, but not specify the form or type of system in which those records must be maintained, which will allow firms to comply with the regulation in a manner that is cost effective. Mandated structural changes to records or required retention technology probably would not be the most cost effective solution for every firm, so not specifying the form or type of system in which the records must be maintained almost certainly would impose a smaller burden on industry, including small

businesses. Comments to FDA's preliminary outreach generally agreed with this position. FDA believes that describing the specific information a covered entity must keep, but not specifying the form or type of system in which those records must be maintained is the most flexible means of proposing this regulation for all businesses. However, FDA also believes that each provision in this proposed rule is necessary to tracing investigations, so we do not propose any additional flexibility for small or very small businesses.

Finally, FDA is proposing several exemptions based on facility type. Since the majority of facilities of each type are small businesses, these exemptions will reduce the small business burden of this regulation. In the proposed rule, FDA exempts retail facilities from having to maintain records of final consumers who purchase retail food products. Requiring firms to collect and maintain consumer information would increase the burden on retail facilities by at least the amount of the current redesign burden and current additional records maintenance burden summarized in Table 40 of this document. Without this exemption, retail firms (including small retail firms) would have to design and maintain an entirely new recordkeeping system.

Most other small business exemptions are infeasible for this regulation because we believe records held by these businesses are an important link in the chain of custody for the food products. As shown in Table 39 of this document, a large percentage of the food industry would be exempt under any blanket small business exemption. Even nonemployee businesses (who have no paid employees, the smallest exemption possible) still constitute a substantial proportion of the food industry. Any type of exemption in the middle of the