

time for FDA traceback investigations is 2–3 days, we believe the same information could be provided in one day with the types of recordkeeping systems currently in use. Therefore, the difference between the cost of a 2–3 day response time and a 1-day response time is assumed to be negligible. However, the shorter access time requirements of 4 hours or 8 hours would likely impose a new burden on a number of firms.

FDA assumes that regardless of whether or not the firms maintain records electronically, every firm would probably have to devise a predetermined compliance strategy to deal with the situation where FDA requested records under this authority. Furthermore, a comprehensive response plan may allow firms to maintain their current business practices, such as maintaining paper records or maintaining records offsite, and still comply with a request, so it may be the lowest cost solution. Therefore, as a first estimate of the potential impact of this proposed rule, FDA assumes a burden for each firm of devising a response plan that could accommodate a 4-hour or 8-hour access time for an FDA record request. Since European firms are required to supply their tracing records on demand to the appropriate authorities, FDA assumes that they already have in place a plan that would accommodate a 4-hour or 8-hours records required response time. (Ref. 14).

In the analysis of previous regulations, we estimated a related

planning cost for food firms. In the juice HACCP rule, (Ref. 15), we estimated a 60-hour labor burden per firm of developing a HACCP plan. Developing a HACCP plan is very complicated and includes the establishment of: (1) Critical control points and critical limits for every hazard identified, (2) protocols on how to manage deviations from these limits, and (3) procedures for verifying and validating all aspects of the plan. By contrast, developing a records access plan requires: (1) Evaluating current recordkeeping practices including records maintenances and records storage practices, which we assume would take on average about 3 hours; and (2) identifying and planning for any changes in recordkeeping practices that would be required, which we assume would also take on average about 3 hours. FDA considers the planning needed to deal with a possible records request under this authority much less complicated than what would be needed in a HACCP plan. If developing a HACCP plan takes 60 hours, then 6 hours of administrative labor per firm (lowered to 3 hours per convenience store firm) is a reasonable estimate of the burden imposed from this planning requirement, which is far more simple than a HACCP plan. We request comments on this assumption. FDA estimates that new businesses will also have to incur records access costs.

FDA requests comments regarding how many firms may need to adopt a new records retention strategy under

both the 4-hour or 8-hour, and 1-day records access time requirements, and the additional time and capital needed to comply with these requirements. We plan to conduct further research on all of these burden estimates before publishing the final rule, and expect that the estimates could change.

Option 2: Comprehensive foreign and domestic coverage with 4-hour and 8-hour records access times and 1 and 2 year records retention times.

FDA assumes that facilities currently collect and keep records with most of the information required by this option in their normal business activities. FDA assumes that learning and redesign costs will be incurred per firm, and that the additional records maintenance costs will be incurred per facility. For all options the learning costs are explained in the general cost section above.

*Redesign Costs, option 2.* Table 4 of this document presents the average redesign cost calculations. For the purposes of presentation, Table 4 only includes calculations for the mean number of exclusive importers affected. FDA assumes that large and small firms incur all redesign costs in the first year following the final rule, while very small firms will incur all redesign costs in the second year following the final rule. The label cost model estimated planning efficiencies of 10 percent for redesign processes further than 1 year in the future, and this savings is included in the categorical totals in table 4.

TABLE 4.—REDESIGN COSTS, OPTION 2

	Firm Count	Middle Estimate	Low Estimate	High Estimate	Average Middle Cost per Firm
<b>Domestic</b>					
Manufacturers	18,474	\$22,488,000	\$15,402,000	\$39,497,000	\$1,217
Wholesalers/Warehouses	38,476	\$46,601,000	\$31,916,000	\$81,845,000	\$1,211
Packaging <sup>1</sup>	34,633	\$42,092,000	\$28,827,000	\$73,926,000	\$1,215
Transporters/Packers	15,171	\$18,243,000	\$12,494,000	\$32,040,000	\$1,203
Retail Grocery and Specialty Food	76,639	\$92,308,000	\$63,220,000	\$162,122,000	\$1,204
Convenience Stores	6,887	\$8,415,000	\$5,763,000	\$14,779,000	\$1,222
Mixed-Type Facilities that Engage in Farming	12,199	\$14,786,000	\$10,127,000	\$25,969,000	\$1,212
Importers	7,561	\$9,165,000	\$6,277,000	\$16,096,000	\$1,212
Total Domestic	210,038	\$254,098,000	\$174,026,000	\$446,274,000	\$1,210
<b>Foreign</b>					
Final Holders	21,091	\$25,565,000	\$17,509,000	\$44,900,000	\$1,212
Manufacturers	36,385	\$44,103,000	\$30,205,000	\$77,459,000	\$1,212