

of the information necessary to comply with options 2–12. Bills of lading, purchase orders, or invoices typically have the full address of all parties, the transaction date, and descriptions of the relevant food articles. Based on the samples, FDA assumes that firms will have to add a limited amount of new information to their standard documents. This new information principally depends on how the precise definition of “description of the food article” developed in these regulations differs from that commonly used by industry under its current recordkeeping practices. In some of the sample bills of lading the description of the food article being transported did not have the precision required under these proposed regulations. In addition, some bills of lading did not have a design that would allow for the identification of other entities in custody, or control of the transported food articles, or an official spot to record the mode of transportation.

The FDA Labeling Cost Model was designed to estimate the costs of designing and printing new food labels, but many of the design issues should be similar when designing and printing a new food product record. For example, both a label and a document designer must make similar decisions regarding wording and spacing, and both activities should include administrative activity, graphic design, and printing. The model also includes cost categories, such as analytical testing and focus groups that we do not use, since they are not relevant for document redesign. FDA does acknowledge that these estimates are only approximations; we believe the values this model generates are reasonable, and request comments on all assumptions. For the purposes of the analysis of options 2–12, FDA assumes a limited information, one-color redesign of a paper document. For the purposes of option 13, FDA assumes an additional full design of a new paper document.

The model also includes an estimate of central tendency, and a low and a high estimate for each cost category included in the document redesign cost. For each component of cost in this model, FDA’s contractor, RTI International, received a range of estimates from food companies. The lowest of these estimates is considered the limit of the low range, and the highest of the estimates is considered the limit of the high range. The low and high range of total cost is calculated by adding together all of the low and high range estimates of each component cost, so the low and high range estimates of this model are unlikely. The estimated

cost of a limited information redesign in year 1 is \$1,309, with an uncertainty range of between \$897 and \$2,299. The estimated cost of a full information redesign in year 1 is \$6,193, with an uncertainty range of between \$4,653 and \$11,198. The label cost model estimates an approximately 10 percent efficiency savings in redesign costs incurred by very small firms in year 2.

The cost of redesigning product records will not be borne by all firms. For each step in the chain of custody, copies of the same bills of lading or invoices probably will be used for records of the immediate previous source, records of the immediate subsequent recipient, and transportation records. Consider the following example of a long chain of custody for a food product: (1) Farmer, (2) transporter, (3) bulk collection (e.g. grain silo), (4) transporter, (5) processor, (6) transporter, (7) warehouse, (8) transporter, and (9) retailer. The number of entities in this series is clearly limited by the total number of transporters in the country, so FDA assumes that all transporting firms have to redesign their records. This supply chain should generate four sets of bills of lading and four sets of invoices for all products. Similarly, a six-step supply chain should generate three separate sets of records. Since farmers are exempt under this proposed regulation, the number of records possibly containing new information is roughly equal to the number of facilities in the supply chain, but FDA assumes a substantial number of nontransporters will depend on storing only the redesigned bill of lading to comply with the regulation. Assuming an equal probability of a firm using the bill of lading or redesigning its own documents, FDA assumes that half of the nontransporting firms will incur redesign costs.

We modify this estimate for convenience stores. Individual convenience stores have a small sales volume and—according to a comment received during FDA’s early outreach efforts—only 11.4 percent of their average total sales are for food products. In addition, the majority of convenience stores are locally owned franchises of large corporations, and these stores may have access to the parent corporation to assist in redesign. FDA therefore assumes that 90 percent of convenience stores will rely on other parties for records redesign. The total costs for other firm types may also be an overestimate; FDA expects that trade groups may assist in the needed redesign of existing records, further lowering the burden, but we do not

estimate the cost savings for this activity.

In addition, we make a further adjustment for foreign facilities: According to comments received, firms exporting from the European Union (EU) are already subject to similar recordkeeping requirements under EU regulation 178/2002. Article 18: *Traceability* of the EU regulation states:
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(1) The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

(2) Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures, which allow for this information to be made available to the competent authorities on demand.

(3) Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand * * *. (Ref. 14).

Because of these regulations, FDA assumes that the firms from EU member states (31.9 percent of all foreign firms that export to the United States) will already be subject to recordkeeping requirements similar to the requirements of this proposed rule. Therefore these foreign firms would not have to redesign their records and would not incur a redesign burden.

Additional records maintenance: FDA expects that personnel at most facilities will incur a burden in order to collect and maintain a limited amount of additional information. However, as in the redesign section previously discussed in this document, FDA assumes that one set of records can serve as source, transportation, and recipient records, so the estimated burden of collecting and maintaining the additional information will be shared among more than one facility.

FDA does not have a direct estimate of this recordkeeping burden; we rely on a previous analysis of Juice Hazard Analysis and Critical Control Point (HACCP) recordkeeping (Ref. 15) because that analysis also dealt with the costs of additional recordkeeping. In that analysis an estimate of 3 minutes per hour is made of the burden that would be incurred by some food