

processing facilities for the additional monitoring of critical control points and keeping HACCP system records that would be required. In this proposed rule the additional monitoring activities required would be negligible since records will likely only need to be modified. Furthermore, compared to the Juice HACCP requirements, there would be less additional information that would need to be maintained in this proposed rule. If the weekly burden for additional monitoring and recordkeeping required for Juice HACCP compliance is 120 minutes (assuming 3 minutes per hour of additional monitoring and recordkeeping for 8 hours a day and 5 days a week) a burden estimate of about 6 minutes per day or 30 minutes per week seems reasonable for this proposed rule. We request comments on this assumption. FDA treats foreign facilities already subject to a similar recordkeeping regulation as already in compliance, and assumes that the burden of additional records maintenance will be shared among an average of two covered entities, including transporters, for an average of 15 minutes per week per facility or 13 hours per year per facility.

Grocery stores, convenience stores, and packaging producers and distributors may have different additional records maintenance burdens. Since, under the proposed rule, grocery stores only have to maintain immediate previous source records, their additional burden may be lower but they also receive many shipment records they would need to maintain. In a comment FDA received during our early outreach efforts, a large retail grocery chain estimated that they received approximately 300 purchase orders per store per year, or approximately 6 purchase orders per week per store. A purchase order could contain many invoices and may be more of a burden to maintain, so FDA considers the estimated additional burden of 15 minutes per week reasonable for grocery stores. We request comments on the assumptions used to derive this estimate.

Convenience stores have a lower records maintenance burden than grocery stores. According to comments received during our early outreach efforts, approximately 50–70 percent of grocery store stock keeping units (SKUs) are food products, while only 11.4 percent of the sales of convenience stores are from food products. SKUs and sales are not equivalent measures of size, but this comparison is a reasonable basis to lower the estimated additional burden for convenience stores relative to grocery stores. Dividing the grocery

store burden by the ratio of the percent of food sales for convenience stores and grocery stores (assumed to be 60 percent, or an average between 50 percent and 70 percent of SKU totals) yields an additional records maintenance burden of approximately 2.5 hours per year for convenience stores. We request comments on the assumptions used to derive this estimate.

Finally, the data sources do not distinguish between facilities that produce packaging for food and packaging for other products. Although we assume that all packaging facilities potentially could be producing or handling food packaging, not all of their output would be dedicated in this way. We assume that, for the average packaging facility, 50 percent of the output is for food packaging and that an information collection burden of 50 percent would be required of packaging facilities. We request comments on this assumption.

*Storage costs:* Although FDA does not believe the marginal burden of storing records to the specified times in any of the options is zero, evidence on record storage times suggests that the burden would be minimal. Since FDA was unable to gather any evidence suggesting the size of this extra burden, however small, and since the specified storage time requirement in these options is well within industry norms, we estimate the cost for extra storage time to be zero.

Many comments received in response to FDA's early outreach supported requirements of either 1 year for perishable products or 2 years for nonperishable products, stating that the maximum allowable 2-year requirement was both reasonable and necessary. In addition, a survey of dietary supplement manufacturing practices conducted by FDA's contractor, RTI International, asked a representative sample of dietary supplement manufacturers how long they kept records of shipped ingredients (Ref. 16). The facilities had a choice of two response types: Keeping records a certain amount of time past the date of expiration, and keeping records a certain amount of time past the manufacturing date. The survey did not distinguish between perishable and nonperishable ingredients. Because of nonresponse weighting, stratification, and deductive disclosure problems, FDA's contractor, RTI International, did not report confidence intervals for these estimates, but the mean number of years that firms kept data records was 2.31 years for facilities that reported retention from the date of the expiration of the ingredient, and 4.57 years for

facilities that reported retention from the date of product manufacture. The lowest mean response from any facility category was 1.94 years from the expiration date of the ingredient, which is still probably more than 2 years from the delivery date.

*Access costs:* For purposes of evaluating the marginal cost of the record access time provision, FDA considered two possible requirements: The combination of 4 hours during normal business hours and 8 hours at other times, or 1-day regardless of when the request was made. Accessing records in a shorter time period than what industry is currently capable of will impose a burden on firms and facilities, and the shorter the required response time the larger the burden. The cost of records access response fall into two categories: Costs that would be incurred only in the event that FDA requests records under this authority, and costs that would be incurred to plan for records access and to change business practices to allow for a rapid response. The latter costs would be incurred regardless of whether or not FDA ever requested records under this authority.

For the first cost, FDA expects that in the event of a records request under this authority, any access requirements less than the current average access time of 2–3 days would impose a burden on businesses involved in providing those records. All other things equal, a 4-hour or 8-hour requirement would probably impose a greater burden than the 1-day requirement. However, we cannot quantify the probability of this burden for the same reason as the lack of quantification in the benefits section: It is impossible to predict when FDA will have to invoke this authority in response to an adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

For the second cost, FDA assumes that a 1-day records access time requirement is approximately the shortest possible response time that would not compel some firms to change their business practices. The costs for a 1-day records access requirement are considered in option 5. We assume that the 4-hour or 8-hour response time required in all options except option 5 is more likely to compel business practice changes and preemptive emergency planning than is the 1-day response requirement. A 1-day response time is possible with the types of recordkeeping systems currently in use, including automated recordkeeping technology, and offsite storage and paper retrieval. While the average access