

regulation, would be required to keep records pertaining to the covered activity even if they are not required to keep records relating to exempt activity. Records must include information reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product. Required times for record-retention would be 1 year for perishables destined for final consumption in their perishable state, and 2 years for all other foods or food packaging. Upon a written request, records must be made available to FDA in 4 hours, if the request is made during the normal business hours of 8 a.m. to 6 p.m., or 8 hours otherwise.

3. Require all elements of option 2, except exclude persons that manufacture, process, pack, hold, receive, distribute, transport, or import outer food packaging.

4. Require all components of option 3 but do not require persons that are required to establish and maintain records on food to establish and maintain records on the food's outer packaging.

5. Require all components of option 4, but change the required time for responding to an FDA records request to 24 hours.

6. Require all components of option 4, but exempt intrastate businesses.

7. Require all components of option 4, but exempt persons who operate farms, and persons who operate restaurants, who also perform a covered activity.

8. Require all components of option 4, but change the record retention requirement to 1 year for all products.

9. Require all components of option 4, but change the record retention requirement to 2 years for all products.

10. The proposed rule. Require all components of option 4, but only cover foreign facilities also covered by the proposed registration regulation published at 68 FR 5377 (February 3, 2003).

11. Require all components of option 4, but only cover foreign facilities that

are the final holder of the product before export to the United States.

12. Require all components of option 4 but cover only domestic persons.

13. Require all components of option 4, but the required information would include the records necessary for facilities to be able to link specific raw ingredients to specific outgoing finished products for all raw ingredients and all products. This option is to analyze the costs and benefits of requiring records that link specific raw ingredients to specific finished products, including ingredients from different sources that are currently commingled before being incorporated into finished products.

In order to clearly identify the marginal cost of each provision specified in the codified, most options represent only one modification of a provision in another option. Option 4 is appropriate to use for comparison with the other options, since it differs by only one provision from almost all other options considered. As the Analysis of Economic Impact section will reflect, FDA has examined the economic implications of this proposed rule by analyzing several regulatory options that address the need for the recordkeeping regulation. FDA is proposing option 10. FDA believes that this option would require creation and maintenance of the records needed to address credible threats of serious adverse health consequences or death to humans or animals while providing adequate flexibility and minimizing industry burden. FDA requests comments on other viable options not considered by this analysis. Note that additional options designed to lower the regulatory burden on small businesses are considered in the initial regulatory flexibility analysis below.

Cost assumptions: The total cost of each of these options will depend on the number of facilities affected and the extra burden these options place on facilities. For all options, FDA would only specify the information a covered

entity must keep, but not specify the form or type of system in which those records must be maintained; we expect that for all options, if possible, firms will choose to collect the additional information not currently included in their existing records. Furthermore, FDA assumes that firms will choose to comply with any new requirements by modifying shipping or purchase records such as Bills of Lading, Invoices, or Purchase Orders. In its cost computations, FDA does not take into account other Federal, State, or local regulations that require similar recordkeeping practices for small sectors of the food economy (e.g., "the BSE rule", § 589.2000) because of the relatively large amount of uncertainty in our knowledge of existing State and local recordkeeping requirements, and because the effect on the cost computations from their inclusion is likely to be very small. For this reason the analysis does not distinguish among entities that may be covered by the recordkeeping requirements in "the BSE rule" which may result in a small overstatement of the costs of the proposed rule. The following discussion of facility counts and per facility costs is not tied to any specific option, but describes the data and assumptions we use to analyze the cost of each option.

Number of facilities and number of firms affected: FDA assumes that for the options that do not consider exemptions, approximately 1,230,000 facilities owned by approximately 960,000 firms would be covered. This number includes domestic facilities that manufacture, process, transport, distribute, pack, receive, hold, or import food or food packaging, and foreign facilities performing any of these activities on food or food packaging destined for consumption or use in the United States. Table 1 contains a summary and breakdown of this estimate.

TABLE 1.—AFFECTED FACILITY AND FIRM DETAILS

Type	Facility Estimate	Facility to Firm Adjust. Factor	Firm Estimate	North American Industry Classification System (NAICS) Codes if Applicable
<i>Domestic</i>				
Manufacturers	43,376	1.17	36,948	3111–3119, 3121
Wholesalers/Warehouses	95,745	1.24	76,952	4224, 4225, 4228, 49312, 49313
Packaging ¹	73,813	1.07	69,266	32221, 32222, 326111, 326112, 326130, 326140, 326150, 326160, 3272, 331315, 331316, 332431, 332439, 42261, 323110, 323111, 323112, 323113, 323114, 323115