

would likely hamper trace-back capability by less than an exemption of the same number of domestic facilities.

Moreover, option 10 has the added benefit of simplicity in that the foreign coverage would be the same as that covered under the registration rule. This parallel coverage to the registration rule would make monitoring both recordkeeping and registration practices less costly.

*Option 11, same as option 4 except that foreign coverage includes only the final holders before export:* In addition to the exemptions in option 10, this option exempts an additional single category in the middle of the foreign supply chain and with a large number of facilities. Consequently, the benefits under this option are lower than under option 10 by both the speed criterion and the thorough investigation criterion. However, as we explained in the discussion of option 10, the

proportionally smaller importance of imported foods in the domestic food supply implies that the exemption should have relatively little effect on benefits.

*Option 12, same as option 4 except that all foreign facilities are excluded:* This option exempts all foreign suppliers from record-keeping requirements. When compared to options 10 and 11, the number of foreign firms covered under this option is the lowest. As such, the benefits of this option, when compared to the other two, are the lowest as well using both the speed criterion and the ability to conduct a thorough investigation.

*Option 13, comprehensive coverage that requires facilities to be able to tie specific input ingredients to specific products:* This option generates the highest benefits. A complete list of the specific source of all ingredients would be available for all processed and raw

foods, greatly aiding traceback and trace forward investigations. In addition, of all the options, this would allow investigators to most quickly identify candidate traceback facilities, since it would allow FDA to effectively narrow our search to specific entities.

Table 38 of this document presents the overall ranking of each option based on the previous summary. Option 13, requiring input ingredients to be connected to output ingredients through records, has the highest absolute benefits, followed by option 2. The lowest ranked option in terms of absolute benefits is the baseline, option 1, and the lowest benefits of the possible interventions would be the proposed rule with a complete foreign facility exemption, due to the large number of foreign facilities where adulteration might occur. FDA requests comments on this ranking.

TABLE 38.—RANKING OF EFFECTIVENESS OF EACH MECHANISM UNDER EACH OPTION

Option:	Benefit 1	Benefit 2	Overall Ranking
1) No action	13	13	13
2) 4 or 8 hour records access	2	2	2
3) Outer packaging exemption	3	3	3
4) Exclude recordkeeping on outer packaging	3	3	3
5) 24-hour records access	7	9	8
6) Intrastate exemption	10	10	10
7) Mixed-type facilities that engage in farming	5	5	5
8) 1-year record retention	7	7	7
9) 2-year record retention	6	6	6
10) Proposed. Same foreign coverage as Registration	8	8	8
11) Cover only final foreign holders	11	11	11
12) Exempt all foreign suppliers	12	12	12
13) Input to output requirement	1	1	1

#### B. Initial Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this proposed rule would have a significant economic impact on a substantial number of small entities.

*Impact per firm:* We define small as employing fewer than 500 full-time-equivalent workers. The SBA uses several criteria for identifying a small firm based on its NAICS code, but having less than 500 employees is the most common SBA small definition in the food industry (Ref. 31). We also consider two definitions of very small: Less than 20 employees and less than 10 employees. The great majority of firms are considered small when classified by any of these definitions. Table 39 presents the percent of firms in each of these categories. Not included in this

table are farm numbers. We calculated farm percentages using the Agricultural census through the NASS, but the Agricultural census only classifies farm size by sales and acreage, not by the number of employees (Ref. 19). Fifty percent of farms have less than \$10,000 in annual sales. Neither SBA definitions nor employee data exist for exclusive food importers; we assume that the percentage of small firms in this category is similar to the percentage in other food categories. We do not include foreign firms in this analysis because the Regulatory Flexibility Act does not