

supply chain very likely would make records unavailable and therefore would break the chain of custody of many products during tracing investigations.

The Bioterrorism Act exempts farms and restaurants. Because most farms and restaurants are small businesses, this exemption provides regulatory relief to small entities. In addition, in this proposed rule the term “farm” includes facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; “farm” also includes facilities that manufacture or process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. Most of these facilities are small entities. The statutory exemptions provide considerable relief to small entities without compromising the purpose of the recordkeeping regulation. FDA will continue to conduct research regarding possible further exemptions, and requests comments regarding possible exemptions that would provide additional relief for small businesses

while still accomplishing the goals of the Bioterrorism Act.

### C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule would include a “Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” The current inflation-adjusted statutory threshold is \$112,300,000. FDA has determined that this proposed rule does constitute a significant rule under the Unfunded Mandates Reform Act.

Most of the requirements of the Unfunded Mandates are fulfilled in the Executive Order 12866 analysis, above. The requirements under the Unfunded Mandates Act of 1995 include assessing the rule’s effects on future costs; productivity; particular regions, communities, or industrial sectors; economic growth; full employment; job creation; and exports.

Future costs: The future costs from the recordkeeping rule include the recurring costs, which reach their long-term value in the third year after the proposed rule would become final. These costs would be incurred by domestic facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food, and the foreign facilities that are subject to this proposed rule (foreign manufacturers, processors, packers, and holders of food that would be required to register).

Recurring costs from collecting new information would be incurred in each future year. The estimates of these costs were modeled using the previous analysis of the juice HACCP regulation as a frame of reference. An hourly burden of 30 minutes a week was used for the additional monitoring and recordkeeping that would be required from this proposed rule. This hourly burden estimate was modified for foreign facilities and convenience stores to allow for structural differences assumed in their operations. For a fuller illustration of the future costs of the proposed rule, see Table 20 of this document.

TABLE 42.—FUTURE COSTS

	Mean	Low	High
Year 3 and later years	\$221,130,000	\$212,313,000	\$229,680,000

*Particular regions, communities, or industrial sectors:* The costs of the recordkeeping requirement will be shared among domestic manufacturers, processors, packers, transporters, receivers, holders, and importers of food, and the foreign facilities that would be subject to this proposed rule (foreign holders, packers, manufacturers, and processors that would be required to register) as well as domestic consumers. The higher costs incurred by domestic and foreign suppliers as a result of these regulations will mostly be passed on to consumers in the form of higher food prices. Since consumer demand for food is highly inelastic almost all of the higher costs incurred by food suppliers will be passed on to consumers. Consequently, higher food prices will reduce real incomes for all consumers. However, we believe that the benefits from these regulations will justify the reduction in real incomes. These benefits are measured as an improved ability by the FDA to respond to and contain threats of serious adverse health consequences from accidental or deliberate contamination of food.

*National productivity, economic growth, job creation, and full employment:* Although this proposed regulation is costly, we do not expect it to substantially affect national productivity, growth, jobs, or full employment. The total costs will be small relative to the economy, and will be offset by benefits. The improved ability to respond to, and contain, serious adverse health consequences means less illness and fewer sick days taken by employees, and lower adjustment costs by firms that would otherwise need to hire replacement employees.

*Exports:* This proposed rule would require additional records to be kept throughout the production and distribution chain for food. The additional recordkeeping costs would increase the total costs of production and distribution for all of the regulated products, including products sold within the United States and across national borders. These increased costs will be largely passed on to consumers in the form of higher prices, which will tend to reduce the quantity demanded of the regulated products. The increased

prices of U.S. exports could reduce the quantity of U.S. exports demanded, particularly in comparison with exports from countries that do not implement similar recordkeeping regulations. We expect this effect to be insignificant, because under the proposed rule (option 10, described above), the increases in the price of U.S. exports (and resulting decreases in quantity demanded) would be quite small.

### D. SBREFA Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of \$100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that