

businesses as defined by the Small Business Administration. Because most of the importers affected are small, all options considered in the Benefit-Cost Analysis in section IV.A of this document are regulatory relief options.

A few comments stated that FDA's analysis of the impact of prior notice on small businesses was inadequate. The comments also wished to see a breakdown of costs of the rule per small business by industry sector. Unfortunately, FDA does not have detailed information on which businesses subject to this interim final rule are small, nor did comments provide such information. Therefore, FDA cannot perform a detailed analysis of the costs per small business by industry sector. With limited data, FDA can estimate an average cost per importer for some of the prior notice cost categories, estimate some costs of the rule per retail establishment, and provide an average estimate of cost per establishment if the costs of the rule were evenly distributed across the supply chain.

2. Costs per Entity

This interim final rule requires FDA be notified of incoming products

electronically before the food arrives at a U.S. port. The annual cost of doing so is about \$2,400 per submitter (based on \$187.5 million in notification costs/77,427 U.S. importers). This calculation is presented in table 52 of this document. Also presented in table 52 is the cost per importer to learn about the prior notice interim final rule and to coordinate the information that needs to be submitted; the costs per importer of these two activities are about \$850 and \$400, respectively.

As discussed and shown in tables 1B and 2 of this document, about 3,100 U.S. importers are estimated to not have electronic transmitting capacity and will have to obtain computer equipment (at a cost of about \$2,000 per importer) and Internet access (at a cost of about \$240 annually) in order to comply with this interim final rule. FDA could not provide flexibility for those importers who do not have electronic transmitting capacity, because paper notices could not be submitted in the prior notice timeframe and would therefore actually be more burdensome to importers, and because FDA would not be able to receive, review, and respond to paper prior notices that are submitted on a routine basis.

This interim final rule will cause some loss of product value if the prior notice requirement causes perishable products to have to wait any length of time before arriving at a U.S. port. The costs of lost product value vary with the required notice time. FDA does not have information on the subset of importers who will be affected by these costs; therefore, we cannot calculate a cost per importer for these potential losses. We do discuss the various costs associated with this possibility in the options outlined previously.

Table 52 of this document shows the average costs per importer to learn the rule, coordinate information, and submit prior notice. Table 52 also shows the average costs to the importer to absorb the costs of not being able to use BRASS and to absorb costs of lost value of perishable products. Table 52 also shows these average costs per retail establishment and per establishment across the supply chain. Numbers for establishments come from the County Business Patterns, U.S. Census, and Non-Employer statistics. A complete discussion of these establishment numbers can be found in the FDA Registration of Food Facilities interim final rule (Ref. 20).

Table 52.--Costs per Importer and per Establishment

Activity	Total Costs	Cost per importer (n= 77,427)
Learning costs	\$66,240,000	\$856
Coordination costs	\$31,095,000	\$402
Annual costs to fill out prior notice screens	\$187,500,000	\$2,422
Costs for BRASS users	\$48,462,000	\$626
Lost value for perishables	\$12,877,000	\$166
Total estimated average costs per importer		\$4,472
Total estimated average costs per retail establishment (n= 238,697)		\$1,450
Total estimated average costs per establishment in the distribution chain (n= 454,968)		\$761

3. Additional Flexibility Considered

Because of the requirements of the Bioterrorism Act, FDA is precluded from selecting some of the options that typically would be considered to lessen the economic effect of the interim final rule on small entities, including granting an exemption to small entities. FDA concludes that it would be inconsistent with section 307 of the Bioterrorism Act to allow small entities a later effective date, since the Bioterrorism Act establishes an effective date for prior notice that applies to FDA-regulated food imported or offered

for import into the United States, whether or not FDA has issued a final rule by this deadline. Thus, FDA concludes that Congress intended for prior notice to apply to FDA-regulated food by the effective date established in 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 rulemaking 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 \$113 million. FDA has determined that this interim final rule is significant under the Unfunded Mandates Reform Act. FDA has carried out the cost-benefit analysis in preceding sections (*see* table 47 of this document for the total costs). The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on the following factors: