

to inform of a threat. While FDA recognizes that in some instances and depending on the nature of the threat, it may not be able to target only certain facilities with which to communicate (e.g., a threat against a food product used as an ingredient in many finished products), this does not mean that having product category information would not help FDA focus its resources in other situations (e.g., a threat specifically against soft drink beverage facilities).

(Comment 189) Some comments stated that including food product categories was necessary for the registration system to have any utility.

(Response) FDA agrees with these comments and has chosen to include product categories as a required element in the registration.

c. U.S. agent.

(Comment 190) Many comments state that requiring a U.S. agent would generate no benefits and might even inhibit communications between the facility and FDA. Comments offer alternatives such as not requiring the U.S. agent to reside or maintain a place of business in the United States, exempting facilities that provide an e-mail address from the U.S. agent requirement, and making the U.S. agent optional.

(Response) FDA does not agree that a U.S. agent will inhibit communications with FDA. The facility may opt to

register with FDA directly and have FDA communicate directly with the facility in case of an emergency. Therefore, requiring a U.S. agent will not lower the expected benefits, as FDA still would have a contact in the United States for each facility with which the agency can communicate on routine matters (e.g. issuance of new regulations or guidance applicable to the facility). For some facilities that lack the ability to communicate easily with the United States, due, for example, to language barriers or lack of telephone or Internet access, the U.S. agent will be an important link for both registering the facility, if the owner, operator, or agent in charge authorizes the U.S. agent (if an individual) to register the facility, and communicating with FDA. For a facility that prefers to register and communicate with FDA itself, the U.S. agent still provides additional benefits, such as of being in the same, or nearby, time zone.

d. Frequency of updates.

(Comment 191) Many comments request that FDA require less frequent updates of registration information on the basis of high costs to update registration, without generating offsetting benefits.

(Response) FDA has lengthened the update period to 60 days, but has not extended it to the 6 to 12 months requested in many comments. The usefulness of the registration database

depends in large part on its accuracy. Allowing longer times for updates will considerably reduce the accuracy of the database, while, as shown in the analysis of costs, will not significantly lower the costs. For most facilities, there will be little difference in costs for updates for 60 days versus annually. The largest costs will be to large manufacturers/processors, which are estimated to update twice a year, at a cost of approximately 2 hours of labor. However, allowing yearly updates would mean that more than 50 percent of the registrations in the database would contain incorrect information at any given point in time, versus less than 10 percent with 60 day updates. Although, FDA is unable to quantify the benefit of a more accurate database, the functionality of the database will be substantially better with a smaller percentage of registrations containing inaccurate information.

Additionally, when foreign food facilities attempt to import their product into the United States, their prior notice will be checked against the registration database. If there are discrepancies between the registration database and information in the prior notice, the shipment will be flagged for followup by FDA personnel, as deemed appropriate. Discrepancies confirmed by FDA border inspections may cause FDA or CBP to examine the shipment.

Table 16.--Summary of Annualized Costs and Qualitative Benefits

	Discount Rate	Final Rule	Longer Updates	No Product Categories	No U.S. Agent
Domestic costs	3%	\$6.3	\$5.9	\$5.8	\$6.3
Foreign costs	3%	\$185.5	\$185.2	\$185.1	\$11.5
FDA costs	3%	\$6.5	\$6.5	\$6.5	\$6.5
Total costs		\$198.3	\$197.6	\$197.4	\$24.3
Domestic costs	7%	\$4.8	\$4.5	\$4.5	\$4.8
Foreign costs	7%	\$136.5	\$136.3	\$136.2	\$9.3
FDA costs	7%	\$4.9	\$4.9	\$4.9	\$4.9
Total costs		\$146.2	\$145.7	\$145.6	\$19.0
Benefits			lower	lower	lower

V. Interim Final Regulatory Flexibility Analysis

FDA has examined the economic implications of this interim final 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 has concluded that this interim final rule would have a significant economic impact on a substantial number of small entities. The following analysis, together with other relevant sections of this document, serves as the agency's final

regulatory flexibility analysis under the Regulatory Flexibility Act.

(Comment 192) Several comments state that FDA underestimated the impact of the registration on small entities. Small domestic facilities may be adversely affected if their foreign trading partners stop exporting to the United States and small entities may incur higher costs than estimated in the