

Table 9.--Sensitivity analysis of foreign facility costs (in millions)

Alternative U.S. agent costs	First year costs	Annual costs
Baseline estimate	\$306.0	\$228.8
U.S. agent fee of \$700	\$247.6	\$164.5
U.S. agent fee of \$1200	\$345.0	\$271.7
26% already have a U.S. agent	\$283.9	\$209.7
10% already have a U.S. agent	\$310.2	\$232.4
8% already have a U.S. agent	\$308.8	\$231.2
8% stop exporting	\$320.4	\$239.4
24% stop exporting	\$291.7	\$218.2
Lowest estimate	\$220.5	\$144.6
Highest estimate	\$364.6	\$267.4

(Comment 184) Several comments predict that some foreign facilities would cease exporting to the United States due to the cost of procuring a U.S. agent. Comments mention this as a cost to both foreign facilities and domestic facilities. For foreign facilities that ship small quantities to the United States, some comments assert that the cost of a U.S. agent could exceed the profits from shipping to the United States. For these facilities, it would make economic sense to stop exporting to the United States. Other comments assert that some domestic facilities, particularly small businesses, might lose important suppliers. These comments state that the loss of foreign suppliers could have a significant negative impact on their businesses. FDA also received comments on the effect of requiring a U.S. agent on domestic small businesses.

(Response) FDA agrees that some foreign facilities may choose to stop exporting to the United States because the cost of registering and procuring a U.S. agent will exceed the benefits to the facility of exporting food to the United States. As mentioned previously, the number of foreign facilities that will choose to stop exporting to the United States is uncertain, as it will depend on the cost of registration for the individual facility and the return on the shipment in the United States versus its return in other markets. No comments provided any quantitative estimates of the number of facilities that would stop exporting to the United States. These costs were included qualitatively in the PRIA. The effect of requiring a U.S. agent on domestic small businesses will be considered in the Regulatory Flexibility Analysis.

(Comment 185) Several alternatives to the proposed requirement for a U.S. agent are suggested by commenters, including making the U.S. agent requirement optional, requiring a U.S. agent only if the facility does not have an e-mail contact, and requiring that the U.S. agent reside or maintain a place of business in North America.

(Response) FDA is constrained by the Bioterrorism Act, which requires all foreign facilities subject to this rule to have a U.S. agent. Also, FDA believes that the statute requires that the U.S. agent reside or maintain a place of business in the U.S. proper, not North America generally. Therefore, choosing not to require a U.S. agent or having the person reside or maintain a place of business outside the United States is not consistent with congressional intent. However, while not a legally available option, FDA does provide an estimate of the cost for an option in which a U.S. agent is not required.

e. Duplicate requirements with other licensing or registering authorities.

(Comment 186) FDA received many comments that the registration requirement duplicates other registration requirements for FDA, other U.S. government agencies, other governments, and State and local authorities. These comments suggest that FDA obtain the registration information from these other authorities rather than require an additional registration. Specific registration requirements mentioned by commenters included FDA low acid canned foods, FDA feed manufacturers, FDA seafood Hazard Analysis and Critical Control Point importers, TTB, EPA, USDA, Australia, Iceland, New Zealand, Chile, California, and FIRMS.

(Response) FDA has determined that it is most cost-effective for FDA to require registration by all affected facilities under this rule. Using data from other registration systems would be cost-effective, if FDA could collect the data from other systems at a total lower cost, to both facilities and FDA, than original collection of the data. For FDA to use another regulatory agency's registration system, FDA needs to: (1) Be able to get the data from the other agency; (2) capture all of the required information; (3) avoid duplicate registrations; (4) verify that the data are correct; (5) update the registration in a timely manner; and (6) issue a new registration number and confirmation to the registered facility.

Using other registration systems would likely increase costs for FDA to get the data from the other system. This would require interagency cooperation and compatibility of IT systems by the statutory deadline of December 12, 2003. In addition to creating the existing IT system, FDA would have to develop the ability to accept large transfers of data from other systems. Additionally, accepting data from other registration systems will require facilities to provide any data elements not included in those registration systems to FDA separately, which will also result in higher costs for FDA.

Using other registration systems would not lower the cost of registration for covered facilities. Even if another registration system is used, facilities will still incur research costs to learn about the registration requirements to determine whether they need to register or if they had already fulfilled the requirements, so research costs for facilities will be unchanged under both