

7. Option Seven: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Intrastate and Interstate Commerce, Including Mixed-Type Facilities, as Defined in Option 6. Permits the U.S. Agent to Register on Behalf of the Foreign Facility

Permitting the U.S. agent to register on behalf of the foreign facility would reduce the number of paper registrations significantly. Foreign facilities still would have to go through administrative steps to learn about the regulation and to find and hire a U.S. agent. However, foreign facilities now would have a third option for registering. In addition to electronic and paper registration by a representative at the facility, the foreign facility can authorize its U.S. agent to register the facility. FDA assumes that U.S. agents who register on behalf of foreign facilities will register electronically. Characteristics of foreign facilities, such as access to the Internet, fluency in English, and whether they are informed about the registration requirement before their product reaches the U.S. port, determine whether foreign facilities would be registered by themselves electronically, registered by mail, or registered by their U.S. agent.

FDA assumes that foreign facilities with Internet access would register directly via the Internet. Registration via the Internet would be the fastest, most reliable method for these facilities, and they would receive their confirmation of registration and facility registration number automatically.

Foreign facilities that do not have Internet access or representatives who read or write in English would register through their U.S. agent. The inability to read and write in English increases the cost for foreign facilities that register directly. U.S. agents operating in response to FDA registration requirements for other FDA-regulated products market themselves to certain regions of the world. FDA anticipates these agents would speak the language of the representative of the foreign facility, as well as English, and so could register in English for the facility.

Foreign facilities that do not have Internet access and do not learn of the registration requirements until their product reaches the U.S. border also are likely to register through their U.S. agent. For electronic registrations, the facility is considered registered once FDA enters the registration data into the registration system and the system generates a registration number. For paper registrations, the facility is

considered registered when FDA sends the registration number to the facility. For electronic registrations, confirmation should happen almost instantly. The electronic submission would be automatically entered into the database, undergo consistency checks, and if the information is entered correctly, the confirmation of registration and the facility's registration number would be sent out electronically.

Paper submissions are subject to longer lag times at several points. First, the facility may have to mail or phone in a request for a registration form. Second, the facility may have to wait to receive the form. Third, the registration takes time to travel through the mail from the facility to FDA. Fourth, FDA would require more time to process paper submissions, because the information has to be entered manually into the system. Fifth, FDA has to mail out a copy of the registration as entered, the registration confirmation, and the registration number if the facility's information is complete and legible. Sixth, the registration confirmation has to travel through the mail to the facility. At this time, the facility would know it is registered and have its registration number.

Because time will be important to foreign facilities bringing products into the United States, FDA assumes that they will choose to be registered by their U.S. agent, because the registration process will be much faster. Facilities that do not have Internet access, that have representatives who can read and write in English, and learn about the registration requirements before exporting their product to the United States are most likely to register by a paper submission. These facilities already would have invested the time to learn about the registration requirements and thus are likely to have a hard copy of the form. If time were not a major consideration, a facility is likely to prefer to fill out the registration form onsite. FDA plans to conduct extensive outreach efforts to communicate the registration requirements to affected facilities both domestically and abroad, both at the proposed rule stage and at the final rule stage to minimize the number of facilities that find out about the requirements at the port. FDA does not have the information to estimate how many foreign facilities would not learn about the registration requirements until their goods are at the port. FDA instead estimates the number of foreign paper submissions to FDA as the percent of foreign facilities that do not have Internet access and whose managers are able to read and write in

English. FDA requests comments on this assumption.

Under this option, U.S. agents would have a larger role than under other options. U.S. agents may charge a higher fee if they register for the facility. A higher U.S. agent fee is considered in the sensitivity analysis.

Port delays would be shorter under this option than under alternative options. Foreign facilities still would have delays associated with communication and finding a U.S. agent, but the process would be shortened by allowing the U.S. agent to register on behalf of the foreign facility. This would shorten the time that the product sits in storage and lower the loss of value of the product.

Tables 37, 38, 39, 40, and 41 of this document provide a summary of the data for cost estimates under option 7 for domestic facilities, foreign facilities, and FDA, respectively. The first year costs to foreign facilities would be reduced from \$319.6 to \$311.8 million, annual costs would be reduced from \$228.4 to \$227.6 million. Total costs for the first year would be reduced from \$344.5 to \$336.2 million.

TABLE 37.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 7

2000 CBP	103,125
1999 Nonemployer statistics	68,424
Mixed-type facilities that engage in farming	30,497
Total domestic	202,046

TABLE 38.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 7

Administrative worker wage (includes overhead)	25.1
Manager wage (includes overhead)	56.74
Percent with Internet access US	71%
Research time with Internet (hours)	1
Research time without Internet (hours)	2
Research cost with Internet	\$3,601,000
Research cost without Internet	\$2,941,000
Administrative time for form (hours)	0.75