

TABLE 43.—SENSITIVITY ANALYSIS (RELATIVE TO OPTION 7)—Continued

First Year Costs	Total Domestic Cost (dollars)	Total Foreign Cost (dollars)	Total FDA Cost (dollars)	Total Cost (dollars)
Percentage change from baseline	0%	-15%	0%	-14%

¹ 30,497 mixed-type facilities, time costs under option 7, 10 percent of foreign manufacturers/processors have U.S. agents, 16 percent of foreign facilities are fluent in English, 100,027 foreign holders and packagers, and U.S. agent fee of \$1,000.

b. *Qualitative costs.* For all of the options, except option one, there are a number of costs that FDA was unable to quantify. Loss of products from small exporters who would choose to stop exporting to the United States due to the increased cost of business may represent significant costs. Earlier in the analysis, we estimated that about 16 percent of foreign manufacturers export 10 or fewer line entries per year, and that these manufacturers would cease exporting to the United States. This could result in the elimination of some specialty products that market to very small niche markets in the United States, which would represent a loss to consumers who use these products.

The cost of port delays for facilities that do not learn of the requirements before exporting is another cost FDA was unable to quantify. FDA is unable to estimate how many foreign facilities would not learn about the new requirements before exporting. For this analysis, we estimate the expected cost of learning about registration as the number of hours a worker in a foreign facility needs to learn about the requirements. However, we expect that for some facilities, the cost of learning about the requirements would be much higher than the expected cost. Facilities that do not learn about the registration requirements before reaching the United States port would still have their shipment held at the port. The loss of value may be as low as the cost of storage, or as high as the value of the shipment, if perishable.

Under option 7, FDA expects this cost to be lower. If the U.S. agent registers the foreign facility, this will speed up the registration process and the product

would be released into U.S. commerce faster.

FDA also was unable to quantify the costs incurred by FDA, trade associations, and others for outreach about the registration requirements. FDA will undertake outreach to notify domestic and foreign facilities about registration through public meetings, satellite downlink to five continents, and providing help desk support. FDA also anticipates that trade organizations and others, such as brokers, foreign governments, and U.S. businesses, will undertake to notify facilities of the registration requirements. FDA requests comments on the size and the basis for estimating these costs.

10. Benefits

These provisions would improve FDA's ability to respond to outbreaks from accidental and deliberate contamination from food and deter deliberate contamination. Based on historical evidence, a strike on the food supply has a very low probability, but would be a potentially high cost event. FDA lacks data to estimate the likelihood and resulting costs of a strike occurring. Without knowing the likelihood or cost of an event, we cannot quantitatively measure the reduction in probability of an event occurring or the possible reduction in cost of an event, associated with each regulatory option. Further hindering any quantification of benefits is the interactive effect of the other regulations that are being developed to implement title III of the Bioterrorism Act. Prior notice for imported shipments (section 307 of the Bioterrorism Act) would aid in the enforcement of registration, and in turn, registration would aid in the verification

of prior notice submissions. Registration and recordkeeping also would work cooperatively.

These regulations also improve FDA's ability to prevent and respond to accidental foodborne outbreaks. FDA lacks data on the number of accidental outbreaks that will be prevented or shortened from this proposed rule, as well as from registration working in conjunction with the other regulations being developed to implement title III of the Bioterrorism Act. To understand possible costs of inadvertent foodborne illness and from an intentional strike on the food supply, FDA presents five outbreaks resulting from accidental and deliberate contamination, involving both domestic and imported foods in table 44. Registration will aid FDA in preventing and shortening foodborne outbreaks, but we do not know how frequently an outbreak would occur or the size and severity of the outbreak in the absence of registration. These foodborne outbreaks also do not represent the form a terrorist attack might undertake, but merely illustrate the public health costs of foodborne disasters. It is possible that an intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens would be much larger. However, the probability of an attack occurring and the exact reduction in risk resulting from registration is unknown. Therefore, FDA is unable to quantify the benefits of registration arising from preventing or lessening the impact of a foodborne outbreak. Instead, we examine four mechanisms through which each regulatory option might act and analyze how each of the options affects these mechanisms.

TABLE 44.—SUMMARY OF FIVE FOODBORNE OUTBREAKS

Pathogen	Location and Year	Vehicle	Confirmed or Reported Cases	Estimated Number of Cases	Total Illness Cost (dollars)
<i>Salmonella enteritidis</i>	Minnesota 1994	Ice cream	150 cases; 30 hospitalized	29,100 in MN; 224,00 nationwide	3,187,744,000 to 5,629,792,000
<i>Shigella sonnei</i>	Michigan 1988	Tofu salad	3,175 cases	Not available	45,183,000 to 79,797,000