

- The number of import entries requiring prior notice will not increase over time.

- The discount rate for calculating present value is 7 percent.

We now show how our estimates of costs for the proposed option change under different assumptions. We substitute the following assumptions for those used above:

- In option 4, fifty percent of prior notices will need to be changed if the notice must be submitted by noon on the calendar day prior to entry. (Option

4 is the base for option 5 before amendment.)

- 15 percent of prior notices will still need to be changed even when the amendment option is available.

- The amendment option will eliminate all but 5 percent of the lost value of imported fresh produce and all but 12 percent of lost value of imported fresh seafood.

- The amendment or update time is 4 hours before entry.

- The retail value of imported fresh seafood and produce is 200 percent higher than its wholesale value.

- The number of import entries requiring prior notice will increase 3 percent per year over time.

- The discount rate for calculating present value is 3 percent.

Tables 18 and 19 show the results of the sensitivity analysis. The tables show that the estimated cost of the proposed rule is most sensitive to the assumed fraction of prior notices that will need to be changed. The present value of the proposed rule is most sensitive to the rate of discount.

TABLE 18.—SENSITIVITY ANALYSIS FOR ASSUMPTIONS MADE FOR OPTION 5 (PROPOSED OPTION)

Test	Annual Cost Under Base Assumption	Annual Cost Under Test Assumption	Change in Annual Cost (or Value)	Percent Change in Present Value
50% prior notices changed	\$370,516,823	\$447,312,699	\$76,795,876	21
15% prior notices changed with amendment	\$69,798,077	\$71,727,578	\$1,929,501	3
5% lost value for produce, 12% lost value for seafood	\$69,798,077	\$84,837,174	\$15,039,097	22
Amendment time is 4 hours	\$69,789,077	\$123,843,623	\$54,045,546	77
Retail value is 200% of wholesale value	\$69,798,077	\$73,030,451	\$3,232,374	5
Prior notice entries increase 3% in second year	\$69,798,077	\$71,588,777	\$1,790,700	3

TABLE 19.—PRESENT VALUES FOR SENSITIVITY ANALYSIS FOR ASSUMPTIONS MADE FOR OPTION 5 (PROPOSED OPTION)

Test	Present Value of Base Total Cost	Present Value of New Total Cost Under Test Assumption	Change in Present Value	Percent Change in Present Value
50% prior notices changed	\$5,258,695,269	\$6,355,779,211	\$1,097,083,942	21
15% prior notices changed with amendment	\$962,713,183	\$1,042,325,126	\$79,611,943	8
5% lost value for produce, 12% lost value for seafood	\$962,713,183	\$1,177,557,426	\$214,844,243	22
Amendment time is 4 hours	\$962,713,183	\$1,786,840,054	\$824,126,871	86
Retail value is 200% of wholesale value	\$962,713,183	\$1,008,889,954	\$46,176,771	5
Prior notice entries increase 3% in second year	\$962,713,183	\$988,294,611	\$25,581,428	3
3% Discount rate	\$962,713,183	\$2,222,803,507	\$1,260,090,324	131

**Benefits:** Requiring prior notice of imported food shipments and defining the required data elements should improve FDA's ability to detect accidental and deliberate contamination of food and deter deliberate contamination. Having notice of an imported food shipment before it reaches a U.S. border would allow FDA personnel to be ready to respond to shipments that appear to be adulterated, whether through intentional or accidental means, as well as when FDA receives credible evidence that an entry

represents a serious threat to human or animal health.

Historical evidence suggests that a terrorist or other intentional strike on the food supply is a low-probability, but 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

are the complementary effects of the other regulations that are being developed to implement Title III of the Bioterrorism Act.

To understand possible costs of an intentional strike on the food supply, FDA examined five outbreaks resulting from accidental and deliberate contamination, and from both domestic and imported foods. An intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens could be much larger than the examples given.

TABLE 20.—SUMMARY OF FIVE FOODBORNE OUTBREAKS

Pathogen	Location and year	Vehicle	Confirmed or reported cases	Estimated number of cases	Total illness cost
<i>Salmonella enteritidis</i>	Minnesota, 1994	Ice cream	150 cases; 30 hospitalizations	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 \$79,795,000