

TABLE 31.—SENSITIVITY ANALYSIS

Test	Option	Effect on Present Value Mean Cost (\$)	Percent Effect
10% increase in records maintenance	10	\$276,513,000	7.02%
10% increase mixed-type facilities that engage in farming	10	\$17,061,000	0.46%
10% decrease in percent European	10	\$33,529,000	0.91%
10% increase in redesign	10	\$38,006,000	1.03%
10% increase in learning	10	\$32,185,000	0.87%
10% increase in access	10	\$18,873,000	0.51%
16% decrease in number of foreign firms	10	(\$138,484,000) <sup>1</sup>	(3.93%) <sup>1</sup>
1% increase in identity preservation premium	13	\$490,117,000	0.52%

<sup>1</sup> Numbers in parentheses are negative.

*Benefits:* These options would improve FDA's ability to address adulterated food and food packaging that presents a threat of serious adverse health consequences or death to humans and animals. FDA is unable to quantify the benefits of these regulations, though we consider them substantial. While the probability of a deliberate contamination of the food supply may be low, the potential cost of a deliberate contamination of the food supply may be high. Below we present some examples to demonstrate what such a contamination may look like. Without having any hypothesis on the likelihood of a deliberate contamination, it is impossible to quantitatively measure the benefits of the reduced impact due to each of these regulatory options.

Further hindering any quantification of benefits is the interactive effect of other regulations that are being developed to implement Title III of the Bioterrorism Act of 2002. The registration (section 305 of the Bioterrorism Act) and recordkeeping regulations would work cooperatively to identify and track possible sources of an outbreak. The prior notice for imported shipments (section 307 of the Bioterrorism Act) would allow the agency time to identify possible sources of risk from adulterated food and its packaging that presents a threat of serious adverse health consequences or death to humans and animals, which could then be investigated with the aid of the new registration and recordkeeping regulations.

To understand possible costs of an intentional attack on the food supply, we examine five outbreaks resulting from accidental and deliberate contamination, and from both domestic and imported foods. 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. Also, intentional attacks may be fundamentally more difficult to trace than natural outbreaks due to deliberate obfuscation of the source and possible multiple contamination events of different food types and food facilities. We then examine mechanisms through which each regulatory option discussed in this analysis may act and analyze how each of the options affects the mechanisms.

TABLE 32.—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
Outbreaks resulting from deliberate contamination					
<i>Salmonella Typhimurium</i>	Dalles, Oregon 1984	Salad bars	751 cases; 45 hospitalized	Not available	10,687,000 to 18,875,000
<i>Shigella dysenteriae</i> type 2	Texas 1996	Muffins and doughnuts	12 cases; 4 hospitalized	All cases identified	83,000
Outbreaks resulting from imported foods					
<i>Cyclospora cayatanensis</i>	United States and Canada 1996	Raspberries (probably imported from Guatemala)	1465 cases identified, less than 20 hospitalized	Not available	3,941,000