

of known cases for the outbreak of \$10,687,000 to \$18,875,000.

Shigella dysenteriae type 2 among laboratory workers

Twelve people working in a laboratory who consumed muffins left in the laboratory break room contracted shigellosis. Affected workers had diarrhea, nausea, and abdominal

discomfort. Investigators concluded that the outbreak likely was the result of deliberate contamination. All twelve affected workers were treated by, or consulted with, a physician. Nine affected workers went to the emergency room, four of whom were hospitalized (Ref. 28).

To estimate the cost of this outbreak, FDA assumed that the eight cases

requiring consultation with a doctor, but not requiring hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of gastroenteritis resulting from salmonellosis. This gives a cost of \$83,000 for illnesses associated with the event.

TABLE 34.—SUMMARY OF COSTS FOR CASES OF SHIGELLOSIS

Severity	Number of cases	Cost per case (dollars)	Total cost (dollars)
Mild	0	0	0
Moderate	8	2,593	21,000
Severe	4	15,516	62,000
Grand total			83,000

Cyclospora cayatanensis in imported raspberries

In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported (Ref. 29). Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20

states, two Canadian provinces, and the District of Columbia (Ref. 30).

Cyclosporiasis typically causes watery diarrhea, loss of appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days (Ref. 30). We estimated the cost of a mild case of cyclosporiasis as two and a half times higher than the cost of a mild case of gastroenteritis from salmonellosis due to the longer

duration. The reports of cyclosporiasis outbreaks did not include information on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20 hospitalizations were reported from the cyclosporiasis outbreak (Ref. 29). No deaths were confirmed.

TABLE 35.—SUMMARY OF COSTS FOR CASES OF CYCLOSPORIASIS

Severity	Number of cases	Cost per case (dollars)	Total cost (dollars)
Mild	879	1,650	1,450,000
Moderate	586	3,748	2,196,000
Severe	19	15,516	295,000
Grand total			\$3,941,000

Mechanisms: The new recordkeeping provisions we describe in the options section would not only help FDA determine the cause of a particular outbreak by tracing the source, they would also reduce further adverse health effects by enabling FDA to trace forward to locate adulterated food and its packaging that presents a threat of serious adverse health consequences or death to humans and animals. We expect that, working in concert with other regulations, having complete records identifying all links in the chain of custody for a particular product will allow FDA to more efficiently deploy its compliance and regulatory resources in

an event of an outbreak. Having complete records increases the probabilities of FDA being able to trace back to the source of an outbreak and of FDA being able to trace forward to locate adulterated food and its packaging. FDA conducts approximately 20 emergency traceback investigations per year. Although no investigation has been completely halted by a lack of adequate records in the past several years, inadequate records have hindered investigations. For example, FDA attempted to conduct approximately 38 tracebacks in a *Cyclospora* outbreak in 1997. Of those, we were able to complete 33, and the majority of failures

were due to the lack of available records. More commonly, incomplete records severely impede the ability of FDA to conduct effective investigations.

Faster required record access times may allow FDA to more rapidly identify the source of an outbreak and limit its effects. Over the past several years of FDA traceback investigations, the normal response time between a request for data and the receipt of the records from the firm is 2–3 days. The response times in these options would greatly speed up the traceback process, which would be critical in limiting a deliberate or accidental major outbreak.