

exposure to the hazard. The FDA prior notice system alone will not prevent such exposures, but by increasing the amount of information available and

giving FDA notice in advance of arrival, an essential component of the barrier against accidental or deliberate contamination of food is formed. FDA is

better able to integrate intelligence, vulnerability, and entry data to plan import surveillance activities as a result.

Table 50.--Examples of Outbreaks Resulting From Imported Foods

Pathogen	Location and Year	Vehicle	Number of Cases
<u>Salmonella</u> Poona	Western United States, 2001	Cantaloupe (from Mexico)	29 cases, 4 hospitalizations, 2 deaths
S. Lexington S. Java ETEC; <u>E. coli</u> O6:H16 and O25:NM Giardia	Cruise ship, 2000	Raw frozen shrimp cooked on board	224 cases, with 9 (possibly more) laboratory confirmed
<u>Cyclospora</u> <u>cayatanensis</u>	United States and Canada, 1996	Raspberries (probably imported from Guatemala)	1,465 cases identified, fewer than 20 hospitalizations
<u>Salmonella typhi</u> , hepatitis A	Florida, 1996	Homemade cheese (from Mexico)	9 cases Salmonella, 14 cases Hepatitis A
<u>Salmonella</u> Stanley	17 States, 1995	Alfalfa sprouts (seeds from Netherlands)	242 cases
<u>Shigella flexneri</u> , type 6 (SF6)	Illinois, 1994	Green onions (Mexico suspected)	171 cases

We can examine the high costs of a potential terrorist event by comparing costs of responding to a terrorist event with and without the advantage of having the FDA prior notice system. For example, if U.S. officials or FDA receives intelligence concerning the possibility of an intentional contamination of an incoming food shipment, in absence of prior notice, even with information on the type of food product, officials would be unlikely to know when and where the food was expected to cross U.S. borders.

In this case, it is likely that officials would slow down the movement of food shipments through the border ports or possibly even close down some ports of entry to prevent the contaminated articles from entering the United States.

Information on the west coast port lock-out during Fall 2002, indicated that the closing of 29 major west coast ports cost the U.S. economy \$1 billion a day (Refs. 14 and 15). Given that there are 361 ports of entry for the entire United States, if U.S. officials had to close all ports to prevent contaminated food from

entering the country, the U.S. economy could lose upwards of \$12.5 billion each day the ports remain closed. This cost exceeds the first year costs (\$367 million), the annual costs (\$261 million), and the present value of costs (\$3 billion at the 7 percent discount rate and \$4 billion at the 3 percent discount rate) for the chosen option of this rule. Thus, having the FDA prior notice system does not eliminate, but may significantly reduce the costs of a terrorist attack on the food supply as compared to not having the system.

TABLE 51.—COST BENEFIT SUMMARY TABLE

	Annualized costs over 20 years at 7% discount rate (\$ millions)	Annualized costs over 20 years at 3% discount rate (\$ millions)
Option 5—2 hour prior notice for vehicle, 4 hour for rail and air, 8 hour vessels (interim final rule)	\$272	\$269
Benefits—FDA will know in advance what articles of food are being imported or offered for import, before they arrive at the port. In the event of a credible threat, FDA will be able to mobilize and assist in the detention and removal of specific products that may pose a serious health threat to human or animals.		

B. Small Entity Analysis (or Final Regulatory Flexibility Analysis)

FDA has examined the economic implications of this interim final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a

substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. FDA finds that this interim final rule will have a

significant economic impact on a substantial number of small entities.

1. Number of Establishments Affected

FDA finds that this interim final rule would affect 77,427 U.S. importers. Most of these importers have fewer than 500 employees, thus making them small