

Table 15.--Summary of Five Foodborne Outbreaks

Pathogen	Location and Year	Vehicle	Confirmed or Reported Cases	Estimated Number of Cases	Total Illness Cost
<u>Salmonella enteritidis</u> (Ref. 20)	Minnesota, 1994	Ice cream	150 cases, 30 hospitalized	29,100 in Minnesota 224,000 Nationwide	\$3,187,700,000 to \$5,629,800,000
<u>Shigella sonnei</u> (Ref. 21)	Michigan, 1988	Tofu salad	3,175 cases	Not available	\$45,200,000 to \$79,800,000
Outbreaks Resulting From Deliberate Contamination					
<u>S. Typhimurium</u> (Ref. 22)	Dalles, Oregon, 1984	Salad bars	751 cases, 45 hospitalized	Not available	\$10,700,000 to \$18,900,000
<u>S. dysenteriae</u> type 2 (Ref. 23)	Texas, 1996	Muffins and doughnuts	12 cases, 4 hospitalized	All cases identified	\$83,000
Outbreaks Resulting From Imported Foods					
<u>Cyclospora cayatanensis</u> (Ref. 24)	United States and Canada, 1996	Raspberries (probably imported from Guatemala)	1,465 cases identified, less than 20 hospitalized	Not available	\$3,900,000

## BILLING CODE 4160-01-C

a. *Food-contact substances.*

(Comment 187) Some comments stated that there would be no benefits to requiring the registration of articles that contact food and their components. Commenters noted that none of the foodborne outbreaks included in the benefits section resulted from articles that contact food. However, other comments noted the potential for articles that contact food to leach into and contaminate food and concluded that it was necessary to require the registration of articles that contact food.

(Response) FDA has revised the interim final rule to exclude facilities that manufacture/process, pack, or hold food-contact substances, as defined in section 409(h)(6) of the FD&C Act. Accordingly, FDA does not need to address these comments, because these facilities are not subject to the interim final rule.

b. *Food product categories.*

(Comment 188) Many comments claim that, for several reasons, including food product categories would have no benefits: One, facilities would be unable to categorize their products correctly; two, FDA would fail to communicate with facilities that use as ingredients potentially affected foods; and three, the food product categories do not make useful distinctions between categories. Comments claimed that these limitations would make food product code categories useless and even have a negative impact on FDA's ability to communicate with facilities by diverting resources that could be better used elsewhere.

(Response) FDA disagrees with these comments. Consultations with FDA field personnel identify food product categories as an essential part of registration. FDA field personnel state that they would use food product category information to identify facilities potentially affected by a

particular emergency, such as a terrorist threat or class 1 recall and for planning inspections. For example, needing to contact only 200 facilities with information about a threat instead of 20,000 will enhance FDA's speed and the reliability of the message. FDA believes that facilities can correctly categorize their products, and FDA will provide interactive help menus as part of the electronic registration system to aid facilities in correctly identifying the appropriate food product categories for their products. Also, FDA will provide a link to the agency's product code builder, which will allow facilities to search for their particular products.

FDA staff have experience using food product categories in their current enforcement activities and have found them to make useful distinctions between foods. FDA is also aware that some products may be ingredients in other food products and will use that information in selecting which facilities