

TABLE 1.—AFFECTED FACILITY AND FIRM DETAILS—Continued

Type	Facility Estimate	Facility to Firm Adjust. Factor	Firm Estimate	North American Industry Classification System (NAICS) Codes if Applicable
Transporters/Packers	16,773	1.11	15,171	481112, 481212, 483111, 483113, 483211, 4841, 48422, 48423, 488320, 488510, 488991
Retail Grocery and Specialty Food	207,657	1.35	153,277	44511, 445220, 445230, 44529, 445310, 446191,
Convenience Stores	128,985	1.87	68,866	44512, 447110
Mixed-Type Facilities that Have Farms	30,497	1.25	24,397	—
Importers	5,036–32,768	1.25	4,029–26,214	—
Total Domestic	601,883–629,615		448,905–471,090	
<i>Foreign</i>				
Final Holders	77,427	1.25	61,942	
Manufacturers	125,450	1.17	106,858	
Other Facility Types	457,836	1.25	366,269	—
Total Foreign	660,713		535,068	

<sup>1</sup> Includes both outer packaging and food contact substances.

*Data sources for the number of facilities and firms affected:* Except for the firm-to-facility adjustments explained below, the unit of observation for all data used for this analysis is the number of establishments performing a particular activity. To estimate the number of establishments, FDA uses several sources: The 2000 County Business Patterns (Ref. 1) and the 1999 Nonemployer Statistics from the U.S. Census Bureau (Ref. 2), the FDA Field Accomplishments and Compliance Tracking System (FACTS), the FDA Operational and Administrative System for Import Support (OASIS), and the 1997 National Agricultural Statistics Service (NASS) Survey (Ref. 3). All datasets used in this analysis were the latest available as of the time of writing.

The Census Bureau creates the 2000 County Business Patterns (CBP) by analyzing data from the Business Register, the Census Bureau's file of all known single and multiestablishment companies with at least one employee. Data for single-location firms are obtained from the Economic Censuses, the Annual Survey of Manufacturers, Current Business Surveys, and administrative records from the U.S. Internal Revenue Service, Social Security Administration, and the Bureau of Labor Statistics.

Facilities not included in the CBP are counted in the Nonemployer Statistics, also from the Census Bureau. Nonemployer businesses are companies

with no paid employees. The Census Bureau primarily obtains data about nonemployer businesses from business income tax returns filed with the Internal Revenue Service.

The FDA FACTS tracking system is an online database designed to monitor compliance related information for each facility that is regulated by FDA. The database contains an updated list of regulated facilities. FACTS and the Census Bureau use different categories for facilities, making a direct comparison of FACTS with the CBP and Nonemployer Statistics difficult. In our estimates, FACTS facility counts are the primary source of data on importers and foreign facilities, and interstate manufacturers, wholesalers, and warehouses.

*Manufacturing, warehouses, wholesalers, and packaging facilities:* The primary source for the total (both intrastate and interstate) number of manufacturers, warehouses, wholesalers, and packaging facilities is the 2000 CBP and 1999 Nonemployer Statistics for the NAICS codes identified in table 1 of this document. The NAICS codes identify industry groups and subgroups. Often the data are more aggregated in the 1999 Nonemployer Statistics than in the CBP; when the nonemployer statistics only exist for an aggregated NAICS code, we adjust the total number of facilities identified in the aggregated nonemployer category by the ratio of CBP counts in the relevant

subcategory and aggregated category. For example, the 1999 Nonemployer Statistics identified 4,700 facilities under code 4931, but does not break the total down further. Our adjustment changes the 4,700 facilities to 964 [ $4,700 \times (1,461/7,123)$ ] facilities in subcategories 49312 and 49313. The sum of the number of facilities under the codes 49312 and 49313 in the CBP is 1,461, and 7,123 is the number of facilities under the aggregated code 4931 in the CBP.

The term “packaging” described by the data used in this analysis varies from FDA's interpretation of “packaging” in section 306 of the Bioterrorism Act because it is broader and includes food contact substances, which fall within the act's definition of food. In this economic analysis, we use the term “manufacturer and distributor” of outer packaging to refer to all persons who manufacture, process, pack, hold, receive, distribute, transport, or import “packaging” as that term is used in the Bioterrorism Act. FDA was unable to find any data that discriminated between outer packaging manufacturers and distributors and those that manufacture or distribute materials that FDA currently regulates as food contact substances, including plastic beverage bottles and inner cereal box liners. The data used for the analyses include the number of manufacturers and distributors of the following types of packaging: Paperboard containers, paper