

provided additional information about the category or number of undercounted facilities.

(Comment 164) A comment suggests that FDA failed to include very small facilities in its count of affected entities.

(Response) FDA disagrees with this comment. FDA included in its count more than 68,000 very small facilities from the Nonemployer Statistics published by the U.S. Census Bureau. These are all facilities that are run by a single person with no paid employees. Additionally, the majority of the facilities counted from the County Business Patterns published by the U.S. Census Bureau are considered small businesses under the Small Business Administration definition.

(Comment 165) FDA received a comment that the number of foreign holders may be much larger than the number of U.S. consignees and brokers, because a single broker may use multiple warehouses.

(Response) FDA agrees that a single broker may use multiple warehouses, but FDA also believes the converse is true, that a single warehouse may be

used by multiple brokers. This comment did not provide an alternative estimate of the number of foreign holders. Therefore, FDA has not altered its estimate of the number of foreign holders.

(Comment 166) FDA received many comments that the count of facilities failed to include transportation company facilities that hold food temporarily, while the product is in transit. Comments mention specific types of facilities, such as rail yards, container yards, LTL truck terminals, FTL truck terminals, Customs bonded Container Freight Stations, air cargo handling agents, and air, ocean, and truck bulk cargo terminals. FDA also received comments that the PRIA fails to include mobile facilities, such as river barges that pick up cargo in one location and travel to an alternate location where the barge may store product in its hull for several months prior to delivering the shipment to the purchaser.

(Response) Transport vehicles are not facilities required to register with FDA,

if they hold food only in the usual course of business as carriers. However, facilities that unpack and reload food cargo from road, rail, water, or air transportation or hold food cargo in a facility, or that hold food cargo not only in the usual course of business as a carrier, are required to register. FDA agrees that not all these facilities were counted in the PRIA.

To count these facilities, FDA used the 1997 Economic Census of Transportation and Warehousing (Ref. 7) from the U.S. Census Bureau. Table 1 shows a count of these facilities. This includes the 1,461 warehouses North American Industry Classification System (NAICS 49312 and 49313) counted in the PRIA. These facilities are subtracted from the count of warehouses (NAICS code 493, all warehousing and storage) when final computations of the number of facilities are made. Including the transportation holding facilities in table 1 minus the warehousing facilities already counted in the PRIA increases the total number of facilities required to register by 33,666 facilities.

Table 1.--Transportation Holding Facilities

NAICS Code	Type of Facility	No. of Facilities
4841103	General freight trucking with storage, local, full truckload	542
4841104	General freight trucking with storage, local, less than truckload	373
484121	General freight trucking, long distance	23,111
4881191	Airport operation and terminal services	1,699
4882101	Support activities for rail transportation	816
4883901	Other services incidental to water transportation	640
4842205	Specialized trucking with storage, local	543
4884904	Other services incidental to road transportation	326
488991	Packing and crating (in Support activities for transportation)	795
488999	Other support activities	102
493	All warehousing and storage	6,180
		35,127

(Comment 167) FDA received many comments that FDA underestimates the number of facilities covered by the definition of substances and components of substances that contact food. One comment states that FDA does not include the "upstream" manufacturers that make ingredients

and components that go into food packaging and that any facility that manufactures/processes, packs, or holds a material that could become a component of packaging or other food contact article would be required to register. The comment further states that there is no logical conclusion to this

chain. Also, some comments assert that FDA did not account for warehouses that hold articles that can migrate to food from food packaging or other articles that contact food.

Another comment states that FDA's count of the number of domestic facilities is overly inclusive if FDA's