

intention is to include only finished packaging and that the OASIS database used for the count of foreign facilities does not include suppliers of food contact articles.

(Response) Under the interim final rule, manufacturers/processors, packers, and holders of food contact substances as defined in section 409(h)(b) of the FD&C Act are not required to register with FDA. Therefore, it is unnecessary for FDA to respond to the comments asserting the number of these facilities was underestimated. FDA also removes the estimated count of 32,428 facilities in the PRIA from the final analysis.

(Comment 168) One comment states that FDA's count of foreign facilities from OASIS (Ref. 2) did not include manufacturers/processors of articles that contact food and substances that could migrate to food from food packaging.

(Response) FDA agrees with this comment. The count of manufacturer/processors in OASIS (Ref. 2) did include manufacturers of food and food additives, but did not include all manufacturers/processors of substances that could migrate to food from food packaging. However, these facilities are not covered under the interim final rule. Therefore, FDA has not added them to the count of foreign facilities.

(Comment 169) A number of comments states that FDA had underestimated the number of facilities by failing to include individuals that market foods and dietary supplements through direct selling. These individuals often hold food for sale to an intermediary other than the final consumer. Estimates provided by comments were that there are 10 million individuals in the United States and as many as 40,000 direct marketers with a single company. Another comment referred to hundreds of thousands of direct sellers.

(Response) Direct marketers may be required to register if they hold food for distribution to nonconsumers in the United States. However, FDA does not agree that there are 10 million direct marketers in the United States that could potentially be required to register. FDA found estimates of 10 million (Ref. 9) and 12 million (Ref. 8) direct marketers in the United States, but these estimates were of all the direct marketers of both nonfood and food products in the United States. FDA does not have a complete census of the number of marketers of food versus nonfood products. To approximate the percentage of direct marketers selling food, FDA divided the number of direct marketing companies selling food by the number selling all types of products, using data from the directory of

companies on the Web site of a large direct selling trade organization (Ref. 8). Of 141 companies in the directory, 7, or 5 percent, market food/beverages. However, most of these direct marketers of food may not be required to register. Direct marketers may be exempt: (1) If their primary function is to sell directly to consumers, or (2) if the establishment is an individual's private residence. FDA assumes that most direct marketers of foods would qualify for one of these exemptions.

To estimate how many direct marketers sell to consumers as their primary function, FDA looked at the type of distributorship. If the marketer has a one or two-person distributorship, FDA assumes that their primary function is to sell to consumers. FDA assumes if a marketer has a multiperson distributorship, they are likely to distribute to other sellers as their primary function. (These are not definitions that FDA will use to determine if selling to consumers is the primary function of a facility; this is merely a method used to provide an estimate for the economic analysis.) According to a large direct selling trade organization (Ref. 8), 2.5 percent of direct salespeople are multidistributorships. These numbers suggest that approximately 12,400 ( $10 \text{ million} \times .025 \times (7/141)$ ) direct marketers of food would be required to register with FDA. This number may be an overestimate because some of these marketers may already have been counted in the CBP (Ref. 3) or Nonemployer Statistics (Ref. 4) or may distribute food from their private individual residence.

(Comment 170) FDA also received comments stating that there were thousands and thousands of wineries in Europe that may not have been included in the estimate of the number of foreign facilities.

(Response) FDA does not agree with this comment. FDA's estimate includes approximately 27,000 European alcohol producers. FDA did not have enough data to separate wineries from other types of alcohol production facilities.

(Comment 171) One comment stated that FDA had failed to count collectors of wild plants. The comment estimates that there are 100,000 individuals that harvest wild plants.

(Response) Only facilities are required to register with FDA; individuals are not required to register. Harvesters of wild plants that manufacture/process, pack, or hold product in facilities outside of an individual's private residence would be required to register the facility with FDA. FDA does not agree that there are 100,000 harvesters that meet these

requirements. FDA commissioned a Dietary Supplement Enhanced Establishment Database (DS-EED) in 1999 (Ref. 14). This database gathered data from the American Business Information (now InfoUSA) electronic database, American Herbal Products Association Membership Directory and Resource Guide, Council for Responsible Nutrition Membership Directory, Harris Inc.'s U.S. Manufacturers Database, Hoovers Corporation Infoseek, National Foods Merchandiser '98-99 Retailer Purchasing Guide August 1998, National Products Expo West, Show Directory, March 1998, Official Establishment Inventory, and Thomas Food Industry Register on the Internet. The DS-EED listed 272 ingredient suppliers. The database may have underestimated the number of ingredient suppliers, but only ingredient suppliers that manufacture/process, pack, or hold product in facilities outside an individual's private residence would be required to register the facility with FDA. Some harvesters of wild plants may already be counted in Census databases, and already be included in the count of facilities. Therefore, FDA estimates that there are an additional 272 harvesters/ingredient suppliers for purposes of this analysis.

(Comment 172) Some comments claim that the number of farms that would fall under FDA's definition of a mixed-type facility is much higher than estimated in the PRIA. Under the proposed definition of manufacturing/processing, which included trimming and washing, the comment suggested that most farms wash, cool, or trim outer leaves and so would be required to register.

(Response) Farms are not required to register with FDA. In this interim final rule, FDA defines "farm" as a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting.

Some facilities located on farms may also manufacture/process, pack or hold food, but not meet the definition for farm and therefore, would be considered mixed-type facilities that are required to register. The farm definition also provides that facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership are exempt as farms, as are facilities that manipulate food other than washing, trimming outer leaves, or cooling, provided that all food used in such