

that also manufacture/process food for consumption off that facility must register under this option. Registration may be electronic or by mail, although FDA strongly encourages all facilities to register electronically. The information required on the registration includes the facility's name, address, parent company name and address (if applicable), emergency contact information, trade names, general food product categories under § 170.3, and certification by the owner, operator, or agent in charge of the facility as to the accuracy of the information and the submitter's authority to register the facility.

Under the Bioterrorism Act, foreign establishments are required to register if they manufacture, process, pack, or hold food for consumption in the United States without the food undergoing further processing or packaging outside the United States. In addition to registering, the Bioterrorism Act requires foreign facilities to have a U.S. agent. The U.S. agent is a person residing in or maintaining a place of business in the United States, who the owner, operator, or agent in charge of a foreign establishment designates as its agent. Only one U.S. agent per foreign establishment is permitted and the U.S. agent must reside or maintain a place of business in the United States. The U.S. agent is responsible for acting as a communications link between FDA and the facility.

a. *Coverage—i. Domestic establishments.* Consistent with the Bioterrorism Act, this proposed regulation's legal requirements apply to facilities, as opposed to firms. A firm is composed of facilities under common ownership. As a result, changes in behavior may occur at the firm- or facility-level to comply with this proposed regulation. However, for ease of analysis, FDA will focus on the facility as the unit of analysis. For a count of domestic facilities, FDA used the 2000 County Business Patterns (CBP) (Ref. 1), 1999 Nonemployer Statistics (Ref. 2), the FDA Field Accomplishments and Compliance Tracking System (FACTS) (Ref. 3), and the Census of Agriculture (Ref. 4). The Census Bureau created the 2000 CBP by analyzing data from the Business Register, the Census Bureau's file of all known single and multi-facility companies. These data for single-location firms are obtained by the Census from the Economic Censuses, the Annual Survey of Manufacturers, Current Business Surveys, and administrative records from the Internal Revenue Service, Social Security

Administration, and the Bureau of Labor Statistics.

Table 1 of this document provides a count of businesses in the relevant North American Industry Classification (NAICs) codes in the 2000 CBP. There are 103,125 affected facilities in the 2000 CBP under option two. Facilities not included in the CBP are counted in the Nonemployer Statistics, which is also from the Census Bureau (Ref. 2). Nonemployer businesses are companies with no paid employees. The Census Bureau primarily obtains data about nonemployer businesses from annual business income tax returns filed with the Internal Revenue Service. The Nonemployer Statistics dataset is less disaggregated than the CBP dataset. As a result, including entire counts of facilities in some NAICs codes in the Nonemployer Statistics would result in an overestimate of the number of facilities. For example, NAICs code 4931, warehousing and storage, includes warehouses and storage facilities that store nonfood products, and so is too aggregated for this analysis and includes facilities that would not be required to register. To estimate the number of affected warehouses in NAICs 4931, FDA assumed that the percentage of warehouses that are refrigerated and nonrefrigerated warehouses that store farm products is the same for both the 2000 CBP and the 1999 Nonemployer Statistics, and uses this as an adjustment factor for the 1999 Nonemployer Statistics. With this adjustment, there are 68,424 facilities in the relevant NAICs codes in the 1999 Nonemployer Statistics. Table 2 of this document provides a count of businesses in the relevant NAICs codes in the 1999 Nonemployer Statistics. Manufacturers/processors, packers, and holders of substances that migrate into food from food packaging or other articles that contact food do not correspond to any single NAICs code. Tables 3 and 4 of this document provide numbers of facilities in the 2000 CBP and 1999 Nonemployer Statistics, respectively. Broader NAICs codes, such as 322 and 326 that include facilities that deal only in nonfood products have only the number of facilities reported that could reasonably be expected to deal in substances that migrate into food from food packaging or other articles that contact food. For example, stationery manufacturers have been removed from the estimate. The Nonemployer Statistics have more aggregated counts than the 2000 CBP. To get a more accurate count of facilities in the Nonemployer Statistics, the count of facilities in each aggregated NAICs

codes is reduced by the percentage of facilities believed to be dealing with substances that migrate into food from packaging in the 2000 CBP. However, this number may be an overestimate as for some NAICs codes, in which it was not clear if the facilities were producing substances for food or nonfood use. For example, plastic forms may be made into food packaging or may be used for other purposes. To further adjust the number of facilities to include only facilities that manufacture/process, pack, or hold substances that migrate into food from food packaging or other articles that contact food, the numbers in each category are adjusted by data reported in The Rauch Guide to the U.S. Packaging Industry (Ref. 5). The Rauch guide reports that the packaging of consumer products accounts for 78 percent of all packaging and that 55 percent of the total used for consumer products is used for food and beverages. This means 43 percent of packaging is used to package food and beverages. To reflect this data, the NAICs categories for end, or near-end use packaging were reduced by 57 percent. NAICs categories for explicit food use, such as kitchen utensils and cutlery were assumed to have 100 percent of facilities manufacturing/processing, packing, or holding food.

Basic chemicals or other components incorporated into packaging may be intended for food or nonfood uses. FDA was unable to determine how many of these components are intended for food use. FDA also was not able to distinguish between manufacturers/processors, packers, or holders of immediate food packaging, which would be considered "substances that migrate into food from food packaging or other articles that contact food," and manufacturers/processors, packers, or holders of outer food packaging, which would not. Therefore, FDA included for purposes of this analysis: (1) Facilities manufacturing/processing, packing, or holding basic chemicals or other components incorporated into packaging for both food and nonfood use, and (2) manufacturers/processors, packers, and holders of both immediate and outer food packaging. Because this approach results in an overestimation of the number of facilities subject to this proposed rule, FDA requests comments on the number of these types of facilities that would be required to register.

Also covered under this proposed rule are slaughterhouses that process FDA regulated meats and renderers. FDA requests comments on the number of these facilities.

The Census data sets do not identify facilities engaged only in intrastate