

TABLE 2.—MIXED-TYPE FACILITIES THAT ENGAGE IN FARMING—Continued

Commodity	Total No. of Farms	Percent Mixed-Type	No. of Mixed-Type Facilities that Engage in Farming
Honey	7,688	50%	3,844
Syrup	4,850	100%	4,850
Herbs	1,776	10%	178
Total			30,497

Importers: FDA bases the number of importers on a database collected from shipment records that list all companies that were listed as importers or consignees for a covered product in 2001. These data were collected through FDA's OASIS system, which is an automated system for processing and making admissibility determinations for shipments of FDA-regulated products seeking to enter U.S. domestic commerce. Many of these facilities are of a type that would already be counted in the FDA FACTS or CBP (or nonemployer statistics) data. In order to avoid double counting, FDA assumes the following: (1) Any facility that identifies itself through its name as being a facility type covered by the CBP will already be counted in the CBP; (2) any facility that is a consignee only will already be counted in the CBP since its main business is not simply importing; (3) any facility self-identified as an importer only is not in the CBP; and (4) all other facilities will be considered in an uncertain range of facilities affected. Since it is uncertain whether these facilities would already be counted in the CBP, we will use a uniform distribution to assign a probability of double counting in all of our cost estimates. For example, if the uniform distribution generates a probability of 0.5, then we will assume that half of these unclassified facilities are already in the CBP. A uniform distribution implies that any probability from zero to 100 is equally likely. FDA requests comments on these assumptions.

Foreign establishments: FDA estimated the number of foreign manufacturing establishments that will be affected by the regulation from a count of foreign manufacturers identified in the OASIS system. We were unable to find reliable data on the number of foreign nonmanufacturing establishments and made the following assumptions to estimate their numbers: For the final holders of the article before the food or food packaging is imported into the United States, we assumed the same number of facilities as on the

domestic side of the importation process, for a total of approximately 77,000 foreign final holders. For other firm types, we assumed that the ratio of foreign to domestic facilities of other types is approximately equal to the ratio of foreign to domestic manufacturers. We also assumed that the facility to firm ratio is the same for both foreign and domestic establishments. We request comments on the assumptions used to arrive at these estimates, as well as on reliable sources of data that would improve these estimates.

Firm adjustment: Even though recordkeeping requirements apply to each facility within a firm, some of the overall burden will be estimated at a firm level in order to better capture the true burden of the regulation. In order to estimate the number of firms affected, we used the 1999 Statistics of U.S. Businesses, also from the U.S. Census Bureau (Ref. 5). This dataset is based on the CBP and Nonemployer Statistics, but calculates both the number of establishments and the number of firms for each NAICS code. The Census Bureau has not updated this dataset for the latest 2000 CBP, so we use the 1999 ratio of establishments to firms to adjust the 2000 CBP and 1999 nonemployer establishment count numbers to firm numbers.

Costs per facility or per firm: Some costs of the regulatory options apply to firms, while other costs apply to individual facilities. FDA assumes that the costs to facilities are the same for transfers within firms as for transfers between firms. We request comments on this assumption. Costs fall into several broad categories:

Additional record information: Any possible new regulation may require more information on the input, output, or source ingredients than is kept in existing food facility records. A limited amount of new information could be accommodated by a simple redesign of existing records, whereas requiring more new information may require a completely new design and collection. The extreme version of this requirement is explored under option 13: requiring

all raw ingredients to be connected through records to all final products would cause a substantial change in recordkeeping and other business practices for many commingled commodities.

Information Collection and Maintenance: The burden of maintaining extra information is a direct function of the amount of information required by this proposed regulation that is not normally collected by industry. This burden estimate will be substantially correlated with the redesign burden described previously.

Storage time: A longer storage time may place more of a burden on industry, but will also increase the probability of having records available should an outbreak occur. The major determinant of the impact on costs of storage time requirements is whether the proposed storage times will be longer than normal industry practices. FDA believes that the storage times proposed in option 2 are within normal industry practices. Requiring longer retention times than those proposed in option 2 for records on perishable foods might impose an additional burden. This issue is discussed in more detail below and in options 2, 8, and 9.

Records access time: As in storage time, the major determinant of the impact of any required response time for records access is what firms would reasonably be able to achieve in an emergency situation with current business practices.

Data sources and cost estimates common to options:

Labor costs: For all labor costs, FDA used a wage rate for an administrative worker of \$25.10 from the Bureau of Labor Statistics occupational wage rates for the year 2000 (Ref. 6), doubled to include overhead costs. We assume that all labor for all options is by administrative workers. FDA lacks wage data specific to each of the foreign countries that export to the United States, so we used the wage rate for an administrative worker in the United States for the foreign wage rate. We