

regulations would not cover most of the category “Other Facility Types” in the last row of Table 1 of this document. Only facilities that do de minimis processing or packaging of food, such as affixing a label, are included in this option from the category of “Other Facility Types”. Because the minimal degree of processing that de minimis processing facilities perform, they are not included in the OASIS count of foreign manufacturers.

We assume that domestic packers and repackers are the domestic counterpart

to foreign de minimis food processing facilities. This seems reasonable since the amount of processing performed by packers and repackers is minimal. To estimate the number of foreign packers and repackers, FDA takes the number of packers and repackers in the FACTS database, 6,204, and adjusts it by the ratio of foreign manufacturers in OASIS to the number of domestic manufacturers in FACTS. This adjustment of 3.64 (125,450 foreign facilities divided by 34,437 domestic

facilities), estimates the total number of foreign packers and repackers (or foreign de minimis processing facilities) as 22,600. The facilities-to-firms adjustment factor of 1.25, used to compute the number of firms in the “Other Facility Types” category, indicated that 18,080 firms were included in the foreign de minimis category. Table 18 reports the numbers of facilities and firms that were used in the cost estimates. FDA requests comments on these estimates.

TABLE 18.—NUMBER OF FACILITIES AND FIRMS AFFECTED. OPTION 10

| Type | Facility Estimate | Facility to Firm Adjust. Factor | Firm Estimate |
|--|-------------------|---------------------------------|----------------|
| Domestic | | | |
| Manufacturers | 43,376 | 1.17 | 36,948 |
| Wholesalers/Warehouses | 95,745 | 1.24 | 76,952 |
| Packaging ¹ | 36,907 | 1.07 | 34,633 |
| Transporters/Packers | 16,773 | 1.11 | 15,171 |
| Retail Grocery and Specialty Food | 207,657 | 1.35 | 153,277 |
| Convenience Stores | 128,985 | 1.87 | 68,866 |
| Mixed-Type Facilities that Engage in Farming | 30,497 | 1.25 | 24,397 |
| Importers | 18,902 | 1.25 | 15,122 |
| Total Domestic | 578,842 | | 425,366 |
| Foreign | | | |
| Final Holders | 77,427 | 1.25 | 61,942 |
| De minimis Processors/Packagers | 22,600 | 1.25 | 18,080 |
| Manufacturers | 125,450 | 1.17 | 106,858 |
| Other Facility Types | 0 | 0 | 0 |
| Total Foreign | 225,477 | | 186,879 |

¹ Includes both outer packaging and food contact substances.

Since “Other Facility Types” is such a large and uncertain category, the exclusion of most of the category has a significant impact on all cost estimates.

The estimated ranges of the costs for learning, records access planning, additional records maintenance, and records redesign, as well as the total for

this option are reported in table 19. The costs reported in the table are identified by the applicable Code of Federal Regulations (CFR) section and are expressed in present value terms to account for the fact that some costs are one-time costs while others are

recurring costs. The cost estimate that is greater than 95 percent of all other estimates generated by the model is reported as the high value. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low value.

TABLE 19.—COST DESCRIPTION IN PRESENT VALUE TERMS: OPTION 10

| 21 CFR Section | Mean | Low | High |
|-------------------------------------|---------------|---------------|---------------|
| 1.337, 1.345, and 1.352, (Learning) | \$138,357,000 | \$134,017,000 | \$142,346,000 |
| 1.337, 1.345, and 1.352, (Redesign) | \$381,292,000 | \$326,799,000 | \$430,439,000 |
| 1.361 (Access Planning) | \$78,834,000 | \$73,176,000 | \$84,179,000 |