

products and shortenings may not allow the wide range of substitutions possible in margarines and spreads. Rather, the functional requirements for baked products will likely require replacement of at least some of the *trans* fat with saturated fat. This partial replacement of *trans* with saturated fat is consistent with reports by industry observers (Refs. 121 and 122) and with the examples of the alternative commercial shortenings described in several of the comments. In these examples, the shortenings reformulated to be lower in *trans* fat were higher in saturated fat but were lower in total saturated fat plus *trans* fat than were the traditional, nonreformulated shortenings. Under this final rule, products lower in both saturated fat and *trans* fat will have a competitive advantage because the rule requires prominent declaration of both types of fat on the label.

Based on its consideration of the comments and its own evaluation, FDA continues to believe that the likely substitutions for *trans* fat for margarines will be as described in the November 1999 proposal (64 FR 62746 at 62771). FDA does not have enough information to project the substitutions for *trans* fat due to direct consumer choice, and therefore assumes (for simplicity) that direct consumer choice will show the same range of substitutions as does margarine reformulation. We will describe the effects of these substitutions for *trans* fat on the health benefits of *trans* fat labeling in section VI.E of this document.

Because of the functional requirements for baked products, FDA continues to believe that the most plausible replacement for *trans* fat in baked products is 50 percent *cis*-monounsaturated fat and 50 percent saturated fat. However, because of the uncertainty in quantitative estimation of baked product reformulation, FDA is not including baked product reformulation in its quantitative estimate of benefits and costs of *trans* fat labeling. As note earlier, to the extent that baked products are reformulated,

this analysis will be an underestimate of the actual benefits of this rule.

D. Costs

The costs of this rule are the activities that change as a result of this rule. The total cost of these regulations is the sum of the total testing costs, total relabeling costs, and total reformulation costs. All labels must be in compliance with this final rule by a single effective date. All costs are estimated at the effective date, taken to be 30 months from the publication date of this final rule. If the effective date is more than 30 months from the date of publication, then the actual costs of this rule will be lower than estimated here.

1. Products Affected

This final rule covers all food and dietary supplement labeling within FDA's jurisdiction. With a few exceptions, labeling for all FDA regulated foods and dietary supplements will have to be changed by the next uniform effective date following publication of this rule, or about 2 to 3 years after the date of publication. One exception is for products with less than 0.5 g *trans* fat per serving that also use the "simplified format" for labeling and that do not make nutrition claims or declare vitamins or minerals. The labeling for these products will not have to be changed. FDA does not have data to estimate how many products fall into this category, so the cost estimate does not reflect this exception and is therefore an overestimate of the actual cost of the rule. The other exception is for products that sell less than 100,000 units per year in the United States, that are made by firms that have fewer than 100 employees, that do not make nutrition or health claims, and that have filed a notification with FDA in accordance with § 101.9(j)(18). These products are not required to display the Nutrition Facts panel that is being amended by this rule. Again, FDA does not have data to estimate how many products fall into this category, so the

cost estimate does not reflect this exception and is therefore an overestimate of the actual cost of the rule.

To estimate the costs of this rule, FDA has used the FDA Labeling Cost Model developed for FDA under contract by RTI International in April 2002 (Ref. 129). This labeling model has more current data than the previous labeling cost model developed for the implementing rules of the 1990 amendments (Ref. 74). The model indicates that there are approximately 308,000 food and dietary supplement stock keeping units (SKUs) sold in the United States in categories for which some products will need to be relabeled. A SKU is a specific product sold in a specific size. For example, there is one SKU for 16 ounce (oz) containers of Brand X Diet Peach Tea. The same brand and flavor of tea (a product) in a 12 oz container would be another SKU, and a 12 oz container of the same brand but different flavor of tea would be still another SKU. The model also indicates that there are about 154,000 products potentially affected by this rule. Table 3 of this document shows the data on the number of SKUs and products affected. From the categories listed in table 3 as "Selected Baking Ingredients," "Selected Candy," "Selected Condiments, Dips and Spreads," and "Selected Dressings and Sauces," FDA excluded products, such as baking powder, bottled water, gum, jam, and vinegar, that qualify for the "simplified" format and are certain not to be affected by this rule. Even with these products removed, this estimate is still certain to be an overestimate of the actual SKUs and products affected by this rule because FDA has imputed costs to all products and SKUs within these broad product categories. Labels on many products categories such as "Selected Beverages" and "Dietary Supplements" are not likely to need to be changed. However, FDA has no basis to make better estimates of the actual number of products and SKUs affected by this rule.

TABLE 3.—NUMBER OF SKUs AND PRODUCTS AFFECTED BY PRODUCT CATEGORY

Product Categories	Number of SKUs	Number of Products
Baked Goods	47,200	29,600
Selected Baking Ingredients	7,700	3,300
Baby Foods	1,100	800
Selected Beverages	32,100	8,400
Breakfast Foods	3,600	2,400