

already been reformulated to eliminate *trans* fat. For margarine reformulation, FDA has estimated no increase in ingredient costs, because the price of reformulated margarine products that are already on the market is no higher than the price of margarine products containing 0.5 g or more per serving of *trans* fat. The different ingredients used in the products appear to have had no impact on the cost of production. However, as greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs. However, given that

increases in costs of inputs, if any, have not been passed on with a change in 15 percent of margarine products, it seems quite reasonable that an additional smaller change (10 percent) will not result in significant increases in ingredient costs. Therefore, FDA estimates that 10 percent of the margarine products that have not yet been reformulated will be reformulated to reduce *trans* fat content to less than 0.5 g per serving. We assume that reformulating 10 percent of margarine products will result in a 10 percent reduction in the average *trans* fat content of margarine as a product

category. The reformulation will therefore reduce the *trans* fat content of margarines as a whole by 10 percent. In the analysis for the proposed rule, FDA estimated that there were 820 margarine products. Data in the new Labeling Cost Model indicate only 300 margarine products. The new data was used to estimate that 30 margarine products will reformulate as the result of this rule from 8 (10 percent of 84) to 82 (10 percent of 820), if 10 percent of the total number of margarine products are reformulated. Table 6 shows the cost of margarine reformulation.

TABLE 6.—COST OF MARGARINE REFORMULATION

Cost of Reformulating per Product	\$440,000
Products Reformulating	30
Total Cost	\$13,200,000

FDA has not attempted to estimate the ongoing increased cost of substitutes for partially hydrogenated oil. Competition provides producers with incentives to use the least expensive ingredients that are acceptable for the quality of product they are making. Therefore, in general, any change in existing formulations (such as is expected to occur as a result of this rule) can increase the cost of ingredients. Even a very small increase in the price of a minor ingredient can amount to an increase in production costs of millions of dollars when multiplied by millions of units. However, there is good reason to believe

that, in the long run, ingredient costs may not increase. To the extent that producers rely on newly formulated ingredients made with new technologies, the price of these ingredients largely depends on the industrial capacity to produce them. As the demand for such ingredients increases, producers will have more incentive to increase capacity and the prices of these ingredients will fall. In the case where producers make use of different mixes of oils, agricultural inputs are well known for being able to be supplied in greater and greater quantities without an increase in price.

FDA does not have sufficient information on the types of substitutes that will be used, on the volume of substitutes that will be needed, or on the future price of the substitutes at the time that reformulation is completed.

5. Cost Summary

Costs for testing, relabeling, and reformulation are all expected to occur by the first effective date of the final rule, or about 2 to 3 years after publication. Table 7 shows the estimates of total cost.

TABLE 7.—RANGE OF COSTS BY CATEGORY AND TOTAL COST

Cost Category	Low	Medium	High
Testing	\$40,298,000	\$44,930,000	\$59,282,000
Relabeling	\$85,964,000	\$126,835,000	\$204,986,000
Reformulation	\$13,200,000	\$13,200,000	\$13,200,000
Total	\$139,000,000	\$185,000,000	\$275,000,000

FDA acknowledges that there is a significant degree of uncertainty in the cost estimates provided here. The most significant source of potential divergence from the reported estimates would be an ongoing increased cost of substitutes for partially hydrogenated oil for producers of reformulated products. FDA has not included any costs for this item in this analysis, so that, if substitute oils do cost more, the costs here are underestimates.

Reformulation is a second significant area of uncertainty. The unknowns

include the number of products that will be reformulated, the cost of reformulation, the number of abandoned attempts at reformulation, the length of time actually needed to reformulate products, and the degree to which the reformulation of some products reduces the cost of reformulating other products of the same or different type. The estimates that are provided in this analysis might be either over- or underestimates of the actual costs of reformulation.

A third major area of uncertainty includes the number of labels that will be changed. Actual costs are likely to be lower than those estimated here because this analysis estimated costs based on broad categories of products some of which will not have to change their labels.

E. Benefits

To estimate the health benefits of *trans* fat labeling in the November 1999 proposal, FDA followed the general approach used to estimate the health