

of the rule will be about equal and will cancel each other out. This would leave a high estimate of 5.5 percent decrease and a low estimate of a 0.5 percent decrease in *trans* fat intake as discussed above. However, for the purpose of this final analysis, FDA has chosen a very low estimate of consumer response to the new label. FDA is using an estimate even lower than the low estimate above: a decrease of 0.1 percent of *trans* fat intake. The actual change that occurs may be larger. However, FDA chose this amount so as not to overestimate benefits of this rule. To the extent that actual consumer response is higher than FDA's estimate, this analysis will underestimate the benefits of *trans* fat labeling.

i. *Margarine reformulation.* In the November 1999 proposal, in scenarios 2 through 4, FDA estimated that 30 percent of margarine products had already been reformulated to eliminate *trans* fat, and that all of the remaining margarine products would be reformulated to remove *trans* fat by the effective date for *trans* fat labeling.

(Comment 35) A comment stated that FDA had overestimated the proportion of margarine that had already been reformulated and said that the actual amount was about 15 percent of margarine products. Several comments disagreed with FDA's estimate that all margarine would reformulate by the effective date for *trans* fat labeling. These comments noted that reformulation is very expensive, requires a long time to accomplish, and would, under certain circumstances, require the use of more expensive inputs. Other comments stated that private benefits of reformulating margarine products would not exceed the private costs for manufacturers unless the margarine products could make nutrient content claims. These comments gave a number of examples to demonstrate that even reformulated margarines were not likely to be able to comply with the proposed definitions for nutrient content claims.

FDA accepts the comment about current margarine products. For this analysis, FDA estimates that about 15 percent of margarine has already been reformulated to remove *trans* fat. In response to the comments about projected margarine reformulation, FDA notes that the analysis for the November 1999 proposal did include the cost of reformulation and the time needed for reformulation. In that analysis, FDA did not include higher ingredient costs for margarine reformulation, 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, in response to the comments, FDA acknowledges that, as greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs.

As noted earlier regarding consumer response to *trans* fat labeling, the declaration of *trans* fat in this final rule is prominent and straightforward. This feature may tend to increase the incentives for manufacturers to reformulate their products to be lower in *trans* fat. However, the provisions of this final rule also do not link *trans* fat with saturated fat or with a % DV for *trans* fat and do not change existing regulations regarding claims. The absence of these features may tend to decrease the incentives for manufacturers to reformulate their products to be lower in *trans* fat in comparison to the incentive that would have been introduced by the proposed rule. Therefore, in response to the comments regarding projected margarine reformulation, FDA recognizes that different features of this final rule may tend to either increase or decrease the incentive for reformulation in comparison to the incentive that would have been introduced by the proposed rule.

Although FDA acknowledges considerable uncertainty in the likelihood of additional margarine reformulation, FDA is aware of evidence suggesting that at least some margarine products are likely to reformulate in response to *trans* fat labeling. As stated in the analysis for the proposed rule, in several European countries, the actual, demonstrated market response to consumer concern about *trans* fat is that margarine products have been reformulated to reduce or eliminate *trans* fat (64 FR 62746 at 62781) (Refs. 102, 124, 125, and 127). Also, many people who now consume margarine products do so in order to consume a more heart-healthy product than butter. Because the rule would require the prominent declaration of the amount of *trans* fat on a separate line below saturated fat, these margarine consumers are likely to search for margarine products with lower levels of both saturated fat and *trans* fat. Additionally, publicity generated about the issue by consumer groups and the media has highlighted margarine as a source of *trans* fat and has given prominent attention to reformulated margarine products. As more margarine products are reformulated, consumer

groups may shift their focus to those remaining margarine products that have not reformulated. This suggests that with sufficient information on *trans* fat content consumers are likely to pressure margarine producers to reduce *trans* fat. This consumer pressure will generate some competitive pressures among margarine producers to reduce *trans* fat content even in the absence of nutrient content claims.

In response to comments received, because of the absence of *trans* fat claims in this rule, and recognizing the uncertainty, FDA is using a low estimate of margarine reformulation in this final rule. FDA estimates that reformulation will reduce the *trans* fat content of margarines as a whole by 10 percent due to *trans* fat labeling. Because the *trans* fat in margarine accounts for about 0.36 percent of energy intake, this reduction corresponds to a decrease in *trans* fat intake of 0.036 percent of energy. The actual decrease may be larger, but FDA chose this lower amount so as not to overestimate benefits of this rule. The additional 10 percent margarine reformulation will mean that, including previous reformulations, about 23 percent of *trans* fat will have been removed from margarine. This estimated reduction is far lower than the 100 percent reduction seen in several European countries. The estimated 10 percent reformulation has the advantage of being an underestimate. To the extent that more *trans* fat is removed from margarine than FDA's estimate, this analysis will underestimate the benefits of *trans* fat labeling.

ii. *Reformulation of other products.* In two scenarios in the November 1999 proposal, FDA projected that some baked products would be reformulated to remove *trans* fat (64 FR 62746 at 62767). In that analysis, the baked products were separated into two categories corresponding to SIC codes: breads, cakes and similar products (SIC code 2051) and cookies and crackers (SIC code 2052). Considering the *trans* fat contributions of the two categories of baked goods (64 FR 62746 at 62765), the overall projected reformulation of baked goods corresponded to a 5 percent reduction in *trans* fat intake in scenario 3 and a 10 percent reduction in scenario 2.

(Comment 36) A number of comments stated that FDA had overestimated the proportion of baked goods products that would reformulate or the proportion of *trans* fat that could realistically be removed from baked goods by reformulation. Some comments noted that reformulation was very expensive, required a long time to accomplish, and would under certain circumstances