

composition of their products, to anticipate the response of consumers and competitors to the new information, to change the labeling, and possibly to change the composition of their existing food products. Even after the effective date of the rule, food manufacturers will observe the response of consumers to the information on *trans* fat, and some may develop and market new products with less *trans* fat than similar existing products.

FDA assumes that producers will decide whether or not to change the composition of existing products on a product-by-product basis, depending on expected private returns. They will choose to reformulate the existing products when the expected private benefits exceed the expected private costs of reformulating the products. In other words, if a product is expected to lose market share without reformulation because of the new disclosure, then manufacturers will compare the private costs from decreased sales to the cost of reformulation.

2. Anticipated Changes in *Trans* Fat Intake

FDA anticipates that, taken together, changes in food purchases by consumers and reformulation by producers in response to this rule will result in an overall decrease in *trans* fat intake in the U.S. population. In the November 1999 proposal, FDA developed four scenarios to demonstrate potential quantitative changes in *trans* fat intake (64 FR 62746 at 62767). FDA also estimated the current *trans* fat intake of the population as a starting point for its scenarios for projected intake changes.

a. *Revised estimate of current trans fat intake.* In section IV of this document, FDA discussed the uncertainties associated with estimates of *trans* fat intake from: (1) National food consumption survey, (2) national disappearance data, and (3) food frequency questionnaires done in observational studies of U.S. population groups. Although there are uncertainties associated with each type of estimate, FDA chose estimation of *trans* fat intake based on a national food consumption survey as most suitable for use in this economic analysis. Estimates of intake based on national disappearance data generally overestimate intake due to losses in processing and use, and food groups derived from disappearance data correspond to commodities rather than to foods as consumed. Therefore, an estimate based on a national food consumption survey was better suited to the present analysis than was an estimate based on national

disappearance data. Estimates of *trans* fat intake based on food frequency questionnaires may have the advantage of having been validated versus biomarkers such as *trans* fat content of adipose tissue. Such estimates are suitable for their intended use in ranking and classifying *trans* fat intake of subjects in observation studies. However, food frequency questionnaires are not necessarily designed to provide accurate absolute (numerical) intake estimates. As described in the November 1999 proposal (64 FR 62746 at 62753), estimates of nutrient intakes based on food frequency data may be subject to systematic bias toward either over- or underestimation of intake, depending on the design of the food frequency questionnaire (Ref. 27). Available estimates of *trans* fat intake from food frequency questionnaires in observational studies are lower than estimates of *trans* fat intake from a national food consumption survey (Ref. 26), as summarized in the November 1999 proposal (64 FR 62746 at 62752 to 62753) and in section IV of this document. Additionally, the available food frequency results pertain to the intake of specific U.S. population groups in the observation studies, not to the overall U.S. population. Therefore, an estimate based on a national food consumption survey was better suited to the present analysis than was an estimate based on food frequency questionnaires done in observational studies. One disadvantage of an estimate based on a national food consumption survey is that, as described in section IV, food intake is generally under-reported in consumption surveys (Ref. 26). Therefore, intake of *trans* fat, in grams, estimated from a national consumption survey is likely to underestimate actual intake. However, intake of *trans* fat from national consumption survey data is likely to underestimate actual intake to a lesser extent than does the lower reported intake of *trans* fat from food frequencies done in observation studies. Additionally, intake of *trans* fat, as a percent of total energy, from a national consumption survey is more likely to be an unbiased estimate (Ref. 26).

As described in the November 1999 proposal (64 FR 62746 at 62765), information on *trans* fat content of foods is limited, and there have been few estimates of *trans* fat intake based on national dietary surveys using food records or recalls. As described in section IV of this document and in the November 1999 proposal (64 FR 62746 at 62752 and 62765), an available estimate by Allison et al. (Ref. 26), based

on CSFII 1989–91, reported mean *trans* fat intake of 5.3 g/day (d) (2.6 percent of energy). However, for the purposes of economic analysis, FDA needed to estimate the mean intake of *trans* fat from specific food groups. Therefore, in the November 1999 proposal, FDA indirectly estimated *trans* fat intake based on a report from the Research Triangle Institute (RTI) (Ref. 73). The RTI report used a special 1995 USDA database of *trans* fat content of foods (Ref. 40), together with the mean intake of food groups from USDA's CSFII 1994–96, and matched the CSFII 1994–96 food groups with Standard Industrial Classification (SIC) Codes for food product categories. FDA limited its estimate to foods with *trans* fat from partially hydrogenated fats and oils (64 FR 62746 at 62765). (Although *trans* fat does occur naturally in dairy foods, it is generally present in dairy products at less than 0.5 g *trans* fat per serving, and therefore most dairy products would not have been affected by the November 1999 proposal (64 FR 62746 at 62775)).

In the November 1999 proposal, FDA estimated that current average *trans* fat intake from hydrogenated fat was 2.91 percent of energy (calories) for adults, which is about 7.62 g/d for men and 5.54 g/d for women (Ref. 73 and 64 FR 62746 at 62765). Among food product categories, average *trans* fat intake of adults, as a percent of energy, was: margarine, 0.39 percent; bread/cake, 0.67 percent; cookies/crackers, 0.98 percent; other food groups, 0.87 percent. The estimated intake of *trans* fat from margarine included FDA's adjustment based on the assumption that approximately 30 percent of margarines currently on the market had already been reformulated to remove *trans* fat.

(Comment 33) Comments generally agreed that FDA's estimate of current *trans* fat intake was reasonable and in the range of other estimates of *trans* fat intake. Comments from the margarine industry agreed with FDA's overall estimate of *trans* fat intake from margarine but stated that FDA had overestimated the percent of margarines (30 percent) that had already been reformulated to remove *trans* fat. One comment indicated that the proportion of margarines with less than 0.5 g *trans* fat per serving is about half of FDA's estimate, or 15 percent of margarines. Some comments pointed out the importance of *trans* fat intake from food groups that were not itemized separately in FDA's summary table, including chips and snacks and French fried potatoes. Because FDA had restricted its estimate to *trans* fat intake from partially hydrogenated fats and oils, some comments requested clarification