

labeling. In table 2, current *trans* fat intake from margarine is 0.359 percent of energy, reduced 15 percent from the 0.423 percent of energy intake in table 1 of this document to adjust for the estimated 15 percent of margarine that has already been reformulated to remove *trans* fat. This adjustment reduces the total *trans* fat intake from hydrogenated products to 1.96 percent

of energy in table 2, compared with 2.03 percent of energy in table 1. Table 2 shows that, by the effective date of the rule, FDA projects that *trans* fat intake will decrease by 0.0378 percent of energy. This decrease will be composed of 0.0359 percent of energy due to removal of 10 percent of *trans* fat from margarine by reformulation, and an additional 0.0019 percent of energy due

to direct consumer choice. The additional 0.0019 percent of energy represents 0.1 percent of all remaining *trans* fat from hydrogenated fat after margarine reformulation (1.964 percent - 0.0359 percent = 1.928 percent; 0.1 percent x 1.928 percent = 0.0019 percent).

TABLE 2.—ESTIMATED DECREASES IN *Trans* FAT INTAKE AND CONTRIBUTION FROM FOOD GROUPS DUE TO LABELING, AT EFFECTIVE DATE OF RULE

Food group	Before Effective Date of Rule	Change at Effective Date of Rule	
	Mean daily <i>trans</i> intake <sup>1</sup>	Decrease in <i>trans</i> fat contribution from food group	Decrease in <i>trans</i> fat intake
	Percent of energy from <i>trans</i> fat	Percent decrease in <i>trans</i> fat	Decrease in percent of energy from <i>trans</i> fat
Total Margarine	0.359% <sup>2</sup>	10%	0.0359%
Other food groups with partially hydrogenated fats and oils	1.605%	none	
Total from hydrogenated products	1.964%		
Total decrease due to reformulation			0.0359%
Additional decrease due to consumer choice			0.0019% <sup>3</sup>
Total decrease			0.0378%

<sup>1</sup> *Trans* fat intake for men and women age 20 and over from CSFII 1994–96, see table 1 of this document.

<sup>2</sup> *Trans* fat intake from margarine, 0.359 percent of energy, already decreased by 15 percent from intake in table 1, to account for margarine that has already been reformulated to decrease *trans* fat.

<sup>3</sup> Estimated decrease due to consumer choice at effective date is 0.1 percent of all remaining *trans* fat from hydrogenated fat after margarine reformulation.

iv. *Substitutions for trans fat.* In the November 1999 proposal, FDA assumed that manufacturers would most likely replace *trans* fat in margarine with: (1) *Cis*-monounsaturated fat, (2) 50 percent *cis*-monounsaturated fat and 50 percent *cis*-polyunsaturated fat, or (3) 50 percent *cis*-monounsaturated fat and 50 percent saturated fat, and that they would most likely replace *trans* fat in baked products with 50 percent *cis*-monounsaturated fat and 50 percent saturated fat (64 FR 62746 at 62771). In making these assumptions, FDA relied, in part, on a report from RTI estimating that current food technology would require the incorporation of about 0.5 g saturated fat for every 1 g *trans* fat removed by reformulation (64 FR 62746 at 62767).

(Comment 38) Some comments stated that FDA had ignored the question of macronutrient substitutions, or had assumed that reformulation would replace *trans* fat with 100 percent *cis*-monounsaturated fat. According to the comments, functional requirements for margarines, shortenings and baked products would require that some *trans*

fat be replaced by saturated fat, and this requirement was not accounted for in FDA's projections for reformulation. Other comments noted FDA's assumptions regarding macronutrient substitutions, but stated that FDA had overestimated the extent to which *trans* fat could be replaced by *cis*-unsaturated fat, because of functional and cost requirements of various products. These comments generally implied that FDA had overestimated the expected amount of reformulation because saturated fat would need to replace *trans* fat in any reformulation. Comments pointed out that the amount of saturated fat, a cholesterol-raising fat, is already declared on the nutrition label. Therefore, according to the comments, replacement of *trans* fat with saturated fat would not provide a competitive advantage or an incentive to reformulate and, with higher total saturated fat, the reformulated product might not meet the criteria for proposed defined nutrient content claims.

In response to the comments, FDA notes that it did consider the type of macronutrients substituted for *trans* fat,

and these were accounted for in the mathematical model used to calculate the health benefits (64 FR 62746 at 62771). FDA is aware that there is a range of functional requirements for margarines and spreads, including tub and stick forms and regular and lower fat varieties. Therefore, FDA assumed a range of ingredient substitutions for margarines and spreads, including both saturated and *cis*-unsaturated fat. Replacement of *trans* fat with a range of combinations of saturated and *cis*-unsaturated fat in margarines and spreads is consistent with reports from North America and Europe (Refs. 104, 124, 125, 126, 127, and 128). In a survey of U.S. margarines, tub margarines with *trans* fat less than 0.5 g per serving did not have increased saturated fat compared with other tub margarines (Ref. 104). In the U.S. study, a stick margarine with less than 0.5 g *trans* fat per serving had higher saturated fat than other stick margarines with comparable fat content, but had lower saturated fat plus *trans* fat than the other stick margarines (Ref. 104). FDA is aware that the functional requirements for baked