

of *trans* fat by cis-monounsaturated fat. To account for each type of macronutrient substitution, we used the corresponding factors from table 9 for changes in serum lipids. For example, for cis-polyunsaturated fat, table 9 gives the factor, 1.81 mg LDL-C/dL, for replacement of 1 percent of energy from cis-polyunsaturated fat by *trans* fat. For Method 1, based on changes in LDL-C, the replacement of 0.1 percent of energy from *trans* fat with the same percent of energy from cis-polyunsaturated fat would decrease CHD risk by 0.177 percent (-0.1 percent of energy from *trans* fat x 1.81 mg LDL-C/dL per percent of energy from *trans* fat x 0.7 percent change in CHD risk per mg LDL-C/dL x 1.4 adjustment factor for regression dilution = -0.177 percent change in CHD risk). As noted previously, we project that, due to *trans* fat labeling, *trans* fat will be replaced by combinations of different types of fatty acids or carbohydrate. The changes in

CHD risk associated with specific combinations of fatty acids or carbohydrate are shown in the last three data columns. The first four data columns show the change in CHD risk associated with each individual type of fatty acid and carbohydrate. The column showing *trans* fat replaced by 100 percent saturated fat is included in table 9 for completeness in illustrating the data and methods we used to estimate changes in CHD risk with different macronutrient substitutions. The inclusion of this column does not indicate that FDA projects that *trans* fat will be replaced by 100 percent saturated fat, or that FDA would encourage such an inappropriate substitution. Rather, the substitutions for *trans* fat that FDA considers most likely are shown later, in table 10.

As mentioned earlier, and in the November 1999 proposal (64 FR 62746 at 62769), the economic analysis used changes in both LDL-C and HDL-C as a

second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL-C. To allow readers to reproduce all of our estimated changes in CHD risk, table 9 shows changes in CHD risk based on Method 2, LDL-C and HDL-C, as well as Method 1, LDL-C. In addition, the cells that show a decrease in CHD due to a 100 percent replacement of *trans* fat for saturated fat represent the relationship between HDL-C and CHD, a relationship that is more uncertain than the causal relationship between LDL-C and CHD. FDA accounted for the replacement of *trans* fat with different combinations of macronutrients by projecting a range of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits (64 FR 62746 at 62771–62773).

TABLE 9.—SUMMARY OF CHANGES IN SERUM LIPIDS AND CHD RISK WITH DIFFERENT MACRONUTRIENT SUBSTITUTIONS
A. CHANGE IN SERUM LIPIDS WITH SUBSTITUTION OF *Trans* FATTY ACIDS FOR DIFFERENT TYPES OF FATTY ACIDS OR CARBOHYDRATE

Macronutrient	Cis-monounsaturated Fatty Acid	Cis-polyunsaturated Fatty Acid	Saturated Fatty Acid	Carbohydrate	Half cis-monounsaturated and half cis-polyunsaturated	Half cis-monounsaturated and half saturated	Half cis-monounsaturated and half carbohydrate
Change in Serum Lipid When Replaced by <i>Trans</i> Fat	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy
LDL	1.5	1.81	-0.02	1.26	1.66	0.74	1.38
HDL	-0.4	-0.34	-0.53	-0.06	-0.37	-0.47	-0.23

B. CHANGE IN CHD RISK WITH REPLACEMENT OF *Trans* FATTY ACIDS BY DIFFERENT TYPES OF FATTY ACIDS OR CARBOHYDRATE

Macronutrient	Cis-monounsaturated Fatty Acid	Cis-polyunsaturated Fatty Acid	Saturated Fatty Acid	Carbohydrate	Half cis-monounsaturated and half cis-polyunsaturated	Half cis-monounsaturated and half saturated	Half cis-monounsaturated and half carbohydrate
Change in CHD Risk With Replacement of <i>Trans</i> Fat	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy
Method 1, LDL	-0.147	-0.177	0.002	-0.123	-0.162	-0.073	-0.135
HDL	-0.140	-0.119	-0.186	-0.021	-0.130	-0.163	-0.081
Method 2, LDL + HDL	-0.287	-0.296	-0.184	-0.144	-0.292	-0.235	-0.216

(Comment 39) As described previously in this document, FDA received numerous comments in support of the November 1999 proposal. Several of these comments noted specifically that labeling of *trans* fat has the potential for substantial public

health benefits. A number of comments noted that consumption of *trans* fat increases the risk of CHD by increasing total blood cholesterol and LDL-C, and that *trans* fat labeling would enable consumers to decrease their *trans* fat intake and therefore decrease their risk

of CHD. Some comments added that, because *trans* fat also increases the risk of CHD by decreasing HDL-C, therefore the health benefits of *trans* fat labeling would be greater than the benefits associated with the effect of *trans* fat on LDL-C alone. A few comments