

(table 9), described earlier in this section. Earlier in this section, FDA has revised its estimate of projected decreases in *trans* fat intake due to labeling (table 2) and discussed the likely substitutions of different types of fat for *trans* fat. Using this information, FDA revised the expected changes in CHD risk due to *trans* fat labeling.

As shown in table 2, a 0.0378 percent of energy decrease in *trans* fat intake is expected to occur by the effective date of the rule. Approximately 3 years will be needed for predicted changes in *trans* fat intake to result in changes in CHD risk (Ref. 137). Table 10 shows the decreases in CHD risk that would be expected, 3 years after the effective date, for different examples of macronutrient substitutions for *trans* fat. The three specific substitutions shown in table 10 are those that FDA used to represent the range of likely ingredient substitutions for *trans* fat in margarine: (1) 100 percent *cis*-monounsaturated fat, (2) a mixture of 50 percent *cis*-

monounsaturated and 50 percent *cis*-polyunsaturated fat, or (3) a mixture of 50 percent *cis*-monounsaturated and 50 percent saturated fat (Ref. 73). Table 10 shows that, using one of these three substitutions, the predicted decrease in CHD risk would range from 0.027 percent to 0.061 percent for Method 1 and from 0.090 percent to 0.110 percent for Method 2.

FDA has identified these likely substitutions, but recognizes that once reformulation begins, different combinations of ingredients may emerge. In order to estimate the health effects of reformulation, however, it is less important to identify the exact formulas to be used than it is to identify the range of possible changes in CHD risk. To estimate the potential health benefits from the reformulation of margarine, FDA used a probabilistic model with a distribution of effects based on the distribution of possible changes in CHD risk associated with the three ingredient substitutions. FDA used

a distribution rather than a weighted average because we did not know which combination was most likely, or what distribution of combinations would emerge. (The formal distribution we used was a BetaPERT, which uses three points: A minimum, an intermediate, and a maximum. The model used the change in CHD risk for a mixture of 50 percent *cis*-monounsaturated and 50 percent saturated fat as the minimum, the change with 100 percent *cis*-monounsaturated fat as intermediate, and the change for a mixture of 50 percent *cis*-monounsaturated and 50 percent *cis*-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.)

As shown in table 10, the probabilistic model of substitutions for *trans* fat predicted a decrease in CHD risk of 0.052 percent using Method 1 and 0.106 percent using Method 2.

TABLE 10.—PREDICTED CHANGES IN CHD RISK DUE TO *Trans* FAT LABELING ACCORDING TO MACRONUTRIENT SUBSTITUTION FOR *Trans* FAT

Time after Effective Date for Final Rule ¹	Decrease in <i>Trans</i> Fat Intake (% of Energy)	Source of Decrease	Substitution for <i>Trans</i> Fat	Percent Decrease in CHD Risk		
				Method 1, LDL	HDL	Method 2, LDL and HDL
3 years	0.0378	Consumer choice and margarine reformulation	mono	-0.056%	-0.053%	-0.108%
			mono+ poly	-0.061%	-0.049%	-0.110%
			mono+ sat	-0.027%	-0.062%	-0.090%
			Substitution from probabilistic model.	-0.052%	-0.054%	-0.106%

¹ The time after the effective date for the final rule includes 3 years for decreases in *trans* fat intake to result in changes in CHD risk.

Approximately 3 years will be needed for predicted changes in *trans* fat intake to result in changes in CHD risk (Ref. 137). Table 10 shows that the 0.0378 percent of energy decrease in *trans* fat intake expected to occur by the effective date of the rule will result, 3 years after the effective date, in a 0.052 percent decrease in CHD risk using Method 1 and a 0.106 percent decrease in CHD risk using Method 2. FDA estimated these decreases in risk using a mathematical model that accounted for the three likely substitutions for *trans* fat in reformulation of margarine and direct consumer choice, discussed previously. Table 10 shows the predicted decrease in CHD risk for each of the substitutions separately, and the overall estimate from the mathematical model.

3. Value of Changes in Health

In the previous sections, FDA presented potential changes in food markets because of this final rule and described calculations of the decreases in CHD that would result from those market changes. Uncertainties in these analyses include:

- The size of consumer substitutions among existing products;
- The amount of producer reformulation to avoid losing market shares;
- The types of ingredient substitutions producers will make to reduce the amount of *trans* fat in their products; and,
- The decrease in CHD that will result from decreased *trans* fat in the diet.

FDA used three specific substitutions to represent the range of likely

ingredient substitutions for *trans* fat in margarine: (1) 100 percent *cis*-monounsaturated fat, (2) a mixture of 50 percent *cis*-monounsaturated and 50 percent *cis*-polyunsaturated fat, or (3) a mixture of 50 percent *cis*-monounsaturated and 50 percent saturated fat (Ref. 73).

FDA estimated the benefits from the final rule for two methods. The two methods give low and high estimates of the change in CHD risk brought about by changing intakes of *trans* fat. Method 1 assumes that the reduction in CHD risk associated with reduced *trans* fat intakes comes about only through the reduction in LDL-C. Method 2 assumes that the reduction in CHD risk comes about through a combination of reducing LDL-C and increasing HDL-C.