

TABLE 12A.—SUMMARY OF INPUTS, DATA SOURCES, AND ASSUMPTIONS—Continued

Name of Input	Value or Distribution Used	Type of Estimate	Source of Data or Assumption
Percent of SKU label changes that can be coordinated with scheduled labeling changes.	84% of branded SKUs, 50% of private label SKUs.	FDA interpolation of information on 24 and 36 month compliance period proportions.	RTI labeling cost model, Ref. 129.
Per product category cost of relabeling.	Varies (table 5 of this document).	Data.	RTI labeling cost model, Ref. 129.
Number of margarines reformulated.	30 (table 6 of this document).	Low assumption based on uncertainty.	Assume 10% of margarine products reformulate.
Per product cost of reformulation.	\$440,000 (table 6 of this document).	Data.	Industry supplied information (64 FR 62745 at 62782, November 17, 1999).
Overall change in CHD risk per change in trans fat intake.	0.147% decrease in CHD risk per 0.1% of energy decrease in trans fat intake. Method 1 (table 8 of this document).	Low estimate, assuming change in CHD risk is entirely through effect of trans fat on LDL-C.	Multiply change in trans fat intake by factors below: $-0.1\% \times 1.5 \times 0.7 \times 1.4 = -0.147\%$, decrease in CHD risk.
Overall change in CHD risk per change in trans fat intake.	0.287% decrease in CHD risk per 0.1% of energy decrease in trans fat intake. Method 2 (table 8 of this document).	Intermediate estimate, assuming change in CHD risk is through effect of trans fat on both LDL-C and HDL-C. Excludes other possible mechanisms linking trans fat to CHD risk.	Multiply change in trans fat intake by factors below: $-0.1\% \times -0.4 \times -2.5 \times 1.4 = -0.140\%$, decrease in CHD risk due to change in HDL-C. Add to result from Method 1: $-0.147\% + (-0.140\%) = -0.287\%$, decrease in CHD risk, Method 2.
Change in LDL-C with change in trans fat intake.	1.5 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (table 8 of this document).	Data.	Published meta-analyses, Refs. 62 and 69.
Change in HDL-C with change in trans fat intake.	-0.4 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (table 8 of this document).	Data.	Published meta-analyses, Refs. 62 and 69.
Changes in LDL-C and HDL-C with substitutions of other macronutrients for trans fat.	Various coefficients shown in table 9 of this document.	FDA's best estimate from available data.	Published meta-analyses, Ref. 65, combined with meta-analyses in Refs. 62 and 69.
Changes in CHD risk with changes in LDL-C.	0.7% increase per 1 mg/dL increase in LDL-C (table 8 of this document).	Data.	Published meta-analyses, Refs. 59, 60, and 61.
Changes in CHD risk with changes in HDL-C.	2.5% increase per 1 mg/dL decrease in HDL-C (table 8 of this document).	Data.	Published meta-analyses, Refs. 59, 60, and 61.
Adjustment for regression dilution.	Factor of 1.4 increase in relationship of change in CHD risk with changes in LDL-C and HDL-C (table 8 of this document).	Data.	Published data, Ref. 64.
Overall change in CHD risk due to labeling.	-0.052%, Method 1; -0.106%, Method 2 (table 10 of this document).	Factors above combined with probabilistic model to account for macronutrient substitutions.	BetaPERT distribution, using the change in CHD risk for a mixture of 50% cis-monounsaturated and 50% saturated fat as the minimum, the change with 100% cis-monounsaturated fat as intermediate, and the change for a mixture of 50% cis-monounsaturated and 50% cis-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.