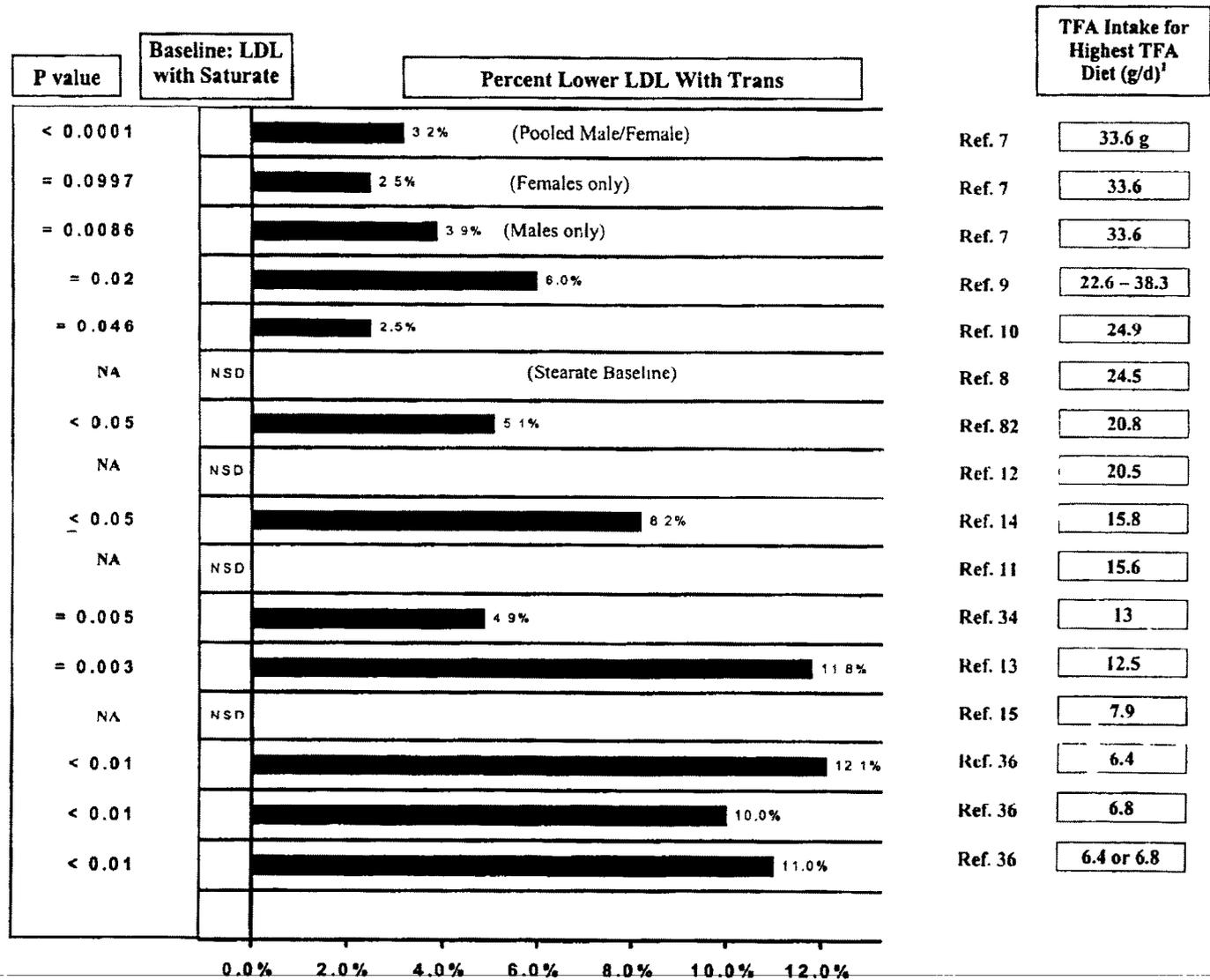


ATTACHMENT A

Percent Lower LDL-Cholesterol Observed With Trans Fat Diet Than With Saturated Fat Diet



Key:

TFA = Trans fatty acid

g/d = grams/day

NSD = No significant difference between LDL Cholesterol levels observed for highest trans fat and highest saturated fat diet

P value = Level of Statistical Significance reported by investigators with respect to the difference between the LDL Cholesterol level observed

Baseline LDL with Saturate = Comparative LDL Cholesterol level observed with highest saturated fat experimental diet

Ref. = Study reference numbers used in FDA's TFA labeling proposal (64 Fed. Reg. 62746 (November 17, 1999)).

Percent Lower LDL With Trans = Percent lower LDL Cholesterol observed with the highest trans fat experimental diet than with highest saturated fat experimental diet. For purposes of establishing a consistent basis for comparison of study results, the expressed was calculated by subtracting the average LDL Cholesterol reported for the trans fat diet from the average LDL Cholesterol reported for the saturated fat diet (e.g., in a study in which the average LDL Cholesterol for the highest saturated fat diet is 3.07 mmol/liter and for the highest trans fat LDL-Cholesterol is 3.00 mmol/liter, the calculation would be $((3.07 - 3.00) \div 3.07) \times 100$, resulting in a value of 2.3%).

NA = Not applicable

¹ Values for all studies were obtained from FDA's trans fat labeling proposal (64 Fed. Reg. 62746 (November 17, 1999)).

**Saturated Fat and Trans Fat Content of Experimental Diets Used in Intervention Studies
Comparing the Relative Effects of Saturated Fat and Trans Fat on Serum
LDL-Cholesterol Levels² Expressed on the Basis of a 2000 Kcal/Day Diet**

Ref. No.	Study Diets	% Kcals from Fat		Equivalent Grams Per Day for 2000 Kcal Diet		TFA DIET: Relative Fatty Acid Content in 2000 Kcal Diet
		SFA	TFA	SFA	TFA	
7	SFA Diet	19.4%	0.8%	43.11 g/d	1.77 g/d	111% DV SFA <u>plus</u> TFA is 500% of average intake. SFA:TFA ratio = 1:1.
	TFA Diet	10%	11%	22.22 g/d	24.44 g/d	
8	SFA Diet	20%	0.3%	44.44 g/d	0.66 g/d	>100% DV SFA <u>plus</u> TFA is 340% of average intake. SFA:TFA ratio = 1:1
	TFA Diet	10.3%	7.7%	22.88 g/d	17.11 g/d	
9	SFA Diet	16.4%	0.9%	36.44 g/d	2 g/d	>122% DV SFA <u>plus</u> TFA is 377% of average intake. SFA:TFA ratio = 1:1
	TFA Diet	11.0%	8.5%	24.44 g/d	18.88 g/d	
10	SFA Diet	13.8%	0.8%	30.67 g/d	1.78 g/d	78.9% DV SFA <u>plus</u> TFA is 400% of average intake.
	TFA Diet	7.1%	8.7%	15.78 g/d	19.33 g/d	
11	SFA Diet	13.9%	<1%	30.89 g/d	2 g/d	110% DV SFA <u>plus</u> TFA is 200% of average intake. SFA:TFA ratio = 1.74:1.
	TFA Diet	9.9%	5.7%	22 g/d	12.67 g/d	
12	SFA Diet	20.9%	0.7%	46.44 g/d	1.55 g/d	151% DV SFA <u>plus</u> TFA is 300% of average intake.
	TFA Diet	13.6%	6.6%	30.22 g/d	14.66 g/d	

² This chart compares the saturated fat and trans fat content of the experimental diets in each study comparing the experimental saturated fat ("SFA Diet") with the experimental trans fat ("TFA Diet"). The percent of Kcal provided by saturated fat and trans fat in each diet is converted to grams per day, using the common basis of a diet containing 2000 kcal per day. This permits the relative amount of saturated fat and trans fat in experimental diets to be evaluated in the context of the 2000 kcal diet upon which FDA food labeling requirements are based. The percent of calories attributable to saturated fat and trans fat for the experimental diets was obtained from FDA's TFA labeling proposal (64 Fed. Reg. 62746 at 62798 - 62821 (Appendix A) (November 17, 1999)). Insufficient data were available for studies Ref. 15, 47 to perform calculations.

Key: SFA - Saturated Fat

TFA - Trans Fat

% DV SFA - Saturated Fat level expressed as percentage of 20 gram Daily Value.

TFA is x% of Average Intake - Trans Fat level expressed as percentage of 5 gram estimated average intake in the United States.

Ref. No.	Study Diets	% Kcals from Fat		Equivalent Grams Per Day for 2000 Kcal Diet		TFA DIET: Relative Fatty Acid Content in 2000 Kcal Diet
		SFA	TFA	SFA	TFA	
13	SFA Diet (Baseline)	13%	0.8%	28.66 g/d	1.7 g/d	85% DV SFA <u>plus</u> TFA is 200% of average intake. SFA:TFA ratio = 1.8:1 grams.
	TFA Diet (Corn Oil Margarine)	7.7%	4.2%	17.11 g/d	9.33 g/d	
14	SFA Diet	22.4%	2.6%	49.77 g/d	5.78 g/d	> 100% DV SFA <u>plus</u> TFA is 400% of average intake. SFA:TFA ratio = 1:1.
	TFA Diet	10%	9.5%	22.22 g/d	21.11 g/d	
34	SFA Diet	11.2%	2.7%	24.9 g/d	6 g/d	87.75% DV SFA <u>plus</u> 173 % of average intake. SFA:TFA ratio = 2:1.
	TFA Diet	7.9%	3.9%	17.55 g/d	8.7 g/d	
36	SFA Diet	15.5%	1.3%	34.44 g/d	2.89 g/d	<u>Canola TFA Diet</u> : 100% DV SFA <u>plus</u> 100% average intake of TFA (plus 26% MUFA/PUFA (57 g/d)).
	TFA Diet (canola-TFA)	8.9%	2.4%	19.78 g/d	5.33 g/d	
36	SFA Diet	17.7%	1.5%	39.33 g/d	3.33 g/d	<u>Sunflower TFA Diet</u> : 146% DV SFA <u>plus</u> 142% average intake of trans fat (plus 19.4% kcals MUFA/PUFA (43 g/d)).
	TFA Diet (sunflower-TFA)	13.2%	3.2%	29.33 g/d	7.1 g/d	
82	SFA Diet	16.7%	N/A	37.11 g/d		94.4% SFA DV <u>plus</u> TFA is 300% of average intake.
	TFA Diet	8.5%	6.72%	18.88 g/d	14.9 g/d	

STUDY REFERENCE LIST

- Reference 7: Mensink, R. P., and M. B. Katan, "Effect of Dietary trans Fatty Acids on High-Density and Low-Density Lipoprotein Cholesterol Levels in Healthy Subjects," *New England Journal of Medicine*, 323:439-445, 1990.
- Reference 8: Zock, P. L., and M. B. Katan, "Hydrogenation Alternatives: Effects of trans Fatty Acids and Stearic Acid Versus Linoleic Acid on Serum Lipids and Lipoproteins in Humans," *Journal of Lipid Research*, 33:399-410, 1992.
- Reference 9: Almendingen, K., O. Jordal, P. Kierulf, B. Sandstad, and J. I. Pedersen, "Effects of Partially Hydrogenated Fish Oil, Partially Hydrogenated Soybean Oil, and Butter on Serum Lipoproteins and Lp(a) in Men," *Journal of Lipid Research*, 36:1370-1384, 1995.
- Reference 10: Aro, A., M. Jauhiainen, R. Partanen, I. Salminen, and M. Mutanen, "Stearic Acid, trans Fatty Acids, and Dairy Fat: Effects on Serum and Lipoprotein Lipids, Apolipoproteins, Lipoprotein(a), and Lipid Transfer Proteins in Healthy Subjects," *American Journal of Clinical Nutrition*, 65:1419-1426, 1997.
- Reference 11: Nestel, P. J., M. Noakes, G. B. Belling, R. McArthur, P. Clifton, E. Janus, and M. Abbey, "Plasma Lipoprotein Lipid and Lp(a) Changes with Substitution of Elaidic Acid for Oleic Acid in the Diet," *Journal of Lipid Research*, 33:1029-1036, 1992.
- Reference 12: Judd, J. T., B. A. Clevidence, R. A. Muesing, J. Wittes, M. E. Sunkin and J. Podeszasy, "Dietary trans Fatty Acids: Effects on Plasma Lipids and Lipoproteins of Healthy Men and Women," *American Journal of Clinical Nutrition*, 59:861-868, 1994.
- Reference 13: Lichtenstein, A. H., L. M. Ausman, W. Carrasco, J. L. Jenner, J. M. Ordovas and E. J. Schaefer, "Hydrogenation Impairs the Hypolipidemic Effect of Corn Oil in Humans Hydrogenation, trans Fatty Acids, and Plasma Lipids," *Arteriosclerosis and Thrombosis*, 13:154-161, 1993.
- Reference 14: Wood, R., K. Kubena, B. O'Brien, S. Tseng, and G. Martin, "Effect of Butter, Mono- and Polyunsaturated Fatty Acid-Enriched Butter, trans Fatty Acid Margarine, and Zero trans Fatty Acid Margarine on Serum Lipids and Lipoproteins in Healthy Men," *Journal of Lipid Research*, 34:1-11, 1993.
- Reference 15: Wood, R., K. Kubena, S. Tseng, G. Martin, and R. Crook, "Effect of Palm Oil, Margarine, Butter, and Sunflower Oil on the Serum Lipids and Lipoproteins of Normocholesterolemic Middle-Aged Men," *Journal of Nutritional Biochemistry*, 4:286-297, 1993.
- Reference 34: Judd, J. T., D. J. Baer, B. A. Clevidence, R. A. Muesing, S. C. Chen, J. A. Weststrate, G. W. Meijer, J. Wittes, A. H. Lichtenstein, M. Vilella-Bach, and E. J. Schaefer, "Effects of Margarine Compared With Those of Butter on Blood Lipid Profiles Related to Cardiovascular Disease Risk Factors in Normolipemic Adults Fed Controlled Diets," *American Journal of Clinical Nutrition*, 68:768-777, 1998.
- Reference 36: Noakes, M., and P. M. Clifton, "Oil Blends Containing Partially Hydrogenated or Interesterified Fats: Differential Effects on Plasma Lipids," *American Journal of Clinical Nutrition*, 68:242-247, 1998.
- Reference 82: Lichtenstein, A. H., L. M. Ausman, S. M. Jalbert, and E. J. Schaefer, "Effects of different forms of dietary hydrogenated fats on serum lipoprotein cholesterol levels," *New England Journal of Medicine*, 340:1933-1940, 1999.