

[Docket No. 94P-0036]

RIN 0910-AB66

4258 03 JUL -3 P1:58

**Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims - Final Rule**

**Index of References**

References 1-86 are the same as those in the *Trans* Fatty Acid Proposal (64 FR 62745; Nov. 17, 1999; Docket No. 94P-0036)

1. Kris-Etherton, P. M., and R. J. Nicolosi, "*Trans* Fatty Acids and Coronary Heart Disease Risk," International Life Sciences Institute, Washington, DC, 1995.
2. Department of Health and Human Services (DHHS) "The Surgeon General's Report on Nutrition and Health," p. 96, Washington, DC, 1988.
3. Kris-Etherton, P. M., editor, "*Trans* Fatty Acids and Coronary Heart Disease Risk," Report of the Expert Panel on *Trans* Fatty Acids and Coronary Heart Disease, *American Journal of Clinical Nutrition*, 62:655S-708S, 1995.
4. National Research Council/National Academy of Sciences, "*Diet and Health, Implications for Reducing Chronic Disease Risk*," pp. 4, 8, 42, 193, 196, 213, and 657, National Academy Press, Washington, DC, 1989.
5. Second Report of the Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults, National Cholesterol Education Program, National Institutes of Health, Bethesda, MD, September 1993.
6. U.S. Department of Agriculture (USDA)/DHHS, "Dietary Guidelines for Americans," 4th ed., 1995.
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.
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.

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.

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.

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.

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.

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.

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.

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.

16. Aro, A., A. F. M. Kardinaal, I. Salminen, J. D. Kark, R. A. Riemersma, M. Delgado-Rodriguez, J. Gomez-Aracena, J. K. Huttunen, L. Kohlmeier, B. C. Martin, J. M. Martin-Moreno, V. P. Mazaev, M. Thamm, P. van't Veer, and F. J. Kok, "Adipose Tissue Isomeric *trans* Fatty Acids and Risk of Myocardial Infarction in Nine Countries: The EURAMIC

Study," *Lancet*, 345:273-278, 1995.

17. Roberts, T. L., D. A. Wood, R. A. Riemersma, P. J. Gallagher, and F. C. Lampe, "Trans Isomers of Oleic and Linoleic Acids in Adipose Tissue and Sudden Cardiac Death," *Lancet*, 345:278-282, 1995.

18. Ascherio, A., C. H. Hennekens, J. E. Burling, C. Master, M. J. Stampfer, and W. C. Willett, "Trans-Fatty Acids Intake and Risk of Myocardial Infarction," *Circulation*, 89:94-101, 1994.

19. Ascherio, A., E. B. Rimm, E. L. Giovannucci, D. Spiegelman, M. Stampfer, and W. C. Willett, "Dietary Fat and Risk of Coronary Heart Disease in Men: Cohort Follow Up Study in the United States," *British Medical Journal*, 313:84-90, 1996.

20. Pietenini, P., A. Ascherio, P. Korhonen, A. M. Hartman, W. C. Willett, D. Albanes, and J. Virtamo, "Intake of Fatty Acids and Risk of Coronary Heart Disease in a Cohort of Finnish Men: The Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study," *American Journal of Epidemiology*, 145:876-887, 1997.

21. Willett, W. C., M. J. Stampfer, J. E. Manson, G. A. Colditz, F. E. Speizer, B. A. Rosner, L. A. Sampson, and C. H. Hennekens, "Intake of *trans* Fatty Acids and Risk of Coronary Heart Disease Among Women," *Lancet*, 341:581-585, 1993.

22. Kromhout, D., A. Menotti, B. Bloemberg, C. Aravanis, H. Blackburn, R. Buzina, A. S. Dontas, F. Fidanza, S. Giampoali, A. Jansen, M. Karvonen, M. Katan, A. Nissinen, S. Nedeljkovic, J. Pekkanen, M. Pekkarinen, S. Punsar, L. Rasanen, B. Simic, and H. Toshima, "Dietary Saturated and *trans* Fatty Acids and Cholesterol and 25-Year Mortality from Coronary Heart Disease: The Seven Countries Study," *Preventive Medicine*, 24:308-315, 1995.

23. Troisi, R., W. C. Willett, and S. T. Weiss, "Trans Fatty Acid Intake in Relation to Serum Lipid Concentrations in Adult Men," *American Journal of Clinical Nutrition*, 56:1019-1024, 1992.

24. Enig, M. G., S. Atal, M. Keeney, and J. Sampugna, "Isomeric *trans* Fatty Acids in the U.S. Diet," *Journal of the American College of Nutrition*, 9:471-486, 1990.

25. Hunter, J. E., and T. H. Applewhite, "Reassessment of *trans* Fatty Acids Availability in the U.S. Diet," *American Journal of Clinical Nutrition*, 54:363-369, 1991.

26. Allison, D. B., S. K. Egan, L. M. Barraj, C. Caughman, M. Infante, and J.T. Heimbach, "Estimated Intakes of *Trans*-Fatty Acid and Other Fatty Acids by the US Population," *Journal of the American Dietetic Association*, 99:166-174, 1999.
27. FASEB Expert Panel (Anderson, S. A., ed.), "Guidelines for Use of Dietary Intake Data," Federation of American Societies for Experimental Biology and Medicine, Bethesda, MD, 1986.
28. Beecher, G. R. and R. H. Matthews, "Nutrient Composition of Foods," pp. 430-439, in *Present Knowledge in Nutrition*, 6th ed., edited by M. L. Brown, International Life Sciences Institute, 1990.
29. Ali, L. H., G. Angyal, C. M. Weaver, and J. I. Rader, "Comparison of Capillary Column Gas Chromatographic and AOAC Gravimetric Procedures for Total Fat and Distribution of Fatty Acids in Foods," *Food Chemistry*, 58:149-160, 1997.
30. Ali, L. H., G. Angyal, C. M. Weaver, J. I. Rader, and M. M. Mossoba, "Determination of Total *trans* Fatty Acids in Foods: Comparison of Capillary-Column Gas Chromatography and Single-Bounce Horizontal Attenuated Total Reflection Infrared Spectroscopy," *Journal of the American Oil Chemists Society*, 73:1699-1705, 1996.
31. Report of a Joint Expert Consultation, "Fats and Oils in Human Nutrition," *FAO Food and Nutrition Paper 57*, World Health Organization, pp. 1-7, 73-79, and 103-105, 1993.
32. Report of the Cardiovascular Review Group, Committee on Medical Aspects of Food Policy, "Report on Health and Social Subjects, 46. Nutritional Aspects of Cardiovascular Disease," Department of Health, London, HMSO, p. 10, 1994.
33. Government of Canada, "Consultation Document on Nutrient Content Claims," January 19, 1996.
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.
35. Derby, B. M., and S. B. Fein, "Meeting the NLEA Education Challenge: A Consumer Research Perspective," in *Nutrition Labeling Handbook*, R. Shapiro (ed.), Marcel Dekker, Inc.,

New York, 1995.

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.
37. London, S. J., F. M. Sacks, J. Caesar, M. J. Stampfer, D. Siguel, W. C. Willett, "Fatty Acid Composition of Subcutaneous Adipose Tissue and Diet in Post Menopausal U.S. Women," *American Journal of Clinical Nutrition*, 54:340-345, 1991.
38. Hu, F. B., M. J. Stampfer, J. E. Manson, E. Rimm, G. A. Colditz, B. A. Rosner, C. H. Hennekens, and W. C. Willett, "Dietary Fat Intake and the Risk of Coronary Heart Disease in Women," *New England Journal of Medicine*, 337:1491-1499, 1997.
39. FASEB Expert Panel (Senti, F.R. ed),"Health Aspects of Dietary *trans* Fatty Acids," Federation of American Societies for Experimental Biology and Medicine, Bethesda, MD, 1985.
40. USDA, Agricultural Research Service, USDA Food Composition Data, Selected Foods Containing *trans* Fatty Acids, 1995 (internet address: <http://www.nal.usda.gov/fnic/foodcomp/Data/index.html>).
41. Government of Canada, "Revised Proposals for Nutrient Content Claims," Tunney's Pasture, Ottawa, Ontario, March 18, 1998.
42. Association of Official Analytical Chemists International (AOAC), AOAC Official Method 965.34 "Isolated *trans* Isomers in Margarines and Shortenings, Infrared Spectrometric Method," AOCS-AOAC Method, *Official Methods of Analysis of AOAC International*, 16th ed., 3d revision, 1997, 41.1.36. AOAC International, Gaithersburg, MD.
43. American Oil Chemists' Society (AOCS), AOCS Official Method Cd 14-95 (Replaces Cd 14-61, reapproved 1997), "Isolated *trans* Isomers Infrared Spectrometric Method," *AOAC Official Methods and Recommended Practices*, edited by D. Firestone, Champaign, IL.
44. AOAC, 1998, AOAC Official Method 994.14, "Isolated *trans* Unsaturated Fatty Acid Content in Partially Hydrogenated Fats," *Official Methods of Analysis of AOAC International*, 16th ed., 41.1.36A, AOAC International, Gaithersburg, MD. 1998, revision March 1998.
45. AOCS, AOCS Recommended Practice Cd 14d-96 (Reapproved 1997), "Isolated *trans*

Geometric Isomers-Single Bounce-Horizontal Attenuated Total Reflection Infrared Spectroscopic Procedure,” *AOCS Official Methods and Recommended Practices*, edited by D. Firestone, Champaign, IL.

46. AOCS, AOCS Official Method Ce 1f-96 (Reapproved 1997) “Determination of cis- and trans-Fatty Acids in Hydrogenated and Refined Oils and Fats by Capillary GLC,” *AOCS Official Methods and Recommended Practices*, edited by D. Firestone, Champaign, IL.

47. AOCS, AOCS Official Method Ce 1c-89 (Reapproved 1993, updated 1995), “Fatty Acid Composition by GLC-cis, cis and trans Isomers,” *AOCS Official Methods and Recommended Practices*, edited by D. Firestone, Champaign, IL.

48. AOAC, 1998, AOAC Official Method 985.21 “Total trans Fatty Acid Isomers in Margarines, Gas Chromatographic Method,” *Official Methods of Analysis of AOAC International*, 16th ed., 41.1.37, AOAC International, Gaithersburg, MD. 1998, revision March 1998.

49. AOCS, AOAC Official Method Cd-14b-93, “Fatty Acid Composition of Partially Hydrogenated Oils - A Combined GLC-IR Method,” (Revised 1995), *AOCS Official Methods and Recommended Practices*, edited by D. Firestone, Champaign, IL.

50. AOAC, 1997, AOAC Official Method 994.15, “Total cis- and trans Octadecenoic Isomers and General Fatty Acid Composition in Hydrogenated Vegetable Oils and Animal Fats, Capillary Gas Chromatographic-Infrared Spectrophotometric Method,” *Official Methods of Analysis of AOAC International*, 16th ed., 3d revision, 1997, 41.1.35A, AOAC International, Gaithersburg, MD.

51. Duchateau, G. S. M. J. E., H. J. vanOosten, and M. A. Vasconcellos, “Analysis of cis- and trans-Fatty Acid Isomers in Hydrogenated and Refined Vegetable Oils by Capillary Gas-Liquid Chromatography,” *Journal of the American Oil Chemists' Society*, 73:275-282, 1996.

52. Adam, M., M. Chew, S. Wasseman, A. McCollum, R. E. McDonald and M. M. Mossoba, “Determination of trans Fatty Acids in Hydrogenated Vegetable Oils by Attenuated Total Reflection Infrared Spectroscopy: Two Limit Collaborative Studies,” *Journal of the American Oil Chemists' Society*, 75:353-358, 1998.

53. Ratnayake, W. M. N., “AOCS Method Ce 1c-89 Underestimates the trans Octadecenoate

Content in Favor of the cis Isomers in Partially Hydrogenated Vegetable Oils,” *Journal of the American Oil Chemists' Society*, 69:192, 1992.

54. Select Committee on Nutrition and Human Needs United States Senate, “Dietary Goals for the United States,” U.S. Government Printing Office, February, 1977.

55. American Heart Association, “Rationale of the Diet-Heart Statement of the American Heart Association,” *Circulation*, 65: 839A-854A, 1982.

56. American Heart Association, “Fat, AHA Scientific Position,” 1997.

57. Davis, C. E., B. M. Rifkind, H. Brenner, and D. J. Gordon, “A Single Cholesterol Measurement Underestimates the Risk of Coronary Heart Disease: an Empirical Example from the Lipid Research Clinics Mortality Follow-up Study,” *Journal of the American Medical Association*, 264:3044-3046, 1991.

58. Gillman, M. W., L. A. Cupples, D. Gagnon, B. E. Millen, R. C. Ellison, and W. P. Castelli, “Margarine Intake and Subsequent Coronary Heart Disease in Men,” *Epidemiology*, 8:144-149, 1997.

59. Gordon, D. J., J. L. Probstfield, R. J. Garrison, J. D. Neaton, W. P. Castelli, J. D. Knoke, D. R. Jacobs, S. Bangdiwala, and H. A. Tyroler, “High-density Lipoprotein Cholesterol and Cardiovascular Disease. Four Prospective American Studies,” *Circulation*, 79:8-15, 1989.

60. Gordon, D. J., and B. M. Rifkind, “High-density Lipoprotein - the Clinical Implications of Recent Studies,” *New England Journal of Medicine*, 321:1311-1316, 1989.

61. Gordon, D. J., “HDL and CHD - An Epidemiological Perspective,” *Journal of Drug Development*, 3(Supplement 1):11-17, 1990.

62. Katan, M. B., P. L. Zock, and R. P. Mensink, “Trans Fatty Acids and Their Effects on Lipoproteins in Humans,” *Annual Review of Nutrition*, 15:473-493, 1995.

63. Kris-Etherton, P. and S. Yu, “Individual Fatty Acid Effects on Plasma Lipids and Lipoproteins: Human Studies,” *American Journal of Clinical Nutrition*, 65(Supplement):1628S-1644S, 1997.

64. Law, M. R., N. M. Wald, T. Wu, A. Hacksaw, and A. Bailey, “Systematic Underestimation of Association Between Serum Cholesterol Concentration and Ischaemic Heart Disease in Observational Studies: Data from the BUPA Study,” *British Journal of Medicine*,

308:363-366, 1994.

65. Mensink, R. P., and M. B. Katan, "Effect of Dietary Fatty Acids on Serum Lipids and Lipoproteins. A Meta-analysis of 27 Trials," *Arteriosclerosis and Thrombosis*, 12:911-919, 1992.

66. Rothman, K. J., and S. Greenland, "Causation and Causal Inference," Chapter 2 in *Modern Epidemiology*, 2d ed., Philadelphia, Lippincott-Raven, pp. 7-28, 1998.

67. Shekelle R. B., A. M. Shryock, P. Oglesby, M. Lepper, J. Stamler, S. Liu, W. J. Raynor, "Diet, Serum Cholesterol and Death from Coronary Heart Disease-The Western Electric Study," *New England Journal of Medicine*, 304:65-70, 1981.

68. Zarkin G. A., N. Dean, J. A. Mauskopf, and R. Williams, "Potential Health Benefits of Nutrition Label Changes," *American Journal of Public Health*, 83:717-724, 1993.

69. Zock, P. L., M. B. Katan, and R. P. Mensink, "Dietary *trans* Fatty Acids and Lipoprotein Cholesterol," *American Journal of Clinical Nutrition*, 61:617, 1995.

70. ASCN/AIN Task Force on *Trans* Fatty Acids, "Position Paper on *Trans* Fatty Acids," *American Journal of Clinical Nutrition*, 63:663-670, 1996.

71. NIH Consensus Development Panel, "Triglyceride, High-density Lipoprotein and Coronary Heart Disease," *Journal of the American Medical Association*, 269:505-510, 1993.

72. Schucker R. E., A. S. Levy, J. E. Tenney, and O. Mathews, "Nutrition Shelf-labeling and Consumer Purchase Behavior" *Journal of Nutrition Education*, 24:75-81, 1992.

73. Research Triangle Institute, "Analysis of Changing Food Labels to Include Information on *Trans* Fatty Acids," 1998.

74. Research Triangle Institute, "Estimated Health Benefits of Nutrition Label Changes," 1991.

75. American Heart Association, "Coronary Heart Disease and Angina Pectoris," (internet address [http://www.amhrt.org/Scientific/HS\\_stats\\_98/04cornry.html](http://www.amhrt.org/Scientific/HS_stats_98/04cornry.html)).

76. U. S. Bureau of the Census, "Statistical Abstract of the United States: 1997," 117th ed., Washington, DC, 1997.

77. Cutler, D. M., and E. Richardson, "Measuring the Health of the U.S. Population," Brookings Papers on Economic Activity: *Microeconomics*, 1997.

78. Letter from Bob Brown, Frito-Lay, Inc., to Richard Williams, FDA, November 3, 1998.



79. Letter from Amanda Honeycutt, Research Triangle Institute, to Kathleen Koehler, FDA, November 3, 1998.
80. Memorandum to the file, from David Zorn, FDA, dated November 10, 1998.
81. Guthrie, J. F., B. M. Derby, and A. S. Levy, "What people know and do not know about nutrition, In Frazao, E. (Ed.), *America's Eating Habits: Changes and consequences.*" *U. S. Department of Agriculture, Economic Research Service, Food and Rural Economics Division. Agriculture Information Bulletin No. 750*, pp. 243-280, April 1999.
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.
83. Ascherio, A., M. B. Katan, P. L. Zock, M. J. Stampfer, and W. C. Willett, "*Trans* fatty acids and coronary heart disease," *New England Journal of Medicine*, 340:1994-1998, 1999.
84. Willett, W. C., and A. Ascherio, "Response to the International Life Sciences Institute report on *trans* fatty acids," *American Journal of Clinical Nutrition*, 62:524-526, 1995.
85. Mensink, R. P., P. L. Zock, M. B. Katan, and G. Hornstra, "Effect of dietary *cis* and *trans* fatty acids on serum lipoprotein[a] levels in humans," *Journal of Lipid Research*, 33:1493-1501, 1992.
86. Nestel, P. J., M. Noakes, G. B. Belling, R. McArthur, P. M. Clifton, and M. Abbey, "Plasma cholesterol-lowering potential of edible-oil blends suitable for commercial use," *American Journal of Clinical Nutrition*, 55: 45-50, 1992.
87. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Choose Sensibly," *Nutrition and Your Health: Dietary Guidelines for Americans*. 5<sup>th</sup> ed. Washington DC; Home and Garden Bulletin No. 232, 2000.
88. Dietary Guidelines Advisory Committee. Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans. To the Secretary of Health and Human Services and the Secretary of Agriculture. U.S. Department of Agriculture. Washington DC; pp. 1-37, 2000.
89. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on

Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), Chapter II. "Rationale for Intervention" and Chapter V "Adopting Healthful Lifestyle Habits to Lower LDL Cholesterol and Reduce CHD Risk," 2001. (internet address: <http://www.NHLBI.nih.gov>)

90. IOM/NAS, "Letter Report on Dietary Reference Intakes for *Trans* Fatty Acids," Food and Nutrition Board, Institute of Medicine, July, 2002.

91. Krauss, R.M., R.H. Eckel, B. Howard, L.J. Appel, S.R. Daniels, R.J. Deckelbaum, J.W. Erdman, P. Kris-Etherton, I.J. Goldberg, T.A. Kotchen, A.H. Lichtenstein, W.E. Mitch, R. Mullis, K. Robinson, J. Wylie-Rosett, S. St. Jeor, J. Suttie, D.L. Tribble, T.L. Bazzarre, "American Heart Association Dietary Guidelines. Revision 2000: A Statement for Healthcare Professionals from the Nutrition Committee of the American Heart Association." *Circulation* 102:2296-2311, 2000.

92. FDA, "Questions and Answers on *Trans* Fat Proposed Rule," Nov. 1999. (Internet address: <Http://www.cfsan.fda.gov/~dms/qatrans.html>)

93. van de Vijer, L.P.L., A.F.M. Kardinaal, C. Couet, A. Aro, A. Kafatos, L. Steingrimsdottir, J.A. Amorin Cruz, O. Moreiras, W. Becker, J.M.M. van Amelsvoort, S. Vidal-Jessel, I. Salminen, J. Moschandreas, N. Sigfusson, I. Martins, A. Carbajal, A. Ytterfors, G. van Poppel, "Association Between *trans* Fatty Acid Intake and Cardiovascular Risk Factors in Europe: the TRANSFAIR Study," *European Journal of Clinical Nutrition* 54: 126-135, 2000.

94. U.S. FDA/CFSAN, "Guidance for Industry. Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements." 1999. (internet address: <Http://www.cfsan.fda.gov/~dms/ssaguide.html>)

95. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) *JAMA* 285: (19) 2486-2497, 2001.

96. Derby, B.M. and A.S. Levy, "Do food labels work? Gauging the effects of food labels pre- and post-NLEA," In P.N. Bloom & G.T. Gundlach (Eds.), *Handbook of Marketing and Society*. Sage, Thousand Oaks, CA, pp. 372-398. 2001.

97. Food Marketing Institute, "Trends in the United States: Consumer Attitudes and the

Supermarket 1997,” Washington, DC, pp. 17-18, 66-67, 70-73, and 75, 1997.

98. Judd, J.T., D.J. Baer, B.A. Clevidence, P.K. Kris-Etherton, R.A. Muesing, M. Iwane., “Dietary *cis* and *trans* Monounsaturated and Saturated Fatty Acids and Plasma Lipids and Lipoproteins in Men.” *Lipids* 37:123-131, 2002.

99. de Roos, N.M., M.L. Bots, M.B. Katan, “Replacement of dietary saturated fatty acids by *trans* fatty acids lowers serum HDL cholesterol and impairs endothelial function in healthy men and women.” *Arterioscler Thromb Vasc Biol* 21: 1233-7, 2001.

100. deRoos, N.M., E.G. Schouten, M.B. Katan, “Consumption of a Solid Fat Rich in Lauric Acid Results in a More Favorable Serum Lipid Profile in Healthy Men and Women than Consumption of a Solid Fat Rich in *Trans*-fatty Acids.” *Journal of Nutrition* 131: 242-245, 2001.

101. Denke, M.A., B. Adams-Huet, B.S. Nguyen, “Individual Cholesterol Variation in Response to a Margarine- or Butter-Based Diet. A Study in Families.” *JAMA* 284: 2740-2747, 2000.

102. Oomen, C.M., M.C. Ocke, E.J. Feskens, M.A. van Erp-Baart, F.J. Kok, D. Kromhout, “Association between *trans* fatty acid intake and 10-year risk of coronary heart disease in the Zutphen Elderly Study: a prospective population-based study.” *Lancet* 357: 746-51, 2001.

103. Canadian Government, “Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Nutrition Claims and Health Claims), *Canadian Gazette* Part I, 135:39-62, June 16, 2001.

104. List, G., K.R. Steidley, and W.E. Neff, "Commercial spreads formulation, structure and properties," *Inform* 11:980-986, September 2000.

105. AOAC, “AOAC Official Method 996.06, Fat (Total, Saturated, and Unsaturated) in Foods,” *Official Methods of Analysis of AOAC International*, 17th ed., Chapter 41, pages 20-24, AOAC International, Gaithersburg, MD. 2000.

106. Firestone, D., “General Referee Report: Fats and Oils,” *Journal of the Association of Official Analytical Chemists* 83: 467-470, 2000.

107. DeVries, J.W., L. Kjos, L. Groff, B. Martin, K. Cernohous, H. Patel, M. Payne, H. Leichtweis, M. Shay, and L. Newcomer, “Studies in Improvement of Official Method 996.06,”

*Journal of the Association of Official Analytical Chemists* 82:1146-54, 1999.

108. Guidance for Industry, FDA Nutrition Labeling Manual -- A Guide for Developing and Using Data Bases," 1998. (internet address: <http://www.cfsan.fda.gov/~dms/nutrguid.html>)

109. Levy, A.S., S. Fein, and R.E. Schucker, "Performance Characteristics of Seven Nutrition Label Formats." *Journal of Public Policy and Marketing*, 15:1-15, 1996.

110. Stouffer Foods Corp. Dkt. 9250 (September 26, 1994) slip op

111. Center for Food Safety and Applied Nutrition (CFSAN)/FDA, "Questions and Answers Volume II, A Guide for Restaurants and Other Retail Establishments," 1996. (internet address: <Http://www.cfsan.fda.gov/~frf/qaintro.html>)

112. U.S. Department of Agriculture (USDA)/DHHS, "Dietary Guidelines for Americans," 1st ed., 1980.

113. National Center for Health Statistics. Healthy People 2000 Final Review. Hyattsville, Maryland: Public Health Service. pp. 76-92, 2001.

114. USDA, Agricultural Research Service, "Data Tables: Results from USDA's 1994-96 Continuing Survey of Food Intakes by Individuals and 1994-96 Diet and Health Knowledge Survey. Table Set 10.," USDA, Agricultural Research Service, 1997.

115. Smiciklas-Wright H., D.C. Mitchell, S.J. Mickle, A.J. Cook and J.D. Goldman. "Foods Commonly Eaten in the United States. Quantities per Eating Occasion and in a Day, 1994-1996." U.S. Department of Agriculture NFS Report No 96-5, pre-publication version, 2002. (Pages i to xii, 1 to 8, 202 to 204, 216 to 244, 252).

116. Koehler, K. M., D. Zorn and C. Nardinelli. "Estimation of Trans Fat Intake from Food Groups by U.S. Adults." Memo to file, 2002.

117. Krebs-Smith, S. M., P. M. Guenther, A. Cook, F. E. Thompson, J. Cucinelli and J. Udler. U.S. Department of Agriculture, Agricultural Research Service, "Foods Commonly Eaten in the United States. Quantities Consumed Per Eating Occasion and in a Day, 1989-91," U.S. Department of Agriculture NFS Report No. 91-3, November, 1997. (Pages i to xi, 1 to 7, 196 to 198, 210 to 238, 248 to 249).

118. "Discovery Health Pulse Top-Line Poll Results", Penn, Schoen & Berland Associates, Inc., Washington, D.C., 1999.

119. Kim, S. Y., R. M. Nayga Jr., and O. Capps Jr., "The Effect of Label Use on Nutrient Intakes: An Endogenous Switching Regression Analysis," *Journal of Agricultural and Resource Economics*, 25:215-231, 2000.
120. Kochhar, S. P., "Stable and Healthful Frying Oils for the 21st Century," *Inform*, 11:642-647, 2000.
121. Haumann, B. F., "Fat Modification. Tools: Hydrogenation, Interesterification," *Inform*, 5:668-678, 1994.
122. "Questions Remain over Hydrogenated Fats," *Inform*, 5:358-363, 1994.
123. "Legal Sea Foods Leads the Way in Healthy Eating with Innovative All-Natural and Heart-Healthy Frying Oil," Legal Sea Foods, 1998. [http://www.lsf.com/fresh/11\\_3\\_98.htm](http://www.lsf.com/fresh/11_3_98.htm)
124. Bayard, C. C. and R. L. Wolff, "Trans-18:1 Acids in French Tub Margarines and Shortenings: Recent Trends," *Journal of the American Oil Chemists Society*, 72:1485-1489, 1995.
125. Becker, W., "Intake of *Trans* Fatty Acids in the Nordic Countries," *Scandinavian Journal of Nutrition/Nahringsforskning*, 40:16-18, 1996."
126. Haumann, B. F., "Widening Array of Spreads Awaits Shoppers," *Inform*, 9:6-13, 1998.
127. Ovesen, L., T. Leth, and K. Hansen, "Fatty Acid Composition of Danish Margarines and Shortenings, with Special Emphasis on *Trans* Fatty Acids," *Lipids*, 31:971-975, 1996.
128. Ratnayake, W. M. N., G. Pelletier, R. Hollywood, S. Bacler, and D. Leyte, "Trans Fatty Acids in Canadian Margarines: Recent Trends," *Journal of the American Oil Chemists Society*, 75:1587-1594, 1998.
129. RTI International, FDA Labeling Cost Model, April 2002.
130. Muller, H., B. Kirkhus, and J. I. Pedersen, "Scrum Cholesterol Predictive Equations with Special Emphasis on *Trans* and Saturated Fatty Acids. An Analysis from Designed Controlled Studies," *Lipids*, 36:783-791, 2001.
131. Stampfer, M. J., F. M. Sacks, S. Salvini, W. C. Willett, and C. H. Hennekens, "A Prospective Study of Cholesterol, Apolipoproteins, and the Risk of Myocardial Infarction," *New England Journal of Medicine*, 325:373-381, 1991.
132. "Decline in Deaths from Heart Disease and Stroke--United States, 1900- 1999," *MMWR*

*Morbidity and Mortality Weekly Report*, 48:649-656, 1999.

133. National Institutes of Health, National Heart Lung and Blood Institute, "Morbidity and Mortality: 1998 Chartbook on Cardiovascular, Lung and Blood Diseases," National Institutes of Health, National Heart Lung and Blood Institute, Bethesda, MD October 1998. (Page 31)

134. American Heart Association, 2000 Heart and Stroke Statistical Update. American Heart Association, Dallas, Texas, 1999 (Page 10).

135. National Report 2001-2002: Consumer Attitudes About Nutrition. Untied Soybean Board, Chesterfield, Missouri, 2002

136. U.S. Census Bureau, County Business Patterns, 1999, United States, Washington, DC, 2001.

137. Stinnett, A. A., M. A. Mittleman, M. C. Weinstein, K. M. Kuntz, D. J. Cohen, L. W. Williams, P. A. Goldman, D. O. Staiger, M. G. M. Hunink, J. Tsevat, A. N. A. Tosteson, and L. Goldman, "Appendix C. The Cost-Effectiveness of Dietary and Pharmacologic Therapy for Cholesterol Reduction in Adults," In Gold, M. R., J. E. Siegel, L. B. Russell and M. C. Weinstein, editors, *Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York, 1996, pp 349-391.

138. Law, M. R., N. J. Wald and S. G. Thompson, "By how much and how quickly does reduction in serum cholesterol lower risk of ischaemic heart disease?" *British Medical Journal* 308: 387-373, 1994.

139. USDA, Agricultural Research Service, USDA Nutrient Database for Standard Reference, Release 15, 2002 (Internet address: [http://www.nal.usda.gov/fnic/cgi-bin/nut\\_search.pl](http://www.nal.usda.gov/fnic/cgi-bin/nut_search.pl)).

140. IOM/NAS, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Protein and Amino Acids (Macronutrients)," Chapter 8, National Academy Press, Washington, DC, pp. 335-432, 2002 (Internet address: <http://www.nap.edu>).

141. Congressional House Record, "Nutrition Labeling and Education Act of 1990," H 12951-12953, October 26, 1990.

142. USDA, Agricultural Research Service, "Food and Nutrient Intakes by Individuals in the United States, 1 Day, 1989-91." Table 8.1, USDA, Agricultural Research Service, 1995, p.

118.

143. AOAC, *Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, AOAC International, Gaithersburg, MD, 2002.

144. AOCS, *Official Methods and Recommended Practices of the AOCS, 2001-2002 Methods-Additions and Revisions*, AOCS Press, Champaign, IL.

145. AOCS, AOCS Recommended Practice Cd 14d-96, "Isolated *trans* Geometric Isomers-Single Bounce-Horizontal Attenuated Total Reflection Infrared Spectroscopic Procedure," *AOCS Official Methods and Recommended Practices, 2001-2002 Methods-Additions and Revisions*, AOCS Press, Champaign, IL.

146. AOCS, AOCS Official Method Ce 1f -96, "Determination of *cis*- and *trans*-Fatty Acids in Hydrogenated and Refined Oils and Fats by Capillary GLC," *AOCS Official Methods and Recommended Practices, 2001-2002 Methods-Additions and Revisions*, AOCS Press, Champaign, IL.

147. Kaufman, Marc, "McDonald's to Give Fat a Break, Washington Post, September 4, 2002, p. A07.

148. Beil, Laura, "*Trans* Fat - Linked to Heart Disease - Isn't Listed on Food Labels," Bayarea and Wire Service Sources, September 16, 2002.

149. McDonald's Press Release, "McDonald's USA Announces Significant Reduction of *Trans* Fatty Acids with Improved Cooking Oil., 2002, <http://www.Mcdonalds.com>

150. Pepsico Inc. Press Release, "Frito-Lay Eliminates *Trans* Fats From America's Favorite Salty Snacks: Doritos, Tostitos and Cheetos, 2002.

151. Fischer, K., "Sorting fat from fiction." *Prepared Foods*, October, 2002, pp 39-44.

152. Schakel, S. F., L. Harnack, C. Wold, N. Van Heel, and J. H. Himes. "Incorporation of *trans*-fatty acids into a comprehensive nutrient database," *Journal of Food Composition and Analysis*, 12:323-331, 1999.

153. Bialostosky, K., J. D. Wright, J. Kennedy-Stephenson, M. McDowell, and C. L. Johnson, "Dietary intake of macronutrients, micronutrients, and other dietary constituents: United States, 1988-94." National Center for Health Statistics. Vital and Health Statistics, series 11, number 245. 2002. Pages 1-9, 84-85, 150-158.

154. Zock, P. L. and R. P. Mensink. "Dietary trans-fatty acids and serum lipoproteins in humans," *Current Opinions in Lipidology* 7:34-37, 1996.
155. Memo to file from D. Zorn, Comments and responses to comments from Interagency Economic Peer Review, 2002.
156. Letter to file from J.D. Graham to Secretary T.G. Thompson, September 18, 2001.
157. Garber, A.M. and C.E. Phelps, "Economic Foundations of Cost-Effectiveness Analysis," *Journal of Health Economics*, 16:1-31, 1997.
158. U.S. Census Bureau, *Statistical Abstract of the United States*, pp. 413-416 and 436, 2002.
159. Viscusi, W.K. and J.E. Aldy, "The Value of Statistical Life: A Critical Review of Market Estimates throughout the World," AEI-Brookings Joint Center for Regulatory Studies, January 2003.
160. Alberini, A.; M. Cropper; A. Krupnik, et al., "Does the Value of a Statistical Life Vary with Age and Health Status? Evidence from the United States and Canada," *Resources for the Future*, pp. 1-34, April 2002.