

**BEFORE THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

**In the Matter of Food Labeling:
Trans Fatty Acids in Nutrition Labeling;
Consumer Research to Consider Nutrient Content
and Health Claims and Possible Footnote
or Disclosure Statements;
Reopening of the Comment Period**

Docket No. 03N-0076

**Comments of the Staff of
the Bureau of Economics,
the Bureau of Consumer Protection,
and the Office of Policy Planning
of the Federal Trade Commission**

April 15, 2004*

*** These comments represent the views of the staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission. They are not necessarily the views of the Federal Trade Commission or any individual Commissioner. The Commission has, however, voted to authorize the staff to submit these comments.**

¹ 69 Fed. Reg. 9,559 (Mar. 1, 2004).

² The Daily Value is the recommended amount of how much or how little of a nutrient a person should eat in a day, calculated based on a 2,000 calorie diet. The percent DV, listed on the Nutrition Facts Panel, is the percentage of the DV of a nutrient in a serving of food. *See* FDA Center for Food Safety and Applied Nutrition,

In brief, this comment notes:

- The FTC staff supports the development of a DV for trans fat. As we have stated in previous comments to the FDA, a DV for trans fat will aid consumers' understanding of the relative significance of trans fat in the context of their total diet. In addition, the FDA can use the DV to define qualifying criteria for trans fat nutrient content claims and health claims, which can play a critical role in educating consumers about diet and health.
- The FTC staff continues to support the FDA's rule requiring manufacturers to list the absolute amounts of both saturated fats and trans fats in a food on the Nutrition Facts Panel so consumers can readily compare the amount of each fat in particular products.
- If the FDA concludes that the scientific evidence indicates that the similar effects of trans and saturated fats are more important than their differences, then the FTC staff does not object to combining the DV for saturated fat and trans fat. Before it adopts any format, however, the FTC staff recommends that the FDA conduct consumer research to determine which format is most effective in communicating to consumers the amount of saturated and trans fats in a food.
- The FTC staff believes that, if a DV is added, it does not appear to be necessary to require that the Nutrition Facts Panel include a separate footnote or similar disclosure relating fat content and a healthy diet, such as "Intake of saturated fat and trans fat should be kept low while maintaining a nutritionally adequate diet."

Comment at Section IV.2-4.

²⁰ 2003 IOM Report, *supra* note 18.

²¹ 69 Fed. Reg. at 9,559.

²²

greatly benefit consumer health. A “trans fat free” descriptor might help consumers identify healthier products more easily. A “reduced trans fat” descriptor could spur manufacturers to reduce the trans fat content of foods when it may not be feasible to eliminate the trans fat completely.

Health claims also can greatly benefit consumer health.²⁴ For example, a claim that eating foods low in trans fats may decrease one’s risk of heart disease would provide consumers with a clear health reason to select foods that are lower in trans fats. At this time, the FDA has not approved any health claim relating trans fat to coronary heart disease.

The research-based method IOM has now proposed for deriving a DV for trans fat may be a practical approach.²⁵ A determination of the appropriateness of the methodology, however, is outside the scope of expertise of the FTC staff. Nevertheless, we support the FDA’s willingness to consider and seek comment on the IOM proposal because establishing a DV for trans fats is likely to yield significant benefits for consumers and competition.

IV. COMBINED DAILY VALUE

The IOM’s 2003 report recommends that the Nutrition Facts Panel declare separately the absolute amount of saturated fat and trans fat in a food, together with a percentage representing the DV of the two types of fat combined.²⁶ Another option would be to provide separate DVs for trans and saturated fats.

²⁴ See 2003 FTC Staff Comment, *supra* note 5.

²⁵ The IOM’s proposed method will generate a DV that acknowledges it is unrealistic to eliminate all trans fat in a healthy diet. The FDA has stated that, although the IOM has recommended that intake of trans fats should be as low as possible, they are “are unavoidable in ordinary diets,” and so setting a limit of zero on trans fat intake “would require extraordinary changes in dietary intake patterns that might introduce other undesirable effects and unknown health risks.” 67 Fed. Reg. at 69,171; *see also* 2002 IOM Report, *supra* note 9, at 8-2.

²⁶ 2003 IOM Report, *supra* note 18, at 100. As noted by the IOM, Canada adopted this approach in a recent revision of its food labeling regulations. *Id.* at 101; II C. Gaz. 137:154-405, *Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Nutrient Content Claims and Health Claims)*, Reg. SOR/2003-11 (Dec. 12, 2002).

FTC staff continues to support the FDA's decision in the Trans Fat Final Rule to require marketers to declare the absolute amounts of both saturated fats and trans fats in a food.²⁷ We believe that it is important for the Nutrition Facts Panel to declare the amount of trans and saturated fat separately, so consumers can compare the amount of each fat in particular products if the type of fat in the food is important to their purchasing decision.²⁸ Presenting the amount of each fat separately also is consistent with the practice of using the Nutrition Facts Panel to present accurate and objective information about food nutrients. As FTC staff stated in a previous comment, the FDA recognizes that trans fats are chemically distinct from saturated fats.²⁹ Listing the amount of these fats d

²⁷ 21 C.F.R. Part 101; Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41,434 (July 11, 2003).

²⁸ For larger packages, the FDA requires that marketers provide additional information about macronutrient content in a footnote in the lower part of the Nutrition Facts Panel. We suggest that the FDA consider adding a reference to trans fats in this footnote to supplement the existing reference to saturated fat. We recognize that the FDA is considering whether to derive separate DVs for trans and saturated fats, or to derive one DV for total trans and saturated fat content. If the FDA derives one DV for total saturated and trans fat content, the reference must be combined. If the FDA opts to derive separate DVs for saturated and trans fats, the entries could be separate or combined. In that case, the FDA may want to conduct a copy test or other similar research to determine whether the combined or separate presentation of the reference in the footnote on the lower part of the panel should be consistent with the combined or separate presentation of the DV in the Nutrition Facts Panel.

²⁹ 2000 FTC Staff Comment, *supra* note 5.

³⁰ *Id.*

and these have important effects on heart health.³¹ A combined DV format would highlight the central message that both types of fats are a health concern,³² and it may convey this message in a way that consumers can easily comprehend. Although this format does not communicate the DV of each type of fat, the Nutrition Facts Panel would provide the absolute amount of each type of fat.

A format that provides separate DVs for trans and saturated fats, however, would likely make it easier for consumers to evaluate and compare products based on its content of each type of fat. Research indicates that trans fats, unlike saturated fats, may reduce good cholesterol.³³ Some consumers thus may want to choose foods based on the amount of trans fat in them. Unlike the combined DV,³⁴ separate DVs for trans fats and saturated fats would likely better communicate the amount of each specific type of fat in a food. Consumers, however, may find this format more difficult if they are interested in making purchasing decisions based on the total proportion of a day's saturated fat and trans fat in a food.

Another format would include separate DVs for trans and saturated fats, with a separate line that provides the total amount of trans and saturated fat with a combined DV. The advantage of this format is that it would present both the separate and combined DV so that consumers would have information about either or both nutrients relative to overall diet. On the

³¹ See, e.g., 2003 IOM Report, *supra* note 18, at 100-01; Gina Kolata, *Scientists Begin to Question Benefit of 'Good' Cholesterol*, N.Y. Times (Mar. 15, 2004), available at www.nytimes.com/2004/03/15/health/15HEAR.html?th=&pagewanted=print&position=.

³² See, e.g., FDA Center for Food Safety and Applied Nutrition, *Questions and Answers about Trans Fat Nutrition Labeling*, available at www.cfsan.fda.gov/~dms/qatrans2.html#s2q3 (“It is important to choose foods with the lower combined amount of saturated fat and trans fat and the lower amount of cholesterol.”); *id.* (“Q: Are all fats the same? A: Simply put: no. While unsaturated fats (monounsaturated and polyunsaturated) are beneficial when consumed in moderation, saturated fat and trans fat are not. Saturated fat and trans fat raise LDL (“bad”) cholesterol. Therefore, it is advisable to choose foods low in both saturated and trans fats as part of a healthful diet.”) (Emphases and italics omitted.)

³³ See, e.g., 2002 IOM Report, *supra* note 9, at 8-58.

³⁴ The combined DV “does not promote one type of fat as being more unhealthful than the other.” 2003 IOM Report, *supra* note 18, at 101.

other hand, the presentation of three percentages for closely related nutritional elements might be confusing for some consumers, and the separate entry for total trans and saturated fat would take up scarce space on the label.

The optimal format for conveying information about trans fats effectively thus depends principally on an assessment of the scientific evidence on the relative roles of trans and saturated fats. Science-based agencies, like the FDA, have the expertise to evaluate the scientific evidence. Because the science linking the two fats' relative effects on cholesterol is still developing, important health-related differences between the two fats may be discovered in the future. Separate DVs would seem more amenable to reflecting such scientific changes than a combined DV.

³⁵ See, e.g., Kolata, *supra* note 29. See also 2002 IOM Report, *supra* note 9, at 8-58 (summarizing studies showing effects of trans fats on HDL); Christopher P. Cannon, *et al.*, Comparison of Intensive and Moderate Lipid Lowering with Statins After Acute Coronary Syndromes, *N. Eng. J. Med.* 350:15 (Apr. 8, 2004), *available at* www.nejm.org (emphasizing importance of lowering LDL).

³⁶ For example, Kraft Foods and Frito-Lay have announced initiatives to decrease their products' trans fat content. See Kraft's Global Initiatives to Respond to Obesity, *at* <http://164.109.16.145/obesity/responses.html>; Frito Lay Snacks Containing Zero Grams of Trans Fat, *at* www.fritolay.com/nutrition/transfatfree.shtml.

³⁷ See J. Howard Beales, III, Richard Craswell, & Steven Salop, *The Efficient Regulation of Consumer Information*, 24 J.L. & Econ. 491 (1981). Whether competition on combined saturated and trans fat content is preferable to competition on saturated fat content and trans fat content separately depends, again, on whether the underlying science suggests that the

disclosure on the Nutrition Facts Panel would take up precious space but add little, if any, helpful information for consumers.

VI. CONCLUSION

In this comment, the FTC staff supports the development of a DV as recommended by the IOM's report. The DV is an important element of the Nutrition Facts Panel, and the FDA can use the DV to facilitate the development of criteria for nutrient content and health claims. In conjunction with trans fat nutrient content and health claims that the FDA approves or permits, the DV may help marketers communicate health information to consumers more effectively and spur competition on health attributes of the product. In the FDA's view, the DV will have a similar effect to that of the trans fat label.

(same).

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