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.
I. INTRODUCTION

Scientific evidence has shown that both trans fatty acids (“trans fats”) and saturated fats increase LDL (“bad”) cholesterol levels, thereby increasing the risk of cardiovascular disease. In response to this evidence, the Food and Drug Administration (FDA) has initiated a series of rulemakings concerning how to provide consumers with information on food labels about trans fat content. Most recently, on March 1, 2004, the FDA reopened the comment period to solicit comments on an approach developed by the National Academies’ Institute of Medicine (IOM) to derive a Daily Value (DV) for trans fat content. In light of the Federal Trade Commission’s (FTC) jurisdiction over and extensive experience with food advertising, the FTC staff submits its views on the development of a DV for trans fats and related labeling issues.

The FTC has considerable expertise in food advertising and labeling issues. The FTC enforces the Federal Trade Commission Act, which prohibits deceptive or unfair acts or practices in or affecting commerce. Through implementing its law enforcement mandate, the FTC has developed considerable expertise in understanding the role of advertising and labeling in providing information to consumers. Specifically, the FTC staff has followed the scientific and regulatory developments relating to trans fats and on three prior occasions has submitted


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, Guidance on How to Understand and Use the Nutrition Facts Panel on Food Labels, available at www.cfsan.fda.gov/~dms/foodlab.html#seeimage6. In this comment, the term DV is also used as shorthand for the percent DV.


4 Id. The FTC and the FDA have overlapping jurisdiction to regulate the advertising, labeling, and promotion of foods. Under a long-standing liaison agreement between the agencies, the FDA exercises primary responsibility for regulating food labeling, while the FTC has primary responsibility for ensuring that food advertising is truthful and not misleading. Working Agreement Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971).
comments to the FDA concerning how to include trans fat information on food labels.5

The Commission’s staff also has experience examining the effects of regulation on market performance, including the performance in markets for foods.6 FTC staff research suggests that labeling and advertising regulations have a strong effect on the type and amount of health information that consumers receive. Specifically, labeling and advertising regulations that permit sellers to disseminate truthful and non-misleading information about diet and health are likely to lead to better informed consumers, more competition on the health attributes of food, and formulation of healthier products.

We support the development of a DV for trans fats. The DV is an important element of the Nutrition Facts panel because it enables consumers to determine and compare products’ nutritional value in the context of their total diet. It also facilitates the FDA’s efforts to define criteria for nutrient content claims and health claims that permit marketers to better communicate health information to consumers more easily and spur competition on health attributes of foods.7


7 As noted in a previous comment, the FDA does not necessarily have to develop a DV before it can approve or permit nutrient content and health claims. See 2003 FTC Staff
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.”
II. BACKGROUND

In 1999, the FDA proposed that marketers disclose trans fat information on food labels based on its review of scientific evidence showing that consumption of trans fats raised LDL (“bad”) cholesterol levels. The FDA tentatively decided to require marketers to provide the combined amount of saturated and trans fats in the existing entry for “Saturated Fat” on the Nutrition Facts panel, with a footnote indicating the amount of trans fat content. The agency proposed that the combined saturated and trans fat entry in one’s diet be limited to 10% of total calories, the same amount that it had established for saturated fat alone. The FDA also proposed a “Trans Fat Free” nutrient content claim (and several synonymous claims) for foods that contain less than 0.5 grams of trans fat and less than 0.5 grams of saturated fat per serving.

In a September 2002 report, the IOM addressed the relationship between trans fat in the diet and health. The IOM found that there was “a positive linear trend” between trans fat intake and total and LDL cholesterol and, therefore, increased risk of coronary heart disease (“CHD”). The IOM concluded that trans fats “provide no known benefits to human health,” and that “any incremental increase in trans fatty acid intake increases CHD risk.” The IOM suggested that trans fat intake “be as low as possible while consuming a nutritionally adequate diet,” but it did not suggest a procedure for determining a DV.

In response to the IOM report, the FDA again reopened its rulemaking proceeding to


9 Id. at 62,755.


11 Id. at 8-2.

12 Id.

13 Id.
receive public comments and proposed that trans fats be listed separately from saturated fats on the Nutrition Facts panel. In light of the IOM’s conclusions, the agency, however, did not assign a DV for trans fats. Instead, the FDA proposed that the separate trans fat entry would be accompanied by a footnote informing consumers, “Intake of trans fat should be as low as possible.” The FTC staff filed a comment supporting the agency’s proposal to list trans fats separately from saturated fats but raised concern that the accompanying footnote might confuse consumers as to the relative risks of saturated fat, cholesterol, and trans fat.

In July 2003, the FDA issued its Trans Fat Final Rule requiring manufacturers of foods and dietary supplements to list the amount of trans fat separately on the Nutrition Facts Panel without a DV or an accompanying footnote statement. The Trans Fat Final Rule becomes effective in 2006. The FDA also withdrew proposed rules regarding the establishment of “reduced” and “free” trans fat claims “because the level of scientific evidence does not currently support the establishment of an appropriate reference value for daily consumption of trans fat . . . from which the agency could derive a DRV [Daily Recommended Value] for trans fat.” The FDA further requested comment on a variety of labeling issues, such as format, and asked for the

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14 See 2000 FTC Staff Comment, supra note 5.
16 Id.
17 2002 FTC Staff Comment, supra note 5.
18 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). The Trans Fat Final Rule requires dietary supplement manufacturers to list trans fat on the Supplement Facts panel if their products contain 0.5 gram or more of trans fat.
After the comment period closed, the IOM issued its report “Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification.” In that report, the IOM suggested a method to develop a DV for trans fat. Specifically, the IOM said that a DV could be determined by “estimating minimal trans fat intake levels via menu modeling and then further evaluating them against achievable health-promoting diets.” Accordingly, the FDA reopened the comment period to allow consideration of this procedure to develop a DV for trans fat and related labeling issues.

III. DEVELOPMENT OF A DAILY VALUE

In its Trans Fat Final Rule, the FDA required marketers to list trans fat content without a DV, because the IOM had not yet provided a procedure for determining the DV. As discussed above, the IOM has now recommended an approach that could be used to derive a DV for trans fat. The FDA seeks public comment on the IOM’s suggested approach.

A DV for trans fat serves two important purposes. First, it allows consumers, at a glance and without calculation, to understand the relative significance of a nutrient in the context of their total diet. Even consumers with little substantive understanding of nutrition can use the DV to make better-informed dietary choices.

Second, the FDA can use the DV to define qualifying criteria for trans fat nutrient content claims and health claims. As we have suggested in previous comments, marketers’ ability to communicate nutrient content claims such as “reduced trans fat” or “trans fat free” can

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23 See 2003 FTC Staff Comment, supra note 5, at Section IV.2; 2000 FTC Staff Comment, supra note 5, at Section V. Nutrient content descriptors may catch the attention of consumers who might not otherwise read the Nutrition Facts panel. See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421 (Nov. 27, 1991).
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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{29} Listing the amount of these fats separately gives consumers more precise information about a food’s content; a separate listing of the amount also accommodates future scientific developments that could reveal additional distinctions that have health implications between the types of fat.\textsuperscript{30}

The FDA requests comment whether a combined DV or separate DVs for saturated and trans fats best supplement the separate listing of the amount of each fat. The combined DV format may make it easy for consumers to evaluate and compare products based on total cholesterol-raising fat. Both trans and saturated fats raise total cholesterol and bad cholesterol,
and these have important effects on heart health.\textsuperscript{31} A combined DV format would highlight the central message that both types of fats are a health concern,\textsuperscript{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.\textsuperscript{33} Some consumers thus may want to choose foods based on the amount of trans fat in them. Unlike the combined DV,\textsuperscript{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

\begin{itemize}
  \item 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.”); \textit{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.)
  \item See, e.g., 2002 IOM Report, \textit{supra} note 9, at 8-58.
  \item The combined DV “does not promote one type of fat as being more unhealthful than the other.” 2003 IOM Report, \textit{supra} note 18, at 101.
\end{itemize}
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.

Based on the current state of the science, however, the FDA has emphasized the two fats’ common effects in increasing bad cholesterol, not their different effects in decreasing good cholesterol. Despite the fact that trans fats may decrease good cholesterol while saturated fats do not, there is uncertainty about the precise role that good cholesterol plays relative to bad cholesterol in preventing heart disease.35 Although a separate DV format would better accommodate changing science, if the FDA is confident that the two fats’ similar effects are more important than their differences, combining the DV for the two types of fat appears reasonable.

Marketers have an incentive to compete on health attributes, driving the development of healthier products. For example, some marketers are already reformulating their products to decrease the amount of trans fat.36 Different DV formats may have different effects on marketers’ incentives to compete on the basis of saturated fat and trans fat content. For example,

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/transfattfree.shtml.
a combined DV may be more likely to encourage competition on the total of saturated fat and trans fat than separate DVs. The FDA should also consider this likely effect on competition in weighing which DV format is optimal.

Before it adopts any format, however, we recommend that the FDA test different formats to see how consumers would understand and use this DV information. This research should assist the FDA in selecting the format that best communicates the message that consumers should minimize their intake of saturated and trans fats as part of overall diet.

V. FOOTNOTE STATEMENT

We believe that the addition of a DV – whether combined or separate – for saturated and trans fats appears to obviate the need for a footnote or similar disclosure on the Nutrition Facts Panel explaining the relationship between cholesterol-raising lipids and a healthy diet, such as “Intake of saturated fat and trans fat should be kept low while maintaining a nutritionally adequate diet” or “Healthy diets start with diets low in saturated fat, trans fat, and cholesterol.”

The DV itself will incorporate the concept that consumers should limit the amount of saturated fats and trans fats in their diet as well as provide consumers with a meaningful benchmark for selecting foods that would make up such a diet. Moreover, a DV for trans fats will facilitate the FDA’s efforts to define qualifying criteria for nutrient content and health claims. If such claims are approved or permitted by the FDA, consumers will quickly get the message that they should minimize their intake of these fats as marketers with products low in or free of cholesterol-raising fats make nutrient content and health claims. It thus appears that a footnote or similar

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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 effects of the fats are more similar than they are different.


39 See 2000 FTC Staff Comment, supra note 5, Sections IV and V (noting value of health claims and nutrient content descriptors); 2003 FTC Staff Comment, supra note 5, at 8-13.
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 foods. If the FDA views the two fats’ similar effects on cholesterol as more significant than the differences, we do not object to presenting a combined DV for trans and saturated fat, but we recommend that the FDA conduct consumer research to test which format is most effective in communicating information on dietary fats to consumers. The use of a DV appears to make a footnote or similar disclosure on the Nutrition Facts Panel advising consumers to minimize their intake of cholesterol-raising fats unnecessary.

Respectfully submitted,

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