



American Dietetic Association  
*Your link to nutrition and health.<sup>sm</sup>*

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October 9, 2003

Food and Drug Administration  
Department of Health and Human Services  
Attention: HFA-305  
Docket #: 03N-0076  
5630 Fishers Lane  
Rockville, MD 20852

Dear Sir or Madam:

The American Dietetic Association (ADA) represents nearly 70,000 food and nutrition professionals serving the public through the promotion of optimal nutrition, health and well being. ADA appreciates this opportunity to respond to the Food and Drug Administration's (FDA) advanced notice of proposed rulemaking (ANPR) published in the July 11, 2003 *Federal Register* on trans fatty acids in nutrition labeling. Included with these comments are copies of previously submitted comments by ADA in April 2000 and January 2001.

**General Comments**

ADA commends FDA's decision to require nutrition labels to include the amounts of trans fatty acids contained in packaged foods. Providing this information will help millions of people who wish to reduce overall consumption of foods that may increase their risk of coronary heart disease (CHD), make healthy food choices and lower their cholesterol. As FDA is aware, clinical studies demonstrate that trans fat can raise blood cholesterol and presents relative risks for CHD that are similar to those for saturated fat (*Institute of Medicine, 2002*).

ADA encourages FDA to accompany the new trans fatty acid labeling requirements with public and private consumer education efforts. Such efforts are critical to increase public awareness and understanding of trans fat, as well as to help prevent

consumer confusion. Continued consumer nutrition education efforts are needed to accompany our evolving knowledge of science, as well as changes in the marketplace and on food labels. As new information emerges about the physiologic function of various fatty acids, even sophisticated consumers are likely to be confused in the absence of clear consumer messages and food labels. Education can and should be a shared responsibility among the public and private sectors and FDA should encourage individuals and organizations to participate in these efforts.

### **Amendment of 1999 FDA proposed rule to require *trans* fat declaration on a separate line without a percent Daily Value**

ADA supports FDA's recent action to require that *trans* fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under saturated fat, but without a percent Daily Value (% DV.) We believe this new labeling information on *trans* fat will provide consumers with information they need to help them make healthy food choices in the context of their total daily diet.

ADA recognizes the challenge FDA faces in determining a % DV for *trans* fat in foods. To date, no scientific body has recommended a DV for *trans* fat, which would be used to calculate a % DV. The Institute of Medicine's September 2002 Dietary Reference Intakes for Macronutrients report recommended that "*trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet." The DRI did not establish a tolerable upper intake level. In addition, data on the current amount of *trans* fats in many food items is limited (U.S. Department of Agriculture, 2003)

As stated in our previous comments on *trans fat* labeling, ADA discourages both the combination of saturated fat and *trans* fat in one line in the nutrient declaration and the use of a combined %DV for saturated and *trans* fat. All numbers on the current food label are based on specific chemical definitions for each nutrient. Placing *trans* fat within the category of saturated fat would be scientifically inaccurate, since *trans* fat, as it is derived from unsaturated fat, has a different chemical structure from saturated fat but functions differently metabolically than an unsaturated fat. Combining the two types of fat into a common category suggests that *trans* fat is a form of saturated fat. That is misleading and potentially sets a precedent for changing interpretation of the entire food label.

### **FDA request for consumer research data**

As stated in the July 11, 2003 ANPR, FDA has a mandate to provide nutrition information on food labels to assist consumers in maintaining healthy dietary practices. In response to FDA's request for consumer research data to help

evaluate footnotes or qualifying criteria for *trans* fat in various nutrient content claims (saturated fat, trans fat, cholesterol, lean and extra lean) and health claims, we direct attention to recent findings from research conducted by the International Food Information Council (IFIC) Foundation (IFIC Foundation 2002) and submitted to FDA on consumer use of the food label, with specific reference to *trans* fat declaration and the previously proposed (November 2002) *trans* fat Daily Value footnote.

A summary of the research conducted indicates that when consumers use the current Nutrition Facts panel to ascertain a product's overall healthfulness, they tend to rely on a variety of components such as calories, total fat, saturated fat and sodium. However, when consumers use the proposed Nutrition Facts panel containing a *trans* fat footnote, they place disproportionate weight on the *trans* fat nutrition information, discounting other important nutrient content information.

Consumers repeatedly identified food products without *trans* fat as the healthier choice when they were given nutrition label information along with a trans fat footnote. For example, butter was overwhelmingly chosen over margarine as the preferred food despite the fact that the combined total of saturated and *trans* fat (7 grams saturated fat and 0 grams trans fat) for butter as listed on the label was almost twice that of margarine (2 grams saturated fat and 2 grams of *trans* fat). The report further states that when consumers were asked why they chose the *trans* fat-free product as the healthier choice when the footnote was present, they almost always cited the trans fat content, overlooking information about calories, total fat, sodium, saturated fat, cholesterol or other nutrient or food components. Consumers indicated that the footnote conveyed to them that *trans* fat was worse than saturated fat.

The ANPR assumes that a footnote, one of several identified in the FDA notice, is the appropriate way to proceed. Given the potential influence of footnotes on consumer's dietary choices, currently demonstrated as a negative response to food choices for health, ADA strongly recommends that FDA gather additional information on their potential use in nutrition labeling and their effect on consumer choices. First, ADA recommends that RDA determine whether footnotes are meaningful to consumers and be constructed to not direct consumers to unintended or negative dietary choices. The previously proposed footnote statement "Intake of *trans* fat should be as low as possible" clearly led consumers to avoid *trans* fat without attention to saturated fat or other nutrients or food components. Any alternative footnote or label statement warrants further testing to ensure that consumers are not driven toward products that are devoid of *trans* fat, regardless of the level of saturated fat, total fat or cholesterol.

An upcoming Food and Nutrition Board (FNB) report is expected to address the issue of the use of dietary reference intakes (DRI) in nutrition labeling. This report will elaborate on principles for developing label reference values or other

information for nutrients described in DRI reports. FDA may be able to draw from the FNB report and other consumer research data before proposing footnotes or qualifying criteria for nutrient content claims related to trans fat. Likewise effect of criteria for *trans* fat, saturated fat and dietary cholesterol in health claims should be carefully considered and tested prior to allowing claims on foods.

Finally, and perhaps most importantly, ADA strongly advocates continued, intensified and pilot-tested consumer education about how to read and use food labels and about saturated fat, *trans* fats and cholesterol. Dietetics professionals are uniquely trained and qualified to facilitate this process and help consumers translate emerging scientific evidence into practical dietary behaviors. We applaud and appreciate the agency's efforts in this important public health arena.

Sincerely,

Marianne Smith Edge

Marianne Smith Edge, MS, RD, FADA  
President

Attachments: ADA Comments from April 2000 and January 2001  
[http://www.eatright.org/Member/PolicyInitiatives/83\\_lg042500.cfm](http://www.eatright.org/Member/PolicyInitiatives/83_lg042500.cfm)  
[http://www.eatright.org/Member/PolicyInitiatives/83\\_transfats.cfm](http://www.eatright.org/Member/PolicyInitiatives/83_transfats.cfm)

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References:

Institute of Medicine/National Academy of Sciences, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids (Macronutrients)*. National Academy Press, Washington, DC, pp. S1-S17, 8-1 to 8-97, and 11-1 to 11-48.

U.S. Department of Agriculture, Center for Nutrition Policy and Promotion, *Notice of Availability of Proposed Food Guide Pyramid Daily Food Intake Patterns and Technical Support Data and Announcement of Public Comment Period*, Federal Register, Vol. 68, No. 176, September 11, 2003.

International Food Information Council Foundation, *Impact of trans fat label information on consumer food choices*. Study conducted January 10-24, 2003.

Washington, DC: IFIC Foundation, 2003. Accessed at <http://www.ific.org/research/transres.cfm>.