

report on DRIs for macronutrients (Ref. 140) did not make quantitative recommendations for *trans* fat for establishing a DRV. Accordingly, in the absence of a scientific basis or recommendation by an authoritative body, FDA is not establishing a DRV for *trans* fat. FDA intends to revisit this issue when there is more scientific information that the agency can use to establish an appropriate reference level for *trans* fat intake.

The agency recognizes that the absence of a DRV, and thus, the absence of a % DV for *trans* fat on food labels, nutrition educators will need to direct efforts at educating consumers further about the effects of *trans* fat on LDL-C levels and CHD risk. However, because of the public health impact of CHD in the United States, the agency believes it is necessary to proceed at this time with this final rule to list *trans* fat in nutrition labeling so that consumers will have quantitative information to use in implementing dietary guidelines to cut back on *trans* fat. By adding quantitative information on *trans* fat content, consumers will have information to use in comparing products and making diet selections that will reduce their intake of *trans* fat in the context of their daily diet by substituting lower *trans* fat products for those previously consumed that were higher in *trans* fat.

The agency does not believe it would be any more difficult for consumers to look at a separate line for information on *trans* fats than it has been for any other separate fat listing. Listing them separately will allow consumers to readily see levels of each in food products and make decisions accordingly. In addition, the agency stated earlier that it believes public awareness about *trans* fat has increased since publication of the November 1999 proposal as a result of media attention, press releases, label statements, and industry announcements. FDA concludes that this increased awareness, in conjunction with an education program about the change, will allow consumers to use this new information to help maintain healthy dietary practices and will minimize any confusion caused by the change. To maximize the impact of declaring *trans* fat in the Nutrition Facts panel, a coordinated educational effort among public health professionals and organizations focusing on all three cholesterol-raising dietary components, i.e., saturated fat, *trans* fat, and cholesterol, will be required. Such a program is discussed in Comment 28 below.

The comment that was concerned that use of a separate line for *trans* fat would not encourage industry to reduce "heart-unhealthy" fats did not present any data to show the effectiveness of the various options in achieving this goal. Following implementation of mandatory nutrition labeling rules in 1993, the industry reformulated many foods products to reduce levels of nutrients about which consumers were concerned (Ref. 96). Accordingly, FDA believes that the required addition of information on *trans* fat content to nutrition labels, coupled with a consumer education program on the health effects of dietary *trans* fat, will provide incentive to the food industry to minimize the level of *trans* fat present in individual food products. Some parts of the food industry have responded to consumer concerns, e.g., levels of *trans* fat in margarine products have been lowered (Ref. 104), and companies have announced plans to use reformulated fats that are lower in *trans* fat (Refs. 149 and 150). The agency believes that requiring *trans* fat labeling will prompt others in the food industry to reformulate some of their products to offer lower *trans* fat alternatives.

Accordingly, FDA is revising § 101.9(c) by adding paragraph § 101.9(c)(2)(ii) to require the quantitative declaration of *trans* fat in the Nutrition Facts panel. This new paragraph requires the listing of *trans* fat on a separate line under the statement for saturated fat. As is the case for all subcomponents of total fat, it is to be indented and separated by a hairline, with the amount expressed as grams per serving to the nearest 0.5 g increment below 5 g and to the nearest gram increment above 5 g. If the serving contains less than 0.5 g, the content must be expressed as 0, except when the statement "Not a significant source of *trans* fat" is used. In addition, the agency is clarifying that the word "*trans*" may be italicized to indicate its Latin origin. This provision to allow for italics provides an exception to § 101.9(d)(1)(ii)(A) that requires that a single easy-to-read type style be used throughout the nutrition label. Therefore, paragraph (d)(1)(ii)(A) is being revised to state that "except as provided for in paragraph (c)(2)(ii) of this section," a single easy-to-read type style is to be used throughout the nutrition label.

As a result of adding paragraph (c)(2)(ii) for *trans* fat, the agency is redesignating current paragraph (c)(2)(ii) (polyunsaturated fat) as paragraph (c)(2)(iii) and current paragraph (c)(2)(iii) (monounsaturated fat) as (c)(2)(iv).

(Comment 17) In response to the November 2002 reopening of the comment period on the November 1999 proposal to require a footnote stating "Intake of *trans* fat should be as low as possible" when *trans* fat is listed, FDA received some comments that supported the proposed footnote statement. A few comments noted that the proposed footnote was needed to raise consumer awareness and understanding about the relevance of *trans* fat in the diet and to assist them in making healthy food choices. Another comment stated that the footnote is consistent with the IOM/NAS report on macronutrients. Two of the comments strongly recommended that the footnote be modified to state that "Combined total intake of saturated and *trans* fats should be as low as possible." The comments argued that the footnote proposed by FDA gives undue emphasis to *trans* fat and will cause some consumers to evaluate products based on the content of *trans* fat instead of on the content of both *trans* and saturated fats, as is recommended in dietary guidance. One of the comments included the results of a national online survey that tested the communication effectiveness of the proposed footnote relative to no footnote and to the alternative footnote "Combined total intake of saturated and *trans* fats should be as low as possible." Respondents were faced with a food comparison that required them to take both saturated fat and *trans* fat into account to correctly identify the "more healthful" of two food products, described by the comment as the product with the lowest total amount of saturated and *trans* fats combined. The two foods being compared were both high in saturated fat (70% DV (14 g) and 35% DV (7 g) saturated fat) but the food highest in saturated fat (14 g) had no *trans* fat (food 1) while the one with half as much saturated fat (7 g) had 2g of *trans* fat (food 2). With no footnote, over half of the respondents who identified a product as more healthful (57 percent) correctly identified the more healthful food (food 2) and 12 percent chose food 1. In the presence of the FDA proposed footnote, 39 percent of the respondents who identified a product as more healthful incorrectly chose food 1 as more healthful, presumably focusing on the zero *trans* fat content in the higher fat food, with only 45 percent choosing the food with the lowest total amount of saturated and *trans* fats combined. In the presence of the alternative footnote, which mentioned the need to keep the intake of both saturated and *trans* fats low a majority of respondents again correctly chose food 2 (69 percent) as