

nutrition labeling regulations, of classifying nutrients based on their chemical definition or structure, rather than their physiological effect (58 FR 2079 at 2089). Moreover, the comments argued that listing *trans* fat on a separate line now would avoid having to do it later if future scientific research shows that the effects of *trans* fat consumption are significantly different from the effects of saturated fat consumption.

Several comments argued that by providing a separate line for *trans* fat, consumers can be educated more easily about the health effects of *trans* fatty acids. These comments disagreed with FDA's position in its November 1999 proposal that *trans* fat should be combined with saturated fat because consumers lack knowledge about *trans* fat information and do not understand the term *trans* fat. Also, some comments stated that FDA's rationale for not listing *trans* fat more prominently (i.e., that consumers are not familiar with the term "*trans* fat") is not justified since consumers do not generally know much about mono- or polyunsaturated fats yet quantitative information may be provided for them in nutrition labeling and must be provided when claims are made about fatty acids or cholesterol. A few comments also stated that creating a separate line for *trans* fat establishes a basis for current and future consumer education about the health risks and benefits of a variety of fatty acids that affect LDL-C and HDL-C levels.

A few comments in favor of a separate line for *trans* fat in nutrition labeling specifically addressed the need to establish a DRV for *trans* fat. One comment stated that FDA could establish a DRV for *trans* fat based on international recommendations for *trans* fat consumption. Another comment indicated that a DRV for *trans* fat could be established at a level equal to or below the average daily intake of *trans* fat. One other comment stated that the only basis for establishing a daily value would be the amount of naturally-occurring *trans* fat in ruminant (dairy) products since they have not been shown to be associated with increased risk of CHD; otherwise, the DRV for *trans* fats formed through partial hydrogenation should be zero. However, the majority of those commenting stated that scientific evidence is not sufficient to support the establishment of a DRV for *trans* fat because no public health or scientific organization has proposed guidelines for dietary intake levels of *trans* fat at this time. Some of these comments said that *trans* fat should be treated in a manner consistent with poly- and monounsaturated fats, i.e., without a % DV, until such time as

there is a basis for establishing a DRV for *trans* fat. A few comments suggested waiting until the IOM/NAS completes its report on DRIs for macronutrients. A few comments noted that listing *trans* fat on a separate line with no % DV would be less useful to consumers because they would not be able to determine if the amount were high or low in the context of the daily diet. One comment stated that if there is enough scientific evidence to require the mandatory labeling of *trans* fat, the agency should provide the information that will help consumers to interpret the magnitude of the amount in the food. Additionally, other comments stressed the importance in helping consumers understand the relevance of the nutrient amount in the context of the total diet.

One comment objected to the option of having a separate line for *trans* fat on the basis of consumer confusion. It said that adding a fourth line of fatty acid information would confuse consumers because they would have to look at several separate values when comparing food products. This comment also was concerned that the use of a separate line would not encourage the food industry to reduce "heart-unhealthy" fat in the food product.

FDA agrees with comments that point out that there are chemical differences between saturated and *trans* fatty acids. The agency noted these differences in its November 1999 proposal when it proposed to include the amount of *trans* fat in the declaration of saturated fat. The intent was to assist consumers in understanding the cholesterol-raising properties of the food by declaring the two fatty acids under the name "saturated fat" without changing the definition of saturated fat, but FDA acknowledged that this action "may confuse consumers and lead some to misclassify *trans* fatty acids as saturated fats" (64 FR at 62746 62755). The agency is persuaded by the large number of comments on this issue that the proposed action was, in fact, interpreted by many as incorrectly classifying the two different fatty acids as "saturated fat" and that it is necessary to disassociate *trans* fat from saturated fat to prevent misleading consumers in this way.

FDA also acknowledges that while the two types of fatty acids have similar effects on LDL-C, there are other physiological distinctions between them. Because the overall weight of scientific evidence in support of the finding that consumption of *trans* fat, like saturated fat, contributes to increased LDL-C levels increasing the risk of CHD, was sufficiently compelling to warrant *trans* fat labeling, the agency

did not focus on other physiological effects of *trans* fat. While studies on a variety of physiological effects of *trans* fat are ongoing and results preliminary, the agency is persuaded by comments that the declaration of *trans* fat on a separate line will best accommodate future scientific development. This will be helpful if future research more clearly elucidates the physiological mechanisms of each and confirms that *trans* fat does have adverse effects on other CHD risk factors or health conditions that differ significantly from saturated fat.

As pointed out by comments, doing so has the advantage of being consistent with: (1) The format used to list the other subcomponents of total fat, namely saturated, polyunsaturated and monounsaturated fats; (2) the declaration of quantitative amounts contiguous to the listing of the nutrient rather than in a footnote; and (3) the agency's regulatory precedent of classifying nutrients based on their chemical definition or structure. Consistency with the existing format can be expected to assist consumers in recognizing *trans* fat as a subcomponent of total fat. It will also be responsive to consumer interest in knowing the full breakout of fatty acids since, when poly- and monounsaturated fats are declared, the amounts for saturated, *trans*, polyunsaturated, and monounsaturated fats will add up to the amount of total fat except for minor deviations that may result from application of rounding rules in § 101.9(c)(2).

The agency agrees with the majority of the comments that the scientific evidence is not sufficient to support the establishment of a DRV for *trans* fat at this time. The comments that attempted to suggest a basis for doing so did not suggest particular values or submit scientific evidence to justify the establishment of such values. FDA emphasizes that existing DRVs are based on quantitative dietary intake recommendations developed from extensive scientific evidence that establishes values that will promote public health (58 FR 2206 at 2217). DRVs have not been based on international recommendations, which may not be germane in the United States, or on average dietary intake levels, which may not represent healthy dietary consumption patterns. The FDA is not aware of any international recommendations that it could rely on, nor did the comment provide any such specific recommendations. The agency has relied extensively on reports from the IOM/NAS in developing the current Reference Dietary Intake (RDIs) and DRVs. However, the recent IOM/NAS