

After further review and discussion, the United States and Canada can consider the possibility of mutual recognition of nutrition labels.

3. Option to Include *Trans* Fat as a Part of Total Fat

(Comment 15) Several comments recommended a new option that would place an asterisk (or other symbol) after the declaration of total fat (i.e., "Total Fat*") that references a footnote stating the number of grams of *trans* fat included in the total fat declaration (e.g., "**Includes ___g *trans* fat"). A few comments proposed an alternative to this option that would declare *trans* fat in a parenthetical statement on the same line with "total fat" (i.e., "Total Fat ___g (includes ___g *trans* fat)").

Some of these comments suggested that declaring *trans* fat as a part of total fat alleviates many of the concerns voiced about the proposed option. The comments stated that this option discloses the amount of *trans* fat in scientifically accurate terms and is consistent with current regulations that include the quantity of *trans* fat within the amount declared for total fat. A comment said that this option should be used until a DRV is established for *trans* fat. Another comment suggested that the DRV for total fat should be increased to accommodate *trans* fat. Other comments stated that current dietary guidelines recommend monitoring both total fat and saturated fat intake, especially for consumers concerned about their heart health, and that the AHA recommends focusing on the total amount of fat consumed to address concerns about *trans* fat consumption.

The comments stated that placing the asterisk beside "total fat" has advantages for consumers. At least one comment stated that this type of listing may be more readily seen by consumers since it gives greater prominence to the *trans* fat information. Other comments stated that including *trans* fat as a part of total fat avoids the confusion that consumers would experience with FDA's proposed option when amounts declared for saturated fat would appear to have increased.

The agency disagrees with those comments suggesting that concerns about *trans* fat consumption can be addressed by focusing on the total amount of fat consumed. FDA agrees that *trans* fats are chemically a component of total fat; however, that is also true for saturated, polyunsaturated, and monounsaturated fatty acids that are listed as subcomponents of total fat in many food labels. Therefore, the agency does not agree that *trans* fatty acids should be listed only as a part of

total fat until there is an established DRV for *trans* fatty acids, particularly since DRVs also have not been established for poly- or monounsaturated fatty acids. The agency also points out that the current DRV for total fat includes all fatty acids, so does not need to be increased to accommodate *trans* fatty acids.

Further, placing an asterisk after "Total Fat" on the label with a footnote stating the grams of *trans* fat, or a statement of the grams of *trans* fat beside the total fat on the label likely would lead to the same types of objections that were raised when that approach was considered for saturated fat. Moreover, previous comments in comment 13 raised concerns about consumers overlooking quantitative information in a footnote. Further, comments raised concern about not maintaining the chemical distinction for individual fatty acids, as has been the past agency practice. Placing *trans* fat on the same line of total fat may raise questions about how *trans* fat is to fit within the % DV for total fat. The agency is not persuaded by any the comments that the problems with this option would be any different than those with the option to label *trans* fat on the same line as saturated fat. Thus, the agency is not persuaded that the nutrition label should identify levels of *trans* fat in the total fat declaration through the addition of a footnote or parenthetical listing.

Moreover, while total fat in the diet is important, the composition of that total fat intake is at least equally, if not more, important. Recent recommendations from the Dietary Guidelines 2000 (Ref. 87) and the Dietary Guidelines Advisory Committee (Ref. 88) have emphasized reducing intake of both saturated and *trans* fats while placing less emphasis on reducing total fat intake. For example, while the 1995 edition of the Dietary Guidelines recommended that Americans choose a diet "low" in fat and saturated fat (Ref. 6), the 2000 edition now recommends "moderate" total fat (Ref. 87) with guidance that consumers needing to reduce their total fat intake do so by cutting back on saturated and *trans* fats. Similarly, the 2000 AHA Guidelines specifically recommend limiting "intake of foods with high content of cholesterol-raising fatty acids" (i.e., saturated and *trans* fatty acids) rather than total fat (Ref. 91). The 2001 NCEP report increased the recommendation for individuals with elevated LDL-C for total fat intake from 30 to 35 percent of calories provided that saturated and *trans* fats be kept low (Ref. 89).

The comments suggesting that *trans* fat information would have greater prominence and be more readily seen when related to total fat rather than saturated fat did not provide any data to support this position. While doing so would move *trans* fat up one line in the Nutrition Facts label, FDA has no basis to conclude that this would make it more prominent to consumers.

The agency acknowledges that the options of using an asterisk next to total fat with a footnote listing *trans* fat or listing *trans* fat parenthetically next to total fat would avoid any possible confusion experienced by consumers as a result of the proposed option if levels of saturated fat appeared to have increased when, instead, amounts of *trans* fat were added to the amount of saturated fat. However, other options, such as the option of declaring *trans* fat on a separate line would also avoid the possibility of such confusion and, at the same time, would more clearly identify *trans* fat as a separate subcomponent of total fat, in a manner similar to the other subcomponents, i.e., saturated, poly- and monounsaturated fats.

For the reasons noted previously, the agency is not persuaded that the nutrition label should identify levels of *trans* fat in the total fat declaration through the addition of a footnote or parenthetical listing.

4. Option to Include a Separate Line for *Trans* Fats

(Comment 16) Many comments recommended that *trans* fat content be declared on a separate line on the Nutrition Facts panel because of the problems ascribed to the proposed option. In general, these comments stated that there is no scientific evidence to support FDA's proposal to combine saturated and *trans* fatty acids because both of these fatty acids have different chemical structures and physiological effects. They asserted that a separate line on the nutrition label for *trans* fats would fully inform consumers about the kind of fats that are in the foods they select and consume. These comments urged the agency to list *trans* fat in the same way as other subcomponents of total fat, i.e., saturated and poly- and monounsaturated fats. They stated that doing so would clarify the chemical differences between the fatty acids, including saturated fatty acids, and would be easier for consumers to understand since it eliminates the need for a footnote. Comments also noted that adding a separate line for *trans* fat would be consistent with FDA's regulatory precedent, which was established with the 1993 mandatory