

saturated fat and *trans* fat in a food and dividing by the DRV for saturated fat (20 g). In effect, this is equivalent to having a combined DRV for saturated and *trans* fat of 20 g. FDA agrees with the comments that suggest that this approach is problematic in that by displacing the DV for saturated fat with *trans* fat, the DV, in essence, is lowered for saturated fat. However, the DV for saturated fat has not changed. Therefore, it would be scientifically more accurate to keep the DV for saturated fat intact, without displacing it with *trans* fat. This approach would be consistent with the recent IOM/NAS macronutrient report (Ref. 140) that does not treat saturated and *trans* fats together. FDA concludes that there is an insufficient scientific basis at this time for combining the declared amounts of *trans* and saturated fats and calculating the % DV. Additionally, FDA is persuaded by the arguments discussed previously that point to the differences between saturated fat and *trans* fat that it is inappropriate to do so.

Accordingly, the agency concludes that other options that disassociate *trans* fat from the listing of saturated fat would be preferable to the proposed option. The other options identified in the proposal and those suggested in comments are discussed later.

2. Option to List Saturated and *Trans* Fat on Same Line

(Comment 14) Several comments preferred the option identified in the November 1999 proposal that would list "Saturated + *trans* fat" with the amount in grams and the % DV based on the combined value, and the individual amounts of both saturated and *trans* fats in a footnote. One comment suggested that the footnote declare the specific amount of *trans* fat only, while another suggested that the individual amounts be listed in separate lines immediately below the combined amount rather than in a footnote. These comments stated that this type of declaration shows that: (1) There are two different fatty acid categories, thereby maintaining the chemical definitions of *trans* fat and saturated fat and indicating equal importance to health; (2) gives them equal prominence with poly- and monounsaturated fats; (3) suggests to consumers that *trans* fats have similar cholesterol-raising properties as saturated fats; and (4) provides an easy method for comparing the "heart-unhealthy" fat content of foods. The comments also argued that this type of declaration indicates the combined total amount of saturated and *trans* fats, a number that would stay constant when saturated and *trans* fats are substituted

for each other, and it was therefore clearer to declare the sum of both.

Alternatively, a few comments recommended declaring the individual amounts for saturated fat and *trans* fat on one line in the nutrition label, i.e., "Saturated fat _g + *trans* fat _g." These comments pointed out that declaring saturated and *trans* fats in this way would be consistent with the chemical definitions for each type of fatty acid and would help consumers see that *trans* fats are different from saturated fats. The comments argued that research may elucidate new properties or biological effects of both saturated and *trans* fatty acids, warranting this distinction between them. From a consumer perspective, one of the comments also argued that, if FDA begins to mandate the placement of nutrient content information in locations other than the current nutrient list, consumers may become increasingly confused about where on the food label to locate information that they need.

Two comments urged the agency to harmonize its *trans* fat labeling policy internationally, noting that this format, i.e., "Saturated fat _g + *trans* fat _g," was proposed by Canada in June 2001, for use in mandatory nutrition labeling in that country (Ref. 103).

Other comments did not favor listing saturated and *trans* fats on the same line as "Saturated + *trans* fat" for the same reasons expressed in opposition to the proposed option, namely because *trans* and saturated fats are chemically different, because they have different effects on HDL-C, and because, according to preliminary data, *trans* fat may have effects on non-heart disease risks that saturated fats are not reported to have. In addition to concerns about the chemical and physiological differences between *trans* and saturated fats, some comments expressed opposition to labeling the two on the same line because public health and scientific organizations that are instrumental in establishing daily reference intake values have not yet established a DV for *trans* fat. Many other comments objected to having saturated and *trans* fats on one line, in any manner, if it resulted in *trans* fat being included in the calculation of the % DV for saturated fat. Specific arguments against including *trans* fat when calculating the % DV for saturated fat are discussed in the preceding comment.

The agency is not persuaded by comments supporting this option. While this option does indicate more clearly than the proposed rule that saturated and *trans* fats represent two different

categories of fat, it would still necessitate a displacement of the % DV for saturated fat by *trans* fat and would not disassociate the two fats in terms of potential physiologic effects. Based on the reasons set forth in response to Comment 13, we believe that it would be scientifically more accurate to not displace the % DV for saturated fat with *trans* fat. In addition, this option would not be consistent with our rationale, as explained in the response to Comment 13, for why a chemical definition approach to labeling is preferred. Such an approach avoids the uncertainty about physiological effects now or in the future. While the two fatty acids do both lead to increased LDL-C, advisory groups (as noted in comment 10 of this document) have stated that substitution of *trans* fat for saturated fat lowers HDL-C. Low levels of HDL-C can be a predictor of CHD. While evidence concerning the differing effects of saturated fat and *trans* fat on other disease risk factors is preliminary, FDA is convinced by comments that it is preferable to disassociate the two fatty acids and maintain a chemical definition approach to labeling. Accordingly, the agency finds this option unacceptable.

Those comments stating that saturated and *trans* fat are substituted for each other recognized that the two types of fats have some functional similarities. However, comments were not unanimous in stating that the combined total amount of saturated and *trans* fats would stay constant when one of the two fatty acids was raised or lowered. Some comments indicated that *trans* fats could be reduced significantly with a smaller concomitant increase in saturated fat. In addition, FDA points out that the intent of this rulemaking is not to make such substitutions easier from a labeling perspective but to encourage the reduction of both types of fats to assist consumers in maintaining healthy dietary practices.

FDA recognizes that Canada has issued final rules on nutrition labeling that declare saturated fat and *trans* fat on one line. However, FDA has determined, based on comments to this final rule, that such declaration would not be an appropriate approach for the agency at this time. Such an option would not account for the chemical and physiological differences between saturated and *trans* fat, and thus, would be inconsistent with the agency's past approach to labeling that is based on chemical differences. Further, there are additional differences between Canada's new nutrition labeling rule and existing U.S. regulations, under § 101.9, that will need to be reviewed by both countries.