

were enacted, provision of nutrition labeling information was voluntary except in certain circumstances. At the time when nutrition labeling was voluntary, many foods did not provide nutrition labeling, demonstrating that the disclosure suggested by the “unfolding principle” was incomplete. To remedy this situation, Congress enacted the 1990 amendments, mandating that nutrients of public health significance be declared on food labels under section 403(q) of the act.

As mentioned earlier, section 403(q)(2)(A) of the act provides for the inclusion of an additional nutrient(s) if the Secretary (as delegated to FDA in § 5.10) determines that it should be included in nutrition labeling to assist consumers in maintaining healthy dietary practices. FDA is not asserting, as its basis for mandatory *trans* fat nutrition labeling, a rationale that is different from that which Congress declared by statute for such mandatory labeling. Lacking any congressional direction to do otherwise, the agency considers it implicit that any such added nutrients would be listed in a similar manner to those specified in section 403(q)(1) of the act. Accordingly, the agency is amending § 101.9 *Nutrition Labeling of Food*, to add *trans* fat as a mandatory component of nutrition labeling on all foods in accordance with section 403(q)(2)(A) of the act.

B. Format, Including Percent of Daily Value (% DV), for Nutrition Labeling of Trans Fat

FDA received many comments regarding the proposed option for nutrition labeling of *trans* fatty acids and other options discussed in the preamble. In addition, comments were received suggesting that *trans* fat be listed in conjunction with the listing of total fat.

The agency did not receive comments supporting either of the two options that would declare only the combined amount of saturated fat and *trans* fat rather than the individual amounts present. In light of the lack of support for these two options and the fact that these options do not allow consumers to determine the individual amounts of saturated fat and *trans* fat, the agency is not considering them further.

FDA also received a few comments that supported the proposed footnote statement “Intake of *trans* fat should be as low as possible” or a modification of it. However, the overwhelming majority of comments opposed the use of the footnote.

1. Proposed Option

(Comment 13) Many comments supported the proposed option of having the amount of *trans* fat included in the amount declared for “Saturated Fat” and in the calculation of the corresponding % DV with a footnote stating “Includes ___ g *trans* fat” when the food contains *trans* fat. Comments stated that combining both saturated and *trans* fat in the declaration of saturated fat maintains a consistent public health message and provides consumers with a less confusing means to identify “heart-unhealthy” fats in one place on the label. Comments suggested that, to assist consumers, *trans* fat should be included with saturated fat because saturated and *trans* fats have similar physiological and functional properties and because there is no DV for *trans* fat. Comments suggested that combining saturated and *trans* fats will decrease the likelihood that consumers would look only at the declared level for *trans* fat and choose a food because it has little or no *trans* fat, even though it contains a high amount of saturated fat. Furthermore, the comments suggested that combining *trans* with saturated fats would create an incentive for manufacturers to decrease “heart-unhealthy” fats in foods.

Comments supporting inclusion of *trans* fat in the calculation of the % DV for saturated fat stated that such action is reasonable for purposes of consumer information. One of these comments argued that *trans* fats are already included in recommendations to limit total fat to 30 percent of calories, a number that should not be increased, and are excluded from definitions of unsaturated fats for labeling purposes (i.e., § 101.9(c)(2)(ii) and (c)(2)(iii)). This comment acknowledged that including *trans* fat would in effect lower the reference value for saturated fat. The comment argued that this would help Americans reduce their risk of heart disease, quoting from the IOM/NAS report “Diet and Health” which states that “saturated fatty acid intake [should] be maintained at less than 10 percent of total calories by individuals,” but that “further reduction, to 8 or 7 percent of calories or lower, would confer greater health benefits.” The comment said that including *trans* fat in the % DV would help Americans follow this advice.

However, many comments opposed this option of including *trans* fat with saturated fat, arguing that including *trans* fat with saturated fat is scientifically inaccurate and misleading because *trans* and saturated fats are chemically, functionally, and physiologically different. Comments

pointed out that chemically *trans* fats are unsaturated fatty acids that contain one or more double bonds in a *trans* configuration while saturated fats do not contain double bonds. Moreover, comments stated that *trans* fatty acids do not have the same functional characteristics as saturated fats because their melting and crystallization kinetics are quite different. Comments also pointed out that *trans* fat is physiologically distinct from saturated fat, stating that *trans* fat decreases HDL-C levels and that saturated fat does not. In addition, there were comments suggesting that *trans* fat adversely affects other factors that contribute to CHD, such as lipoprotein(a), and may cause adverse effects unrelated to CHD. For these reasons, the comments were adamant that *trans* fat should not be treated as though it is “bioequivalent” to saturated fat and, consequently, the listing of *trans* fat should be disassociated from the listing of saturated fat.

In addition, several comments objected to combining both *trans* and saturated fats on the grounds that it is inconsistent with FDA’s regulatory precedent of classifying nutrients based on their chemical definition or structure, rather than their physiological effect. Specifically, the comments cited FDA’s decision when implementing the 1990 amendments to establish a chemical definition for saturated fat rather than a physiological definition (58 FR 2079 at 2089).

A few comments expressed concern that by including *trans* fat with saturated fat, FDA is creating a category of “bad” or “cholesterol-raising” fat that is inconsistent with the current nutrition label, which provides consumers with information about the nutrient profile of a product rather than providing information about perceived health effects. Other comments stated that FDA’s proposal to combine *trans* fat and saturated fat may mislead consumers, albeit misleading them for their own good, by causing them to misclassify *trans* fats as saturated fats or causing them to assume that the DV for saturated fat has been reduced (the effect of combining the quantitative amounts of *trans* and saturated fats and determining the % DV using the established DV for saturated fat). Further, several comments stated that adding *trans* fat to the amount of saturated fat declared may mislead and confuse consumers by leading them to incorrectly conclude that the amount of saturated fat has increased.

Other comments stated that, because of the magnitude of CHD risk in the prospective studies, *trans* fat should be