

labeled more prominently than proposed in the November 1999 proposal. These comments argued that listing the amount of *trans* fat in a footnote is more confusing and implies that it is unimportant. In addition, comments stated that footnotes, which can use smaller type size, are more difficult to read. One comment stated that it was not surprising that consumers were unfamiliar with the term since it was not allowed to appear on Nutrition Facts labels. This comment suggested that consumer knowledge about *trans* fat would improve as more dietary recommendations are made for limiting *trans* fats and as they are listed in food labeling.

Other comments objected to including *trans* fats when calculating the % DV for saturated fat stating that the effects of *trans* fat on LDL-C have not been proven to equal the effects of saturated fat on LDL-C, so they should not be held to the same standard. These comments argued that including *trans* fat in the calculation of % DV assumes that *trans* fat is equivalent to saturated fat on a gram-for-gram basis, whereas the agency admitted in the proposal that available studies do not allow for such a conclusion. The comments stated that no authoritative bodies have recommended that *trans* fat be considered as a part of the dietary recommendation for saturated fat. Also, they stated that including *trans* fat, in effect, lowers the DRV for saturated fat and there is no new data on saturated fat that supports this action, i.e., that there is no basis for concluding that saturated fats are now sufficiently worse than previously believed to justify an apparent reduction in recommended intakes. One comment also argued that if the declaration of % DV changed on a product as a result of including *trans* fat with saturated fat, consumers may incorrectly assume a change has been made which made the product less healthy when, in fact, no such change had occurred.

One comment said that FDA should not include *trans* fat in the calculation of % DV unless the DRV for saturated fat is increased to 22 g since the agency had actually rounded down the DRV for saturated fat from 22.2 g (equivalent to 10 percent of calories from a 2,000 calorie diet) to 20 g when implementing the 1990 amendments (see 58 FR 2206 at 2219). Another comment objected to the idea of increasing the DRV for saturated fat because products that do not contain *trans* fat would appear healthier (i.e., have a lower % DV) even though the amount of saturated fat in the product would remain the same.

Based on comments received, FDA is persuaded that there are inherent weaknesses and inconsistencies in its proposed option. Therefore, the agency has reconsidered its proposal to include *trans* fats in the declaration of saturated fat with a footnote indicating the amount of *trans* fat. The agency acknowledges that declaring the amount of saturated fat and *trans* fat together, even with the proposed footnote, could lead some consumers to believe that the two types of fatty acids are chemically and physiologically the same. Clearly, *trans* fats contain double bonds and thus, are chemically distinct from saturated fat. Likewise, although both saturated and *trans* fats do raise LDL-C levels, physiologic distinctions between the two types of fatty acids do exist as discussed previously in Comments 10 and 11. While findings on some of these distinctions are preliminary, they do not support the position which the agency took in the November 1999 proposal that the two fatty acids should be declared as one combined entity because of similar physiological effects.

The agency re-evaluated its position, noted in the final rules implementing the 1990 amendments, that there is insufficient knowledge about the physiological effects of particular fatty acids to use anything other than a chemical definition for saturated fats (58 FR 2079 at 2089). In that rulemaking, FDA reconsidered its regulatory position in place since 1973 (38 FR 2132 at 2134, January 19, 1973) of linking the definition of saturated fatty acids to effects of particular fatty acids on blood total and LDL-C and determined that a chemical definition was a more appropriate approach. The agency stated that a chemical definition avoids much of the controversy regarding blood cholesterol effects of short to medium and certain very long chain fatty acids because the definition is not subject to changes in knowledge about the physiological effects of a particular fatty acid. In addition, the agency stated that a chemical definition approach to labeling fatty acids avoids the uncertainty about physiological effects other than those related to CHD (58 FR 2079 at 2089). Based on its re-review of the position noted in the final rules implementing the 1990 amendments, the comments received on proposed rule opposing a contrary position, and current science on *trans* fat, the agency is persuaded that it would be important to approach *trans* fat labeling on the basis of using a chemical definition and not based on physiological effects. Accordingly, the agency concludes that

it is necessary to disassociate saturated and *trans* fats on the nutrition label so that consumers do not misinterpret the declaration of saturated fat by thinking that *trans* fats are included in that definition.

The agency also acknowledges the concerns expressed in comments about the prominence given to the information on *trans* fat. Current food labeling regulations do allow for a smaller type size for footnotes (§ 101.9(d)(1)(iii)) and limit the declaration of amounts in footnotes to statements saying that the food is not a significant source of specified nutrients (e.g., § 101.9(c)(3)). Consequently, consumers may overlook quantitative information on *trans* fat content placed there.

In the November 1999 proposal, FDA expressed concern that consumers may not yet know what *trans* fats are or know about their impact on health (64 FR 62746 at 62755). The agency agrees with the comment that suggested that consumer knowledge would improve as more dietary recommendations are made for limiting *trans* fats and as they are listed in nutrition labeling. In addition, the agency notes that media attention to *trans* fat has been widespread since publication of the November 1999 proposal. For example, public awareness about *trans* fats was increased as reports of the IOM/NAS report on *trans* fatty acids were issued (Ref. 140), as consumer and health groups issue press releases and reports about *trans* fats (Refs. 147 and 148), as food manufacturers add information about the *trans* fat content of products to labels, and as industry announcements are made about the *trans* fat content of packaged and restaurant foods (Refs. 149 and 150). In addition, the agency is planning a consumer education program discussed later in Comment 28 to further heighten consumers' knowledge of what *trans* fats are and their impact on health. Thus, the agency no longer believes that its prior reasoning, i.e., that *trans* fat would need to be included in the declaration of saturated fats in order for consumers to understand that *trans* fats are heart unhealthy is necessarily true. Consumers should be more aware of *trans* fat based on the public exposure to information on *trans* fat over the past years and FDA efforts before the rule becomes effective.

In the November 1999 proposal, FDA tentatively concluded that, in the absence of dietary recommendations for *trans* fats, it was reasonable to include *trans* fats in the % DV for saturated fat (46 FR 62746 at 62756). Consequently, FDA proposed that the % DV be calculated by combining the amount of