

amount of *trans* fat is “material” only when *trans* fat is present at greater than 1 g per serving because it would then significantly impact the overall fatty acid contribution to the diet. Another comment stated that *trans* fat declaration should be required only when *trans* fat is present at greater than 2 g per serving because that threshold would capture the food categories that contribute the vast majority of *trans* fat to the diet but would exclude products that contain only a trivial amount of *trans* fat. This comment stated that mandatory *trans* fat labeling of products with 2 g *trans* fat or less per serving would have a significant labeling burden although the foods make little overall contribution to *trans* fat in a mixed diet and have not been shown to have any public health impact. Another comment suggested that, if no claims are made, *trans* fat declaration should be voluntary if *trans* fat is present at 0.5 g or less per serving. One comment suggested that, if there are no claims about fatty acids or cholesterol, *trans* fat declaration should not be required when the food is “low” in total fat. The comment stated that a food “low” in total fat conforms with dietary recommendations; that no material improvement in food choices can be made from knowledge of the specific *trans* fat level in a “low fat” food; and that the level of *trans* fat in a “low fat” food is not enough to have any adverse impact on public health.

One comment stated that *trans* fat declaration should be optional because consumers prefer simplicity and clarity in nutrition labeling and consumers are unlikely to benefit from added verbiage about a nutrient that is not familiar to them. One comment suggested that *trans* fat declaration should be voluntary, but should be required under the same conditions that declaration of monounsaturated and polyunsaturated fat is required. The comment stated that *trans* fat declaration would then be required when fatty acid or cholesterol claims are made, and this would be the case for important food sources of *trans* fat, such as margarines, which often make such claims. According to the comment, although not all foods would choose or be required to disclose *trans* fat, the foods that are predicted to reformulate and that generate the expected health benefits of *trans* fat labeling would do so. After the initial disclosure of *trans* fat by these foods, additional foods would disclose *trans* fat due to competitive pressure (described by the comment as “the unfolding principle”). The comment stated that market incentives and

facilitation of information flow, rather than mandatory disclosure, are the best ways to achieve *trans* fat disclosure.

FDA disagrees with comments opposed to mandatory declaration of *trans* fat. The 1990 amendments mandated nutrition labeling on most foods to provide consumers with information about specified nutrients that would help them maintain healthy dietary practices, as well as to create an incentive to food companies to improve the nutritional qualities of their products. Section 403(a) requires that food be adequately labeled and that material facts about a food’s characteristics be disclosed to consumers. Section 403(q)(2)(A) of the act gives the Secretary (as delegated to FDA in § 5.10 (21 CFR 5.10)) the authority to require that information on additional nutrients be included in nutrition labels, if the Secretary determines that providing such information will assist consumers to maintain healthy dietary practices. In the legislative history of the 1990 amendments, Congress noted that “Scientific evidence has clearly linked dietary habits to good health. For this reason, it is important for FDA to provide consumers with better information about the foods they eat.” (Ref. 141). As described in section IV of this document, scientific studies have demonstrated consistently that consumption of *trans* fat increases LDL-C, a major risk factor for CHD.

New studies and recent expert reports (Refs. 87, 90, 95, and 140) have been published and confirm the relationship between *trans* fat intake and risk of CHD. These studies’ reports corroborate the agency’s earlier finding in the proposed rule that information on *trans* fat on the nutrition label will assist consumers to maintain healthy dietary practices. Dietary Guidelines 2000 cautions consumers that foods high in *trans* fatty acids tend to raise blood cholesterol and gives examples of food sources of *trans* fat (Ref. 87). The Guidelines advise Americans who need to reduce fat intake to “do so primarily by cutting back on saturated and *trans* fats” (Ref. 87). Likewise, the Executive Summary of the NCEP 2001 report urges primary prevention of CHD in the United States through lifestyle changes (Ref. 95). The NCEP’s Therapeutic Lifestyle Changes Diet recommends that those who wish to lower their LDL-C level reduce their intake of saturated fat and keep consumption of *trans* fat low (Ref. 89). Similarly, the IOM/NAS report recommends “that *trans* fat consumption be as low as possible while consuming a nutritionally adequate diet” (Ref. 90). It is clear that

persons interested in following these recommendations and maintaining optimal LDL-C levels must be able to determine levels of both saturated and *trans* fats in individual food products. This information provides consumers with the ability to maintain healthy dietary practices. Information on saturated fat content is already available in Nutrition Facts panels on food labels. The practical way to inform consumers of the level of *trans* fat in individual food products is for the information also to be included in the Nutrition Facts panel.

Government and industry surveys consistently find that a majority of American consumers report looking at the nutrition label the first time they purchase a food product (e.g., about 75 percent according to FDA surveys (Ref. 96) and 51 percent according to a 1997 industry survey (Ref. 97). According to the FDA surveys, the most frequently reported label use and the one which increased most following the implementation of the 1990 amendments was “to see how high or low the food is in things like calories, salt, vitamins, fat, etc.” (70 percent in 1995, up 12 percent from 1994) (Ref. 96, table 16.1).

These survey data show that consumers rely on the Nutrition Facts label as a guide to choosing foods that meet their dietary objectives. As consumers learn more about the dietary significance of *trans* fat and the dietary advice to limit its consumption, the Nutrition Facts panel is where label users will expect and want to find this information. If they cannot find information on *trans* fat content there or if it is only there when claims are made about fatty acids or cholesterol, they will be hampered in their ability to implement the most recent dietary guidance, and are likely to be misled about a food’s basic characteristics.

Therefore, FDA, as delegated by the Secretary, has concluded that *trans* fat is a material fact which cannot be omitted from the label. In addition, information on the *trans* fat content of food will assist consumers in maintaining healthy dietary practices. As such, FDA is acting in accordance with section 403(a) and (q)(2)(A) of the act to require that information on *trans* fat content be included in nutrition labeling. Including *trans* fat as a mandatory component of nutrition labeling will allow consumers to choose foods that will reduce their intake of *trans* fat, along with saturated fat, within the recommended intake level for total fat in a manner that is consistent with the most recent dietary guidance.