

§ 101.9(c)(2)(i) (21 CFR 101.9(c)(2)(i)) to include *trans* fatty acids so that the declaration of saturated fat on the nutrition label would provide consumers with complete information on all “heart-unhealthy” fatty acids. In addition, the petitioner requested that all saturated fat claims in § 101.62(c) (21 CFR 101.62(c)), the saturated fat threshold on all cholesterol claims in § 101.62(d), the claims for “lean” and “extra lean” in § 101.62(e), and disqualification and disclosure levels for health and nutrient content claims be amended to reflect the combined levels of saturated and *trans* fatty acids. Further, CSPI requested that FDA: (1) Limit “vegetable oil” claims (e.g., “made with vegetable oil”) to foods that are low in both saturated and *trans* fatty acids, and (2) require that “partially hydrogenated” fat be listed on food labels as “partially saturated.”

On July 13, 1998, CSPI amended its petition in a way that would maintain the definition of saturated fat in § 101.9(c)(2)(i), yet provide consumers with information on the *trans* fatty acid content of the food. Specifically, CSPI suggested that FDA either: (1) Disclose the sum of *trans* and saturated fats next to the term “saturated fat\*” with an asterisk at the bottom of the label that states “contains \_\_\_ grams of *trans* fat,” or (2) disclose the sum of *trans* and saturated fats next to the term “saturated + *trans* fat” when *trans* fat was present.

In response to CSPI’s petition, FDA issued a proposed rule in the **Federal Register** of November 17, 1999 (64 FR 62746), entitled “Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims” (hereinafter identified as “the November 1999 proposal”). In that document, FDA proposed to amend its nutrition labeling regulations to require that the amount of *trans* fatty acids in a food, including dietary supplements, be included in the amount and percent Daily Value (%DV) declared for saturated fatty acids, with a footnote indicating the amount of *trans* fatty acids in a serving of the product, when the product contains 0.5 or more grams (g) *trans* fatty acids per serving. FDA reviewed recent research that showed that consumption of diets containing *trans* fatty acids, like diets containing saturated fats, results in increased serum low-density lipoprotein cholesterol (LDL-C), a major risk factor for CHD. The proposed rule was issued to assist consumers in maintaining healthy dietary practices (64 FR 62746 at 62754).

#### *B. Nutrient Content and Health Claims*

In the **Federal Register** of November 27, 1991 (56 FR 60478), FDA also published a proposed rule entitled “Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food.” Although the agency proposed definitions for fat, fatty acid, and cholesterol nutrient content claims, it did not propose a definition for the nutrient content claim “saturated fat free.” However, the comments in response to that proposal recommended that FDA define the claim “saturated fat free.”

In the **Federal Register** of January 6, 1993 (58 FR 2302), FDA issued a final rule entitled “Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definition of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food,” (hereinafter the “nutrient content claims final rule”). In that rule, the agency stated that it did not set a *trans* fat criterion for most claims because the evidence suggesting that *trans* fatty acids raise serum cholesterol was inconclusive at that time (58 FR 2302 at 2332 and 2340). However, FDA did set a *trans* fat criterion for the “saturated fat free” claim stating that “because of the uncertainty regarding this issue, the fact that consumers would expect a food bearing a ‘saturated fat free’ claim to be free of saturated fat and other components that significantly raise serum cholesterol, and the potential importance of a saturated fat free claim, the agency believes that it would be misleading for products that contain measurable amounts of *trans* fatty acids to bear a ‘saturated fat free’ claim” (58 FR 2302 at 2332). The *trans* fat criterion for the claim “saturated fat free” was set at a level not to exceed 1 percent of total fat in the food (58 FR 2302 at 2419). The agency stated that 1 percent was the appropriate threshold because analytical methods for measuring *trans* fatty acids below that level were not reliable (58 FR 2302 at 2332). This action was taken under the authority of section 403(r)(2)(A)(vi) of the act, which prohibits a claim if it is misleading in light of the level of another nutrient in the food.

Some comments that FDA received after publication of the nutrient content claims final rule objected to the 1 percent criterion for *trans* fatty acids in the definition of “saturated fat free.” One comment pointed out that a cookie containing 1.5 g of total fat would be allowed to have only 0.015 g of *trans* fatty acids, an amount that could not be

accurately measured. In response to these comments, in the **Federal Register** of August 18, 1993 (58 FR 44020 at 44032), the agency amended the definition of “saturated fat free” to require that a food contain less than 0.5 g of *trans* fatty acids in addition to less than 0.5 g of saturated fat per reference amount customarily consumed (hereinafter referred to as “reference amount”) and per labeled serving to be eligible to bear the claim.

In the November 1999 proposal, FDA concluded that dietary *trans* fatty acids have adverse effects on blood cholesterol measures that are predictive of CHD risk (64 FR 62746 at 62754). Consequently, to avoid misleading claims, the agency proposed that the amount of *trans* fatty acids be limited wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. In the November 1999 proposal, the agency did not propose to take action requested by CSPI to amend § 101.65(c)(3) (21 CFR 101.65(c)(3)) to state that “made with vegetable oil” is an implied claim that the product is low in saturated fat and *trans* fats combined (64 FR 62746 at 62762) because the agency proposed to amend nutrient content claims for saturated fat to include a *trans* fatty acid criterion. The agency stated that the proposed amendments to nutrient content claims and the requirements for implied nutrient content claims in § 101.65(c)(3) adequately addressed the petitioner’s request.

In addition, in the November 1999 proposal, FDA requested comment on whether “*trans* fat free” claims would help consumers maintain healthy dietary practices and whether they would provide incentive to the food industry to reduce the amount of *trans* fat in the food supply (64 FR 62746 at 62759). FDA proposed a definition for the *trans* fat free claim. FDA concluded that there was no basis for defining “low *trans* fat” without quantitative recommendations for daily intake of *trans* fat. Further, FDA did not define a “reduced *trans* fat” claim because it was concerned that a reduced *trans* fat claim would detract from educational messages that emphasize lower intakes of saturated fat. Persons who believed that a “reduced *trans* fat” claim would be useful were advised to submit a petition under § 101.69 (21 CFR 101.69).

In the November 1999 proposal, FDA proposed to deny CSPI’s request that the agency require that “partially hydrogenated” fat be listed as “partially saturated” fat (64 FR 62746 at 62762). Among other reasons, the agency stated that “hydrogenated” and “partially