

have a lower probability of meeting FDA compliance requirements.

VI. Nutrient Content Claims, Health Claims, Disclosure and Disqualifying Levels

In its November 1999 proposal, FDA proposed a definition for the nutrient content claim “*trans* fat free” and proposed limits on the amounts of *trans* fat wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. Several comments to that proposal requested that the final rule define the claim “reduced *trans* fat” or amend the claim “reduced saturated fat” to require a reduction of saturated and *trans* fats combined. To address this issue, the agency reopened the comment period (65 FR 75887) to consider “reduced *trans* fat” and “reduced saturated and *trans* fat” claims.

With regard to the specific definitions, FDA proposed that “*trans* fat free” and “saturated fat free” should be defined as less than 0.5 g *trans* fat and less than 0.5 g saturated fat per reference amount and per labeled serving; “low saturated fat” as 1 g or less of saturated fat and less than 0.5 g of *trans* fat per reference amount and not more than 15 percent of calories from saturated fat and *trans* fat combined; “reduced saturated fat” as at least 25 percent less saturated fat and at least 25 percent less saturated fat and *trans* fat combined; “lean” as 4.5 g or less of saturated fat and *trans* fat combined; and “extra lean” as less than 2 g of saturated fat and *trans* fat combined. In addition, cholesterol claims were allowed only on foods containing 2 g or less of saturated fat and *trans* fat combined, and disqualifying and disclosure levels were set at 4 g or less of saturated fat and *trans* fat combined. FDA did not propose to define “low *trans* fat.”

The comments relating to claims were very diverse and indicated strongly opposing views. With regard to the “*trans* fat free” claim, some comments favored the proposed definition, while other comments suggested increasing the saturated fat limit, eliminating the saturated fat limit, or not defining this claim. Similarly, some comments supported the “saturated fat free” claim, while other comments recommended that the *trans* limit be increased to 2 g. For “low saturated fat” some comments favored the proposed definition, while others suggested increasing the *trans* fat limit as high as 2 g. One comment recommended that this claim be less than or equal to 1.5 g of saturated and *trans* fats combined.

A number of comments supported having a “reduced *trans* fat” claim and others were against it. The vast majority of the comments in favor of this claim suggested that *trans* fat be reduced by at least 25 percent, but there was little agreement on the secondary saturated fat criterion. The comments ranged from no limit on saturated fat, to no increase in the level of saturated fat, a limit of less than or equal to 2 g, or at least a 25 percent reduction. The comments on “reduced saturated” fat were similar to the comments on “reduced *trans* fat” in that there was no agreement on the level of the secondary criterion, i.e., *trans* fat for this claim. In addition, some comments recommended having the claim “reduced saturated and *trans* fats” for greater flexibility, while others opposed such a claim. Of those in favor, some comments recommended a reduction of at least 25 percent in saturated and *trans* fats combined, one comment favored a 33 to 50 percent in saturated and *trans* fats combined, and one comment wanted a 25 percent reduction in saturated fat and a 25 percent reduction in *trans* fat.

Finally, the comments on disclosure and disqualifying levels were equally divergent. Some comments favored the proposed criterion of 4 g or less of saturated and *trans* fats combined, while others recommended a limit of 4 g of saturated fat and 4 g of *trans* fat, or believed that there should be no limit on *trans* fat. One comment stated that *trans* fat thresholds should be incorporated into the criteria defining nutrient content claims and health claims only to the extent that such criteria are necessary to prevent the claim from misleading consumers. The comment stated that this is the approach FDA applied in establishing the saturated fat thresholds for cholesterol content claims in § 101.62(d) and is an appropriate construct for nutrient content claims about *trans* fat.

The objections in the comments against the proposed definitions were generally based on scientific, legal, or economic arguments. Some of the comments believed that the agency is acting in advance of sufficient scientific justification, while others stated that the agency should have acted sooner. There was disagreement as to whether the adverse effects of *trans* fat are comparable to that of saturated fat. Some of the comments stated that the proposed definitions assume that *trans* fat and saturated fat are “bioequivalent.” These comments particularly objected to changing the disclosure and disqualifying level of 4 g of saturated fat to 4 g of saturated and *trans* fat combined (i.e., holding the

current level constant and including *trans* fat). These comments argued that the effects of saturated fat and *trans* fat have not been proven to be the same on a gram-for-gram basis and, therefore, should not be treated interchangeably. Other comments stated that there is no scientific evidence showing any adverse effects on serum cholesterol levels or cardiovascular health from *trans* fat in a mixed diet to support FDA’s proposed definitions for nutrient content claims.

Other comments argued that the proposed claims should be included in the final rule for public health reasons, while others argued that less restrictive claims would benefit the public health to a greater extent because they would encourage more reformulation. Some of these comments pointed out that the “*trans* fat free” claim, in particular, is not meaningful because very few foods could meet the proposed criteria and therefore would not be used enough to be helpful.

Several comments asserted that FDA did not meet its burden under the first amendment because the threshold levels proposed by FDA for *trans* fat for certain nutrient content and health claims, which, if exceeded, would prohibit the use of the claims on food and have the effect of restricting the use of specific claims that would be truthful and not misleading. The comments reasoned that FDA could only limit claims where the level of *trans* fat in a food product would make the claim misleading. Further, the comments reasoned that, before FDA could prohibit a claim, FDA would need to establish that the use of a disclaimer on the label or the disclosure of *trans* fat on the label could not prevent the claim from being potentially misleading.

Economic concerns regarding the proposed nutrient content claims are discussed in section IX of this document.

FDA has carefully reviewed the comments and finds that it has insufficient scientific information at this point in time to support a decision on the appropriate definition for the nutrient content claims discussed in the November 1999 proposal and the December 5, 2000, notice to reopen the comment period. The comments that expressed a preference for a specific threshold level of *trans* fat for various claims did not provide a scientific rationale to support the level. In the past, the development of definitions for nutrient content claims and the establishment of disclosure and disqualifying levels generally have been dependent upon scientific agreement of appropriate quantitative reference values for daily consumption of the