

that is tied to a similar symbol at the bottom of the Nutrition Facts box and the statement that "Intake of *trans* fat should be as low as possible." The agency asked for comments on the proposed footnote statement.

A few comments to the November 2002 reopening of the comment period supported the proposed footnote statement, "Intake of *trans* fat should be as low as possible," with or without some modification to the statement. However, the majority of comments strongly opposed the proposed footnote statement and recommended that FDA drop the footnote and finalize the quantitative (gram/serving) label declaration of *trans* fat on a separate line below saturated fat with no % DV. A more thorough review of the comments can be seen in comment 17 of the *trans* fat final regulation found elsewhere in this issue of the **Federal Register**.

The dominant concern, from both industry and consumers, was that the footnote would create a goal of achieving a "zero" *trans* fat intake level so that the market (that is, manufacturer reformulations and consumer preferences) would be driven toward products that were devoid of *trans* fat, regardless of the level of saturated fat. One comment submitted two consumer surveys that suggest the proposed footnote statement may lead consumers to identify foods with much higher levels of saturated fat but no *trans* fat as "more healthful" than those containing lesser amounts of saturated fat and *trans* fat combined (see comment 17 in the *trans* fat final regulation found elsewhere in this issue of the **Federal Register**).

Another concern expressed in comments was that the proposed footnote statement was inconsistent with the IOM/NAS report (Ref. 1) and other dietary guidelines. The comments argued that the footnote statement implies that intake of *trans* fat should be zero, in other words, a de facto DV of "zero" whereas the IOM/NAS macronutrient report states that the intake of *trans* fat is unavoidable in ordinary diets. Moreover, the report states that eliminating them from an ordinary diet would require significant changes in dietary intake patterns that may result in unknown and unquantifiable health risks. The IOM recommendation was that intake of *trans* fat should be as low as possible "while consuming a nutritionally adequate diet." The comments noted that the IOM/NAS macronutrient report makes similar recommendations for saturated fat and cholesterol, which also have adverse effects on LDL-C.

Thus, the comments expressed the belief that the proposed footnote statement could mislead consumers into selecting foods with more saturated fat in an effort to avoid foods containing *trans* fat. Virtually all comments conveyed that *trans* fat and saturated fat (and perhaps cholesterol) need to be viewed in tandem—not one at the exclusion of the other(s).

Comments also raised concerns about the absence of consumer studies to determine how the proposed footnote would be perceived. As noted previously, industry comments perceived it as a warning label for consumers to avoid *trans* fat-containing foods at all costs, resulting in an increased intake of saturated fat and negating years of government health messages to limit saturated fat intake. Comments also indicated concerns about an additional footnote adding clutter to the label and thereby discouraging consumers from reading it. The comments strongly supported consumer research on the proposed and other possible footnote statements to determine consumers' understanding of *trans* fat in light of such statements and how *trans* fat may be perceived relative to other cholesterol-raising lipids in a food, as well as how consumers would react to the footnote.

In the *trans* fat final regulation, found elsewhere in this issue of the **Federal Register**, we amend regulations on nutrition labeling to require that *trans* fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fat but without a % DV or the proposed nutrient content claims or footnote statement. In that document, we concurred with the comments that support consumer testing to ensure that any claim or footnote statement about *trans* fat, alone or in combination with other nutrients, such as saturated fat and cholesterol, provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction. However, we concluded that based on information and arguments presented in the comments, it is premature to establish new or revised definitions for nutrient content claims or require the use of the proposed footnote statement in the nutrition label. Instead, we decided to issue this ANPRM and solicit comment and consumer research on: (1) An appropriate basis for establishing qualifying criteria for *trans* fat in *trans* fat nutrient content claims and current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a

message about cholesterol-raising lipids as well as disclosure and disqualifying levels; (2) whether such claims mislead consumers about the total fatty acid profile if levels of all cholesterol-raising lipids are not addressed, and if so, whether qualifiers or disclosure statements would remedy this problem; (3) the use of a footnote, (4) the language that may be appropriate for use in a footnote, and (5) the impact of nutrient content or health claims or a footnote or disclosure statement on consumers' food selections.

II. Agency Request for Information

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

FDA has a mandate to provide nutrition information on food labels to assist consumers in maintaining healthy dietary practices. As explained in the *trans* fat final regulation, published elsewhere in this issue of the **Federal Register**, although the science now supports a relationship between *trans* fat intake and risk of CHD, the agency believes that the current level of scientific evidence does not provide the type of quantitative information that the agency would need to support the establishment of a DRV for *trans* fat. In 1993, when the agency established a DRV for saturated fat (58 FR 2206, January 6, 1993), it based the DRV on quantitative guidelines set forth by the National Academy of Science 1989 report "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 4) and a report from the National Cholesterol Education Program (National Heart, Lung, and Blood Institute of the National Institutes of Health) (Ref. 5) that stated that saturated fat should provide less than 10 percent of total calories. The agency derived a DRV of 20 grams for saturated fat (rounded) as the amount of saturated fat that would provide approximately 10 percent of the reference caloric intake (i.e., 2,000 calories/day) (55 FR 29476 at 29483, July 19, 1990). There is no such quantitative recommendation at this time for *trans* fat, either as an absolute amount or as a percentage of caloric intake. The IOM/NAS report recommended keeping *trans* fat intake as low as possible while recognizing that *trans* fat is unavoidable in ordinary, nonvegan diets and that trying to eliminate *trans* fat from the diet entirely would require significant changes in eating patterns that may introduce undesirable effects. In the absence of a DRV for *trans* fat, the agency is providing for mandatory *trans* fat labeling, without a % DV, to provide