

more healthful, with 17 percent choosing food 1.

The majority of the comments strongly opposed the proposed footnote statement and recommended that FDA drop the footnote and finalize the quantitative (grams per serving) label declaration of *trans* fat on a separate line below saturated fat with no % DV. Several comments stated that the proposed footnote statement is inconsistent with the IOM/NAS macronutrient report and incorrectly establishes a de facto DV or UL of zero for *trans* fat intake that the IOM/NAS never intended to establish. Some of these comments explained that the proposed footnote statement takes into consideration part of the recommendation from the IOM/NAS report that recommends the intake of *trans* fat be as low as possible, while ignoring the part that states “\* \* \* while consuming a nutritionally adequate diet.” The comments claimed that the omission of the latter part of the recommendation significantly changes the meaning of the statement and the recommendation of the IOM/NAS, namely that the IOM did not intend to recommend that *trans* fat be totally eliminated from the daily diet. These comments noted that the IOM/NAS report did not establish an UL for *trans* fat despite the relationship between intake of *trans* fat and CHD stating that *trans* fatty acids are unavoidable in ordinary, nonvegan diets, and to attempt to eliminate them would require significant changes in dietary intake patterns which may result in unknown and unquantifiable health risks. The comments went on to say that the IOM committee indicated that “[I]t is possible to consume a diet low in *trans* fatty acids by following the dietary guidance provided in Chapter 11” of their report. The comments concluded that the proposed footnote statement is inconsistent with the IOM/NAS report and could mislead consumers into substituting more foods with saturated fat in an effort to avoid foods containing *trans* fat.

Similarly, several comments described the proposed footnote statement as an unjustified warning statement on the label of foods that contain *trans* fat. Some of these comments stated that consumers will perceive the footnote as a de facto % DV of zero and will not understand the meaning of the portion of the proposed footnote statement “as low as possible;” consumers will perceive it as a warning to avoid *trans* fat-containing foods at all costs. Several comments stated that the footnote would be misleading because consumers would be confused about the

relative impact of saturated fat (by thinking up to 20 g, i.e., the DV for saturated fat, is heart healthy) compared to *trans* fat (thinking *trans* fat intake must be kept to zero to be heart healthy). Some of these comments mentioned that the dietary recommendation to reduce saturated fat is a well established goal of federal agencies and other health organizations and that Americans consume much more saturated fat than *trans* fat. The comments stressed, therefore, that any footnote statement on the nutrition label about *trans* fat should not undermine the important health message consumers have learned over the years about limiting saturated fat intake.

Comments also criticized the proposed footnote for being more prescriptive than, and inconsistent with, other Federal Government dietary recommendations, such as the Dietary Guidelines for Americans 2000 and the NCEP Adult Treatment Panel III Report, 2001. According to the comments, the recommendations of these reports support the need for Americans to choose diets that are low in saturated fat and cholesterol and moderate in fat while reducing, not eliminating, dietary consumption of *trans* fat.

Comments also pointed out that the IOM/NAS report gives essentially identical advice for saturated fat and cholesterol as it gives for *trans* fat, yet FDA’s proposed footnote singled out only their recommendation for *trans* fat. The comments argued that this placed undue emphasis on the role of *trans* fat in heart health.

Many of the comments expressed concern that the proposed footnote statement is potentially misleading to consumers and will undermine the key goals of this rulemaking. To that end, the comments strongly recommended that FDA drop the proposed footnote statement from the final rule and take time to conduct consumer research to determine the impact of the proposed footnote statement on consumers’ understanding and comprehension. A few comments cited FDA’s obligation under the 1990 amendments (paragraph 2(b)(1)(A)) to ensure that nutrition labeling is “conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.” The comments argued that the proposed footnote statement should be consumer tested to ensure that the nutrition information provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction. The majority of comments that opposed the proposed

footnote statement commented that even in the absence of a DV, consumers can still find quantitative information useful (similar to the listing of monounsaturated and polyunsaturated fats on the nutrition label).

Many of the comments recommended that FDA not move forward with the proposed footnote until the IOM/NAS completes a study, which is underway, of the uses of DRIs in nutrition labeling. The comments noted that the IOM is under contract with FDA, USDA and Health Canada to assess the objectives, rationale, and recommendations for the methodology for selecting reference values for nutrition labeling of foods based on DRIs and will identify guiding principles for use in setting reference values for nutrients on the food label. The comments also noted that the IOM committee is expected to complete its work on this project in mid-2003 and to issue a report in September 2003.

One comment stated that the prescriptive nature of the proposed footnote may also violate international obligations of the United States under the World Trade Organization (WTO). The comment stated that WTO’s Agreement on the Sanitary and Phytosanitary (SPS) Measures requires that SPS measures intended to protect human health be based upon sound science. The comment questions this regarding the proposed footnote statement because it implies a benefit to consumers who avoid consuming *trans* fat foods when the IOM/NAS suggests that eliminating *trans* fats entirely in the diet would lead to greater harm by impeding dietary intake of essential nutrients. The comment also stated that if the proposed footnote statement was not a SPS measure, it would violate WTO’s Agreement on Technical Barriers to Trade, which requires that “technical” regulations fulfill a legitimate purpose and be no more trade restrictive than necessary. The comment expressed the opinion that the proposed footnote statement oversimplifies and misrepresents the IOM/NAS report on which it is based and that the statement is more trade restrictive than necessary because alternatives to such a footnote statement, such as a consumer education program, are available to assist consumers in understanding the quantitative *trans* fat labeling in the absence of a DV.

Some comments expressed concern that the proposed footnote statement would provide a disincentive to the industry such that many foods would be reformulated to reduce or remove *trans* fat but, as a result, saturated fat content would be increased. Other comments expressed concern about the lack of