

products could be reformulated in a manner that would result in net health benefits. Some of these comments stated that *trans* fat is beneficial because foods with *trans* fat replace foods with higher amounts of saturated fat. Some comments stated that feasible reformulations that would lower *trans* fat would also increase saturated fat, thereby reducing or eliminating health benefits. Other comments emphasized that manufacturers need competitive incentives in order to incur the costs of reformulation, and did not agree that the Nutrition Facts panel and label claims in the November 1999 proposal provided sufficient incentives for reformulation.

In the November 1999 proposal, FDA based its estimate of health benefits on scenarios of projected decreases in *trans* fat intake due to labeling and reformulation. As summarized in section VI.C of this document, FDA received specific comments regarding the likely decrease in *trans* fat intake due to expected consumer responses to *trans* fat labeling and due to the projected amount of product reformulation. Based on the comments received, on the provisions of this final rule and on its own reevaluation, FDA has revised its estimate of the expected decrease in *trans* fat intake due to labeling (table 2, section VI.C). Because of uncertainties regarding the magnitude of consumer response to *trans* fat labeling we have chosen a very low estimate of consumer response to the new label, a decrease of 0.1 percent of *trans* fat intake (section VI.C.). As described in section IV of this document, current dietary guidance does not consider *trans* fat to be beneficial, but recommends that intake of both *trans* fat and saturated fat should be limited. When products containing partially hydrogenated fats or oils are reformulated to lower the *trans* fat content, functionality may require the reformulated products to have more saturated fat than the original product. However, as shown in a number of examples included with comments, the total amount of saturated fat plus *trans* fat in the reformulated product is commonly lower than in the original product. Substitution of the reformulated product for the original product in the diet would have net health benefits using Method 1, LDL-C, and even higher health benefits using Method 2, LDL-C and HDL-C. FDA acknowledges that different products have different functionality requirements for fats and oils, and the constraints on reformulation alternatives are different for tub and

stick margarines and spreads, household shortenings, frying fats for snacks and chips, and baking fats for cookies, crackers, cakes and other baked goods. FDA has summarized specific comments regarding reformulation alternatives in section IX.C of this document, has taken these into account in projecting the expected amount of margarine reformulation (table 2), and is accounting for the replacement of *trans* fat with different combinations of macronutrients in its models for calculating changes in valuation of health states in section IX.E.3 of this document. Therefore, FDA does not agree with the comments that feasible reformulations would eliminate health benefits by increasing saturated fat. In section V of this document, FDA stressed the importance of providing information on *trans* fat on the nutrition label to assist consumers in choosing healthier diets. As described in section IX.E.3 of this document, in response to comments regarding reformulation, FDA recognizes that different features of this final rule may tend to either increase or decrease the incentives for reformulation. Therefore, because of this uncertainty, in this analysis FDA is using a deliberately low estimate, 10 percent, for the decrease in *trans* fat intake due to margarine reformulation. Also, FDA is not using a quantitative estimate for any decrease in *trans* fat intake due to reformulation of baked products or of other products containing hydrogenated fats and oils. To the extent that the decrease in *trans* fat intake due to reformulation is greater than FDA's estimate, this analysis will underestimate the benefits of *trans* fat labeling.

(Comment 41) As summarized in section IV.9 of this document, one comment recommended that comparisons of the health effects of saturated fat and *trans* fat should be explicit and consistent throughout the final rule. The comment noted that in FDA's November 1999 proposal, the preliminary regulatory impact analysis estimated that the effects of *trans* fat and saturated fat on LDL-C were similar for a given percent of energy, but the review of the science did not make a gram-for-gram comparison of the effects of saturated and *trans* fat. The comment stated that if there is uncertainty about the comparative effects of saturated fat and *trans* fat on LDL-C, then this should be reflected in FDA's estimate of health benefits. The comment also noted that, in the preliminary regulatory impact analysis, use of Method 2, LDL-C and HDL-C, would approximately double the expected health benefits of

*trans* fat labeling, compared with Method 1, LDL-C. The comment suggested that if the adverse health effects of *trans* fat are approximately double those of saturated fat, this should be taken into account in the provisions for labeling and claims. This comment also suggested that FDA had misinterpreted the relative risk results of the prospective observational studies and questioned whether these studies actually indicated that the risk of CHD due to *trans* fat intake was much greater than would be expected due to LDL-C and HDL-C. According to the comment, relative risk estimates in prospective studies depend on the base risk used for comparisons. Individuals in some study groups, such as the Nurses Health Study, may have lower overall CHD risk than individuals in the general population because the participants are volunteers whose lifestyles may be healthier than average. A systematic difference between the study and general populations may result in inaccuracies when the relative risk from the study population is related to the absolute risk in the general population.

A few comments to the November 15, 2002, notice to reopen the *trans* fat comment period questioned the scientific validity of certain of the observations and conclusions in the IOM/NAS report. The comments stated that the IOM/NAS report relied upon a regression equation in an article by Ascherio et al. (Ref. 83), published in the NEJM, for its observation that *trans* fatty acids may have a more adverse effect on CHD risk than saturated fatty acids and for its conclusion that, similar to saturated fatty acids, there is a positive linear trend between *trans* fatty acid intake and LDL-C and risk of CHD. The comments stated that the Ascherio et al. article was a commentary that was not peer-reviewed and should not be accorded the weight given by the IOM report. Additionally, comments suggested that additional research is needed to establish whether there is a positive linear trend between *trans* fat intake and LDL-C. The comments asserted that there may be an alternate explanation for the results described by Ascherio et al., and mentioned unpublished work done at the University of Cincinnati. The comments did not mention the existence of any other evidence for a linear trend between *trans* fat intake and LDL-C, and implied that, in the absence of the Ascherio article (Ref. 83), there would be no basis for the existence of such a linear trend.

As stated in section IV.9 of this document, regardless of whether FDA reviewed the effects of saturated fat and