

of reported *trans* intakes with current knowledge and methods (64 FR at 62752–62753).

In the November 1999 proposal, FDA reviewed an analysis that used the results of the 1989–1991 Continuing Survey of Food Intakes by Individuals (CSFII), a national food consumption survey of the U.S. population conducted by the USDA (Ref. 26). This study reported a mean *trans* fatty acid intake of 5.3 g/day (2.6 percent of calories) for persons 3 years and older. One way to evaluate the accuracy of survey intake estimates is to compare the reported caloric intakes to known requirements, or to levels from intervention trials that have been shown to maintain body weight for some period of time. The authors of this study stated that these reported caloric intakes were 20–40 percent below known physiologic requirements, suggesting significant under-reporting of intakes (Ref. 26). The reported caloric intakes in the CSFII were also approximately 265 to 1,000 calories/day below levels required to maintain body weights for U.S. subjects in intervention trials (Ref. 26). Therefore, the estimates of intakes from the CSFII survey data are likely significantly under-reported, particularly when expressed on a gram per day basis.

The second type of *trans* fatty acid intake estimate considered in the November 1999 proposal was derived from estimates of *trans* fatty acids available in the U.S. food supply calculated from USDA-Economic Research Service fats and oils production figures and food disappearance data for fats and oils. Three studies provided daily per capita estimates of *trans* fatty intakes of 12.8 g, 10.2 g, and 8.1 g. (Refs. 24, 39, and 25, respectively). Although all three estimates were “corrected” for losses due to waste in processing and use, per capita intake estimates based on disappearance data generally overestimate intakes (Ref. 4).

Finally, observational studies conducted in U.S. populations also can provide intake estimates. In the November 1999 proposal, FDA reviewed several observational studies, including several prospective cohort studies conducted in U.S. populations who were healthy at the time of enrollment (Refs. 19, 21, and 38). Estimates of daily *trans* intakes ranged from 1.3 to 3.2 percent of calories and from 1.5 to 6.4 g/day for adult participants in these studies. These ranges of intake estimates are somewhat lower than those in the CSFII survey so are therefore also likely underestimated. However, even with these relatively low intake estimates,

these studies found that among free-living adults, those adults consuming *trans* fatty acids at the highest quintiles of intake had increased relative risk of CHD as compared to adults consuming *trans* fatty acids at the lowest quintiles of intake.

In summary, the different types of studies, and different studies within a study type, estimated different intake levels for the U.S. population. The estimates from the food disappearance data are likely overestimated. The estimates from the observational studies and the national food consumption survey are likely underestimated. All estimates used the same compositional data base which, as noted above, has very limited data on the *trans* fat content of foods. Although we have no external “gold standard” against which to determine which estimate is most accurate, the available intake estimates suggest that average intakes of U.S. consumers probably fall within the range of 1.3 g to 12.8 g/day.

Because of the multiple sources of uncertainty in intake estimates, caution must be exercised to avoid over-interpretation of the available dietary intake estimates and their relationship to the *trans* fat levels used in the intervention trials. It is important to note, however, that the agency’s determination of the scientific basis for and public health importance of *trans* fat labeling was based on the totality of the scientific evidence. In this evaluation, FDA weighted the results of the intervention trials most heavily. The intervention trials clearly demonstrate, in a cause and effect manner, an adverse effect of *trans* fat intakes on LDL-C levels, and therefore on CHD risk, across a broad range of intakes (less than 1 percent to 7 percent of calories), dietary patterns, and population groups. For the purposes of determining that the scientific evidence was sufficient to conclude that *trans* fat labeling was warranted from a public health perspective, FDA finds that the intervention and observational studies provided strong evidence of both a causal relationship between *trans* fat intake and risk of CHD and applicability to the general U.S. population. Therefore, FDA does not need to rely solely on dietary intake estimates to make this determination.

Because of the serious public health consequences of CHD in the U.S. population, prudent public health dictates that we help consumers control those risk factors which they can alter directly through their own behavior. Heart-healthy diets that limit the intakes of both saturated and *trans* fats can serve this purpose as is evidenced by

recommendations in the recent expert panel reports (Refs. 87, 89 through 91, and 140).

(Comment 6) Many comments addressed the issue of the relevance of intervention study intakes to usual conditions of use in the United States. Some comments expressed concern that FDA’s conclusions relied on intervention studies in which the intakes of *trans* fatty acids were very high and not representative of U.S. intakes of about 5.3 g/day (3 percent of calories).

FDA disagrees with the comments that it relied heavily on intervention trials with high *trans* fat intake. A range of fatty acid intakes was included in the dietary intervention assessments. For example, the four U.S. research investigations with chemical analyses of the diets included a total of 15 study diets (Refs. 12, 13, 34, and 82). These studies included diets with little or no *trans* fat (e.g., 0.4 to 0.6 percent of calories), diets that contained moderate levels of *trans* fat (e.g., 3 to 4 percent of calories), as well as diets with a higher intake of *trans* fat (e.g., 6 to 7 percent of calories). FDA relied on the totality of the evidence, i.e., intervention studies that had *trans* fat intakes that ranged from very low levels (less than 1 percent of calories) to intakes up to 6 to 7 percent of calories and on findings from observational studies that showed an adverse relationship between *trans* fat intakes and CHD risk among U.S. population groups consuming their usual diets.

Thus, in the aggregate, the U.S. intervention studies included an assessment of the effect of a wide range of *trans* fatty acid levels that overlap the range of intake estimates for the U.S. population. As noted in FDA’s response to Comment 5, the relevance of the findings from the intervention studies for the U.S. population are shown by the consistent findings of an adverse relationship between *trans* fat and CHD risk in the prospective studies of free-living U.S. population groups. Thus, the relevance of the *trans* intakes used in the intervention studies for the U.S. population was confirmed by the consistent findings in the prospective studies that showed an adverse association between *trans* intake and CHD risk among free-living U.S. population groups. The recommendations of recent expert panels that Americans limit their intakes of *trans* fat shows that a broad-based scientific agreement exists as to the public health merits of *trans* fat labeling for the U.S. population within the context of current dietary intakes.