

FDA disagrees with this statement. While the agency recognizes that AOCS methods have not been extended to cover matrices other than fats and oils, the AOAC method 996.06 (*Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002) (Ref. 105) is suitable for the analysis of *trans* fat in a wide range of foods of varying fat content. As noted in comment 19, above, AOAC Method 996.01 is not suitable for quantifying *trans* fatty acids for food labeling purposes because the capillary column specified is not sufficiently long to obtain adequate separation of the *cis* and *trans* fatty acids.

(Comment 23) A few comments recommended that FDA consider listing amounts of *trans* fat to the nearest tenth or hundredth of a gram, rather than to the nearest 0.5 g. One of these comments stated that Canada has established a rounding limit of 0.1 g for food labeling indicating that analytical methods are capable of detecting that amount.

FDA disagrees with these recommendations. FDA notes that while these recommended levels might be quantifiable by laboratories using GC methodology such as that described in AOAC method 996.06 (*Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002) (Ref. 105), they will pose a problem for laboratories that are set up to quantify *trans* fatty acids by infrared spectroscopy (IR) methodology because the detection limits of the currently available IR methods are higher than those of the GC methods. More importantly, however, there are no unambiguous methods for confirming the very low levels suggested by the comment.

Moreover, FDA notes that the increment for listing *trans* fat is consistent with increments used for listing total fat and saturated fat. Therefore, the agency is finalizing § 101.9(c)(2)(ii) to state that *trans* fat shall be expressed, as proposed, to the nearest 0.5 g increment below 5 g and to the nearest gram increment above 5 g.

(Comment 24) One comment noted that the IR method of choice in the November 1999 proposal, AOCS Recommended Practice Cd 14d-96 (Ref. 45), generally overestimates *trans* fat at low levels because of interferences and issues with both accuracy and detection limits. The comment noted further that the AOCS GC method Ce 1f-96 (Ref. 46) has better sensitivity, but has not been validated for many types of food products and that significant work is needed to validate this method for other food matrices.

FDA agrees that the detection limits of the AOCS GC method (Ce 1f-96) (Revised 2002, Ref. 146) are lower than those of the AOCS IR recommended practice (Cd 14d-96) (Revised 1999, Ref. 145). FDA notes that AOCS Recommended Practice Cd-14d-96 is applicable to the determination of isolated *trans* double bonds in natural or processed oils and fats with *trans* levels equal or greater than about 0.8 percent. The lower limit of quantitation for this IR recommended practice may be higher (i.e., the method may be less accurate for determination of low levels of *trans* fat) for complex systems such as commercial food products (Ref. 145).

The AOCS Official Method Ce 1f-96 (Ref. 146) is designed to evaluate the level of *trans* isomers formed during refining or during hydrogenation of vegetable oils or fats and the scope of the method does not extend beyond these matrices. FDA notes that the recent improvements in AOAC Official Method 996.06 as referenced in Revision 1, 2002 (Ref. 105), have resulted in the applicability of this GC method to a wide range of food products.

(Comment 25) One comment asked if *trans* fat values below 0.5 g are to be declared as "0," how FDA will address the labeling of foods like butter, where *trans* fat content fluctuates seasonally above and below 0.5 g per serving. The comment stated that FDA should err on the side of conservatism and require that labeling be based on the highest levels found in such products over the entire year.

FDA has long recognized that variations occur naturally in the nutrient content of foods. The compliance procedures that FDA follows, which are found in § 101.9(g)(2), provide that a sample for nutrient analysis must consist of a composite of 12 subsamples, taken one from each of 12 randomly chosen shipping cases. FDA will then analyze the nutrient content of this composite test sample. Upon determination of the laboratory analyses, FDA uses the compliance procedures set forth in § 101.9(g)(5) and (g)(6) to determine if the values declared for those nutrients that have recommended dietary limits, such as saturated fat and cholesterol, misbrand the label. The content of a sample composite of these nutrients is in compliance if the analyzed value is no more than 20 percent greater than the value declared on the label. Stated another way, for nutrients listed in § 101.9(g)(5), the ratio between the nutrient level obtained by laboratory analysis and the product's label value, multiplied by 100, cannot be greater

than 120 percent for the product to be in compliance. For example, if the laboratory value is 4 grams, and a product's label value is 2 gram, the ratio  $(4/2) \times 100 = 200$  percent. This value is greater than 120 percent, hence, the product is out of compliance.

FDA did not address this issue in the proposal because the declaration of "saturated fat" included *trans* fats, and saturated fats are addressed in § 101.9(g)(5) and (g)(6). Now that FDA is requiring that *trans* fat be declared in the main body of the nutrition label (i.e., the amount of *trans* fat is not in a footnote), FDA is making a conforming amendment to § 101.9(g)(5) and (g)(6) to include *trans* fatty acids.

FDA's policy since the 1970s assigns the manufacturer the responsibility for assuring the validity of a product label's stated nutrient values (Ref. 108). Accordingly, the source of the data used to calculate nutrition labeling values is the manufacturer's prerogative, but FDA's policy recommends that the nutrient values for labeling be based on product composition, as determined by laboratory analysis of each nutrient. If a manufacturer knows that a nutrient is likely to vary over seasons or due to other factors (e.g., location, growing conditions, product transport, or processing practices), in order to assure compliance, the manufacturer should analyze samples of the product over the various seasons or relative to other factors to account for variability of nutrient content.

To ensure that label values will accurately represent the nutrient content of food products to consumers and also have a high probability of being in compliance with nutrition labeling regulations, FDA recommends the calculation of a one-sided 95 percent prediction interval as the most appropriate and the preferred method to use in computing label values (Ref. 108).

Prediction intervals take into account the variability of a nutrient. Mean values do not. A manufacturer of a product, like butter, whose *trans* fat content fluctuates seasonally, would want to analyze samples of *trans* fat during each season and statistically consider using 95 percent prediction intervals to calculate the nutrition label value for *trans* fat. A predicted value on a nutrition label may sometimes indicate a level of a nutrient such as saturated fat at a higher level than is actually in the product, but it will never show a lower level than the product contains. While sometimes predicted values and mean values round to the same nutrient level, products bearing mean values on their nutrition labels