

2002 notice (67 FR 69171) to reopen the comment period, about the shortness of the comment period and requests to extend the comment period. However due to the high level of interest in the public health and economic aspects of this rule, the agency did not believe it was in the public interest to provide for additional time for comment. A longer comment period, however, will be provided for the ANPRM being published elsewhere in this issue of the **Federal Register**.

(Comment 18) A few comments requested that the term “*trans* fatty acids” not be used interchangeably with “*trans* fat” as proposed in § 101.9(c)(2)(i)(B) in the November 1999 proposal. These comments stated that the term “fatty acid” would be confusing to consumers and is inconsistent with the terminology used in nutrition labeling and claims for other fatty acids, i.e., “saturated fat,” “polyunsaturated fat,” and “monounsaturated fat.” The comments stated that while “fatty acid” is technically correct, labels should use the easier term to understand, i.e., “*trans* fat.”

The agency agrees that there should be consistent terminology used on the food label and notes that proposed § 101.9(c)(2)(i)(B), which dealt primarily with the proposed footnote about *trans* fat content, is deleted from this final rule. The agency did not move the sentence providing for the use of the term “*trans* fatty acids” to new § 101.9(c)(2)(ii). Therefore, the term “fatty acids” is not to be used on the Nutrition Facts panel.

Conforming Amendments

Because this final rule is making *trans* fat a mandatory nutrient to be placed on a separate line in nutrition labeling, there are a number of conforming amendments throughout § 101.9 that must be made. Section 101.9(c) requires that information on mandatory nutrients, such as saturated fat and *trans* fat, be included in all nutrition labeling unless otherwise excepted from such labeling as provided for in specified paragraphs.

Special provisions within § 101.9(c) allow for shortened formats that provide manufacturers flexibility to omit noncore nutrients (i.e., mandatory nutrients other than calories, total fat, sodium, total carbohydrate, and protein) that are present in insignificant amounts from the list of nutrients and group them in a summary statement at the bottom of the label that states “Not a significant source of _____” (see 58 FR 2079 at 2083, Comment 8, January 6, 1993). These special provisions are

found in § 101.9(c)(1)(ii) for calories from fat, § 101.9(c)(2)(i) for saturated fat, § 101.9(c)(3) for cholesterol, § 101.9(c)(6)(i) for dietary fiber, § 101.9(c)(6)(ii) for sugars, and § 101.9(c)(8)(iii) for vitamin A, vitamin C, calcium, or iron. For consistency with the labeling scheme for these other noncore mandatory nutrients, new § 101.9(c)(2)(ii) provides that if the *trans* fat content is not required and, as a result, not declared, the statement “Not a significant source of *trans* fat” must be placed at the bottom of the table of nutrient values. Also, for added consistency, new § 101.9(c)(2)(ii) will point to an exception to this requirement under § 101.9(f). Section 101.9(f) provides for a simplified format to be used on labels of products containing insignificant amounts of more than half the nutrients required to be in the Nutrition Facts label. Except as specified in § 101.9(f)(4), products that qualify for the simplified format do not have to use the statement “Not a significant source of _____” for noncore nutrients that are omitted from the label under § 101.9(c). An example of such an exception would include when nutrition claims are made for the product.

Current § 101.9(c)(2)(i) requires label declaration of saturated fat content information on a separate line (the “Not a significant source of _____” statement would not be an option), if claims are made about fat or cholesterol and if “calories from saturated fat” is declared. In the November 1999 proposal, § 101.9(c)(2)(i) was amended to also require label declaration of saturated fat content information when claims are made about fatty acids. Current § 101.9(c)(2)(i) did not include claims about fatty acids because at the time that regulation was proposed (56 FR 60478, November 27, 1991), it was thought unnecessary since no claims were proposed for fatty acids that were present at less than 0.5 g per reference amount. However, when the “saturated fat free” claim was established in the final rules (58 FR 2302 at 2331), FDA inadvertently did not amend § 101.9(c)(2)(i) to require the declaration of saturated fat content on a separate line when fatty acid claims were made. As a result, the declaration of saturated fat content was not required when “saturated fat free” claims were made. This is inconsistent with regulations governing claims for all other nutrients that require the listing of the nutrient that is the subject of the claim within the Nutrition Facts panel so that consumers can easily find quantitative information supporting claims made for

a product. Because no comments objected to the proposed requirement in the November 1999 proposal for a label declaration of saturated fat content when fatty acid claims are made, which would require that saturated fat content be listed when a “saturated fat free” claim is used, FDA is finalizing this part of the regulation as proposed. Similarly, new § 101.9(c)(2)(ii) also requires label declaration of *trans* fat content information if claims are made about fat, fatty acids, or cholesterol.

In reference to the statement “Not a significant source of _____” that is to be placed at the bottom of the list of nutrient values, the agency proposed in the November 1999 proposal (64 FR 62746 at 62757) to remove the phrase “in the same type size” in § 101.9(c)(2)(i) where it refers to the size of the statement. This action was intended to correct a technical error in the regulations caused by the fact that current § 101.9(d)(1)(iii) allows the statement, along with all footnotes, to be in type size no smaller than 6 point type while it requires the listing of nutrient values to be in type size no smaller than 8 point type. Accordingly, the phrase “in the same type size” in § 101.9(c)(2)(i) would require the “Not a significant source of _____” statement to be in 8 point type, conflicting with § 101.9(d)(1)(iii). This technical error was addressed in amendments published on August 18, 1993 (58 FR 44063 at 44065–66). To correct the problem, FDA stated at that time (58 FR 44063 at 44065–66) that it was removing the sentence from § 101.9(c)(8)(iii) that required the “Not a significant source of _____” statement to be in the same type size as nutrients listed in the Nutrition Facts panel. However, the agency failed to notice the same error in § 101.9(c)(2)(i), (c)(3), (c)(6)(i), and (c)(6)(ii). Inadvertently, the conflicting sentence was never removed from § 101.9(c)(8)(iii), nor were the statements requiring “in the same type size” removed from any of the other paragraphs. In this final rule, FDA is making the correction in § 101.9(c)(2)(i) and in new § 101.9(c)(2)(ii). The agency intends to remove the phrase “in the same type size” from the remaining sections of § 101.9(c) in the future.

In addition, current nutrition labeling rules provide exemptions for select nutrients when food products qualify for simplified formats (see § 101.9(f)).

FDA is revising § 101.9(f) that pertains to the use of a simplified format when a food product contains insignificant amounts of seven or more of the mandatory nutrients. This section implements section 403(q)(5)(C) of the act, which states that “If a food contains