

cottage cheese) (60 FR 56541, November 9, 1995)) to ensure that the use of nutrient content claims in the labeling of these products would be consistent with the provisions of the NLEA. In the final rule (61 FR 58991, November 20, 1996), FDA revoked all of the previously mentioned standards except for lowfat yogurt and nonfat yogurt. FDA delayed final action on its proposal to revoke these standards for 120 days because of the technical difficulties and economic considerations associated with their revocation (61 FR 58991 at 58999). FDA acknowledged that if the standards for lowfat and nonfat yogurts were revoked, modifying the standardized food yogurt to make the nutrient content claims "lowfat" or "nonfat" under the provisions of § 130.10 would require vitamin A fortification to make the product nutritionally equivalent to full fat yogurt. FDA also acknowledged that such a fortification requirement could potentially result in significant relabeling, reformulation, and equipment costs to manufacturers. The agency had hoped that the 120-day deferral would provide an appropriate balance between the problem the industry was facing and consumers' interest in consistently and fairly labeled foods. Unfortunately, this issue has not been resolved. According to the yogurt standard proposed by NYA, manufacturers would continue to be able to make lowfat and nonfat yogurts without having to meet the nutritional equivalence requirement. FDA seeks comment on whether the yogurt industry is better able and equipped to meet the nutritional equivalence requirements of § 130.10 than it was in 1996 when FDA deferred action on this issue. FDA also seeks comment on the need and appropriateness of continuing to exempt yogurt from the nutritional equivalence requirement, unlike other standardized foods making lowfat and nonfat nutrient content claims.

IV. NYA Requested Amendments

The requested amendments of the yogurt standard and the cultured milk standard submitted by NYA are set forth in the following paragraphs. The following language is as suggested by NYA; FDA has made only minor nonsubstantive changes. FDA will evaluate the need and appropriateness of these regulations proposed by NYA following the receipt of public comments.

NYA's suggested standard of identity for yogurt is as follows:

Section 131.200 Yogurt.

(a) *Description.* Yogurt is the food produced by culturing one or more of the

standard dairy ingredients specified in paragraph (b) of this section. Yogurt contains at least 10^7 CFU/g active yogurt cultures, at the time of manufacture, of the characterizing lactic acid-producing bacteria, *Lactobacillus delbrueckii subsp. Bulgaricus* and *Streptococcus thermophilus*, and the manufacturer may have records demonstrating that, under proper conditions of distribution and storage, the yogurt will contain at least 10^6 CFU/g live and active cultures through the manufacturer's assigned code life (i.e., shelf life) for the product. One or more of the optional ingredients specified in paragraph (c) of this section may also be added. All ingredients used are safe and suitable. Yogurt, before the addition of optional ingredients specified in paragraph (c) of this section, contains not less than 8.25 percent milk solids not fat from the standard dairy ingredients specified in paragraph (b) of this section, and has a pH of 4.6 or lower. Dairy ingredients comprise at least 51 percent of the food's overall ingredients by weight. The food may be homogenized and the ingredients specified in paragraph (b) of this section shall be pasteurized or ultra-pasteurized prior to the addition of the characterizing yogurt bacterial cultures.

(b) *Standard dairy ingredients.* Cream, milk, partially skimmed milk, skim milk, or the reconstituted versions of these standard dairy ingredients may be used alone or in combination. Whey protein concentrate (WPC), minimum protein concentrate 34 percent, may be used if the total quantity of WPC used in this paragraph and paragraph (c) of this section does not result in a quantity of WPC that exceeds 25 percent of the total milk solids not fat. When one or more of the ingredients specified in this paragraph is used, it shall be included in the culturing process.

(c) *Optional dairy ingredients.* (1) Dairy ingredients. Any milk-derived ingredients used for technical or functional purposes.

(2) Optional safe and suitable cultures, in addition to the characterizing cultures.

(3) Safe and suitable sweeteners.

(4) Flavoring ingredients.

(5) Color additives.

(6) Stabilizers and emulsifiers.

(7) Preservatives.

(8) Vitamins and minerals.

(i) If added, vitamin A shall be present in a minimum quantity of 500 International Units (IU) per reference amount customarily consumed (RACC).

(ii) If added, vitamin D shall be present in a minimum quantity of 100 IU per RACC.

(9) Any safe and suitable ingredients added for nutritional or functional purposes.

(d) *Methods of analysis.* (1) Enumeration of live and active cultures—As determined by the method prescribed by the International Dairy Federation.

(2) Milk solids not fat content—Calculated using the following methods from the "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th Ed. (Copies are available from the Association of Official Analytical Chemists, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2417, or available for inspection at the Office of the Federal Register, 800 North Capitol St., NW., suite

700, Washington, DC). Subtract the milkfat content (as determined by the method prescribed in section 16.059 "Roese-Gottlieb Method (Reference method) (11)—Official Final Action, under the heading "Fat") from the total milk solids content (as determined by the method prescribed in section 16.032, "Method I—Official Final Action," under the heading "Total Solids").

(3) pH—As determined under § 114.90(a) of this chapter, "Potentiometric method for the determination of pH."

(e) *Nomenclature.* (1) If the food contains the amount of live and active *Lactobacillus delbrueckii subsp. Bulgaricus* and *Streptococcus thermophilus* cultures as indicated in paragraph (a) of this section, the food is "yogurt," except:

(i) If the finished food complies with the requirements of § 101.62(b)(4)(i) of this chapter, and is not "lowfat yogurt" or "nonfat yogurt," then the food must comply with § 101.62(b)(4)(ii) of this chapter, and the name of the food is "reduced fat yogurt."

(ii) If the finished food contains at least 0.5 g, but not more than 3.0 g, total fat per RACC, then the name of the food is "lowfat yogurt."

(iii) If the finished food contains less than 0.5 g total fat per RACC, the name of the food is "nonfat yogurt."

(2) The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter.

(3) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The word "sweetened" if a sweetener is added without the addition of characterizing flavor.

(ii) The phrase "vitamin A" or "vitamin A added," or "vitamin D" or "vitamin D added," as appropriate. The word "vitamin" may be abbreviated "vit."

(f) *Declaration of ingredients.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

NYA's suggested standard of identity for cultured milk is as follows:

Section 131.112 Cultured Milk/Fermented Milk.

(a) *Description.* Cultured milk or fermented milk is the food produced by culturing one or more of the standard dairy ingredients specified in paragraph (b) of this section with characterizing microbial organisms. One or more of the optional ingredients specified in paragraph (c) of this section may also be added. All ingredients used are safe and suitable. Cultured milk or fermented milk, before the addition of optional ingredients specified in paragraph (c) of this section, contains not less than 8.25 percent milk solids not fat from the standard dairy ingredients specified in paragraph (b) of this section, and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid, before the addition of bulky flavors. Dairy ingredients comprise at least 51 percent of the food's overall ingredients by weight. The food may be homogenized and the ingredients specified in paragraph (b) of this