

III. Matters of Particular Interest to FDA

FDA requests that interested persons submit data and information concerning the need for, and the appropriateness of, revoking the standards for lowfat and nonfat yogurt and amending the standards for yogurt and cultured milk. FDA specifically requests comment on the following provisions set forth in the petition:

1. A single standard of identity for yogurt, which includes provisions for lowfat and nonfat yogurts;
2. A minimum of 10^7 CFU/g of live and active characterizing cultures at the time of manufacture of yogurt;
3. An acidity of pH 4.6 or lower, rather than the current requirement of titratable acidity expressed as lactic acid in yogurt;
4. The use of optional milk-derived ingredients after pasteurization and culturing of yogurt;
5. The use of reconstituted dairy ingredients and WPC as basic dairy ingredients in yogurt, and the specifications related to WPC, when used;
6. The optional use of any milk-derived ingredient that provides a technical or functional purpose in yogurt;
7. The minimum dairy ingredients content requirement of 51 percent of the total weight of yogurt;
8. The use of any safe and suitable nutritive or nonnutritive sweeteners in yogurt;
9. The use of safe and suitable emulsifiers in yogurt;
10. The use of safe and suitable preservatives in yogurt;
11. The use of any safe and suitable ingredient added for a nutritional or functional purpose in yogurt;
12. The use of the descriptor "nonfat" on a yogurt that may contain less than 0.5 g of total fat per RACC (i.e., 225 g for yogurt (21 CFR 101.12));
13. The use of the descriptor "lowfat" on a yogurt that may contain at least 0.5 g but not more than 3.0 g total fat per RACC; and
14. The need to amend the standard for cultured milk to provide for the alternate term "fermented milk" and to make it consistent with any changes made in the standard for yogurt, and the appropriateness of the proposed amendments to the standard for cultured milk.

After reviewing the comments received, FDA will determine the need for, and appropriateness of, each of the amendments requested by NYA and will decide what actions are appropriate. To facilitate comment, in the following

paragraphs FDA discusses some of the amendments requested by NYA.

1. The standards for yogurt and cultured milk proposed by NYA permit the use of any safe and suitable ingredient added for a nutritional or functional purpose. NYA states that this provision is necessary to maintain enough flexibility in the standards to permit the use of novel ingredients as they are developed. FDA recognizes the need for food standards to permit flexibility in food technology, so long as that technology does not alter the basic nature or essential characteristics of the food. The existing regulatory framework governing standardized foods already provides for the addition of substances for a nutritional purpose. Under the provisions of § 130.10, standardized foods may be modified to contain nutrients not specifically permitted by the relevant standard of identity and to make an expressed nutrient content claim defined by FDA regulation. FDA also notes that flexibility in the use of ingredients for a functional purpose may be achieved by specifying the ingredients by functional use category, e.g., "emulsifiers" or "preservatives," rather than by listing the specific ingredients. FDA seeks comment on the need for any functional ingredient categories, in addition to the ones proposed by the petition, in the manufacture of yogurt.

2. NYA proposed amendments to the current standard of identity for cultured milk (§ 131.112) to provide for the alternate term "fermented milk" and to allow the use of currently prohibited ingredients that would be permitted by NYA's proposed standard for yogurt. NYA stated that under its proposed amendments, if the food otherwise meets the yogurt standard of identity but does not contain the characterizing cultures at the required levels, then the food qualifies as cultured milk or fermented milk. The standard of identity for cultured milk has been in place for several decades. In light of consumer experience with the standard for cultured milk, FDA solicits comment on the need to amend it and the appropriateness of the amendments requested by NYA.

3. The current standards for yogurt, lowfat yogurt, and nonfat yogurt permit heat treatment after culturing, with the requirement that such treatment be declared in the name of the food. FDA notes that NYA's proposed standard does not allow for heat treatment after culturing, and seeks comment on the appropriateness of omitting this provision.

4. NYA proposed a maximum pH of 4.6 for yogurt and stated that this level

reflects the lower end of titratable acidity levels found in common industry practice. NYA also stated that measuring pH, rather than titratable acidity expressed as lactic acid, reflects the current industry practice and is a more accurate and convenient method of measuring acidity. FDA seeks comment both on the acidity level proposed by NYA and the use of pH rather than titratable acidity.

5. FDA notes NYA's assertion that consumers expect yogurt to contain significant amounts of live and active cultures, as well as NYA's proposed requirement to measure live and active cultures at the time of manufacture. NYA proposed that manufacturers "may" test their yogurt products to demonstrate that the products, under proper distribution and storage conditions, would be expected to contain at least 10^6 CFU/g of live and active cultures through the manufacturer's designated code life (i.e., shelf life) for the product and at the anticipated time of consumption. However, as a legal requirement, NYA proposed a minimum of 10^7 CFU/g at the time of manufacture because, NYA maintained, once the products enter the stream of commerce, products are subject to different distribution and storage conditions that are not within the manufacturer's control. FDA seeks comment on: (1) Whether the presence of live and active cultures is an essential characteristic of yogurt and, if so, in what amounts; (2) the appropriateness of NYA's proposed provision that manufacturers "may" conduct tests to ensure the presence of live and active cultures through the assigned code life for the product; and (3) whether NYA's proposed standard of identity for yogurt would adequately ensure the presence of appropriate amounts of live and active cultures in yogurt throughout the shelf life of the product and at the point of purchase or consumption. FDA also seeks comment on any alternative provisions that may be needed to fulfill this requirement.

Finally, FDA seeks comment on vitamin A fortification. FDA previously proposed to revoke a number of lowfat and nonfat standards in parts 131 and 133 (21 CFR part 133) (i.e., §§ 131.122 (Sweetened condensed skimmed milk), 131.123 (Lowfat dry milk), 131.132 (Evaporated skimmed milk), 131.135 (Lowfat milk), 131.136 (Acidified lowfat milk), 131.138 (Cultured lowfat milk), 131.143 (Skim milk), 131.144 (Acidified skim milk), 131.146 (Cultured skim milk), 131.185 (Sour half-and-half), 131.187 (Acidified sour half-and-half), 131.203 (Lowfat yogurt), 131.206 (Nonfat yogurt), and 133.131 (Lowfat