

Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

#### SUPPLEMENTARY INFORMATION:

##### I. The Petition

The National Yogurt Association (NYA) submitted a citizen petition on February 18, 2000, requesting that FDA revoke the standards of identity in part 131 (21 CFR part 131) for lowfat yogurt (§ 131.203) and nonfat yogurt (§ 131.206), amend the current standard of identity for yogurt (§ 131.200), and amend the standard of identity for cultured milk (§ 131.112).

In its petition, NYA stated that its proposed standard establishes that: (1) Yogurt is a food product containing a minimum level of certain live and active cultures; (2) takes into account current industry practices; (3) recognizes the need to allow for use of future technologies; and (4) establishes a clear, consistent, modernized, and flexible yogurt standard that would benefit both industry and consumers. Specifically, NYA's proposed yogurt standard: (1) Requires a minimum level of active cultures of  $10^7$  colony-forming units (CFU) per gram (/g); (2) requires an acidity of pH 4.6 or lower; (3) requires a minimum level of total dairy ingredients of 51 percent; (4) provides for preculture homogenization and pasteurization; (5) permits the use of reconstituted milk and whey protein concentrate (WPC) as "standard dairy ingredients"; (6) provides for the use of any milk-derived ingredients under optional dairy ingredients; (7) permits the use of safe and suitable sweeteners, emulsifiers, and preservatives; (8) permits the optional use of any safe and suitable ingredients added for nutritional or functional purpose; and (9) makes provisions for lowfat and nonfat yogurts based on total fat content of the food per reference amount customarily consumed (RACC). In addition, NYA requested that the current standard of identity for cultured milk be amended to "conform" to the proposed standard for yogurt. Specifically, NYA's proposed amendments to the cultured milk standard: (1) Provide for the alternate term "fermented milk"; (2) require a minimum level of total dairy ingredients of 51 percent; (3) permit the use of reconstituted milk and WPC as "standard dairy ingredients"; (4) provide for the use of any milk-derived ingredient under optional dairy ingredients; (5) permit the use of safe and suitable sweeteners, emulsifiers, and preservatives; and (6) permit the use of any safe and suitable ingredients

added for a nutritional or functional purpose.

FDA is publishing this document in accordance with section 701(e)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(1)), which directs the Secretary of Health and Human Services to publish proposals made by petition to amend or repeal a dairy food standard, so long as the petition includes reasonable grounds for the action requested, and to provide interested persons with an opportunity to present their views. FDA tentatively finds that NYA's petition presents reasonable grounds. Therefore, FDA requests comment on whether the actions proposed in the petition would promote honesty and fair dealing in the interest of consumers.

##### II. Grounds for the Suggested Changes to Yogurt, Lowfat Yogurt, Nonfat Yogurt, and Cultured Milk Standards

NYA pointed out that several provisions of the standards of identity for cultured milk, yogurt, lowfat yogurt, and nonfat yogurt are currently stayed (47 FR 41519, September 21, 1982). The stayed provisions are: (1) Those provisions of §§ 131.112(d)(1), 131.200(c)(1), 131.203(c)(1), and 131.206(c)(1) that restrict the type of milk-derived ingredients that may be used, to those so named, to increase the nonfat solids content of cultured milk and yogurts; (2) those provisions of §§ 131.200(a), 131.203(a), and 131.206(a) that exclude the use of reconstituted dairy ingredients as the basic ingredient in the manufacture of yogurts; (3) those provisions of §§ 131.200(c), 131.203(c), and 131.206(c) insofar as they exclude the addition of preservatives to yogurts; (4) those provisions of §§ 131.200(a), 131.203(a), and 131.206(a) that set a minimum titratable acidity of 0.9 percent, expressed as lactic acid; and (5) the provision in § 131.200(a) that the 3.25 percent minimum milkfat level applies to yogurt after the addition of one or more of the optional sources of milk solids not fat listed in § 131.200(c)(1). NYA contended that these stayed provisions create multiple gaps in the standards for which no guidelines exist and, as a result, the integrity of the food "yogurt" is not maintained.

According to NYA, yogurt has been characterized for centuries by its live and active cultures, and thus a minimum content of live and active cultures is crucial to the yogurt standard of identity to promote honesty and fair dealing in the interest of consumers. NYA noted that consumers identify yogurt with live and active cultures and

expect yogurt to contain a significant amount of these cultures when they purchase the product, but have no assurance under the current standard that the yogurt will contain such cultures. NYA maintained that its proposed standard recognizes the defining characteristics of yogurt and establishes that yogurt is a product of fermentation of certain characterizing cultures, and that the finished food contains a significant quantity of these live and active cultures consistent with consumer expectations.

NYA also stated that the proposed amendments to the standard for cultured milk would further serve consumer interest. Under its proposed actions, NYA maintained that foods otherwise satisfying the standard of identity for yogurt that do not contain the required level of the characterizing live and active cultures would not be named "yogurt"; rather they would be named "cultured milk" or "fermented milk." Consequently, NYA stated, consumers would not be misled into believing that these foods contain a significant amount of live and active cultures.

NYA also maintained that its proposal would ensure that aspects of yogurt labeling, such as the use of nutrient content claims, are consistent with the requirements of the Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101-535). NYA stated that its proposed standard maintains the three yogurt types (full fat, lowfat, and nonfat yogurts) so manufacturers can continue to make lowfat and nonfat yogurts without meeting the nutritional equivalence requirement as described in § 130.10 (21 CFR 130.10). In addition, NYA maintained that its proposed standard would change the milkfat content requirements of lowfat and nonfat yogurts to "directly parallel" the nutrient content claim requirements for the terms "lowfat" and "nonfat" established under the NLEA (21 CFR 101.62(b)).

Additionally, NYA noted that food technology has advanced and industry practices related to yogurt manufacturing have changed since the yogurt standards have been in place. Consequently, NYA asserted that the current yogurt standards impede the yogurt industry and do not allow manufacturers to implement advances in food technology. NYA stated that its proposed standard establishes a modernized, flexible standard of identity for yogurt, taking into account current industry practices and recognizing the need to allow for use of future technologies.