



GENERAL MILLS

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January 21, 2004

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

Re: [Docket No. 00P-0685] Milk and Cream Products and Yogurt Products;  
Petition to Revoke Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend  
Standards for Yogurt and Cultured Milk

Dear Sir or Madam:

General Mills is the manufacturer of Yoplait™ yogurt in the United States and is currently the category leader. The yogurt category has become an extremely varied and fast growing area of the grocery store. Between 1997 and 2002, sales of yogurt grew by 40 percent<sup>1</sup>.

Consumers desire more new and innovative yogurt products. The Standards of Identity for yogurt, lowfat yogurt, and nonfat yogurt need to be modernized to provide flexibility that recognizes new and future technologies that will benefit both the consumer and industry. Updating of the standards will also simplify regulatory oversight by clarifying the intent of stayed provisions.

The comments herein focus on the proposed *petition to revoke standards for lowfat yogurt and nonfat yogurt and to amend the standards for yogurt and cultured milk*. **General Mills strongly supports the petition submitted by the NYA with a single modification related to pH provision, which is noted below along with other comments.** General Mills believes that the revisions proposed will provide clarity, consistency, and flexibility for the development of

<sup>1</sup> Mintel Yogurt Report, June 2003

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new yogurt products, processes, and technologies that deliver high quality, safe, and wholesome products for consumers.

Provisions of interest to FDA follow:

1. *A single standard of identity for yogurt, which includes provisions for lowfat and nonfat yogurts.* **General Mills strongly supports one standard of identity for yogurt that includes provisions for lowfat and nonfat yogurts.** Most yogurt available in the US marketplace is currently lowfat or nonfat yogurt. These products have become commonplace to consumers. Many consumers make their yogurt selection based upon the fat level listed on the front panel whether it is for taste, weight management or other needs. By placing lowfat and nonfat standards within the yogurt standard, these products will continue to be labeled clearly for consumers to make their choices. Also, with the one standard, manufacturers will have the opportunity to make yogurt at all fat levels, including those between 2.0 percent and 3.25 percent milkfat, which is currently not an option. This will provide the consumer with more product options available to them. Thus, placing yogurt, lowfat yogurt and nonfat yogurt under the yogurt standard of identity is appropriate.

2. *A minimum of  $10^7$  CFU/g of live and active characterizing cultures at the time of manufacture of yogurt.* **General Mills supports the requirement of a minimum of  $10^7$ CFU/ g of live and active characterizing cultures at the time of manufacture.** Yogurt is characterized by having live and active cultures. They are what distinguish yogurt from other dairy products. Therefore stating a minimum level of live and active cultures is a key criterion in defining the characteristics of yogurt in the standard of identity.

In addition, consumers who are lactose intolerant can tolerate the lactose in yogurt due to the expression of the lactase enzyme by the yogurt bacteria.

The alleviation of the symptoms of lactose intolerance is dependent on the presence of viable yogurt bacteria.<sup>2</sup>

Manufacturers should be responsible for verifying a level of  $10^7$ CFU/ g of live and active characterizing cultures at the time of manufacture. General Mills believes that the program administered by the National Yogurt Association would provide validation that the standard is met. This program is a voluntary program in the US that requires verification that each unique base formula reaches a standard level of culture at the time of manufacture and that the culture remains active throughout shelf-life. A substantial change to the formula requires resubmission of verification data.

Testing the product while it is under the manufacturer's control is appropriate since once it is out of the manufacturer's control there are a variety of factors that may affect the number of live and active cultures. The manufacturer should be held accountable only for what is controllable.

*3. An acidity of pH 4.6 or lower, rather than the current requirement of titratable acidity expressed as lactic acid in yogurt. **General Mills does not support use of pH as the primary measure of acidity.** Rather, General Mills supports the use of titratable acidity (TA) as the basis for acidity requirements, with provisions to allow the use of pH as an indirect measure of acidity. Different formulations and milk supplies may have different buffering capacity, thus yogurts with the same TA may have different pH levels. Also, flavor correlates better with TA than pH. Therefore, TA is a better measurement of total lactic acid content.*

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<sup>2</sup> Savaiano et al. (1984) American Journal of Clinical Nutrition, **40**, 1219; Martini *et al.* (1987). American Journal of Clinical Nutrition, **46**, 636; Rao *et al.* (1991) Milchwissenschaft, **46**, 219

Calibration curves can be created that allow accurate correlation between pH and TA in a given formula. Because current technology makes pH easier and quicker to measure than TA, many have used this approach.<sup>3</sup>

Although General Mills supports TA as the requirement, we do not support the provision of 0.9 percent expressed as lactic acid, which is stayed in the current Standard of Identity. This level of acid is undesirable for US consumers, making the product too tart. We do support the recently adopted Codex standard level of 0.6 percent expressed as lactic acid.

General Mills would propose that the wording in the standard to be changed to: "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 titratable acidity of 0.6 percent or greater, expressed as lactic acid."

*4. The use of optional milk-derived ingredients after pasteurization and culturing of yogurt. **General Mills supports the use of optional milk-derived ingredients after the pasteurization and culturing of yogurt.** See #6 for additional comments.*

*6. The optional use of any milk-derived ingredient that provides a technical or functional purpose in yogurt. **General Mills supports the optional use of any milk-derived ingredient that provides a technical or functional purpose in yogurt.** Updating the yogurt standard of identity to allow the use of milk-derived ingredients for technical or functional purposes only clarifies a practice that is already in place due to a stay in 1982<sup>4</sup>. Instead of designating a list of milk-derived ingredients that may be used, it allows any milk-derived ingredients that provide a technical or functional purpose in yogurt. This*

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<sup>3</sup> A.Y. TAMIME AND R. K. ROBINSON (1999) *Yoghurt Science and technology*, 2<sup>nd</sup> ed. Woodhead Publishing Limited, p. 554

<sup>4</sup> 47 Fed. Reg. at 41519

takes into account the wide range of milk-derived ingredients that are available and new ones that may be developed in the future. Manufacturers may be innovative with new ingredients without waiting for an amendment to the standard.

General Mills supports that milk-derived ingredients may be added during the manufacturing process, before or after pasteurization. The milk-derived ingredients must be safe and suitable, complying with general FDA safety requirements.

*10. The use of safe and suitable preservatives in yogurt.* **General Mills strongly supports the use of safe and suitable preservatives in yogurt.** Since the stay in 1981<sup>5</sup>, the use of safe and suitable preservatives have become a common practice in the industry. Preservatives allow for yogurt to move through the distribution channels and to the consumer with minimal impact on the wholesomeness of the product. Many single serve yogurt products are highly portable and consumers use them outside of the home (e.g., lunchboxes), despite clear “Keep Refrigerated” labeling. Preservatives help to maintain the wholesomeness of yogurt products that may be subjected to abusive temperatures. Preservatives would continue to be labeled according to 21 CFR Part 101. The preservatives added should allow the levels of live and active cultures to continue to meet the requirements listed in the standard.

*11. The use of any safe and suitable ingredient added for a nutritional or functional purpose in yogurt.* **General Mills supports the use of any safe and suitable ingredient added for a nutritional or functional purpose in yogurt.** Innovation and increasing variety are primary growth drivers for the yogurt category. With this added provision to the standard of identity, manufacturers would be able to provide additional new products with novel

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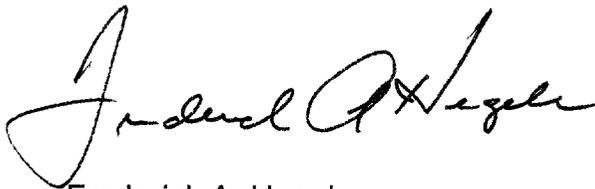
<sup>5</sup> 47 Fed. Reg. at 41519

ingredients to consumers that they cannot provide now. The integrity of the yogurt would be protected by the other provisions of the standard of identity, including the requirements for percent dairy ingredients, the live and active culture and a standard for acidity.

Furthermore, it should be clarified that all ingredients under, (c) optional ingredients, may be added before or after pasteurization. The optional ingredients must be safe and suitable, complying with general FDA safety requirements.

In addition, it should be clarified that the use of any safe and suitable substance/ingredient added for a non-functional purpose (processing aid) in yogurt is permitted under 21 CFR 101.100.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Frederick A. Hegele". The signature is fluid and cursive, with a large initial "F" and "H".

Frederick A. Hegele

Senior Regulatory Officer