



June 20, 2005

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

Re: Comments to the Advance Notice of Proposed Rulemaking on Food Labeling:
(Docket No. 2004N-0456).

Dear Sir or Madam:

The National Yogurt Association (“NYA”) is pleased to submit these comments to the Food and Drug Administration (“FDA” or the “Agency”) in response to the Advance Notice of Proposed Rulemaking (“ANPR”) on “Food Labeling: Serving Sizes of Products That Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes,” (hereinafter referred to as the “Serving Size ANPR”) published in the *Federal Register* of April 4, 2005.¹

¹ 70 Fed Reg. 17010 (April 4, 2005).



NYA is the national nonprofit trade association representing the producers of live and active culture (“LAC”) yogurt products as well as suppliers to the yogurt industry. NYA’s member companies are among the largest yogurt manufacturers in the United States. NYA sponsors scientific research regarding the health benefits associated with the consumption of yogurt with LAC and serves as an information resource to the American public about these attributes.

For refrigerated yogurt, regulations specify that reference amount customarily consumed (“RACC”) as 225 grams (“g”) (or 8 ounces (“oz”)). This RACC, however, is based on data that are decades old. Indeed, more recent data from the National Health and Nutrition Examination Survey (“NHANES”) show that the mean and median amount consumed for yogurt have significantly declined and a more accurate RACC is 170 g (6 oz). Accordingly, NYA respectfully requests that the Agency update the RACC for refrigerated yogurt to reflect the current amount customarily consumed.

I. Background on the Serving Size ANPR

As part of its efforts to combat the rise of obesity, the FDA created the Obesity Working Group (“OWG”). The OWG developed an action plan to, among other things, help consumers lead healthier lives through better nutrition. To achieve this goal, the OWG recommended that the Agency develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity, which include reevaluating the existing RACCs.²

Under the Federal Food, Drug and Cosmetic Act (“FD&C Act”), serving size is statutorily defined as “an amount customarily consumed.”³ To comply with this statutory requirement FDA developed RACCs for food products based three statistical estimates of food consumption data: (1) mean (i.e., average); (2) median (i.e., 50th percentile value); and (3) mode (i.e., most frequently consumed amount).⁴ At the time the RACC for yogurt was developed, the data demonstrated that the 225 g was appropriate. However, recent data show that this figure no longer represents current consumption amounts for yogurt.

² 70 Fed. Reg. at 17012.

³ FD&C Act § 403(q). (21 U.S.C. § 343(q)).

⁴ 56 Fed. Reg. 60394 (Nov. 27, 1991).

II. Yogurt is an Important Part of the Daily Diet

Yogurt is a nutrient dense food and contains many essential minerals and vitamins, including riboflavin B2, Vitamin B12, phosphorous and potassium. These products are made from nonfat, lowfat and, more recently, whole milk, which allows consumers to choose a variety of fat levels. Sugar content may also vary for yogurt with “light” and reduced calorie products. In addition, yogurt is a good source of protein and calcium. On average, an 8 oz serving contains 8-10 g of protein, or 16-20% of the Daily Recommended Value (“DRV”). After culturing, the amount of protein in yogurt can even exceed that of fluid milk.⁵

Yogurt is also commonly known as an excellent source of calcium, which is important in developing and maintaining strong, healthy bones and helps to regulate blood pressure in women during pregnancy.⁶ The Dietary Guidelines for Americans 2005 notes that studies specifically on milk and other milk products, such as yogurt and cheese, showed a positive relationship between the intake of milk and milk products and bone mineral content or bone mineral density in one or more skeletal sites.⁷ Recent studies also suggest that increasing calcium may reduce the risk of colon cancer.⁸ Some yogurts contain up to 35% of the Recommended Daily Intake (“RDI”) for calcium. In fact, a serving size of yogurt may contain slightly more calcium than an equivalent serving of milk.⁹

Consumers have become increasingly aware that yogurt contains nutritional and other health benefits. Indeed, yogurt consumption has doubled in 17 years and tripled in 21 years with retail sales reaching nearly \$2.8 billion in 2003.¹⁰ With these figures, it is clear

⁵ NYA, “Health Update,” (<http://www.aboutyogurt.com/healthUpdate/>).

⁶ Shield, Jodie, “The Importance of Dietary Calcium,” (<http://www.aboutyogurt.com/expertsCorner/shieldCalcium.asp>).

⁷ Department of Health and Human Services, and USDA, “Dietary Guidelines for Americans,” chapter 5, page 26 (2005).

⁸ Shield, Jodie, “The Importance of Dietary Calcium,” (<http://www.aboutyogurt.com/expertsCorner/shieldCalcium.asp>).

⁹ NYA, “Health Update,” (<http://www.aboutyogurt.com/healthUpdate/>).

¹⁰ NYA, “Know It’s Yogurt” brochure, (April 2005).

that Americans are consuming more yogurt and these products are becoming an integral part of a healthy diet.

III. RACC for Refrigerated Yogurt Should be Changed to 170g (6 oz)

A. Method for Developing RACC

As briefly mentioned above, the FD&C Act requires FDA to establish serving sizes for food products based on the amount customarily consumed.¹¹ After the enactment of the Nutrition Labeling and Education Act of 1990 (“NLEA”),¹² FDA set forth the methodology for establishing RACCs.¹³ Using data from U.S. Department of Agriculture (“USDA”) food consumption surveys,¹⁴ FDA developed RACCs for food products based three statistical estimates: (1) mean (i.e., average); (2) median (i.e., 50th percentile value); and (3) mode (i.e., most frequently consumed amount).¹⁵ Following extensive notice and comment rulemaking, FDA established 225 g (8 oz) as the RACC for yogurt.

B. The Yogurt RACC No Longer Reflects Current Consumption Data and Must be Updated

The RACC specified in the regulations was derived from old data obtained from the 1977-1978 and 1987-1988 consumption surveys.¹⁶ However, recent consumption data show that the RACC for yogurt has significantly declined and 225 g no longer reflects the amount customarily consumed.

With the availability of NHANES data, it is possible to evaluate accurate and current consumption information for yogurt. NHANES is a complex multistage probability

¹¹ FD&C Act § 403(q). (21 U.S.C. § 343(q)).

¹² Public Law No. 101-535.

¹³ 56 Fed. Reg. 60394 (Nov. 27, 1991); 58 Fed. Reg. 2229 (Jan. 6, 1993).

¹⁴ USDA, Nationwide Food Consumption Survey/Individual – Spring to Winter Quarters 1977-1978; and USDA, Nationwide Food Consumption Survey/Individual Intake – 1987-1988.

¹⁵ 56 Fed. Reg. 60394 (Nov. 27, 1991).

¹⁶ 58 Fed. Reg. at 2236-2237.

sample of the civilian United States population. The survey collects 1-day food intake data, in addition to nutrition, demographic, and health information. NHANES is administered in different locations in the United States over the 2-year period and also involves interviews, a physical exam, and laboratory tests.

For purposes of calculating yogurt consumption, NHANES data from 1999-2000 and 2000-2001 were analyzed. Total participants included 9,965 subjects in the 1999-2000 survey and 11,039 subjects in the 2000-2001 survey. These subjects were further selected into a subgroup to reflect consumption data for the specific population of 4 years and older, similar to the requirement for the RACC.¹⁷

The same statistical measures that were used to develop the original RACC for yogurt were obtained using the more recent 1999-2000 and 2000-2001 NHANES data. It was determined that the mean amount of yogurt consumed per eating occasion (“EO”) for the entire NHANES population was 166.4 g/EO (or 5.87 oz), and the median was 168.9 g/EO (or 5.96 oz). Yogurt consumption in 90th percentile for the entire NHANES population was 245.0 g/EO (or 8.64 oz). For the subgroup of the NHANES population (i.e., 4 years and older), the mean consumption was 172.4 g/EO (or 6.1 oz) and median was 169.4 g/EO (or 5.97 oz), while the 90th percentile was 245.3 g/EO (or 8.65 oz). These figures are summarized in the table below.

	Mean	Median	90th Percentile
Entire NHANES Population	166.4 g/EO (5.87 oz)	168.9 g/EO (5.96 oz)	245.0 g/EO (8.64 oz)
NHANES subpopulation of all subjects 4 years and older	172.4 g/EO (6.1 oz)	169.4 g/EO (5.97 oz)	245.3 g/EO (8.65 oz)

¹⁷ 21 C.F.R. § 101.12.

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Both the mean and median results for the consumption data in the NHANES populations clearly show that Americans consume approximately 170 g (6 oz) of yogurt per eating occasion. Indeed, the amount specified in the regulations as the RACC for yogurt (i.e., 225 g (8 oz)) is closer to the amount consumed by the 90th percentile of these populations.

To comply with the statutory definition of serving size, FDA should modify the RACC for yogurt to reflect current and accurate consumption data. In addition, the positive nutrient profile of yogurt is not substantially altered by lowering the serving size. Indeed, a 6 oz yogurt product remains a nutrient dense healthy food choice. Therefore, NYA respectfully requests the Agency to amend the existing RACC for yogurt from 225 g (8 oz) to 170 g (6 oz).

If you have any questions or require additional information, please do not hesitate to contact us.

Respectfully submitted,

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National Yogurt Association

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