



## National Milk Producers Federation

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*"Connecting Cows, Cooperatives, Capitol Hill, and Consumers"*

Agri-Mark, Inc.  
Arkansas Dairy Cooperative Association  
Associated Milk Producers, Inc.  
Continental Dairy Products, Inc.  
Cooperative Milk Producers Assn.  
Dairy Farmers of America, Inc.  
Dairymen's Marketing Cooperative, Inc.  
Dairyalea Cooperative Inc.  
Ellsworth Cooperative Creamery  
Farmers Cooperative Creamery  
First District Association  
Foremost Farms USA  
Just Jersey Cooperative, Inc.  
Land O'Lakes, Inc.  
Lone Star Milk Producers, Inc.  
Manitowoc Milk Producers Coop.  
MD & VA Milk Producers Cooperative Association, Inc.  
Michigan Milk Producers Assn.  
Mid-West Dairymen's Company  
Northwest Dairy Association  
Prairie Farms Dairy, Inc.  
St. Albans Cooperative Creamery, Inc.  
Scioto County Co-op Milk Producers' Assn.  
Select Milk Producers, Inc.  
Southeast Milk, Inc.  
Swiss Valley Farms, Co.  
Tillamook County Creamery Assn.  
United Dairymen of Arizona  
Upstate Niagara Cooperative, Inc.  
Zia Milk Producers

July 28, 2010

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

### **Re: Point-of-Purchase Nutrition Information (Front-of-Pack and Shelf Tag Nutrition Symbols), Docket No. FDA-2010-N-0210**

To whom it may concern:

The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. NMPF's 30 member cooperatives produce the majority of the U.S. milk supply, making NMPF the national policy voice of more than 40,000 dairy producers.

NMPF is pleased to submit comments on point-of-purchase nutrition information. Per the Federal Register notice<sup>1</sup>, the Food and Drug Administration (FDA) is interested in data related to nutrition information on the principal display panel (PDP) of food products and the role it plays in food purchasing decisions by consumers. Information requested by FDA mainly focused on design considerations and extent of consumer use and understanding of "front-of-pack" labeling (FOP) or shelf tags in retail stores. In addition to the value of front-of-pack claims and symbols available to a consumer making food purchases, NMPF would also like to stress the importance that the name of the food on a package plays in conveying nutrition information to the consumer.

FDA regulations require specific information (e.g. the name of the food) to appear on the PDP of all packaged foods. The name of the food will either be determined by the product's standard of identity or its common or usual name. Many food products have

<sup>1</sup> "Front-of-pack and shelf tag nutrition symbols; Establishment of docket; Request for comments and information." Federal Register (April 29, 2010) 75: 22602-22606.

**Jerry Kozak, President/Chief Executive Officer**

**Randy Mooney, Chairman**

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established standards of identity, which may specify compositional characteristics and/or manufacturing parameters for the product, for example those for milk, yogurt, cheeses, and ice cream (21 CFR 131.110, 131.200, 133, and 135.110, respectively).

Products for which no standard of identity has been established may be placed on the market under an apt “common or usual name” so long as that name is not confusingly similar to the name of another food and it must describe the basic nature of the food<sup>2</sup>; however, if the name is likely to cause confusion, the product is misbranded, within the meaning of section 403(g) of the Federal Food, Drug, and Cosmetic Act. For example, a product is misbranded if the product name includes a standardized food name, e.g., “milk”, as part of a name for that product, e.g., “soymilk.” The FDA has so ruled on a number of occasions, issuing warning letters to several manufacturers who have misbranded foods by misusing names of standardized dairy products<sup>3</sup>. Adding the name of a plant material in front of the word “milk” does not result in an appropriate name for non-dairy products, as these products do not contain milk or milk ingredients, the plant-based liquids are not permitted ingredients in milk, nor do they represent the common or usual names of these beverages. NMPF has addressed the category of plant-based imitation dairy products that are marketed using the names of standardized dairy products (e.g., soymilk, rice yogurt, etc.) from a regulatory standpoint in previous communications with FDA and has illustrated the lack of compliance of these misbranded non-dairy products with the standards of identity for the products they attempt to imitate<sup>4</sup>.

Standards of identity were designed to maintain the integrity of food products, to ensure that foods meet the expectations of the consumer, and to promote honesty in the marketplace. The lack of enforcement by FDA of the long-standing labeling provisions of various standards of identity for milk and dairy products and other pertinent federal

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<sup>2</sup> 21 Code of Federal Regulations 101.3.

<sup>3</sup> FDA Warning Letter dated August 8, 2008 from Alonza E. Cruse, District Director, FDA Los Angeles District to Mr. Long H. Lai, Lifesoy, Inc.;

Letter dated July 18, 1985 from Lillie Taylor, Assistant to the Director, Division of Regulatory Guidance, CFSAN to C. Hwang, Dr. Chung’s Foods Company, Ltd.;

Letter dated September 29, 1983 from James R. Taylor, Jr., Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods to Mr. Kok Ee Lynn, Senior Officer, Singapore Institute of Standards and Industrial Research.

<sup>4</sup> Letter dated April 28, 2010 from Jerry Kozak, President and CEO, NMPF to Margaret A. Hamburg, Commissioner, FDA;

Letter dated November 2, 2001 from Dr. Robert Byrne, Vice President, Regulatory Affairs, NMPF to Dr. Christine Lewis, Director of Office of Nutritional Products, Labeling and Dietary Supplements;

Letter dated February 14, 2000 from Dr. Robert Byrne, Vice President, Regulatory Affairs, NMPF to Joseph Levitt, Director, CFSAN.

labeling regulations has led to rampant consumer fraud related to the inferior nutrient content of these non-dairy products compared to their true dairy counterparts.

The name of a food as it appears on the front of the package does convey nutritional information to the consumer about the product. In fact, preliminary consumer survey data indicate that consumers think non-dairy alternatives with the term “milk” or “yogurt” in their name contain protein, vitamins, and minerals that are equivalent to what is present in dairy milk or yogurt, respectively. However, although many of these non-dairy beverages and foods are fortified with calcium and other nutrients associated with dairy products, a market basket survey indicates these products are nutritionally inferior to the dairy product they are trying to imitate (see Tables 1 and 2, attached). Often only certain nutrients are fortified and/or the level to which they are fortified is below that of dairy milk. Tables 1 and 2 illustrate the significant variability among and within the category of plant-based imitation “milks” and “yogurts”, respectively, in terms of their formulations or compositions and their nutrient profiles. Regardless of what nutrients are added to the product and therefore declared on the label, there is also variability among plant-based beverages in terms of the actual consumption<sup>5,6,7,8,9,10</sup> (due to sedimentation) and ultimate bioavailability<sup>11,12,13,14</sup> of these nutrients.

While consumers who conduct a thorough comparison of the Nutrition Facts panels and ingredient statements would be able to discern the nutritional differences between dairy products and plant-based imitation foods (as is shown in Tables 1 and 2), the majority of consumers spend very short periods of time (less than 15 seconds) looking at food

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<sup>5</sup> Heaney, R. P., K. Rafferty, and J. Bierman. 2005. Not all calcium-fortified beverages are equal. *Nutrition Today* 40:39-44.

<sup>6</sup> 2002. The challenge of calcium fortification in beverages *in* *Innovations in Food Technology*. Jungbunzlauer, Issue 14, p 26-28.

<sup>7</sup> Munchbach, M. and G. Gerstner. 2010. Calcium fortification in dairy products. *Food Marketing & Technology*. February issue, p 4-8.

<sup>8</sup> Gerstner, G. 2004. Feasibility of calcium fortification in dairy and soy drinks. *Wellness Foods Europe*. October/November issue, p 24-29.

<sup>9</sup> Wade, M. A. 2004. Calcium: The chosen form. *Prepared Foods*. May issue.

<sup>10</sup> Heaney, R. P., and K. Rafferty. 2006. The settling problem in calcium-fortified soybean drinks. *Journal of the American Dietetic Association* 106:1753.

<sup>11</sup> Heaney, R. P., K. Rafferty, and J. Bierman. 2005. Not all calcium-fortified beverages are equal. *Nutrition Today* 40:39-44.

<sup>12</sup> Heaney, R. P., K. Rafferty, M. S. Dowell, and J. Bierman. 2005. Calcium fortification systems differ in bioavailability. *Journal of the American Dietetic Association* 105:807-809.

<sup>13</sup> Zhao, Y., B. R. Martin, and C. M. Weaver. 2005. Calcium bioavailability of calcium carbonate fortified soymilk is equivalent to cow's milk in young women. *Journal of Nutrition* 135:2379-2382.

<sup>14</sup> Heaney, R. P., M. S. Dowell, K. Rafferty, and J. Bierman. 2000. Bioavailability of the calcium in fortified soy imitation milk, with some observations on method. *American Journal of Clinical Nutrition* 71:1166-1169.

packages when making food purchases<sup>15</sup>. Many consumers rely on visual cues from the front of the package (the product imagery, style of packaging, nutrient claims) **and the name of the food** to make inferences about the nutrient content of the product. *Given their physical state, similar packaging, images on the label, recommended uses, label claims (e.g. “as much calcium as milk”), along with the inclusion of the term “milk” in the name of the product on the PDP, consumers are being misled into thinking these imitation beverages are nutritionally equivalent to dairy milk.* This consumer assumption was recently acknowledged by the 2010 Dietary Guidelines Advisory Committee in their discussion of non-dairy calcium sources:

“A lot of the things, like soy milk and rice milk and the alternatives, don’t have the same nutrient composition (as milk). So, make sure people understand that.”<sup>16</sup>

Therefore, as the effect of nutrition symbols and schemes on food packages is evaluated, NMPF reminds FDA that the name of the food also has an impact on consumers’ perception of the nutritional value of a product. Capitalizing on the dairy halo of good health by pairing a standardized dairy term – like “milk” or “yogurt”, which consumers expect to contribute specific essential nutrients to the diet – with nutritionally-inferior, non-standardized, formulated plant-based foods is defrauding the consumer by misrepresenting the true nutrient content of these imitation products. The names of non-dairy alternatives must reflect current regulations and standards of identity, and should not mislead consumers as to the true nutrient value of the product. NMPF again requests the FDA to significantly increase enforcement efforts to prevent the misbranding of certain food items that are imitations of standardized dairy products.

Please contact NMPF if you would like any additional information.

Sincerely,



Beth Panko Briczinski, Ph.D.  
Director, Dairy Foods & Nutrition

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<sup>15</sup> Sutherland, L. A., L. A. Kaley, and L. Fischer. 2010. Guiding Stars: The effect of a nutrition navigation program on consumer purchases at the supermarket. *American Journal of Clinical Nutrition* 91(suppl):1090S-1094S.

<sup>16</sup> Slavin, J. Archived recordings of the Sixth (Final) Meeting of the 2010 Dietary Guidelines Advisory Committee May 12, 2010. From audio transcript Section 2, 2:16 (hr:min).

Table 1. Market Basket Survey: Nutrient Composition of Misbranded Non-Dairy Plant-Based Beverages Compared to Lowfat Milk. Shaded cells indicate a lack of nutritional equivalence (greater amount of sodium or calories; lesser amounts of other essential nutrients) of the non-dairy beverages compared to lowfat milk.

Products <sup>1</sup>	Nutrient Composition (per serving)											
	Calories	Protein (g)	Sodium (mg)	Potassium (mg)	Vitamin A (%DV)	Calcium (%DV)	Calcium Fortificant <sup>2</sup>	Vitamin D (%DV)	Phosphorus % DV	Riboflavin (%DV)	Vitamin B-12 (%DV)	Magnesium (%DV)
<i>Milk<sup>3</sup> lowfat, 1%, with added vitamin A and vitamin D</i>	102	8	107	366	10	30	na	32	23	27	18	7
<b>Soy-Based Beverages</b>												
365 Everyday Value™ Original Soymilk	90	6	110	350	10	30	CC	30	8	40	50	8
8th Continent® Original Regular Soymilk	80	8	95	360	10	30	CP	25	25	30	20	6
Archer Farms® Plain Soymilk	100	7	120	ns <sup>4</sup>	10	30	CC	30	ns	30	50	ns
Edensoy® Original Soymilk	140	11	105	440	0	10	CC	ns	15	6	ns	15
Harris Teeter® Vanilla Organic Soymilk, Ultra-Pasteurized	90	7	130	300	10	30	CC	30	ns	30	50	ns
Nature's Promise® Vanilla Organic Soymilk, Ultra-Pasteurized	90	7	130	300	10	30	CC	30	ns	30	50	ns
Pearl® Original Organic Soy Milk	110	7	110	300	20	30	CP	35	ns	ns	ns	ns
Silk®, Original, Plain Soymilk (Natural)	100	7	120	300	10	30	CC	30	ns	30	50	10
Soy Dream® Classic Original Soymilk	130	7	150	140	0	4	na	ns	ns	ns	ns	15
Trader Joe's® Original Organic Soy Milk	90	7	70	290	10	30	CC	30	ns	30	50	ns
Vitasoy® Plain Soymilk	110	7	160	320	6	30	CC	20	20	20	15	10
WestSoy® LowFat Plain Soymilk Drink	80	4	90	150	10	20	CP	25	15	ns	ns	ns
Wild Harvest® Original Soy Milk	100	6	160	ns	10	30	CC	ns	ns	ns	ns	ns
WildWood™ Plain Organic Soymilk	90	7	70	290	20	30	CC	30	10	40	50	10

	Nutrient Composition (per serving)											
Products <sup>1</sup>	Calories	Protein (g)	Sodium (mg)	Potassium (mg)	Vitamin A (%DV)	Calcium (%DV)	Calcium Fortificant <sup>2</sup>	Vitamin D (%DV)	Phosphorus % DV)	Riboflavin (%DV)	Vitamin B-12 (%DV)	Magnesium (%DV)
Milk <sup>3</sup> lowfat, 1%, with added vitamin A and vitamin D	102	8	107	366	10	30	na	32	23	27	18	7
ZenSoy Plain Soy Milk	110	7	80	ns	10	30	CC	30	ns	30	50	ns
<b>Rice-Based Beverages</b>												
Good Karma Foods Organic Original Whole Grain <sup>®</sup> Ricemilk	100	1	140	ns	10	25	CP	25	15	ns	25	ns
Wild Harvest <sup>®</sup> Original Rice Milk	100	0	90	ns	10	30	CP	ns	ns	ns	ns	ns
B.R.A.T. <sup>™</sup> Organic Original Ricemilk	100	1	130	ns	10	30	CL	10	ns	ns	10	ns
Nature's Promise <sup>®</sup> Vanilla Enriched Ricemilk	120	0	95	ns	10	30	CP	30	15	30	50	ns
Harris Teeter <sup>®</sup> Naturals Vanilla Ricemilk	120	0	95	ns	10	30	CP	30	15	30	50	ns
Cereal Match <sup>®</sup> Rice Milk	100	1	50	120	10	10	CL	10	ns	ns	ns	ns
<b>Almond-Based Beverages</b>												
Silk <sup>®</sup> Pure Almond <sup>™</sup> Original Almondmilk	60	1	150	150	10	30	CC	25	6	2	ns	4
Blue Diamond <sup>®</sup> Almond Breeze <sup>®</sup> Refrigerated Original Almondmilk	60	1	150	180	10	30	CC	25	2	2	ns	4
<b>Hemp-Based Beverages</b>												
Pacific <sup>™</sup> Foods Hemp Milk Original	160	4	130	170	10	50	CP	30	30	35	25	25
Living Harvest <sup>®</sup> Foods Tempt <sup>™</sup> Original Hempmilk	100	2	25	ns	10	40	CP	20	20	25	20	15
Original Hemp Bliss <sup>®</sup> Organic Hempmilk	110	5	95	ns	0	2	na	ns	ns	ns	ns	ns
<b>Peanut-Based Beverages</b>												
Signs & Wonders <sup>®</sup> Peanut Milk	110	3	15	91	0	0	na	ns	ns	ns	ns	ns

<sup>1</sup>The list of products is not exhaustive, because of numerous varieties of each brand. Products are representative in terms of what is currently available. When multiple products were manufactured under a single brand name, when possible, the product selected was that which was most comparable to the dairy product (i.e., plain, unsweetened varieties).

<sup>2</sup>Abbreviations for type of calcium fortificant:

na = not applicable (no exogenous calcium fortificant)

CC = calcium carbonate

CP = calcium phosphate or tricalcium phosphate

CL = calcium lactate

<sup>3</sup>Values obtained from USDA National Nutrient Database for Standard Reference ([www.ars.usda.gov](http://www.ars.usda.gov)).

<sup>4</sup>ns = "not specified" These nutrients are not required to appear on the nutrition information panel. However, it should be noted that the products are not fortified with these nutrients, and therefore are not likely a significant source.

Table 2. Market Basket Survey: Nutrient Composition of Misbranded Non-Dairy Foods (Yogurt Analogs) Compared to Lowfat Yogurt. Shaded cells indicate a lack of nutritional equivalence (greater amounts of sodium or calories; lesser amounts of other essential nutrients) of the non-dairy foods compared to lowfat yogurt.

Products <sup>1</sup>	Nutrient Composition (per serving)										
	Calories	Protein (g)	Sodium (mg)	Potassium (mg)	Vitamin A (%DV)	Calcium (%DV)	Vitamin D (%DV)	Phosphorus (%DV)	Riboflavin (%DV)	Vitamin B-12 (%DV)	Magnesium (%DV)
<i>Yogurt<sup>2</sup>, plain, lowfat, 12 g protein per 8 oz.</i>	154	8	104	352	4	28	1	21	19	15	7
Yogurt Analogs											
Wildwood™ Soyogurt, Unsweetened, Plain	110	7	53	320	0	27	0	13	11	0	11
Ricera™ Vanilla Rice Yogurt	180	4	213	93	27	27	27	ns	ns	ns	ns
Stonyfield O'Soy Organic Vanilla Soy Yogurt	150	9	53	413	3	20	ns	13	13	0	13
Silk® Live!® Vanilla Soy Yogurt	150	7	27	ns	0	40	ns	ns	ns	ns	ns
Whole Soy & Co.® Plain Soy Yogurt	190	11	20	ns	3	47	ns	ns	ns	ns	ns

<sup>1</sup>The list of products is not exhaustive, because of numerous varieties of each brand. Products are representative in terms of what is currently available. When multiple products were manufactured under a single brand name, when possible, the product selected was that which was most comparable to the dairy product (i.e., plain, unsweetened varieties).

<sup>2</sup>Values obtained from USDA National Nutrient Database for Standard Reference ([www.ars.usda.gov](http://www.ars.usda.gov)).

<sup>3</sup>ns = "not specified" These nutrients are not required to appear on the nutrition information panel. However, it should be noted that the products are not fortified with these nutrients, and therefore are not likely a significant source.