

Dairy Vs. Plant-Based 'Milks': A Regulatory Standoff

By **Katie Gates Calderon, Elizabeth Fessler and Lindsey Heinz**

Law360, New York (August 24, 2017, 10:59 AM EDT) -- You may have noticed a vast change in the dairy aisle at your local supermarket in recent years as plant-based milk alternatives have grown increasingly popular among consumers. In fact, sales of nondairy milk products more than doubled from 2009 to 2015 alone.[1]

Beyond more familiar products like soy and almond milk, the plant-based milk industry now includes products like pea milk and hemp milk. The increasing alternative market has been driven by a range of factors, from food allergies to ethical concerns about the treatment of animals.

As plant-based milk alternatives take up more shelf space at supermarkets, the definition of what constitutes “milk” has become a hot-button issue in the United States, with legislative, regulatory and litigation movement seeking to clarify — and often, to limit — which food products may be classified or labeled as “milk.”

Milk: What Counts Under FDA’s Current Regulatory Scheme?

The U.S. Food and Drug Administration defines milk as “the lacteal secretions ... obtained by the complete milking of one or more healthy cows.”[2] Further, FDA regulations require that new foods resembling and substituting traditional foods be called “imitation” if the new food contains less protein or essential vitamins or minerals than the original.[3]

Given these parameters, dairy industry groups like the National Milk Producers Federation (NMPF) argue that plant-based milk producers are attempting “to profit from milk’s good name by emulating the wording, but not the superior nutrition, of our products.”[4] As the NMPF recently stated, “Regardless of what food technologists might try, milk still only comes from mammals.”[5]

In the face of this rapidly-changing market and the consistent labeling of plant-based beverage products as “milk,” the dairy industry alleges that FDA has done little to enforce the definition. For example, the FDA referenced the issue in 2008 and 2012 warning letters to soy product manufacturers, but ultimately did not



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utilize its enforcement powers to prohibit the use of the term “milk” on the products in question.[6]

According to critics in the dairy industry, the FDA’s inaction has effectively “allowed” soy, almond, coconut or other plant-based milk manufacturers to use “milk” on their labels without repercussions. That said, the FDA has not taken any action to affirmatively approve the use of the term “milk” on plant-based products, either.

For example, the FDA never made a determination on the Soyfood Association of North America’s (SFA) citizen petition — submitted in 1997 — to issue a regulation recognizing the name “soymilk” as an appropriate common or usual name established through common usage.[7] In short, both manufacturers and counsel advising them are left without a clear answer regarding the proper labeling of plant-based milk products.

Recent Efforts to Change — or Enforce — the Regulatory Scheme

This long simmering issue — as evidenced by competing letters submitted to the FDA from the NMPF and the SFA[8] after the SFA’s 1997 citizen petition — recently reached a boiling point. Dairy milk sales have been declining for decades, with a variety of factors contributing to the trend, including more beverage options and concerns about growth hormones given to cows.[9]

The dairy industry also attributes the decline to consumer confusion about the health benefits of plant-based alternatives, which the industry claims are nutritionally inferior to dairy milk but still use its name and imagery to create false equivalence.[10] As a result, the dairy industry, with help from congressional lawmakers, has renewed its fight against the use of “milk” on non-dairy products and has taken the fight to Congress.

The “Defending Against Imitations and Replacements of Yogurt, Milk, and Cheese to Promote Regular Intake of Dairy Everyday” Act, or DAIRY PRIDE Act, was introduced in both the U.S. House of Representatives and Senate in January 2017. The Act would require the FDA to enforce dairy food-labeling regulations for milk, yogurt and cheese products that do not contain milk from “hooved mammals.”[11] The bill highlights the nutritional differences between milk and plant-based alternatives, and suggests that the FDA’s lack of enforcement has resulted in consumer confusion.[12]

Wisconsin Senator Tammy Baldwin highlighted the tension between the dairy and plant-based industries when she stated in a press release that “[i]mitation products have gotten away with using dairy’s good name for their own benefit, which is against the law and must be enforced.”[13] Currently, both versions of the bill remain pending before legislative committees.

Moreover, in July 2017, the NMPF met with FDA personnel to discuss its view that the FDA should enforce the current regulations and prevent plant-based products from using the term “milk” on their products. NMPF President and CEO Jim Mulhern reiterated that consumers have been misled regarding the comparable nutritional values of the products and noted that “imitation milks” “are nothing but a factory-made slurry of ground-up nuts or seeds combined with water, sugar, emulsifiers and thickeners,” while cow’s milk is a natural product with nine essential nutrients, not matched by its imitators.[14]

Meanwhile, the Good Food Institute (GFI), a “nonprofit organization ... advocating for and encouraging research into alternatives to conventional animal foods,” recently entered the regulatory fray by submitting its own citizen petition.[15] The March 2, 2017, petition seeks a regulation “clarifying that

new foods may be named by reference to other ‘traditional’ foods in a manner that makes clear to consumers their distinct origins or properties.”[16]

The proposed regulation would apply to products other than plant-based milk alternatives, but the petition specifically points to plant-based milks like “almond milk,” as an example of a term that clearly identifies the product’s origins and properties. The petition maintains, among other points, that consumers are used to food products with qualifiers, noting the use of phrases like “organic, low-fat, reduced fat, fat-free, reduced calorie, low-carb, gluten-free, wheat-free, dairy-free, soy-free, no artificial colors, non-GMO, grown without pesticides, raised without antibiotics, no added sugars” in labeling and advertising.[17]

It further contends that preventing plant-based products from using modifiers of common names would violate a manufacturer’s First Amendment rights to provide information about its products.[18]

Litigation of “Milk” Product Labels

As often happens where a regulatory gray area exists, consumers in California have taken to the courts. Consumers have brought lawsuits over the name “milk” being used to market and sell plant-based alternatives, seeking to move the needle regarding the definition of milk (or at least capitalize on the existing ambiguity). Plaintiffs have thus far not had much success; several courts have ruled that appropriate “qualifiers” — e.g., “soy,” “almond” and “coconut” — effectively limit any potential consumer confusion.

For example, in 2013, a court in the Northern District of California in *Ang v. WhiteWave Foods Co.* dismissed claims that soy, almond and coconut products were misleadingly labeled as “milk,” finding the claims preempted by the Food, Drug, and Cosmetic Act (FDCA) and implausible as a matter of law.[19] There, the court found the definition of milk “pertains to what milk is, rather than what it is not, and makes no mention of non-dairy alternatives such as the Silk Products.”[20]

Thus, the regulations required the products be labeled with the common or usual name. Ultimately, the court determined that “soymilk,” “almond milk,” and “coconut milk” accurately described the products and that consumer confusion was “highly improbable.”[21] On the same day, another judge in a Northern District case, *Gitson v. Trader Joe’s*, dismissed similar claims regarding “soymilk” as preempted by the FDCA because the use of “milk” was not false or misleading, and the products were not being passed off as milk under FDA’s standard of identity just because milk is part of the description.[22]

Two additional cases were filed this year claiming that the labeling and advertising of plant-based milks suggest they are nutritionally superior to dairy milk. A Central District of California court dismissed claims premised on the allegedly misleading advertising of Almond Breeze almond milk in *Painter v. Blue Diamond Growers*.[23]

There, in addition to finding preemption under the FDCA, the judge explained that “the claim of customer confusion is patently implausible” because the term “milk” is so clearly qualified by the use of the plant term, and the nutritional information is accurately provided.[24] The court added that “even the least sophisticated consumer would know instantly the type of product they are producing.”[25]

In *Kelley v. WWF Operating Co.*, a case in the Eastern District of California, the court stayed a consumer’s claims similarly premised on the allegedly false, misleading and deceptive advertising of Silk Almond Milk.[26] The plaintiff alleged that she was led to believe that almond milk was “nutritionally superior to

dairy milk” by WWF’s television commercials.[27] The court ruled that the doctrine of primary jurisdiction applied, referring the issue to the FDA to determine whether the product should be labeled “imitation” under applicable regulations.[28]

Thus, the current trend from a litigation standpoint in the United States can be summarized as follows: (1) while the FDA has defined milk, the use of a qualifier accurately describes the products, making any different requirements preempted by the FDCA; and (2) the use of qualifiers likely tells reasonable consumers what they are purchasing and therefore cannot be false or misleading.

Jurisdictions Outside the U.S. Have Taken a Definitive Stance Against Using “Milk” on Plant-Based Products

In considering how to label and market consumer products or when advising clients on these issues, plant-based milk producers and their counsel should be aware that jurisdictions outside the U.S. unequivocally enforce the prohibition against using “milk” on plant-based products.

In a June 2017 decision by the European Court of Justice, the court confirmed that European Union regulations prevented “milk” designations from being used on plant-based products, even if the designation was clarified by plant terms.[29]

Canada also prohibits plant-based milk alternatives from being labeled as “milk.”[30] Instead, products like soy or almond milk are labeled as “beverages.” Despite this stronger regulatory enforcement, cow’s milk sales in Canada have continued to decline since 2009 likely due, in part, to the availability of dairy milk substitutes.[31]

Conclusion

Considering the FDA’s lack of action and the lack of movement by the DAIRY PRIDE Act bills in Congress, the “milk” controversy likely will not be conclusively resolved in the near future. Unfortunately, this creates uncertainty for manufacturers and companies seeking innovative ways to develop, label and market new plant-based products.

That said, the FDA’s continued inaction in this area arguably signals that the agency, consistent with GFI’s position in its citizen petition, may now view the use of plant qualifiers on product labels as sufficient to differentiate plant-based products from dairy milk.

Indeed, this conclusion would seem consistent with the FDA’s 2015 decision to allow Hampton Creek to continue to label its mayonnaise-alternative “Just Mayo” despite the fact that mayonnaise, by regulatory definition, must contain eggs.[32] There, the FDA concluded that, with appropriate changes to the product’s label to ensure it was truthful and not misleading, Hampton Creek could continue to call the product “Just Mayo.”[33]

With plant-based products continuing to use “milk” without pushback from the FDA, many companies are likely to continue to use the term to describe milk alternatives. Moreover, the longer terms like soymilk, almond milk and coconut milk remain in use, the stronger the argument those terms are the common and usual name of the products as established by common use.[34]

While the term “milk” will almost certainly be subject to additional legislative and judicial scrutiny, true clarification will require the FDA to either amend its regulatory framework or utilize its enforcement

powers to limit the use of “milk” on plant-based product labels. Until then, grocery store aisles in the U.S. will likely continue to house milk derived from both cows and coconuts.

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[1] Lindsay Whipp and Scheherazade Daneshkhu, Big Business Identifies Appetite for Plant-Based Milk, Financial Times (July 15, 2016), <https://www.ft.com/content/7df72c04-491a-11e6-8d68-72e9211e86ab>.

[2] 21 C.F.R. § 131.110(a).

[3] 21 C.F.R. § 101.3(e); see also Guidance for the Industry: A Food Labeling Guide, available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064872.htm>.

[4] Press Release, National Milk Producers Federation, NMPF Statement on July 31 Letter to FDA from Good Foods Institute Seeking Changes in Dairy Food Definitions (July 31, 2017), <http://www.nmpf.org/latest-news/press-releases/jul-2017/july-31-nmpf-statement-july-31-letter-fda-good-foods-institute>.

[5] Id.

[6] Warning Letter from Alonza Cruse, FDA District Director, to Long H. Lai, Lifesoy, Inc. (Aug. 8, 2008), <https://wayback.archive-it.org/7993/20170112200226/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048184.htm>; Warning Letter from Barbara Cassen, FDA District Director, to Yan Hui Fang, CEO of Fong Kee Tofu Company, Inc. (Mar. 3, 2012), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm295239.htm>.

[7] Citizen Petition, Recognized the Term “Soymilk” as the Established Common of [sic] Usual Name, FDA-1997-P-0016 (Feb. 28, 1997), available at <https://www.regulations.gov/docket?D=FDA-1997-P-0016>

[8] See, e.g., Letter from Nancy Chapman, Executive Director of Soyfoods Association of North America, to Joseph Levitt, Director of the Center for Food Safety & Applied Nutrition (Mar. 9, 2000), <https://www.fda.gov/ohrms/dockets/dailys/00/apr00/041700/c000012.pdf>; Letter from Dr. Beth Panko Briczinski, Vice President Dairy Foods & Nutrition at NMPF, to FDA Division of Dockets Management (May 5, 2014), <http://www.nmpf.org/files/NMPF%20Comments%20on%20Evap%20Cane%20Juice%202014%20May%2005.pdf> (citing additional letters sent to FDA in February 2001, November 2001, April 2010, and July 2010).

[9] Monika Evstatieva and Audie Cornish, Why Are Americans Drinking Less Cow’s Milk? Its Appeal Has Curdled, NPR: The Salt (May 16, 2017),

<http://www.npr.org/sections/thesalt/2017/05/16/528460207/why-are-americans-drinking-less-cows-milk-its-appeal-has-curdled>.

[10] See Press Release, National Milk Producers Federation, NMPF Urges FDA: Enforce U.S. Standards for Dairy Food Labeling (July 25, 2017), <http://www.nmpf.org/latest-news/press-releases/jul-2017/july-25-nmpf-urges-fda-enforce-us-standards-dairy-food-labeling>.

[11] DAIRY PRIDE Act, H.R. 778, 115th Cong. (2017); DAIRY PRIDE Act, S. 130, 115th Cong. (2017), at § 4.

[12] *Id.* at § 2.

[13] Press Release, Tammy Baldwin, U.S. Senator for Wisconsin, U.S. Senator Tammy Baldwin Stands Up for Wisconsin Dairy Farmers (Jan. 12, 2017), <https://www.baldwin.senate.gov/press-releases/dairy-pride-act>.

[14] Press Release, National Milk Producers Federation, NMPF Urges FDA: Enforce U.S. Standards for Dairy Food Labeling (July 25, 2017), <http://www.nmpf.org/latest-news/press-releases/jul-2017/july-25-nmpf-urges-fda-enforce-us-standards-dairy-food-labeling>.

[15] Citizen Petition, Request that the FDA Issue Regulations Clarifying How Foods May Be Named by Reference to the Names of Other Food, FDA-2017-P-1298 (March 2, 2017), available at <https://www.regulations.gov/docket?D=FDA-2017-P-1298>.

[16] *Id.* at 2.

[17] *Id.* at 4. GFI also notes that many consumers are increasingly moving away from animal products like dairy for a variety of reasons including allergies, concerns about health, environment impact and animal treatment. *Id.* at 5-6.

[18] *Id.* at 28-34.

[19] *Ang v. WhiteWave Foods Co.*, No. 13-CV-1953, 2013 WL 6492353, at *4 (N.D. Cal. Dec. 1, 2015).

[20] *Id.* at *3.

[21] *Id.* at *4.

[22] *Gitson v. Trader Joe's*, No. 13-cv-01333-VC, 2015 WL 9121232, *1-2 (N.D. Cal. Dec. 1, 2015).

[23] *Painter v. Blue Diamond Growers*, No. 2:17-cv-02235, Doc. 21, p. 2 (C.D. Cal. May 24, 2017).

[24] *Id.* at 3-4.

[25] *Id.* at 4.

[26] *Kelley v. WWF Operating Co.*, No. 1:17-cv-00117, 2017 WL 2445836, at *1 (E.D. Cal. June 6, 2017).

[27] *Id.*

[28] Id. at *6.

[29] Case C-422/16, Verband Sozialer Wettbewerb eV v. Tofu Town.com GmbH, 2017.

[30] C.R.C., c. 870, B.08.003 (“Milk or Whole Milk (a) shall be the normal lacteal secretion obtained from the mammary gland of the cow, genus Bos”).

[31] Michelle St. Pierre, Changes In Canadians’ Preferences For Milk And Dairy Products, Statistics Canada (April 12, 2017), <http://www.statcan.gc.ca/pub/21-004-x/2017001/article/14786-eng.htm>.

[32] Warning Letter from William Correll, Jr., Director of Office of Compliance at the Center for Food Safety & Applied Nutrition, to Joshua Tetrick, Founder & CEO of Hampton Creek Foods Inc. (Aug. 12, 2015), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm458824.htm>; Close Out Letter from from William Correll, Jr., Director of Office of Compliance at the Center for Food Safety & Applied Nutrition, to Joshua Tetrick, Founder & CEO of Hampton Creek Foods Inc. (Dec. 18, 2015), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm478309.htm>.

[33] Beth Kowitz, The Mayo Wars Just Ended, *Fortune* (Dec. 17, 2015), <http://fortune.com/2015/12/17/hampton-creek-just-mayo-fda/>.

[34] 21 C.F.R. § 102.5(d).