

February 2, 2017



Stephen Ostroff, MD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Susan T. Mayne, PhD
Director
Center for Food Safety and Applied Nutrition
5001 Campus Drive
College Park, MD 20740

Dear Dr. Ostroff and Dr. Mayne:

I write on behalf of the Soyfoods Association of North America (SANA), a trade association that represents manufacturers, processors, and distributors of soy-based products and soybean farmers from the United States, Mexico, and Canada. We write to you in response to a recent letter you received signed by several House of Representatives members and the recent legislation introduced by Senator Tammy Baldwin (D-WI). The Congressional letter 1) argued that “the use of the term “milk” by manufacturers of plant-based products is misleading to consumers, harmful to the dairy industry, and a violation of milk’s standard of identity and 2) requested the FDA to exercise its legal authority to investigate and take appropriate action against the manufacturers if these misbranded products. The legislation sets forth that “no food may be introduced or delivered for introduction into interstate commerce using a market name for a dairy product if the food does not meet the criterion set forth for dairy products under paragraph (z)(2) of section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) (as added by section 4(a)).

SANA urges FDA to recognize the term “soymilk” as a lawful common or usual name for the liquid food obtained as a result of combining: (1) aqueous-extracted whole soybean solids and water; or, (2) other edible-quality soy protein solids, soybean oil, and water, as requested in a February 28, 1997 Citizen’s Petition. SANA requests a meeting with you and your staff to discuss the basis for its conclusion that use of the name “soymilk” complies with FDA’s regulations on common or usual names and identity labeling of food in packaged form,¹ as well as with FDC Act § 403(g), which renders a food misbranded if it purports to be or is represented as a food governed by a standard of identity and fails to conform to that standard.

Resolution of this issue remains pertinent today as the term soymilk has now been incorporated into government regulations for nutrition assistance programs, federal dietary guidelines, USDA data bases, and communications including but not limited to the Dietary Guidelines for Americans, National School Lunch Program, the Women, Infants, and Children program, and ChooseMyPlate. USDA and DHHS have recognized soymilk as a nutritional alternative for dairy products for individuals who cannot or do not consume cow’s milk and your agency granted soy products containing 6.25 grams of soy protein a heart health claim in 1999. There are multiple nutritional benefits of including soyfoods in our diets and many Americans consume soymilk as a nutritious alternative for cultural, religious, and health reasons.

This letter provides (1) a summary of prior related communications with and by the agency, (2) data on consumer understanding of the name “soymilk” confirming that the name is not false or misleading, (3) additional

¹ 21 C.F.R. § 102.5 and § 101.3.

information confirming common usage of the name “soymilk” by industry, consumers, and the federal government, and (4) information on the long use of “soymilk” by consumers. For the sake of brevity, those documents and the information referenced therein are incorporated by reference.

I. Background

SANA is a trade association that represents 32 large and small soyfoods companies, large and small soy processors, growers and suppliers of soybeans, and food scientists. SANA members manufacture and distribute a variety of soy-based products, including soymilk, tofu, miso, tempeh, meat alternatives and other items, in the United States and elsewhere in North America.

On February 28, 1997, the Soyfoods Association of America (the predecessor of SANA) filed a citizen petition asking FDA to issue a regulation recognizing that the name “soymilk” is an appropriate “common or usual name” that had become established through common usage. That petition noted that the name “soymilk” had been in commercial use since 1947, and had been included in USDA materials dating back to 1963. To date, FDA has not made a determination on the petition.

A few years after submission of the citizen petition, the National Milk Producers Federation (NMPF) began pressing FDA to take regulatory action against products that include “milk” as part of their name, but do not meet the standard of identity for milk in 21 C.F.R. § 131.110. In response to NMPF’s initial trade complaint, SANA submitted a letter to the agency dated March 9, 2000, which noted that NMPF’s complaint misstated the law concerning the use of the name “milk,” and that FDA itself had begun using the name “soymilk” in documents pertaining to the agency’s authorization of a health claim for soy protein and coronary heart disease in 1999. NMPF has since made additional submissions to FDA pressing its case.²

On September 16, 2005, SANA met with officials from Center for Food Safety and Applied Nutrition’s (CFSAN) Food Labeling and Standards Staff and its Office of Compliance to review the status of SANA’s citizen petition, and to request confirmation that FDA would not object to the use of the name “soymilk” in federal nutrition programs. CFSAN indicated that its principal concerns related to whether consumers understand that a product labeled as “soymilk” does not contain milk, and whether the labeling of such a product would give rise to confusion regarding the absence of the allergen “milk.” However, the agency provided no data or other information to suggest that consumers are misled or confused by use of the name “soymilk.”

In a warning letter issued to a soymilk manufacturer on August 8, 2008, FDA included a comment that milk is a standardized food, and therefore the agency does not consider “soy milk” to be an appropriate common usual name for a product that does not contain milk.³ The letter provided no explanation of the basis for the comment.

More recently, in a warning letter issued to the manufacturer of products marketed as “Muscle Milk” on June 29, 2011, FDA concluded in part that the products were misbranded under FDC Act § 403(g)(1) because they purported to be “milk,” but did not conform to the standard of identity for milk.⁴ FDA further stated that the products were misbranded under FDC Act § 403(a)(1) because their statements of identity were in “significantly smaller and less prominent type than the words ‘MUSCLE MILK,’” and because the principal display panel included the statement “contains no milk” despite the fact that the products contain a number of milk-derived ingredients.

II. The name “soymilk” is not false or misleading

² See Letter from Jerry Kozak, NMPF, to Margaret A. Hamburg, FDA (April 28, 2010), and Letter from Beth Panko Briczinski, Ph.D., Director, Dairy Foods & Nutrition, Re: Point-of-Purchase Nutrition Information (Front-of-Pack and Shelf Tag Nutrition Symbols), Docket No. FDA-2010-N-0210 (July 28, 2010)

³ <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048184.htm>

⁴ <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm261684.htm>

In its submissions to FDA, NMPF alleges in part that the name “soymilk” violates FDC Act § 403(a), which renders a food misbranded if its labeling is false or misleading. Consumer survey evidence gathered by SANA establishes that NMPF’s unsupported allegation has no basis in fact.

After SANA’s meeting with CFSAN officials in September of 2005, a SANA member retained Market Tools, a professional market research firm, to conduct a study to determine consumer perception and understanding of the name “soymilk” (2006 Consumer Study). The study surveyed 814 adult primary grocery shoppers ages 18-64. The study concluded that consumers are not confused about the content of soymilk nor do they think cow’s milk is an ingredient in soymilk. When asked the unaided question “What do you think are the main ingredients of soymilk?” the top responses were soy (53%) and soybeans (23%). Extremely few respondents (3%) cited “milk” as an ingredient in soymilk, and no consumers cited “cow’s milk” as an ingredient in soymilk. When further prompted to select specific ingredients that they thought were in soymilk, nearly all survey participants listed soy protein (88%), followed by water (75%), soybeans (68%), vitamins and minerals (65%), and calcium (61%), whereas only 3% of respondents selected “cow’s milk”. In addition, survey participants were asked if they accidentally purchased soymilk when they went to the store to purchase cow’s milk. Only 5% of respondents claimed that this happened.

With respect to FDA’s concern regarding potential consumer confusion over allergen labeling, SANA understands that concern in the context of products such as “Muscle Milk” that use the word “milk” without a qualifying term that makes clear that the product is not bovine in nature, and that feature claims that FDA believes to be false and misleading with respect to the presence of a major food allergen (i.e., “does not contain milk”). However, soymilk products do not raise these issues. As discussed in prior correspondence with FDA, use of the qualifying term “soy” proclaims that “soymilk” is not bovine in nature, and the 2006 Consumer Study confirms that consumers understand this product attribute. Although that study did not specifically address issues pertaining to allergen declaration, there is nothing in the study findings to suggest that food allergic consumers might be confused by the absence of “milk” in the ingredient list of soymilk products, or by the absence of “milk” in any allergen statements for soymilk products. Indeed, the finding that only 3% of respondents believe that soymilk contains cow’s milk suggests that any such confusion is highly unlikely.

Notably, the term “soymilk” is commonly used in the food allergic community.⁵ For example, the Allergy & Anaphylaxis Network (FAAN), a leading source of information about food allergy, maintains a web page on milk allergy that explicitly recommends “soymilk” as a suitable alternative to cow’s milk for children being weaned from a milk-free formula.⁶ A similar recommendation to consumers is provided by the American Academy of Pediatrics.⁷ Given the use of the term “soymilk” by organizations trusted for advice by food allergic consumers, there is no basis to suspect that those consumers are misled or confused by the use of name “soymilk.”

III. “Soymilk” has been established as a common or usual name through common usage by industry, consumers, the federal government, health professionals, and court cases

As SANA has noted in prior communications with FDA, 21 C.F.R. § 102.5 explicitly permits the establishment of a common or usual name by common usage. Given the longstanding and increasingly widespread use of the name “soymilk” in the marketplace, the extent to which it is recognized and used by consumers, and its use in consumer communications by the two federal agencies with principal jurisdiction over food, it is clear that “soymilk” has been established as a common or usual name through common usage.

⁵ As noted in the citizen petition, the terms “soymilk,” “soy milk,” and “soybean milk” have all been used to describe the liquid food in question. SANA is not aware of any information to suggest that consumers perceive any difference between the terms “soymilk” and “soy milk.”

⁶ <http://www.foodallergy.org/page/milk-allergy>

⁷ <http://www.healthychildren.org/English/healthIssues/conditions/abdominal/pages/Milk-Allergy.aspx?nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfnstatusdescription=ERROR%3a+No+local+token>

In its citizen petition, SANA noted that the name “soymilk” had been in use since 1947. In fact, the name has been in use at least since 1929, when La Sierra Soy Milk was introduced by La Sierra Industries in Arlington, California.⁸ By 1949, the first edition of the American Soybean Association’s Soybean Blue Book listed seven companies in the United States as “manufacturers and handlers” under the category “soy milk.” By the mid-1970’s, soymilk appeared as one word in subsequent product introductions into the marketplace.

Consumer demand for soymilk has grown over ten-fold in the past 20 years. There were \$84 million in sales in 1992, the first year that Soyatech began tracking soyfood sales; today, sales exceed \$ 1 billion.⁹ The increase in demand reflects an increase in consumer awareness and consumption of soymilk. In 1999 only 18% of consumers reported that they had tried soymilk; whereas in 2014, the number of consumers who have tried soymilk has more than doubled to 49% of all consumers.¹⁰ According to this same 2013 survey sponsored by the United Soybean Board, among Americans who order soy in restaurants, soymilk is a common choice at 20 % (up from 16% in 2009).¹¹

SANA believes that consumer awareness of soymilk has been driven in part by federal agencies’ use of that name in consumer communications. In prior correspondence, SANA has referenced FDA and USDA documents that use the name “soymilk.” One such document is an FDA Consumer Magazine article that dates back more than 10 years and continues to be readily available on the Internet. Titled *Soy: Health Claims for Soy Protein, Questions About Other Components*, the article addresses the health benefits of soy products, and includes eight references to “soymilk.”¹² As FDA has reviewed the heart health claim, SANA has provided additional evidence of the health benefits of soy protein, a prominent ingredient of soymilk.¹³

More significantly, the 2015-2020 Dietary Guidelines for Americans, Eighth Edition¹⁴ included this recommendation under the Dairy Section, “Healthy eating patterns include fat-free and low-fat (1%) dairy, including milk, yogurt, cheese, or fortified soy beverages (commonly known as “soymilk”). USDA has elected to include “Calcium-fortified soymilk (soy beverage) as part of the Dairy Group in the agency’s consumer communications at ChooseMyPlate.gov, the federal government’s principal means of providing dietary guidance to consumers.¹⁵ In doing so, USDA implicitly recognized that “soymilk” is a name that is readily understood by consumers. USDA included fortified soymilk in Dairy Section in Choose My Plate as a provider of calcium, vitamin D, and potassium.¹⁶

This terminology is consistent with USDA’s longstanding use of the name “soymilk” in its National Nutrient Database for Standard Reference. In the 1963 edition of its Agriculture Handbook No. 8, USDA provided compositional characteristics of “soybean milk”, in both fluid and powder form; and in its “Home and Garden Bulletin No. 208”, printed in 1977, the USDA listed the nutritive values of various soyfoods products including “soymilk.”¹⁷ Again in 1986, USDA published the Agriculture Handbook No. 8-16 – Composition of Foods: Legumes and Legume Products which discusses the commercial production of “soy milk” in the United States.¹⁸

⁸ Soyinfo Center, www.soyinfocenter.com.

⁹See Soyfoods: The U.S. Market 2010, published by Soyatech, Inc. and SPINS. For more information, contact Soyatech at 800.424.SOYA, or by email at customerservice@soyatech.com.

¹⁰ 18th Annual Consumer Attitudes about Nutrition, 2011 Edition. United Soybean Board, St. Louis, MO, March, 2011, page

10. http://www.soyconnection.com/sites/default/files/ConsumerAttitudes_Med_062714.pdf

¹¹ <http://www.soyconnection.com/sites/default/files/ConsumerAttitudes2011.pdf>

¹² FDA Consumer. 2000 May-Jun; 34(3):13-5, 18-20.

¹³ <http://www.soyfoods.org/wp-content/uploads/update-of-research-on-soy-and-CHD.pdf>

¹⁴ https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf Chpt. 1, pg23 and Chpt 2, pg 49

¹⁵ What foods are included in the dairy group? Choose My Plate.gov. 2017. January 31, 2017.

<https://www.choosemyplate.gov/dairy>.

¹⁶ Nutrients and Health Benefits <https://www.choosemyplate.gov/dairy-nutrients-health> Dairy Section. January 31, 2017.

¹⁷ Agriculture Handbook No. 8 – Composition of Foods: Raw, Processed, and Prepared. Revised December 1963, approved for reprinting October 1975. USDA, Washington, D.C., pages 58-59.

¹⁸ Agriculture Handbook No. 8-16 – Composition of Foods: Legumes and Legume Products. Revised December 1986. USDA, Washington, D.C., pages 9.

Health-related organizations frequently use the term “soymilk” or “soy milk” in their literature. The American Diabetes Association recommends trying “fortified soy milk” for those that are lactose intolerant¹⁹ and also lists “fortified soy milk” as a food choice for vegetarians to obtain sufficient calcium and vitamin D.²⁰ The term is also included in the American Diabetes Association’s food and fitness advice for protein and vegetarian diets.²¹ “Soy milk” is listed in multiple places on the American Diabetes Association’s website, including the guide “Where Do I Begin? Living with Type 2 Diabetes”²² as well as in other guides that demonstrate creating a healthful plate.

The Academy of Nutrition and Dietetics lists “fortified soymilk” as a food source of the important nutrients calcium, vitamin D, and vitamin B₁₂²³ and includes “fortified soymilk” as part of healthful meal ideas for vegetarians.²⁴ When discussing feeding vegetarian and vegan infants and toddlers, the Academy of Nutrition and Dietetics recommends weaning infants with “fortified soymilk”.²⁵

The use of the term “soymilk” is widespread within the scientific community. In a PubMed search of peer reviewed, scientific articles “soy milk” produces 748 hits, while “soymilk” produces 382 hits. Dr. Reilly’s research on the acceptance of soymilk²⁶ and Dr. Zhao’s research on the nutritional quality of soymilk²⁷ are widely referenced.

Federal judges have also ruled that consumers are not misled by use of the term “soymilk” on beverage packages, especially because these packages are also labeled “dairy-free”. In April 2014, plaintiffs filed a court case against Trader Joe’s²⁸, claiming that products calling themselves “soymilk” are “illegally labeled certain products as “soymilk.” But FDA regulations prohibit companies from doing that because the FDA does not “consider ‘soy milk’ to be an appropriate common or usual name because it does not contain ‘milk.’” Judge Vince Chhabria dismissed the allegation citing that “the fact that the FDA has standardized milk does not categorically preclude a company from giving any food product a name that includes the word “milk.” Rather, as the language of section 343(g) indicates, the standardization of milk simply means that a company cannot pass off a product as “milk” if it does not meet the regulatory definition of milk. Trader Joe’s has not, by calling its products “soymilk,” attempted to pass off those products as the food that the FDA has standardized (that is, milk).”²⁹

IV. Soymilk is a unique beverage and it has a long history of use in numerous non-dairy drinking cultures

Soymilk is a unique beverage distinct from milk. As discussed previously, soymilk is a product with a long history of use as such, and with a long history of consumption in countries where milk is not consumed. Archaeological evidence (a Chinese mural incised on a stone slab) shows that soymilk and tofu were being made in Northern China during the Eastern/Later Han period (A.D. 25-220).³⁰ The earliest known written reference to

¹⁹ <http://www.diabetes.org/food-and-fitness/food/what-can-i-eat/dairy.html>

²⁰ <http://www.diabetes.org/food-and-fitness/food/planning-meals/meal-planning-for-vegetarians/nutrients-vegetarians.html>

²¹ <http://www.diabetes.org/food-and-fitness/food/planning-meals/meal-planning-for-vegetarians/vegetarians-and-protein.html>

²² <http://www.diabetes.org/living-with-diabetes/recently-diagnosed/living-with-type-2-diabetes/assets/where-do-i-begin-english.pdf>

²³ <http://www.eatright.org/Public/content.aspx?id=6374>

²⁴ <http://www.eatright.org/Public/content.aspx?id=6373>

²⁵ <http://www.eatright.org/Public/content.aspx?id=8060>

²⁶ Reilly JK, Lanou AJ, Barnard ND, Seidl K, Green AA, Acceptability of soymilk as a calcium-rich beverage in elementary school children, *J Am.Diet. Assoc.* 2006; 106:590-593.

²⁷ Zhao Y, Martin BR, Weaver CM. Calcium bioavailability of calcium carbonate fortified soymilk is equivalent to cow's milk in young women. *J Nutr.* 2005 Oct;135(10):2379-82.

²⁸ *Gitson v. Trader Joe’s Co.*, No 13-cv-01333-VC, 2015 N.D. Cal. April 03, 2014.

²⁹ *Gitson v. Trader Joe’s Co.*, No 13-cv-01333-VC, 2015 WL 9121232, at *2 (N.D. Cal. Dec. 1, 2015).

³⁰ Chen, Wenhua, 1990. The origin of doufu - When was it first made? (abstract). Paper presented at the Sixth International Conference on the History of Science in China, held Aug. 1990 at Robinson College, Cambridge, England.

soymilk appeared in about A.D. 1500 in China, in a poem by Su Ping.³¹ The earliest known European reference to soymilk was in 1665 by Domingo Fernández de Navarrete, who served as a Dominican missionary in China.³² Soymilk was also mentioned in 1790 by Juan de Loureiro, a Portuguese Jesuit missionary who lived in what is now Vietnam.³³ Each of these and many other early references mentioned soymilk as part of the process for making tofu. The world's earliest known discussion of soymilk as a drink in its own right appeared in 1866, when the Frenchman Paul Champion, who had traveled in China, stated that the Chinese had taken their cups to tofu shops to get hot soymilk which they drank for breakfast.³⁴

Soymilk was first referred to in the United States by Henry Trimble in 1896 in the *American Journal of Pharmacy*.³⁵ In 1909, a U.S. pediatrician developed the first soy-based infant formulas and soymilk from full-fat soy flour. In 1910, Li Yu-ying, a Chinese citizen in Paris founded the world's first soy dairy and was granted the first British patent for soymilk production (No. 30,275. "Vegetable milk and its derivatives"). In 1913, Li Yu-ying was granted the first U.S. patent for soymilk (No. 1,064,841). By 1917, soymilk was being produced commercially in the U.S. by J.A. Chard Soy Products in New York City.³⁶

VI. Conclusion

For the reasons stated above and in SANA's pending citizen petition and prior correspondence with FDA, the name "soymilk" complies with pertinent provisions of the FDC Act and its implementing regulations. The Department of Health and Human Services and the U.S. Department of Agriculture have acknowledged the nutritional contributions of soymilk to the diet and included "calcium fortified soymilk" as part of the 2015-2020 Dietary Guidelines for America. For the children and families that do not consume cow's milk, USDA has included nutritionally equivalent dairy alternatives such as soymilk in the school meals program and the food packages for women and children who have health, cultural and religious reasons to avoid dairy products. SANA would welcome the opportunity to address any further questions you may have about any of the issues addressed herein and ask that the agency recognize "soymilk" as a common and usual name.

Sincerely,



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Executive Director

CC: Doug Balentine, PhD, Director Office of Nutrition and Food Labeling
Claudine Kavanaugh, PhD, MPH, RD, Senior Advisor for Nutrition Policy in the Office of Foods and Veterinary Medicine

³¹ Su Ping. 1500. Ode to tofu. Quoted by Wai, 1964, p. 91-92.

³² Navarrete, Domingo Fernández de. 1665. A Collection of Voyages and Travels. Published by the author, London. See p. 251-52, Chap. 13.

³³ Loureiro, Juan de. 1790. The Flora of Cochin China, Vol. 2, Lisbon, Portugal. See p. 441-42.

³⁴ Champion, Paul. 1866. On the production of tofu in China and Japan. *Bulletin de al Societe d'Acclimation* 13(6):562-65. June.

³⁵ Trimble, Henry. 1896. Recent literature on the soja bean. *American J. of Pharmacy* 68:309-13. June.

³⁶ Piper, C.V.; Morse, W.J. 1916. The soy bean with special reference to its utilization for oil, cake and other products. *U.S.D.A. Bulletin* No. 439. Dec. 22. p. 9; Horvath, A.A. 1927. The soybean as human food. Chinese Government Bureau of Economic Information, Booklet Series, No. 3. p. 47.