Maryland's Dairy Industry: 2023

A Report
To
Governor Wes Moore

From

The Maryland Dairy Industry Oversight and Advisory Council

2023

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Summary

This report to Governor Wes Moore is an assessment of the current state of the dairy industry in Maryland as well as policy recommendations to support the sector. It represents the recommendations of a committee that includes milk processors, dairy farmers, dairy cooperative leaders, Maryland Farm Bureau members, Maryland Grange members, and consumers, as well as representatives from state and local health departments, agriculture departments, the Maryland Department of Agriculture (MDA), the General Assembly, and University of Maryland officials.

The Governor's Maryland Dairy Industry Oversight and Advisory Council (Council) is charged with improving and sustaining the economic viability of Maryland's dairy industry and reporting annually to the Governor.

Dairy production is a crucial part of Maryland agriculture, providing fresh milk to processors in the state and beyond. It is particularly important in central and western Maryland counties where it is concentrated because it is a value-added product that utilizes hay, corn silage, grain, and soybean oil meal, thus increasing the importance of field crops. According to the University of Maryland, dairy farming requires about 200,000 acres of cropland to generate feed for the 40,000 milk cows and replacement heifers. It is unlikely that the demise of the dairy industry would be offset by other value-added agricultural enterprises and would result in a loss of agriculture in general and the associated jobs and economy.

2023 brought lower prices, higher feed costs to dairy farmers

The U.S. Department of Agriculture (USDA) reported in September 2023 that the amount dairy farmers are receiving for milk declined significantly from 2022. The all-milk price in July 2023 averaged $17.40 per hundredweight (cwt.) This was down $8.10 from July 2022. Meanwhile, the cost of feeding cows has increased. The federal Dairy Margin Coverage (DMC) program is designed to help offset losses for U.S. farmers. In June and July of this year, DMC milk margins above feed costs fell to $3.65 and $3.52 per cwt. These are the lowest margins in the history of the DMC program, which started in 2019. The USDA considers this "catastrophic and results in DMC payments to farmers.

Number of Maryland dairy farms falls below 300

The number of Maryland dairy farms continues to fall. As of the writing of this report in September 2023, the Maryland Department of Health (MDH) regulates 297 dairy farms in the state, down from 312 last year. A decade ago, there were 505 dairy farms. Broken down by county:

Baltimore County - 8
Caroline County - 4
Carroll County - 20
Cecil County - 29
Charles County - 3
Kent County - 7
Montgomery County - 3
Prince George's County - 2
Queen Anne's County - 4
St. Mary's County - 15

Frederick County - 48
Garrett County - 37
Harford County - 13
Howard County - 2
Talbot County - 4
Washington County - 98

Dale Johnson, Farm Management Specialist with the University of Maryland, states in Attachment 1 to this report: "The main reason for the loss of dairy farms is perennially low milk prices. Disregarding the high milk price years of 2014 and 2022, the average price over the remaining eight years is about $ 17.60 per cwt. national supply has outpaced demand. Costs of production on Maryland farms are about $20 per cwt which does not include family living withdrawals, principal payments on loans, or major capital improvements. Dairy farmers must try to make up the difference with cull and calf sales, crop sales, federal payments, and other miscellaneous income."

Maryland's current milk processing capacity includes 44 operations (Attachment 2). There are seven large, commercial dairy processors. The rest are smaller, on-farm processors. Processors in the state annually process more than 10 billion pounds of milk, according to MDH and the Federal Milk Market Order. More than 40,000 loads of milk are hauled from farms throughout the mid-Atlantic to Maryland processors each year. Final products of all types are shipped throughout the nation and the world from Maryland. One plant, Nestle Dreyer's Ice Cream in Laurel, is among the largest ice cream factories in the world.

Recommendations to Governor Moore and the General Assembly

The Advisory Council recommends that Governor Wes Moore, the General Assembly, and relevant state agencies:

1. Continue to prohibit the sale of raw milk for human consumption in Maryland.
2. Promote the importance of the Maryland dairy industry to the public.
3. Oppose the marketing of plant-based beverages as 'milk.'
4. Encourage the use of flavored and full-fat milk in schools.
5. Support value-added agriculture by simplifying and reducing regulatory impediments at the state and county levels.

Recommendation 1:
The Governor and the General Assembly should continue to prohibit the sale of raw milk directly to Maryland consumers for human consumption.

The Council is certain that the health risks associated with raw milk consumption are based on well-documented, sound science, and repeats its recommendation against allowing the sale of raw milk directly to consumers for public consumption. Pathogens in milk can cause very serious, sometimes life-altering conditions, and sometimes even death.

The only method proven to be reliable in reducing the level of pathogens in milk and milk products is proper pasteurization. Should raw milk be allowed for sale directly to the consumer, MDH anticipates an increase in the number of milk-related outbreaks and will likely incur more costs and require additional staffing for the routine regulation of raw milk as well as in the investigation and control of these outbreaks.

Recommendation 2:

MDA and other state entities should promote the value and importance of the state's dairy industry to the public.

MDA's Marketing program should continue to work with Maryland Public Television's Maryland Farm & Harvest to encourage episodes on the dairy industry. Also, the state's Farm to School program should continue to celebrate dairy farming with the state's school children. Additionally, the Maryland Agricultural Education Foundation should be supported in its mission to explain agriculture to educators and school children.

Recommendation 3:

MDA should encourage the U.S. Food and Drug Administration (FDA) to ensure that plant-based beverages are not marketed as milk.

In February 2023, the FDA issued draft guidance, Attachment 3, that notes that common or usual names of plant-based beverages, such as "soy milk" and "almond milk," have been established by common usage. It also includes the FDA's draft recommendation for plant-based products that are labeled with the term "milk" in their names, such as "soy milk" or "almond milk," and that have a nutrient composition that is different than milk, include a voluntary nutrient statement that conveys how the product compares with milk.

Federal legislation, the 2023 Pride Act is currently offered as a bi-partisan attempt to prevent the marketing of plant-based beverages as milk. It is recommended that the state's leadership support this congressional legislation.

Recommendation 4:

The State of Maryland should work to increase access to flavored and full-fat milk in schools, as flavored and full fat milk is more likely to be consumed by children.

Research published in February 2020 in the academic journal, *The American Journal of Clinical Nutrition*, concludes "Observational research suggests that high cow milk fat intake is associated with lower childhood adiposity. International guidelines that recommend reduced fat milk for children may not lower the risk of childhood obesity." doi.org/10.1093/ajcn/nqz276

Recommendation 5:

The State of Maryland should support value-added agriculture by simplifying and reducing regulatory impediments at the state and county levels.

Maryland dairy farmers may seek to add value to their farming operations beyond the production of milk. This is an important opportunity that should be supported by the State. For example, some farms may provide boarding for show cattle, pursue cheese or ice cream production, or wish to sell directly to consumers. All of these are viable options that should be supported. Twenty-six, or 8.5 percent of Maryland dairy farms, now do some sort of value-added processing and marketing. Others send their milk out of state for production into products that ultimately return for sale in Maryland—losing critical margin along the way.

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2023 Maryland Dairy Economics

Dale M. Johnson
October 2023
Department of Agricultural and Resource Economics, University of Maryland

Dairy production is a significant agriculture enterprise in Maryland generating farm gate milk revenues of approximately $165 million annual average over the five years 2018-2022. The relative importance of the dairy industry can be seen when comparing it to the revenues of other Maryland agricultural industries - beef cattle about$80 million, fruits and vegetables, about $60 million, and hogs, about $8 million (USDA National Agricultural Statistics Service).

Dairy production is particularly important in central and western Maryland counties where it is concentrated because it is a value-added product that utilizes hay, corn silage, grain, and soybean oil meal, thus increasing the importance of field crops that ensure profitability of open space. It requires about 200,000 acres of cropland to generate feed for the >40,000 milk cows and replacement heifers. It is unlikely that the demise of the dairy industry would be offset by other value-added agricultural enterprises and would result in a loss of agriculture in general and the associated jobs and economy. However, dairy production is contracting. Since 2014, about 155 of the 455 dairy farms (34%) have ceased operation.

2014-2023 Dairy statistics

Year	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023 est.
Number or Dairy farms	455	443	424	411	381	348	339	325	310	300
Cows per farm	110	111	113	117	118	124	124	125	132	135
Total number of cows	50,000	49,000	48,000	48,000	45,000	43,000	42,000	42,000	41,000	40,500
Lbs of milk sold per cow	19,680	20,000	19,854	19,750	20,378	19,349	20,714	20,667	20,341	20,500
Pounds of milk sold	984,000,000	980,000,000	953,000,000	948,000,000	917,000,000	832,000,000	870,000,000	868,000,000	834,000,000	830,250,000
Average price of milk/cwt	$25.00	$17.60	$16.40	$17.80	$16.20	$18.40	$17.30	$18.10	$25.60	$19.00
Value of milk sold	$246,250,000	$172,656,000	$156,456,000	$168,922,000	$148,716,000	$153,272,000	$150,510,000	$157,108,000	$213,504,000	$157,747,500

USDA National Agricultural Statistics Service, Maryland Department of Agriculture (2023 projected - University of Maryland Extension)

Milk prices

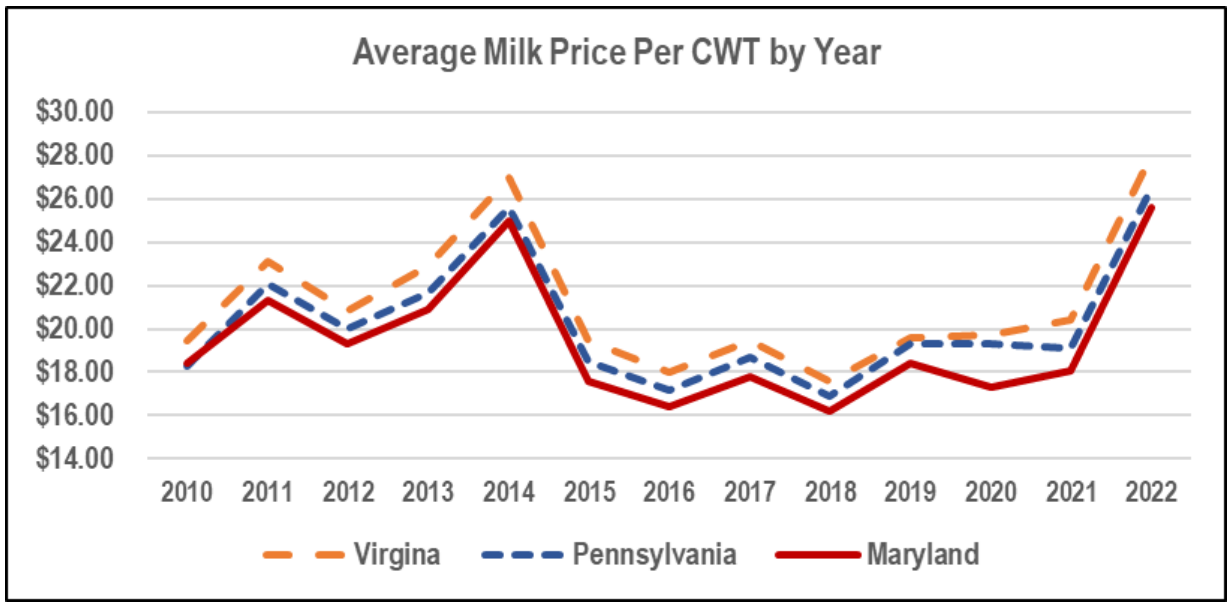
The main reason for the loss of dairy farms is perennially low milk prices. Disregarding the high milk price years of 2014 and 2022, the average price over the remaining eight years is about $ 17.60 per cwt. national supply has outpaced demand. Costs of production on Maryland farms are about $20 per cwt (Johnson, University of Maryland) which does not include family living withdrawals, principal payments on loans, or major capital improvements. Dairy farmers must try to make up the difference with cull and calf sales, crop sales, federal payments and other miscellaneous income.

It is even more revealing to look at milk prices since 2010. The chart and graph below show average milk prices per cwt for Virginia, Pennsylvania, and Maryland since 2010. The average Maryland price over this time period is $1.78 per cwt below the Virginia price and $0.82 per cwt below the Pennsylvania price.

Average Milk Price Per CWT by Year

State/Year	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	Average
Virgina	$19.43	$23.10	$20.83	$22.93	$26.97	$19.46	$18.03	$19.46	$17.57	$19.60	$19.70	$20.40	$28.00	$ 21.19
Pennsylvania	$18.28	$22.09	$20.01	$21.63	$25.62	$18.48	$17.16	$18.66	$16.87	$19.28	$19.28	$19.10	$26.50	$ 20.23
Maryland	$18.40	$21.30	$19.30	$20.90	$25.00	$17.60	$16.40	$17.80	$16.20	$18.40	$17.30	$18.10	$25.60	$ 19.41

USDA National Agricultural Statistics Service, Maryland Department of Agriculture



Land Prices

Other economics work to the detriment of Maryland dairy farms. The average price of farmland and buildings in Maryland (2023) is much higher than the average price of land & buildings in Pennsylvania and Virginia as seen below.

Price of land including buildings

Maryland	$9,700 per acre
Pennsyvania	$7,610 per acre
Virgina	$5,500 per acre

USDA National Agricultural Statistics Service

While higher land values increase a farm owner's net worth and provide more collateral to borrow against, it makes it more difficult to buy additional land to expand operations. It also makes it almost impossible for young farmers to get into dairying since a dairy operation cannot economically justify those land values inflated from development encroachment.

Feed prices

Feed prices are also working against Maryland dairy farms. The following table shows the average national corn and soybean prices for the past five marketing years (September 1 – August 31). Prices have been high for the past two marketing years. Analysts of the dairy farm sector began to put more attention on the threat of high feed costs. Dairy subsidy programs, which for decades had operated to keep milk prices high, were modified to make payments based on a combination of relatively low and relatively high feed prices.

Average price per bushel for the marketing year*

Year	2018/19	2019/20	2020/21	2021/22	2022/23
Corn	$3.61	$3.56	$4.53	$6.00	$6.55
Soybeans	$8.48	$8.57	$10.80	$13.30	$14.20

USDA World Agriculture Demand and Supply Estimates

*Marketing year is September 1 - August 31

Farm Level Economics

From the years 1994 -2020, Dale Johnson collected farm-level data on income and expenses from Maryland dairy farmers. This was done through farm visits so that Johnson did not have to take possession of confidential, personal, tax, and accounting information. This typically occurred during March to May after taxes have been filed and before farmers begin work in the fields.

The table below illustrates the income, expenses, and profit per hundred pounds (CWT) of milk produced by 25 dairy farms (18 non-organic and 7 organic) for the years 2018-2020. The average cost of production for non-organic farms for the years 2018-2020 is $20.41 per cwt (line 19). This does not include operator & family labor (family living) and debt principal payments. The average milk price per cwt for the same time period is $17.46 (line 4). This is $2.95 below the cost of production. While farmers have cattle sales and other income that help return a profit, the profit is inadequate for many farms. For example, the average total profit per farm is $56,809 (line 21). Out of this profit, farmers must extract family living (often more than one family) and debt principal payments (land, equipment, livestock, and operating debt) which often results in a negative cash flow. There is a wide variability in farm financial performance; some farms are worse off than others. The third column under non-organic farms shows that the least profitable 9 non-organic farms have a higher cost of production of $21.15/CWT (line 19) than average and lower income than average of $21.84/CWT (line 7). They barely break even at $0.70/CWT (line 20) or $15,755/farm (line21) before family living and debt principal payments are extracted.

The economics of organic farms are very different. Organic farms tend to be smaller at 86 cows compared to 134 (line 1). The production per cow is lower at 90 CWT/cow compared to 207 CWT/cow (line 2) because of several factors including cattle breed and feeding systems that rely primarily on pasture. Milk price is higher at $33.80/CWT compared to $17.46/CWT (line 4). Costs are also higher at $31.69/CWT compared to 20.41/CWT (line 19). Profit per CWT is higher at $9.48/CWT compared to $2.05/CWT (line 20). During this period the 7 organic farms did much better than the average non-organic farms. In comparing profit per farm, the organic farms average profit per farm of $75,777 was much higher than the average profit for non-organ farms of $56,809 (line 21). However, organic production is not an option for most dairy farms. Most organic cooperatives do not take on new farms. Some organic cooperatives have limited the amount of milk they pay the organic price.+

	2018-2020 Average of Maryland Dairy Farms	Conventional (Non-Organic) Farms			Organic
	Income, Expenses, and Profit per CWT	Total 18 Farms	High 9 Farms	Low 9 farms	7 Farms
1	Average number of cows	134	158	112	86
2	CWT of milk sold per cow	207	212	201	90
3	**Farm income**				
4	Milk sales	17.46	17.84	16.97	33.80
5	Cattle sales	1.23	1.11	1.39	3.56
6	Other income	3.77	3.99	3.49	4.12
7	Total income	22.46	22.94	21.84	41.48
8	**Farm expenses**				
9	Feed purchased	5.81	5.58	6.12	10.40
10	Seed, fertilizer, chemicals	2.17	2.32	1.96	2.02
11	Depreciation and repairs	3.17	3.39	2.88	6.40
12	Labor	0.84	0.80	0.89	0.62
13	Medical and breeding	0.92	0.75	1.14	0.51
14	Car, Truck, Fuel, Hauling	1.92	1.95	1.88	2.29
15	Rent	1.01	0.98	1.05	1.62
16	Interest	0.75	0.62	0.93	1.10
17	Custom hire	1.32	1.15	1.55	1.90
18	Other expenses	2.49	2.31	2.73	4.83
19	Total Expenses	20.41	19.85	21.15	31.69
20	Profit per CWT	2.05	3.08	0.70	9.79
21	Net profit per farm	56,809	102,996	15,755	75,777

Attachment 2

County	Entity Name	Address	City
Baltimore City	ATWATER'S	2905 WHITTINGTON AVE	BALTIMORE
Prince Georges	BIONATFOODS	11559 EDMONSTON RD	BELTSVILLE
Baltimore	BLUE STAR FARM LLC	3201 OLD YORK RD	WHITE HALL
Harford	BROOMS BLOOM DAIRY	1616 S FOUNTAIN GREEN RD	BEL AIR
Washington	CAPRIKORN FARMS LLC	20312 TOWNSEND RD	GAPLAND
Talbot	CHAPELS COUNTRY CREAMERY	10380 CHAPEL RD	EASTON
Washington	CHEESE GOATEES	19128 REIDTOWN RD	HAGERSTOWN
Worcester	CHESAPEAKE BAY DAIRY	4111 WHITESBURG RD	POCOMOKE
Cecil	CHESAPEAKE GOLD FARMS	41 GROVE MILLER LN	NORTH EAST
Washington	CLEAR SPRING CREAMERY	14312 ST PAUL RD	CLEAR SPRING
Saint Marys	CLOVER HILL DAIRY	27925 WOODBURN HILL RD	MECHANICSVILLE
Baltimore City	CLOVERLAND FARMS DAIRY	2701 LOCH RAVEN RD	BALTIMORE
Harford	DAILY CRISIS FARM	2837 BRADENBAUGH RD	WHITE HALL
Frederick	DAIRY MAID DAIRY LLC	259 E 7TH ST	FREDERICK
Washington	DELITEFUL DAIRY	16230 LONG DELITE LN	WILLIAMSPORT
Kent	DOGWOOD LANE DAIRY	1611 ST JAMES RD	WORTON
Worcester	DUMSERS DAIRYLAND INC	501 S PHILADELPHIA AVE	OCEAN CITY
Kent	EVES CHEESE STORAGE	100 N CROSS ST	CHESTERTOWN
Harford	FAWN VIEW FARM	5329 ONION RD	PYLESVILLE
Garrett	FIREFLY FARMS INC	107 S MAIN ST	ACCIDENT
Baltimore City	FRUMEX PALETAS LLC	5921 MORAVIA PARK DRIVE, UNIT C-4	BALTIMORE
Montgomery	GEMMA GELATO	1088 TAFT ST	ROCKVILLE
Baltimore City	GOOD KARMA CREAMERY	2905 WHITTINGTON AVENUE	BALTIMORE
Frederick	GROSSNICKLE FARMS	8816 DEVILBLISS BRIDGE RD	WALKERSVILLE
Garrett	HIGH COUNTRY CREAMERY AND MARKET LLC	97 LOCKER LN	GRANTSVILLE
Worcester	ISLAND CREAMERY BERLIN	120 N MAIN ST	BERLIN
Prince Georges	ITALIAN KITCHEN LTD	4521 KENILWORTH AVE	BLADENSBURG
Harford	KEYES CREAMERY	3712 ALDINO RD	ABERDEEN
Garrett	LAKESIDE CREAMERY	20282 GARRET HWY	OAKLAND
Washington	LANCO DAIRY FARMS COOP LLC	14738 WARFORDSBURG ROAD	HANCOCK
Prince Georges	MARVA MAID / MAOLA LANDOVER	1805 SOUTH CLUB DR	LANDOVER
Howard	MARYLAND & VIRGINIA MILK PRODUCERS	8321 LEISHEAR RD	LAUREL
Allegany	MEADOW MOUNTAIN NUTRITIONAL INC	14500 NATIONAL PIKE	FROSTBURG
Washington	MISTY MEADOW FARM CREAMERY	14325 MISTY MEADOW RD	SMITHSBURG
Prince Georges	MOBY DICK HOUSE OF KABOB	3329 75TH AVE	HYATTSVILLE
Frederick	MOO COW CREAMERY @ WALNUT RIDGE FARM	3935 BUSSARD RD	MIDDLETOWN
Howard	NESTLE DREYERS ICE CREAM CO	9090 WHISKEY BOTTOM RD	LAUREL
Caroline	NICE FARMS CREAMERY	25786 AUCTION ROAD	FEDERALSBURG
Prince Georges	PA BOWEN FARMSTEAD	15407 DR BOWEN RD	BRANDYWINE
Washington	PALMYRA FARM CHEESE LLC	18811 WAGAMAN RD	HAGERSTOWN
Baltimore	PITANGO PLANT	PRIGEL FAMILY CREAMERY	GLEN ARM
Montgomery	POTOMAC ICE CREAM LLC	19209 M CHENNAULT WAY	GAITHERSBURG
Baltimore	PRIGEL FAMILY CREAMERY	4852 LONG GREEN RD	GLEN ARM
Allegany	QUEEN CITY CREAMERY & DELI LLC	108 HARRISON ST	CUMBERLAND
Montgomery	SACRED MOUNTAIN LLC DBA MOORENKO'S ICE CREAM	8810 BROOKVILLE ROAD	SILVER SPRING
Frederick	SAPUTO CHEESE USA	428 EAST PATRICK STREET	FREDERICK
Montgomery	SAVAGE ACRES FARM INC	23301 MOUNT EPHRAIM RD	DICKERSON
Frederick	SOUTH MOUNTAIN CREAMERY LLC	8305 BOLIVAR RD	MIDDLETOWN
Baltimore City	TAHARKA BROTHERS	3515A CLIPPER MILL RD	BALTIMORE
Baltimore City	THE CHARMERY ICE CREAM	1700 W 41ST ST #400	BALTIMORE
Talbot	THE SCOTTISH HIGHLAND CREAMERY	102-104 S MORRIS ST	OXFORD
Prince Georges	TITO'S ICE CREAM	5351 46TH AVE	HYATTSVILLE
Baltimore	TOTALLY COOL INC	36-40 GWYNNS MILL CT	OWINGS MILLS
Carroll	WHISPERING BREEZE FARM CREAMERY	4307 ANGELL ROAD	TANEYTOWN
Montgomery	WOODBOURNE CREAMERY AT ROCK HILL ORCHARD	28600 RIDGE RD	MOUNT AIRY
Prince Georges	YORK CASTLE ICE CREAM CO INC	6771 MID CITIES AVE	BELTSVILLE

Have milk processed off site into dairy products

Only permitted MD Raw milk aged cheese processor

ATTACHMENT 3

Contains Nonbinding Recommendations

Draft-Not for Implementation

Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2023-D-0451 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2371.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

February 2023

Table of Contents

Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

I. Introduction

The purpose of this guidance is to provide FDA's current view on the naming of plant-based foods that are marketed and sold as alternatives for milk (plant-based milk alternatives) in accordance with sections 403(a)(1) and 403(i)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(a)(1) and 343(i)(1)). The guidance also includes our recommendations on the use of voluntary nutrient statements. Industry's use of these voluntary nutrient statements would provide consumers with additional nutrition information to help them understand certain nutritional differences between these products and milk and make informed dietary choices.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

A. Overview and Purpose

FDA seeks to improve dietary patterns in the United States to help reduce the burden of nutrition-related chronic diseases and advance health equity. We are committed to accomplishing this by promoting healthy starts through improved maternal, infant, and child health, creating a healthier food supply for all, and empowering consumers with more

[1] This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

informative and accessible labeling to choose healthier diets. Ensuring plant-based milk alternative labels are clear will help enable consumers to quickly ascertain the attributes of products they are purchasing for themselves and their families.

In the *Federal Register* of September 28, 2018, we issued a notice entitled "Use of the Names of Dairy Foods in the Labeling of Plant-Based Products" (notice) requesting comment on the labeling of plant-based alternatives with names that include the names of dairy foods.[2] We invited comment on a variety of issues, including how consumers use plant-based dairy alternatives, how consumers understand terms included in the names of plant-based dairy alternatives, and whether consumers are aware of and understand differences between plant-based dairy alternatives and their dairy counterparts. In addition, we commissioned and conducted focus groups to further inform our understanding of these issues.

In response to the notice, we received over 13,000 comments,[3] most of which focused on plant-based milk alternatives. The comments, other research reviewed, and our analysis of the data (Ref. 1) suggest a potential public health concern related to the substitution of milk with plant-based milk alternatives that contain lower amounts of certain nutrients than found in milk. Given this potential public health concern, this draft guidance focuses only on plant-based alternatives to milk and not plant-based alternatives to other dairy products. Specifically, this draft guidance includes recommendations for the naming and voluntary nutrient statements that, if finalized, would help consumers understand certain nutritional differences between plant-based milk alternatives and milk.[4]

We are issuing this guidance to provide industry with recommendations on voluntary nutrient statements. The use of these statements would support the FDA's goal to improve healthy dietary patterns by providing consumers with additional and more accessible information to enhance their ability to make informed choices about the foods they buy and eat. This draft guidance also provides clarity on the naming of these products.

B. Plant-based Milk Alternatives

There has been an increase in availability in the marketplace and consumption of plant-based milk alternatives. In 2010, one-fifth of U.S. households purchased or consumed plant-based milk alternatives. By 2016, one-third of U.S. households purchased plant-based milk alternatives, totaling $1.5 billion in sales that year (Ref. 2). From 2017 to 2019, sales of plant-based milk alternatives increased nearly 15 percent reaching $2 billion, with refrigerated products accounting for approximately 90 percent and shelf-stable products accounting for around 10 percent (Ref. 3). In 2020, retail sales continued to increase, rising to approximately $2.4 billion (Ref. 4). The variety of plant-based milk alternatives available in the marketplace has also greatly expanded from soy, rice, and almond to include cashew, coconut, flaxseed, hazelnut, hemp seed, macadamia nut, oat, pea, peanut, pecan, quinoa, and walnut-based

[2] See 83 FR 49103.

[3] See www.Regulations.gov Docket FDA-2018-N-3522-0001.

[4] This guidance does not address other types of mammalian milk, such as goat milk, sheep milk, and camel milk, that may be used as substitutes for milk. These types of milk are used far less frequently than plant-based milk alternatives as substitutes for milk and therefore do not pose the same potential public health concern.

beverages. While some plant-based milk alternative products have "beverage" or "drink" in their labeling, the majority of products have the word "milk" in their names (Ref. 3). Consumers purchase plant-based milk alternatives for various reasons, such as allergies, intolerances, religious practices, and lifestyle choices (e.g., vegan diet). Consumers often use plant-based milk alternatives in a similar way as milk, such as in cereal, coffee, and smoothies (Refs. 1 and 3). Additionally, more than a third of respondents to a Consumer Reports survey said that in the past year they have purposely used plant-based milk alternatives as a substitute for milk (Ref. 6).

FDA has not established compositional requirements for plant-based milk alternatives. The composition of these products, including their nutrient profiles, varies depending on the plant source(s), processing methods, and added ingredients. Plant-based milk alternatives are made from liquid-based extracts of plant materials, such as tree nuts (e.g., almond, walnuts, macadamia), legumes (e.g., soybean), seeds (e.g., hemp, flax), or grains (e.g., rice, oat). Water is generally the primary ingredient in these products. In addition to water and the plant extract(s), the products may be fortified with various vitamins and minerals. Other ingredients, such as vegetable oil(s), nutritive and/or non-nutritive sweeteners, salt, and/or other functional or flavoring ingredients, may be added. In addition to direct plant extractions, alternate processing methods are used where individual plant protein solid(s), plant oil(s), water, and other ingredients are combined to formulate a plant-based milk alternative (Ref. 7).

C. Consumer Understanding of Plant-based Milk Alternatives

1. Composition and Naming

In response to FDA's notice mentioned above, several comments included data from consumer studies about consumers' understanding and use of plant-based milk alternatives in comparison to milk. Overall, these studies indicate that consumers understand that plant-based milk alternatives do not contain milk when shopping for various types of products labeled with the term "milk." In particular, one consumer survey suggested that about three-quarters of its respondents understood that plant-based milk alternatives do not contain milk; fewer than 10 percent believed that plant-based milk alternatives do contain milk, and the remainder did not know (Ref. 1).

Focus groups commissioned and conducted by FDA suggested that "milk" is strongly rooted in consumers' vocabulary when describing and talking about plant-based milk alternatives. The focus groups indicated that most participants were not confused about plant-based milk alternatives containing milk and refer to plant-based milk alternatives as "milk." Participants further indicated that they feel familiar and comfortable with the term "milk" when describing plant-based milk alternatives and they preferred to use the term when given a choice of names for plant-based milk alternatives (e.g., "milk," "beverage," "drink," etc.). Participants also said that the term "beverage" and "drink" may suggest lower quality than a product called "milk" (Ref. 1). Other research also appears to show that consumers understand that plant-based milk alternatives are distinct products and choose to purchase plant-based milk alternatives because they are not milk. For example, as noted above, some consumers purchase plant-based milk alternatives because of allergies, intolerances to milk, or lifestyle choices (e.g., vegan diet) (Ref. 1).

2. Nutritional Content

While consumers appear to understand that plant-based milk alternatives are distinct products from milk, several consumer studies submitted in response to the notice indicate that consumers, including consumers who purchase plant-based milk alternatives, do not understand the nutritional differences between milk and plant-based milk alternatives (Ref. 1). In general, research suggests that many consumers lack an accurate understanding about the specific nutrients in plant-based milk alternatives (Ref. 6). The research also suggests that a majority of consumers who purchase plant-based milk alternatives state they do so because they believe the products are healthier than milk (Ref. 6). Additionally, in focus groups conducted by FDA with consumers of plant-based milk alternatives, frequent mentions were made that plant-based milk alternatives may be healthier than milk because they are lower in fat and cholesterol, and do not contain animal ingredients (Ref. 1). Further, a survey reported that 53 percent of its respondents believe that plant-based milk alternatives labeled with the term "milk" in their name have a nutritional content similar to milk. Another survey indicated that the term "milk" paired with "almond" creates a more favorable perception of the nutritional content of the product compared to "almond drink," "almond beverage," or "almond juice." The survey data also indicated that its respondents expect that plant-based milk alternatives are comparable in nutrition to milk and this belief is stronger in those who purchase plant-based milk alternatives (Ref. 1). Some comments submitted to the notice said that consumers do understand the nutritional differences between plant-based milk alternatives and milk; however, the comments did not provide studies or other data to support this assertion.

D. Definition of Milk and Use of the Term "Milk" in the Names of Plant-based Milk Alternatives

1. Statute and Regulations

The FD&C Act gives us the authority to establish definitions and standards of identity for foods.[5] Definitions and standards of identity are established by regulation under the common or usual name of the food. Such foods are said to be "standardized." Under the statute, products that purport to be or are represented as a food for which a definition and standard of identity has been established must conform to the definition and standard and their labels must bear the name specified therein.[6]

Foods that do not have an established definition and standard of identity are "non-standardized foods." The labels of non-standardized foods must bear the common or usual name of the food, if there is such a name.[7] A common or usual name is the name by which an article is known to the American public. Common or usual names are generally established by common usage, although, in some cases, they may be established by regulation.[8] The fact that a standard of identity has been established for a food (under its common or usual name) or that a name is

[5] See 21 U.S.C. 341.
[6] See 21 U.S.C. 343(g).
[7] See 21 U.S.C. 343(i)(1).
[8] See 21 CFR 102.5(d).

specified among the standard of identity regulations for a food does not preclude use of the name in the common or usual name of another food.[9] However, such use must not be misleading.

In the absence of a common or usual name or other name established by federal law or regulation, food sold in packaged form must be labeled with an accurate description of the food or a fanciful name commonly used by the public.[10] Such description or name must not be false or misleading and is referred to as the statement of identity.[11] Words or statements required to appear on the label or labeling must be in such terms as to render them likely to be understood by the ordinary individual under customary conditions of purchase and use.[12]

The FD&C Act also provides for labeling of a food product as an "imitation" of another food.[13] We have defined an imitation food as one that substitutes for and resembles another food and is nutritionally inferior to that food.[14] Nutritional inferiority is defined in part as any reduction in the content of an essential nutrient that is present at a level of two percent or more of the Daily Reference Value or Reference Daily Intake, depending on the nutrient, per reference amount customarily consumed.[15]

2. Identity and Naming of Milk and Plant-based Milk Alternatives

In 1973, FDA established a definition and standard of identity for milk.[16] Milk has since been defined as "the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows." Products that purport to be or are represented as milk are required to conform to the definition and standard, and their labels must bear the name "milk."[17] Products that do not purport to be and are not represented as milk are not subject to these requirements.

Plant-based milk alternatives are not milk; they are made from plant materials rather than the lacteal secretion of cows. Consequently, under the FD&C Act, they may not be offered for sale as "milk."[18] Although many plant-based milk alternatives are labeled with names that bear the term "milk" (e.g., "soy milk"), they do not purport to be nor are they represented as milk. The comments and information we reviewed indicate that consumers understand plant-based milk

[9] See, e.g., the standard of identity for composite units of frozen raw breaded shrimp (21 CFR 161.175(c)(6) and (e)(6)) and the common or usual name regulation for non-standardized breaded composite shrimp units (21 CFR 102.55(a)) (the names of both the standardized food and non-standardized food including "breaded shrimp"); see, e.g., the standard of identity for bread (21 CFR 136.110(a), (c)(1), and (e)(1)) and common usage names of non-standardized bakery products made without wheat flour (e.g., "rice bread") (the names of both the standardized food and the non-standardized food including "bread").

[10] See 21 CFR 101.3(b)(3).

[11] See 21 U.S.C. 343(a)(1); see also 21 CFR 101.3(b).

[12] See 21 U.S.C. 343(f).

[13] See 21 U.S.C. 343(c).

[14] See 21 CFR 101.3(e)(1).

[15] See 21 CFR 101.3(e)(4); Recently, FDA committed to not requiring a producer of non-vitamin-fortified skim milk to label that product as "imitation" (see *South Mt. Creamery, LLC v. United States FDA*, 438 F. Supp. 3d 236 (2020)).

[16] See 21 CFR 131.110.

[17] See 21 U.S.C. 403(g) and 21 CFR 131.110(e).

[18] See 21 U.S.C. 343(b).

alternatives to be different products than milk. While many circumstances attending retail sale of the products are similar to those attending retail sale of milk (e.g., packaging, labeling, location in grocery store), the comments and information we reviewed indicate that consumers, generally, do not mistake plant-based milk alternatives for milk.

Standards of identity have not been established for plant-based milk alternatives. As such, plant-based milk alternatives are non-standardized foods and must be labeled with their common or usual names, or in the absence thereof, a statement of identity that accurately describes the food.[19] The names of some plant-based milk alternatives appear to be established by common usage, such as "soy milk" and "almond milk."

3. First Amendment Considerations

FDA also recognizes that there are First Amendment considerations when regulating commercial speech such as food labels and labeling.[20] For example, FDA is aware of the current lawsuits that challenge state legislative limits to the use of words associated with traditional food products on alternative food product labels, and that some courts have scrutinized such labeling restrictions under the First Amendment. To support a prohibition on such speech, the proponent must demonstrate either that the speech in question is inherently false or misleading or that the regulation is appropriately tailored to directly advance a substantial governmental interest. As of February 2023, some cases remain pending. Some courts have held that, under the First Amendment, the states have failed to justify bans on plant-based alternative products using names associated with meat and/or dairy products.[21] However, some courts have held that a

[19] See 21 U.S.C. 343(i)(1) and 21 CFR 101.3(b).

[20] The First Amendment to the United States Constitution prohibits laws that, among other things, abridge the freedom of speech. See, e.g., *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2371 (2018). However, the government may, consistent with the First Amendment, require the disclosure of factual information in marketing commercial products where the disclosure is justified by a government interest and does not unduly burden protected speech. See *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). The government may also prohibit commercial speech that concerns unlawful activity or is false or inherently misleading. See *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n,* 447 U.S. 557, 563-64 (1980). The government may further regulate commercial speech that is not false or deceptive and does not concern unlawful activities where the regulation directly advances a substantial governmental interest and is no more extensive than necessary to advance that interest. See *id.* at 564.

[21] See *Turtle Island Foods v. Strain*, 594 F. Supp. 3d 692 (M.D. La. 2022) (finding Louisiana may not restrict plant-based meat product to be marketed or sold with terms like "burger" and "sausage" on their labels because there was no evidence that the law was necessary to prevent consumer confusion, and the state failed to address why a less restrictive alternative, such as a disclaimer, would not be sufficient to advance the government interest), *appeal pending*, 22-30236 (5th Cir.); *Miyoko's Kitchen, Inc. v. Ross*, 3:20-cv-00893, 2021 U.S. Dist. LEXIS 193462 (N. D. Cal. Aug. 10, 2021) (finding California may not restrict plaintiff's use of the word "butter" and the phrases "lactose free" and "cruelty free" on the labeling of its "vegan butter"); *Turtle Island Foods v. Soman*, 424 F. Supp. 3d 552 (E.D. Ark. 2019) (preliminarily enjoining Arkansas from enforcing law that prohibited selling an agricultural product under the name of another food), *permanent injunction entered*, 2022 U.S. Dist. LEXIS 179206 (E.D. Ark. Sept. 30, 2022). See also *Ocheesee Creamery LLC v. Putnam*, 851 F.3d 1228 (11th Cir. 2017) (although "a state can propose a definition for a given term, . . . it does not follow that once a state has done so, any use of the term inconsistent with the state's preferred definition is inherently misleading" particularly where that definition is inconsistent with common usage).

state can require that the labeling on the plant-based alternative product include a prominent disclosure indicating that the product is plant-based.[22]

E. Role of Milk in Healthy Eating Patterns

The U.S. Dietary Guidelines for Americans (Dietary Guidelines) make recommendations for healthy eating patterns that can help reduce chronic disease risk and help individuals meet nutrient needs. Depending on calorie needs and age, the *Dietary Guidelines, 2020-2025* recommends 1⅔-2 cup equivalents (whole-fat) from the Dairy Group per day for toddlers ages 12-23 months and between 2-3 cup equivalents (low-fat or fat-free) from the Dairy Group per day for children (≥2 years of age) and adults to achieve a healthy eating pattern (Ref. 8). However, about 90 percent of the U.S. population does not meet these recommendations (Ref. 8). The Dairy Group includes, but is not limited to, all fluid, dry, or evaporated milk, including lactose-free and lactose-reduced products and fortified soy beverages (soy milk), as well as cheese, yogurt, and soy yogurt alternatives. According to the 2017-2018 National Health and Nutrition Examination Survey (NHANES), the majority of dairy consumed in the U.S. (49 percent) is from milk, primarily as a beverage or on cereal. Overall, dairy intake has not changed over time; however, it has decreased among youth and significantly decreased among children two to five years of age (Ref. 9). Total dairy intake is highest among non-Hispanic White and Hispanic individuals and lowest among non-Hispanic Black individuals for all ages (Ref. 9).

The Dietary Guidelines identify the Dairy Group as a key contributor of calcium, protein, vitamin A, vitamin D, magnesium, phosphorus, potassium, riboflavin, vitamin B-12, as well as zinc, choline, and selenium. The *Dietary Guidelines, 2020-2025* (Ref. 8) identifies calcium, vitamin D, and potassium as nutrients of public health concern across all age groups, including ages 12-23 months, and the Scientific Report of the 2020 Dietary Guidelines Advisory Committee (2020 DGAC Report) (Ref. 9) notes vitamin A, magnesium, and choline as nutrients that pose a special public health challenge[23] for individuals one year of age and older. FDA also identified calcium, vitamin D, and potassium as nutrients of public health significance, requiring them to be declared on the updated Nutrition Facts label.[24] The Dairy Group in the *Dietary Guidelines, 2020-2025* includes soy beverages fortified with calcium, vitamin A, and vitamin D because they are similar to milk based on their nutrient composition and use in meals.

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[22] See *Turtle Island Foods v. Richardson*, 425 F. Supp. 3d 1131 (W.D. Mo. 2019) (declining to issue a preliminary injunction against Missouri over a law that prohibited "misrepresenting a product as meat that is not derived from harvested production livestock or poultry" where Missouri issued guidance stating that it would not take enforcement action if the label contained an appropriate qualifier indicating that the product was plant-based or lab-grown), aff'd, 992 F.3d 694 (8th Cir. 2021); *Upton's Nats. Co v. Stitt*, 2020 U.S. Dist. LEXIS 216883 (W.D. Okla. Nov. 19, 2020) (preliminarily upholding mandated disclosure that the product is plant-based in same font size as the product name). In addition, after Mississippi was sued over a law that banned the use of meat product terms to describe plant-based foods, *Upton's Naturals Co. v. Bryant*, 3-19-cv-462 (S.D. Miss.), the state withdrew its proposed implementing regulation and replaced it with a new proposed regulation stating that the state would not consider labeling to be violative if the labeling included an appropriate qualifier indicating the product was plant-based. Plaintiffs then withdrew the lawsuit.

[23] The 2020 DGAC Report explains that "nutrients that pose a special public health challenge" are nutrients that are currently under-consumed, but there is insufficient data to assess adverse clinical and health outcomes.

[24] See 81 FR 33742 at 33884; see also 21 CFR 101.9(c)(8)(ii).

The *Dietary Guidelines, 2020-2025* provides dietary recommendations, including for the Dairy Group and the nutrients it provides, within and across life stages. Diets that do not meet the recommended amounts from the Dairy Group contribute to low intakes of nutrients, particularly calcium and vitamin D. Inadequate consumption of calcium and vitamin D can result in impaired peak bone mass accrual, low bone mass, and osteoporosis (Ref. 9). Although calcium and vitamin D are important across the lifespan, calcium and vitamin D are critically needed during the time period when peak bone mass is still actively accruing (adolescence through 30 years of age), and, for women, in the post-menopausal period when bone remodeling occurs (Ref. 8). Additionally, adequate intake of vitamin D is important because of its role in the regulation of calcium and phosphorus metabolism and bone health. However, as noted above, the percentage of youth with Dairy Group intakes below recommended levels increases dramatically starting at age 9 years, with 79 percent or more between ages 9 and 13 years falling below recommended intakes (Ref. 9). The 2020 DGAC Report cautions that, because foods in the Dairy Group are a significant source of these important nutrients, the downward trend in consumption in youth should be monitored.

While all foods recommended in the Dairy Group in the Dietary Guidelines provide calcium and the other important nutrients of interest, dairy is generally consumed in forms with higher amounts of sodium (e.g., cheeses) and saturated fat (e.g., higher fat milks and yogurts). The Dietary Guidelines advise that consuming more dairy in low-fat or fat-free forms than current amounts would provide more vitamin A, vitamin D, potassium, and choline and decrease amounts of sodium, cholesterol, and saturated fats.

F. Nutritional Differences between Plant-based Milk Alternatives and Milk

While the nutritional value of milk and its role in healthy eating patterns is well documented, the nutritional content of plant-based milk alternatives varies considerably across types (e.g., "almond milk" vs. "oat milk") and within the same type depending on the raw materials used, processing, fortification with vitamins and minerals, and addition of other ingredients, such as sugar and oil (Refs. 5, 11, and 12). As noted above, the *Dietary Guidelines, 2020-2025* includes soy beverages and soy yogurt alternatives that are fortified with calcium, vitamin A, and vitamin D in the Dairy Group because they have similar nutrient compositions and use in meals. However, the *Dietary Guidelines, 2020-2025* states that "other products sold as "milks" but made from plants (e.g., almond, rice, coconut, and hemp "milks") may contain calcium and be consumed as a source of calcium, but they are not included as part of the dairy group because their overall nutritional content is not similar to dairy milk and fortified soy beverages."

The Scientific Report of the 2015 Dietary Guidelines Advisory Committee (2015 DGAC Report) included a modeling analysis "to examine the nutritional consequences of not consuming milk and milk products, to explore possible food alternatives to fill the nutrient gaps left in the diet if milk and milk products are not consumed" (Ref. 10). The analysis demonstrated that, while individuals can consume these nutrients from sources other than milk, the number of potential alternatives to provide sufficient calcium would provide too many calories and/or be a large amount to consume daily. Therefore, the Dietary Guidelines recommend three cup equivalents from the Dairy Group for individuals nine and older to support an increased requirement for calcium that is needed during these life stages. The question of bioavailability of calcium in

non-dairy products was not addressed in the modeling analysis. (Ref. 10). Calcium- and vitamin D-fortified plant-based milk alternatives are alternatives to milk to consider, but they may vary in other potentially important nutrients (e.g., protein, magnesium, phosphorus, and potassium).

The 2020 DGAC Report built on this analysis by evaluating beverages' contribution to healthy eating patterns, and the inclusion of only fortified soy beverages in the Dairy Group remained. Further, the 2020 DGAC Report notes that inadequate intakes from the Dairy Group may contribute to low intakes of calcium, protein, vitamins A and D, magnesium, and phosphorous. Some of these essential nutrients can be difficult to replace in a healthy dietary pattern. Americans already consume less from the Dairy Group than what is recommended by the Dietary Guidelines and the nutritional composition of plant-based milk alternatives varies greatly and often is not similar to milk. Therefore, consistently consuming plant-based milk alternatives that do not have a similar nutritional composition to milk in place of milk, without the addition of other foods to supply the missing nutrients, could lead to further inadequate intakes of nutrients of public health concern and other nutrients that pose a special public health challenge. This, in turn, could lead to adverse health effects such as impaired peak bone mass accrual, low bone mass, and osteoporosis (see Section II.E. of this Guidance).

Recognizing the important role of milk in healthy dietary patterns, the Department of Agriculture's (USDA) National School Lunch Program (NSLP), School Breakfast Program (SBP), and Child and Adult Care Food Program (CACFP) require milk to be served as part of a reimbursable meal. However, recognizing that some children and adults cannot consume milk due to non-disability medical or other special dietary needs (e.g., lactose intolerance), the Richard B. Russell National School Lunch Act (School Lunch Act) requires that fluid milk substitute served as an alternative to milk in the NSLP, SBP, and CACFP must be nutritionally equivalent to milk and meet nutritional standards set by the U.S. Department of Agriculture (USDA).[25] Specifically, the School Lunch Act requires that the nutritional standards for fluid milk substitute must, at a minimum, be fortified with calcium, protein, vitamin A, and vitamin D to levels found in milk.[26] Citing that milk is the primary food source for riboflavin, vitamin B-12, magnesium, phosphorus, and potassium for children, USDA's Food and Nutrition Service (FNS) extended the nutrition standards for fluid milk substitute to include these additional vitamins and minerals.[27] Therefore, a fluid milk substitute must contain a minimum amount of calcium, protein, vitamin A, vitamin D, magnesium, phosphorus, potassium, riboflavin, and vitamin B-12 (Appendix 1) to be part of a reimbursable meal in the NSLP, SBP, and CACFP.[28] These are the same nutrients that the Dietary Guidelines identify as key contributions from the Dairy Group except for zinc, choline, and selenium (see Section II.E. above). Choline and selenium were not discussed in the *2005 Dietary Guidelines* which was the current version at the time USDA's FNS developed the fluid milk substitute nutrient criteria. Certain soy-based beverages are also allowed as substitutes for milk in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC Program). To maintain consistency, the WIC Program

[25] See sections 9(a)(2)(B)(i) and 17(g)(4)(B) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1758(a)(2)(B)(i) and 1766((g)(4)(B)).
[26] Ibid.
[27] See 7 CFR 210.10 (d)(3), 220.8(d), and 226.20(g)(3).
[28] Ibid.

uses the same nutrition standards as the NSLP, SBP, and CACFP for defining allowable soy-based beverages as alternatives to milk.[29]

As discussed above (Section II.C.b.), consumer studies indicate that, in general, while consumers do not understand the nutritional differences between plant-based milk alternatives and milk, they believe plant-based milk alternatives are healthier than milk and expect that products labeled with the term "milk" in the name are comparable in nutrition to milk (Ref. 1). Considering that consumers may not understand the nutritional differences between plant-based milk alternatives and milk and the potential public health concerns associated with replacing milk with plant-based milk alternatives that do not have a similar nutritional composition to milk,[30] FDA is providing recommendations for voluntary nutrient statements for plant-based milk alternatives that include "milk" in their names (e.g., "soy milk," "almond milk," "oat milk," etc.) and have a nutrient composition that is different than milk to help consumers understand the nutritional differences between such products and milk.[31]

III. Questions and Answers

The following section provides information and recommendations in a question and answer format about: (1) naming principles for plant-based milk alternatives; and (2) recommendations for voluntary nutrient statements.

1. Identity and Names

1.1. Is there an established standard of identity for plant-based milk alternatives?

No, plant-based milk alternatives are non-standardized foods as no definition or standard of identity has been prescribed for them by regulation.

1.2. What are the common or usual names of plant-based milk alternatives?

Common or usual names have been established by common usage for some plant-based milk alternatives. Among these names are "soy milk" and "almond milk" and others that qualify the term "milk" with the plant source of the food. Names that qualify the terms "beverage" or "drink" with the plant source of the food are used less frequently, but also appear to be in common usage. These names include "soy beverage" and "almond beverage."

1.3. Do plant-based milk alternatives need to include the term "milk" in their names (e.g., "soy milk," "almond milk," etc.)?

[29] See 7 CFR 246.10(e)(10-12).

[30] Plant-based milk alternatives that contain the minimum amount identified in Appendix 1 (USDA's FNS Fluid Milk Substitutes Nutrient Criteria) are considered nutritionally similar to milk.

[31] At this time, FDA is not aware of a potential public health concern associated with substituting other mammalian milks for milk. The percent of U.S. households that purchase plant-based milk is much higher than those that consume other mammalian milks (e.g., goat, camel). Therefore, the recommendations for a voluntary nutrient statement in this guidance focus on plant-based milk alternatives and not other mammalian milks.

No. Non-standardized foods are required to be labeled with their common or usual name if such a name exists.[32] As explained in 1.2, many plant-based milk alternatives appear to have multiple common or usual names. Under section 403(i)(1) of the FD&C Act (21 U.S.C. 343(i)(1)), plant-based milk alternatives must be labeled with a common or usual name, but there is no requirement that they be labeled with more than one common or usual name. Consequently, a plant-based milk alternative may be labeled with the term "beverage," "drink," or "milk."

1.4. How should the term identifying the plant source appear in reference to the term "milk," "beverage," or "drink"?

In the names of plant-based milk alternatives, the term "milk" (or "beverage" or "drink") should be qualified by the plant source of the food. The name may be a single word (i.e., "soymilk"), multiple words (e.g., "soy milk"), or hyphenated (e.g., "soy-milk").

1.5. Is "plant-based milk" an appropriate name for plant-based milk alternatives?

No, while "plant-based" or "plant" may be used to describe a plant-based milk alternative, we do not recommend using only these terms in the name of the food. "Plant-based milk" is not the common or usual name of plant-based milk alternatives. Moreover, omitting a descriptor of the particular legume, nut, grain, seed, or other plant-source in the name of the food may be confusing to consumers, as the product would not be readily distinguishable from other types of plant-based milk alternatives. The nature or source of the characterizing or predominant ingredients is important information for consumers and should be included in the name or statement of identity to identify and describe the food and distinguish it from similar foods. Consumers should be able to easily determine the particular plant source when looking at the name of the food on the label (e.g., almond or oat).

1.6. How should plant-based milk alternatives that are blends of different plant sources be labeled?

If a plant-based milk alternative is derived from different plant sources, we recommend that the different plant sources be included in the name so that consumers can easily identify the nature of the food and distinguish it from similar foods. We recommend that the predominant plant source be stated first in the name or statement of identity. For example, a plant-based milk alternative that is a blend of walnuts and cashews, with walnuts predominating, should be labeled with "walnut" first, followed by "cashew"; possible names include: "Walnut & Cashew Milk," "Walnutmilk with Cashewmilk," or "Walnut-Cashew Milk."

For plant-based milk alternatives that are blends of two or more plant-sources, the name should accurately convey to the consumer that multiple plant sources are present. For example:

[32] See 21 U.S.C. 343(i)(1).

- "Soy and Nut Milk Blend" (for a product that contains a blend of soy, almonds, and cashews)
- "7 Grain Plant-Milk Blend" (for a product that contains a blend of only grains (e.g., oats, wheat, barley, rice))

All plant sources must be declared in the ingredient statement as required by 21 CFR 101.4.

1.7. Should plant-based milk alternatives be labeled "imitation milk"?

As previously discussed, we have defined an imitation food under the FD&C Act as one that substitutes for and resembles another food and is nutritionally inferior to that food. Not all plant-based milk alternatives meet this definition, but to the extent they do, based on our current understanding, we intend to exercise enforcement discretion with respect to section 403(c) of the FD&C Act (21 U.S.C. 343(c)).

When section 403(c) of the FD&C Act (21 U.S.C. 343(c)) was enacted in 1938, Congress was seeking to protect the consumer from uninformed purchase of an inferior substitute product which could be mistaken for a traditional food product (e.g., jams).[33] The information we reviewed demonstrates that consumers generally do not mistake plant-based milk alternatives as milk, understand that they are distinct products, and often purchase plant-based milk alternatives because they are not milk (e.g., lactose-intolerance, vegan diet).

1.8. Should plant-based milk alternatives be labeled as "dairy-free" or "non-dairy"?

The use of truthful and not misleading label statements (e.g., "dairy-free," "non-dairy") that help inform consumers that the products are derived from plants, and are not milk and do not contain milk, is encouraged. However, the term "dairy-free milk" is not an adequate name for any plant-based milk alternative because it does not describe the nature of the plant-source and therefore does not distinguish the product from other types of plant-based milk alternatives. The nature or source of the characterizing or predominant ingredients is important information for consumers and should be included in the name or statement of identity to identify and describe the food and distinguish it from similar foods. Thus, such terms are not appropriate names for plant-based milk alternatives but may be used as additional information on product labels to help inform consumers that the products are not made with dairy or milk.

[33] See 38 FR 2138 (Jan. 19, 1973).

2. Recommendations for Voluntary Nutrient Statements

FDA recommends that plant-based milk alternatives that use the term "milk" in their name (e.g., "soy milk," "almond milk," "oat milk," "almond-macadamia milk blend," etc.) and have a nutrient composition that is different than milk (e.g., calcium, protein, vitamin A, vitamin D, magnesium, phosphorous, potassium, riboflavin, or vitamin B12 (see Appendix 1)) bear an additional nutrient statement on the product label describing how it is nutritionally different. The use of these statements is voluntary.

2.1. What is the purpose of voluntary nutrient statements for plant-based milk alternatives?

FDA recommends the use of these statements to help consumers understand certain nutritional differences between milk and plant-based milk alternatives that use the term "milk" in their name (e.g., "soy milk," "almond milk," "oat milk," "almond-macadamia milk blend," etc.) and have a nutrient composition that is different than milk. As discussed above, milk plays an important role in healthy diets, and the Dietary Guidelines encourage increased consumption of milk to help alleviate specific nutrient shortfalls. Additionally, consumer research indicates that, while the majority of consumers understand that milk and plant-based milk alternatives are different products, consumers may not understand the nutritional differences between them. Consumer research also indicates that consumers perceive plant-based milk alternatives labeled with the term "milk" to have a more favorable nutritional profile than similar products labeled with terms like "drink" or "beverage" (Ref. 1).

2.2. How should manufacturers determine if their plant-based milk alternatives have different nutrient compositions to milk?

To determine if a plant-based milk alternative is nutritionally different than milk, FDA recommends using USDA's FNS fluid milk substitutes nutrient criteria (e.g., calcium, protein, vitamin A, vitamin D, magnesium, phosphorous, potassium, riboflavin, and vitamin B12; see Appendix 1). These are the same nutrients that the Dietary Guidelines identify the Dairy Group as a key contributor of except for zinc, choline, and selenium (see Section II.E.).

2.3. What information does FDA recommend be included in the voluntary nutrient statement?

Due to the potential public health concern of underconsumption of certain nutrients otherwise provided by milk, we recommend that plant-based milk alternatives that use the term "milk" in their name (e.g., "soy milk," "almond milk," "oat milk," "almond-macadamia milk blend," etc.) and have a nutrient composition that is different than milk

(Appendix 1) bear a voluntary nutrient statement on the product label about the nutrient levels compared to milk, such as:

- "Contains lower amounts of [nutrient name(s)] than milk."

This type of voluntary nutrient statement will clearly communicate to consumers when a plant-based milk alternative is lower in nutrients in comparison to milk (see also question 2.8).

2.4. How does FDA recommend the voluntary nutrient statement be presented on the label?

We recommend placing the voluntary nutrient statement on the principal display panel (PDP) near and visually connected to the name of the product if space allows. A symbol (e.g., "†") may be placed next to the name of the product that directs consumers to the voluntary nutrient statement on the PDP. We also recommend that the voluntary nutrient statement be prominent on the food label so that it is easily identifiable for consumers.

Figure 1: Example of Voluntary Nutrient Statement on Product Label next to Product Name

Figure 2: Example of Voluntary Nutrient Statement on Product Label next to Product Name - *Close-up of Voluntary Nutrient Statement*

Figure 3: Example of Voluntary Nutrient Statement on Product Label Using a Symbol

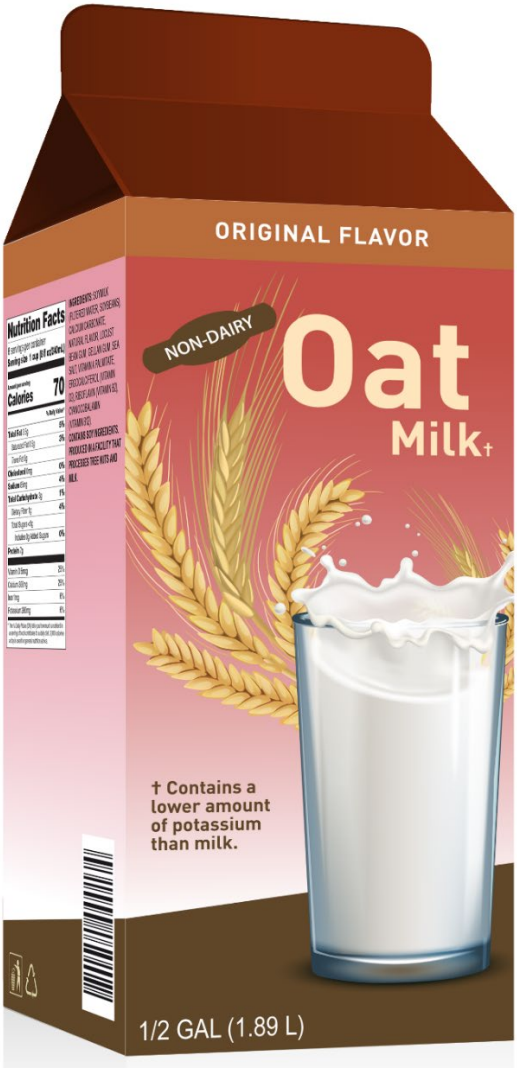
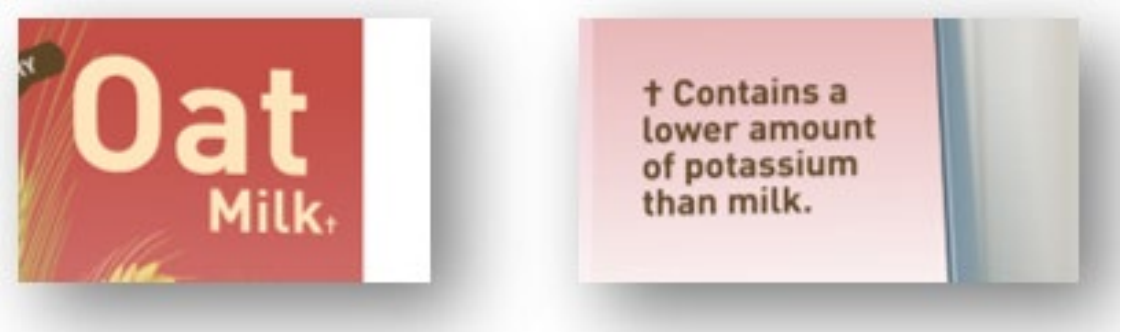


Figure 4: Example of Voluntary Nutrient Statement on Product Label Using a Symbol - *Close-up of Symbol and Voluntary Nutrient Statement*



2.5. Why does FDA recommend certain plant-based milk alternatives bear additional information on their label when nutrition information is already provided in the Nutrition Facts label?

We recommend plant-based milk alternatives that use the term "milk" in their name and have a nutrient composition that is different than milk (Appendix 1) bear additional information because consumer research indicates that consumers may not understand the nutritional differences between plant-based milk alternatives and milk (Ref. 1). The term "milk" may create a more favorable perception of plant-based milk alternatives' nutritional content compared to the use of terms like "drink" or "beverage" (Ref. 1). Further, product labels for half of the top 10 brands of plant-based milk alternatives include direct nutrient comparisons to milk, primarily for calcium (e.g., "50% more calcium than milk"), yet some of these products may contain lower amounts of other important nutrients found in milk including under-consumed nutrients discussed in section II.E. (Refs. 3, 11, and 12).

Because milk plays an important role in healthy eating patterns, it is important to provide consumers with additional information about how a plant-based milk alternative may be nutritionally different than milk by providing that information on the PDP. Additionally, not all the important nutrients found in milk, as identified by the Dietary Guidelines (e.g., vitamin A, magnesium, magnesium, phosphorus, riboflavin, and vitamin B12), are required to be listed on the Nutrition Facts label. Therefore, a voluntary nutrient statement on the PDP that describes how the plant-based milk alternative is nutritionally different than milk, based on USDA's FNS nondairy beverages nutrient criteria (Appendix 1), will provide additional information to consumers to help them make informed decisions about the products they purchase and consume.

2.6. If my plant-based milk alternative contains the same amount of nutrients of public health concern as milk, but has lower levels of magnesium, which is not under-consumed, does FDA recommend that my product still bear a voluntary nutrient statement?

Yes, if a manufacturer chooses to use the term "milk" in the name of a plant-based milk alternative that has a lower amount of magnesium than milk, we recommend the product bear a voluntary nutrient statement on the PDP, such as:

- "Contains a lower amount of magnesium than milk."

To provide information to consumers about the nutritional differences between milk and plant-based milk alternatives that use the term "milk" in their name, we recommend such plant-based milk alternatives that are lower in any nutrient listed in USDA's FNS non-dairy beverages nutrient criteria (Appendix 1) bear a voluntary nutrient statement. Magnesium is a nutrient listed in USDA's criteria.

2.7. The name "Almond Milk" appears in multiple places on the label of my plant-based milk alternative that does not have a similar nutrient composition as milk. Does FDA recommend that there be a voluntary nutrient statement or a symbol leading to a voluntary nutrient statement next to all the uses of "Almond Milk" on the label?

Our goal in recommending that plant-based milk alternatives that have a nutrient composition that is different than milk (Appendix 1) and use the term "milk" in their name bear a voluntary nutrient statement is to make the information readily available to consumers to help them make more informed purchasing choices. However, we recognize that space is limited on food labels. Therefore, we recommend a voluntary nutrient statement or a symbol (e.g., "†") leading consumers to the voluntary nutrient statement on the PDP be placed next to the product name when it appears on the PDP, but not necessarily when it appears in other places on the label.

Figure 5: Example of Voluntary Nutrient Statement on Product Label When Name Appears on Label Multiple Times

Figure 6: Example of Voluntary Nutrient Statement on Product Label When Name Appears on Label Multiple Times - *Close-up of Symbols and Voluntary Nutrient Statement*

2.8. May plant-based milk alternatives that have a nutrient composition that is different than milk bear a relative claim comparing the product to milk?

Yes. Currently, some plant-based milk alternatives make relative claims comparing the products' nutrition profile to milk on the PDP (e.g., "50% more calcium than milk," "contains similar amounts of calcium as milk"[34]). However, some products may contain lower amounts of other important nutrients found in milk that are identified in USDA's FNS nondairy beverages nutrient criteria (Appendix 1). In these scenarios, we recommend that a voluntary nutrient statement or a symbol (e.g., "†") leading consumers to the voluntary nutrient statement on the PDP be placed next to such relative claims. We also recommend that the voluntary nutrient statement be as prominent on the food label as the relative claim so that it is easily identifiable for consumers. This will help ensure consumers have information about the plant-based milk alternative's nutrient profile in comparison to milk.

[34] For more guidance on food labeling, see FDA's Guidance for Industry, *Food Labeling Guide* (January 2013) available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide.

Figure 7: Example of Voluntary Nutrient Statement next to a Relative Claim Comparing the Product to Milk

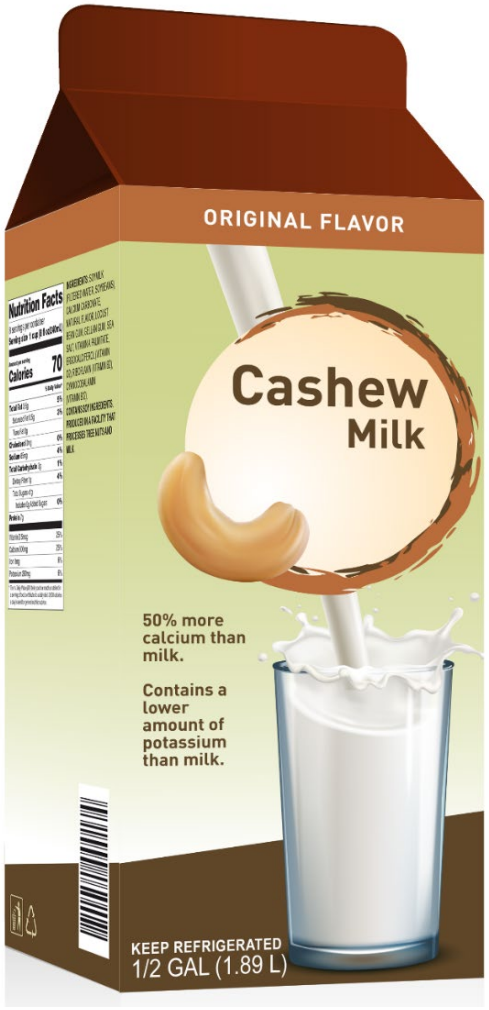


Figure 8: Example of Voluntary Nutrient Statement next to a Relative Claim Comparing the Product to Milk - *Close-up of Relative Claim and Voluntary Nutrient Statement*

Figure 9: Example of Voluntary Nutrient Statement Using a Symbol next to a Relative Claim Comparing the Product to Milk

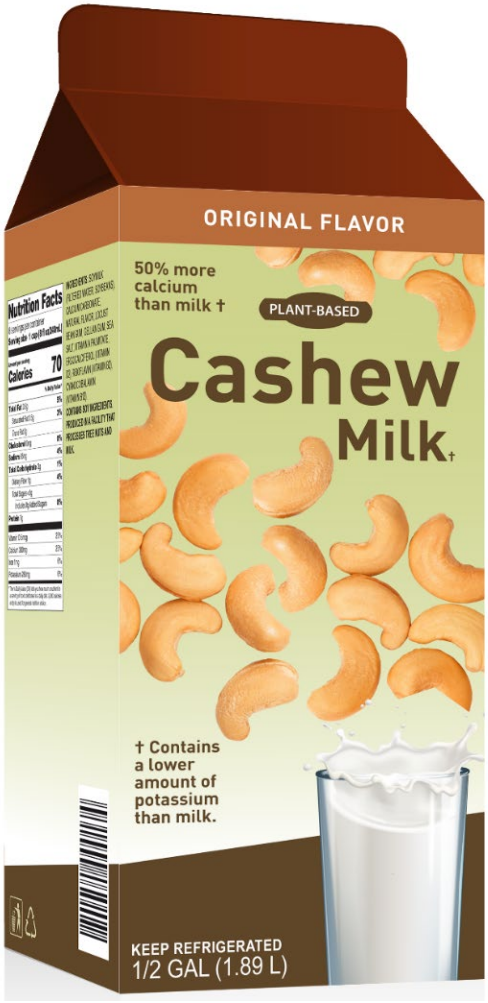
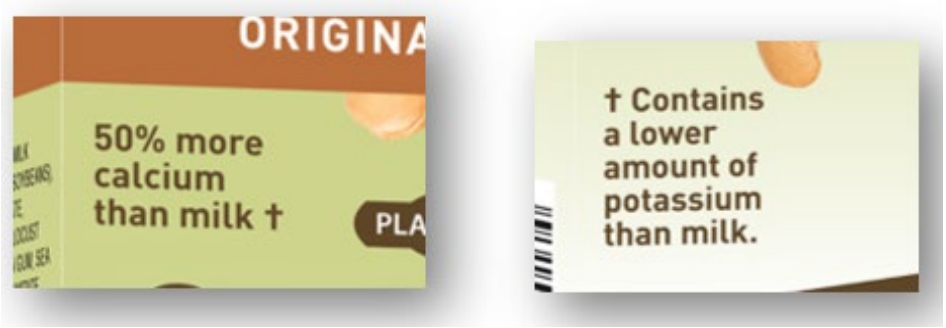


Figure 10: Example of Voluntary Nutrient Statement Using a Symbol next to a Relative Claim Comparing the Product to Milk - *Close-up of Relative Claim and Voluntary Nutrient Statement*



2.9. May a manufacturer make a statement about other nutrients not in USDA's FNS nondairy beverages nutrient criteria or about higher amounts on the label?

Yes, manufacturers may make truthful and not misleading statements about nutrients that are not listed in USDA's FNS nondairy beverages nutrient criteria (Appendix 1). As stated in Q&A 2.8, comparison statements also may be included in the nutrient statements.

- "Contains 20% more of the Daily Value for iron than milk."
- "Contains 50% more calcium than milk."

2.10. If a plant-based milk alternative is named "Soy Beverage" and it bears a relative claim comparing the product to milk, does FDA recommend that it bear a voluntary nutrient statement?

Yes, FDA also recommends that plant-based milk alternatives that use "beverage" or "drink" in their name (e.g., "almond beverage," "oat drink," etc.) and bear a relative claim comparing the product to milk (e.g., "50% more calcium than milk") use a symbol next to the claim; the symbol would lead to a voluntary nutrient statement about other nutrients found in milk (Appendix 1) that are present in lower amounts in the plant-based milk alternative. Similar to plant-based milk alternatives that use the term "milk" in their name, this will help ensure consumers have information about a plant-based milk alternative's nutrient profile when comparisons to milk's nutrient content are made.

2.11. Some plant-based milk alternatives come in sweetened varieties with added sugars. Does FDA recommend that the added sugars content of such products be communicated to consumers in the voluntary nutrient statement?

No, FDA's recommendations for voluntary nutrient statements are limited to the nutrients listed in Appendix 1. We note that plant-based alternatives come in unsweetened and sweetened versions, and the amount of added sugars in the sweetened versions varies. The Dietary Guidelines recommend limiting consumption of added sugars as part of its key recommendations for a healthy eating pattern. Data show that the added sugars content of sweetened plant-based milk alternatives appears to be similar to or lower than sweetened, flavored milks' (e.g., chocolate milk, strawberry milk) added sugars content (Ref. 13). Additionally, the gram amount and percent Daily Value of Added Sugars must be declared on the updated Nutrition Facts label,[35] making the information readily available to consumers.

[35] See 21 CFR 101.9(c)(6)(iii).

2.12. Do the voluntary nutrient statement recommendations outlined in this guidance apply to other plant-based dairy alternatives such as plant-based cheese, yogurt, or kefir alternatives?

No, the voluntary nutrient statement recommendations outlined in this guidance are limited to plant-based milk alternatives and are not intended apply to any other foods.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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Appendix 1

USDA's FNS Fluid Milk Substitutes Nutrient Criteria (7 CFR 210.10 (d)(3), 220.8(d), 226.20(g)(3), and 246.10(e)(10-12))

Nutrient	Per cup (8 fluid ounces) (minimums)
Calcium	276 milligrams (mg)
Protein	8 grams
Vitamin A	500 International Units (IU)*
Vitamin D	100 IU*
Magnesium	24 mg
Phosphorus	222 mg
Potassium	349 mg
Riboflavin	0.44 mg
Vitamin B12	1.1 micrograms

*FDA is aware that USDA has issued a proposed rule (85 FR 4094) to update the units of measure for vitamin A and vitamin D to align with how they are declared on the updated Nutrition Facts label, which is in micrograms.