



# QUARTERLY DAIRY LEGAL WEBINAR



**PennState Law**

Center for Agricultural  
and Shale Law



# QUARTERLY DAIRY LEGAL WEBINAR

**2<sup>nd</sup> Quarter of 2022, April – June**

***Focus Topic:* Labeling Standards for Plant-Based Dairy Substitutes**

Tuesday, July 26, 2022

12:00pm – 1:00pm (ET)



**PennState Law**

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# Quarterly Dairy Legal Webinar Series

## #8 in the series – covering the 2nd quarter of 2022



### Dairy Webinars

[July 2021 Quarterly Dairy Legal Webinar: Geographical Indications](#)

[April 2021 Quarterly Dairy Legal Webinar: Federal Milk Marketing Order Reform](#)

[January 2021 Quarterly Dairy Legal Webinar Part 2: International Trade with Becky Rasdall](#)

[January 2021 Quarterly Dairy Legal Webinar Part 1: Industry Round-Up](#)

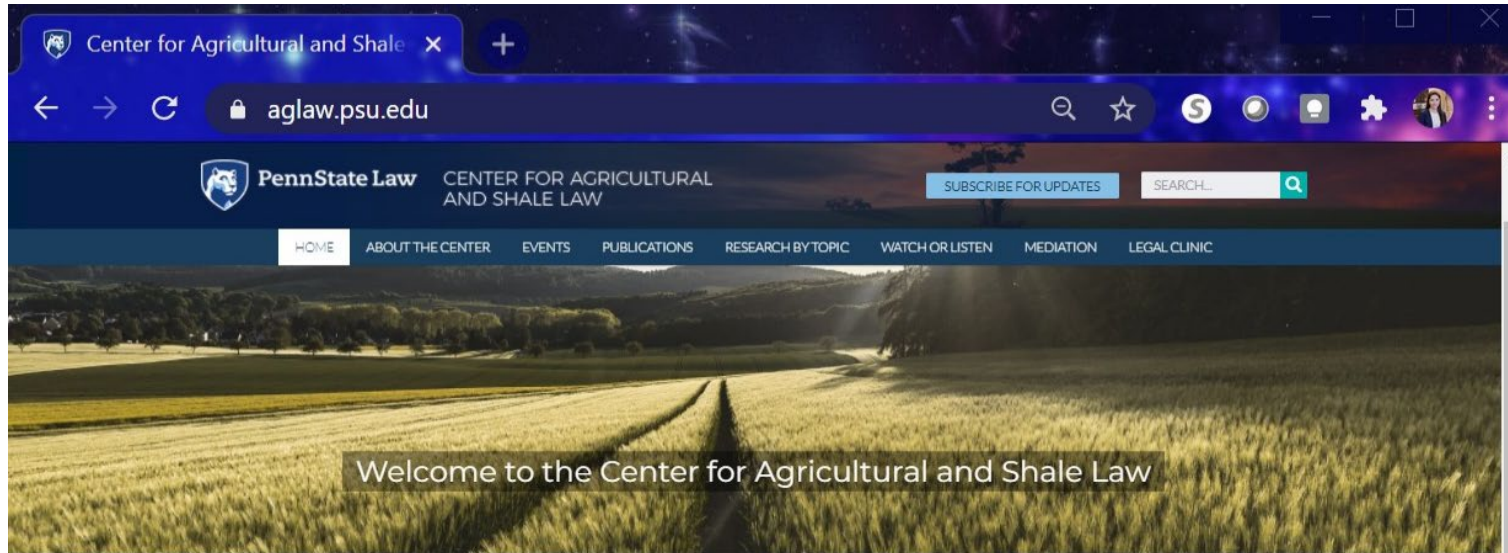
[November 2020 Quarterly Dairy Legal Webinar Part 2: Federal Milk Marketing Order 51](#)

[November 2020 Quarterly Dairy Legal Webinar Part 1: Industry Round-Up](#)



# **Dairy Quarterly Legal Webinar Series– Standard Agenda**

- Recent Legal Developments in the Dairy Industry
- Focus Topic of Importance to Dairy Industry
- Questions



## Agricultural Law Weekly Review

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### Agricultural Law Weekly Review – Week Ending April 16, 2021

COVID-19: Farmer to Families Food Box Program Ends; Fresh Produce Box Purchases and Dairy Donation Program Planned 🌱 According to statements made by Secretary Vilsack posted to USDA's website on April 14, 2021, the Farmer to Families Food Box Program will be terminated at the close of April 2021 when the current funded vendor contracts end. On April 14, 2021, Reuters reported that USDA Communications Director Matt Herrick stated USDA is focused on different hunger initiatives, including expanding food stamp benefits and increasing food purchases through existing government food distribution programs. On April 9, 2021, USDA released a Pre-Solicitation Announcement [...]

April 21st, 2021

[Read More >](#)

### Agricultural Law Weekly Review – Week Ending April 9, 2021

Antitrust: Court Approves \$58 Settlement in Peanut Class Action Suit 🌱 On April 5, 2021, the U.S. District Court for the Eastern District of Virginia approved a \$58 million settlement agreement between the plaintiff peanut farmer Settlement Class and defendant peanut shellers Birdsong Corporation and Olam Peanut Shelling Company, Inc. in a civil antitrust class action suit alleging that the defendant companies over- and under-reported peanut inventories to the U.S. Department of Agriculture (USDA) to manipulate prices. In re Peanut Farmers Antitrust Litigation, No. 2:19-cv-00463. The approval follows the court's March 2021 back-to-back orders, absent accompanying explanatory opinions, approving the [...]

### Tweets by @AgShaleLaw

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@AgShaleLaw

#ShaleLaw HotLink: "Unrestrained shale growth could trigger another price war" buff.ly/3xg9gF3 @APIenergy @BNNBloomberg #APISmartBrief #shale #oilandgas #shaleoil #OPEC

**PSU Ag & Shale Law**  
@AgShaleLaw

#AgLaw HotLink: "Tyson Fresh Meats to join US CattleTrace" buff.ly/3eoxq7H @MeatPoultry #tyson #meats #freshmeat

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# Dairy Quarterly Legal Webinar

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## **Today's Agenda:**

Round-up of the past quarter's legal and regulatory developments impacting the dairy industry

- **Presenter: Brook Duer, Staff Attorney**

Focused topic of interest to dairy producers and professionals:

- **Topic: Labeling Standards for Plant-Based Dairy Substitutes**
- **Presenter: Chloe Marie, Research Specialist**





## **Quarterly Dairy Legal Update: April – June of 2022**

**Dairy and Dairy Products Law** – the Center’s Newest ***Virtual Resource Room***

During the second quarter of 2022, the Penn State Center for Agricultural and Shale Law went live with a new Virtual Resource Room on its website at [aglaw.psu.edu](http://aglaw.psu.edu) titled, “Dairy and Dairy Products Law.” No commodity is surrounded by as complex a regulatory structure in terms of production requirements, sanitation and food safety, and pricing controls and income support mechanisms, both at a federal level and through robust state regulatory involvement. This virtual resource room endeavors to collect a representative set of resources for legal and other researchers’ access, acknowledging that it is a selected set of resources organized in one chosen format.



# Pennsylvania Milk Marketing Board (PMMB) Actions

## **Pennsylvania Milk Marketing Board Continues \$1.00 Over-Order Premium**

On March 22, 2022, the Pennsylvania Milk Marketing Board (PMMB) issued [Official General Order No. A-1013](#), continuing the then-current \$1.00 per hundredweight over-order premium (OOP) for all Class I milk produced, processed, and sold in Pennsylvania for the next six months, effective April 1, 2022, through September 30, 2022. The over-order premium, which is set in 6-month intervals, has remained at \$1.00 since April 2019.



# PMMB

## **Pennsylvania Milk Marketing Board Petitioned to Consider Alternatives to Current Over-Order Premium**

On May 27, 2022, the Pennsylvania Department of Agriculture (PDA) filed a [petition](#) with the Pennsylvania Milk Marketing Board (PMMB) requesting a hearing on “alternatives to the over-order premium (OOP) as currently imposed and administered” to be held before the Board next considers the level and duration of the current OOP which expires on September 30, 2022. This petition acts as a follow-up to issues raised at the March 2, 2022, public hearing on the level and duration of the OOP during which testimony and evidence pertaining to alternatives to the current distribution and administration of the OOP was excluded from consideration by [Board Order](#).



# PMMB

## **Hearing Scheduled on “Existence” Of Pennsylvania’s Over-Order Premium**

On July 11, 2022, the Pennsylvania Milk Marketing Board (PMMB) entered an [order](#) scheduling a hearing beginning on August 30, 2022, and continuing through and including September 1, 2022, if necessary, to adjudicate the May 27, 2022, petition filed by the Pennsylvania Department of Agriculture. The initial order was subsequently [amended](#) to change the location to the DEP Building on Elmerton Avenue, Harrisburg, PA. According to the Order, the PMMB will take evidence on “the existence, level and duration” of Pennsylvania’s current over-order premium.



# USDA / FDA

## **USDA AMS Release Report Analyzing Milk Handled Through Federal Orders**

On May 18, 2022, the United States Department of Agriculture, Agricultural Marketing Service, published a report titled "[\*Measures of Growth in Federal Orders\*](#)" which analyzed 2021 activity in Federal Milk Marketing Order markets, as follows: "Total Receipts of milk pooled under Federal Milk Marketing Orders totaled 136.8 billion pounds marketed by 23,292 dairy producers across all Federal orders in 2021. Total receipts were 0.7 percent lower than 2020. Pooled producer numbers were 6.5 percent lower than 2020. The average daily delivery of producer milk per pooled producer was 6.4 percent higher compared to 2020. In 2021, milk marketed through Federal orders accounted for 61 percent of all milk sold and 61 percent of fluid grade milk sold to U.S. plants and milk dealers."



# USDA / FDA

## **OMB Reviewing Draft Guidance on Plant-Based Dairy Alternative Labeling**

On March 31, 2022, the Office of Management and Budget (OMB) received a notice for review from the U.S. Food and Drug Administration (FDA) titled "[Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry](#)," which is now pending review with OMB. Although the text of the notice has not been published by FDA or OMB, in September 2018, FDA requested public comment ([83 FR 49103](#)) to instruct the agency's approach on plant-based product labeling and dairy food names. The request, which received nearly [12,000 comments](#), called for information on how consumers understand terms like "milk," "cultured milk," "yogurt," and "cheese," when used on plant-based product labels and how consumers use plant-based products with dairy names. The 2018 comment request also sought to discover whether consumers understand and are aware of differences in the "basic nature, characteristics, ingredients, and nutritional content" of dairy products and like-named plant-based products. FDA stated that the draft guidance is one of a [series of actions of FDA](#) over the past four years to further regulate standards of identity and plant-based labeling. OMB lists [six completed stakeholder meetings](#) regarding FDA's submitted draft guidance: June 16- Earthjustice; June 13-VanScoyoc Associates; June 1- VanScoyoc Associates; May 23-The Good Food Institute; May 16- Watson Green, LLC (on behalf of NMPF); May 5-Plant Based Foods Association.





# National Dairy Stakeholders' Actions & Issues

## **Federal Court Affirms Denial of Interstate Raw Butter Sales Petition**

On June 10, 2022, the District of Columbia (D.C.) U.S. Circuit Court of Appeals issued an [opinion](#) affirming the 2020 decision of the lower federal court and the U.S. Food and Drug Administration (FDA) to deny a 2016 petition for rulemaking filed by California dairy producer Mark McAfee requesting FDA change the federal regulatory scheme to permit the interstate sale of butter manufactured from unpasteurized milk (raw butter). According to the opinion, in 1938 Congress codified the standard of identity for butter as “made exclusively from milk or cream, or both” and that “[n]o [other]. . . standard of identity. . . shall be established for. . . butter. . .” 21 U.S.C. § 321a and 341. The federal Public Health Service Act authorized the FDA in 1987 to ban the interstate distribution of “any milk or milk product” that has not been pasteurized. 21 C.F.R. § 1240.61. In 1992, FDA confirmed that “milk product” includes butter. 57 F.R. 343. McAfee’s argument on appeal was that by imposing the pasteurization requirement on butter in 1987 it had impermissibly altered butter’s 1938 Congressionally established standard of identity. The Circuit Court disagreed and noted that simply because the FDA cannot alter the standard of identity of butter does not mean it cannot regulate butter for other purposes, such as distribution, pursuant to the Public Health Service Act.



# National Dairy Stakeholders' Actions & Issues

## Comment Period Opens on 2025 Dietary Guidelines Scientific Questions

On April 15, 2022, the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) published a notice in the Federal Register requesting comments, due May 16, 2022, in response to a list of proposed scientific questions that will guide the upcoming 2025-2030 edition of the Dietary Guidelines for Americans (87 FR 22540). The departments' notice, also announced by HHS and USDA (and authored by Asst. Sec. of Health Dr. Rachel Levine), begins the five-step process to develop and publish 2025-2030 Dietary Guidelines. The departments' scientific questions build directly on the 2020 Dietary Guidelines Advisory Committee's future directions (published as part of the committee's the Scientific Report of the 2020 Dietary Guidelines). Among several recommendations, the future directions called for future departments to "investigat[e] the relationships between the consumption of sugar-sweetened beverages and juice during the complementary feeding period and obesity in childhood and other measures of growth, size, and body composition" because the systemic reviews used by the 2020 committee "identified limited evidence about intakes of sugar-sweetened beverages and juices and their relationship with growth, size, and body composition." One of the proposed scientific questions is "What is the relationship between beverage consumption (beverage patterns, dairy milk and milk alternatives, 100% juice, low- or no-calorie sweetened beverages, sugar-sweetened beverages, coffee, tea, water) and (1) growth, size, body composition, risk of overweight and obesity, and weight loss and maintenance? (2) risk of type 2 diabetes?"



# REGIONAL DAIRY ACTIONS & ISSUES

## **Lawsuit Claims Dairy Farmers of America and Select Milk Conspired to Suppress Member Payments**

- On April 4, 2022, six New Mexico dairy cooperative members filed a [complaint](#) in the U.S. District Court for the District of New Mexico against Dairy Farmers of America (DFA) and Select Milk Producers, Inc. (Select), alleging that the defendant dairy cooperatives conspired to depress members' raw milk price in violation of the Sherman Act ([15 U.S.C. § 1](#)). *Othart Dairy Farms, LLC v. Dairy Farmers Of America, Inc.*, No. [2:22-cv-00251](#). The plaintiffs claim that DFA and Select—who the plaintiffs state control at least 75% of the Southwest dairy market—have used their market share to suppress dairy prices by sharing and coordinating pricing information and decisions and by “selective[ly] . . . nonpooling” milk, which the plaintiffs claim “allow[s] the cooperatives as entities to market members’ milk at higher prices without passing those increases on to farmers.” The plaintiff dairy producers further claim that the monthly rates DFA and Select pay their respective members “are almost always within a few pennies of each other,” which the plaintiffs state “would not be the case absent the conspiracy alleged herein.” On May 31, 2022, all Defendants filed a Motion to Dismiss For Failure to State a Claim on which briefing has not been completed.



# INTERNATIONAL DAIRY & TRADE

## **U.S. Rejects Canada's USMCA Dairy Tariff-Rate Quota Proposals**

On May 5, 2022, U.S. Trade Representative Katherine Tai [met](#) with Canadian Minister of Trade Mary Ng in Ottawa. This was the first meeting since the January 4, 2022, disclosure of the [December 20, 2021, USMCA Arbitration Panel Final Report](#) concluding that Canada breached Article 3.A.2.11(b) of the United States-Mexico-Canada Agreement (USMCA) by reserving dairy tariff-rate quotas exclusively for the use of Canadian dairy processors. Tai formally rejected Canada's March 1, 2022, [proposal of revised TRQs allocation and policy changes](#). The revision simply added "distributors" to processors as eligible TRQ applicants. [Congressional](#) representatives and the [National Milk Producers Federation and U.S. Dairy Export Council](#) had urged rejection.

On May 25, 2022, Ng [stated](#), "Canada has met its obligations under CUSMA to ensure that our TRQ system is compliant. We respect the right of the United States to initiate the dispute resolution mechanism as part of the agreement." Canada's TRQ application process proceeded.

On May 12, 2022, New Zealand filed an identical [request for consultation](#) alleging Canada has breached the Trans-Pacific Partnership (TPP) trade agreement by limiting its TRQs to only processors' use.



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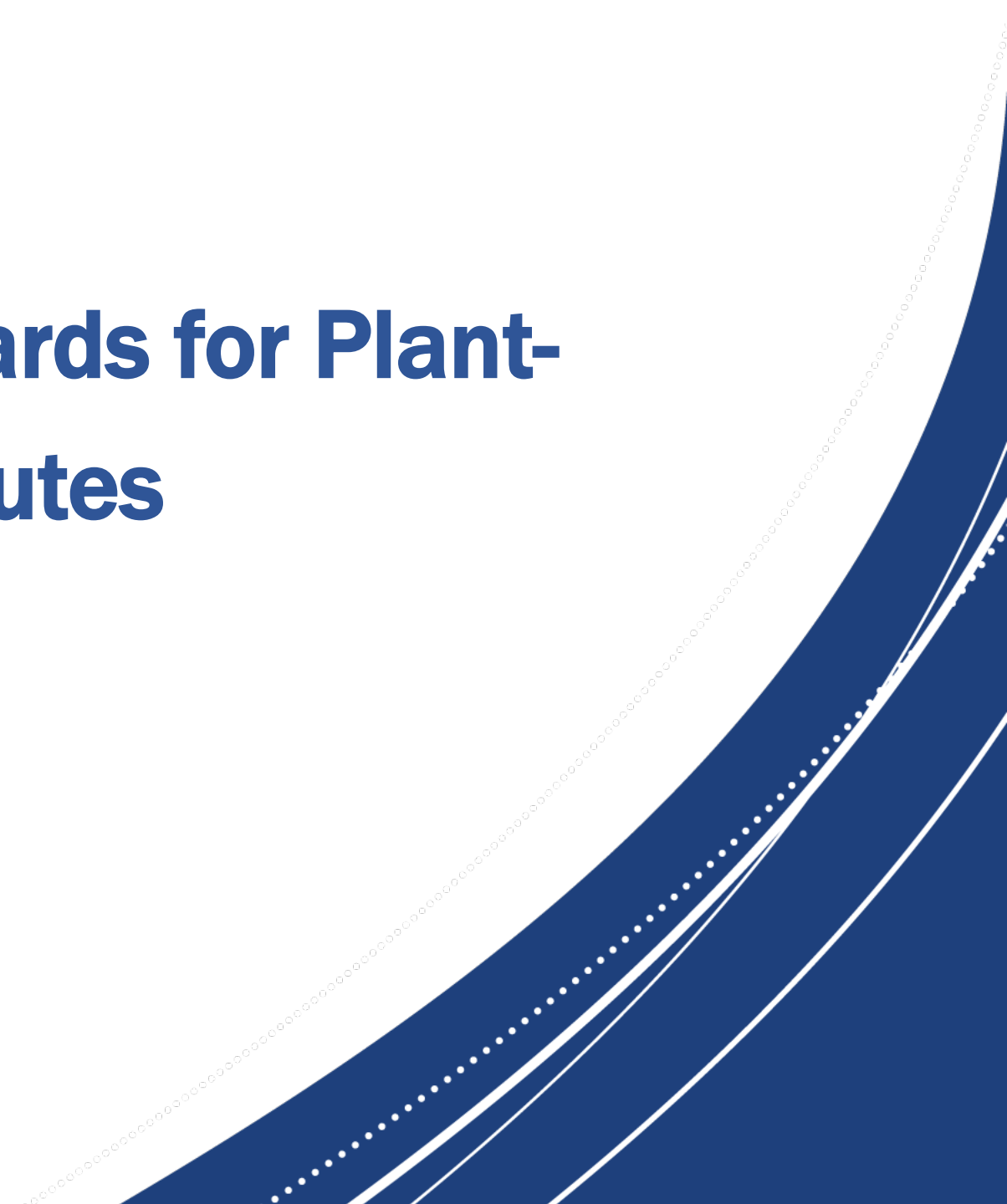
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# **The Labeling Standards for Plant- Based Dairy Substitutes**

**with Chloe Marie**

Tuesday, July 26, 2022

12:00pm – 1:00pm (ET)





## Plant-Based Food and Beverage Market Trends

***“Global retail sales of plant-based food alternatives may reach \$162 billion by 2030, or 7.7% of the expected \$2.1 trillion global protein market.”***

*“Plant-based dairy sales are largely comprised of milk alternatives, which is a **fairly mature market**, enabling 10% penetration of the total dairy market. Other alternative dairy products – including yogurt, ice cream, cheese and butter – are small today but will aid overall growth.”*

*“The Asia-Pacific region may command the largest share of the global plant-based market, with our scenario analysis suggesting the market could reach **\$64.8 billion by 2030**, up from \$13.5 billion 2020. The region is expected to exceed 5 billion people by 2030, straining its resources. We believe this will drive strong demand for plant-based protein.”*

*“Both North America and Europe may account for about **\$40 billion** over that same timeframe, with Middle East and Africa reaching **\$8.2 billion** and Latin America **\$8.8 billion**.”*

*“... Asia may drive the bulk of alternative dairy (59%) and North America and Europe could both account for about 35% of other plant-based product sales.”*

*“Animal and dairy protein demand is poised to reach \$2.1 trillion by 2030, based on our scenario analysis. Of this, animal protein could account for \$1.5 trillion as growing middle-class populations in developing economies seek to eat more meat as incomes rise. Dairy is also poised to expand, reaching \$623 billion in size by 2030.”*

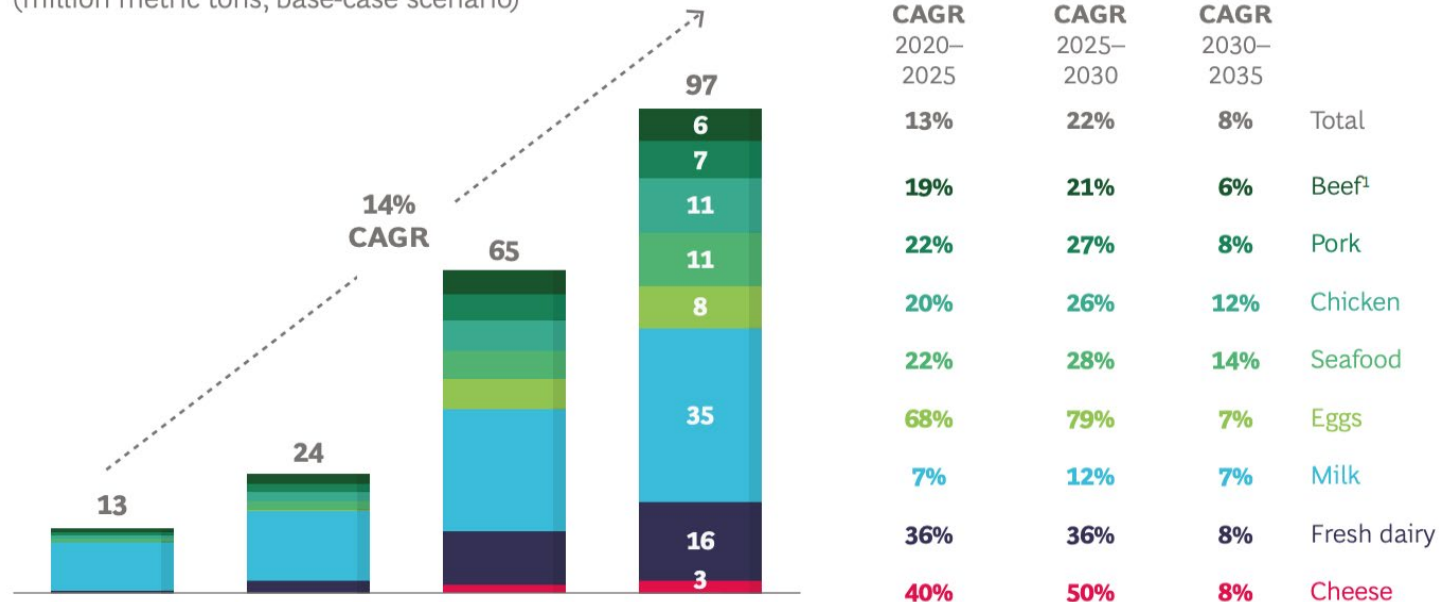




# Plant-Based Food and Beverage Market Trends

## Exhibit 4 - Milk and Other Dairy Alternatives Will Dominate the Market, Followed by Chicken and Seafood

Consumption of alternative proteins by product (million metric tons, base-case scenario)



Sources: US Department of Agriculture; Euromonitor; UBS; ING; Good Food Institute; expert interviews; Blue Horizon and BCG analysis.

<sup>1</sup>Including veal.



## Plant-Based Food and Beverage Market Trends

*“U.S. per capita fluid cow’s milk consumption has been trending downward since about the mid-1940s, and it fell at a **faster rate during the 2010s** than it did during each of the previous six decades. Milk consumption per person person fell at an average annual rate of 1.0 percent during the 2000s. It then fell at an average annual rate of 2.6 percent during the 2010s.”*

*“Products known to compete with fluid cow’s milk include plant-based milk alternatives, such as ‘almond milk’ and ‘soy milk.’ Using retail scanner data, Stewart et al. (2020) confirmed that **sales of these beverages negatively affect purchases of fluid cow’s milk**. However, given that the increase in their sales is much smaller than the decrease in sales of fluid cow’s milk, plant-based milk alternatives can only explain a **small share of overall sales trends**. Sales of plant-based milk alternatives **may be contributing to, but are not likely to be, a primary driver of sales trends for fluid cow’s milk.**”*

*[Examining the decline in U.S. Per Capita Consumption of Fluid Cow’s Milk, 2003-18](#), USDA Economic Research Service (October 2021)*



# FDA Authority Over the Naming of Food & Beverages

Under the Federal Food, Drug and Cosmetic Act (FDCA), the U.S. Food and Drug Administration (FDA) regulates **standardized food** (21 CFR 101.3(b)(1)) and **nonstandardized food** (21 CFR 101.3(b)(2)).

- The principal display panel (PDP) must bear a **statement of identity** of the product
- A statement of identity must be:
  - A **name specified by Federal law or regulation**; or, in the absence thereof,
  - A **common or usual name** of the food; or, in the absence thereof,
  - An **appropriately descriptive term**, or when the nature of the food is obvious, a **fanciful name commonly used** by the public for such food.
- Nonstandardized food must also bear a common or usual name; however, in a situation where such a name may mislead the public, FDA may establish a new common or usual name by regulation (21 CFR part 102, subpart B).

Under the Federal Food, Drug and Cosmetic Act (FDCA), a food is considered misbranded “**if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations** as provided by section 341 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard ... (21 U.S.C. § 343(g)).



# FDA Standards of Identity for Food and Beverages

Standards of Identity for Food and Beverages “were developed to help protect consumers and promote honesty and fair dealing. SOIs have been established to ensure that the characteristics, ingredients and production processes of specific foods are consistent with what consumers expect.” Source: <https://www.fda.gov/food/food-labeling-nutrition/standards-identity-food>

Standards of Identity have been established for:

- Milk and cream (21 CFR part 131, subpart B)
  - *“Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows ...” 21 CFR 131.110(a)*
- Cheeses and related cheese products (21 CFR part 133, subpart B)
- Yogurt (21 CFR 131.200(a))

**Standards of Identity have NOT been established for plant-based food and beverage and are thus considered nonstandardized foods, subject to 21 US.C. § 343.**

- **FDA has not established a common or usual name by regulation for plant-based dairy substitutes**



# FDA Letters on the Labeling of Plant-Based Dairy Substitutes

## FDA letter to the Singapore Institute of Standards and Industrial Research (September 29, 1983)

We have no regulations that pertain specifically to soy milk and soy bean drink. Further, we have not recognized the term "soy milk" as a common or usual name or appropriately descriptive term for statements of identity or ingredient designations of any food. As a result, we would object to any soy product entering this country that was labeled as "soy milk". The term "soy bean drink" could serve as a statement of identity for some soy products if their basic nature and ingredients would support such a statement. However, we would need to review the specific product and its labeling in order to give meaningful advice in this area.

## FDA 2008 and 2012 warning letters to soy milk manufacturers Lifesoy® and Fong Kee Tofu Company, Inc.

*"We do not consider 'soy milk' as a common or usual name or appropriately descriptive term for statements of identity or ingredient designations of any food. As a result, we would object to any soy product entering this country that was labeled as 'soy milk'."*



# Litigation Overview

## **Gitson, et al. v. Trader Joe's Company**, USDC N.D. California, No. 3:13-cv-1333

- Plaintiffs were purchasers of Organic Chocolate Soy Milk and Organic Soy Milk products manufactured, marketed, distributed and sold by Trader Joe's Company.
- *"Adding the name of a plant material in front of the word 'milk' does not result in an appropriate name for non-dairy products, as these products do not contain milk or milk ingredients ... There can be no doubt that these products have been formulated and positioned to mimic the positive quality attributes of milk from lactating cows and, because of this, are nothing more than imitation milks that should be labeled as such."* Complaint (March 25, 2013)

## **Ang, et al., v. Whitewave Foods Co., et al.**, USDC N.D. California, No. 3:13-cv-1953

- Plaintiffs were purchasers of Silk® and Horizon Plant-Based milk and dairy products manufactured, marketed, distributed and sold by Whitewave Foods Co., Dean Foods Co., WWF Operating Co., and Horizon Organic Dairy, LLC.
- *"Defendants' actions illegally mislead the public by inappropriately employing names and terms reserved by law for standardized dairy products, thereby creating false impressions that these products provide comparable quality, taste, or nutritional benefits when they do not."* Complaint (April 29, 2013)

## **Painter v. Blue Diamond Growers, et al.**, USDC C.D. California, No. 2:17-cv-2235

- Plaintiffs were purchasers of Almond Breeze Almond Milk Beverage manufactured, marketed, distributed and sold by Blue Diamond Growers
- *"By calling its Almond Beverages 'milk', a term historically used to define cow's milk, Defendant has capitalized on reasonable consumers' understanding of the well-known health benefits and essential nutrients that dairy milk provides without actually providing those health benefits and essential nutrients."* Complaint (March 22, 2017)





# Litigation Overview

## **Gitson, et al. v. Trader Joe's Company**, USDC N.D. California, No. 3:13-cv-1333

- *"... Plaintiffs' cannot save their claims by pointing to the FDA's standard of identity for 'milk' and FDA warning letters to two soy milk manufacturers. These warning letters are not binding. Nor does either the standard of identity or the warning letters address reasonable-consumer standard under state law or the critical context and express disclosures plainly set forth on the soy milk products at issue ... such claims are preempted on the grounds that they cannot be premised on the FDA's purported interpretations of the FDCA."* Defendant's motion to dismiss (July 12, 2013)

## **Ang, et al., v. Whitewave Foods Co., et al.**, USDC N.D. California, No. 3:13-cv-1953

- *"Plaintiffs cannot allege in good faith that a reasonable consumer would view 'soymilk,' 'almondmilk' or 'coconutmilk,' sold under the long-established Silk brand for plant-based beverages, and believe that she were purchasing a product made from cow's milk. Such logic also necessarily would lead to the conclusion that the majority of consumers would pick up a package of feta cheese that stated it was made from sheep's milk and believe that the presence of the word 'milk' on the label meant that the product actually came from a cow. The absurdity of these allegations stems from the erroneous notion that the reasonable consumer has adopted the FDA's narrow definition of the word "milk" and applies that definition to every product in the marketplace indiscriminately. This defies common sense."* Defendants' motion to dismiss (August 1, 2013)

## **Painter v. Blue Diamond Growers, et al.**, USDC C.D. California, No. 2:17-cv-2235

- *"Plaintiffs' claims are expressly preempted under the Federal Food, Drug & Cosmetic Act ("FDCA") because her complaint seeks to impose new and more stringent labeling requirements on almondmilk manufacturers than are required by the U.S. Food and Drug Administration ("FDA") and under the FDCA. Alternatively, Plaintiffs' claims should be dismissed or stayed under the primary jurisdiction doctrine because if the appropriate product name for almondmilk is going to be changed, it should be determined in the first instance by the expert agency, the FDA."* Defendants' motion to dismiss (April 17, 2017)



# Litigation Overview

## **Gitson, et al. v. Trader Joe's Company**, USDC N.D. California, No. 3:13-cv-1333

- *“If a food label does not violate the federal statute, any state law claim arising from that label is automatically preempted, because when it comes to food labels, state law may only impose liability for what the federal statute proscribes ... The threshold question in this case, then, is whether the use of the word ‘soymilk’ in the Trader Joe’s products could conceivably violate the federal Food, Drug and Cosmetic Act. The answer to that question is no.”* Court order (December 1, 2015)

## **Ang, et al., v. Whitewave Foods Co., et al.**, USDC N.D. California, No. 3:13-cv-1953

- *“An agency’s reasonable interpretation of its own regulation is entitled to wide deference. However, the brief statements in the two warning letters cited by Plaintiffs are far from controlling ... Moreover, it is simply implausible that a reasonable consumer would mistake a product like soymilk or almond milk with dairy milk from a cow. The first words in the products’ names should be obvious enough to even the least discerning of consumers. And adopting Plaintiffs’ position might lead to more confusion, not less, especially with respect to other non-dairy alternatives such as goat milk or sheep milk.”* Court order (December 10, 2013)

## **Painter v. Blue Diamond Growers, et al.**, USDC C.D. California, No. 2:17-cv-2235

- *“Any further labeling requirements, achieved through a lawsuit pursuant to California’s Sherman Law, would directly or indirectly establish labeling requirements not identical to the FDCA – and thus are preempted.”*
- *“By using the term ‘almondmilk,’ even the least sophisticated consumer would know instantly the type of product they are purchasing. If the consumer is concerned about the nutritious qualities of the product, they can read the nutrition label – which Plaintiff does not allege is false or misleading.”* Court order (May 24, 2017)



# Litigation Overview

## **Melissa Cuevas v. Topco Associates, et al., C.D. Cal., No. 5:17-cv-462**

- Plaintiff was a purchaser of Full Circle “Almondmilk” beverage manufactured, marketed, distributed and sold by Topco Associates, LLC and alleged that *“Defendant has deceptively informed and led its customers to believe that they were purchasing, for a premium price, a dairy milk alternative that is nutritionally equivalent, and even superior, to dairy milk, as defined by the U.S. Food & Drug Administration,”* as a result the Almond beverages are preempted under California state law and the federal Food, Drug and Cosmetic Act (FDCA).
- Defendant argued that Plaintiff’s claims are preempted under federal law, *“because Plaintiffs seek to impose labeling requirements beyond and contrary to federal law”* and that Plaintiff failed to state a plausible claim, because a reasonable consumer could not be deceived into believing that almond milk has the nutritional equivalency to dairy milk. Defendants asked the court to dismiss the case or, at a minimum grant a stay under primary jurisdiction.
- The court ordered a stay of the case pending the FDA’s determination of question presented in *Kelley v. WWF Operating Company* of whether plant-based products are “imitation” of dairy milk.

## **Kelley v. WWF Operating Company, E.D. Cal., No. 1:17-cv-117**

- The court declared it *“is not the appropriate forum to decide in the first instance whether almondmilk ‘substitutes for,’ is ‘nutritionally inferior’ to, and ‘resembles’ dairy milk such that it should be labeled ‘imitation’ milk under § 101.3(e) - an issue which forms the entire basis for Plaintiffs’ case,”* and therefore decided to stay the case pending a determination from the FDA.

Both cases have since been voluntarily dismissed.



## Litigation Overview

In *Miyoko's Kitchen v. Ross, et al.*, USDC N.D. Cal., No. 3:20-cv-893, a federal district court in California ruled that **plant-based food producer can use dairy terms to describe vegan butter**.

December 2019 – the California Department of Food & Agriculture (CDFA) [requested](#) Miyoko's Kitchen, Inc. to review the label for their vegan butter bearing the terms “butter,” “lactose free,” “hormone free,” “cruelty free,” and “revolutionizing dairy with plants” as well as website pictures of animal agriculture.

“The product cannot bear the name ‘Butter’ because the product is not butter” as defined in 21 U.S.C. 321a as a product “made exclusively from milk or cream, or both, with or without common salt ... and containing no less than 80 per centum by weight of milk fat.”

February 2020 – Miyoko's Kitchen, Inc. [filed](#) a lawsuit against CDFA, challenging the regulatory authority of the state and arguing speech suppression.

August 2021 – the Federal district court [found](#) that:

*“... there is no denying that § 312a's dairy and fat-content requirements exclude Miyoko's ‘vegan butter’ ... this alone cannot doom commercial speech ...” “Quite simply, language evolves.”*

And determined that the state of California may not regulate Miyoko's use of the terms “butter,” “lactose free,” “cruelty free,” and “revolutionizing dairy with plants” whereas the term “hormone free” is not constitutionally protected commercial speech.



# FDA Draft Guidance on Plant-Based Dairy Substitute Labeling

September 2018 – FDA issued a notice seeking comments on the use of the names of dairy foods in the labeling of plant-based products ([83 FR 49103](#)) – *“We are interested in learning how consumers use these plant-based products and how they understand terms such as, for example, ‘milk’ or ‘yogurt’ when included in the names of plant-based products. We also are interested in learning whether consumers are aware of and understand differences between the basic nature, characteristics, ingredients, and nutritional content of plant-based products and their dairy counterparts.”*

- FDA received approximately 12,000 comments ([nonrulemaking docket FDA-2018-N-3522](#))

January 2022 – FDA [announced](#) it will consider a series of new topics for guidance documents or revisions to existing guidance documents, including potential guidance on the labeling of plant-based milk alternatives and animal-derived foods for 2023.

March 2022 – The Office of Management and Budget (OMB) [received](#) a notice for review from FDA, titled “Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry, which is now pending review with OMB.

- The OMB has already conducted [six stakeholder meetings](#).



# FDA Draft Guidance on Plant-Based Dairy Substitute Labeling

First, the guidance would reverse FDA’s longstanding practice of permitting compound names like “soy milk” and “almond milk,” imposing an arbitrary de facto requirement on companies that have used those names in their labeling for decades to change either their product labels or the products themselves, at significant cost. The use of new product names or comparative nutrient statements that are not imposed on animal-based dairy products could also unfairly drive consumers away from plant-based milk products. Imposing this unique burden on plant-based milk products would be arbitrary, especially because the standard of identity for milk includes no nutritional standards and there are significant variations in the nutritional composition of animal-based milks on the market. Moreover, other food labels are not required to display statements calling out nutritional differences with other products (e.g., almond butter or apple butter as compared with peanut butter).

[Follow-up letter](#) sent to FDA by the Good Food Institute (GFI) (May 23, 2022)





For decades, the FDA has declined to clarify standards for plant-based milks, even as other Federal agencies have increasingly adopted plant-based milks and names into programs. The Soyfoods Association of North America requested that FDA recognize the term “soymilk” through a “common or usual name regulation” in 1997. No action was taken. In 2018, the Plant Based Foods Association (PBFA) created an industry standard for plant-based milks to promote consistency and clarity in labeling across the category. Again, no action was taken by FDA. There is no reason for OMB to now allow regulation in this space, which would contradict FDA’s own rules as well as court rulings.

Furthermore, FDA’s own Standards of Identity do not prescribe nutritional components, and FDA has not previously asked producers to disclose other wide variations in nutritional components – including among milks derived from different animals. Goat milk, for example, has less folate, zinc, riboflavin and vitamin B12 than cow milk. Buffalo milk has twice as much saturated fat as cow milk, as well as considerably more calcium.

Any guidance, even if voluntary, that asks plant-based milks to identify differences without doing the same for animal milk is discriminatory towards the plant-based industry as well as the hard-working farmers who grow crops like oats and almonds. FDA should not be using its labeling authority to harm a growing industry and the millions of American consumers for whom plant-based foods are an important part of their diet.

Therefore, if this draft guidance contains any such provisions, we urge you to return it to the Food and Drug Administration without moving forward. Thank you for your consideration of our views.

## FDA Draft Guidance on Plant-Based Dairy Substitute Labeling

[Letter](#) sent to OMB Director The Honorable Shalanda Young from Members of the U.S. Congress (May 18, 2022)



# EU Labeling Framework for Plant-Based Substitutes to Dairy

## **PART III**

### **Milk and milk products**

1. "Milk" means exclusively the normal mammary secretion obtained from one or more milkings without either addition thereto or extraction therefrom.

However, the term "milk" may be used:

- (a) for milk treated without altering its composition or for milk the fat content of which is standardised under Part IV;
- (b) in association with a word or words to designate the type, grade, origin and/or intended use of such milk or to describe the physical treatment or the modification in composition to which it has been subjected, provided that the modification is restricted to an addition and/or withdrawal of natural milk constituents.

[Regulation \(EU\) No. 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organization of the markets in agricultural products and repealing Council Regulations \(EEC\) No. 922/72, \(EEC\) No. 234/79, \(EC\) No. 1037/](#)



# EU Labeling Framework for Plant-Based Substitutes to Dairy

2. For the purposes of this Part, "milk products" means products derived exclusively from milk, on the understanding that substances necessary for their manufacture may be added provided that those substances are not used for the purpose of replacing, in whole or in part, any milk constituent.

The following shall be reserved exclusively for milk products.

(a) the following names used at all stages of marketing:

- (i) whey,
- (ii) cream,
- (iii) butter,
- (iv) buttermilk,
- (v) butteroil,
- (viii)cheese,
- (ix) yogurt,



# EU Labeling Framework for Plant-Based Substitutes to Dairy

4. As regards milk, the animal species from which the milk originates shall be stated, if it is not bovine.
5. The designations referred to in points 1, 2 and 3 may not be used for any product other than those referred to in that point.  
However, this provision shall not apply to the designation of products the exact nature of which is clear from traditional usage and/or when the designations are clearly used to describe a characteristic quality of the product.

[Regulation \(EU\) No. 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organization of the markets in agricultural products and repealing Council Regulations \(EEC\) No. 922/72, \(EEC\) No. 234/79, \(EC\) No. 1037/](#)

[2010/791/EU: Commission Decision of 20 December 2010 listing the products referred to in the second subparagraph of point III\(1\) of Annex XII to Council Regulation \(EC\) No. 1234/2007](#)



# EU Labeling Framework for Plant-Based Substitutes to Dairy

## Amendment 171

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 32 a (new)

Regulation (EU) No 1308/2013

Annex VII – part III – point 5

#### *Present text*

5. The designations referred to in points 1, 2 and 3 may not be used for any product other than those referred to in that point.

However, this provision shall not apply to the designation of products the exact nature of which is clear from traditional usage and/or when the designations are clearly used to describe a characteristic quality of the product.

#### *Amendment*

***(32a) In Part III of Annex VII, point 5 is replaced by the following:***

"5. The designations referred to in points 1, 2 and 3 may not be used for any product other than those referred to in that point.

***Those designations shall also be protected from:***

***(a) any direct or indirect commercial use of the designation;***

***(i) for comparable products or products presented as capable of being substituted not complying with the corresponding definition;***

***(ii) in so far as such use exploits the reputation associated with the designation;***

***(b) any misuse, imitation or evocation, even if the composition or true nature of the product or service is indicated or accompanied by an expression such as "style", "type", "method", "as produced in", "imitation", "flavour", "substitute", "like" or similar;***

***(c) any other commercial indication or practice likely to mislead the consumer as to the product's true nature or composition.***

However, this provision shall not apply to the designation of products the exact nature of which is clear from traditional usage and/or when the designations are clearly used to describe a characteristic quality of the product. "

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