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WHAT'S IN YOUR GLASS? WHETHER MILK LABELS SHOULD BE BASED ON CREATION PROCESS OR END PRODUCT (PART I OF III) *

Sam Masters**

INTRODUCTION

Milk. Santa drinks it, babies cry for it, and the galaxy is named after it, but defining and labeling it has made the courtroom a war zone.¹ It may seem like just a weekly item on your grocery list; but milk is a noun, verb, adjective, and even a river that runs from Alberta, Canada, through Montana.² How can something so familiar be so difficult to define?³

The Food and Drug Administration (FDA) defines milk as the “lacteal secretion . . . obtained by the complete milking of one or more healthy cows.”⁴ This narrow definition has raised legal concerns about

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1. Michelle E. Hoffer, *Almond Beverage, Oat Water, and Soaked Soybean Juice: How the Dairy Pride Act Attempts to Remedy Consumer Confusion About Plant-Based Milks*, 55 U. RICH. L. REV. 657, 658 (2021).

2. *Milk*, MERRIAM-WEBSTER.COM, <https://www.merriam-webster.com/dictionary/milk> [<https://perma.cc/VY2A-9EEN>] (June 5, 2022). As a noun, milk is “a fluid secreted by the mammary glands of females for the nourishment of their young[,] . . . milk from an animal . . . used as food by people[, or] a food product produced from seeds or fruit that resembles and is used similarly to cow’s milk.” *Id.* As a noun, milk could also be “a liquid resembling milk in appearance: such as . . . the latex of a plant [or] the contents of an unripe kernel of grain.” *Id.* When used as a verb, milk means “to draw milk from the breasts or udder . . . or to draw something from as if by milking: such as . . . to induce (a snake) to eject venom [or] to draw or coerce profit or advantage from illicitly or to an extreme degree[.]” *Id.* As an adjective, milk means either “giving milk” or “bred or suitable primarily for milk production.” *Id.* Lastly, as a geographical name, Milk refers to a “river 625 miles (1006 kilometers) long in the Canadian province of Alberta and the U.S. state of Montana; flows southeast into the Missouri River[.]” *Id.*

3. Kate Yoder, *The FDA is Confused About the Definition of ‘Milk,’ So We Talked to a Dictionary Expert*, GRIST (July 30, 2018), <https://grist.org/article/the-fda-is-confused-about-the-definition-of-milk-kory-stamper/> [<https://perma.cc/4DJS-E4MV>].

4. The full definition states:

Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or

labeling plant-based milk products as milk because the products do not explicitly fit within the FDA's definition.⁵ After significant litigation, courts have sided with plant-based companies and allowed the term milk to be used, despite the FDA definition.⁶

Importantly, this blog series is not about the traditional “Milk Wars”: plant-based milk versus cow's milk. Rather, this series focuses on milk made from bio-identical dairy proteins, a product that will likely enter the market soon, and how it should be labeled before it is sold in national grocery stores and restaurants.⁷ Bio-identical milk, developed through precision fermentation food technology, creates an animal-free product that has a “bio-identical dairy protein” to that found in traditional cow dairy.⁸ This presents a novel question: Should

ultrapasteurized, and shall contain not less than 8 ¼ percent milk solids not fat and not less than 3 ¼ percent milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.

21 C.F.R. § 131.110(a) (2022).

5. Dan Charles, *Soy, Almond, Coconut: If It's Not from a Cow, Can You Legally Call It Milk?*, NPR (Dec. 21, 2016), <https://www.npr.org/sections/thesalt/2016/12/21/506319408/soy-almond-coconut-if-its-not-from-a-cow-can-you-legally-call-it-milk> [<https://perma.cc/APZ9-X2R6>]; Hoffer, *supra* note 1, at 680 (“In this way, the argument could be made that the FDA is unknowingly in the pocket of big industry. However, there is evidence that this capture is known and accepted by the FDA as well.”). If the FDA is in the pockets of the milk industry, then this explains why the definition is so narrow and why the FDA is not making any action toward changing it. *See id.* at 680–82.

6. *See Ang v. Whitewave Foods Co.*, No. 13-CV-1953, 2013 WL 6492353 (N.D. Cal. Dec. 10, 2013); *Miyoko's Kitchen v. Ross*, No. 20-CV-00893, 2020 WL 8361994 (N.D. Cal. Aug. 21, 2020); *Gitson v. Trader Joe's Co.*, No. 13-CV-01333, 2015 WL 9121232 (N.D. Cal. Dec. 1, 2015); *Kelley v. WWF Operating Co.*, No. 1:17-CV-117, 2017 WL 2445836 (E.D. Cal. June 6, 2017); *Painter v. Blue Diamond Growers*, 757 F.App'x 517 (9th Cir. 2018).

7. Ariana Lang, *What Is Lab Milk? Benefits and Drawbacks*, HEALTHLINE (June 29, 2020), <https://www.healthline.com/nutrition/lab-milk> [<https://perma.cc/2526-R7H8>]. There are currently no beverages sold widely on the market that use this bio-identical protein. *Id.* However, Perfect Day commercially sells ice cream that is made with their animal-free whey protein. *Id.* This product, “Brave Robot,” is sold at many grocery stores across the country and online. *FAQs (We know from experience.)*, BRAVE ROBOT, <https://braverobot.co/pages/faqs> [<https://perma.cc/VX6U-AGWB>]. The description online specifies that “[t]he FDA requires a declaration of milk proteins as the non-animal whey protein is molecularly identical to dairy protein. However, the animal-free dairy protein is produced WITHOUT the use of animals, and with zero compromise on taste and nutrition.” *Id.* This description does not provide consumers with an understandable explanation of what the product is and where it comes from. *Id.* Interestingly, the advertising strongly weighs the fact that it is produced in a fermentation tank as well as the fact that it is the identical protein structure found in cow's milk. *Id.*

8. Maria Godoy, *Dairy Ice Cream, No Cow Needed: These Egg and Milk Proteins Are Made Without Animals*, NPR (Aug. 2, 2019), <https://www.npr.org/sections/thesalt/2019/08/02/747026144/dairy-ice-cream-no-cow-needed-these-egg-and-milk-proteins-are-made-without-anima> [<https://perma.cc/74X3->

a product be labeled based on the process through which it is derived or merely by the composition of the end product?⁹ There does not seem to be a conclusively right or wrong answer to this question but, instead, strong arguments on both sides of the debate.

Bio-identical milk is in the developing stages, and—unlike cultured meat, an analogous product—its label has not been widely litigated.¹⁰ This blog series will turn to the beef and cultured meat industries to develop a framework for the arguments on either side of the product-versus-process debate. Cultured meat is a product created in a laboratory, and the end product biologically has the same “meat tissue that comes from a cow.”¹¹ Both bio-identical milk and cultured meat are made in a lab and consist of biologically equivalent end products to those of traditionally animal-derived products like cow’s milk and animal meat.

Now is an opportune time to create a regulation for bio-identical milk. The threat bio-identical milk will pose to dairy farmers and plant-based milk companies will play out in court.¹² If the FDA acts now, they can mitigate the number of claims brought for mislabeling,

6XQP] (“If you can produce just the proteins that you want without keeping a living animal alive, that’s going to be a lot more efficient, so it’s better for the environment,” says Bruce Friedrich of the Good Food Institute, which promotes plant- and cell-based alternatives to animal protein.”).

9. See Green Queen Team, *Animal-Free Dairy is Here. But is it Vegan?*, GREEN QUEEN, <https://www.greenqueen.com.hk/animal-free-dairy-is-here-but-is-it-vegan-irina-gerry-change-foods/> [https://perma.cc/QAK6-UFTD] (May 5, 2021).

10. Christine Lawson, *What is M-E-A-T?*, NAT’L L. REV. (Feb. 18, 2021), <https://www.natlawreview.com/article/what-m-e-t> [https://perma.cc/WXC2-2ERU].

11. Jennifer Penn, “*Cultured Meat*”: *Lab-Grown Beef and Regulating the Future Meat Market*, 36 UCLA J. ENV’T L. & POL’Y 104, 109 (2018); THL, *What is Lab-Grown Meat, and How is Cultured Meat Made?*, HUMANE LEAGUE (Sept. 8, 2021), <https://thehumaneleague.org/article/lab-grown-meat> [https://perma.cc/9M98-Z5GU] (“[T]he process of making lab-grown meat starts with the careful removal of a small number of muscle cells from a living animal, typically using local anesthesia to provide relief from pain. . . . Then, a lab technician places the harvested cells in bioreactors before adding them to a bath of nutrients. The cells grow and multiply, producing real muscle tissue, which scientists then shape into edible ‘scaffoldings.’”).

12. Sydney Wyatt, *Labeling Lawsuits: Why Naming Plant-Based Foods is So Contentious*, U.C. DAVIS: SCIENCE SAYS (Feb. 12, 2021), <https://davissciencesays.ucdavis.edu/blog/labeling-lawsuits-why-naming-plant-based-foods-so-contentious> [https://perma.cc/2RFG-NGWX] (“[T]he National Milk Producers Federation [NMPF] continues to push for enforcement of these standards to restrict plant-based alternatives’ use of ‘milk.’”). This push by the NMPF, and why so many lawsuits are raised, is based on a fear of losing the market to these alternative products. *See id.*

consumer confusion, and a plethora of other label-related causes of action.¹³

The three parts of this blog series use the cultured meat industry as a lens to analyze both sides of the product-versus-process debate to develop a framework for a milk-labeling regulation that explicitly includes bio-identical dairy products. Part I provides an overview of the current regulations of milk, the creation processes of bio-identical dairy proteins and cultured meats, and the pending regulations for dairy products. Part II analyzes the arguments made on both sides of the process-versus-product debate within the cultured meat industry and then applies these arguments to the bio-identical milk industry. Finally, Part III proposes a three-part solution that promotes consumer clarity, product marketability, and judicial efficiency through a new FDA Standard of Identity (SOI) of milk and the creation of an “FDA: Certified Laboratory Grown” seal.

I. BACKGROUND

A. *Who Regulates What And Why It Matters*

There are two government agencies responsible for regulating food in the United States: the FDA and the United States Department of Agriculture (USDA).¹⁴ Meat, seafood, and eggs are regulated by the USDA’s Food Safety and Inspection Service (FSIS), and dairy is regulated by the FDA.¹⁵ The FDA has SOIs which “describe in detail what a food product must contain, how it must be proportioned and, sometimes, how it must be manufactured.”¹⁶ The FDA SOI for milk is

13. See Iselin Gambert, *Got Mylk?: The Disruptive Possibilities of Plant Milk*, 84 BROOK. L. REV. 801, 810–17 (2019) (addressing various lawsuits regarding labeling of plant-based milk).

14. Erica Bakota, *FDA vs. USDA: What’s The Difference?*, GOVLOOP (Aug. 22, 2019), <https://www.govloop.com/community/blog/fda-vs-usda-whats-the-difference/> [<https://perma.cc/63HH-THH4>]; *About FSIS*, FOOD SAFETY & INSPECTION SERV., U.S. DEP’T AGRIC., <https://www.fsis.usda.gov/about-fsis> [<https://perma.cc/4B36-DU6S>].

15. Bakota, *supra* note 14; FOOD SAFETY AND INSPECTION SERV., *supra* note 14.

16. Press Release, Claudine Kavanaugh, Dir. Off. Nutrition & Food Labeling, U.S. Food & Drug Admin., Ctr. for Food Safety & Applied Nutrition, *FDA in Brief: FDA Reopens Comment Period Related to General Principles for Food Standards of Identity Modernization* (Feb. 20, 2020), <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-reopens-comment-period-related-general-principles-food-standards-identity> [<https://perma.cc/3LKU-FRC5>].

“the lacteal secretion . . . obtained by the complete milking of one or more healthy cows.”¹⁷

The U.S. Code provides an extensive list of ways that a food product can be deemed misbranded.¹⁸ The pertinent sections are as follows: “(b) Offer for sale under another name . . . (c) Imitation of another food . . . [and] (g) Representation as to definition and standard of identity.”¹⁹ The recourse for misbranding food ranges from a mailed letter requesting a correction to criminal prosecution.²⁰ As the SOI and misbranding laws and regulations currently stand, milk from any type of plant, process, or animal other than a healthy cow—including, for example, an unhealthy cow—is considered misbranded and not compliant with the SOI.²¹

The FDA expects products resulting from “[a]dvancements in cell culture technology” to be on the market in the “not too distant future” and has begun planning how regulations should reflect these advancements.²² To further their goal of bringing “safe and properly labeled products to the market,” the FDA and FSIS entered an agreement in 2019 to allot duties to each agency regarding the oversight of food produced from cell technology.²³ Despite the agencies’ intention to offer clarity, the agreement merely sets forth broad provisions, such as requiring labels for cultured meat to “be preapproved and then verified through inspection, as required by FSIS

17. 21 C.F.R. § 131.110(a) (2022).

18. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343 (deeming a food misbranded “[i]f it is offered for sale under the name of another food[;] . . . [i]f it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ‘imitation’ and, immediately thereafter, the name of the food imitated[; or] . . . [i]f it purports to be or is represented as a food for which a definition and [SOI] has been prescribed . . . 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 . . .”).

19. *Id.*

20. *Types of FDA Enforcement Actions*, U.S. FOOD & DRUG ADMIN. (Nov. 6, 2017), <https://www.fda.gov/animal-veterinary/resources-you/types-fda-enforcement-actions> [<https://perma.cc/Z62W-J7S6>].

21. Gambert, *supra* note 13, at 806.

22. *Food Made with Cultured Animal Cells*, U.S. FOOD & DRUG ADMIN. (Oct. 6, 2020), <https://www.fda.gov/food/food-ingredients-packaging/food-made-cultured-animal-cells> [<https://perma.cc/EV3H-USLX>].

23. *Id.*

regulations.”²⁴ This agreement does not indicate who is responsible for the oversight of dairy products created through cell-cultured technology. The main takeaway of the agreement is that the “[FDA and FSIS] will develop a more detailed joint framework” in the future, but presently there is “no widespread industry understanding of the labeling requirements for cell-cultured meat and poultry products [that] currently exist[.]”²⁵

B. What Are Bio-Identical Dairy Proteins?

Only a few companies around the world are mounting the potentially lucrative feat of making dairy products without using animals.²⁶ Perfect Day is one of the leading companies in this developing industry.²⁷ Like their competitors, Perfect Day discovered what gave milk its “amazing nutrition and ability to make so many

24. *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-amenable Species*, U.S. FOOD & DRUG ADMIN. (Mar. 7, 2019) [hereinafter *Formal Agreement Between FDA and USDA*], <https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell> [https://perma.cc/5SDF-GUHW] (The FDA and FSIS “will develop a more detailed joint framework or standard operating procedure to facilitate coordination of shared regulatory oversight related to the harvest of biological material. . . . USDA-FSIS will . . . [r]equire that the labeling of human food products derived from the cultured cells of livestock and poultry be preapproved and then verified through inspection, as required by FSIS regulations.”).

25. Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animals Cells, 86 Fed. Reg. 49491 (Sept. 3, 2021) (outlining a proposed labeling-requirement framework); *Formal Agreement Between FDA and USDA*, *supra* note 24; Walter G. Johnson, *Conflict Over Cell-Based Meat: Who Should Coordinate Agencies in U.S. Biotechnology Regulation?*, 74 FOOD & DRUG L.J. 478, 479–80 (2019).

26. See, e.g., Sally Ho, *Got Milk? These 6 Microbial Biofermented Alt Dairy Startups Are Changing the Industry*, GREEN QUEEN, <https://www.greenqueen.com.hk/microbial-biofermented-alt-dairy-startups/> [https://perma.cc/X53T-EW3J] (Feb. 25, 2022); *What is ‘Animal Free Dairy’? Change Foods Explains*, FOOD FRONTIER (May 14, 2021), <https://www.foodfrontier.org/what-is-animal-free-dairy/> [https://perma.cc/89TL-K7A9]; Knvul Sheikh, *Got Impossible Milk? The Quest for Lab-Made Dairy*, N.Y. TIMES (Aug 2, 2019), <https://www.nytimes.com/2019/08/02/science/lab-grown-milk.html> [https://perma.cc/7SDK-EDAM].

27. Rosie Wardle, *New Joint Venture Takes Perfect Day a Step Closer to Cow-Free Milk*, CPT CAP. (Feb 1, 2019), <https://cptcap.com/new-joint-venture-takes-perfect-day-a-step-closer-to-cow-free-milk/> [https://perma.cc/4RPV-X6KZ]; Adele Peters, *This Animal-Free Dairy Isn’t Plant-Based. It’s Grown from Real Cow Protein (With No Cows Involved)*, FAST CO. (May 4, 2021), <https://www.fastcompany.com/90607741/this-animal-free-dairy-isnt-plant-based-its-grown-from-real-cow-protein-with-no-cows-involved> [https://perma.cc/2CXE-CYSX].

delicious foods.”²⁸ These nutritionally and functionally magical ingredients are whey protein and casein protein.²⁹

To create these proteins, cow genes obtained from published scientific databases are introduced to an organism called microflora.³⁰ Perfect Day gives microflora the genetic blueprint corresponding to whey protein, enabling it to produce real milk protein.³¹ The microflora is put into a fermentation tank where it becomes protein in a process called precision fermentation.³² New Culture, another company trying to be at the forefront of this industry, is spending its resources on creating casein protein to make an animal-free mozzarella.³³ New Culture’s process is similar to Perfect Day’s; they “house [their] microorganisms in large fermentation tanks, feed them sugar, and then gather the animal-free casein [they have] trained them to produce.”³⁴

Arguably, the most significant part of this process is the final product. These companies have found a way to create the central ingredient in milk and make an animal-free dairy product that “has a similar taste and nutritional profile to [cow’s] milk” and performs in the same way.³⁵ Additionally, this product has the same “chemical composition as cow’s milk,” prompting this question: Should the FDA change the SOI of milk to include this new product that only differs from milk in the creation process but results in a nearly identical final product?³⁶

28. Isabella Jabbour, *Forget Synthetic Meat, Lab-Grown Dairy is Already Here*, MEDIUM (Dec. 29, 2021), <https://medium.com/visionary-hub/forget-synthetic-meat-lab-grown-dairy-is-already-here-7f54e0310f11> [https://perma.cc/32YN-QK27].

29. *Id.*

30. *What is ‘Animal Free Dairy’? Change Foods Explains*, *supra* note 26.

31. *Partnering with Nature to Use Less and Make More*, PERFECT DAY, <https://perfectday.com/process> [https://perma.cc/W3S4-HUJJ].

32. *Partnering to Redesign Our World*, PERFECT DAY, <https://perfectday.com/enterprise-biology/> [https://perma.cc/P4S5-23PN]; Godoy, *supra* note 8 (“The company took the genetic code for the main proteins in whey, a byproduct of cheese-making, then had it artificially synthesized into a molecule of DNA—so the process is ‘totally animal free.’”).

33. *We’re Fueled by Fermentation: How We Make Our Animal-Free Casein*, NEW CULTURE, <https://www.newculturefood.com/> [https://perma.cc/A56V-XERL].

34. *Id.*

35. Wardle, *supra* note 27.

36. *Id.*

C. *What Is Cultured Meat?*

To appreciate why the cultured meat industry is a valuable predictor of what will happen when bio-identical milk comes to market, one must understand that both products—bio-identical milk and cultured meat—create a biologically equivalent product to their animal-derived counterparts. The principal components in animal meat are the “matrix of muscle and fat cells, interlaced with blood vessels and enrobed by connective tissue.”³⁷ To create cultured meat, bioengineers take small amounts of tissue from an animal and “isolate individual cells.”³⁸ These cells are put into a container where they are fed “nutrients, oxygen and moisture . . . at body temperature.”³⁹ These cells will grow and divide until they have covered the entire surface area of the container.⁴⁰ Once the cells have finished dividing, the “[m]uscle cells fuse together to create long muscle fibers and fat cells begin to produce lipids.”⁴¹ This single layer of tissue is “combined with other layers (as many as twenty thousand)” to create a product that biologically has the exact same “meat tissue that comes from a cow.”⁴²

D. *The DAIRY PRIDE Act: Imaginative Acronym, Unusable Legislation*

Four years after its initial introduction, the Defending Against Imitations and Replacements of Yogurt, Milk, and Cheese to Promote Regular Intake of Dairy Everyday Act (the DAIRY PRIDE Act) was reintroduced in 2021.⁴³ This legislation recognizes that, although the

37. Natalie R. Rubio, *So Far Cultured Meat Has Been Burgers—The Next Big Challenge is Animal-Free Steaks*, CONVERSATION (July 5, 2019), <https://theconversation.com/so-far-cultured-meat-has-been-burgers-the-next-big-challenge-is-animal-free-steaks-117727> [<https://perma.cc/LM5B-MJWZ>].

38. *Id.*

39. *Id.*

40. *Id.*

41. *Id.*

42. Penn, *supra* note 11, at 109; *What is Lab-Grown Meat, and How is Cultured Meat Made?*, *supra* note 11.

43. *DAIRY PRIDE Act Re-Introduced in House & Senate*, WIS. AG CONNECTION (Apr. 23, 2021), <http://www.wisconsinagconnection.com/story-state.php?Id=414&yr=2021> [<https://perma.cc/TK4L-TS7R>]; Press Release, Tammy Baldwin, Sen., Wis., U.S. Senators Tammy Baldwin and Jim Risch Stand Up for America’s Dairy Farmers (Mar. 14, 2019), <https://www.baldwin.senate.gov/press-releases/dairy-pride-2019> [<https://perma.cc/N8GS-9S8K>].

FDA has regulations that define dairy products, these restrictions are not currently enforced.⁴⁴ If enacted, this Act will bar products from being sold as dairy that do not “contain[] as a primary ingredient, or [are] derived from, the lacteal secretion . . . obtained by the complete milking of one or more hooved mammals.”⁴⁵ Functionally, if this Act is passed, plant-based and animal-free dairy products would have to adopt unappetizing names like “nut juice,” “soy beverage,” or “lab drink.”⁴⁶

44. *DAIRY PRIDE Act Re-Introduced in House & Senate*, *supra* note 43; Hoffer, *supra* note 1, at 670; Joshua Yeager, *Almond Beverage? Oat Drink? Just Don't Call it 'Milk,' Central Valley Dairy Groups Say*, *VISALIA TIMES DELTA* (Feb. 14, 2020), <https://www.visaliatimesdelta.com/story/news/2020/02/14/almond-beverage-oat-drink-just-dont-call-milk-central-valley-dairy-groups-say/4761447002/> [<https://perma.cc/ED2K-MU83>].

45. *DAIRY PRIDE Act*, S. 1346, 117th Cong. § 4 (2021) (providing that “no food may be introduced or delivered for introduction into interstate commerce using a market name for a dairy product if the food does not meet the criterion set forth for dairy products under paragraph (z)(2) of section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) (as added by section 4(a))”).

46. Hoffer, *supra* note 1, at 670; Yeager, *supra* note 44.