



VIA ELECTRONIC SUBMISSION TO DIVISION OF DOCKETS MANAGEMENT

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition to Amend the Yogurt Standard of Identity to Include Ultrafiltered Nonfat Milk as a Basic Dairy Ingredient

The undersigned submits this petition under Section 401 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs initiate rulemaking to amend the yogurt standard of identity (21 C.F.R. § 131.200) for the purpose of promoting honesty and fair dealing in the interest of consumers.

A. ACTION REQUESTED

Chobani, LLC respectfully requests that the yogurt standard of identity (21 C.F.R. § 131.200) be amended to include ultrafiltered nonfat milk as a basic dairy ingredient permitted in the manufacture of yogurt.

Specifically, in 21 C.F.R. § 131.200, revise paragraph (b) to insert “ultrafiltered nonfat milk”, which reads as follows:

§ 131.200 Yogurt.

* * * * *

- (b) Basic dairy ingredients. Cream, milk, partially skimmed milk, skim milk, **ultrafiltered nonfat milk**, or the reconstituted versions of these ingredients may be used alone or in combination.

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B. STATEMENT OF GROUNDS

Background

Chobani is a food maker with a mission of making high-quality and nutritious food accessible to more people, while elevating our communities and making the world a healthier place. In short: making good food for all. In support of this mission, Chobani is a purpose-driven, people-first, food-and-wellness-focused company, and has been since its founding in 2005 by Hamdi Ulukaya, an immigrant to the U.S. The Company manufactures yogurt, oat milk, and creamers – Chobani yogurt is America's No.1 yogurt brand, made with natural ingredients without artificial preservatives. Following the 2023 acquisition of La Colombe, a leading coffee roaster with a shared commitment to quality, craftsmanship, and



impact, the Company began selling cold-pressed espresso and lattes on tap at 32 cafes, as well as ready-to-drink coffee beverages at retail.

Chobani uses food as a force for good in the world – putting humanity first in everything it does. The company's philanthropic efforts prioritize giving back to its communities and beyond: working to eradicate child hunger, supporting immigrants, refugees and underrepresented people, honoring veterans, and protecting the planet. Chobani manufactures its products in New York, Idaho, Michigan and Australia, and its products are available throughout North America and distributed in Australia and other select markets.

Summary of Request

This citizen petition is filed with the intention of modernizing the yogurt standard of identity, while continuing to promote honesty and fair dealing in the interest of consumers. We appreciate the Food and Drug Administration's (FDA) diligent work revising the yogurt standard of identity over the last several years, yet we believe that there are additional opportunities to promote innovation in manufacturing yogurts to meet consumer demands for certain nutritional attributes and that better reflect contemporary technologies and processing methods, while still maintaining the essential characteristics of yogurt.

We are requesting that FDA revise the yogurt standard to allow the use of ultrafiltered nonfat milk as a basic dairy ingredient in the manufacture of yogurt. Ultrafiltered nonfat milk is currently allowed as an optional dairy ingredient in yogurt, as are other safe and suitable milk-derived ingredients but cannot be used as one of the basic dairy ingredients under the current standard of identity.¹ Our requested change would better reflect modern technologies and processing methods available to manufacturers, including the wide and growing commercial availability of ultrafiltered milks. At the same time, the change would not fundamentally alter the basic nature and essential characteristics of yogurts available to consumers in the marketplace. Yogurt produced with ultrafiltered nonfat milk has organoleptic properties that are within the range of variation already seen with yogurts in the marketplace today, such as the variation in thickness and texture between a traditional drinkable yogurt and strained, high-protein yogurt, and yogurts made with the addition of milk proteins and stabilizers, which are currently permitted under the standard of identity. Furthermore, the literature identifies yogurt made with ultrafiltered milk as having an equal or preferred taste to regular yogurt, confirming that the product will meet consumer expectations for yogurt,² in addition to meeting consumer demands for products that are lower or zero sugar, high in protein, and lactose-free. The change to the standard is within the Commissioner's legal authority and would maintain honesty and fair dealing in the interest of consumers.

¹ 21 C.F.R. § 131.200(b) and (c).

² Recent research by Dushkova et al., 2021 demonstrated that ultrafiltered goat skim milk had better sensory yogurts compared to yoghurts made without ultrafiltration. Employing ultrafiltration improved the quality and increased the nutritive value of protein, calcium, and phosphorus of buffalo milk yoghurt. The process of ultrafiltration also has an advantage of controlled acidity development in the product due to reduced lactose content of milk which is advantageous to lactose intolerant people by eliminating or decreasing cramps or other digestive discomforts (Meena et al., 2015).

In this petition, we rely on a definition of “ultrafiltered nonfat milk” consistent with that used in FDA’s proposed rule on the use of ultrafiltered milk in standardized cheese products. FDA proposed to define ultrafiltered nonfat milk as “raw or pasteurized nonfat milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein:whey protein ratio of the milk and resulting in a liquid product”.³ FDA expanded on this definition in the context of yogurt in 2016, explaining, “the milk may be UF [ultrafiltered] until a desired protein concentration is reached and, depending on the processing conditions (*e.g.*, use of diafiltration), can result in removal of the majority of lactose and water-soluble minerals and vitamins”.⁴ When this type of milk is used, it is to be declared in the ingredient statement of the finished food as “ultrafiltered nonfat milk”, consistent with guidance from FDA (M-I-08-7 4 May 7, 2008). Like other basic dairy ingredients permitted by the yogurt standard, ultrafiltered nonfat milks are governed by provisions of the Pasteurized Milk Ordinance (PMO) that ensure their quality and food safety in other Grade A milk products. The regulatory principles governing milk and milk ingredient sanitation and quality are sufficient to ensure no deleterious effects to safety or the sensory quality of the final product.⁵

The yogurt Chobani produces under its TMP is made with ultrafiltered nonfat milk produced with diafiltration that contains minimal lactose as the basic dairy ingredient; skim milk is also used as an ingredient, which allows us to achieve a target lactose content in the batching process that is the minimum amount needed for the fermentation to achieve a final yogurt product with a pH of 4.6 or less, while ensuring selected sensory and performance characteristics. That lactose is consumed in the fermentation process, resulting in a product with zero sugar content, including zero lactose. (Importantly, the lactose content could be adjusted by varying the amount and type of other basic dairy ingredients used, which means that other yogurts made with ultrafiltered nonfat milk could have some amounts of sugars if the product is formulated in that way). The inherently lower lactose content of ultrafiltered nonfat milk, however, would mean that the sugar content of yogurts produced with this ingredient would generally have lower sugar content than regular yogurts. Further, a yogurt made with ultrafiltered nonfat milk would typically have high protein content, but without the need for added isolated milk proteins.

The statement of grounds for this petition is based on the following:

- 1) The use of ultrafiltered nonfat milk as a basic ingredient does not fundamentally alter the basic nature and essential characteristics of yogurt;
- 2) Permitting the use of ultrafiltered nonfat milk allows for flexibility and efficiency in the manufacture of yogurts and reflects modern technologies and processing methods;
- 3) Using ultrafiltered nonfat milk in the manufacture of yogurt provides numerous advantages to consumers;
- 4) Granting the petition would harmonize the yogurt standard of identity with existing FDA policy and international standards, as well as advance FDA’s nutrition policy agenda.

³ 70 Fed. Reg. 60751, 60751 (Oct. 19, 2005).

⁴ 87 Fed. Reg. 76568, 76559 (Dec. 15, 2022).

⁵ The concentrated forms of ultrafiltered milk can be reconstituted in production such that the reconstituted form does not differ significantly from the respective ultrafiltered milk in regard to specified water:solids ratio. Water can be added at a sufficient quantity to reconstitute the concentrated ultrafiltered milk to achieve a specified water:solids ratio and a desired protein concentration in finished food. Such a practice would be consistent with existing FDA guidance for dried forms of cream, milk, or skim milk (21 CFR 101.4 (b) and (c)), as well as the treatment of other basic dairy ingredients in the yogurt standard of identity. In addition, ultrafiltered milk may undergo diafiltration, consistent with the definition proposed above.

We discuss these arguments in support of our proposed change to the standard of identity further below.

1) The Use of Ultrafiltered Nonfat Milk as a Basic Ingredient Does Not Fundamentally Alter the Basic Nature and Essential Characteristics of Yogurt

Physiochemical and Organoleptic Properties of Yogurt Made with Ultrafiltered Milk Do Not Differ Meaningfully from Other Yogurts Available on the Market

Microbiological, physicochemical, organoleptic, and rheological characteristics are the fundamental characteristics of yogurts that influence the acceptance and choices of consumers. There are no meaningful differences between traditional yogurts and those made from ultrafiltered nonfat milk in these attributes.⁶

Chobani, as a manufacturer of both strained, high-protein yogurts and yogurts made from ultrafiltered nonfat milk (as a test product under the TMP), has collected data over the last few months demonstrating comparable organoleptic qualities between the two yogurt products. These data illustrate similar texture, pH, syneresis, and performance of strained, high-protein yogurt manufactured from traditional nonfat milk versus ultrafiltered nonfat milk (See Appendix, Table 1). In addition to the organoleptic data, Chobani has collected consumer feedback during our TMP period demonstrating positive feedback about the product and its usefulness in supporting personal dietary goals like reducing sugar or supporting diabetic-friendly meal plans (See Appendix, Figure 1 and Table 2).

Any physiochemical or organoleptic differences exhibited in yogurts manufactured with ultrafiltered nonfat milk are within the range of observable variability in yogurts currently available commercially in the marketplace owing to other processing steps or optional ingredients permitted under the current standard of identity. For example, stirring yogurt after culturing is a common processing step used in the U.S. and around the world. In fact, even in the production of strained yogurt (e.g., Greek), production involves stirring/blending the white mass to transfer it from a fermentation vessel to a filtration system (or bags) or to pump it to a mechanical separator for concentrating. When yogurt is stirred, the viscosity thins as bonds are broken in the gel and the yogurt is fluidized which makes pumping, cooling, and mixing easier.⁷ It is not uncommon (nor disallowed under the standard) to stir the yogurt gel prior to packaging to incorporate added ingredients such as fruit flavorings, stabilizers, or sweeteners.

At the same time, the use of additional dairy protein ingredients (such as whey protein concentrates and milk protein concentrates) as optional dairy ingredients (as currently permitted under the standard) in the manufacture of yogurt can have significant effects on yogurt attributes. In general, an increase in the protein content of a yogurt milk base yields a yogurt with increased firmness, viscosity, and gel strength mainly due to the increased amount of protein participating

⁶ See Appendix – Chobani Literature Review in support of Citizen Petition

⁷ Renan et al., 2008. The rebodding of stirred yoghurt: interactions between proteins. J Dairy Res. Nov;75(4):450-456.

in the gel network.^{8,9,10} Therefore, any minor physiochemical variations attributable to the use of ultrafiltered nonfat milk as a basic ingredient are well within the wide variations achievable under the current standard using optional dairy ingredients and other optional ingredients.

Lactose Content Is Not a Characterizing Component of Yogurt

Although ultrafiltered milk has reduced lactose content compared to other basic dairy ingredients used in yogurt, lactose content in the finished product is not material to the essential characteristics of yogurt and as discussed further below, lack of lactose is a desirable attribute to consumers.

Lactose is the primary carbon source for bacterial cultures during fermentation. However, up to 70% of the lactose in milk remains after fermentation in the manufacture of yogurt.^{11,12} The acidity of milk and maximum cell biomass concentration (~10¹⁰ CFU/g) limit the propagation of bacteria in yogurt.¹³ Thus, much of the lactose present in traditional milk is not utilized nor acted on by bacterial cultures during the fermentation process.

While the remaining lactose in traditional yogurt contributes a small degree of sweetness to the final product, it is far outweighed in sensory attributes through the addition of other sweetener ingredients with greater intensity, including sucrose and other high-intensity sweeteners. Additionally, sweetness is not an essential characteristic of yogurts given that the acid flavor profile is most predominant in unsweetened, plain yogurts, which account for a large proportion of the current yogurt market.¹⁴

Moreover, the current standard of identity does not prescribe a minimum level of lactose with respect to any basic dairy ingredient when making yogurt; manufacturers may alter the level of lactose present in the starting basic dairy ingredients by using selected combinations or using lactase enzymes. It is important to note manufacturers bear the responsibility for selecting the basic dairy ingredient(s) in a standardized yogurt in a way that ensures the finished yogurt will still achieve all requirements in the standard of identity (e.g., milk solids, pH, etc.). These other elements of the standard help to ensure that the selected basic dairy ingredient will result in a product that meets consumer expectations for yogurt.

Chobani's internal studies on our test product under the TMP demonstrate a minimum amount of lactose required in

⁸ Abrahamsen & Holmen, 1980. Yogurt from hyperfiltrated, ultrafiltrated and evaporated milk and from milk with added milk powder. *Milchwissenschaft*. 35:399-402.

⁹ Biliaderis, et al., 1992. Rheological and Sensory Properties of Yogurt from Skim Milk and Ultrafiltered Retentates. *Int. Dairy J.* 2:311-323

¹⁰ Mistry and Hassan 1992. Manufacture of nonfat yogurt from a high milk protein powder. *J. of Dairy Sci* 75:947-957.

¹¹ Chandan and Kilara 2013. *Manufacturing Yogurt and Fermented Milks*. Editor. Blackwell Publishing Ltd. 9600 Garsington Road, Oxford OX4 2DQ, UK.

¹² Ohlsson et al., 2017. Lactose, glucose and galactose content in milk, fermented milk and lactose-free milk products. *International Dairy J.* 73:151-154

¹³ Tamime and Robinson 2007. *Yoghurt-Science and Technology*, 2nd ed.

¹⁴ Chen et al., 2017. Role of lactic acid bacteria on the yogurt flavour: A review. *International J. Food Properties* 20: (S1), S316-S330.

ultrafiltered nonfat milk that is sufficient to allow for effective and efficient fermentation to reach the pH/titratable acidity requirements for yogurt and achieve a characterizing level of traditional yogurt cultures (*Lactobacillus delbrueckii* ssp. *Bulgaricus* and *Streptococcus thermophilus*). Such a level can be managed as an in-process specification for the ingredient through testing and/or through certificates of analysis provided by ingredient suppliers. As discussed above, Chobani currently produces a yogurt under its TMP that contains both ultrafiltered nonfat milk and skim milk, with the amount of each ingredient carefully selected to achieve a particular target lactose content that is the minimum amount needed for fermentation to act upon the lactose and produce a yogurt with the required pH and titratable acidity content. Accordingly, while lactose is needed at the fermentation stage at some level, as we discuss above, lactose is not an essential characteristic of yogurt in the finished product, and it should not be considered an essential property of a basic dairy ingredient that can be used in a yogurt.

Other Constituents of Ultrafiltered Nonfat Milk

We acknowledge that other constituents—including protein, minerals, vitamins, and water—vary in ultrafiltered nonfat milk and are different than the levels in milk (or nonfat milk) (see Table below). However, these variations are not sufficient to fundamentally alter the basic nature and essential characteristics of yogurt. As discussed previously, yogurts made from ultrafiltered nonfat milk as basic ingredient exhibit similar physiochemical and organoleptic attributes as traditional yogurt. Any (subtle) differences observed in these properties, for example in texture or thickness, are within the variations expected by consumers within the current yogurt set, owing to differences in starting milk, cultures, stabilizers, or added proteins.

Table. Typical chemical composition of dairy ingredients used in formulating yogurt mix (adapted from Chandan and Kilara, 2013)¹⁵

Ingredient	Total Solids (%)	Fat (%)	Protein (%)	Lactose (%)	Ash (%)
Whole milk	12.6	3.5	3.5	4.9	0.7
Nonfat milk	9.5	0.1	3.6	5.1	0.7
Whipping cream	42.7	36.8	2.2	3.2	0.5
Fluid ultrafiltered milk	25-30	11-14	10-12	<5	>2.5
Fluid ultrafiltered nonfat milk	15-20	<0.5	10-12	<5	>2.5
Fluid ultrafiltered nonfat milk, with diafiltration	18-20	<0.5	16-17	<1	>1.5

There are important nutritional considerations in the use of ultrafiltered nonfat milk in the manufacture of yogurt (See Appendix, Table 3). Compared to regular skim milk, ultrafiltered nonfat milk is lower in sugar (lactose) and sodium than traditional nonfat milk, yet is higher in selected nutrients of interest relative to traditional nonfat milk, including vitamin B12, calcium, phosphorous, zinc, and selenium, whereas potassium, choline, thiamin, and vitamin B5 (pantothenic acid) are slightly reduced.

¹⁵ Chandan and Kilara 2013. Manufacturing Yogurt and Fermented Milks. Editor. Blackwell Publishing Ltd. 9600 Garsington Road, Oxford OX4 2DQ, UK.

Yogurts made from ultrafiltered nonmilk deliver levels of important nutrients consistent with other yogurts present in the marketplace today (See Appendix, Table 4). For example, yogurt made from ultrafiltered milk is a good source of calcium, phosphorous, zinc, and selenium. Both Greek Yogurt and yogurts from ultrafiltered nonfat milk are high-quality proteins as determined by Protein Digestibility-Corrected Amino Acid Scores (PDCAAS) testing. However, a few nutrients are reduced, including potassium, choline, and pantothenic acid. Yet, in the context of population nutrition guidance, potassium levels of yogurt made from ultrafiltered nonfat milks are consistent with other foods that count towards Americans overall consumption of dairy for the purposes of dietary monitoring and guidelines development. For example, the potassium content of yogurt from ultrafiltered nonfat milk is comparable to that of soy yogurt (80 mg/170g; 1.7% DV), USDA Food Data Central FDC ID: 1100458). Choline and pantothenic acid have not been considered in modeling studies conducted by the Dietary Guidelines Advisory Committee when considering changes to the dairy recommendations to include non-dairy alternatives.¹⁶

2) Permitting the Use of Ultrafiltered Nonfat Milk Allows for Flexibility and Efficiency in the Manufacture of Yogurts and Reflects Modern Technologies and Processing Methods

Ultrafiltration is one commonly used membrane filtration technique in the food and beverage industry to separate components based on their molecular weight sizes. The semipermeable membrane technology allows the retention of high molecular weight molecules such as milk proteins and removal of water and low molecular weight components such as lactose and soluble minerals from the milk. With this technology, it is possible to produce dairy products containing high protein and lower lactose (and lower total sugar) than with traditional milk.

Standardization of milk by employing ultrafiltration technology offers an important efficiency application in the dairy industry, particularly for the manufacture of fermented dairy products.^{17,18} Standardization allows the compositional consistency of milk products to be maintained, assists in controlling the processing properties of the milk and provides opportunities to develop new products with improved functionalities.¹⁹ Protein standardization of the milk using ultrafiltration has been suggested to be superior to fortification of the milk bases with evaporated milk or milk powder in enhancing the product quality.²⁰

While there are several technologies or processing methods available to produce high protein yogurts, each has its advantages and disadvantages. One way to improve the texture quality of yogurts is to increase the dry matter content. Traditional methods for increasing the dry matter content are based on adding powdered milk, evaporated milk, or protein concentrates. It is worth noting that evaporation and drying processes can reduce the product quality due to the negative effect of thermal treatment on heat-sensitive milk components. For example, the addition of whole milk

¹⁶ 2015 Dietary Guidelines for Americans Advisory Committee Report, Appendix E-3.6: Dairy Group and Alternatives. <https://health.gov/our-work/nutrition-physical-activity/dietary-guidelines/previous-dietary-guidelines/2015/advisory-report/appendix-e-3/appendix-e-36>

¹⁷ Jørgensen et al., 2019. Processing of high-protein yoghurt—A review. *International Dairy J.* 88:42–59.

¹⁸ Kumar et al., 2013. Perspective of membrane technology in dairy industry: A review. *Asian-Australasian J. Animal Sci.* 26(9):1347.

¹⁹ Rattray & Jelen 1996. Protein standardization of milk and dairy products. *Trends Food Sci & Tech.* 7(7):227–234.

²⁰ Rosenberg 1995. Current and future applications for membrane processes in the dairy industry. *Trends in Food Sci. & Tech.* 6(1):12–19.

powder to yogurt is involved in oxidized flavor.²¹ Skim milk powder (SMP) may be insufficient to produce yogurt of consistent physical attributes over the seasons owing to natural variations. Moreover, the potential development of excess acidity of the final product, a consequence of the high lactose content of the powder, remains the limiting factor for the use of SMP.²² The use of whey powder is limited in yogurt manufacture because it can be associated with some defects in texture, flavor, and appearance. In this context, whey protein in dairy products higher than 1 to 2% w/w may impart an undesirable whey flavor as well as under some conditions a grainy texture, its use is more appropriate for drinking yogurt.²³

Similarly, there are limited options to achieve a lactose-free yogurt, and few currently available to manufacturers under the current standard of identity. We note that adding the lactase together with the culture after the pasteurization of the milk poses challenges:

- Although lactase is commonly used to hydrolyze lactose and produce lactose-free milk, this process has a ceiling on lactose hydrolysis when yogurt cultures *S. thermophilus* and *Lb. bulgaricus* grow in milk,²⁴ in addition to being expensive and time consuming. Notably, pre-hydrolysis of lactose seems to inhibit the activity of some yogurt cultures probably due to the switch from lactose to glucose as a main carbon source or to the increased osmotic pressure in lactose-hydrolyzed milk.²⁵
- If a “neutral” lactase enzyme is added to the milk at the same time as the yogurt culture, only a limited time is left for lactose digestion, as most neutral lactases are completely inactivated at a pH < 5.5,²⁶ which is reached after 2.5–3 hours of incubation in a regular yogurt making process – this time is too short for effective fermentation of milk and the production of lactose-free yogurt. This limitation can be overcome by monitoring and increasing the lactase dosage or by the addition of a relatively high of lactase – a costly ingredient – to obtain a lactose-free status.
- Lactase can split lactose into its component sugars – glucose and galactose – to ease digestion, but the total carbohydrate content does not change.
- Using starter cultures selected for greater β -galactosidase activity has also been shown to influence lactose content of the final yogurt. However, these cultures are also limited in their efficacy to remove all lactose.²⁷

In contrast, ultrafiltration allows for the removal of most of the lactose in milk and lower the carbohydrate/sugar content, while at the same time achieving a milk that is higher in protein. Therefore, permitting the use of ultrafiltered nonfat milk allows for flexibility and efficiency in the manufacture of yogurts and reflects modern technologies and

²¹ Karam et al., 2013. Effect of dairy powders fortification on yogurt textural and sensorial properties: a review. J. Dairy Res. 80:400–409.

²² Tamime & Robinson 2000. Yogurt Science and Technology. Washington, DC: CRC Press Woodhead

²³ González-Martínez et al., 2002. Influence of substituting milk powder for whey powder on yogurt quality. Trends in Food Sci and Tech 13:334–340.

²⁴ Zhang et al., 2019. Low-sugar yogurt making by the co-cultivation of *Lactobacillus plantarum* WCFS1 with yogurt starter cultures. J. Dairy Sci. 103:3045–3054.

²⁵ Kárnyáczki & Csanádi 2017. Texture profile properties, sensory evaluation, and susceptibility to syneresis of yogurt prepared from lactose-free milk. Acta Aliment. 46:403–410.

²⁶ Dekker 2016. Reference module in food sciences. 1st ed. Elsevier; Amsterdam, The Netherlands: 2016. Enzymes Exogenous to Milk in Dairy Technology: β -D-Galactosidase; pp. 1–8.

²⁷ Li 20at., 2023. Advances in low-lactose/lactose-free dairy products and their production. Foods 12: 2553-2574.

processing methods.

3) Using Ultrafiltered Nonfat Milk as A Basic Dairy Ingredient in The Manufacture of Yogurt Provides Numerous Advantages to Consumers

Chobani maintains that the changes sought by this petition are likely to result in several nutritional advantages to consumers. Consumers are interested in healthful products with natural ingredients, produced transparently and with a minimal addition of additives.²⁸ Permitting the use of ultrafiltered nonfat milk as a basic dairy ingredient achieves some of these stated goals.²⁹ Moreover, granting the petition would help advance FDA's nutrition policy goals related to reducing sugar consumption.

Chobani's own data collected during the TMP period demonstrates favorable consumer feedback for the product (See Appendix, Figure 1 and Table 2) based on its unique nutritional attributes. In addition, growing market share of the product represents continued consumer interest and preference for the product (See Appendix, Table 5).

An Excellent Source of High-Quality Protein

Using ultrafiltered nonfat milk as a dairy basic ingredient in yogurt manufacturing can yield yogurt products with high-quality and complete protein, through a natural physical process. Ultrafiltered nonfat milks can maintain the same whey:casein ratio as traditional milk and maintain milk's high-quality protein status (as measured by the Protein Digestibility-Corrected Amino Acid Score). Using ultrafiltered nonfat milk as a dairy basic ingredient in yogurt manufacturing can yield yogurt products with high-quality and complete protein, naturally, at levels that contribute around quarter of the daily recommended intake of protein (10g – 30g protein/ RACC; 20% - 60% DV), without adding other milk proteins (such as whey protein concentrate or powdered milk that are usually not lactose-free and depending on the process of manufacturing may impart negative effects on flavor and texture, examples are provided above).

Increasing the high-quality, naturally occurring protein content in yogurts can help cater to growing consumer demand for these properties and for clean label products. 67% of consumers tried to consume more protein in 2023, according to IFIC.³⁰ Protein consumption becomes especially important for older adults (those over 60) to maintain muscle mass and prevent sarcopenia.³¹ Consumers have specific and growing interest in consuming high-protein yogurt. Such innovation may cater to growing consumer demand for these properties and for clean label products.

Decreasing Total Sugar Intake

Using ultrafiltered nonfat milk as a basic dairy ingredient in yogurt manufacturing can yield yogurt products with lower or zero total sugar levels, and such innovation may cater to growing consumer demand for yogurts with these

²⁸ Naturalness: Trends, convictions and innovations 29 May 2020.

²⁹ Malika O'Doherty – Trends April 11, 2024.

³⁰ [Wellness trends influencing consumers in 2024 - NIQ \(nielseniq.com\)](https://www.nielseniq.com/en/insights/trends/wellness-trends-influencing-consumers-in-2024/)

³¹ Putra et al., 2021. Protein Source and Muscle Health in Older Adults: A Literature Review. *Nutrients* 13: 743.

properties. In the United States, about 72% of adults report they are seeking to limit or reduce sugar intake,³² they are also seeking out zero-sugar claims on products.³³ Ultrafiltration of milk as an approach to naturally lowering the amount of sugar in yogurts is helpful for consumers who are looking to reduce the amount of sugar in their diet or adhere to lifestyle, medical, or other dietary restrictions on sugar. Further, this reduction in sugars is achieved without the need to substitute non-nutritive sweeteners for sugars. While non-nutritive sweeteners could be added to a yogurt made with ultrafiltered nonfat milk, they would not have to be added to maintain the “zero sugar” content of the food. We expect this would be viewed as advantageous to those consumers interested in selecting products that do not contain non-nutritive sweeteners.

Facilitating Avoidance of Lactose

Avoiding lactose is a priority for many consumers, including the estimated 68% of the world’s population who experience lactose malabsorption.³⁴ Lactose-free dairy products may help eliminate many of the unpleasant symptoms associated with lactose-intolerance. Many lactose intolerant people follow “avoidance strategy”, which involves the complete exclusion of dairy products from their diet. Observational studies noted that avoidance of dairy products was associated with poor bone health, higher blood pressure and an increased risk of diabetes mellitus.³⁵ Statements about lactose content (i.e., “lactose-free” or “reduced lactose”) are specifically permitted on the label to help facilitate consumer avoidance of lactose due to food intolerance. Ultrafiltered nonfat milk can therefore be used to make lactose-free yogurts, offering an excellent solution for lactose intolerant individuals, in addition to helping them meet their dietary calcium and high-quality protein requirements.

Building Healthier Dietary Patterns

Dairy foods are important for their role in providing essential nutrients, which is why they are recommended parts of healthy eating patterns. The *2020-2025 Dietary Guidelines for Americans*³⁶ recommends lowfat and nonfat yogurts as parts of healthy dietary patterns. Yogurts made from ultrafiltered nonfat milk can deliver levels of essential vitamins and minerals that consumers have come to expect from yogurts and are consistent with the types of foods which count towards Americans overall consumption of dairy for the purposes of dietary monitoring and guidelines development.³⁷ Greater availability of yogurt options on the market, especially those that facilitate avoidance of certain attributes like sugar or lactose, can support Americans in better meeting healthy dietary patterns.

³² International Food Information Council. 2023 Food & Health Survey. 23 May 2023.

³³ <https://www.foodnavigator-usa.com/Article/2023/12/07/Sugar-reduction-in-2024-How-consumer-demands-health-policies-will-influence-product-launches>.

³⁴ National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. Definition & Facts for Lactose Intolerance, Accessed July 12, 2021.

³⁵ Facioni et al., 2020. Nutritional management of lactose intolerance: the importance of diet and food labelling. *Transl Med*. 8:260-269.

³⁶ U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2020-2025 Dietary Guidelines for Americans 8th Edition.

³⁷ U.S. Department of Health and Human Services. Appendix E-3.6: Dairy Group and Alternatives, Accessed July 12, 2022. <https://health.gov/our-work/food-nutrition/previous-dietary-guidelines/2015/advisoryreport/appendix-e-3/appendix-e-36>.

4) Granting the Petition would Harmonize the Yogurt Standard of Identity with Existing FDA Policy and International Standards, and Advance FDA's Nutrition Policy Agenda

The changes requested by this citizen petition will result in harmonization with existing FDA policy and international standards for manufacturing yogurt as well as with other North American countries standards for yogurt, including Canada and Mexico. Specifically, allowing for the use of ultrafiltered nonfat milk in the manufacture of yogurt in the United States would be consistent with the CODEX standard for fermented milks (CODEX STAN 243-2003), the Mexico NOM for yogurts (NOM-181-SCFI/SAGARPA-2018), and the Canadian market (where no explicit standard exists). This change will increase consistency for consumers across these markets and manufacturers looking to harmonize operations across North America.

As for existing FDA policy, in the last few years FDA has taken similar approaches to allowing ultrafiltered nonfat milk in the manufacture of other standardized dairy foods, including cottage cheese (via a TMP to Well's Dairy) and in other standardized cheeses (via a 2005 proposed rule to permit the use of ultrafiltered nonfat milk).

More broadly, FDA has been advancing nutrition policies that seek to reduce the population's added sugars intake.³⁸ While a yogurt produced with ultrafiltered nonfat milk results in lower *total* sugars content, and may have the same *added* sugars content (Og) as other yogurts, this reduction in total sugars can help consumers meet their nutrient intake requirements within calorie limits and we view it as consistent with the agency's policy goals related to sugar consumption.

For these reasons, Chobani believes that permitting the use of ultrafiltered nonfat milk in yogurt making would bring significant benefits to consumers while maintaining the essential characteristics of yogurt and would increase flexibility and efficiency in the dairy aisle.

C. ENVIRONMENTAL IMPACT

An amendment to a food standard is categorically excluded from the requirement to prepare an environmental assessment (21 C.F.R. § 25.32(a)). To our knowledge, no extraordinary circumstances exist.

D. ECONOMIC IMPACT

The requested change to the standard will not have an economic impact on either the producers or the consumers of yogurt. The proposed revision would not impose any additional costs on regulated entities, as they merely allow for an

³⁸ See FDA's Nutrition Initiatives, <https://www.fda.gov/food/food-labeling-nutrition/fdas-nutrition-initiatives>.



additional ingredient to be used in yogurt. We also note that the petition, if granted, is not intended to confer an economic benefit or advantage to any segment of, or particular company within, the yogurt industry as it would allow any yogurt manufacturer to use ultrafiltered nonfat milk as a basic dairy ingredient in yogurt.

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition.

A handwritten signature in cursive script, reading "Matt Graziose", is written over a horizontal line.

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