FFHD

Review Article



Kombucha: Probiotic beverage or ultra-processed food: A global review using nutritional classification

Carlos Aulesa^{1*}, Carmen Gongora²

¹Emerit Biochemistry professor, Vall d'Hebrón Hospital, University Autonomous Barcelona, Spain; ²Educational Psychologist, Barcelona, Spain

*Corresponding author: Carlos Aulesa, Emerit Biochemistry professor, Vall d'Hebrón Hospital, University Autonomous Barcelona, Spain

Submission Date: September 26th, 2023; Acceptance Date: November 28th, 2023; Publication Date: December 18th, 2023

Please cite this article as: Aulesa C., Gongora C. Kombucha: Probiotic beverage or Ultra-Processed Food? A Global Review Using Nutritional Classification. *Functional Foods in Health and Disease* 2023; 13(12):690-701. DOI: https://www.doi.org/10.31989/ffhd.v13i12.1236

ABSTRACT

AObjectives: The aim of this work is, to know the true essence and content of kombucha through the statistical analysis of the food classification and nutritional component of the world database of kombucha-registered trademarks, which has been provided to us by the OpenFoodFact Foundation.

Method: To gain an understanding of kombucha, a study on the global market for this beverage has been conducted. A total of 2,818 kombucha brands are currently marketed and registered as of April 1, 2023. This research has been made possible thanks to the fact that OpenFoodFact. App provides us with detailed descriptions of the products, nutritional components, as well as Nutri-Score, Nova, and Eco-Score classifications for each registered trademark.

Results: The statistical analysis of 2,673 brands from the 13 main Kombucha-producing countries reveals that, based on the Nutri-Score classification, 57% are deemed healthy (categories A, B, and C), while 43% are categorized as unhealthy (categories D and E). In terms of the Nova classification, 70% fall under the healthy categories (1, 2, 3), with the remaining 30% classified as unhealthy, specifically falling into category 4 as ultra-processed.

Conclusions: The world market kombucha study shows contradictory results depending on the chosen food classification and the country. Global basic advice for its consumption and specific tips for groups such as people with diabetes or cardiovascular disease are proposed.

Running Title: Global analysis market shows us kombucha's distribution worldwide brands through the statistical analysis of OpenFoodFact database.

Keywords: Kombucha, Probiotic fermented food, SCOBY, Nutri-Score food classification, Nova food classification, ultraprocessed food.





INTRODUCTION

Kombucha is the most popular fermented beverage traditionally produced by fermenting sweetened tea with a symbiotic culture of bacteria and yeast (SCOBY) [1]. Currently, industrial kombucha is commercially sold as a tea-type beverage in markets and is made by large multinational corporations [2-3]. Furthermore, it can also be prepared at home or by small local companies using the traditional way of preparation [4-5].

Today, consumers are looking for alternative drinks that, in addition to hydrating, are healthy. Kombucha is a fermented drink with a high concentration of bioactive substances, including polyphenolic compounds (catechins, theaflavins, flavanols), known for their antiinflammatory and antioxidant properties, as well as organic acids (gluconic and glucuronic acids, lactic), vitamins, minerals, and essential amino acids. [5-6]. Some of the possible health benefits of consuming kombucha include boosting the immune system, preventing cardiovascular diseases, and having antidiabetic properties among others [7-8].

Kombucha was not considered a probiotic fermented food until 2021, according to the statement of The International Scientific Association of Probiotics and Prebiotics (ISAPP) [9], which established kombucha as a reservoir of probiotic substances or considered a probiotic beverage.

Nowadays, developing Nutrition classification schemes (NCSs) that are healthy and sustainable and take care of the ecological footprint is an important starting point to encourage the adoption of healthy and sustainable diets at the population level [10-11]. In this context, Nova and Sega classification criteria for food product processing take on a new role [12]. According to many authors [13], kombucha that incorporates additives in their composition should be considered ultra-processed products and labeled and classified in the 4 Nova category (UPFD). However, given the lack of a common global legislative framework and the divergence of legal recommendations in each country [14], most producers do not follow this regulation, and only a few of

<u>FFHD</u>

them, depending on the land, facilitate information about Nova Classification of their kombucha.

The aim of this work is to understand the true nature and composition of kombucha through statistical analysis of the food classification and nutritional components within the global database of registered trademarks. This database has been generously provided by the OpenFoodFact Foundation (as of April 1, 2023), and we extend our gratitude for their collaboration in the development of this study (https://world.openfoodfacts.org/). The results obtained from this analysis of the global Kombucha market will allow us to develop general advice for its consumption and specific tips for consumer groups such as diabetics and cardiovascular disease (CVD) patients. According to the Federal Food and Drug Administration (FDA) [15-16] and respecting the legislative framework of each country [14].

MATERIAL AND METHODS Information about the nature and production process of Kombucha: Kombucha is a slightly acidic and carbonated beverage that is crafted through the fermentation of select tea varieties sweetened by a blend of bacteria and yeast forming a symbiotic culture known as SCOBY. In recent years, it has surged in popularity, earning a notable place in the tea flavor market. Originating in China around 220 BC, Kombucha relies on traditionally sweetened black or green tea, specifically Camellia sinensis, as its fermentation substrate [1-2]. Its usage subsequently expanded to Europe, particularly in Russia and Germany, and it has gained increasing global traction [2]. Over numerous decades, it has been embraced worldwide for its advantageous therapeutic and prophylactic properties, with more recent recognition for its potential detoxifying and immune-boosting attributes [5]. Beyond the conventional use of black or green tea

leaves, various studies explore alternative substrates, including red grapes, snake fruit, lemon balm, etc. [5]. Regardless of the chosen substrate, the Symbiotic Culture of Bacteria and Yeast (SCOBY) emerges as a pivotal factor in Kombucha preparation, playing a crucial role in initiating the fermentation processes.

Another important aspect of this Review to gain a comprehensive view of the nature and health benefits of the kombucha drink has been to highlight the fact that there are different types of kombucha, on the market:

Artisanal kombucha: Artisanal kombucha is meticulously crafted either by hand at home or in small local enterprises, employing the traditional method of preparing green or black tea with a 5-10% sucrose content. The process involves fermenting the tea mixture with a Symbiotic Culture of Bacteria and Yeast (SCOBY) at room temperature for 7-10 days. Strict adherence to basic hygiene protocols is maintained to prevent crosscontamination, including the use of sterile containers and utensils. Additionally, temperature and final pH levels are carefully controlled throughout the fermentation process [4-5]. Numerous factors such as fermentation time, tea type, sugar quantity, temperature, as well as geographical location, culture, and climate contribute to the unique microbiological composition of kombucha. The resulting product remains unpasteurized and free from additives. Packaged in recyclable glass containers, it requires refrigeration for preservation and is ideally suited for the local proximity.

Industrial Kombucha: Industrial Kombucha is sold commercially as a tea drink flavor in supermarkets produced by large multinational corporations (PepsiCo, Coca Cola, Danone, Tesco, Amazon Fresh, Unilever) [2-3,13,17]. Industrial production is supervised by the Kombucha-Brewers Institution (KBI), which is known as a non-profit trade association of kombucha producers around the world, which promotes or advises what methods to use in industrial manufacturing, mainly in the EE. UU [14], such as final chemical sterilization (with added sulfite) or temperature pasteurization of the drink

and the addition of preservatives, sweeteners, flavorings, colorings, etc., to enhance its commercial appeal.

(Code of Practice v 3.0, Kombucha brewers.org), losing, in this case, part of the probiotic characteristics and functionality of this drink, to enhance its commercialization, while preserving its antioxidant properties, organic acids, vitamins, etc. Finally, this product, packaged in glass/cans, or plastic containers, should be kept in a refrigerator. Commercial kombucha also has several other complex industrial processes, not equivalent to domestic processes.

Open Food Facts Database OpenFoodFact: The OpenFoodFacts database was used to obtain information about nutritional components and food classification using the Nutri-Score, Nova, and Eco-Score systems (https://world.openfoodfacts.org).

OpenFoodFacts.app is a collaborative project of globally traded food products. This database is licensed under an Open Database License (ODBL) and contains nutritional data (nutritional ingredients, allergens, etc.) and all the information that can be found on product labels. For this study, data was collected from the OpenFoodFacts database on April 1, 2023. Duplicates or different presentations for products of the same composition and brand were removed.

Food Nutrient Quality Classification System Nutri-Score:

The Nutri-Score classification system proposed by the group of independent French scientists led by Serge Hercberg [18] suggests frontal labeling based on nutritional quality according to five different letters (A, B, C, D, and E) associated with a specific color for each one. This score calculation was developed from the United Kingdom Food Standards Agency nutrient profiling system. Nutri-Score is the front-facing nutritional labeling system used by several European countries, including France, Belgium, and Spain, to provide users with clearer nutritional information [19-22]. It serves as a useful starting point to help consumers make healthier choices.

Nutri-Score acts like a nutritious traffic light: it is a 5letter, color-coded grading system, with dark green A being the most nutritious and red E the worst, going through B, C, and D. The A/B/C classification is for recommended foods, while the D/E classify products as having poor nutritional quality.

Nutri-Score is criticized for not considering aspects that are important both in the quality of the product and in its impact on the health of the consumer, such as the presence of certain additives, the level of processing, etc. [23]. It should be noted that to improve the calculation of Nutri-Score, an independent scientific committee reviews the basis of the algorithm. This Review is based on scientific and public health considerations, not commercial interests.

NOVA food classification: Carlos Monteiro created the Nova classification and was the first to classify foods due to their degree of processing and the additives they incorporated [24-26]. The Nova food classification proposes four categories: minimally processed foods (MPF), processed culinary ingredients, processed foods (PF), and ultra-processed foods and drinks, known by their acronym in English (UPFD). This food classification approach has been incorporated into major international diet and health reports and adopted by national governments within policies on dietary food guidelines [27-29].

Nova classification is a relatively simple and crude system of classifying foods based mainly on their degree of processing and the number of food additives they contain. It is in stark contrast to many existing food classification systems based on the nutritional qualities of their composition.

Concerning kombucha, the Nova classification establishes that when alcoholic beverages are identified as food and are produced by fermentation of group 1 foods (white or black tea), they are classified in principle as Group 3 of processed foods (PF). However, kombucha is a product of complex fermentation, which many times in the large industry ends with chemical or temperature pasteurization, with the addition of food additives to improve its presentation and conservation. Thus, clarification is needed for which group it is assigned, as we can observe when studying the various classifications of kombucha in each country according to its peculiar food legislation.

Statistical analysis: The statistical analysis has been conducted using the Stata v.14.0 calculation program. We have chosen the non-parametric statistical tests given the heterogeneity and diversity of formulation and presentation of kombucha from the various countries studied. The non-parametric tests that have been used are Mann-Whitney, chi-squared(chi2), Spearman's correlation, and IQR range (interquartile 25-75%). All

statistical tests with a p score less than 0.05 have been considered as significant [30].

RESULTS

The database for the statistical analysis of the 2,818 different brands of kombucha registered in 54 countries has been provided to us by OpenFoodFact.app (The Open Knowledge Foundation), on April 1st, 2023. The original database has been previously treated to delete duplications and errors and, in our case, eliminate countries that did not have at least 10 kombucha brands registered in the app (Andorra, Luxembourg, Brazil. etc.). The same products have also been eliminated with various presentations, leaving a final database of 2673 brands, with the thirteen kombucha-producing most important countries (Fig 1).





New variables have been created in this database, in the case of Nutri-Score classification, such as the binary variable (0,1): labeled as "NutriHealth" is considered (0) when it presents A/B/C categories and (1) when it presents a D or E categories. In the case of the Nova classification, the binary variable (0,1) labeled as" NovaHealth" has also been created when the product had a 1/2/3 category (0) and (1) when it had a 4 ultra-processed category.

To analyze the prebiotic nutritional character of kombucha, we studied the distribution of the Nutri-Score categories of the 1463 registered brands of kombucha,

<u>FFHD</u>

which have provided their nutritional composition to the app to develop the Nutri-Score scale of the product. The preliminary results show that 57% of kombucha can be placed in the healthy categories (A/B/C) and 43% can be placed in the unhealthy categories (D or E). Given the heterogeneity of the nutritional composition of all the products from the various countries, Table 1 shows the

medians of the nutritional components that present significant differences between the categories and the calculation of their interquartile IQR range (percentile 25-75%), according to their classification categories. The results can be deemed statistically robust as they analyze 1,463 registered trademarks, representing over 55% of the total 2,673 brands (as of April 1, 2023).

	NutriScor Categories A/B/C Median (IQR)	NutriScore Categories D/E Median (IQR)	Mann-Whiney Z	р
n	833(57%)	630(43%)		
Energy (Kcal)	11.3 (8.0-14.0)	19.0 (16.9-24.0)	-26.81	0.0001*
Carbohydrates (g/100ml)	2.6 (1.9-3.4)	3.4 (2.5-5.0)	-25.58	0.0001*
Sugars (g/100ml)	2.3 (1.1-2.9)	4.0 (3.6-4.6)	-26.23	0.0001*

Table 1. Significant Nutritional Components of Kombucha (NutriScore)

IQR-Interquartile range(25-75%); *diference significative(p<0.05)

To examine the nature of kombucha processing from the perspective of the Nova classification, we have analyzed the distribution of Nova among the 581 registered kombucha brands that have contributed information to the app worldwide (constituting only 22% of the brands).. The preliminary results obtained show us that 70% are considered healthy (categories 1,2 or 3), and 30% are unhealthy (category 4). Table 2 shows the nutritional components that could present significant differences between the categories and the calculation of their IQR range according to their classification category.

Table 2. Table 2. Significant Nutritional Components of Kombucha (Nova)

	Nova Categories 1/2/3 Median (IQR)	Nova Categories 4 Median (IQR)	Mann-Whiney Z	р
n	410(70%)	171(30%)		
Energy (Kcal)	15 (12.0-18.2)	16 (8.94-20)	-0.255	0.798
Carbohydrates (g/100ml)	3.38 (2.81-4.26)	3.75 (2.61-4.9)	1.06	0.288
Sugars (g/100ml)	2.92 (2.11-3.8)	3.75 (2.61-4.9)	-0.985	0.325

IQR-Interquartile range (25-75%)

Furthermore, the peculiarities of kombucha classified in "category 4" of Nova" of ultra-processed foods and drinks (UPFD) have been carefully analyzed. It is observed that 57% of the kombucha have some

additives that classify them as ultra-processed, and the remaining 43% have other causes, such as sugar greater than 3 g/100 ml, saturated fat greater than 3 g/100 ml, salt greater than 0.7 g/100 ml, energy greater than 14

<u>FFHD</u>

kcal, or some industrial procedure for processing the product, such as (chemical sterilization, temperature pasteurization, etc.), that also classifies them as "category 4" (UPDF). The most used additives in this drink are carbon dioxide at 27%, steviol glycoside at 26%, erythritol at 21%, citric acid at 10%, and several others with another 16%.

DISCUSSION

Firstly, if we analyze the production of kombucha worldwide, the United States emerges as the leading producer, accounting for 1,063 registered kombucha brands (40%). Hence, world production trends mainly come from the USA. If we consider Europe (EU), the total retail sum of all Countries, also presents an important production with a registered 1174 brands (44%) (Fig 1), of which the output of France stands out with 558 brands (48%), Spain with 275 registered brands (23%) and the sum of the rest of the countries together (UK, Italy, Germany, etc.) is already minority (29%). Finally, in the "Others" section, Canada, Australia, and New Zealand have been included, totaling 436 registered trademarks (16%).

The distribution analysis of the Nutri-Score categories of the 1463 global registered brands shows us that 57% of the kombucha can be considered healthy (A/B/C categories), and 43% consider them unhealthy D or E categories (Table 1). Afterward, the analysis of the nutritional contents of the kombucha from Nutri-Scorn's A/B/ C categories showed us an increase significantly in the carbohydrate content observed, especially sugars, from 2.9 g/100 (A/B/C categories) to 3.26 g/100 ml on the (D/E) categories(p=0.0001). Therefore, consuming categories D and E kombucha is not advisable, especially for people with carbohydrate metabolism problems, such as type 1 or 2 diabetes and metabolic syndrome. Moreover, following an examination of recent clinical trials investigating the daily consumption of kombucha in both type 2 diabetics (T2D) and healthy adults, where no significant increase in glucose levels was observed [31-32], kombucha might emerge as a viable alternative for diabetics contending with the challenge of adhering to a routine of consuming only water. However, additional research such as human clinical trials is required to confirm these findings.

The distribution analysis of kombucha by its Nova processing classification shows us that only 581 registered kombucha brands from 2673 as of April 1st, 2023, have provided the information to the app worldwide for the calculation of the Nova categories (only 22% of the brands). The results indicate that 70% fall under the category of considered healthy (categories 1/2/3), while 30% are categorized as unhealthy "category 4 ultra-processed food" (UPFD).The analysis of the nutritional components by Nova food classification shows us that there are no significant differences(p>0.05) between the important nutritional components (Table 2).

In addition, the particularities of the kombucha classified in group 4 of Nova have been analyzed indepth. We can see that 57% of the kombucha in "category 4" are due to the presence of additives that are especially visible in USA products; the remaining 43% indicate other causes, as some industrial procedures to improve its product's conservation (temperature pasteurization, chemical sterilization, etc.) that also classifies them, as categorized 4 ultra-processed foods (UPFD).

The most used additives in kombucha drinks are carbon dioxide at 27%, steviol glycoside at 26%, erythritol at 21%, citric acid at 10%, and several others at another 16%. In addition, 23% of drinks have two additives, steviol and erythritol, 17% of the kombucha only incorporate carbon dioxide as an additive, and 3% have more than three additives. Additionally, food additives such as steviol glycoside, erythritol, citric acid, and various others have only been identified through the Nova classification when explicitly listed on the product label. In addition, using any of these food additives,

Functional Foods in Health and Disease 2023; 13(12):690-701

FFHD

especially the polyol sweetener Erythritol (E968), is controversial. Erythritol has a controversial history, approved in Europe in 2003 by the EFSA (European Food Safety Authority). This stems from the publication of side effects linked to its consumption, including gastrointestinal problems in 2010 [33], induced anaphylaxis in 2013 [34], and notably, a recent global collaborative scientific article directly associating the intake of erythritol (at a daily intake of 30 g) with an increased risk of cardiovascular events [35]. Although some authors have pointed out that the study has several methodological inconsistencies [36-37], other researchers indicate that this study is important evidence that should already be enough for the authorities to reevaluate their policy regarding artificial sweeteners' cardiovascular and metabolic risks [38]. Additional research is required to confirm this finding.

Furthermore, it is important to highlight the fact of the Nova rating, that only 22% of the global average of registered kombucha brands give us information about Nova. In the USA market, the percentage of Nova rating is 34%, and only 10% in Europe. Respect the difference observed between the two markets; this fact may be due to a greater coincidence of the American client regarding healthy products, so the US market is directed to cover these needs (39), or perhaps due to the stricter legislation in the USA than in Europe with multiple different legal countries frameworks regarding the production and labeling of kombucha. [14]., These figures are surprising in the current global context of maximum consumer information on additives and industrial processes of the product. Therefore, people with cardiovascular problems shouldn't consume kombucha with Nova "category 4" (UPFD) or any other kombucha not valued by the Nova or Siga classifications [24], [40], for the risk of containing erythritol.

In a nutshell, kombucha constitutes a paradox from the point of view of its food classification (Nutri-Score, Nova) since kombucha is based on a product considered

natural, such as green or black tea, which is fermented with an ecological consortium of a symbiotic culture of yeasts and acetic bacteria (SCOBY). Still, due to the complex industrial process and the presence of additives allowed by legislation, it is considered by Nova in some countries as an ultra-processed product (UPFD), advising against its consumption. Hence, some Spanish authors highlight that given the widely demonstrated negative effect that consumption of UPDF has on health [39], the front labeling of products with the Nutri-Score should at least be accompanied by a complementary label indicating the level of processing, such as NOVA or Siga classification, to allow customers to choose based on their personal health and nutritional priorities [23].On the other hand, concerning the "harmful character" of kombucha, some testimonial cases of hepatotoxicity, metabolic acidosis, and cardiotoxicity have been reported [41-43]. Pregnant or breastfeeding women who have weakened immune systems should avoid kombucha tea. According to the Center for Disease Control (CDC) [43], excessive consumption (>340 grams,>12 oz daily) of kombucha poses a risk to the health of the drinker. Therefore, it is essential to recommend this limit to avoid adverse reactions [15].

The FDA's recognition of toxicity and reported clinical cases involving kombucha's adverse effects (hepatotoxicity, metabolic acidosis, cardiotoxicity) are key factors preventing its classification as a functional beverage Additionally, its non-compliance with the FCC's definition poses a significant barrier. According to the FCC, functional foods must contain biologically active compounds in defined, effective, and non-toxic amounts, offering clinically proven health benefits. These benefits should leverage specific biomarkers to enhance overall health, diminish chronic disease risk, and manage associated symptoms (Step 3 risk from a safety perspective). Moreover, kombucha falls short of meeting the criteria outlined by the Japanese Food for Specific Health Uses (FOSHU). The 'specific health use' claim

Functional Foods in Health and Disease 2023; 13(12):690-701

<u>FFHD</u>

under FOSHU mandates a comprehensive review of safety and efficacy. Consequently, kombucha is ineligible for accreditation from the FCC and is unable to secure international official certification as a functional beverage (46-47).

Furthermore, in a recent review by Hati S. and Prajapati JB (2022) on probiotic use for enriching dairy products, various fermented probiotic products, such as probiotic yogurt, fermented milk, bifidus products, kefir, koumiss, and probiotic cheese, are mentioned. Notably, kombucha is excluded as a probiotic fermented product for enrichment due to insufficient evidence. Health promotion claims for kombucha are primarily based on chemical analyses and animal/cell culture models (48)."

Finally, suppose the additives added to commercial kombucha constitute a personal health problem: in that case, an alternative option is to make the drink at home, which can be an easy and economical solution, using the traditional way of elaboration, green or black tea with 5-10% sucrose and fermenting the mixture with (SCOBY) at room temperature for 7-12 days, following standard basic hygiene rules to avoid cross-contamination (containers and sterile utensils) and controlling temperature and final pH (4,5,15). Another viable ecological solution is to go to the local kombucha producers in our cities, who sell in bulk the product made by hand with the traditional formula without pasteurizing or additives, as it is a local, low-volume, and proximity production; in addition, this option allows the client to use their recyclable glass container [45]. On the other hand, industrial kombucha is a positive option for health. It constitutes a good alternative to consuming sugary drinks for regular people, provided that the consumption of both kombucha (home artisanal or industrial) does not exceed the intake of 340 grams/12 oz per day, according to the CDC [41].

In summary, kombucha produced at home and by hand in small businesses appears as the healthiest option to be considered by consumers, with additional nutritional values at the same time; the fact of promoting the local industry and the recycling of glass products and, in short, boost the local circular economy and for all these reasons the consumption of kombucha would be strongly recommended for health and this drink could be considered an eco-friendly beverage.

CONCLUSIONS

Kombucha can be considered in our study as a probiotic drink according to the Nutri-Score food classification, and its consumption is recommended from the point of view of antioxidant, anti-inflammatory, mineral, and vitamin content. However, for people who have problems with carbohydrate metabolism (Diabetes 1, 2, metabolic syndrome), it is advisable to limit the consumption of kombucha with Nutri-Score (D/E) categories since these kombucha have a higher sugar content.

The analysis of only 22% of the kombucha on the market valued and labeled with Nova food classification, shows us that 54% of the kombucha with Nova value "category 4" (UPFD) have the presence of additives. In addition, the use of erythritol, as a sweetener in 21% of the kombucha studied and the recent publication of its relationship with cardiovascular disorders; Hence, its consumption is not recommended for people with cardiovascular diseases (CVD) or the intake of any other kombucha whose product label is not assessed by the Nova or Siga food classifications for the risk of containing erythritol.

Kombucha produced at home and in an artisan way in small local or proximity companies appears as the most advisable option from the food and healthy point of view, with additional nutritional values and without food additives. At the same time, it promotes a local recycling industry and creates an eco-friendly circular economy.

In summary, kombucha has emerged as one of the most popular and positive alternatives to sugary drinks, touted for its health benefits. However, it's important to note that, as per the FFC (Functional Food Center and FOSHU (The Japanese Foods for Specific Health Uses), kombucha should not be classified as a functional drink, as it does not align with the established criteria for functional beverages [46-47]. This study offers fundamental guidance on its consumption while also addressing the limitations it poses for specific population groups, such as individuals with diabetes or cardiovascular diseases (CVD).

List of abbreviations: SCOBY: Symbiotic Culture Consortium of Bacteria and Yeast; ISAPP: International Scientific Association of Probiotics and Prebiotics; NCS: Nutrition Classification Schemes; UPFD: Ultra-processed Food and Drinks; CDV: Cardiovascular Disease: FDA: Food and Drug Administration; KBI: Kombucha-Brewers-Institution; EE. UU: United States; ODBL: Open Database License; MPF: Minimally Processed Foods; PF: Processed Foods; IQR: Interquartile Range; EU: European Union; T2D: Type 2 Diabetes, E968: Polyol Sweetener Erythritol, EFSA: European Food Safety Authority; CDC: Centers for Diseases Control and Prevention; FFC: Functional Food Center; FOSHU: The Japanese Foods for Specific Health Uses

Ethics statement: The study was conducted following the relevant laws and the institutional guidelines of the Declaration of Helsinki.

Declaration of Competing Interest: The authors certify that they have no known conflict of financial interest or personal relationships that may have influenced the work presented in this paper.

Authors' contributions: Carlos Aulesa and Carmen Gongora contributed equally to this manuscript. Both authors drafted individual sections of this manuscript and contributed to revising all.

Acknowledgments: We want to thank the journalist Alba Aulesa for her collaboration in correcting the original text.

REFERENCES

 Jayabalan, R., Malbasa, R.V., Loncar, E., Vitas, J.S., Sathishkumar, M. A Review on Kombucha Tea-Microbiology, Composition, Fermentation, Beneficial Effects, Toxicity, and Tea Fungus. Comprehensive Review in Food Science and Food Safety 2014, vol 13,538-550.

DOI: https://doi.org/10.1111/1541-4337.12073

 Kim, J., Adhikari. K. Current Trends in Kombucha: Marketing Perspectives and the Need for Improved Sensory Research Beverages 2020, 6(1), 15.

DOI: https://doi.org/10.3390/beverages6010015

- Batista, P., Penas, MR., Pintado, M., Oliveira-Silva, P. Kombucha: Perceptions and Future Prospects. Foods 2022, 11, (13),1977. DOI: <u>https://doi.org/10.3390/foods11131977</u>
- Cesar da Silva, J., Mafaldo, IM., De Lima Brito, I., Tribuzy de Magalhaes, AM. Kombucha: Formulation, chemical composition, and therapeutic potentialities. Current Research in Food Science 2022,5: 360–365. DOI: https://doi.org/10.1016/j.crfs.2022.01.023
- Esatbeyoglu, T., Sarikaya Aydin, S., Gultekin Subasi, B., Erskine, E., Gok, R., Ibrahim, S, Yilmaz, B., et al. Additional advances related to the health benefits associated with kombucha consumption. Critical Review in Food Science and Nutrition 2023, January 20;1-18.

DOI: https://doi.org/10.1080/10408398.2022.2163373

 Antolak, H., Piechota, D., Kucharska, A. Kombucha Tea: A Double Power of Bioactive Compounds from Tea and Symbiotic Culture of Bacteria and Yeasts (SCOBY). Antioxidants 2021, 10, 1541.

DOI: <u>https://doi.org/10.3390/antiox10101541</u>

- Vina, I., Semjonovs, P., Linde, R., Deninna, I. Current Evidence on Physiological Activity and Expected Health Effects of Kombucha Fermented Beverage. J Med Food 2014,17 (2): 179–188. https://doi.org/10.1089/jmf.2013.0031
- Mousavi, SM., Hashemi, SA., Zarei, M., Gholami, A., Wey Lai, C., Chiang Hung, W, Omidifar, N., Baharani, S., Mazraedoost, S.Recent Progress in Chemical Composition, Production, and Pharmaceutical Effects of Kombucha Beverage: Evid Based Complement Alternative Medicine 2020, vol 2020, Article ID 4397543;1-14. DOI: https://doi.org/10.1155/2020/4397543
- Marco, ML., Sanders, ME., Ganzle, M., Arrieta, MC., Cotter, PD., De Vuyst, L., Hill, C., Holzapfel, W., et al. The International Scientific Association for Probiotics and Prebiotics (ISAPP) consensus statement on fermented food. Nature Reviews Gastroenterology and Hepatology 2021, Vol

Functional Foods in Health and Disease 2023; 13(12):690-701

18, March 196-208. DOI: <u>https://doi.org/10.1038/s41575-</u> 020-00390-5

- Springmann, M., Spajic, L., Clark, M.A., Poore, J., Herfoth, A., Webb, P., Rayner, M., et al. The healthiness and sustainability of national and global food-based dietary guidelines: a modeling study. BMJ 2020;370:m2322. DOI: <u>https://doi.or/10.1136/bmj.m2322</u>
- Scherer, L., Behrens, P., Tukker, A. Opportunity for a dietary win-win-win in nutrition, environment, and animal welfare. One Earth 2019 November 22; 1:349-60. DOI: https://doi.org/10.1016/j.oneear.2019.10.020
- Saferidi, P., Scrinis, G, Huybrechts, I, Woods, J Vineis, P., Millet, C. The neglected environmental impact of ultraprocessed foods. The Lancet Planet Health 2020,4(10): E437-8, Oct. DOI: <u>https://doi.org/10.1016/s2542-5196(20)30177-</u> <u>7</u>
- Whelan, K., Jones, N. Fermented foods: availability, cost, ingredient nutritional content, and on-pack claims. Journal of Human Nutrition and Dietetics 2022,35(2). DOI: <u>https://doi.org/10.1111/jhn.12905</u>
- Mukherjee A, Gómez-Sala B, O'Connor EM, Kenny JG, and Cotter PD. Global Regulatory Frameworks for Fermented Foods: AReview. Front. Nutr 2022 vol 9. DOI: <u>https://doi.org/10.3389/fnut.2022.902642</u>
- Nummer, BA. Kombucha brewing under the Food and Drug Administration model food code: Risk Analysis and Processing Guidelines. J Environ Health 2013;76(4):8-11, PMID:24341155.
- 16. FDA Guidance & Regulation (Food and Dietary Supplements), Food Code 2022.
- Nyhan, LM., Lynch, KM., Sahin, AW., Arendt, EK. Advances in Kombucha Tea Fermentation: A Review. Appl. Microbiol. 2022, 2(1),73–103.
 DOI: https://doi.org/10.3390/applmicrobiol2010005
- Hercberg, S. Development of a nutritional policy designed to meet public health challenges. Sante Publique 2014 May-Jun;26(3):281-2. PMID: 25291875
- Chantal, J., Hercberg, S. Development of a new front-of-pack nutrition label in France: the five-colour Nutri-Score. World Health Organization. Regional Office for Europe. Public Health Panorama 2017, 03 (04), 712 - 725. World Health Organization. Regional Office for Europe.
- Galan, P.; Babio, N. Salas Salvado, J. Nutri-Score: Nutri-Score: front-of-pack nutrition label useful for public health in Spain which is supported by a strong scientific background. Nutr. Hosp. 2019. vol 36, (5), 1213–1222. DOI: https://doi.org/10.20960/nh.02848

 Dréano-Trécant L, Egnell M, Hercberg S, Galan P, Soudon J, Fialon M, Touvier M, Kesse-Guyot E, Julia C. Performance of the Front-of-Pack Nutrition Label Nutri-Score to Discriminate the Nutritional Quality of Foods Products: A Comparative Study across eight European Countries. Nutrients. 2020; 12(5), 1303-1308.

DOI: https://doi.org/10.3390/nu12051303

FFHD

- Hercberg, S., Touvier, M., Salas-Salvado, J. The Nutri-Score nutrition label. A public health tool based on rigorous scientific evidence aiming to improve the nutritional status of the population.Int J Vitam Nutr Res(2022),92(3–4),147-157.
- Romero Ferreiro, C.; Lora Pablos, D.; Gomez de la Cámara, A. Two Dimensions of Nutritional Value: Nutri-Score and NOVA. Nutrients 2021 ,13(8), 2783.
 DOI: https://doi.org/10.3390/nu13082783
- Monteiro, CA., Cannon, G., Levy, R., Moubarac, JC., Jaime, P., Martins, Ap., Canella, D., et al. The star shines bright. Food classification. Public health. Word Nutrition WPHNA 2016, vol 7,1-3,28-38
- Monteiro, C.A., Cannon, G., Moubarac, J.C., Levy, RB., Louzada, ML., Jaime, PC. The Decade of Nutrition, The NOVA food classification, and the trouble with ultra-processing. Public Health Nutrition 2018, vol 21, 1, pp: 5-17. DOI: https://doi.org/10.1017/s1368980017000234
- Monteiro, C., Astrup, A., Ludwig,D. Does the concept of "ultra-processed food" help inform dietary guidelines beyond convectional classification systems? Yes. Am J Clin Nutr 2022, vol 116(6):1476-1481.

DOI: https://doi.org/10.1093/ajcn/ngac122

- Chazelas, E., Deschasaux, M., Srour, B., Kesse-Guyot, E., Julia, C., Alles, B., Hercberg, S, et al. Food additives: distribution and Co-occurrence in 126,000 food products in the French market. Scientific Report 2020,10,3980. DOI: https://doi.org/10.1038/s41598-020-60948-w
- Dickie, S., Woods, J., Machado, P., Lawrence, L. Nutrition Classification Schemes for Informing Nutrition Policy in Australia: Nutrient-Based, Food-Based, or Dietary-Based? Current Development in Nutrition 2022 vol 6, (8), nzac112. DOI: <u>https://doi.org/10.1093/cdn/nzac112</u>
- Talens, P., Cámara, M., Daschner, A., López, E., Marín, S., Martínez, JA., Morales, J.Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on the impact of consumption of ultra-processed foods on the health of consumers Revista del Comité Científico de la AESAN 2020, 31, pp: 49-76.

Page 700 of 701

- 30. Domenech I Massons, J M. Bioestadística.Metodos estadisticos para investigadores, Ed Herder, Barcelona.1977
- 31. Mendelson, C., Sparkes, MC., Merenstein, DJ., CChristensen, C., Sharma, V., Desale, S., Auchtung, JM., Kok et al. Kombucha tea as an antihyperglycemic agent in humans with diabetes randomized controlled pilot investigation. Front.Nutr.2023.10:1190248. DOI: https://doi.org/10.3389/fnut.2023.1190248
- 32. Atkinson FS., Cohen M ., Lau, K., Brand-Miller, JC.Glycemic and insulin index after a standard carbohydrate meal consumed with live kombucha: A randomized, placebocontrolled, crossover trial. Front Nutr 2023, vol 10. DOI: https://doi.org/10.3389/fnut.2023.1036717
- 33. Statement about the safety of erythritol (E 968) in light of new data, including a new pediatric study on the gastrointestinal tolerability of erythritol. EFSA Panel on Food Additives and Nutrient Sources (ANS). European Food Safety Authority (EFSA), EFSA Journal 2010; 8(7):1650. DOI: https://doi.org/10.2903/j.efsa.2010.1650
- 34. Shirao, K., Inoue, M., Tokuda, R., Nagao, M., Yamaguchi, M., Okahata, H., Fujisawa T. Bittersweet": a child case of erythritol-induced anaphylaxis.Allergol int 2013. Jun;62(2):269-71. DOI: https://doi.org/10.2332/allergolint.12-LE-0517

- 35. Witkowski, M., Nemet, I., Alamri, H., Wilcox, J., Gupta, N., Nimer, N., et al. The artificial sweetener erythritol and cardiovascular event risk. Natural Medicine 2023; 29:710-718. DOI: https://doi.org/10.1038/s41591-023-02223-9
- 36. 36. Paul, C., Brady, D. Commentary on the 2023 study: "The artificial sweetener erythritol and cardiovascular event risk" by Witkowski M. et al. Natural Medicine Journal 2023, March.
- 37. 37. Forouh, N., Kuhnle, G., Jones, O., Sanders, T., Mellor, D. Expert reaction to study looking at an artificial sweetener (erythritol) and cardiovascular disease events. Science Media Centre 2023, February
- 38. 38.Pafili, K., Roden, M. The sugar-free paradox: cardiometabolic consequences of erythritol. Signal Transduction and Targeted Therapy 2023,8, article number:251.

DOI: https://doi.org/10.1038/s41392-023-01504-6

39. Juul, F., Parekh, N., Martinez-Steele, E., Monteiro, CA., Chang, V. Ultra-processed food consumption among US adults from 2001 to 2018. Am J Clin Nutr 2022 vol 115,1:211-221. DOI: https://doi.org/10.1093/ajcn/ngab305

- 40. Davidou, S., Christodoulou, A., Fardet, A., Frank, K. The Holistico-Reductionist Siga Classification According to the Degree of Food Processing. An evaluation of Ultra-Processed Food in French Supermarkets.Food Funct 2020,11:2026-2039. DOI: https://doi.org/10.1039/C9F002271F
- 41. Gedela, M., Chakravarthy Potu, K., Gali, V., Alyamany, K., Jha, L. A case of hepatotoxicity related to kombucha tea consumption. South Dakota Medicine. 2016 Vol. 69 (1), p26-28.3
- 42. Holbourn, A., Hurdman, J. Kombucha: Is a cup of tea good for you? BMJ Case Rep. 2017 December 2; 2017: bcr2017221702.

DOI: http://dx.doi.org/10.1136/bcr-2017-221702

43. 43.Soysal, Ali Ugur., Akman, Zafer., Koroglu, Ali Egemen., Yalman, Hakan., Koca, Damla. An Unexpected Cause of Cardiotoxicity: Kombucha Tea.Anatol J Cardiol 2022 ; 26(6): 492-494, 2022.

DOI: https://doi.org/10.5152/anatoljcardiol.2022.1463

- 44. Centers for Disease Control and Prevention (CDC). Case Report: Unexplained severe illnesses possibly associated with the consumption of Kombucha tea. MMWR Morb Mortal Wkly Rep 1995 December 8;44(48):892-3, 899-900. PMID: 7476846. JAMA. 1996 Jan 10;275(2):96-8. PMID: 7476846
- 45. Capozzi, F., Magkos, F., Fava, F., Milani, GP., Agostoni, C., Astruo, A., Saguy IS, Multidisciplinary. Perspective of Ultra-Processed Foods and Associated Food Processing Technologies: A View of the Sustainable Road Ahead. Nutrients 2121,13, 3948.

DOI: https://doi.org/10.3390/nu13113948

- 46. Martirosyan, D., Lampert, T., Ekblad, M.Classification and regulation of functional food proposed by the Funcional Food Center.Funcional Food Science 2022;2(2)25-46. DOI: https://doi.org/10.31989/ffs.v2i2.890
- 47. Martirosyan, D. M., Stratton S. functional food regulation. Bioactive Compounds in Health and Disease 2023; 6(7): 166-171. DOI: https://www.doi.org/10.31989/bchd.v6i7.1178
- 48. Hati S., Prajapati JB. Use of Probiotics for Nutritional Enrichment of Dairy Products. Functional Foods in Health and Disease 2022; 12(11): 713-733. DOI: https://www.doi.org/10.31989/ffhd.v12i12.1013