Plant-Based Milk Alternatives in Child Nutrition

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Plant-based milk alternatives can be distinguished in two main categories, differing in production processes and regulation: plant-based formulas and plant-based drinks. They are now a widely accepted class of products on the international market. The various plant-based milk alternatives differ in nutritional characteristics due to their origin and manufacturing; more importantly, whereas formulas from plant and cow origin can be used interchangeably, plant-based drinks are nutritionally different from cow's milk and can be consumed by children subsequently to the use of formula.

functional foods

plant-based formula

plant-based drinks

plant-based milk alternatives

1. Introduction

Although commonly called "milks", all fluid products derived from a plant should not technically be called such. The term "milk" should be reserved for the fluid secreted from the mammary glands of mammals, thus speaking of mother's milk, as in the case of human milk, cow's milk, donkey's milk, and so on ^{[1][2][3][4][5][6]}. In the case of products derived from a plant and that resemble, in their organoleptic characteristics, milks of animal origin, and even if the term "milks" is commonly used, it would be more correct to speak of "plant-based milk alternatives".

The term "formula", or "formulated or adapted milk", should be reserved for products of animal or plant origin formulated for the specific needs of a child in the first years of life in the presence of physiological or pathological conditions.

In the context of the European Union, the regulatory framework for formulas is set by the Commission Delegated Regulation (UE) 2016/127 of 25 September 2015 ^[Z], supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council ^[8].

All non-formulated plant-based alternatives (e.g., soy-, rice-, oat-based) have nutrient compositions, and therefore nutritional characteristics, that distinguish them from animal milks and formulas ^[9].

With the intent of simplifying the reading, these products as "plant-based formulas" for the former and "plant-based drinks" for the latter.

Plant-based milk alternatives have been present in Asian tradition for centuries, but their diffusion in Western countries has less than a hundred years of history ^[10]. In recent decades, however, there has been a marked increase in demand, and consequently in supply, in Western countries as well, with an increase in market shares, to the disadvantage of cow's milk ^{[11][12][13][14]}. In the absence of specific data in the pediatric age group, we can see that 77% of millennials in the United States make regular use of them ^[15], in Europe 15% of the population avoids cow's-milk products ^[12], and in Italy, the market for plant-based drinks is growing (2016 data) with a +2% increase in soy-based drinks (small market variation, indication of its deep-rooted presence), whereas other "newer" plant-based drinks showed a more significant increase of 75.1% ^[11]. The reasons behind the choice of plant-based milk alternatives can be summarized in the following five main points:

1. With a prevalence of 2–3% of the population of less than 1 year of age, cow's-milk protein allergy (CMPA) is the most common form of infant allergy, with a continuous reduction with advancing age, leading to a prevalence of less than 1% at 6 years ^[16]. As a result, the use of alternative formulas to cow's milk is a mandatory choice in this group of subjects, at least initially, which can then be maintained over time ^[17].

2. Lactose intolerance refers to the clinical picture produced by the insufficient digestion of lactose by intestinal lactase. In addition to lactase deficiency in the first year of life, a more common entity is the non-persistence of the enzyme activity beyond the first year of life. This can lead to the appearance of symptoms of lactose intolerance, such as abdominal pain, bloating, flatulence, or diarrhea, which can manifest from 2 years of age ^{[18][19]} but more commonly from 5 to 6 years of age ^[19]. As plant-based alternatives (both formulas and drinks) are completely (and naturally) lactose-free ^[20], these products are proposed as alternatives to cow's milk ^[18].

3. In cow's milk, the presence of lipids, and in particular of saturated fatty acids and cholesterol, and on the contrary the presence of fiber, vitamins, and phytocompounds in plant-based drinks, can make families inclined towards the latter, with the aim of safeguarding their own health ^{[17][21]}.

4. In the context of an increased intake of plant foods, which in general have a lower impact on the environment than animal foods ^[12], and that of an increased concern for animals used as a food source, plant-based milk alternatives can be part of a green and ethical choice for omnivores and lacto-ovo-vegetarian/vegans alike ^{[5][14][21]}.

5. Finally, in the greater part of the world, milk of animal origin can be in short supply, expensive, or unsafe from a microbiological point of view, thus favoring products of plant origin ^[10].

In soy-based formulas, soy proteins are isolated from the other components of the soybean. In the final product, the minimum protein content is higher than that of cow's-milk formula (2.25 g/100 Kcal vs. 1.8 g/100 Kcal) to compensate for the lower digestibility of plant proteins ^[22]. Moreover, there is a reduction of isoflavones, trypsin inhibitors, phytic acid, and fiber ^{[9][23][24]}, and some components are added (iron, calcium, phosphorus, zinc, methionine, taurine, carnitine, arachidonic acid, docosahexaenoic acid) ^{[22][24][25]} to obtain a final product that satisfies the nutritional needs of an infant or child, according to specific regulatory criteria ^[26].

In rice-based formulas, the final product contains hydrolyzed rice proteins and a series of added compounds (lysine, threonine, tryptophan, carnitine, taurine, iron, zinc), with the same aim of rendering the nutritional composition suitable for the specific needs of a child ^[4]^[24]^[27]. In these formulas, the arsenic content of the rice from which they derive must not exceed 0.10 mg/kg ^[28]. Soy- and rice-based formulas are available with different formulations for children in the first year of life or older than 1 year of age ^[9].

Plant-based drinks derive from the respective plant through a series of industrial steps that include grinding (before or after soaking in water), homogenization (which makes uniform the dimensions of the particles present in the product), and separation of the solid phase from the liquid (filtration, centrifugation). The product is then subjected to treatments aimed at increasing its conservation (e.g., heat treatments such as pasteurization or UHT). Furthermore, during the various production steps, some substances such as vitamins, minerals, and stabilizers can be added in order to improve their nutritional, organoleptic, or stability characteristics ^{[3][5][6][10][11][13][29][30]}. Industrial processes can influence the nutritional characteristics of the final product, thus not always reflecting the characteristics of the plant of origin: e.g., regarding soy-derived drinks, a reduction of trypsin inhibitors and of the fiber oligosaccharide component is caused ^{[6][30]}, and high-temperature treatments reduce the cholesterol-lowering effect of isoflavones ^[31]; however, not all researchers agree ^[32]. Regarding rice drinks, the regulatory limit of the arsenic content of the rice used in its manufacturing is 0.20 mg/kg ^[28].

2. The Role of Plant-Based Milk Alternatives in the Diets of Children 0–12 Months

2.1. Allergy to Cow's-Milk Protein

Cow's-milk protein allergy (CMPA) is a pathological situation in which the subject develops an allergy to components of cow's milk, as well as to other mammals' milks, given the frequent cross-reactivity between the milk proteins of different mammals. It is a problem that affects 2–3% of children in the first year of life and whose prevalence then decreases to drop below 1% at 6 years of age.

The immune response can be Ig-E mediated in 60% of cases, whereas the remaining 40% can be Ig-E negative or consist of mixed forms ^[33]. Though a consistent overlap exists, IgE-mediated forms usually consist of typical immediate reactions (from skin, respiratory, gastrointestinal, or cardiovascular reactions to anaphylaxis), whereas non-IgE-mediated forms can manifest as food-protein-induced enterocolitis syndrome (FPIES) or food-protein-induced proctitis/proctocolitis (FPIAP) ^[33]. Lastly, mixed forms can display an IgE and/or eosinophilic component and manifest, for example, as eosinophilic gastrointestinal disorders ^{[33][34]}.

As it is not possible to use a standard formulated milk based on cow's-milk proteins, the guidelines of the World Allergy Organization (WAO), the American Academy of Pediatrics (AAP), and the European Society of Pediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) recommend using formulas with hydrolyzed cow's-milk proteins (extensively hydrolyzed formula—EHF), for which the efficacy in terms of normal growth and non-allergenicity has been ascertained in 90% of children ^{[16][25][35]}. In the case of specific conditions (e.g., anaphylaxis,

severe enteropathy, multiple allergies, or symptoms not completely resolved by EHF), it is recommended to use formulas based on isolated amino acids (amino-acid formula—AAF), essentially devoid of sensitizing potential ^[16] ^[35]. Two possible alternatives are represented by rice-based and soy-based formulas. The former can be used as a first-line treatment ^[9] and in case of problems with EHF ^{[16][22]}. The latter may present a risk of cross-reactivity with cow's-milk proteins in 10–14% of children: Their use is taken into consideration in the second semester of life (not in the first), once the tolerance to soy proteins has been established, in the presence of problems with hydrolyzed or amino-acid formulas ^{[9][16][22]}, and in the absence of gastrointestinal symptoms ^[24]. The North America Society of Pediatric Gastroenterology Hepatology and Nutrition (NASPGHAN) position paper of 2020 also agrees with the use of infant formulas in the case of CMPA, including soy-based ones ^[36]. In the case of food-protein-induced enterocolitis syndrome (FPIES), the AAP does not recommend the use of soy-based formulas ^[25].

Given the necessity to respect the needs of this age group, plant-based drinks, without a specific formulation for age and pathological condition, should not be used in these subjects ^{[9][16][36]}.

2.2. Galactosemia and Lactose Intolerance

Galactosemia refers to an inborn error of carbohydrate metabolism that makes the subject unable to metabolize that sugar. This aldohexose is metabolized via different enzymatic steps that can be altered, giving rise to the disease ^[37]. The incidence of the disease varies greatly, with estimates ranging from 1 in 480 births to 1 in 60,000 births ^[38].

In the congenital form of lactase deficiency, the newborn is unable to digest lactose to glucose and galactose. This is a very rare disease, as only a few cases have been described, mostly in Finland, probably because of a founder effect ^[18].

Both of these disorders, as well as severe damage to small-intestinal mucosa, are indications for the use of lactose-free infant formulas, including formulas based on isolated soy proteins ^{[22][25][39][40][41]}.

If, on the other hand, lactose intolerance is less pronounced, as could be supposed for infantile colic due to a transient low lactase activity ^[19], a trial of a low-lactose formula may be carried out, but reduced-lactose formula or lactose-free formula are not suggested as a routine approach in these situations ^{[19][25]}.

2.3. Preterm Infants

The two consensuses of ESPGHAN ^[22] and AAP ^[25] agree that soy-protein formulas should not be used in preterm infants ^[22] due to the presence of scarce or detrimental information in this group of subjects. Of the same opinion are the Australian Ministry of Health ^[40] and the review by Vandenplas et al. ^[42].

2.4. Choosing Plant-Based Milk Alternatives for Family Preferences

The feasibility of using formulas based on isolated soy proteins (or rice hydrolyzates ^{[43][44]}) in the case of parent preference (e.g., cultural, religious, or ethical reasons, or vegan families) is recognized and considered acceptable and appropriate by the ESPGHAN ^[22]; the AAP ^[25]; the French-speaking Group of Pediatric Hepatology, Gastroenterology and Nutrition (GFHGNP) of the French Society of Pediatrics ^[44]; the Spanish Society of Pediatrics ^[45]; the European Pediatric Association ^[46]; the Norwegian Nutrition Council ^[47]; the Australian Ministry of Health ^[40]; and the Canadian Ministry of Health ^[39]. Other publications agree with this approach ^{[43][48][49]}. Of the same opinion are the AAP Pediatric Nutrition Manual ^{[50][51]} and the manual by Mangels et al. ^[52].

The position paper of the German Nutrition Society, on the other hand, has a different opinion, which advocates for the use of soy-based formulas only in "exceptional and justified cases (e.g., galactosemia) and on medical recommendation" ^[41].

It is important to note that the vitamin D that fortifies infant formulas is generally vitamin D3 of animal origin (from sheep lanolin). Therefore, technically even soy- or rice-based formulas are not vegan ^[52]. However, looking at botanical sources of vitamin D3, *Cladonia raingiferina* (reindeer lichen) is a known source of vitamin D3 and vitamin D2 at relative high levels (67–204 and 22–55 μ g/100 g of dry matter, respectively), along with ergosterol and 7-dehydrocholesterol ^[53]. It is already exploited as a source of vitamin D3 in commercially available supplements, so researchers speculate that in the future this problem may be solved.

The NASPGHAN position paper on the use of plant-based milk alternatives in the first year of life stresses that the source of milk at that age must be "human milk or an iron-fortified infant formula", since a large part of the needs are met by milk at this age ^[36]. The Health Ministries of New Zealand ^[54], Australia ^[40], and Canada ^[39] also advise against the use of plant-based drinks during the first year of life. The same opinion is also expressed in the Healthy Eating Research publication ^[55]; that of the GFHGNP of the French Society of Pediatrics ^[44]; those of Mangels et al. ^[56], Baroni et al. ^[43], and Sethi et al. ^[30]; and the Handbook of Pediatric Nutrition of the AAP ^[57].

On the contrary, as regards the use of plant-based drinks as ingredients in the preparation of complementary foods (similarly to vegetable broth or water) for use during complementary feeding and not as substitutes for breast milk or formulas, the approval of this possible use can be found in recent publications [43][48][52][58].

3. The Role of Plant-Based Milk Alternatives in the Diet of Children over 12 Months of Age

3.1. Allergy to Cow's-Milk Proteins

In the case that CMPA persists or occurs beyond 1 year of age, the guidelines of ESPGHAN ^[16], NASPGHAN ^[36], the Mexican Association of Gastroenterology (AMG) ^[6], and other recent publications ^{[9][24]} continue to recommend a formula (EHF, AAF, soy- or rice-based formulas) as the first choice to ensure the nutritional needs in a cow's-milk protein-free diet. On the other hand, the conclusions of Healthy Eating Research are slightly different: "Between 1

and 5 years of age, plant-based drinks can be particularly useful for children with allergies or intolerances to cow's milk" ^[55], thus opening to the use of plant-based drinks in these situations after 1 year of age.

3.2. Lactose Intolerance

The non-persistence of lactase activity beyond childhood is a very common situation in which a part of the world population cannot digest lactose, with a prevalence that varies among ethnic groups from 15 to 100% of the adult population ^[18].

In this situation, the advice is to reduce the intake of lactose, and only more rarely is a completely lactose-free diet necessary ^[19]. As regards milks, Berni Canani et al. recommend lactose-free milks or soy-based drinks ^[18].

3.3. Choosing Plant-Based Milk Alternatives for Family Preferences

The position of the Mexican Association of Gastroenterology (AMG) is summarized in a recent publication, with specific reference to soy-based drinks ^[6]. The authors conclude by stating that "there is no evidence on the health benefit of plant-based drinks in childhood nutrition" and that plant-based drinks "should not be utilized as a replacement for breastmilk or as a replacement for breastmilk substitutes in the feeding of children during the first 2 years of life. Their later use as part of the liquid portion of diet must be individualized". They then add that in the vulnerable segments of the population (children, adolescents, the elderly) plant-based drinks should be fortified and included in the context of a balanced diet ^[6]. The position of NASPGHAN is to recommend it up to 2 years of age, apart from breast milk, cow's milk, or formulated milk. The position of ESPGHAN ^[59] regarding the use of infant formulas in the 12-36-month age range (young-child formula-YCF) focuses on formulated milks of animal or plant origin specifically designed for this age range and therefore does not deal with plant-based drinks. The conclusions are nevertheless interesting for the focus of the study: "There is no necessity for the routine use of YCF in children from 1 to 3 years of life, but they can be used as part of a strategy to increase the intake of iron, vitamin D, and n-3 PUFA and decrease the intake of protein compared to unfortified cow's milk. Follow-on formulae can be used for the same purpose. Other strategies for optimizing nutritional intake include promotion of a healthy, varied diet, use of fortified foods, and use of supplements". Furthermore, "the protein content should aim toward the lower end of the permitted range [for 6–12 months formulas] if animal protein is used", i.e., towards 1.6 g of protein/100 Kcal (about 1.1 g/100 mL) ^[59]. These statements are in line with the findings of the European Food Safety Authority ^[60] and taken up by the European Commission in 2016 ^[61] in the sense of not being able to identify a unique role for YCF, as other nutritional strategies can achieve the same results. The American Academy of Nutrition and Dietetics (AND) in its 2016 position paper on vegetarian diets stated that fortified soy-based drinks or cow's milk can be used from 1 year of age in children growing normally and consuming a variety of foods [62]. The British Dietetic Association (BDA) Food Fact Sheet briefly states that "from the age of one year, fortified plantbased drinks can be used in preparing foods and given as the main milk drink" ^[63]. In the recent Guidelines for a Healthy Diet of the Italian Food and Nutrition Research Center ⁶⁴ there are no references to plant-based drinks. Other individual groups have also taken positions on the use of plant-based drinks in children. Wright and Smith believe that "after weaning, typically around 12 months of age, milk of any kind is not required, that children will be fine with water and a good healthy balanced diet", and that plant-based drinks "can easily be included in day-to-day use after weaning, and, used in this fashion, plant milks can be less harmful than dairy milks, at least for certain groups" ^[65]. For Craig et al., from 1 year of age, if the child grows normally and consumes a variety of foods, fortified plant-based drinks derived from soy or peas can be introduced in addition to cow's milk ^[66].

Adequacy of Plant-Based Drinks Compared to Cow's Milk

A plant-based drink, which is not substantially equivalent to cow's milk, is not considered an adequate alternative to cow's milk under 2 years of age ^[36]. For the Spanish Society of Pediatrics, calcium-fortified plant-based drinks "should never be used as the main liquid food of the child, at least until age 2–3 years" ^[45]. The GFHGNP of the French Society of Pediatrics, speaking about iron requirements for a child who follows a vegan diet, recommends soy- or rice-based formulas for "as long as possible, ideally up to 6 years of age" ^[44]. The advice of Healthy Eating Research ^[55], expressed in "Healthy Beverages Consumption in Early Childhood", signed by the Academy of Nutrition and Dietetics, the American Academy of Pediatric Dentistry, the American Academy of Pediatrics, and the American Heart Association, is that between 1 and 5 years of age plant-based drinks be used in case of "specific dietary preferences"—and mentions in particular the vegan and lacto-ovo-vegetarian diets—in addition to medical conditions that may require it. However, they recommend that their consumption is not exclusive (except in the case of soy-based drinks) and that in any case the choice should be evaluated with a practitioner to monitor the adequacy of the whole diet ^[55].

The recent guidelines of the New Zealand Ministry of Health report the possibility of using soy-based drinks from 1 year of age, provided they are fortified with calcium (and vitamin B12 if the child follows a vegan diet and does not receive supplements); rice- and other grain-based drinks are not recommended as the sole substitute for cow's milk up to 5 years of age, and fortified types are generally recommended ^{[54][67]}. For children following a vegan diet, the Australian Ministry of Health guidelines recommend continuing with a soy-based formula up to 2 years of age. Indeed, the same guidelines state that fortified soy-, rice-, or oat-based drinks "can be used after 12 months under health professional supervision" ^[40]. The Canadian joint statement—supported by Health Canada, the Public Health Agency of Canada, the Canadian Pediatric Society, and the Dietitians of Canada and Breastfeeding Committee for Canada—suggests the use of soy-based formulas up to 2 years of age if the child does not take cow's milk. In addition, it states that "soy-, rice-, almond- or other plant-based milks [...], whether or not they are fortified, are not appropriate as the main source of milk for a child younger than two years" ^[39].

Mangels et al., in a handbook on vegetarian nutrition ^[68], leave freedom of use for whole-cow's-milk or soy- or peabased drinks that are fortified and unflavored from 1 year of age, provided that the child—if vegan—grows regularly and has reliable sources of iron and zinc in the diet. In addition, given the lower lipid content of soy- and pea-based drinks compared to whole cow's milk, they recommend the presence of other sources of lipids in the diet up to 2 years of age, when fats should not be limited in the diet of the child. Due to the different nutritional composition, the guide does not recommend other plant-based drinks as the main drink for young children ^[68]. For Vandenplas et al., these plant-based drinks "should ideally not be used as a main drink in children <2 years of age, and if they are considered after 1 year of age, nutritional assessment should occur before, to ensure that the child is achieving their nutritional requirements through their current diet" ^[9]. For Verduci et al., all plant-based drinks "should not be used as a substitute for cow's milk in children <24 months old" ^[24]. For Sethi et al., plant-based drinks are "inappropriate alternatives for breast milk, infant formula or cow's milk in the first 2 years of life," and beyond this age, when consumed for medical reasons, they recommend fortified products that contain at least 6 g of protein in 250 mL of product ^[30]. On the contrary, for Mangels and Driggers, fortified soy-based drinks are an "appropriate substitute for cow's milk" from one year of age; the other alternatives should be used occasionally given the lower protein and energy content ^[56].

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