Journal of Nutrition & Intermediary Metabolism 15 (2019) 27–34

Contents lists available at ScienceDirect

Journal of Nutrition & Intermediary Metabolism

journal homepage: www.elsevier.com/locate/jnim

Considerations for development of lactose-free food

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HIGHLIGHTS

- Lactose-free products are known to have low nutritional and sensory quality and are more expensive than lactose-containing food.
- This review focuses on special considerations, which should be undertaken while developing lactose-free products.
- This is a unique and comprehensive review; and will help the processors to develop the lactose-free foods.

ARTICLE INFO

Keywords:
Lactose intolerance
Lactose-free diet
Specific considerations
Sensory attributes

ABSTRACT

Lactose intolerance is a pathophysiological situation that occurs due to insufficiency of the "lactase" enzyme present in the jejunum. Ingestion of lactose containing products leads to alteration in intestinal digestion and colonic fermentation, leading to diarrhoea and other clinical discomforts. The articles reviewed were selected based on the following key descriptors such as lactose, lactose intolerance, lactose-free diet, non-dairy products, cost, nutritional composition and sensory attributes. Some lactose-free products made from the lactose hydrolysed milk or from the alternate milk sources possessing low nutritional and sensory quality are available in the market. These alternatives are high-priced comparative to the foods containing lactose. So, there is a strong urge to develop lactose-free products that are nutritionally adequate, economical and well accepted by the consumers with main focus on special considerations viz., finding an alternate non-lactose source, ensuring sensory and nutritional attributes, compliance with the concerned regulatory guidelines and economics. This unique comprehensive review will help the manufacturers in developing lactose-free products.

1. Introduction

The primary role of diet is to provide sufficient nutrients as per the metabolic requirements thereby giving the consumer a feeling of satiety [1]. The threshold of a new frontier in nutrition sciences has led to deviate from the past emphasis such as survival and hunger satisfaction. This helps in surpassing the negative impact on health by giving special attention on utilization of foods needed to promote wellbeing and thus lowering the possibility of diseases. Such notions are ignorable in the light of rising cost of health care, the desire of older people for improved life quality and the steady increase in life expectancy [2].

The reclamation of health properties has led food and beverage market to arouse interest among the various companies, thus increasing consumers' enthusiasm for the purchase of functional foods [3]. The rapid increase in consumer awareness and the great interest in the roles of health improvement of specific food or physiologically active food components is a tendency [4] to the convergence of various critical factors, namely the deterioration of personal health driven by a routine occupied with an inadequate selection of convenience food and insignificant physical activity, higher incidence of self-medication, higher level of knowledge of health authorities and media on nutrition and a strong link between nutrition and health [4,5].

Non-dairy probiotic products have global importance due to an ongoing trend of vegetarianism and high prevalence of lactose intolerance among various people all over the world [6]. The drawback associated with the intake of dairy products include lactose intolerance, cholesterol content and allergenic milk proteins, which makes the development of new non-dairy probiotic foods essential [7].

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https://doi.org/10.1016/j.jnim.2018.11.003
Received 24 January 2018; Received in revised form 22 November 2018; Accepted 22 November 2018
Available online 23 November 2018

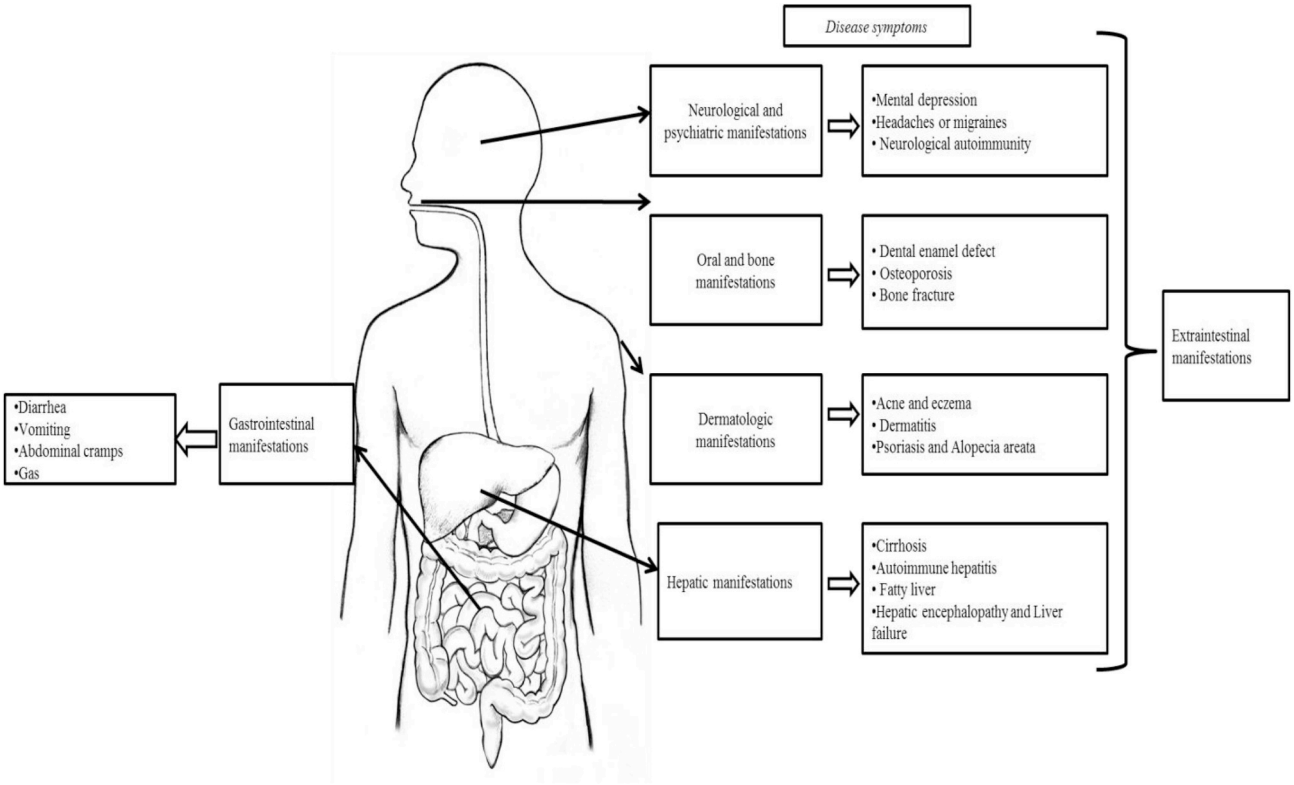

Fig. 1. Manifestations of lactose intolerance.

Lactose intolerance is a condition in which a person cannot digest or absorb lactose due to a genetically programmed decrease in intestinal galactosidase (lactase) that occurs after weaning, a condition known as resistance lactase pathophysiology or due to the damage caused to the lining of the epithelial cells in the digestive tract [8]. Lactose is essential to promote the health of newborns [9]. The intestinal brush border enzyme 'lactase', hydrolyses lactose into absorbable sugars (i.e. glucose and galactose) that provides energy. During the postnatal period, the activity of the intestinal enzyme (lactase) is highest among most newborns. However, among children aged 2–12 years, segregation occurs in two distinct groups, namely, "non-persistent lactase group" with hypolactasia and "lactase persistence group", which include the population that maintains the level neonatal activity lactase even after the childhood stage. The amount of lactose that causes the symptoms (Fig. 1) varies from person to person, depending on the amount of lactose consumed, the degree of lactase deficiency and the form of the product/food product in which lactose is ingested [8]. About 75% of the world's adult population is lactose-intolerant intolerant [10]. Therefore, taking into account all points, we tried to examine the above considerations before developing functional foods for patients with lactose intolerance, keeping in mind the current demand, costs and needs of different age groups (elderly, young and newborns).

2. Methodology

The main aim of the exploring the literature was to review the recent trend of the research which is going on in field of the lactose-free food product development. In this regard, numerous relevant publications were identified from different electronic databases (Sciencedirect, PubMed, SciELO, Google scholar, Linkspringer and Researchgate) using different keyword such as lactose, lactose intolerance, lactose-free diet, non-dairy products, cost, nutritional composition and sensory attributes for studies published before 2016. After checking their suitability, 92 manuscripts were reviewed to get the overviews of the different consideration, which plays an important role before and during the development of lactose-free foods.

3. Importance of developing lactose-free products

Until date, lactose-free diet is the only treatment for people suffering from lactose intolerance. Complete avoidance of lactose allows the gut to heal and resolve nutritional deficiencies and other associated symptoms. Strict adherence to the lactose-free diet also reduces the risk of developing many of the serious long-term complications related to untreated lactose intolerance [11]. However, avoiding lactose and following a lactose-free diet may seem simple, even if it becomes more difficult, as it involves not only eliminating all products containing lactose that require constant monitoring, but also a sense of social isolation and pressure. Since most of the dairy products available in the market contain lactose, the avoidance of such products would lead to a complete change in lifestyle that may not be practicable for everyone. Because of these reasons, the consumer's need in terms of nutrition and sensory properties for lactose-free products is maximized.

4. Specific considerations in the development of lactose-free products

Preparation of lactose-free products is a hard task for the manufacturers with the main challenge being the use of alternatives which are well accepted by lactose intolerant patients. Dairy free products which are found commercially [12] could be a solution for this problem. Apart from this, other challenges faced by the developers are safety of the product, its acceptability and affordability and being in line with the guidelines approved by FDA. Considering all these points, several considerations need to be followed by the manufacturers while developing lactose-free products which are reviewed here.

4.1. Avoidance of lactose-containing sources

The first consideration in designing the lactose-free product

Table 1
Lactose content in different types of milk.

Milk and milk based products		Lactose (g/100 ml)	References
Raw milk			
Cow	Milk	3.7–5.1	[14]
	Colostrum	4.3	[15]
Buffalo	Milk	4.5–5.5	[10]
	Colostrum	5.2	[16]
Goat	Milk	3.6–4.8	[17]
	Colostrum	2.9–4.4	[10]
Human	Milk	6.2–7.5	[10]
	Colostrum	5.3	[18]
Sheep	Milk	3.7–4.8	[19]
	Colostrum	3.3	[20]
Camel	Milk	3.3–4.8	[21]
	Colostrum	3.63	[22]
Yak	Milk	4.17–5.6	[23]
	Colostrum	3.2–4.7	[24]
Milk based products			
Skim milk		4.3–5.7	[25]
Low fat milk		3.7–5.5	[17]
Lactose Hydrolysed milk		0.43–0.6	[26]
Buttermilk		3.6–5.0	[27]
Chocolate flavoured milk		4.1–4.9	[17]
Cream		0.1	[28]
Whipping cream		2.8–3.0	[17]
Ghee (cow milk)		0.0	[28]
Yoghurt		4.70–4.76	[29]
Whey		5.1	[28]
Kumis		5.5	[28]
Cheese	Cheddar	0.09–0.5	[30]
	Cottage	1.0–3.1	[25]
	Mozzarella	0.1–1.59	[31]
	Goat cheese	2.2	[28]
Paneer		2–2.7	[32]
Condensed milk		9.9–14.0	[29]
Evaporated milk		10–11	[17]
Butter		0.8–1.0	[17]
Ice-cream		3.6–8.4	[17]
Kefir		4.0	[33]
Khoa	Cow milk	24.9–24.30	[34]
	Buffalo milk	22–24.20	[35]
Gulabjamun		15.04	[36]
Rabri		11.3	[37]
Basundi	Buffalo milk	11.1	[38]
	Cow milk	8.12–10.8	[39]
Peda		15.3	[40]
Milk cake		7.7	[41]
Burfi		12–15	[39]
Kheer Mohan		1.20	[42]

includes the elimination of food product or food ingredient that contains lactose, as it triggers lactose intolerance. Due to the valuable efforts made by the researchers recently, a wide range of lactose-free and lactose-reduced milk and milk products are available in most of the super markets in Western countries and are nutritionally similar [13] to regular milk and milk products. Table 1 enlists different types of milk and milk based products along with their lactose content which should be considered prior developing the lactose-free product.

4.2. Alternate sources

Avoidance of lactose containing food products leads to the exclusion of major carbohydrate (lactose) source present in milk and milk products. The use of lactase treated dairy products or oral lactase supplementation can be opted which serves as an alternative for lactose containing food or dairy elimination [43]. The lactose content in animal and human milk is in high amount and eliminating lactose from diet completely would lead to deficiency of calcium among children and adults resulting into less dense, fragile bones that can easily cause fracture [44]. Therefore a research for exploring and developing the alternative sources is highly required in order to obtain the desired nutritional requirement of a human body corresponding to particular age group.

Probiotics represent one of the largest functional food markets. Among the non-dairy probiotic products, those made with soy stand out because of the inherent health benefits of soy [7]. Apart from this, other lactose-free sources that are being used for developing food products for lactose intolerant patient includes yogurt, cheese, kefir, etc. Some alternate sources of milk that can be used in place of lactose containing milk and for developing lactose-free products are listed in Table 2 along with their respective nutrient concentration.

Until now various researchers have made numerous attempts to design and develop lactose-free food for the lactose intolerant patients using various lactose-free milk and milk products which is reviewed in Table 3 along with the specific remarks.

Beside these, replacement therapy results in an efficacious strategy for lactose intolerant people with the use of different exogenous lactase enzymes (such as β-galactosidase and tilactase) and probiotic food (containing strains of *Bifidobacterium longum, Bifidobacterium animalis, Lactobacillus bulgaricus, Lactobacillus reuteri, Lactobacillus acidophilus* or *Lactobacillus rhamnosus*) represents one of the largest functional food markets. In accordance with these advantages, recent studied related to lactase enzymes and probiotics along with their effect on the lactose intolerance has been tabulated in Table 4.

4.3. Ensure sensory characteristics along with consumer perception of fluid milk

The demand for lactose-free dairy products/health food is constantly increasing, as consumers are becoming more health conscious day-by-day [80] and offer alternatives for the large population with lactose intolerance. Therefore, it is important to understand the sensory characteristics of lactose-free milk and its products compared to normal milk [81], since the acceptance of dairy products is mainly sensory driven [82]. Therefore, prior to the development of such products, consumer perception is highly required. Milk with probiotic benefits is an attractive attribute for both dairy and non-dairy consumers [83]. Because of the presence of the numerous nutritional compounds, cow's milk is recommended in the dietary guidelines for Americans. However, because of beliefs about lactose intolerance, non-dairy beverages are recommended for people with lactose intolerance, including milk substitutes in federal food programs. Recent studies on consumer perception and acceptance of substitutive beverages indicated the consumers

Table 2
Alternate sources and their composition.

Sources	Carbohydrates (%)	Proteins (%)	Fat (%)	Moisture (%)	Calcium (ppm)	Reference
Soy Milk	1.5	3	1.5	94	3.90	[45]
Rice Milk	45–57.3	15.5	0.79–2.5	18.7	1.5–1.6	[46]
Coconut Milk	5.5–8.3	2.8–4.4	32.2–40.0	64.1–80.4	9.40	[47]
Oat Milk	12	0.7–1.0	1.3–1.52	–	–	[48]
Lactose Hydrolysed Milk	4.8	3.2–3.37	1.5–4.3	87.1–89	112.7–120	[20]

Table 3
Lactose-free products development from alternate sources.

Milk product Developed	Alternate Source Used	Remarks	Reference
Milk	Soybean	• Cholesterol-lowering effects. • High in PUFA thus, prevents heart disease, postmenopausal syndromes, cancers, aging, and osteoporosis.	[49]
	Coconut	• Boost immunity. • Creates a more favourable blood cholesterol profile.	[50]
	Rice	Higher carbohydrate and calcium content as compared to fresh milk.	[51]
	Oat	Plasma cholesterol lowering effects.	[52]
Cheese	Soy milk	• Minimal of cheese moisture and consequently cheese weight. • Increase in protein breakdown.	[53]
	Coconut milk	Increase in the protein and fat content of cheese with the inclusion of coconut milk.	[50]
Creamed cottage cheese	Lactose Hydrolysed cream	Provides cheese with appropriate organoleptic and good textural properties.	[54]
Milk powders	Coconut milk	Higher fat content and able to retain the natural aroma and flavour.	[55]
	Soy milk	• Higher protein content. • Presence of non-digestible oligosaccharide.	[56]
Flavoured lactose hydrolysed milk powder	Low lactose milk	High quality protein and essential nutrients including calcium and minerals.	[57]
Kefir	Soy milk	Good source of isoflavone genistein that suppresses the growth of cancer cells.	[58]
	Oat milk	• 15%–20% oat milk concentration is suitable for consumer preference. • Oat milk results into an increase in total beta-glucan content, whey off and microbiological flora.	[59]
Functional beverage	Peanut- Soy milk	Higher content of some essential amino-acids.	[60]
Yogurt	Ripened jack fruit and soy milk	High protein % and low fat % in addition to nutritionally valuable fibre content.	[61]
	Soy milk	• Good source of protein (3%) • Heart-healthy source of plant-based fat (7%). • Low cholesterol.	[62]
	Coconut milk	• Yogurt produced from coconut milk was comparable with the skimmed cow milk in all sensory quality attributes.	[63]
Ice- Cream	Rice milk	• High nutritive value. • It is possible to produce highly acceptable soft ice cream with different nutritional and sensory characteristics using rice as the major ingredient.	[64]
	Lactose Hydrolysed whey	A good quality product and organoleptically palatable.	[65]
Chocolate Bar	Soy milk	Reduced beany flavour.	[66]
	Soy milk powder	Incorporation of powder gave a positive result in terms of physical and organoleptic properties of the chocolate.	[67]

significantly had better preference that lactose-free cow's milk than all soy drinks. Furthermore, lean and fat-free cow's milk is better accepted than non-fat and lactose-free cow's milk [84].

Until the first half of the 1990s, because of the astringent taste, the product that contained soy extract such as juices and ice creams were not well accepted. Since then, various industries have developed with new technologies, including genetic changes and the use of successful ingredients for the acquisition of products with better sensory characteristics [85]. Recently, an increase in the demand for soy products has shown that consumers are including them in their regular diet by adapting their approach to soy and their derivatives and also changing their expectations for new soy-based probiotic products available in the market [7].

4.4. Nutritional value of lactose free products

Studies have shown that patients who follow a strict lactose-free diet often suffer from various nutritional deficiencies that can generate various health disadvantages, such as immune dysfunction, colon health, etc. [9]. Milk and dairy products are classified as nutrient dense foods. However, these products have an advantage over other foods, i.e., sources rich in calcium [44], which is one of the most important engines for the development of the dairy industry. By increasing the amount of cheese and yoghurt, the needs can be met with the right amount of energy (fat) by keeping the lactose intake below 12 g per meal. Therefore, such dairy products can meet the calcium requirement of lactose intolerant people [10].

A lactose-free product should not just be lactose-free rather it must be comparable with lactose containing products in nutritional profile. Numerous attempts have been made by different researchers for development of nutritionally enriched lactose-free food products (Table 3).

4.5. To meet RDA requirement

The average daily dietary nutrient intake level sufficient to meet the nutrient requirement of nearly 97–98% healthy individuals in a particular life age is termed as RDA (Recommended Dietary Allowances) [86]. It has been observed that lactose-free diet therapy often has low content of certain nutrients i.e. it contains less than 0.01% lactose (the maximum permitted lactose content for lactose-free products by the authorities) and the glucose and galactose content is approximately 1.4% each. Due to the lower carbohydrate content [87] the product also contains less energy as compared to the corresponding traditional product, with approximately 83% of energy content which suggests that the RDA for individual nutritional needs is not being met.

While developing a lactose-free product, it should be ensured that the nutritional profile of the product should not be reduced to such a level which may affect the health and RDA of a person. To ensure this, the sole solution is to include lactose hydrolysed products in their regular diet. The alternative sources (lactose hydrolysed milk, oat milk, etc.) can also be opted along with calcium and vitamin D supplements [8] regularly through other food sources or fortified with these nutrients to meet the RDA.

4.6. Economics

As per the available literature, adherence to a lactose-free diet leads to an economic burden on the patients because lactose-free products which are available in the market have prices much higher as compared to lactose containing products. Thiele [88] carried out a study for analyzing the price variation of the milk and milk products with and

Table 4
Lactase enzymes and probiotics along with their effect on the lactose intolerance.

S. No.	Study	Remarks	Reference
1	To study the effect of β-galactosidase derived from *Kluyveromyces lactis* by adding it to cow's milk prior to consumption.	• Intolerance symptoms are suppressed by this treatment amongst symptomatic malabsorbers. • Eliminates significant incomplete sugar absorption in 60%–77% of malabsorbers.	[68]
2	To compare the efficacy of products with different concentration (20 and 50 g) of lactose, three different β-galactosidase preparations were fed to lactose patients including lactogest (soft gel capsule), lactaid (caplet), and dairyease (chewable tablet) and placebo.	• Digestion and tolerance dramatically improved on introducing β-galactosidase products (with 6000 IU of activity) in 20 g of lactose containing milk among most lactose maldigesters. • In contrast, 50 g of lactose in water overwhelmed the ability of 3000 or 6000 IU of β-galactosidase products to initiate digestion.	[69]
3	To assess the success of supplementation with tilactase or *Lactobacillus reuteri* when compared to placebo.	• In lactose intolerant, tilactase strongly improves both lactose breath test results and gastrointestinal symptoms after lactose ingestion with respect to placebo. • *Lactobacillus reuteri* also is effective but lesser than tilactase.	[70]
4	To study the effectiveness of a new beta-D-galactosidase pellet formulation in the treatment of lactose intolerance patients.	• The formulation resisted inactivation in the stomach, effectively transformed lactose to glucose in vivo and reduced symptoms of lactose intolerance.	[71]
5	To study the effect of supplementation with a standard oral dose of Beta-Galactosidase on hydrogen breath excretion among lactose malabsorbers.	• Oral administration of 15000 Units of β-galactosidase in lactose malabsorber individuals is effective in decreasing significantly the mean peak Hydrogen levels and the cumulative values of breath Hydrogen excretion in a small group of patients.	[72]
6	To see the impact of B. *bassiana* β-galactosidase in lowering the lactose levels in certain food products.	• B. *bassiana* was capable of growth on a variety of carbon sources and β -galactosidase was expressed in every case. • B. *bassiana* produces a variety of extracellular enzymes, including β-galactosidase. As a result this fungus may provide an alternative as a source of β-galactosidase in industry.	[73]

PROBIOTICS

S. No.	Strain	Findings	Reference
1	*Bifidobacterium longum*	• Supplementation of yogurt and bifidobacteria in lactose-intolerant subjects modified the metabolic activities of the colonic microbiota and alleviates symptoms in lactose-intolerant subjects.	[74]
2	*Bifidobacterium animalis* and *Lactobacillus plantarum*	• Probiotic product (combination of new probiotic strains *B. animalis* subsp. *animalis* IM386 and *L. plantarum* MP2026) have the potential for alleviation of some gastrointestinal symptoms in lactose intolerance subjects. • Probiotic product resulted in significant lowering of diarrhoea.	[75]
3	*Lactobacillus bulgaricus* and *Streptococcus thermophilus*	• Chronic consumption of yogurt containing live Lactobacillus bulgaricus and Streptococcus thermophilus ameliorated the maldigestion in men with lactose malabsorption.	[76]
4	*Lactobacillus reuteri*	• L. *reuteri* shows positive association by reducing nausea, flatulence and diarrhoea. • It has increased beta-galactosidase activity and improves secretion of insulin, possibly due to augmented release of incretin.	[77]
5	*Lactobacillus acidophilus*	• DDS-1 strain of L. *acidophilus* improves abdominal symptom compared to placebo with respect to diarrhoea, cramping, and vomiting during an acute lactose challenge.	[78]
6	*Lactobacillus rhamnosus*	• Subject with Lactose Intolerance show reduced inflammatory reaction after consuming dairy products fortified with L. *rhamnosus*.	[79]

without lactose and reported that all the lactose-free products available in the market were costly as compared to the lactose containing food products. As milk and milk products are important suppliers of proteins, vitamins and minerals (especially calcium), a complete avoidance of these products is not viable. However, when the prices of lactose-free products differ too much with respect to lactose containing products, individuals might reduce their milk consumption to avoid additional food expenditures [88]. Therefore, it is mandatory to consider the cost of lactose-free products while developing these food products, so that the extra economic burden on the patients can be avoided.

4.7. Compliance with the FDA and FSSAI guidelines

During the development of food for the lactose intolerant patients, it is very important to adopt the standards and regulation as issued by National and International bodies. For different foods and food allergens, guidelines have been issued by FDA and FSSAI however there is no definition for “lactose-reduced” or “lactose-free” foods till date. According to the information available on FDA website, the manufacturer should keep following points in minds [89] such as.

- The information provided on the food label should be truthful and not misleading.
- The developed product i.e. lactose-free food product should not contain any lactose, and a lactose-reduced product should be one with a meaningful reduction.

As per the FSSAI Regulations for lactose free infant milk substitute [90] and packaging and labelling [91] of lactose free foods are as follow.

- Soy protein-based, lactose-free formula shall have soy-protein and carbohydrate as glucose, dextrose, dextrin/maltodextrin, maltose and/or sucrose
- Lactose-free cow's/buffalo's milk-based formulas shall have carbohydrate as glucose, dextrose, dextrin/maltodextrin, maltose and sucrose.
- The product which contains neither milk nor any milk derivatives

shall be labeled “contains no milk or milk product” in conspicuous manner.
- The container of infant milk substitute for lactose or lactose and sucrose intolerant infants or label affixed thereto shall indicate conspicuously “LACTOSE-FREE or SUCROSE-FREE or LACTOSE and SUCROSE-FREE” in capital letters and statement “TO BE TAKEN UNDER MEDICAL ADVICE” and shall also bear the following statements, namely: “Lactose free Infant Milk Substitute should only be used in case of diarrhoea due to lactose intolerance. The lactose free/sucrose free Infant Milk Substitute should be withdrawn if there is no improvement in symptoms of intolerance”.

On the other hand, According to the proceeding of “Nordic Council of Ministers” [92], the proposed composition and marketing requirements on the basis of lactose content for the lactose intolerance foods are:

Composition requirements.

- *Low-lactose* foods should contain a maximum of 1 g lactose per 100 g of ready to eat food.
- Although *lactose-free* foods should be free of lactose, for analytical reasons, an analyzed content of up to 10 mg lactose per 100 g product (enzymatic analytical method, lactose without water of crystallization) can be accepted.
- Galactose intolerance patients should be able to use *lactose-free* foods; the products should not contain galactose in any form.

Marketing requirements.

- Information should be given in proximity to the name of the food
- Products used as alternatives for lactose-rich foods i.e., comprising maximum of 1 g lactose per 100 g of ready to use product, must be labeled *low-lactose*in close proximity to the name of food.
- Products which are lactose-free according to the criteria given under "compositional requirements” must be labeled as *lactose-free* in close proximity to the name of the food.
- Declaration of nutritive value as well as the lactose content of low-lactose foods.

5. Conclusion

Lactose intolerance affects about 75% of the world's population on ingesting dietary lactose and increases significantly because the condition is often not diagnosed. The only treatment for people with lactose problems is adherence to foods without lactose. However, following a lactose-free diet for lifetime can cause nutritional imbalance in patients. Therefore, there is a strong need to develop the nutritious and economic lactose-free food product while taking care of several prior considerations (exclusion of all possible lactose-containing raw materials, the choice of an alternative source of milk, the acceptable consistency and colour of the product, the improvement of the nutritional quality of the product, product safety and labelling). These considerations will help to develop healthy, lactose-free, nutritionally complete and safe foods for people with lactose intolerance.

Acknowledgements

The authors are highly grateful to School of Agriculture, Lovely Professional University Phagwara, Punjab, India for providing financial assistance and infrastructure for preparation of this review.

List of abbreviations

FDA = Food and Drug Administration
RDA = Recommended dietary allowances
FSSAI = Food Safety and Standards Authority of India

Conflicts of interest

The authors declare no conflict of interest, financial or otherwise.

Author's contributions

Sheenam Suri and Vikas Kumar is the sole author of the review article. Whereas, the other authors have contributed equally for the literature collection, manuscript documentation and its revision.

Availability of data and material

Not applicable.

Consent for publication

The authors confirm that the content of the manuscript has not been published, or submitted for publication elsewhere.

Ethics approval and consent to participate

Research and manuscript are original and unpublished. All authors read and approved the final manuscript.

Funding

This research work has no funding.

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