Sustainable Food Technology

ROYAL SOCIETY OF CHEMISTRY

REVIEW

View Article Online
View Journal | View Issue

Cite this: *Sustainable Food Technol.*, 2023, **1**, 681

Food fortification in India as malnutrition concern: a global approach

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Food fortification is a cost-effective process of adding essential micronutrients to food products in order to address the issue of malnutrition, which is sometimes referred to as 'Hidden Hunger'. The earliest food fortification was suggested by a French chemist in 1820, with a proposal of fortifying salt with iodine. However, food fortification today can be achieved by different novel methods such as biofortification, industrial fortification and food to food fortification. Globally, many developing countries are experiencing nutritional deficiencies in their population, which can be considered as a silent epidemic. This is due to various factors such as disrupted supply chains, increased food prices, and loss of income, which have been exacerbated by the COVID-19 pandemic. Developed countries are successfully reducing malnutrition by introducing novel fortified food options. Moreover, middle-income countries like India are on their way to mitigating the problem of malnutrition by initiating nutrition programmes in coordination with the central and state governments and the global organizations. The present review explores the concept of food fortification in India along with the status of malnutrition and possible ways to eradicate it with fortification.

Received 30th May 2023
Accepted 1st August 2023

DOI: 10.1039/d3fb00079f

rsc.li/susfoodtech

Sustainability spotlight

Food fortification is a sustainable, scientifically proven and cost-effective global intervention that addresses the issues of deficiencies related to micronutrients. It is important to understand the need of food fortification and the guidelines and recommended usage limits for several categories of fortified foods. India, being a developing country is growing in this sector and the fabrication of different schedules for novel product formulation under this category contributes to understanding the needs of the international market. The present review highlights the concept of food fortification in India along with the regulatory guidelines. Also, the current scenario of food fortification in developed countries has been mentioned, which could help to understand the import–export setup.

1. Introduction

Hunger and malnutrition are pervasive among 65 million individuals including refugees and displaced populations. Providing people with a well-maintained diet minimises long-term health problems, alleviates poverty and makes them more resilient to future shocks.[1] This obstruction among most parts of the world can be solved by a cost-effective and sustainable method known as food fortification. The fortification has been described by the World Health Organization (WHO) as "the addition of one or more essential nutrients to a food whether or not it is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups".[2] The purpose of food fortification or enrichment is to improve the nutritional quality of food, avoid specific deficiencies, and offer health advantages. Additionally, functional meals can only be classified as fortified products if the amount of additional component is high enough to cause or trigger a scientifically confirmed health benefit (*e.g.*, reduce the risk of disease).[3,4] However, the substance added to meals to increase their nutritional value shouldn't interfere with the metabolism of other nutrients and should be utilised in an amount that does not cause any harmful health effects. It has been validated that food fortification is typically more cost-effective and lucrative than supplementation to address a given public health crisis, such as iron deficiency in pregnant women.[5]

The interest in enhancing the nutritional aspects of food meant for human consumption began to emerge in the 20th century. But the earliest recorded case of such practice has been discovered roughly in 4000 BC as addition of iron filings in sweet wine by a Persian physician Melampus with a motive to improve the stamina of Persian warriors.[6] Countries like the United States and Switzerland started adding iodine in salt by

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1920, vitamin-D and -A in dairy based products by 1932 and thiamine to flours by 1941.[7] Similarly, India started vanaspati fortification with vitamin-A in 1953 (ref. 8) and salt fortification with iodine in the 1960s, which played a pivotal role in goitre elimination.[9] Moreover, in the current scenario, most of the underdeveloped, developing and developed nations have authorised the fortification of food with several important micronutrients (based on deficiency of the population group) such as iron, zinc, folic acid, iodine and other vitamins as a mandatory practice. Most countries have designed rules and standards for fortified foods to meet the legal requirements, safety and quality of food. Likewise, the Indian food industry was not much interested in fortifying plentiful of foods with some exceptions of margarine and infant formula.[10] However, due to significant cases of malnutrition, Food Safety and Standard (FSS) Regulations, 2011 monitored the negligence of food manufacturers and therefore, the Food Safety and Standards Authority of India (FSSAI) established a board on food fortification to recognise the potential gaps in the nutritional status of Indian diet. Hence, FSS Regulations, 2016 introduced obligatory fortification of maida, atta, rice, salt, milk, oil and vanaspati. Presently, there are hundreds of fortified foods available in the Indian market and the functional food industry is growing with an increase in health awareness among consumers. The current article provides an overview of the food fortification process and different methods employed to implement it. It specifically examines the status of food fortification in India, comparing it to both developed and other developing countries. Additionally, the article highlights the potential consequences that arise from inadequate utilization of food fortification practices.

2. Malnutrition: a global crisis and an alarming condition in India

The convergence of the COVID-19 pandemic, the conflict in Ukraine, and the impact of climate change has resulted in a severe deterioration of the malnutrition and hunger situation since 2019. Sadly, this reversal of progress has undone a decade's worth of efforts to combat these pressing issues.[11] Malnutrition has been apparently reduced in India over the past 10 years, but there are still many gaps and a need for effective information gathered through various studies is essential to combat it, since it hinders the socio-economic growth of the nation. Currently, India is emerging as the fastest growing country in the South Asian region, in the fields of economics, education, and technology. Yet, India has failed to address and eradicate malnutrition which has a detrimental effect on the people of each age group.[12] In Global Hunger Index 2023, India recently ranked 107th out of 121 countries with a score 29.1, which is lying at a serious (20.0–34.9) level of hunger.

2.1 Factors contributing to malnutrition in India

Micronutrient deficiencies frequently lead to malnutrition, which is a significant public health issue, particularly in developing nations.[13] Adults and the females of reproductive age are more prone to micronutrient deficiencies.[14] Mothers' poor nutritional condition is one of the key contributors to malnutrition in India; 36% of women are underweight, and 56% each of women and adolescent girls (15–19 years) experience iron deficiency anaemia (IDA) because of deprived nutrition (WHO-SEARO).[15] Surprisingly, 75% of mothers (new and pregnant) were recorded as anaemic, and many of them gained only half of the weight (5 kg) compared to the global range of weight gain during pregnancy (10 kg).[16] Blood loss during menstruation is one of the prime factors that increases the susceptibility to IDA in adolescent girls.[17] Gender disparity in poor and middle-income families contributes to higher prevalence of anaemia among adolescent girls as they do not get nutritious foods rich in protein and micronutrients in comparison to boys.[17] These factors ultimately contribute to premature and low birth-weight babies due to undernourishment of pregnant women and breastfeeding mothers. As studies have claimed that the nutritional status of a mother and the health of a newborn are closely associated, women who experience malnutrition in childhood because of poverty and gender inequality gives birth to unfit babies.[18,19] Education and general awareness are other limiting factors that contribute to the understanding and importance of balanced diet among women. According to an assessment of NFHS-3 data,[20] women's education is directly correlated with a decline in the proportion of malnutrition and early marriage. Most Indian women lack the knowledge regarding the importance of breastfeeding and its duration to keep infant healthy and immune to several diseases.[21,22] Poor hygiene and sanitation practices are other major obstructions in India, which give rise to diseases like malaria and diarrhoea. This leads to a reduction in the availability of nutritious food as well as disease resistance in children.[23] WHO estimated that intestinal infections or diarrhoea escalated due to poor sanitation account for 50% of malnutrition.[24] Moreover, malnutrition causes weight loss due to depletion of fat and muscle mass which adversely affect the muscle function.[25] Micronutrient deficiencies also affect normal functioning of the cardio-respiratory system, gastrointestinal system and immune system.[25] Delayed wound healing in surgical patients was reported by Stratton *et al.*[26] as a consequence of weak immunity due to malnutrition. Food fortification is widely regarded as the most suitable preventive approach to combat malnutrition resulting from micronutrient deficiencies.[27]

3. Food fortification – a sustainable solution to malnutrition

The Codex General Principles for the Addition of Essential Nutrients to Foods offered direction to the competent national and/or regional authorities entrusted with designing guidelines and legal documents for the secure and systematic incorporation of essential nutrients into foods. These principles form the foundation for a rational and safe approach to fortifying food items with necessary nutrients.[28] The addition of micronutrients to staple food during processing or delivery of fortified supplements to the person with nutritional deficiencies is among the most common ways of fortification. Food fortification is crucial to improving the nutritional quality of the food

supply and promoting consumer well-being, while minimising potential risks to health. The fortification of food with micronutrients, including trace elements, can help combat malnutrition in lower and middle-income countries. Food fortification covers several important aspects, such as:

- Disease prevention: minimization and prevention of occurrence of health risks due to micronutrient deficiencies in public and specific population groups.[29]
- Improved public health: by fortifying the foods that are commonly consumed, the overall nutritional and health status is improved with the prevention or reduction of the prevalence of nutrient deficiencies.[29]
- Cost-effectiveness: food fortification is often a less expensive method of providing nutrients and preventing micronutrient malnutrition.[30,31]
- Targeted intervention: fortification allows for targeted intervention, where specific populations at risk of specific nutrient deficiencies can be targeted by fortifying the foods they commonly consume.[29]
- Easy to consume: fortified foods are easy to consume and often do not require any additional effort or education on the part of the consumer.[29]
- Better reach: fortification can be more efficient to reach a larger and more diverse population compared to direct supplementation.[32]
- No stigma: fortification is discrete and usually does not require any physical indication that the food is fortified.[33]

Several factors associated with food fortification, including the level of fortification, bioavailability of fortificants, and the quantity of fortified food consumed significantly impact health outcomes.[34]

3.1 Types and methods of food fortification

A jointly released document by WHO and the Food and Agriculture Organisation (FAO) described three types of food fortification based upon target population.[35] Mass fortification is designed for the wide public and is nearly always mandatory. Target fortification is designed for a definite population subgroup and can be either mandatory or voluntary, depending on the severity of the public health issue it aims to tackle. Lastly, market-driven fortification allows voluntary fortification of foods by manufacturers available in the marketplace but it operates under regulatory limits set by authorities (Fig. 1).[35,36]

Various researchers have categorized food fortification methods using different terminology, but ultimately, the end goal remains the same.[37–40] Broadly, it has been categorised as classical fortification, industrial fortification, biofortification, food-to-food fortification and point-of-use/home fortification.

3.1.1 Classical food fortification. Fortification offers a means to enhance the nutrient content of staple foods, seasonings, or condiments by increasing the levels of essential micronutrients like vitamins and minerals.[41] Synthetic micronutrients can be incorporated into these foods as a method of fortification.[42] In many developing countries, commonly consumed foods such as fats and oils, salt, sugar, milk, cereal flour (rice, wheat, or maize) serve as the primary vehicles for classical food fortification.[39] Among them, fortification of flours is a simple, highly acceptable and successful method for nutrient delivery due to easy mixing of nutrients available in powdered form. Rice flour fortification with zinc, iron and folate allows rapid absorption with an enhancement in the micronutrient status and growth rate among children under 5 years age in developing countries.[43,44] Lately, classical fortification has been more of a health improvement rather than disease prevention among population.[45] However, classical food fortification is challenging in developing countries as it depends upon food processing means (from production to consumption) where more and more advancement in the economy, regulatory framework, transport, market dynamics and monitoring system is required.[39]

3.1.2 Industrial/large scale fortification. This method allows the addition of one or more nutrients to the final fortified product including flour, salt, sugar and oil.[38] For instance, a significant loss of thiamine, riboflavin and niacin in refined flours occurs during processing of grains and the same is recovered by fortifying the processed food with lower amounts of lost ingredients. Industrial or large-scale fortification is categorised as either mandatory; introduced and controlled by the government (*e.g.* iodised salt and fortified flour), or voluntary; initiative by food manufacturers to add nutrients with a motive of fortification by following regulatory limits directed by government.[37,38] Following the mandatory regulations, over 130 nations have compulsory production of iodized salt.[46] Similarly, mandatory fortification of cereal flours with iron, folic acid, vitamin-A & D and calcium,[47] and sugar fortification with vitamin-A[48] are currently followed by several countries which is providing enormous health benefits to consumers. Moreover, the voluntary fortification scheme has paved the way for more comprehensive regulations and a robust authorising environment in India.[49]

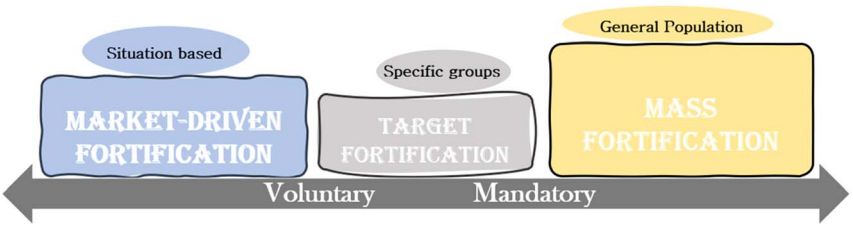

Fig. 1 The different types of food fortification and the target population covered by each type. (Source: ref. 35).

3.1.3 Biofortification. Biofortification is an advanced technique applied during crop production to improve the nutritional value, especially, essential micronutrients like minerals and vitamins through innovative biotechnology practices.[40] Orange sweet potatoes are among the popular examples of food developed using biofortification which were reported to address the vitamin-A deficiency[50,51] and rich in organic acids and β-carotene.[51] Different biofortification methods (conventional breeding, agronomics and transgenic means) have been reviewed previously.[52,53] Soil fertilization with organic salts immediately after sowing has been used as a successful biofortification of pearl millets in India which leads to high iron absorption rates.[54] A similar approach of pre-transplant biofortification was used to enhance selenium content in lettuce and sweet basil.[55] Similarly, maize biofortification with vitamin-A resulted in a notable increase in vitamin-A in Zambian children[56] and the selenium biofortification program in Finland contributed to decreasing the selenium deficiency.[5] Furthermore, 256 school-age children in India experienced changes in their body's levels of haemoglobin, serum ferritin, and total iron, demonstrating the effectiveness of the biofortified food product.[37]

3.1.4 Food to food fortification (FtFF). The approach of incorporating one or more micronutrient-rich foods or replacing antinutrient loaded/nutrient deficient ingredients significantly boosts the quantity of bioavailable micronutrient/s, with a motive of addressing the nutritional needs of populations with low intake of accessible micronutrients.[40] FtFF generally delivers energy, fat, proteins, fiber, carbohydrates, minerals (phosphorus, iron, zinc, potassium, manganese, sodium, and calcium) and vitamin-C.[39,57] Kruger investigated FtFF with cowpea leaves and orange sweet potatoes in combination with conventional micronutrient fortification and fermentation on the mineral and antinutrient contents and Caco-2 cellular uptake of zinc and iron from ready-to-eat maize porridges. The results of nutrient enrichment were promising. In another study, baobab fruit powder dense in proteins, fiber, minerals, vitamins and carbohydrates was used as a fortificant and incorporated in fermented cereal-based dough (mostly maize).[58] Moreover, FtFF could be effectively utilised as an additional strategy in combination with household methods by using locally available nutrient rich staple foods, like basil, with daily eaten foods.[33,39] Such methods of food compositing/blending are considerably safe and hold the potential for standardization, making them viable for commercial-scale applications.[40] For instance, moringa powder in cow cheese[59] and bread,[60] basil powder in cookies[61] and rice cake,[62] spearmint powder in fruit bar,[63] garden cress seed flour in cookies,[64] and amaranth leaf powder in wheat noodles[65] are some of the latest examples of FtFF and the detailed fortificants have been reviewed elsewhere.[33] Furthermore, the selection of natural fortificants in the FtFF method depends upon various factors, like, (a) diverse micronutrients available in food, (b) quantity of micronutrients present in food, (c) types of micronutrient-rich foods, (d) influence of food vehicle on sensory characteristics and (e) consumer acceptability.[33]

3.1.5 Point-of-use/home fortification. As the name indicates, home fortification is the incorporation of minerals and vitamins to food that has been cooked and ready for consumption.[38] WHO renamed this informal term as 'point-of-use' in 2012 to encompass various settings where this intervention can take place, including schools and refugee camps. In 2016, the WHO recommended the point-of-use fortification of complementary foods using micronutrient powders (MNPs) as a crucial approach to enhance micronutrient intake, particularly to improve iron levels and reduce anaemia in children aged 6 to 24 months.[66] MNPs are individual sachets containing a blend of vitamins and minerals in powdered form and can be easily sprinkled onto food without affecting its taste or colour.[67]

4. Food fortification programs running worldwide

In 2006, WHO issued guidelines for effective fortification, covering fundamental aspects like the correct choice of food vehicles and fortificants, determining the concentration of fortification and implementing sustainable food fortification programs.[35] The #Future Fortified Global Summit on Food Fortification took place in September 2015 in Arusha, Tanzania. The summit brought together stakeholders from around the globe to discuss the accomplishments and challenges of industrial food fortification in low- and middle-income countries. Its key objective was to establish a shared vision and strategy for scaling up fortification efforts, contributing to the fulfilment of Sustainable Development Goals and beyond. The outcome of this summit was the creation of the "Arusha Statement on Food Fortification," (available at: **http://www.gainhealth.org/wp-content/uploads/2015/05/Arusha-Statement.pdf**).

In 2002, the Global Alliance for Improved Nutrition (GAIN) was established with a mission to stimulate the public and private sectors to combat malnutrition effectively. As part of its early initiatives, GAIN launched the first large-scale fortification program in 2003. Over the years, GAIN has earned recognition as a strong and reliable platform for facilitating unique partnerships and introducing innovative models to expand nutrition programs. Large-scale fortification was GAIN's pioneering programmatic area, and to this day, it continues to be a central pillar of their ongoing efforts. In countries with substantial malnutrition challenges, like India, Bangladesh, Kenya, and Nigeria, GAIN strategically aimed to create a portfolio of projects that complement each other, maximizing their coverage and impact on the population. For promoting food fortification, GAIN launched a 10 years strategy covering WHO/FAO guidelines on food fortification with micronutrients in 2006, followed by the launch of the Universal Salt Iodization program in 2008 and the scaling up nutrition framework in 2009.[43] By layering these projects, GAIN has effectively increased its reach and influence, becoming an innovative and adaptable force in the battle against malnutrition. GAIN has targeted towards providing the benefits of fortified foods in order to end micronutrient deficiencies among poor population in developing countries.[68]

Furthermore, to simplify the evaluation of the effectiveness of population-based and targeted fortification programs, GAIN devised a Fortification Assessment Coverage Toolkit (FACT). This toolkit allowed for comprehensive assessments, including considerations of equity, across 18 large-scale fortification programs in eight different countries, conducted from 2013 to 2015. The results of these surveys revealed significant variations in coverage levels depending on the specific food vehicle and country.[69]

The Food Fortification Initiative (FFI) Atlanta, GA, USA is a global partnership comprising private, public and civic members and was established in 2002 with an objective to boost fortification of industrially milled cereal flours. FFI monitors and documents food fortification levels for 236 countries and also, tracks global growth in grain fortification. 92 countries have regulation to mandate fortification of at least one industrially milled cereal grain.[70]

The United Nations International Children's Emergency Fund (UNICEF), now officially the United Nations Children's Fund, with its focus on food systems' transformation for the benefit of children, adolescents, and women, is placing a high priority on large-scale food fortification (LSFF) programs. As per the Global Fortification Data exchange (2021), fortification is mandatory, as of 2020, for wheat flour in 85 countries, for maize flour in 17 countries, for rice in 7 countries, for oil in 27 countries and for salt in 124 countries.[71] The final objective of all the food fortification schemes is to contribute sustainably to protect the general public against the health effects of malnutrition.[72] From an economic standpoint, fortification of foods is an excellent public health investment for the countries, which is advantageous on numerous metrics including improved public health outcomes, fostering economic growth and development, *etc*.[73]

5. Food fortification in developed countries

According to Dary and Mora,[8] food fortification has been observed to be a proficient, affordable, and sustainable means to improve the availability of micronutrients and reduce micronutrient insufficiency. Compared with developing and under-developing nations, food fortification has been more successful and effective in developed countries.[8] Food fortification programmes are sustainable because of (a) the operation of large, centralised food industries; (b) packaging and labelling that facilitates scrutiny and implementation; (c) knowledgeable consumers who understand the importance of healthy nutrition and have the means to purchase the product.

Developed economies such as the United States, Canada and European countries have effectively applied food fortification programmes for the intended purpose. As per the Global Nutrition Report (2022), the USA is on track to meet the maternal, infant, and young child nutrition targets effectively.[74] Food fortification officially began in the USA in 1924, with the availability of iodized salt in Michigan state which resulted in a significant decline in goitre from 38.6% to 9%.[75] The United States introduced the dietary reference values in 1942, which provided clarity about the required quantities of micronutrients in order to maintain optimum health.[30] Then, the Food and Drug Administration (FDA) encouraged and regulated food fortification by a standard of identity to specify the types and quantities of nutrients to be added in food.[76] The utilization of a standard of identity, specifying the precise type and level of fortification necessary for a specific staple food to be classified as enriched, has consistently remained a crucial element of fortification regulations and policies in the United States. While these standards have undergone amendments over time, they persist as the foundation for enriching flour with thiamin, niacin, riboflavin, folic acid, and iron, with the optional inclusion of calcium.[77] The formal food fortification by FDA was initiated in 1942 with white flour fortification using iron, niacin and thiamine. Thereafter, iron fortification of cereal flours has contributed to improving iron status among the population of the United States.[78,79] Mandatory folic acid fortification of cereal grains in the United States, Chile and Canada since 1998 showed a significant reduction (30–70%) of neural tube defects in newborns.[30] Vitamin-A fortification in margarine was initiated by Europe in 1927, in order to reduce the child mortality rate due to Vitamin-A deficiency which was later made mandatory.[30] Vitamin-D fortification is voluntary in USA; however, the level of fortification is under regulatory limits.[80] Ready-to-eat breakfast cereals are fortified with vitamin-D in the United States, but the same is unlawful in Canada.[81]

The United States has contributed efficiently to food fortification policy establishment and to guiding fortification programs. Hence, FDA approves the nutrient addition in food under four conditions: (a) nutritional deficiency, (b) restoration of nutrient losses, (c) quality improvement of replacement food and (d) balancing the nutrient content of industrially designed foods that replace large proportions of the natural diet.[30,76]

Furthermore, Europe has virtually eradicated nutritional deficiency-related disorders like goitre, rickets, and pellagra since the beginning of the 20th century.[82] To combat cretinism and goitre, salt fortification was first implemented in Switzerland in 1923 and then spread to other countries.[82] Various European countries have extensively implemented vitamin-D fortification in foods and a recent study about its effects on cancer death statistics showed a significant reduction in the death rate due to vitamin-D food fortification.[83] In the UK, foods are currently supplemented with additional vitamins and minerals, including vitamin-E, folic acid, iron, calcium, and other fortificants.[84]

6. Food fortification in developing countries

More than 80 industrialised and developing countries have successfully tested the effectiveness of fortification.[8] In Sub-Saharan African, fortification of staple foods (wheat, corn and rice flour) has been recognised as a valuable strategy to combat micronutrient deficiencies.[85,86] Food fortification in Nigeria established the Standards Organisation of Nigeria (SON) for establishing standards for food fortification and the National Agency for Food and Drug Administration Control (NAFDAC) for

monitoring of compliances with established fortification standards at distribution and retail levels.[87] In 1993, Nigeria initiated iodized salt as the first national fortification. In 2002, Nigeria mandated the fortification of wheat and semolina flour with vitamin-A, vitamin B-complex, zinc and iron, maize flour with vitamin-A, -B9, and zinc and fortification of sugar and vegetable oil with vitamin-A.[87,88] The National Policy of Food and Nutrition in Nigeria (2016–2026) accentuates biofortification of staple crops with micronutrients along the value chain as well as enforcing standards for food fortification.[89] Despite the existence of multiple regulatory frameworks on fortification in Nigeria, low levels of iron and vitamin-A were recorded in processed foods.[69]

The Government of Kenya (GoK) also approved the mandatory fortification of staple foods in 2012 *i.e.*, cereal flours, salt and vegetable oil.[90] Vitamin-A, -B-complex, iron and zinc fortification in cereal flours, iodine in salt and vitamin-A in vegetable oils has been done in Kenya.[91,92] GoK along with the food safety unit of the Ministry of Health (MoH) and the Kenya Bureau of Standards (KEBS) ensures appropriate fortification of staple foods along with the safety and effectiveness of fortificants.[93] In Indonesia, mandatory fortification of salt, wheat flour and cooking oil (since 2020) with iodine, iron and vitamin-A, respectively, has been followed.[94]

Furthermore, countries like Uganda, Tanzania, Malawi, and Zambia are adopting nutrition policies that incorporate food fortification as part of the strategies for preventing micronutrient deficiencies.[95] In spite of all these efforts by the governments of several African countries, a recent report[96] (UNICEF/WHO/World Bank Group) has surveyed and concluded that Africa has the highest proportion of the countries where the problem of stunting, wasting and overweight among the children under 5 years age has increased significantly. A similar survey report claimed that more than three quarters of children under 5 years age affected from severe wasting are from Southern Asia. However, a significant decline in the number of children with stunting has been recorded in Asia but an increase in stunting among children is noted in Africa since 2000 to 2020.[96]

7. Status of food fortification in India

As a result of widespread consumption, rice and wheat are considered as suitable food vehicles for micronutrient delivery *via* fortification in India. Additionally, oil is a mandatory part of daily diet, accounting for 99% of households in India, and oil is primarily fortified with vitamins-A and -D.[10] In 2016, FSSAI implemented food fortification regulations for fortifying staple foods, namely wheat and rice flour with vitamin B-12, iron, and folic acid to reduce the precedence of micronutrient deficiency across India. On August 21, 2018, FSSAI introduced the Food Safety and Standards (Fortification of Foods) Regulations, 2018. These regulations established mandatory fortification standards for certain micronutrients, stipulating that products must be fortified with these nutrients if they are to be marketed and sold.[97] The food products included under this revision of food legislation (as Schedule-I) has been summarised in Tables 1–3. Additionally, the government has made it mandatory to mention the fortification logo '+F' (Schedule-II) with mentioned dimensions of each symbol and colour codes used in the logo to be printed (in English or Hindi) on the package containing fortified foods (Fig. 2). Furthermore, the revision of regulations has been made at regular intervals and certain major inclusions/amendments are followed as:

Compliance with Standards on Micronutrient Content in Fortified Food was release in 2018 as "any manufacturer who fortifies any food shall ensure that the level of micronutrient in such fortified food does not fall below the minimum level specified in Schedule-I"[97] as mentioned in Tables 1–3. The amendment was done as "any manufacturer who fortifies any food shall ensure that the level of added micronutrients on label

Table 1 Food fortification levels made mandatory by Food Safety and Standards (Fortification of Foods) Regulations, FSSAI 2018 for salt, oil and milk

S. no.	Component	Level of nutrient	Source of nutrient
Iodized salt & double fortified salt (iron fortified iodized salt)			
*1	Iodine content	20–30 ppm (on dry weight basis) at the manufacturing level 15–30 ppm (on dry weight basis) at distribution and retail levels	Potassium iodate
2	Iodine content	850–1100 ppm	Ferrous sulphate or ferrous fumarate
3	Oil fortified with vitamin-A	6–9.9 μg RE per g of oil	Retinyl acetate or retinyl palmitate
4	Oil fortified with vitamin-D	0.11–0.16 μg RE per g of oil	*Cholecalciferol or *ergocalciferol (*only from plant sources)
5	Milk fortified with vitamin-A	*5270–450 μg RE	Retinyl acetate or retinyl palmitate
6	Milk fortified with vitamin-D	*65–7.5 μg	*Cholecalciferol or *ergocalciferol (*only from plant sources)

*1 [Amendment in force from 27th August, 2021; Food Business Operators to comply with the provisions by 1st March, 2022] (Notification No.: F. No. Stds/SP-18/A-1.12/N-1, dated 27th August, 2021). *5 & *6 Level of nutrient per litre of species identified milk (buffalo, cow, goat, sheep and camel)/full cream milk/toned milk/double toned milk/skimmed milk/standardized milk.

Table 2 Food fortification levels made mandatory by Food Safety and Standards (Fortification of Foods) Regulations, FSSAI 2018 for atta, maida and rice

S. no.	Nutrient	Level of fortification
(A) & (B) Atta as well as maida, when fortified, shall contain added iron, folic acid and vitamin B-12 at a level		
1	Iron – ferrous citrate/ferrous lactate/ferrous sulphate/ferric pyrophosphate/electrolytic iron/ferrous fumarate/ferrous bis-glycinate; or	28–42.5* mg
	Sodium iron(III) ethylene diamine tetra acetate trihydrate (sodium feredetate – Na Fe EDTA)	14–21.25 mg
2	Folic acid	75–125 μg
3	Vitamin-B12 – cyanocobalamine or hydroxocobalamin	0.75–1.25 μg
(C) Fortified raw rice (amended as fortified rice*)		
1	Iron – (a) ferric pyrophosphate; or	28–42.5* mg
	(b) Sodium iron(III) ethylene diamine tetra acetate trihydrate (sodium feredetate – Na Fe EDTA)	14–21.25 mg
2	Folic acid	75–125 μg
3	Vitamin-B12 – cyanocobalamine or hydroxocobalamin	0.75–1.25 μg

*C [Amendment in force from 27th August, 2021; Food Business Operators to comply with the provisions by 1st March, 2022] (Notification No.: F. No. Stds/SP-18/A-1.12/N-1, dated 27th August, 2021). * Added at a higher level to account for less bioavailability.

Table 3 Micronutrient levels made mandatory by Food Safety and Standards (Fortification of Foods) Regulations, FSSAI 2018 for fortification of atta, maida and rice (singly or in combination)

S. no.	Nutrient	Level of fortification
1	Zinc – zinc sulphate (zinc oxide in rice)	10–15 mg
2	Vitamin-A – retinyl acetate or retinyl palmitate (retinyl palmitate in rice)	500–750 μg RE
3	Thiamine (vitamin-B1) – thiamine hydrochloride or thiamine mononitrate	1–1.5 mg
4	Riboflavin (vitamin-B2) – riboflavin or riboflavin 5′-phosphate sodium	1.25–1.75 mg
5	Niacin (vitamin-B3) – nicotinamide or nicotinic acid	12.5–20 mg
6	Pyridoxine (vitamin-B6) – pyridoxine hydrochloride	1.5–2.5 mg

Fig. 2 Logo, indicating the food fortification, mandatory on the label/packaging. (Source: ref. 97).

of such fortified food shall fall within the range specified in Schedule-I". Similarly, the statement to be given on the package of iron fortified foods was revised. [Amendment in force from 22nd September, 2021; FBOs to comply with the provisions by 1st April, 2022] (F. No. 1-116/Scientific Committee/Notif.28.6/2010-FSSAI, dated 22nd September, 2021).[97]

Iron content substitution, insertion of new provisions for fortified milk powder and substitution of fortified raw rice as fortified rice are major amendments done in Schedule-I [Amendment in force from 27th August, 2021; FBOs to comply with the provisions by 1st March, 2022] (F. No. Stds/SP-18/A-1.12/N-1, dated 27th August, 2021).[97]

Furthermore, standards for fortified processed foods have been included as an amendment (Schedule-III) which covers the nutrients/sources and level of nutrient in fortified cereal products (breakfast cereals, pasta and noodles), fortified bakery wares (bread, biscuits, rusks and buns) and fortified fruit juices. A similar notification stated that multigrain atta may also be fortified with micronutrients at similar levels as specified for atta (Schedule-I; Table 3), provided that multigrain atta contains more than 50% as wheat flour in it (F. No. REG/Fortification Amendment (1)/Notification/FSSAI-2018, dated 18th December, 2020).[97]

After years of promotion and advocacy, the mandatory iodization of salt for human consumption was established in 1997

and later reaffirmed in 2005. However, in 2000, the legislation mandating salt iodization was repealed, allowing for the sale of non-iodized salt but the same was revised and mandated in 2005.[9] Multiple programs in India have been followed at the state level to fortify wheat flour and vegetable oil.[27] Similarly, small-scale rice fortification projects in Odisha and Andhra Pradesh states of India have been conducted.[98,99] The Ministry of Consumer Affairs, Food and Public Distribution had launched a centrally sponsored pilot scheme on "Fortification of Rice and Its Distribution under Public Distribution System (PDS)" for a period of three years beginning 2019–2020 where the rice blending is done at the milling stage. Wheat fortification was initiated in 12 states under POSHAN Abhiyan (2018) with the motive of improving nutritional status among children, adolescents, pregnant women and lactating mothers. Milk fortification with vitamin-D was initiated in 2017 by the National Dairy Development Board of India (NDDB).

During the period of 2010–2014, GAIN played a crucial role in supporting the production and distribution of a complementary take-home ration called Bal Amrutham to children in Telangana, India, through the Integrated Child Development Services (ICDS) program. Additionally, GAIN extended its support to staple food fortification initiatives in various other states across India.[100]

7.1 Successful schemes promoting food fortification in India

The double fortified salt programme was initially part of the fortification scheme in Tamil Nadu, which began in 2004. The objective was to distribute double-fortified salt among school children in their mid-day meals.[101] Since then, other Indian states have been increasing the utilisation of double-fortified salt to reduce iodine and iron deficiency. The state government of Madhya Pradesh and Gujarat made double-fortified salt available by PDS. In current scenarios, double-fortified salt is available to more than 12 million people across 20 districts at a tremendously subsidised price of just one rupee per kilogram. Additionally, India has played an important role in communicating the benefits of double-fortified salt to the general public.

Eat Right India Initiatives – Eat Right India was initiated to overhaul the nation's food system on a wide scale to ensure that safe, nutritious and sustainable food is available to all Indians. Under demand-side initiatives of FSSAI, food fortification has been promoted on a large scale to address micronutrient deficiencies across India. Additionally, Eat Right India strengthens the coordinated efforts of the government, key players in the food industry, civil society organisations, experts, and professionals, as well as developing organisations and people in the end.[102] Eat Right India is associated with the National Health Policy 2017 with its focus on promotive and preventive programmes like POSHAN Abhiyan and Anaemia Mukt Bharat (**https://eatrightindia.gov.in/eatrightindia.jsp**).

Then Anemia Mukt Bharat programme was launched by the Ministry of Health and Family Welfare in association with UNICEF in 2018. The goal of this scheme was to reduce anaemia among the vulnerable population including women and children. It is a strategic approach to dealing with the crises of anaemia in the country along with POSHAN Abhiyan, which was launched in the same year.[102] The Mid-Day Meal Scheme was launched in 1995 as the National Programme of Nutritional Support to Primary Education (NP-NSPE) and was renamed PM-POSHAN (Pradhan Mantri POshan SHAkti Nirman) in September 2021. This programme was started to enhance the nutritional status of children along with drawing attention for more admissions and regular attendance of children in schools.[12] Additional policies and government initiatives to promote fortification have been mentioned in Table 4.

7.2 Role of GAIN and other organizations in Indian food fortification

For more than 15 years, GAIN have been active in India. LSFF Programs have been implemented largely due to the efforts of GAIN since 2003. Additionally, GAIN collaborates with a wide range of partners, including, state and central governments of India, civil society organisations, companies, and development partners to increase consumer demand, access, and affordability of more nutritious food options.

Tata Trust took the initiative to develop a centralised platform for government stakeholders, ministries, state governments, development partners, and industrial organisations, particularly food producers, processors, and producers of fortification pre-mixes, to collaborate on the fortification of staple foods in 2016. Tata Trust helped FSSAI to establish a Food Fortification Resource Centre to scale up the fortification across India. Moreover, Tata Trust works with FSSAI-specific initiatives such as the fortification of salt, oil, rice, and milk.

Another organization working in India on food fortification is the World Food Programme (WFP). In Gajapati, Odisha, WFP has succeeded in handing over a sustainable model for the fortification of rice served to school children under the Mid-Day Meal Program.[103] The school children who participated in this pilot trial enjoyed eating the iron-rich rice and a significant decrease in anaemia was recorded. Moreover, FFI is also working in 18 Indian states to establish and enhance extensive programmes for the fortification of cereal grains.[104] FFI has assessed the dietary requirement, political will, and viability for the fortification of wheat flour and/or rice through state social safety net programmes and on the open market in each of the covered states.

Cargill in India, with the support of FSSAI, undertook a strategic approach to promote the health benefits of fortified oil by redesigning its brands. The company focused on raising consumer awareness, educating commercial distributors and sales agents about the benefits of fortification. Under its "Nourishing India" platform, Cargill fortified edible oils with essential vitamins and has successfully built brand loyalty among health-conscious consumers along with a significant contribution to combat malnutrition and promote better health and nutrition for the people of India.[105]

8. Comparing the food fortification system of India with developed nations

The guidelines for food fortification in India, the United States, and the European Union (EU) share the common goal of

Table 4 Policies and government initiatives to promote food fortification in India

S no.	Government schemes	Target population	Role in food fortification
1	Food Safety and Standard Authority of India (FSSAI) (2008)	Adults and communities	Supplies micronutrients for food fortification and training for mid-day meal preparation to fortify food for children
2	Food Safety and Standards (Prohibition and Restriction on Sales) Regulations (2011)	Adults and communities	Permitted the sale of only iodized salt for direct human consumption
3	Food Safety and Standards (Food Product Standards and Food Additives) Regulations (2011)	Adults and communities	Vanaspati shall contain synthetic vitamin-A
4	FSSAI in 2018	Adults and communities	Edible oil fortification
5	National Dairy Development Board of India (NDDB)	Adults and communities	Milk fortification with vitamin-D
6	Integrated Child Development Scheme and Mid-day Meal Scheme	Primary school students	Use of double fortified salt (iron and iodine), wheat flour (iron, folic acid and vitamin-B-12) and edible oil (vitamin-A and D)
7	Food Fortification Resource Centre (FFRC) by FSSAI in collaboration with Tata Trusts	Adults and communities	Promote large-scale fortification of food throughout India
8	Pradhan Mantri Poshan Shakti Nirman (PM POSHAN) Abhiyaan under National Food Security Act (2013) (NFSA)	Adults and communities	Fortification of food items
9	NFSA, ICDS, PM POSHAN Other Welfare Schemes (OWS) of Government of India (April-2022)	Adults and communities	Fortification of rice and its distribution under the targeted public distribution system (TPDS)
Other schemes contributing to combat malnutrition			
10	Integrated Child Development Scheme (ICDS) (1975)	Younger children (0–3 years) and most vulnerable population facing undernutrition	Supplementary nutrition, health and nutrition education
11	Reproductive Child Health (RCH-II)	Pregnant and lactating mothers	Iron supplementation
12	Reproductive Child Health (RCH-II) National Rural Health Mission (NRHM)	Pregnant and lactating mothers	Micronutrient supplementation and facility-based management of severe acute malnutrition
13	Mid-day Meal Scheme (MDM) (1995)	Primary school students (6–14 years)	Nutrition through freshly cooked food to children attending school
14	National Health Mission (NHM) (2005)	Maternal, neonatal child and adolescent	Addressing prevention of malnutrition in children
15	National Food Security Act (NFSA) (2013)	Beneficiaries of TPDS	Food subsidy for rice, wheat, *etc.*
16	Village Health Sanitation and Nutrition Committee (VHSNC) (2005)	Adults and communities	Improve sanitation and nutrition in villages
17	Rajiv Gandhi Scheme for Empowerment of Adolescent Girls (RGSEAG) or Sabla Scheme (2011)	Adolescent girls aged 11–18 years	Awareness about health, nutrition, adult reproductive and sexual health
18	Antyodaya Anna Yojana (AAY)	Adults and communities	Food subsidy to population with the fewest resources
19	National Food Security Mission (NFSM)	Adults and communities	Increased production of rice, wheat, and pulses
20	National Iodine Deficiency Disorders Control Programme (NIDDCP)	Adults and communities	Promotion of use of iodised salt
21	Rashtriya Krishi Vikas Yojana (RKVY)	Adults and communities	Supports states for creation of infrastructure, essential to catalyze the existing production of food grains

improving the nutritional value of food products, but there are some key differences in implementing and monitoring the regulations. The initiation of the fortification programme in India lagged behind that of developed nations; for instance, salt iodisation commenced in the 1960s in India, however, in the United States and Europe, the same fortification program

started in 1924 and 1923, respectively. Therefore, more cases of anaemia, child stunting, stillbirth and other nutritional deficiencies have been recorded in India compared to other developed countries. The FSSAI, a regulating body in India, has developed regulations for adding particular vitamins and minerals to food articles such as oil, milk, wheat flour and rice. The Fortification of Foods program of FSSAI is underway in India and it has recommended fortification levels for various food categories; however, the standardisation of several important food categories is still underway. In the United States, FDA also set standards for the quality as well as quantity of any added vitamins or minerals and monitors the safety of fortified food products.

In the European Union (EU), food fortification is regulated by the EU's food safety laws, specifically the EU Regulation (EC) No. 1925/2006. This regulation sets maximum and minimum levels for the fortification of certain food products, as well as guidelines for the quality and safety of any added vitamins or minerals. The EU Regulation allows the voluntary fortification of certain food products with vitamins and minerals, provided that the fortification is safe and does not mislead consumers. The regulation also sets maximum levels for the fortification of certain products, such as cereals, to ensure that fortification does not exceed safe levels.[106] The regulation also mentions the conditions for the use of vitamins and minerals, including their purity, origin, and labelling. It also mandates the provisions for the use of health claims related to the added vitamins and minerals. In addition to this, EU member states have their national regulations on food fortification, which may include specific provisions for certain food products or population groups. It's worth noting that EU legislation on fortification is based on the principle of ensuring the safety of food and protecting consumers from misleading information, rather than promoting the fortification of food.

Despite being a low-cost and easy process for most staples, it has been estimated that less than 20% of the business-to-consumer production of edible oils, salt, and milk, about 3% of wheat flour and 0.1–0.2% of rice are fortified in India, indicating a lower adoption of food fortification than developed countries.[107] Food fortification in India has a limited impact due to several factors, including inadequate production, less consumption by the most susceptible population groups *viz.* low-income women and children, leaks in the public supply chain, and a lack of private distribution outlets in rural areas.[107]

9. Potential hurdles obstructing the success of the Indian functional food market

Stagnation in wages and economic slowdown, raising food insecurity among poor households, unequal access to a variety of diets, and insufficient investments in welfare programmes over the past couple of years have led India to an alarming situation in which the government of India should revisit and reconsider the malnutrition problem.[12] Dalberg assessment stated some serious issues affecting food fortification uptake in India.[107] Firstly, despite the growing political momentum on nutrition at the Central Government level, its translation into consistent state-level actions has been uneven due to limited enforcement powers and weak coordination between departments. Furthermore, there are limited policy incentives for the private sector to engage in food fortification initiatives. Secondly, the structure of Indian industry is another big issue in the uniformity and adoption of food fortification. A handful of major players in salt and oil industries cover 40–90% of the market; however, in the rice, wheat flour and milk industries, there is a multitude of small-scale informal producers. This multiplicity makes organisation, dissemination and capacity building exceedingly difficult, since food fortification demands proper tracking and reporting of processes along with consistent investment in machinery. However, high capital costs of blending equipment, for example, blenders for wheat flour and dosing systems for rice, make it difficult for small-scale millers to afford them. Additionally, the low level of awareness among end users regarding quality, safety, accessibility and scientific validation, regulatory challenges, cultural preferences and price sensitivity is another potential challenge in the Indian fortification system. Consequently, despite its current success, India's food fortification system still has goals to reach.

10. Important actions required for improving the food fortification system in India

Malnutrition is a multifaceted issue and there are three main areas where the Indian government may prioritise its efforts:

○ Food system – in addition to addressing issues of food security and sovereignty, the central government and state governments should concentrate on establishing a robust regulatory and policy framework to support healthier diets for the populace. Moreover, investment on governments should increase investments in biofortification, which is one of the most cost-effective ways to reduce malnutrition and provide desired levels of nutrients naturally. Monitoring after effective implementation is pivotal.[12]

○ Nutrition economics – the development of a new proactive financing mechanism is important which can complement the existing sources. Nutritional inequalities still exist within the communities and across the states; therefore, allocation of resources should be advocated by data through evidence-based and cost-effective solutions.[108] Along with investing in human resources, the federal and state governments must create cost-effective nutrition facilities to guarantee that everyone has access to high-quality nutrition care.

○ Health system – it is important to support community-based programmes like the Village Health Nutrition Day in order to provide healthcare facilities and to spread the awareness on nutrition, family planning, maternal and child health, sanitation *etc.* Many children with severe acute malnutrition can be treated in their communities rather than being committed to a hospital or therapeutic feeding programme.[108]

The researchers of India have developed several novel and advanced methods and techniques that are partially

Table 5 Some novel food fortification methods available in India

S no.	Method/technology	Target food	Fortificant	References
1	Microencapsulation-based technology	Salt	Iron mixed with iodized salt	109
2	Vacuum impregnation technique	Potato chips	Calcium	110 and 111
3	Powder enrichment	Rice	B-Vitamins and iron (fortificant mix)	112
4	Whole grain enrichment/premix method		Vitamins and minerals (fortificant mix) followed by coating	
5	Hot and cold extrusion		Fortificant mix	
6	Batch process	Edible oils	Vitamin premix (pre-blend)	113
7	Continuous process		Vitamin premix (pre-blend)	
8	Agronomic biofortification	Wheat	Zinc	114
9	Agronomic biofortification	Pearl millets	Organic salt	54
10	Microencapsulation	Indian yogurt	Omega-3-fatty acids	115
		Milk	Iron	116

implemented or not commercially launched yet. Such cost effective and superior technologies could help in adequate production with high quality fortified foods (Table 5).

Furthermore, Dalberg Advisors proposed four ideas to LSFF players in order to drive more impact on the Indian food fortification market

(1) Capacity building within the public sector, improvement in centre-state coordination, and nudging a "race to the top".

(2) Promoting technological innovation persistent to food fortification automation and quality assurance.

(3) Well-synchronised social marketing for fortified food.

(4) Adopting advanced finance solutions to crowd-in resources for LSFF.[107]

11. Conclusion

The vulnerability of micronutrient deficiencies, such as vitamins and minerals, can be reduced by fortifying staple foods. There are diverse ways of food fortification available nowadays that can be adopted to enhance the nutritional value of foods. Developing as well as developed countries are following and approving the mandatory and voluntary fortification techniques with a common motive of combating nutritional deficiencies among people, especially, the vulnerable groups of mothers and children. Globally, several major agencies like WHO, GAIN, FFI, UNICEF, WWP *etc.* are effectively contributing to implementation as well as monitoring of food fortification to benefit the population. EU food laws in European countries and FDA in the United States are among the most successful food systems following food fortification with utmost success. Likewise, FSSAI in India is making efforts to fight malnutrition and is designing, implementing and monitoring several legislations for fortification of salt, oils, cereal flours and milk. Awareness of the past interventions and lessons derived from them could be useful for the countries that are poised to improve nutrition around the world, and this will consequently improve the socio-economy and world trading of fortified foods.

Conflicts of interest

No potential conflict of interest was reported by the author(s).

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