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Food Fortification : Issues and Way Forward



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- CONVENOR** : Dr K. Madhavan Nair, Former Deputy Director, ICMR-National Institute of Nutrition, Hyderabad
- REVIEWER** : Dr M.S. Bamji, INSA Honorary Scientist, Hyderabad
- EDITORS** : Dr Pratap Singh Birthal
Dr Malavika Dadlani
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NASC, Dev Prakash Shastry Marg, New Delhi - 110 012

Tel: (011) 25846051-52; Fax: (011) 25846054

Email: naas-mail@naas.org.in; Website: www.naas.org.in

Preface

Unhealthy diet, that is calorie dense and deficient in micronutrients, is a major threat in meeting the SDGs particularly the goal 2, Zero Hunger of a Nation. The National Health Policy (NHP) of India, 2017 has recognized that dietary diversification combined with nutrition and health education and public health measures are the long term sustainable strategies for combating micronutrient deficiencies. NHP has also embarked on short term supplementation and medium term staple food fortification for addressing multiple micronutrient deficiencies. Currently there exist multiple strategies targeting single micronutrient deficiencies of iron, folic acid, vitamin A and Vitamin D in the country. This has raised questions whether layering of different strategies for controlling the same micronutrient deficiency and developing food fortification standards based on the gap between dietary intake and requirement of micronutrients is the right strategy, and whether there is a need for fortification of a single or multiple food vehicles. Considering the dynamic nature of the data on the status of multiple micronutrients and its relationship with the nutrient requirements for Indians, there is a need to calibrate the standards and prioritize the vehicle for fortification.

The National Academy of Agricultural Sciences (NAAS) organized a brainstorming discussion on 'Food Fortification Issues and Way Forward' on March 11, 2022. Issues emerging out of the current staple food fortification guidelines by the FSSAI, the revised nutrient requirements and recommended dietary allowances of nutrients for Indians (ICMR-NIN, 2020), as well as the findings of the nationwide studies on the status of micronutrients (CNNS 2019) and diet and nutrient survey (NNMB 2016) were discussed.

A number of public health and agriculture scientists and professionals (mentioned in the report) participated in the discussion. Their inputs and suggestions have led to a set of recommendations. These recommendations should help to meet the goal of elimination of micronutrient malnutrition in our population and achieve full social and economic potential.

Valuable contributions of Dr K Madhavan Nair, Convener, Dr Pramod Joshi, Secretary NAAS, reviewer Dr M.S. Bamji and all the speakers and discussants is greatly acknowledged. I also thank Drs P.S. Birthal and Malavika Dadlani for their editorial support.

October 2022
New Delhi


(Trilochan Mohapatra)
President

Food Fortification : Issues and Way Forward

1. INTRODUCTION

Micronutrient malnutrition is widely prevalent in India primarily due to inadequate dietary diversity. The strategies to address micronutrient malnutrition include dietary diversification, food fortification, supplementation, public awareness about nutrition and health, and availability of health services and their delivery.

Food fortification has been identified as one of the safest and most effective strategies for preventing and reducing the incidence of micronutrient deficiencies (World Bank, 1994; WHO-FAO, 2006). In India, alongside supplementation, food fortification is also an important means of reducing micronutrient inadequacies (NHP, 2017). However, implementation of the food fortification strategies for correcting deficiencies of iron, Vitamin A and Vitamin D require contextualisation and evidence.

Currently, in the light of the evidence from a few research studies that utilized data from the Comprehensive National Nutrition Survey (CNNS) (MoHFW, 2019), there is an ongoing debate on the exact status of iodine, iron, Vitamin A, Vitamin D deficiencies and anaemia among children and adolescents under 19 years of age. Further, ICMR-NIN has recently proposed nutrient requirements for Indians as three reference values, viz., Estimated Average Requirements (EAR), Recommended Dietary Allowances (RDA) and Tolerable Upper Limits (TUL) (ICMR-NIN 2020a). The current fortification standards by the Food Safety and Standards Authority of India (FSSAI) are based on a single reference value that is RDA recommended by the ICMR-NIN in 2010. Hence, there is an urgent need to consider new information for formulation of the strategies to prevent and control deficiencies of multiple micronutrients. This will help addressing the debate (i) whether layering of different strategies for combating micronutrient deficiencies and evolving food fortification standards based on the gap between the dietary intake and requirement of micronutrients is an appropriate strategy, and (ii) whether there is a need for fortification of a single or multiple food vehicles (Kurpad et al., 2021).

1.1. Dietary Deficiencies

Several studies from the ICMR-National Nutrition Monitoring Bureau (NNMB), the CNNS, The EAT-Lancet Commission on Food, Planet and Health 2019, and The State of Food Security and Nutrition in the World show that the cereal-based Indian diets are acutely deficient in micronutrients, particularly, iron, zinc, and Vitamins A, B2, B12, D and folic acid (NNMB 2012, 2016; FAO, IFAD, UNICEF, WFP and WHO, 2020 and 2021; Sharma et al. 2020). The intake of micronutrient-rich foods such as pulses, vegetables, fruits and animal products is low. The mean percentage energy intake from various food groups in urban and rural India by adults and My Plate recommended by the ICMR-NIN is now available for comparison (ICMR-NIN, 2020b).

1.2. Extent of Biochemical Micronutrient Deficiency

The CNNS, supported by the Ministry of Health and Family Welfare (MoHFW) of the Government of India, the UNICEF, and the Population Council, is the most recent source of information on undernutrition among children and adolescents in India. This is for the first time that such a large

scale survey on micronutrients was conducted using the gold standard methods to assess the incidence of anaemia, micronutrient deficiencies and NCDs. The survey results clearly show that despite significant economic progress, the problem of undernutrition still remains in India (MoHFW, 2019).

Table 1 presents CNNS findings on the prevalence of anaemia and iron, folic acid, zinc, Vitamins B12, A and D deficiencies among children and adolescents in India (MoHFW, 2019). The prevalence of anaemia is lower in the Southern and Northern states than in the Central, Western and North Eastern states. The adolescents, particularly girls, are more iron-deficient. Also, there are marked inter-state differences in the deficiencies of these micronutrients. Compared to the CNNS estimates (Sarna et al., 2020), a higher prevalence of anaemia has been found among pre-school children in the repeat NFHS surveys (> 50% in NFHS 3 in 2005-06 as well as in NFHS 4 in 2015-16, and 67% in NFHS 5 in 2019-21). The difference could be due to differences in the methodologies adopted for blood sampling and hemoglobin analysis.

Table 1 Prevalence % of micronutrient deficiencies in India

Micronutrient deficiency	Pre-school age children	School age children	Adolescents
Anaemia	40 (Highest in children under 2 years)	24	28 Female 40; Male 18
Vitamin A	18	22	16
Vitamin D	14	18	24
Zinc	19	17	32
Folate	23	28	37
Vitamin B12	14	17	31

Source: MoHFW, 2019

The pregnant women and children are at a greater risk of micronutrient deficiencies. This is a result not only of the low dietary intake, but also because of higher physiological nutrient requirement. The pregnancy and childhood development— a period of rapid growth, often increases the demand for specific Vitamins and minerals. The previous periodic NNMB surveys indicate lack of dietary diversity as the leading cause of micronutrient deficiencies, especially iron, Vitamin A, and B-Vitamins.

1.3. Economic Accessibility to Protective Foods

The poor economic access to micronutrient dense protective foods is the major factor for their low intake. In India, farming is the major source of income for more than 40% of the households. In the context of nutrition, homestead farming of micronutrient-dense crops like vegetables, fruits, pulses, and millets, and of animals including the backyard poultry, dairy and fishery can significantly contribute to diversification of food and thus improve the nutrient intake. Promoting consumption of diversified diet was the theme of the Poshan Maah (Nutrition Month) Celebrations in September 2021.

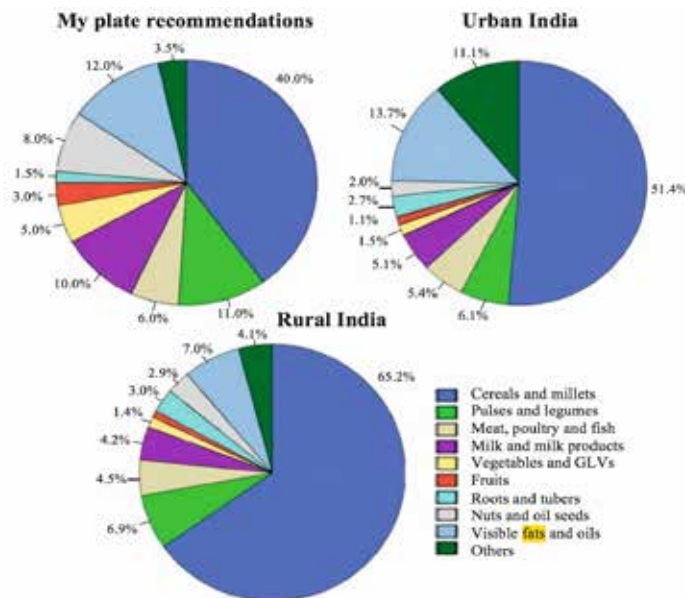
Given this background, there is a need to assess the micronutrient gap between the requirement and intake of micronutrients from the habitual diets and fortified foods. While defining the micronutrient adequacy (even if it is 98%), the goal is to assure that the levels of micronutrients added are safe and efficacious for all the population groups consuming fortified foods. For this, it is critical to look at the method to estimate, if a given fortification strategy is safe and efficacious for most individuals of the populations consuming fortified foods. The same method can also be used for monitoring and evaluating the adequacy of nutrient intake.

In this backdrop, this paper deliberates on the following issues:

- Adopting the new norms of nutrient requirements and recommended dietary allowances (ICMR-NIN, 2020a) for public health and nutrition, especially for setting the standards for fortification of staple foods.
- Contextualizing the recommendations in the light of the nationwide study on the status of the micronutrients (anemia, iron, Vitamin A and D, folic acid and Vitamin B12, and iodine) among 1-19 years old children and adolescents (MoHFW, 2019) and the diet and nutrient survey of NNMB conducted in 2012 and 2016.
- Positioning of the existing fortification strategy in terms of voluntary versus mandatory fortification.

2. FOOD FORTIFICATION: PRESENT STATUS AND EXISTING POLICY

2.1. Micronutrient Deficiencies: Current Situation of Dietary Intake and Prevalence of Deficiencies



Note: Other foods include chips, biscuits, chocolates, sweets and juices

Figure 1 : Mean percent of energy from various food groups in adults (ICMR-NIN, 2020b)

Figure 1 presents an ideal 'My food plate' recommended by the ICMR-NIN. It depicts the percentage energy contributions of 10 food groups, and compares these from the actual diets of the urban and rural people (NNMB, 2012, 2016; ICMR-NIN, 2020 a,b). The consumption of cereals, a source of energy, is 10-15% above the recommended level, but that of the protective foods, which provide most of the essential micronutrients, is below their recommended levels in both the rural and urban areas. Similar conclusions have been drawn from the EAT-Lancet Commission Report on Food, Planet, Health (Sharma et al., 2019). This report provides a comparison of the food consumption patterns in India for different income groups from rural and urban areas, with the EAT-Lancet reference diet. The analysis is based on the data from the Consumption Expenditure Survey (CES) of a nationally representative sample of 0.102 million households from 7469 villages and 5268 urban blocks of India conducted by the National Sample Survey Organization (NSSO) in 2011-12. The analysis shows that consumption of fruits, vegetables, legumes, meat, fish and eggs are significantly lower. The share of calories from the protein sources was only 6 to 8%, compared to 29% in the reference diet. Interestingly, the deficits although are larger for the poor households, the rich households also do not consume adequate quantities of vegetables, fruits and non-cereal protein foods.

There is no dispute that food fortification is a proven approach for addressing the dietary inadequacies of micronutrients like iodine, and Vitamins B1 and B2. India has successfully implemented the mandatory use of iodine fortified common salt (since 1989) and reduced the prevalence of iodine deficiency disorders (IDD) below the public health significance level. This has been achieved in a very systematic way, initially by conducting studies in goiter endemic locations to prove the efficacy and effectiveness of iodine fortification, then testing the strategy in other locations, and finally making the use of iodised salt mandatory with monitoring and risk assessment mechanisms in place. It is north-noting that iodine has limited dietary sources, and therefore, fortification was made a universal strategy (The Gazette of India, 2018).

The dietary intake and inadequacy of micronutrients, for example iron, folic acid, and Vitamins B12, A, and D have not been quantified in any nationally representative sample. India has relied on the prevalence of anaemia in vulnerable segments of the population (rather than status of iron and other hematinics - folic acid and Vitamin B12), Bitot's spot and serum Vitamin A levels in pre-school children, and sporadic data on serum Vitamin D status, and designed its strategies to control their deficiencies rather than understanding and using systematic and pan India micronutrient deficiency prevalence rates. Due to widespread prevalence of anaemia among vulnerable groups, a lifecycle approach for iron and folic acid supplementation (NIPI, 2013) and a massive dose Vitamin A supplementation program for children under 6 years have been in operation for many years.

2.2. Staple Food Fortification FSS (Fortification of Foods) Regulations, 2018

Based on the ICMR-NIN 2010 nutrient requirements, recommended dietary allowances for Indians, the Dietary Guidelines for Indians 2011, and the prevailing evidence on the intakes and deficiencies of micronutrients, the FSSAI has set standards for fortification (Table 2) of staple foods (Nair and Augustine, 2016; Nair, 2019; Gazette of India, 2018). Rice fortification standards were operationalized in 2016 and published in the Gazette of India in 2018. Many states are exploring

scaling up of the rice fortification through safety net programs (Gol, 2020a). In recent times, efforts have been made to include the food fortification as an add-on and mandatory. A critical evaluation of the impact of the existing strategies and the need for layering yet another strategy to correct the deficiency of the same micronutrient is essential before embarking on layering of a new strategy that too as mandatory fortification, for example, rice with iron and other micronutrients.

Table 2: List of vehicles and micronutrients for which standards have been set by FSSAI

Food vehicle	Micronutrients
Salt	Iron fortified iodized salt
Whole wheat flour (Atta)	Iron, folic acid and Vitamin B12
Maida	Iron, folic acid and Vitamin B12
Rice	Iron, folic acid and Vitamin B12
Milk	Vitamin A and Vitamin D
Oil	Vitamin A and Vitamin D

Source: Gazette of India (2018)

2.3. Staple Food Fortification - Voluntary versus Mandatory Fortification

Any policy on the voluntary or mandatory fortification should take into account several factors. For instance, the CNNS survey results on micronutrient status among different socio-economic groups are lower than earlier reports and is a serious concern. It is often argued that despite improvements in food production and supply, the level of malnutrition has almost been static in the country. Most of the malnutrition is attributable to the lack of dietary diversity in the habitual diets of the people of different socio-economic groups. A minimum diversity of foods from 8 food groups is recommended to meet the daily requirements of the micronutrients (ICMR-NIN, 2020b). While the cost of a diversified diet, and its affordability and accessibility remain critical, there are other factors beyond the control of the common man.

India is in an enviable position on account of buffer stock of cereal grains, especially rice, and it helped the Government to ably ensure food availability for the people who need the most during the Covid-19 pandemic. Currently, cereals are a major constituent of the Government's social feeding programs such as the PDS, MDM and ICDS food supplement. There is a perception that micronutrient fortification of the staples, if dovetailed with such large-scale distribution, can help addressing the deficiency of multiple micronutrients. Some experts argue that this is an unsubstantiated perception (Box 1).

Box 1 Voluntary vs mandatory fortification of foods: Gaps in information and evidence

1	Universal micronutrient fortification as a public health strategy to combat anaemia and other micronutrient deficiencies need robust evidence. It needs careful contextual consideration.
2	India has limited experience with large-scale effectiveness studies with the iron fortified rice. There are only four trials done on the impact of iron fortified rice on biomarkers of iron status among school children. This was also done by replacing rice in a standard meal with fortified rice in school settings. Even in these trials, the impact on iron biomarkers was not uniform. Though it improved liver iron stores, there was minimal impact on hemoglobin levels, and thereby on the prevalence level of anemia. The implications of this at scale are difficult to ascertain (Radhika, 2011; WHO, 2018).
3	Global evidence based on the information available from a Cochrane systematic review to inform on the effect of rice fortification on micronutrient status concluded that: Fortification of rice with iron alone or in combination with other micronutrients probably improves the iron status, by reducing the risk of iron deficiency by 35% and by increasing the mean haemoglobin concentrations by about 0.2g/dL, but it makes little or no difference to the risk of anaemia in general (Ashong et al, 2012; WHO 2018). This may be even due to poor bioavailability of iron from fortified rice.
4	Food diversity is a long-term strategy, which ensures the availability of nutrients such as Vitamin C that enhance bioavailability of iron and other micronutrients. Inclusion of fruits rich in Vitamin C in the diets should be considered as a core strategy for Anaemia Mukht Bharat (Nair et al. 2013; Choudhury et al., 2020).
5	There is a possibility that the same nutrient is provided through various foods or supplements (layering) under different safety net programs in India, hence there is concern about its intake exceeding the upper tolerable limit (Gol, 2020 a & b; Kurpad et al., 2021; Ghosh et al., 2021).
6	The consequences of cereal consumption which accounts for 50-60% of the total energy intake in a day in urban and rural areas as against the recommended 40% by the ICMR-NIN for 'My plate for the day', is a matter of concern to the public health professionals (ICMR-NIN, 2020b).

3. REVISED NUTRIENT REQUIREMENTS FOR INDIANS: IMPLICATIONS FOR FORTIFICATION STANDARDS

3.1. Estimated Average Requirement (EAR) as the Recommended Unit of Dietary Requirement of Micronutrients

The ICMR-NIN Expert Group on Nutrient Requirements for Indians, Recommended Dietary Allowances (RDA) and Estimated Average Requirements (EAR) -2020, are the latest version of the national-level nutrition metrics for policy and regulation on public health nutrition (ICMR-NIN 2020a). In this, the methodologies for arriving at the nutrient requirements have been revised and

are different from the earlier Recommended Dietary Allowances (RDA) (ICMR-NIN 2010). The present version of the ICMR-NIN 2020 nutrient requirement relied on internationally harmonized methodology for computation of the nutrient requirements (Nair and Augustine, 2018; Allen et al 2020).

The term nutrient requirement indicates the least amount of the absorbed nutrient that is necessary for maintaining normal physiological functions of the body of practically all healthy people. The requirement of a nutrient varies across individuals. In any given population, it follows a normal distribution. There has been an ongoing debate in applying a unified single nutrient requirement value in public health nutrition for evaluating intake adequacy/inadequacy of the nutrient for the population and for the national food regulatory authority FSSAI for guiding product formulation and labeling of pre-packaged foods.

The ICMR-NIN 2020 document provides details regarding the scope of applying the three widely used single nutrient values, EAR, RDA and TUL (Box 2).

Box 2: Nutrient requirements: EAR, RDA AND TUL

1	The median of the requirement distribution is the estimated average requirement (EAR).
2	The EAR+2SD of spread of the distribution, which represents the 97.5 th percentile of the distribution is the Recommended Dietary Allowance (RDA).
3	The Tolerable Upper Limit of Intake (TUL) is the maximum amount of daily Vitamins and minerals that one can safely take without risk of an overdose or serious side effects.

By definition, EAR represents the average daily intake of a nutrient that will meet the nutritional needs of 50% of the healthy individuals at each life stage. When assessing the health and nutritional status of the population, EAR is recommended as the unit for computation of requirement and intake. In elite populations, the requirement and intake distributions should overlap. In practice, we need to verify whether the same is true or not for all sub groups, to know the actual gap between the requirement and intake, to compute the prevalence of inadequacy (PIA), and to decide the fortification levels for all nutrients.

RDAs are the levels of intake of nutrients that are judged to be adequate to meet the nutrient needs of practically all healthy people. However, if the RDA is set as a nutrient intake metric at the community level, there is a risk of prompting excess intake since each individual below the requirement distribution may not actually require as much. It will not meet the requirement of 2.5% of the population sub-group (Figure 2).

TUL refers to the highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. Currently, several foods are being fortified with micronutrients and the risk of adverse effects will increase, if the intake crosses the TUL.

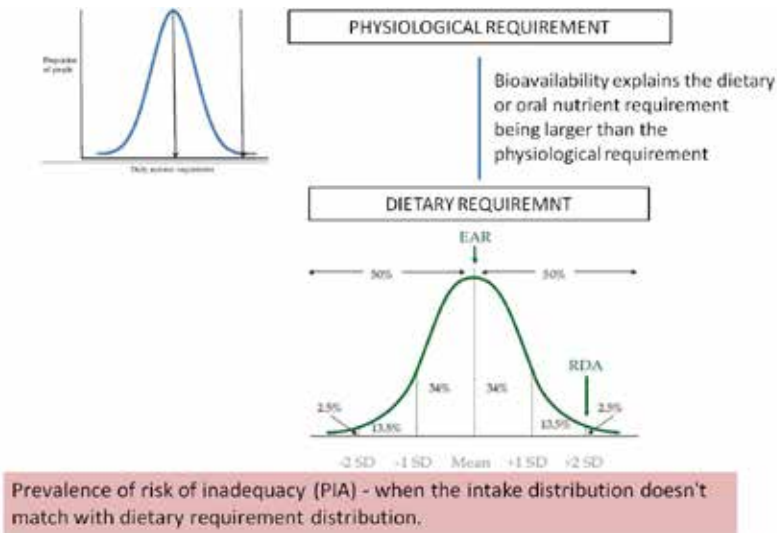


Figure 2 : The Estimated Average Requirement (EAR) and Recommended Dietary Allowance (EAR+2SD=RDA)

3.2. Estimated Average Requirement (EAR) - the Recommended Unit of Dietary Requirement of Micronutrients and Defining Fortification Standards: There is an ongoing debate in applying a unified single nutrient requirement value in public health nutrition, for evaluating intake adequacy/inadequacy of a nutrient for a population, and for guiding product formulation and labeling of pre-packaged foods.

4. STAPLE FOOD FORTIFICATION

There are two critical parameters that guide determination of an optimum quantity of micronutrients in food fortification: (i) the *maximum* permissible proportion of the population at risk of inadequate micronutrient intake after consumption of the fortified food, and (ii) the *minimum* permissible proportion of population that would be at risk of excess micronutrient intake after consumption of the fortified food.

4.1. Metrics of Food Fortification at Population Level

The major issue with staple food fortification is setting standards based on the new nutrient reference values (ICMR-NIN, 2020a). For computing fortification levels, there should be a scientific basis based on the principles and methods. One important principle to be kept in mind is the long-term safe use levels of micronutrients for fortification. In this context, it needs to be noted that due to technological advancement in food fortification, the availability of multiple fortified foods is gradually increasing. Moreover, with appreciation of the widespread multiple micronutrient deficiency in India, multiple interventions (supplementation, fortification of multiple staple foods, including pre-packaged foods and beverages) have been introduced that possibly reach the same population group concurrently. For example, the consumption of iron fortified iodised salt (DFS), iron fortified rice and wheat flour, and other pre-packaged fortified products such as biscuits and

beverages concurrently may lead to iron intake above the TUL, which is not a healthy practice. There is a reasonable ground to suspect that concurrent consumption of multiple iron fortified food may pose risk to health. A study is required to be commissioned to generate evidence. Consumption of the same micronutrient (iron) from different sources is likely to put some populations at a risk of consumption levels that go beyond or closer to the TUL (for iron, TUL is 40-45 mg). This may be compounded further by the programmes for control and prevention of micronutrient deficiency, for example Anaemia Mukh Bharat that provides iron folic acid supplements as per the prescribed dosage through the life cycle.

Taking this into consideration, a method needs to be developed that should allow easy computing of an optimum level of micronutrient for considering it in setting the standards by the FSSAI. This method should also help monitor the long-term changes in intake from multiple sources and avoid layering of strategies. This is a critical agenda, as precision needs to be exercised to reduce or prevent the metabolic disease (based on biomarkers), the consequence of which is difficult to ascertain at present but deserves abundant caution.

Metabolic disease is defined as any of the diseases or disorders that disrupt normal metabolism — the process of converting food to energy at a cellular level. A multitude of enzymes participating in numerous interdependent metabolic pathways carry out this process. The functions of these enzymes are influenced by various types of minerals and Vitamins. The metabolic diseases affect the ability of the cell to perform critical biochemical reactions that involve the processing or transport of proteins (amino acids), carbohydrates (sugars and starches), or lipids (fatty acids). Literature presents some evidence on the association between increased iron/serum ferritin concentration and diabetic risk (Simcox and McClain, 2013; Ford and Cogswell, 1999), dyslipidemia in Korean adolescents (Kim et al., 2016), hypertension in Korean men (Lee et al., 2018) and sex-specific association of ferritin level and risk of type 2 diabetes (Jiang et al., 2019). Probing iron status and its association with markers of non-communicable diseases in Indian children has also raised concerns that cautions against layering of interventions to address anaemia among vulnerable populations (Ghosh et al., 2021). Further, Ghosh et al.(2022) have suggested rationalizing estimates of the deficit/gap between the requirement and dietary intake of micronutrients for fixing standards for food fortification.

4.2. Standards for Micronutrient Fortification of Staple Foods: WHO Recommendations

WHO recommends use of the three metrics, EAR, RDA and TUL to quantitatively derive nutritional parameters and describes the process of deciding on a specific food fortification level with a specific nutrient. WHO has developed statistical software for computing the levels of micronutrients for staple food fortification and has adopted EAR as a basic metric for arriving at the fortification levels. However, WHO suggests that the adequacy of micronutrient intake would exist only when intake distribution crossed EAR to the right as shown in Figure 3 (adopted from WHO-FAO 2006). It was suggested that implementation of this method for fortification might shift the median intake much above the RDA. Further, the intake among a large segment of the population also may shift beyond the TUL.

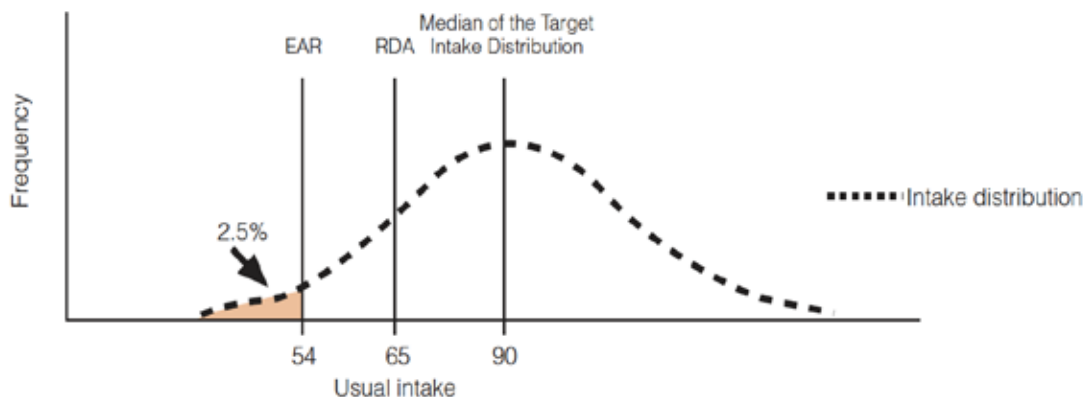


Figure 3 : An example of a usual intake distribution in which 2.5% of the group have intakes below the EAR. WHO Recommended method (WHO-FAO, 2006)

4.3. Nutrient Reference Value (NRV) for Nutrition Labelling of Pre-packaged Foods: Codex Recommendations

The EAR as a nutrient reference value (NRV) for a population was also considered and recommended by the Codex. However, it currently recommends 98th percentile of the nutrient requirement distribution (Individual Nutrient Level 98 or INL 98 similar to the RDA) as the NRV. The reason is that the INL 50 (or EAR) is not as widely published as the INL 98 (Lewis, 2019).

4.4. Standards for Micronutrient Fortification of Staple Foods: National Recommendations

During the brainstorming session, there was detailed deliberation on the available options of EAR and RDA, and it was expressed that since EARs for the Indian population are available, the food regulators should consider it as the most appropriate metric. In this context, a statistical software has been developed and used for computation of the fortification levels (the software was developed by Prof Anura V Kurpad & Dr Santu Ghosh, Department of Biostatistics, St. John’s Medical College, Bengaluru). The analysis estimated the prevalence of inadequacy (PIA) of each micronutrient by assessing intake distribution of 39 age/gender/physiological/ activity groups and three economic strata —low, middle and high income groups. NNMB diet and nutrient intake of both rural and urban India formed the basis (Ghosh et al, 2022). The five steps suggested by the group of experts in a national webinar could be considered for guiding the standards for fortification (Box 3)

Box 3 The five steps involved in deciding on a specific food fortification level with a specific nutrient

	Processes involved
Step 1	Observe the usual distribution of micronutrient intakes in specific population subgroups. Identify which population subgroups (based on age and sex) have the highest prevalence of inadequate intake (PIA) of micronutrient
Step 2	If the PIA of any population sub-group is <50%, calculate the minimum additional micronutrient intake required to bring the prevalence of inadequacy (PIA) of all such sub-groups close to 50% from the current level of intake (pre-fortification) by an iterative process (a process of repeated trial-and-error style cycles, where researchers adjust each cycle according to what they learned in the previous iteration).
Step 3	Estimate the distribution of the usual consumption of the chosen food vehicle for fortification (cereals, salt, milk and oil) by this group.
Step 4	By simulation select an appropriate level of fortification in the chosen vehicle so that PIA is nearer to 50%, and proportion at risk of having intake more than TUL is less than 1%, so that the fortification level of selected micronutrient is safe to the extent of 99%.
Step 5	Calculate the reduction in the PIA that would be expected to occur in all the 39 sub-groups of the population at this level of fortification.

5. CHANGES IN THE FORTIFICATION STANDARDS BASED ON THE ICMR-NIN 2020

5.1. Existing and Proposed Standards for Staple Food Fortification

Five micronutrients namely, iron, folic acid, and Vitamins B12, A and D that have set standards using ICMR-NIN 2010 nutrient reference value of 2018 were considered. The micronutrients, vehicles and fortification levels gazetted by the FSSAI 2018 are provided in Table 2. Discussion centred on five micronutrients and possible ways to address these were proposed (Box 4).

Box 4 Existing and proposed standards for iron fortified cereals and salt

	Level of fortification (per Kg)		Issue: Single vs Multiple layering of iron fortified cereals and salt + supplement iron and folic acid (IFA) on weekly basis	Way forward
	Existing	Proposed		
Rice	28-42.5 mg*	28-42 mg	<ul style="list-style-type: none"> Introduction of iron fortified salt and cereals concurrently increase the risk of intake above TUL of 45 mg. The risk is the highest among boys and men who consume cereals above 250 g. Currently iron fortified iodized salt is not in the urban market and is being introduced in government nutrition programmes (ICDS, MDM and for certain types of Ration card holders). 	<ul style="list-style-type: none"> Existing standard for iron for salt and cereal fortification be retained A caveat be added in the FSSAI regulation that “only one food can be used as a vehicle for fortification at a time”.
Wheat flour	28 mg-42.5 mg*	28mg-42 mg		
Salt	850-1100 ppm	1.0 ±20%, 0.8-1.2 mg/g		

			<ul style="list-style-type: none"> We did not model in IFA iron intake, but considering 60 mg/week, a value of 8 mg/day, is close to the minimum additional iron requirement of 7.5 mg/day for 50% PIA. Thus, if the population (adolescent girls and women of reproductive age) was taking IFA at 100% compliance, there is no need for iron fortification, as one will replace the other. If we assume 50% compliance that gives 4 mg of iron from IFA, then we need half the “minimum requirement” that will give a fortification level of ~18 mg/kg for cereals (round off to 20), and about 0.5 mg/g for salt. 	<ul style="list-style-type: none"> A cautionary statement about limiting the use of iron fortified products when on IFA supplementation, may also be included.
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Box 5 Existing and proposed standards for folic acid in fortified cereals

Level of fortification (per Kg)		Issues	Way forwards
Existing	Proposed	<ul style="list-style-type: none"> Some groups have PIA and some have risk of excess, particularly young children. If we lower the fortification, it may reduce but the PIA will not decrease adequately. Fortification should not be suggested. 	<ul style="list-style-type: none"> Folic acid should be supplemented taking a targeted approach.
75 µg- 125 µg	No Proposal		

Box 6 Existing and proposed standards for Vitamin B12 in fortified cereals

Level of fortification (per Kg)		Issues	Way forward
Existing	Proposed	<ul style="list-style-type: none"> The PIA is not changing uniformly with the computed level of Vitamin B12 fortification. 	<ul style="list-style-type: none"> The effectiveness of @ 8.1 µg/Kg level of addition for improving Vitamin B12 status needs to be determined and monitored. In addition, further research should evaluate the bioavailability of Vitamin B12 from fortified cereals.
0.75 µg- 1.25 µg	No fortification or @ 8.1 µg/kg of cereals with more research		

		<ul style="list-style-type: none"> Issue of very high PIA in children, which is not in line with the current estimates of the prevalence based on biomarker among 0-19 years (CNNS). Prevalence of Vitamin B12 deficiency among children below 10 year was the lowest compared to children >10 year (17% under 10 year compared to 31% among 10-19 years) and also many states had B12 deficiency in the range of 0- 10 % (Kerala, Nagaland, Southern and Northeastern states). Also, where Vitamin B12 fortification is implemented, the recommendation is to add 20 µg/Kg flour, assuming consumption of 75 to 100 g flour per day, to provide 75% to 100% of the EAR. 	<ul style="list-style-type: none"> More research is required to establish Vitamin B12 requirements/ bioavailability/ endogenous source like in gut. Recommended no fortification of cereals with Vitamin B12 and suggested targeted supplementation.
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Box 7 Existing and proposed standards for Vitamin A in fortified oil

Level of fortification (µg Retinol Equivalent (RE) per g of oil)		Issue: Oil intakes are so low and therefore considered the prescribed oil intake for each group based on ICMR-NIN 2020a. Oil and milk are being fortified.	Way forward <ul style="list-style-type: none"> Only oil fortification at the existing level
Existing	Proposed	<ul style="list-style-type: none"> The spread of intake is high even at habitual intaks (and the TUL relatively low). That is more than 0.5% of the population was exceeding TUL even at habitual intake, in many groups 	<ul style="list-style-type: none"> Matches with the existing standard of fortification of oil. Continue with the existing level. Vitamin A should be fortified in oil at 7-8µg/g oil.
6 µg RE- 9.9 µg RE per g of oil	7µg±20% tolerance limit 6.4 µg- 8.4 µg per g of oil		

Box 8 Existing and proposed standards for Vitamin D in fortified oil

level of fortification (µg per g of oil)		Issues: Oil and milk fortified with Vitamin D	Way Forward
Existing	Proposed: 2µg±20% tolerance limit	<ul style="list-style-type: none"> No intake data available. Tropical country and 20 minutes of skin exposure per day (arms and face) is usually sufficient to provide the body with all the Vitamin D it needs. Uncertainty about the contribution of sun exposure to overall Vitamin D nutrition in Indians poses difficulty for estimating the dietary requirement of Vitamin D. Due to close interaction between calcium and Vitamin D, the requirement of Vitamin D varies with the dietary calcium intakes, especially for the bone health outcomes 	<ul style="list-style-type: none"> Fortification range from 0.16-0.24 µg/g oil, which is close to the existing standard and oil is the only vehicle
0.11µg - 0.16µg Vitamin D per g of oil	0.16µg -0.24 µg per g of oil		

5.2. Monitoring

Given the complex interactions between what India eats and the health of its people, precision in the levels of nutrient intake is of utmost importance. Public policies are in place to combat undernutrition and specific micronutrient deficiencies. There seems a lack of information on coverage of various interventions as well as on convergence of these interventions to unify and make them holistic for promoting the health of the nation. As a result, these multiple interventions may be getting layered one over the other for the same economic section of the society. Continuous monitoring of fortified/supplemented intake and of biomarkers of excess is absolutely critical for risk assessment to tailor the fortification levels sustainably and for promoting the health of the population. Good quality metrics and measurement tools are the key to collect data on outreach, output, outcome, and impact of interventions with fortified foods. This is important for different stakeholders, including public and private health system, agri-food manufacturers, policymakers and academicians involved in program evaluation and research, to monitor the progress of program implementation.

6. SUMMARY OF RECOMMENDATIONS

Implementing nutrition-sensitive interventions are key challenges for achieving the Sustainable Development Goals by 2030. To lead productive lives, we need good **nutrition**, and for this, food diversity is a must. This, in turn, can be achieved by adhering to the recommendations of “My plate for the day”.

Taking into consideration revised nutrient requirements and recommended dietary allowances for Indians, their contextualization in the light of the emerging scientific evidence on the status of the micronutrients and the basis for repositioning the existing fortification strategy, the following recommendations merit attention:

1. Dietary diversification is a sustainable strategy to address holistically the problem of malnutrition, including the micronutrient deficiencies. Better strategies, for educating the public, particularly women and children, through behavioural change communication are needed to get the best results.
2. India needs to implement micronutrient fortification appropriate, based on the evidence of dietary inadequacies. There should be a complementary and precise strategy along with the dietary diversification,
3. Fortification of each micronutrient be dealt separately based on the contextual factors.
4. Fortification should be discouraged if there is an ongoing universal supplementation program of specific nutrients (eg., iron in Anaemia Mukd Bharat).
5. Restrict fortification to one food (vehicle) per nutrient rather than layering multiple vehicles as to steer clear of the safety issue, particularly with respect to iron and Vitamin A.
6. Use edible oil as a vehicle for Vitamins A and D, and salt for iron.
7. Close monitoring for addressing the risk and benefit in the context of evidence on the rise in biomarkers of iron vis-à-vis NCD is needed.
8. Short- and long-term monitoring mechanisms need to be established on the impact of food fortification on health and toxicity.
9. There is a need for contemporary and representative data on dietary intakes and prevalence of functional/biochemical deficiency across all age groups.

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LIST OF PARTICIPANTS

1	Dr Ramesh Chand, FNAAS & Member, NITI Aayog	rc.niti@gov.in;rcncap@gmail.com
2	Dr Pramod Kumar Joshi, Secretary, FNAAS	pkj.ncap@gmail.com
3	Dr (Ms) Mahtab S. Bamji. FNAAS	msbamji@gmail.com
4	Dr (Ms) Kamala Krishnaswamy, Former Director ICMR-NIN, FNAAS	kamalakrishnaswamy@gmail.com
5	Dr Vishweshwaraiah Prakash, Former Director, CSIR-CFTRI, FNAAS	prakashvish@gmail.com
6	Dr Narayan Bhaskar, Advisor (Science and Standards), FSSAI, New Delhi, FNAAS	bhasnarayan@gmail.com
7	Dr K Madhavan Nair, FNAAS (Convener)	nairthayil@gmail.com
8	Dr Subbarao M Gavaravarapu, FNAAS	subbarao.gm@icmr.gov.in; gmsubbarao@yahoo.com
9	Dr R Hemalatha, Director, ICMR-NIN	rhemalathanin@gmail.com
10	Dr A Laxmiah, Scientist-G, ICMR-NIN	laxmanavula09@gmail.com
11	Dr N Arulappa, Scientist-F, ICMR-NIN	arlappan@yahoo.com
12	Dr P Rahgu, Scientist-F, ICMR-NIN	raghu_nin2000@yahoo.com
13	Dr G. Bhanuprakash Reddy, Scientist-G, ICMR-NIN	geereddy@yahoo.com
14	Dr (Ms) Pasala Geervani, FNAAS	pgeervani@gmail.com
15	Prof. (Ms) Jamuna Prakash, FNAAS	jampr55@hotmail.com
16	Dr Prema Ramachandran, Director, NFI, New Delhi (Chairperson- Nutrition and Fortification)	f1prema@gmail.com
17	Prof. Anura Kurpad, Prof. & hod, Physiology. St. John's Medical College, Bengaluru	a.kurpad@sjri.res.in
18	Maj. Gen. Dr R.K. Marwaha, Former Additional Director, INMAS, DRDO, Consultant Endocrinologist and President Society for Endocrine Health of Elderly, Adolescents and Children	marwaha_ramank@hotmail.com
19	Dr Rajan Shankar, Senior Advisor - Nutrition, TATA Trust	rsankar@tatatrusters.org
20	Dr Sheila Vir, Public Health Nutrition Consultant Director, Public Health Nutrition and Development Centre , New Delhi	sheila.vir@gmail.com
21	Dr Kapil Yadav, Associate Professor, Centre for Community Medicine, AIIMS, New Delhi	dr_kapilyadav@yahoo.co.in, dr.kapilyadav@gmail.com
22	Dr Santu Ghosh, Department of Biostatistics, St. John's Medical College, St. John's National Academy of Health Sciences, Bengaluru	santu.g@stjohns.in
23	Dr D B. Anantha Narayana, Former Chairman, HPCDC, Indian Pharmacopoeia Commission & Chairman, Scientific Panel Nutraceuticals, FSSAI	dba.narayana@gmail.com

24	Dr Bharati Kulkarni, Scientist-F, ICMR-NIN	dr.bharatikulkarni@gmail.com
25	Prof. HPS Sachdev, Sitaram Bhartiya Institute of Science and Research, Delhi	hpssachdev@gmail.com
26	Dr Sumit Arora, Principal Scientist NDRI, Karnal	sumitak123@yahoo.com
27	Dr RBN Prasad, Chief Scientist &Head (Rtd.), Centre for Lipid Research, CSIR-IICT,Hyderabad	rbnprasad@gmail.com
28	Dr Jagmeet Madan, National President, Indian Dietetic Association	dr.jagmeetmadan@gmail.com
29	Dr Asna Urooj, Professor, Dept of Studies in Food science & Nutrition, University of Mysore	asnau321@gmail.com
30	Dr Seema Puri, Associate Professor, Department of Nutrition, Institute of Home Economics, University of Delhi	dr.seemapuri@gmail.com
31	Dr Sirimavo Nair, Professor in Foods and Nutrition, Dept. of Foods and Nutrition, Faculty of Family and Community Sciences, MS University of Baroda	sirinair@yahoo.com
32	Dr Preetam Mahajan, Assistant Professor, Department of Community Medicine, JIPMER, Karaikal Campus, Pondicherry	preetam3879@gmail.com
33	Prof. Molly Jacob, Professor, Department of Biochemistry, Christian Medical College, Bagayam, Vellore, Tamil Nadu	mjacob@cmcvellore.ac.in
34	Dr Rachita Gupta, National Professional Officer (Nutrition) at World Health Organization	guptarac@who.int
35	Prof. Rebecca Kuriyan, Professor & Head, Division of Nutrition, St. John's Research Institute, Bangalore	rebecca@sjri.res.in
36	Dr Deepti Gulati, Industry Chair, center for Food Fortification, NIFTEM	deepti50@gmail.com

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