Fortification : An Effective Way of Addressing Hidden Hunger

FSSAI Regulations on Fortification of Foods with special emphasis on Oil & Milk

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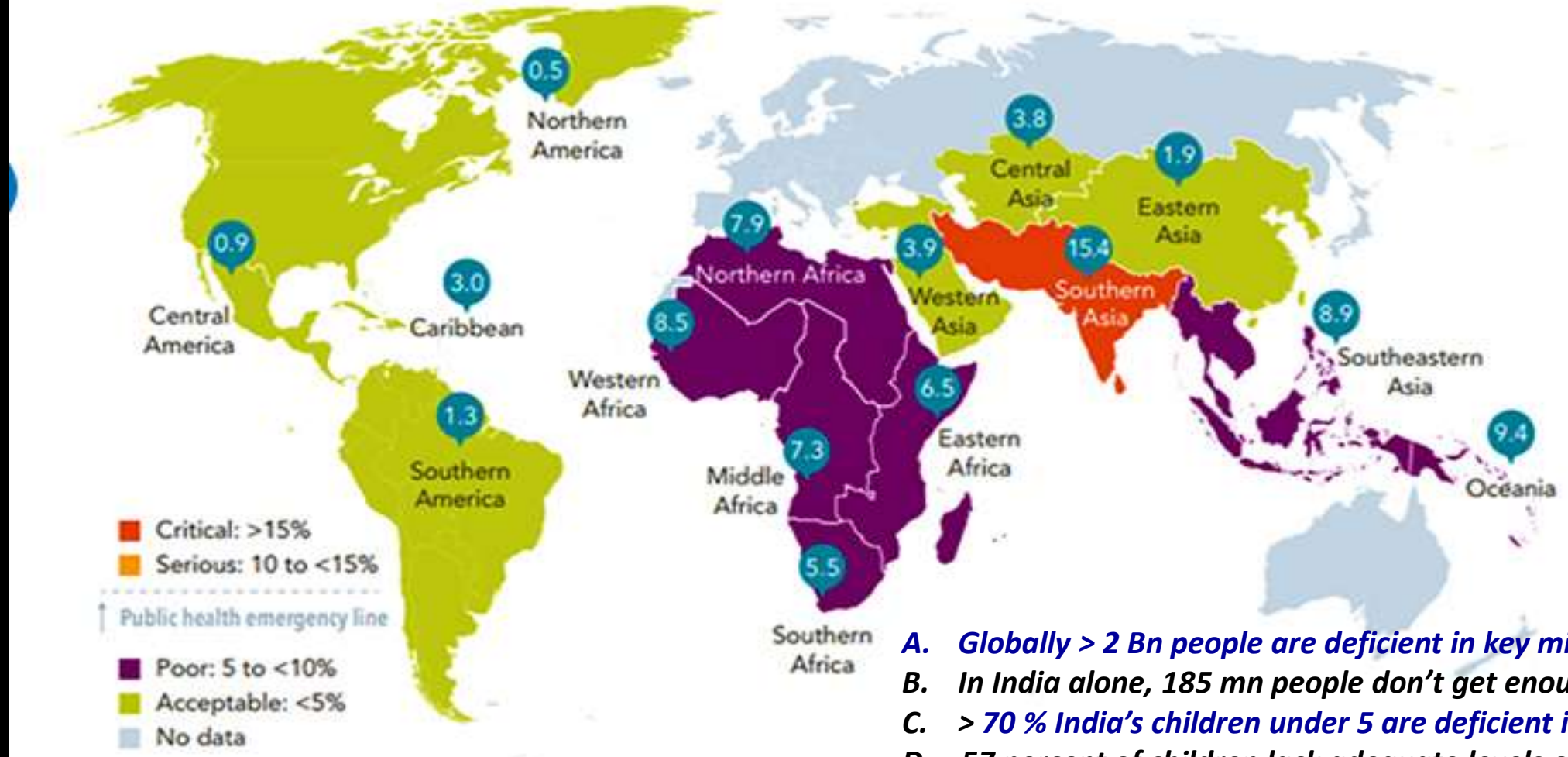
About Myself

- *Post Graduate in Chemistry having a rich 12+ years' experience in food industry.*
- *Handled multiple roles viz. Central Quality, Quality Assurance and Regulatory Affairs – Cavinkare, Hindustan Coco-Cola Beverages, Symrise and ITC Foods Division.*
- *Lead Auditor for FSSC 22000 requirements, Certified Sensory Leader and Internal Auditor for ISO 17025 requirements.*
- *Active Interests – Codex India activities – CCSCH, CCPR, CCCF and BIS activities – FAD 10, FAD 16, FAD 19.*
- *Member of CII, FICCI, AIFPA, PHDCCI, ASSOCHAM, ICMA, FBMI.*
- *Active representation in various Codex committees and NCCP meetings since 2016.*

GLOBAL MICRONUTRIENT DEFICIENCY (%age OF POPULATION)



A. *Globally > 2 Bn people are deficient in key micronutrients*
B. *In India alone, 185 mn people don't get enough nutrients*
C. *> 70 % India's children under 5 are deficient in Vitamin D*
D. *57 percent of children lack adequate levels of Vitamin A.*
E. *This lead to high levels of stunting, wasting and underweight*

Global micronutrient deficiency (as a percentage of the population). Two billion people in the world lack key micronutrients such as Vitamin A or iron. South Asia has the most critical malnutrition levels. Source: UNICEF

GLOBAL STATUS OF MILK and OIL FORTIFICATION

NUTRIENTS	CANADA	UNITED STATES	SINGAPORE	
VITAMIN A	Milk (1200 IU to 2500 IU)	Milk: Min. 2000 IU/Quat (Voluntary)	Margarine (Min. 8.5 mg RA/kg)	
VITAMIN D	Milk (300 IU to 400 IU)	Milk: Min. 400 IU/Quat (Voluntary)	Margarine (Min. 55 mcg of Cholecalciferol/kg)	
	MALAYSIA	SRILANKA	FSANZ	MALAYSIA
VITAMIN A	Margarine (2500-3500 IU/100 g)	Margarine (Min.7.5 mg/g)	NA	Filled Milk (670 IU/100 g)
VITAMIN D	Margarine (250-350 IU/100 g)	NA	Edible oil spread (Min. 55 µg/kg)	NA

Vitamin D 1 IU = 0.025 µg

1 IU Retinol = 0.3 µg Retinol Equivalents

A BRIEF OVERVIEW OF INDIA FORTIFICATION REGULATION

PART 1: GENERAL

Title	Notification date	Key Descriptions
Definitions	Aug 2018	• **Fortification:** *means deliberately increasing the content of essential micronutrients in a food so as to improve the nutritional quality of food and to provide public health benefit with minimal risk to health.* • **Fortificant:** *means a substance added to food to provide micronutrients but does not include nutraceuticals or food for special dietary use.* • **Fortified Food:** *means a food, as specified under FSSR (FPS&FA, 2011) that has undergone the process of fortification as per FSS (Fortification of foods) Regulations, 2018.* • **Micronutrients:** *means essential dietary nutrients including vitamins, minerals or trace elements that are required in very small quantities and are vital to development, disease prevention and wellbeing of human beings.* • **Staple Foods:** *means articles of food intended for mass consumption on a daily basis.*
	Dec 2020	• **Fortified Processed Foods:** *means processed foods (i.e. foods that have been altered from its natural state by industrial processing methods) that have undergone the process of fortification as per the provisions of these regulations. The same may have fortified staples as raw materials and/or fortified with permitted micronutrients and additives as specified under the FSS (FPS&FA) Regulations, 2011*

PART 2: STANDARDS ON FORTIFICATION

Title	Notification Date	Descriptions
General Principles	**Aug 2018**	1. Micronutrients may be appropriately added to foods for the purpose below: a) Preventing or reducing the risk of, or correcting, a demonstrated deficiency of micronutrients b) Reducing the risk of, or correcting, inadequate nutritional status of one or more micronutrients c) Maintaining or improving health, Nutritional quality of food and recommended intake of micronutrients 2. When fortification of food is mandatory, it shall be based on severity and extent of public health need ***Wherever "Iron (as Fe)" is used as a source of nutrient, heme iron shall not be used in any form.***
	Dec 2020	**1. The fortified Processed Foods shall provide 15 – 30% of the Indian adult RDA of micronutrient based on an average calorie intake of 600 Kcal from processed foods (Appx. 1/3rd of daily energy requirement for an adult) – THIS IS DENTING CLAUSE** 2. High Fat, Sugar, Salt (HFSS) Foods shall be excluded from Fortified Processed Foods category. The definition of HFSS foods shall have the same meaning as specified under the FSSR (Labelling and Display) 2020
	Dec 2020 (Draft)	**1. The packaged refined edible vegetable oil > 15 kg shall be fortified with Vit A & Vit D** **2. The packaged Toned, Double Toned, Skimmed Milk or Standardized Milk : Vitamin A and Vitamin D** **NO CLARITY FOR THE FOOD WHICH IS SOLD FOR B2B AND NOT FOR RETAIL SALE**
Micronutrient Compliance	**Aug 2018**	FBO shall ensure that the level of micronutrient in fortified food does not fall below minimum level specified in Schedule - I
	Dec 2020	FBO who fortifies any processed food shall ensure that the level of micronutrients in such fortified processed food shall fall within the range specified in Schedule – III

PART 3: GENERAL OBLIGATIONS

Title	Notification Date	Descriptions
Quality Assurance	Aug 2018	1. Every manufacturer and packer of fortified food **shall give an undertaking on quality assurance** and submit evidence of steps taken in this regard to the Food Authority or such other authority which Food Authority may designate. **2. The undertaking shall be given twice in a year and shall include following** a. Certification by a food laboratory notified by the Food Authority for compliance. b. Up-to-date record keeping and inventory of fortifications including the sources **c. Random testing of fortificants and fortified food** d. Regular audit of technical equipment and processes e. Purity criteria of micronutrients as per IP, BP, FCC, FAO or WHO Specification/Criteria
Packaging & Labelling Requirements	Aug 2018	**1. All fortified food shall be packaged in a manner so ensure the desired level of fortificants till the end of the shelf life.** **2. Mandatory Declaration : "Fortified with…(Name of the fortificant)" and the logo.** **It may also carry a tag line "Sampoorna Poshan Swasth Jeevan" under the logo.** **(Not required for Iodized Salt)** **3. All Provisions of the FSSRs (Packaging and Labelling), 2011 shall also apply to the fortified foods.** **4. Every package of food fortified with Iron shall carry a statement "*People with Thalassemia may take under medical supervision*."**
	Nov 2020 (Draft)	Every package of food, fortified with iron, shall carry a statement "*People with Thalassemia may take under medical supervision and persons with Sickle Cell Anemia are advised not to consume iron fortified food products*"

PART 3: GENERAL OBLIGATIONS – PROMOTION OF FORTIFIED FOODS

Food Authority shall

Organize public awareness, educate and advocate campaigns about benefits of fortified food and effect of malnutrition.

Equip laboratories and research institutions notified under the Act to conduct the nutritional analysis for fortified foods

Advise and promote the use of fortified food in Govt-funded programmes on distribution of fortified foods, in cooperation with concerned departments of the GOI / States / UTs.

Conduct technical assistance programs to FBOs to enable undertake fortification and take steps to encourage the production, manufacture, distribution, sale and consumption of fortified foods.

Fortified Oil

As per Fortification of foods Regulations, Vegetable oil shall be fortified with the following micronutrients, at the level given in the table below.

Nutrient	Level of Nutrient	Source
Vitamin A	6 ug RE – 9.9 ug RE / gm of oil	Retinyl acetate/Retinyl palmitate
Vitamin D	0.11 ug – 0.16 ug / gm of oil	*Cholecalciferol/*Ergocalciferol (*Only from plant source) **Animal source Vitamin D discouraged : Why?**

Note : Vitamin A (retinol): 1 IU= 0.3 µg RE (Retinol Equivalent); Vitamin D (Cholecalciferol or Ergocalciferol): 1 IU= 0.025 µg

RDA% contributions per gram of fortified oil: Vitamin A = 1 to 1.65% ; Vitamin D = 1.1% to 1.6% basis 2010 RDA Table.

As per draft notification dated 4.12.2020, Food Authority proposed for mandatory oil fortification with Vitamin A&D. I.e.: the packaged refined edible vegetable oil weighing not more than 15 kilograms shall be fortified with Vit A and Vit D and shall comply with the level specified in clause (2) of Schedule I

Fortified Milk

As per 2020 amendment regulations, Species identified milk (namely buffalo milk, cow milk, goat milk, sheep milk and camel milk), full cream milk, toned milk, double toned milk, skimmed milk and standardized milk, when fortified, shall be fortified with the following micronutrients at the level given in the table below, wherein the milk is to undergo the process of pasteurization, sterilization, ultra-high temperature sterilization / treatment or boiling.

Nutrient	Level of Nutrient per Litre	Source
Vitamin A	250 ug RE – 450 ug RE	Retinyl acetate/Retinyl palmitate
Vitamin D (*Plant source) - **Animal source Vitamin D discouraged : Why ?**	5 ug – 7.5 ug	*Cholecalciferol/*Ergocalciferol

Note : Vitamin A (retinol): 1 IU= 0.3 µg RE (Retinol Equivalent); Vitamin D (Cholecalciferol or Ergocalciferol): 1 IU= 0.025 µg

RDA% contributions per Litre of fortified Milk: Vitamin A = 41.7 to 75% ; Vitamin D = 50% to 75% basis 2010 RDA table.

As per draft notification dated 4.12.2020, Food Authority proposed for mandatory Milk fortification with Vitamin A&D for TM, DTM, Skimmed Milk and SM. I.e.: The Packaged Toned, double toned, skimmed milk or standardized milk shall be fortified with Vitamin A and Vitamin D and shall comply with the level specified in clause (3) of Schedule –I

NO CLARITY FOR THE FOOD WHICH IS SOLD FOR B2B AND NOT FOR RETAIL SALE

Fortified Milk Powder (Draft)

As per draft notification dated 10.11.2020, Food authority has proposed new standards for Fortified Milk Powder

Milk Powder, when fortified, shall be fortified with such levels of Vit A & D, so that the final reconstituted fortified milk shall comply with the level of nutrients specified for fortified milk.

It shall be only used in the Govt-funded programs for preparation of “Reconstituted Fortified Milk”

In addition to the labelling provisions, the label of Fortified Milk Powder shall also carry the following statements

(a) NOT RECOMMENDED FOR DIRECT CONSUMPTION
(b) ONLY FOR USE UNDER …. (Name of the Govt-funded programme)
(c)TO BE CONSUMED ONLY AFTER RECONSTITUTION OF THE ENTIRE CONTENT AS PER THE DIRECTIONS ON THE LABEL
(d) PACK ONCE OPENED, TO BE CONSUMED ON THE SAME DAY

Permitted Health Claims in Fortified Oil and Milk

As per Advertising and Claims Regulations, 2018, Schedule IV - Health Claims for Fortified Food Articles: If milk and oil are fortified with Vitamin A and D as per fortification of foods regulations, following nutrient function claims are permitted.

(i) Vitamin A helps against night blindness.
(ii) Vitamin D supports strong bones.

Note:

(i) In general, nutrient function claims will be permitted in liquid foods if delivers minimum 7.5% RDA of respective nutrient followed by cause and effect relationship between nutrient and health function is established and justified by peer reviewed or published in a peer reviewed reputed scientific journal.

(ii) Fortified milk delivers 4 to 7.5% RDA for Vitamin A and D per 100 ml.

Practical Challenges

- *Variation in the Nutritional Information due to following reasons;*
  - ❖ *Inherent contribution of vitamin A through milk fat which varies between different type of milks viz. Standardized Milk (4.5% fat), Full cream milk (6% fat), Double toned milk (1.5% fat).*
  - ❖ *Analytical variations due to sensitivity of Vitamin A and D.*
  - ❖ *Operation issues in measuring milk quantity during fortification process. I.e.: Fortification premix quantity will be fixed based on milk quantity.*

- *Micronutrient tolerance limit range requires holistic approach to accommodate contribution form added and natural contents.*

  Basis draft notification dated 12.09.2019, food authority proposal tolerance is +/- 10 per cent of the declared value of micronutrients on the label.

- *Permissibility of fortified milk in milk products. The excessive milk which fortified will be left unused if retail pack intend got over commercially.*

Factors Contributing to the Success and Sustenance of Fortification Programs in India

Offer attractive incentives, awards and subsidies to the food industries who participating directly (manufacturing) or indirectly (promoting) in the food fortification programs.

1.Maximize food fortification program's effectiveness, the perceptions and attitude of the populace towards nutrients nourished India.

1.Monitoring and evaluation are the critical factor in the sustainability of fortification programs. (Avoid over dosage & adulteration).

1.Active participation of all community-based, small-scale, medium-scale and large-scale FBOs in promoting fortified foods.

1.Consumers' cooperation may be won, if additional cost for fortified foods are minimal.

1.Effective legislation to ensure good quality and minimum staple cost to end consumer & Industry.

1.Required involvement of entire food supply chain (including retails, e-commerce players, etc.) by encouraging fortified foods at the national and local level.

1.Provision for affordable and widely accessible testing facilities.

WHY MILK AND OIL ARE AN EFFECTIVE AND BETTER FORTIFICATION VEHICLE

- *Easy miscibility*
- *Milk has base of water and fat, hence both water and oil soluble nutrients can be added.*
- *Minimum cost for process modification.*
- *Fat soluble vitamins can easily be introduced in edible oils.*
- *Milk is the right vehicle for children nourishment from small age.*
- *Both fortified oil and milk reaches to all levels of societies.*
- *Some of the nutrient lost during processing may be added back easily.*
- *Easy digestibility of milk also make this as suitable vehicle.*

CONCERNS RAISED

- *Will milk and oil fortification benefit the poor people?*
- *Some says that even the India is No 1 in milk production but it does not reached to the poor.*
- *Naturally milk has good amount of certain nutrients.*
- *Excessive consumption from all the fortified staple sources.*
- *Usage of food additives and carriers in fortification mixture for plain milk. (In milk no additives are permitted).*

A WORD OF CAUTION

- *Should be done carefully post identifying the deficiencies in the targeted population including vulnerable groups.*
- *Regular monitoring the effectiveness of fortification must be evaluated through various surveys (like NNMB/NHFS).*
- *When deficiency of concerned nutrient got addressed through food fortification programs, It may put on hold or discontinue.*
- *Awareness and communication about the both sides of the coin including to avoid excessive intake of nutrients.*

THANK YOU