

F. No.37/STD/FF/2013-FSSAI/Pt-File
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety and Standards Act, 2006)
FDA Bhawan, Kotla Road, New Delhi 110 002

The 31st January, 2017

Subject: Notice calling for suggestions, views, comments on the consultation paper on Food fortification from General public and other stakeholders within a period of 6 weeks. -reg.

Addressing micronutrient deficiencies is an essential part of the effort of the Government to reduce the levels of malnutrition in the country. Micronutrient malnutrition is prevalent in all age and socio economic groups. Global experience has shown that more than a single approach, a combination of several strategies is required to significantly reduce micronutrient deficiencies. Amongst these, staple food fortification offers a promising opportunity to deliver micronutrient rich foods to large populations.

Fortification is a cost-effective and reliable mean of reducing micronutrient malnutrition. The goal is not to provide 100% daily requirements of micronutrients but rather "fill the gap" between intake from other sources and daily micronutrients needs. Cost of micronutrients is clearly small on a per person-per-year basis and its success require active collaboration among several sectors. Fortification has a great potential of enriching the nutritional quality of food.

In this direction, Ministry of Women and child Development in association with Food Safety and Standards Authority of India has developed a draft consultation paper, outlining the proposed roads -map for the roll out of the fortification initiative in the country.

Comments /Suggestions and/or objections on the consultation paper are invited from the stakeholders and general public. The suggestions, if any, may be addressed as per the attached format to the Joint Technical Advisor, Food and Nutrition Board, 3rd Floor, Jeevan Vihar Building, Parliament Street, New Delhi-110001 or emailed to jjtafnb-wcd@nic.in latest by 7th March, 2017 .

Standards Division, FSSAI
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**NOTICE CALLING FOR SUGGESTIONS, VIEWS, COMMENTS FROM GENERAL
PUBLIC AND OTHER STAKEHOLDERS WITHIN A PERIOD OF 6 WEEKS ON THE
CONSULTATION PAPER ON FOOD FORTIFICATION**

A. PREAMBLE

Micronutrients are essential vitamins and minerals required on a daily basis to ensure good health and to enable the body to fight diseases. They are referred to as micronutrients because individuals need them in small quantities for proper growth and development.

India has a very high burden of micronutrient deficiency diseases such as anaemia, vitamin A deficiency, iodine deficiency disorders etc. Micronutrient deficiencies are prevalent in all age groups and socio-economic groups, but consequences are more severe when it affects children below 24 months of age since they are largely irreversible. Micronutrient deficiency disorders (MNDs) have many adverse effects on human health, not all of which are clinically evident.¹

Indian diets are typically cereals based and the consumption of micronutrient rich foods like pulses / legumes and vegetables / fruits is low leading to deficiencies of multiple micronutrients. The National Nutrition Monitoring Bureau (NNMB) data and the Household Consumer Expenditure Surveys reveal that the intake of foods rich in micronutrients is far lesser than the recommended intakes (RDA) in all age groups.² Common micronutrients deficient in Indian diets are Iron, Iodine, Vitamin A, Folate / Folic Acid, Vitamin B12, and Vitamin D, and their absence has serious consequences.

Micronutrient deficiencies can be prevented and even eliminated by consumption of micronutrients. Dietary diversification, Fortification, Supplementation and bio-fortification along with other measures like infection control, water and sanitation, etc. are strategies to tackle micronutrient malnutrition. The Government of India has over the past few years, expanded the coverage under a number of programmes, which have the potential to improve the current micronutrient deficiencies and other nutrition security situation of the country.

Micronutrient Malnutrition Scenario

According to National Survey data, about 70% preschool children suffer from iron deficiency anaemia³ and 57% preschool children have sub-clinical Vitamin A deficiency.⁴ Iodine deficiency is endemic in 85 percent of districts. Moreover, Neural Tube Defects (NTDs) are the most common congenital malformation in the Indian context with an incidence that varies between 0.5-8/1000 births⁵. It is estimated that 50-70% of these birth defects are preventable.

B. Food fortification: Approach to control micronutrient deficiencies

The public health benefits of food fortification include prevention or minimization of occurrence of micronutrient deficiency in a population of specific population groups; it contribute to the correction of a demonstrated micronutrient deficiency in a population or specific population groups and has a potential for an improvement in nutritional status and dietary intakes that may be, or may become, suboptimal as a result of changes in dietary habits/lifestyles.

¹Improving Child Nutrition, The Achievable Imperative for Global Progress, UNICEF, 2013

² National Nutrition Monitoring Bureau, Technical Report no.26, National Institute of Nutrition, 2012

³National Family Health Survey, 2006-07

⁴ India's undernourished children: A call for reform and action, The World Bank, 2006

⁵India's undernourished children: A call for reform and action, The World Bank, 2006

Fortification fills the gaps in nutritional needs and is one of the most cost-effective strategies available. It also has the added advantage of not requiring any behaviour modification or compliance that is expected in supplementation at the end-user level.

C. Food fortification in practice – Global/Indian experiences

Food fortification has a long history of use in industrialized countries for the successful control of deficiencies of vitamins A and D, several B vitamins (thiamine, riboflavin and niacin), iodine and iron. Salt iodization was introduced in the early 1920s in both Switzerland and the United States of America and has since expanded progressively all over the world to the extent that iodized salt is now used in most countries. From the early 1940s onwards, the fortification of cereal products with thiamine, riboflavin and niacin became common practice.⁶ Currently, around 83 countries in the world have some or the other form of legislation mandating fortification of staple food items.

Fortification is not new to India either. Fortification of Vanaspati with vitamin A and D started more than 50 years ago and has been mandatory in the country since 1953. The tremendous success of salt iodization program is indicative of the significant potential of food fortification. Salt Iodization in India started with the National Goiter Control Program (NGCP) in 1962 and gained momentum in early 80s and mandated the distribution of iodized salt in 1997. Voluntary wheat flour fortification standards were notified in 1970s. Few State Governments have been implementing wheat flour fortification with iron and folic acid through public health programs.

D. Regulatory Provisions for Fortified Foods in India:

Food Safety and Standards Authority of India has a mandate of laying down science based standards. In exercise of the power conferred by clause (d) of sub-section (2) of Section 18 of the Food Safety and Standards Act, 2006 (34 of 2006), the Food Safety and Standards Authority of India, has formulated comprehensive regulations for fortified foods namely Food Safety and Standards (Fortification of Food) Regulations, 2016. The regulations include standards for fortification of Wheat flour, Maida, Rice, Milk, Oil, Salt and Vanaspati. These have been operationalised since 16th October 2016. These regulations are also being notified as draft regulations in the Gazette of India.

E. Potential outreach of food fortification in India

Wheat Flour, Oil and Salt are identified suitable vehicles being consumed regularly in adequate amounts by the Indian population. As per the Household Consumer Expenditure Survey, 2014, 68th Round, people in India consume cereals about 300g/day, oil about 25g/day; salt consumption is also nearly 8-10 g/day. These food items if fortified and consumed regularly have a potential to improve the overall micronutrient status of the population.

F. Proposal:

Proposal is to address Iron Deficiency Anaemia (IDA), Neural Tube defects (NTDs) due to Folate deficiency, Iodine deficiency disorders (IDD), Vitamin-A, Vitamin-D and Vitamin B12 deficiencies through Fortified Foods. Micronutrients and Foods under focus are:

- **Wheat Flour** fortified with Iron, Folic acid & Vitamin B12 (Annexure I)
- **Oil** fortified with Vitamin-A and Vitamin-D(Annexure II)
- **Salt** fortified with Iron and Iodine (Annexure III)

⁶ World Health organization, Guidelines on food fortification with micronutrients, 2006 Source: http://www.who.int/nutrition/publications/guide_food_fortification_micronutrients.pdf

G. Road map:

Given the advantages that food fortification has in combating micronutrient malnutrition, it is incumbent upon all stakeholders to operationalize an effective plan to maximise the availability of fortified foods through various delivery channels for consumers.

The two primary channels available are (i) Public Funded Food Based nutrition programs viz. Integrated Child Development Services (ICDS) Scheme, Mid-Day-Meal (MDM) and Public Distribution System (PDS) and (ii) Open Market Channels.

The proposal is to strategize the roll out plan in a phased manner as under, in view of the challenges that include preparedness of supply as well as demand side (that include industry fragmentation; limited capacity, inadequate enforcement and regulatory monitoring as well as limited demand mainly due to lack of awareness about the benefits of consuming fortified foods, need to create enabling environment) that may be overcome during the coming years:

Phase I: Focus on Public Funded Food Programs:

- Double Fortified Salt: Implementation of use of Double Fortified Salt in MDM and ICDS by December 2018.
- Fortified Edible Oil: Use of fortified oil in the MDM and ICDS programs by December 2019.
- Fortified wheat flour: In addition to the intricacies in the supply side of the wheat flour, a huge challenge is to build capacity of the local chakkis that supply about 40-45 MMT of wheat flour. Therefore, the implementation may need to be done as under:
 - **Stage I: Piloting** the supply of fortified wheat flour in the states where wheat flour supplied through PDS channel and study the process to assess the supply chain issues in ICDS and MDM.
 - **Stage II: Scaling up** the supply of Fortified Wheat Flour in all States, taking learnings from stage I. It is proposed to use fortified wheat flour in MDM and ICDS by December 2019.

Phase II: Open market channels

- Getting the supply side prepared to achieve the universalized availability of these commodities from January 2020.
- Increased availability of Fortified Wheat Flour across the PDS and positive trends in open market.
- Government efforts to focus on generic campaign on micronutrient deficiencies and the response strategy.
- Consumer awareness on micronutrient deficiencies and the role of fortification.

Conclusion:

Global experience has shown that more than a single approach, a combination of several strategies is required to significantly reduce micronutrient deficiencies. Amongst these, staple food fortification offers a promising opportunity to deliver micronutrient rich foods to large populations. Fortification is a cost-effective and reliable means of reducing micronutrient malnutrition. Fortification is a preventive measure for micronutrient malnutrition. The goal is not to provide 100% daily requirements of micronutrients but rather "fill the gap" between intake from other sources and daily micronutrients needs. Cost of micronutrients is clearly small on a per-person-per-year basis and its success requires active collaboration among several sectors. Fortification has a great potential of enriching the nutritional quality of food and in turn, enriching the life of millions of children; by giving them a healthy start to life which they rightly deserve.

Fortification of Wheat Flour with Iron, Folic acid and Vitamin-B12

Suitability of vehicle: Wheat flour is the most commonly consumed staple food in India. The Household Consumer expenditure Survey shows 11.7 kg in rural and 9.7 kg in urban areas as the monthly per capita quantity of cereals consumed in India. The consumption pattern per day on national average for wheat is 160g/ day/ capita.⁷ Therefore, wheat flour is a suitable food vehicle for fortification with Iron, Folic Acid and Vitamin B12.

Health Benefits: Fortification of wheat flour with iron has been shown to improve iron status among specific populations. Many national studies have found that fortifying flour with folic acid reduced the incidence of birth defects such as neural tube defects by 31% to 78%. Several controlled research studies conducted in children and young women have demonstrated that regular consumption of fortified wheat flour with adequate levels of easily absorbed nutrients results in a significant reduction in the prevalence of micronutrient deficiencies. When appropriate levels of easily absorbed iron are used, fortification impact iron status is visible within 12 months if the fortified wheat flour/products are consumed daily. Fortification experts estimate that it may be three years between fortification's initiation and a nutritional impact on iron status. With folic acid, changes in folate status may be observed within 3 to 4 months after fortification is fully implemented. It will take at least 12 months to see an impact on neural tube defects because women need to be consuming folic acid at the time they conceive to prevent birth defects.

Experience thus far: There is adequate evidence that fortification of wheat flour is most effective, simple and an inexpensive strategy for supplying vitamins and minerals to large segments of the population without requiring change in food habits or dietary pattern or measures to address the problem of compliance. The Wheat flour fortification is started as early as 1933 in Canada. Wheat flour fortification is mandatory in 85 countries with the nutrients i.e. minerals (Iron, Zinc and Calcium) and vitamins (A, B1, B2, B3, B6, B9, B12, E). In India, fortified Wheat flour was introduced in PDS in urban areas of West Bengal and Gujarat initiated fortification of wheat flour with iron and folic acid in 2006.

Level of Fortification: The flour fortification standard as established by Food Safety Standards Authority of India (FSSAI) recommends addition of iron, folic acid and B12 to atta or maida at the level of 20 mg/Kg Iron, 1300 micrograms/Kg Folic Acid and 10 micrograms/Kg Vitamin B12. Other nutrients such as Zinc, Vitamin A, Thiamine, Riboflavin, Niacin and Vitamin B6 can also be added to wheat flour.

No adverse effects on health have been reported in the studies published on fortified wheat flour since the standards for fortification are set keeping in view the Recommended Dietary Allowances (RDA) for the population. Children and pregnant and lactating women especially benefit from consuming fortified wheat flour as they require high levels of vitamins and minerals to support physical growth and the development of new tissues.

Constraints:

- There are about 1200 Roller Flour Mills in India; about 800 automated *Chakkis* (stone grinding mills) and approximately 2.8 million small *Chakkis*. These are two different segments. Large automated *Chakkis* that produce atta that is sold as branded Atta in the market. Wheat that is milled in small *Chakkis* is difficult to fortify. Only the *Atta* that is produced by organized sector is fortifiable. Organized sector produces *atta* only for sale as branded *atta* in urban and peri-urban markets. This is actually a miniscule portion of the whole.
- This will require time to scale up as the industry has to install the necessary capacity of automated *chakkis* to handle the huge volume.

Cost implications: The cost of fortifying wheat flour would be 20-25 paisa/kg for wheat flour.

⁷Household Consumer expenditure in India, 2014, NSS 68th round

Fortification of Edible Oil with Vitamin-A and/or Vitamin D

Suitability of Vehicle: Edible oils are the best vehicle to carry fat soluble vitamins like Vitamin A and D that can be easily absorbed by the body. Edible oil has mass penetration across population groups and geographies. Fortification of edible oil has been identified as a complementary strategy to reduce Vitamin A and D to reduce deficiencies. Vegetable oils have a penetration of 99% into the households in India. Vitamin A and D fortification in oil is relevant when the consumption of oil is greater than 5g/day (1.8 kg/ year).⁸ The consumption of edible oil in the country is about 25g/day⁹, i.e., about 12-18 kg/per annum per person, making it an ideal vehicle for delivery of Vitamin A and D.

Health Benefits: Vitamin A and D deficiencies are big public health problems affecting populations across the spectrum of age and gender. Dietary intake of vitamin A and D rich foods across India is very low, with 85% of the population consuming less than 50% of their day's requirement of vitamin A from food sources. Also, the uptake of vitamin A supplementation amongst children (6-59 months) is just about 45%¹⁰. Studies from various parts of the country have suggested prevalence rates of 70-98% among adults and over 80% in pregnant women and school children.¹¹ The effectiveness of edible oil fortification in reducing vitamin A and D deficiencies is proven globally.

Experience thus far: Oil fortification was first introduced in Pakistan in 1965, with the nutrients like Vitamin A and D and it is mandated in 27 countries. Edible oil fortification is not a new idea in India. Government of India had mandated fortification of 'Vanaspati', (hydrogenated oil) with vitamin A as early as in 1953, to increase its nutritive value. Fortified edible oil was introduced in Rajasthan (recently has been made mandatory), Madhya Pradesh and Gujarat with Vitamin A and D.

Level of fortification: The edible oil fortification standard as established by Food Safety Standards Authority of India (FSSAI) is to add 25 IU Retinol per gram of oil and 4.5 IU Vitamin-D per gram of oil.

Constraints: The Indian oil industry is extremely fragmented with hundreds of local producers spread across the country and within the different oil producing states. Oilseeds crushing units, which are estimated to be about 150,000 across the country, include crushing units that are small-scale, medium scale and also large scale.

However, all the edible oil that is produced by organized sector and sold in packaged form is fortifiable. Fortification of edible oil by the organized sector is relatively simple. It is estimated that about 30% of packaged oil is already fortified voluntarily by the industry. Oil produced by unorganized sector and that is sold in loose is not fortifiable.

Cost Implications: The cost of fortifying edible oil with Vitamins A and D will be 10 paisa/Litre. There is no additional packaging and transport cost.

⁸Dary O, Mora JO. Proceedings of the XX International Vitamin A. Consultative Group Meeting. Food fortification to reduce Vitamin A Deficiency: American society for Nutritional Sciences 2002

⁹Household Consumer expenditure in India, 2014, NSS 68th round

¹⁰ MWCD, GOI Rapid Survey on Children, 2013-2014, India Fact Sheet.

¹¹ Mudur G. Indian endocrinologists warn about vitamin D deficiency. BMJ2003;326:12

Fortification of Salt with Iron and Iodine

Suitability of Vehicle: Salt is an ideal vehicle to use for delivering iron and iodine because it is a staple food that is used by everyone. The successful and well established salt iodization infrastructure offers an excellent opportunity to integrate iron as a second nutrient to tackle both iron and iodine deficiencies.

Health Benefits: Anaemia (iron deficiency) and iodine deficiency are most often found in infants to young children under 5 years of age and in women of childbearing age, predominantly in populations of developing countries. If taken on a regular/daily basis, these people would greatly benefit from a salt that is fortified with both iodine and iron. The use of DFS would help in reducing the health problems and health costs related to iodine and iron deficiencies.

Evidence thus far: Fortified Salt was first introduced in USA in the year 1949. Salt was fortified with 2 minerals Iodine and fluorine and mandated in 130 countries. Double fortified salt (Iron and Iodine) was introduced in Bihar school programmes and is available in the open market. Recently it has been introduced by the State of Uttar Pradesh also. Based on the urgent need to reduce high levels Iron deficiency anaemia among the population and the ease of fortifying salt with Iron and Iodine, the same line of wisdom and scientific evidence which led to mandatory fortification of Salt in 1997, now needs to be extended to making fortification of salt with Iron in addition to Iodine mandatory.

Level of Fortification: The Double Fortified Salt (DFS) standard as established by Food Safety Standards Authority of India (FSSAI) recommends addition of Iron at the level of 850 to 1100 parts per million. The standard of DFS is designed for use as a regular salt for cooking and at table. Based on an estimated average salt consumption of 8-10 g per person/day, the DFS is designed to provide 100% daily requirement for iodine and 30%- 40% for iron.

Constraints: To make double fortified salt, the iodised salt manufacturers will require new equipment and access to technology, capacity building and training. The quality of double fortified salt produced is also highly important. Though the cost has been brought down significantly and the cost difference between iodised and double fortified salt is about Rs.2.5 per kg. This is still a significant increase and therefore introduction is to be done in a phased manner.

Cost of Fortification: the cost of fortifying iodized salt with iron is Rs. 2-3 per kg. There is no additional packaging and transportation cost.