

17 Nov 2021

To:

Shri Arun Singhal,
Chief Executive Officer,
Food Safety & Standards Authority of India.

Sub: Experts' concerns on mandatory fortification

Dear Arun Singhal ji,

We thank you for meeting us to discuss our concerns with policies of mandatory fortification. We represent a variety of organizations and networks connected with health, nutrition, right to food, and sustainable agriculture from across India who have spent decades working for the nutrition and right to food of India's people.

The following are some of the issues that we strongly believe the FSSAI should address, based on the concerns being raised.

1. Fortification should not be made mandatory as benefits do not justify the costs and risks:

Our key demand of the FSSAI is that fortification should not be made mandatory. A citizen's choice to eat food without chemicals is permanently ended via mandatory fortification and this would be a grave violation of a basic right. The costs and risks of mandatory fortification to the poorest sections of our society are especially high, as discussed below.

No conclusive evidence of functional impacts: When it comes to iron, it is clear from all available evidence that adding more iron into diets without the supportive enzymes, quality proteins, and other vitamins does not lead to absorption but only to higher ferritin levels, which is associated with biological risks pertaining to increased stores of iron in this form. Indeed, there is no consensus that fortification works to increase hemoglobin levels substantially. A meta-analysis from 17 countries published in the Cochrane review, considered to be the gold standard, shows that rice fortified with iron, vitamin A, or folic acid made no difference to anemia and little difference to Vit A deficiency.[1]

High financial and social costs: Even though the FSSAI has been arguing that fortification is 'cost effective,' over the long term, mandatory fortification will have profound and irreversible infrastructural and market shifts, including consolidation of corporate control over food, and dependence on cereals and ultra-processed packaged foods while removing the focus from local foods. Setting up such a vast program on fortification requires at-scale processes such as testing, monitoring, quality control, storage, all of which are most impractical to ensure in a vast country like India where the majority of our food comes from the unorganized sector and would incur

enormous costs even if they were logistically feasible. These challenges have already been encountered in the pilots that have been carried out. Further, mandatory fortification will create an import dependence for India on foreign entities for the micronutrients and precursors which are not available in India.

Right to livelihood of economic players and self-reliance: The majority of our food is produced, processed and sold in the unorganized sector and is led by small players and MSMEs. The indicative cost of producing rice through fortification for a medium sized mill is Rs 3.2 crore (as mentioned in Pilot Scheme Fortification of Rice and its Distribution under Public Distribution System). It is estimated that there are roughly 130,000 rice millers in India - most of which are small and medium sized. More than 70% of milk produced in India is handled by unorganized sectors or small producers (2018-19 Economic Survey).

Mandating fortification will put such actors at risk as they will not be able to bear the costs associated with testing procedures and infrastructure required for fortification, and would inadvertently lead to empowering the larger players. The Ministry of Women and Child Development's consultation paper in 2017 itself mentioned that oil produced by the unorganized sector is not fortifiable. From the same document and NFSM's World Scenario of Vegetable Oils & Fats, it comes out that there are at least 135,000 small and medium-scale oilseed crushing units in India.

Studies also show that fortification programs lead to reduction in market share of the informal sector and an increased market share of formal players (Dury *et al.* 2019; Fiedler *et al.* 2012). Equally important are organic processors and consumers who might not want to add synthetic chemicals into their products.

Risks from toxicity, especially to the poor, including ones with contraindications: It is well known that iron is a particularly oxidative element and high iron doses are connected to non-communicable diseases as well as increased propensity for infections. For this reason, Iron is not recommended in the initial management of acute illnesses including malaria and TB, as well as Severe Acute Malnutrition (SAM). Most studies confirm that fortification serves only to increase the stored forms of iron such as ferritin rather than its functional form that is hemoglobin. High ferritin stores in the body is known to result in increased incidence of Non Communicable Diseases (NCDs) which is a rising crisis in India. Iron is also contraindicated in Sickle Cell Anemia, Thalassemia and other hemoglobinopathies; again to prevent the toxicity from its stored forms.

India has about 2.4 million cases of TB in 2019,[2] and there are 2 million malaria cases in India per year [3]. These and several other acute infections and conditions which impact primarily poorer sections of the population and high doses of iron and vitamins can make these worse. *How is the FSSAI ensuring the safety of such populations?*

Thus, instead of helping with anemia - mandatory fortification is likely to, in fact, exacerbate public health problems in a country with a high disease burden, malnutrition and rising trends of non-communicable diseases.

Synthetic vitamins are crystalline in nature and hence becomes challenging to dissolve them leading to greater accumulation for them. Further, India already has important ongoing pharmacological

supplementation programs, which are monitored by medical professionals, and which can be stopped when not needed to prevent toxicity. However, mandatory fortification leads to indiscriminate consumption of synthetic nutrients. If external supplementation is required, then pharmacological supplementation is the right approach to take as it is monitored and easily reversible. At the moment, fortification is being layered over supplementation programs like the *Anemia Mukh Bharat* program that is already delivering upto 20 times the iron that fortified rice will deliver, to 60% of India's population. In addition, we have Double Fortified Salt in several states where apart from iodine, iron is being given. Similarly, for vitamin A, children under 5 are getting 100,000 times the dose of fortification every six months. If we add indiscriminate, irreversible doses via mandatory fortification, *where is the evidence that this would not be toxic?*

Health risks emanating from reduced importance of dietary diversity and cerealization: Mandatory fortification will send a faulty message that the poor can get their nutrition from, and fix serious diseases like anemia, by consuming 4-5 foods, mainly cereals that are being fortified. The link between the cerealization of diets and non-communicable diseases is incontrovertible. Such messaging and policy are contradictory to the most important solution to malnutrition, which is improving dietary diversity. Even though the FSSAI has stated that it has a voluntary communications campaign called "Eat Right India," telling people to eat right without ensuring access, as is being provided for fortified cereals in safety net programs, it is futile and will not lead to people actually consuming diverse diets.

These, and many other risks are elaborated in our material and letters that we have previously submitted to the FSSAI. Given so many risks and dubious benefits, it is important to put an immediate stop to making fortification a mandatory policy.

2. FSSAI's decision making processes on fortification need to be more transparent, consultative and devoid of conflict of interest

The FSSAI should take cognizance of, and eliminate conflict of interest: Various entities that are funded by and linked to corporate entities that stand most to benefit from fortification policies globally are part of the Food Fortification Resource Centre (FFRC), housed in the FSSAI, which is a regulatory body. The Tata Trusts, GAIN, FFI and Nutrition International are part of the FFRC and all of these have interest in ensuring that fortification is mandated and promoted. For example, GAIN is a partner of BASF which is one of the world's largest chemicals companies. Nutrition International is supported by DSM (a large multinational that makes nutritional products) and BASF; FFI partners with BASF and has ADM (a multinational food processing company) on its executive management team.

BASF and ADM are part of the 5 companies that stand to create a market of Rs. 3000 crore from India's fortification program, a fact revealed through a media exposé, which the FSSAI has not contradicted with evidence [4]. Since the conflict of interest is so clear, the FSSAI must disclose this publicly and prevent such entities from intervening in national nutrition and food safety policies of India.

The issue of conflict of interest is also applicable to scientists and “experts” who are part of the FSSAI’s panels. A narrow interpretation of conflict of interest and a narrower mechanism put into place to prevent conflict of interest in the FSSAI, without any grievance redressal mechanism for violations, is deeply problematic as food safety of all citizens is at stake here.

FSSAI is a regulator and should not act as a promoter of fortification: The FFRC housed in the FSSAI, is a body with a clear mandate to promote food fortification. It describes its own role as directed at, “*creating a comprehensive and interactive knowledge resource base on Food Fortification for all policy makers, development partners, Food Businesses, Premix and Equipment Manufacturers, grass root level workers and general population [5].*” However, since the FSSAI is a regulatory body with a mandate to create science-based standards for food and to ensure food safety by regulating manufacture, storage, distribution, sale and import of food, the FFRC, a biased promotional entity with clear conflict of interest, should not be housed inside the FSSAI. The FSSAI as our country’s apex food safety regulator cannot be working hand in hand with a promoter. FSSAI should also not be getting into implicit policy-making for promoting fortification.

Make all pilot studies, responses to FSSAI draft notification publicly available: While FSSAI might have set standards for fortification of different micro-nutrients in different foods, considering them as independent, stand-alone consumables, it is not clear what data of India’s diets as well as nutrition interventions (supplementation programs and other interventions) has been used to set these standards. We assume that FSSAI has looked at pilots that have been reportedly implemented around food fortification in PDS/ICDS/MDMS etc., before plunging headlong into promotion of food fortification (which in any case is not the mandate of the regulator).

It has already been communicated by senior government officials in a meeting on fortification organized by the Bhartiya Krishak Samaj at the India International Center on Oct 25, 2021, that the pilots have been fraught with implementational challenges. For scale-up, that would require enormous investments and changes in existing infrastructure and human resources. These include (fortified rice kernel) FRK manufacturing, ensuring the right ratios between fortified and natural grains and providing facilities of testing at scale. These seem neither feasible, nor are the additional costs justified by the highly limited impact upon nutritional status.

We believe that results of the pilots (including how the locations of the pilots were selected, duration decided, pilot protocols worked out etc.) and the full evaluation studies of the pilots (not just a brief abstract, not just ‘before’ and ‘after’ results, but with control groups and interventions along with comparison with other holistic approaches) should be put into the public domain, before any mandatory policies are adopted or scaling up occurs.

In addition FSSAI must make the following responses to draft notification for mandatory fortification of edible oil and milk publicly available -

- Responses received to draft notification
- Responses from Panel on Nutrition and Fortification

In conclusion, we urge that the FSSAI takes the following steps:

- The FSSAI should not impose or promote mandatory fortification because all available evidence suggests that the costs and risks far outweigh the so-called benefits.
- The so-called benefits in terms of efficacy, cost-effectiveness, feasibility, safety etc. on whose basis mandatory rice fortification is being promoted are based on studies that have not been put into the public domain; We demand that information of all the pilots and their evaluations must be put in the public domain to encourage more public debate on the matter of fortification of India's food schemes meant for the poor.
- Before policies such as mandatory fortification that have far-reaching implications are promoted, the details of the discussions held in the scientific panels and committees and the recommendations made by experts in these, minutes of meetings etc. must also be put in the public domain.
- Similarly, the responses received in any consultations held with stakeholders such as industry representatives on mandatory fortification must also be made public, so that people are informed of the basis on which these decisions are made.
- The FFRC which is a promotional body should not be housed in the FSSAI, which is a regulator;
- There should be no representation of those with any conflict of interest in all processes and institutional mechanisms of FSSAI comprehensively (meaningless voluntary declaration before meetings is not enough to address the issue of conflict of interest);

We will be happy to clarify and discuss further on the issues we have raised here. We look forward to getting a timely response from FSSAI on these.

Signed by:

Dr Vandana Prasad,
Dr Arun Gupta,
Dr Dipa Sinha,
and Dr Rajendra Kokane

on behalf of several health, nutrition, right to food, and sustainable agriculture organizations and networks from across India.

[1] <https://www.ncbi.nlm.nih.gov/books/NBK1720/>

[2] <https://pubmed.ncbi.nlm.nih.gov/31684687/>

[3] <https://tbcindia.gov.in/WriteReadData/1892s/India%20TB%20Report%202020.pdf>

[4]

<https://www.downtoearth.org.in/news/food/fortified-rice-scheme-to-create-rs-3-000-crore-market-for-just-five-big-firms-66761>

[5] <https://ffrc.fssai.gov.in/disclaimer>
