WFP
World Food Programme

SAVING LIVES
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A Guide to Setting up Rice Fortification Standards: Examples from the Asia and Pacific Context

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Executive Summary

Staple food fortification is the process of adding essential vitamins and minerals, such as iron, zinc, vitamin A and folic acid, to commonly consumed foods such as rice, wheat flour, salt and cooking oil. In Asia, where rice is a staple food for a large portion of the population and malnutrition and nutrient deficiencies are prevalent, rice fortification can add essential nutrients to the diets of millions of people who might not otherwise have access to them.

The development of rice fortification standards involves a collaborative and consultative approach that engages various stakeholders, including government agencies, food manufacturers, nutrition experts and consumers. By setting standards for rice fortification, governments can ensure that all populations have access to adequately fortified foods that are safe and nutritious. Standards also provide a consistent framework for manufacturers and distributors, ensuring that the fortification process is effective and efficient.

The timeline for the standard development process can vary depending on the complexity of the project and the resources available. Experience in the region shows that it can take anywhere from a few months to several years to develop and implement rice fortification standards.

In the Asia and the Pacific region, rice fortification standards and regulations vary across countries, with some having mandatory rice fortification programmes and others having voluntary or no ongoing programmes. While progress has been made in fortifying salt and wheat flour, other staple foods such as rice are still largely unfortified in many countries. In India, the government has made the fortification of salt with iodine mandatory since 1983, and in 2018 a standard for voluntary fortification of rice with iron, folic acid and vitamin B12 was developed. In 2021, Timor-Leste embarked on developing fortification standards for the staple foods rice, wheat flour, oil and salt.

The World Food Programme (WFP) has been at the forefront of multiple rice fortification initiatives in the region in recent years, supporting countries such as Bangladesh and India in their rice fortification efforts, and using this experience to help countries such as Timor-Leste, which recently began the process to develop fortification standards.

Now, in an effort to expand the scope of rice fortification programmes and harmonize existing efforts and standards across different countries, WFP has developed this document. It is based on the experiences and lessons learned in Bangladesh, India and Timor-Leste, and includes timelines and critical milestones. It offers other countries a practical four-step guide to understanding the critical steps and actions conducive to success as they embark on the process of developing or updating their own rice fortification standards, helping to ensure that inconsistent fortification practices do not become a barrier to trade.

1. Introduction

In 2021, more than half the people affected by hunger in the world (425 million) lived in Asia (1). The factors that can contribute to the micronutrient deficiency burden across various life stages include limited access to diverse and healthy diets due to non-affordability or poor dietary choices resulting from limited knowledge, socio-cultural norms, preferences, and convenience (2). In South Asia, micronutrient deficiencies are at levels that can only be addressed through policy solutions (3).

Addressing these deficiencies through targeted interventions can help improve public health outcomes and reduce the burden of disease in the region. While improving diets through dietary diversification is the ideal solution to addressing micronutrient gaps, food fortification is recognized as a low-cost, effective complementary strategy. Fortification is defined by the World Health Organization (WHO) as: "The practice of deliberately increasing the content of essential micronutrients (i.e., vitamins and minerals) in a food, so as to improve the nutritional quality of the food supply and provide a public health benefit, with minimal risk to health". Large-scale food fortification involves enhancing the vitamin and mineral content of widely consumed foods during post-harvest processing. Essential micronutrients (vitamins and minerals) that are often added during food fortification include iron, zinc, vitamin A, folic acid and other vitamins, either as single compounds or as a blend of several micronutrients (i.e., premix).

The main goal of a fortification programme is to correct inadequate micronutrient intakes; it can be defined as the practice of deliberately increasing the content of essential micronutrients in a food so as to improve the nutritional quality of the food supply and provide a public health benefit, with minimal risk to health.

Figure 1: Food fortification interventions

Large-scale fortification

- **Definition:** Targeted at the population as a whole involving the addition of micronutrients to foods commonly consumed by the general public - particularly those populations considered most at risk. Responsibility is fully transferred to the government or other national stakeholders, less dependency on WFP and self-sustainable. National policy and regulatory frameworks of food fortification are developed and effectively implemented. A country is self-sufficient in fortified food production. Under the effective national policy on food fortification, private sector is independent on the fortified food production.
  Example: Fortified commodities e.g. rice, wheat flour, maize flour, vegetable oils , salt or condiments, and milk are often mandatory legislation.

Small-scale fortification

- **Definition:** A large proportion of consumers depend on small-scale milling for staple cereals. Responsibility is partially transferred to the government or other national stakeholders, reducing dependency on WFP, national policy and regulatory frameworks of fortification is under development or developed but ineffectively implemented. A country is insufficient in local fortified food production or fortified food is partially produced by local suppliers.
  Example: These consumers can be reached by fortifying for instance, wheat, maize, and rice at small-scale millers.

Targeted fortification

- **Definition:** Aimed at specific sub-groups rather than the population as a whole.
  Example: Fortified cereals and biscuits for older infants and children, as well as so-called "home fortification" where micronutrient powders or small amounts of other micronutrient-dense commodities, such as small-quantity lipid-based nutrient supplements (SQ-LNS) are added to foods ready for consumption.

When a country chooses to fortify foods to increase micronutrient intake across the population, standards that specify the required quality and nutrient content provide clarity and protection for manufacturers and consumers. Standards for a specific category of food (e.g., rice, salt, oil, etc.) aim to protect the health of consumers and provide for fair trade practices by creating a level playing field for producers and exporters across different nations (4). These standards define quality in terms of what is safe, such as food safety and hygiene standards, and acceptable, such as a maximum proportion of broken kernels. They also establish the required nutrient content for fortified foods. Standards should be clear without the need for further interpretation, and should also be feasible to achieve, monitor and enforce.

The objective of this document is to provide countries with a methodology for developing or renewing their fortified rice standards so that they meet dietary goals, align with international guidelines, and are safe for the population. The document has been built in two sections. First, it documents the experiences of Bangladesh, India and Timor-Leste – three countries leading rice fortification in Asia and the Pacific – in developing their own rice fortification standards. Second, it uses their experiences to provide a step-by-step overview of the process involved in setting up rice fortification standards.

2. Food fortification regulatory framework

The need for fortification regulatory frameworks

The regulatory framework for food fortification refers to the set of rules, regulations and guidelines established by government authorities to govern food fortification practices within a country or region. It provides the legal and administrative structure for implementing food fortification initiatives.

The food fortification regulatory framework is essential to ensure the safety, efficacy and consistency of fortified foods. It is important for food manufacturers, producers and regulators to follow a set of guidelines to ensure that fortified foods are beneficial and not harmful to health.

In the case of large-scale food fortification programmes, fortification of any staple food must be implemented in coordination and harmonization with other staples that are being fortified, and it must be in line with international practices and guidelines.

Food fortification standards

Standards are an essential component of the regulatory framework for food fortification. They provide the technical specifications and criteria that must be followed by food manufacturers and producers when adding essential nutrients. They need to be country- and context-specific and align with national laws and regional regulations. Standards can encompass various aspects, including:

Nutrient levels (quantities): Specify the permissible levels of fortification for each essential nutrient in different food categories. These levels are determined based on scientific evidence and the specific nutritional needs of the target population.

Nutrient forms: Define the acceptable forms of nutrients that can be used for fortification, such as specific vitamins or minerals.

Food categories: Identify the food categories that are eligible for fortification. This ensures that the selected foods are appropriate for delivering the fortified nutrients to the target population.

Labelling requirements: Dictate the information that must be included on the product labels of fortified foods, such as the nutrient content, serving size and health claims.

Monitoring and compliance: Establish protocols for monitoring the nutrient levels in fortified foods to ensure that they meet the prescribed requirements. Compliance mechanisms are also put in place to address any deviations from the standards.

Food fortification is implemented through two main approaches: mandatory fortification, where the government or regulatory authorities require specific food products to be fortified with certain nutrients, or; voluntary fortification, which allows food manufacturers to choose whether to add specific nutrients to their products.

Fortification standards play a crucial role in supporting both mandatory and voluntary fortification of food products and facilitating regional and global trade. In the case of mandatory fortification, standards set the minimum and maximum requirements for the fortification of specific foods to ensure that they meet the targeted nutrient levels needed to improve the health of the population. They also provide guidance on the forms of nutrients that should be added, the concentration of these nutrients, and the methods used for fortification.

In the case of voluntary fortification, standards are essential to ensure that the fortified products meet the quality and safety requirements necessary for consumer protection. These standards provide a reference for manufacturers to produce high quality fortified products that meet specific nutrient levels without compromising the safety and quality of the food.

Aligning fortification standards with national and international guidelines

Guidelines provide recommendations and best practices for the addition of nutrients to food products and are typically issued by public health authorities or international organizations. They aim to offer guidance to food manufacturers and fortification programmes.

The global source for food standards, guidelines and codes of practice is the Codex Alimentarius Commission established by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Codex sets international food guidelines and codes of practice to protect the health of consumers and ensure fair trade practices within and outside a given country. The adoption of the recommendations is voluntary but they are often used as a basis for national food standards, including fortified foods. Codex has developed guidelines for the fortification of foods with vitamins and minerals to ensure that they are safe, effective and provide the intended nutritional benefits (5).

FAO and WHO have also published a set of guidelines for food fortification with micronutrients (6). These provide recommendations on the selection of nutrients, levels of fortification, and monitoring and evaluation of fortification programmes. WHO has also published guidelines for fortification of wheat flour with vitamins and minerals (7), which provide recommended fortification levels based on estimated average per capita wheat flour consumption. These guidelines are used as a benchmark to set standards for other foods, including rice.

In addition, many countries have their own regulations and guidelines for food fortification. For example, in the United States of America, the Food and Drug Administration (FDA) regulates the fortification of foods with nutrients, including vitamins and minerals. The FDA has established a list of nutrients that can be added to foods and sets specific levels of fortification.

Harmonizing standards at the regional level

The adoption of consistent fortification practices helps prevent trade barriers and disparities in food quality and promotes the free flow of fortified food products across borders, benefiting both producers and consumers. Harmonization of standards with neighbouring countries or surrounding regional trading blocs needs to be considered as countries adopt or update national fortification standards, in particular in countries where import levels of fortified/fortifiable foods are high to allow for an efficient allocation of resources and expertise, to reduce duplication of efforts and costs through leveraging economies of scale. It encourages countries to collaborate and share best practices in fortification, helps strengthen institutional frameworks and ultimately leads to more effective and cost-efficient programs.

3. Developing standards for fortified rice: country examples

In comparison with staple foods such as wheat/maize flour, salt and edible oil, which have been fortified for decades, rice is a more recent addition to the portfolio of staple foods that can be fortified to address nutritional deficiencies. In most settings, fortifying rice should benefit from the regulatory framework already in place for large-scale food fortification and the experience gained in developing current or past standards.

In Asia and the Pacific, three countries mandate the fortification of rice with micronutrients: Papua New Guinea, the Philippines and Solomon Islands. Fortified rice is provided in social safety net programmes in Bangladesh, Bhutan, India, Malaysia and Nepal. It is also available in retail markets through a voluntary, market-based approach in Bangladesh, India and Myanmar, and in Bangladesh workplace benefit programmes offer fortified rice.

In recent years, several countries in Asia have been through the process of developing new standards for fortified rice. These include Bangladesh, India and Timor-Leste, which now offer a good benchmark for other countries embarking on rice fortification. While India and Bangladesh already had standards in place for other foods (including wheat flour, salt and edible oil), Timor-Leste developed a multiple-staple fortification standard process for four foods at the same time: rice, wheat flour, oil and salt.

These experiences are relevant to all countries in the region regardless of their expertise and experience in setting food fortification standards. They are described in the following section and have subsequently been used to develop a recommended standard approach to setting rice fortification standards for other countries.

Bangladesh (2014–2015)

The Government of Bangladesh initiated the standards development process to support the launch of fortified rice into national food systems. Standards were developed simultaneously with acceptance trials and effectiveness studies. These three elements formed the basis of the evidence required before fortified rice could be launched into food systems.

An iterative process led by BSTI and facilitated by WFP

The Bangladesh Standards and Testing Institution (BSTI) led the process. WFP was asked to facilitate and coordinate the initiative based on its experience in leading the standard development process for wheat flour fortification and its credibility as a major distributor of rice through emergencies in the country.

BSTI started by forming a technical committee that was composed of regular members plus guest members such as international non-governmental organizations specialized in the field of fortification. The standards were developed during four different meetings held over some 12 months between the end of 2014 and 2015.

As the technical lead driving the process, it was important for WFP to have the necessary internal technical expertise to ensure credibility with partners and provide appropriate guidance. Technical staff were recruited to build expertise and capacity and to develop the initial standards based on standard operating procedures provided by BSTI.

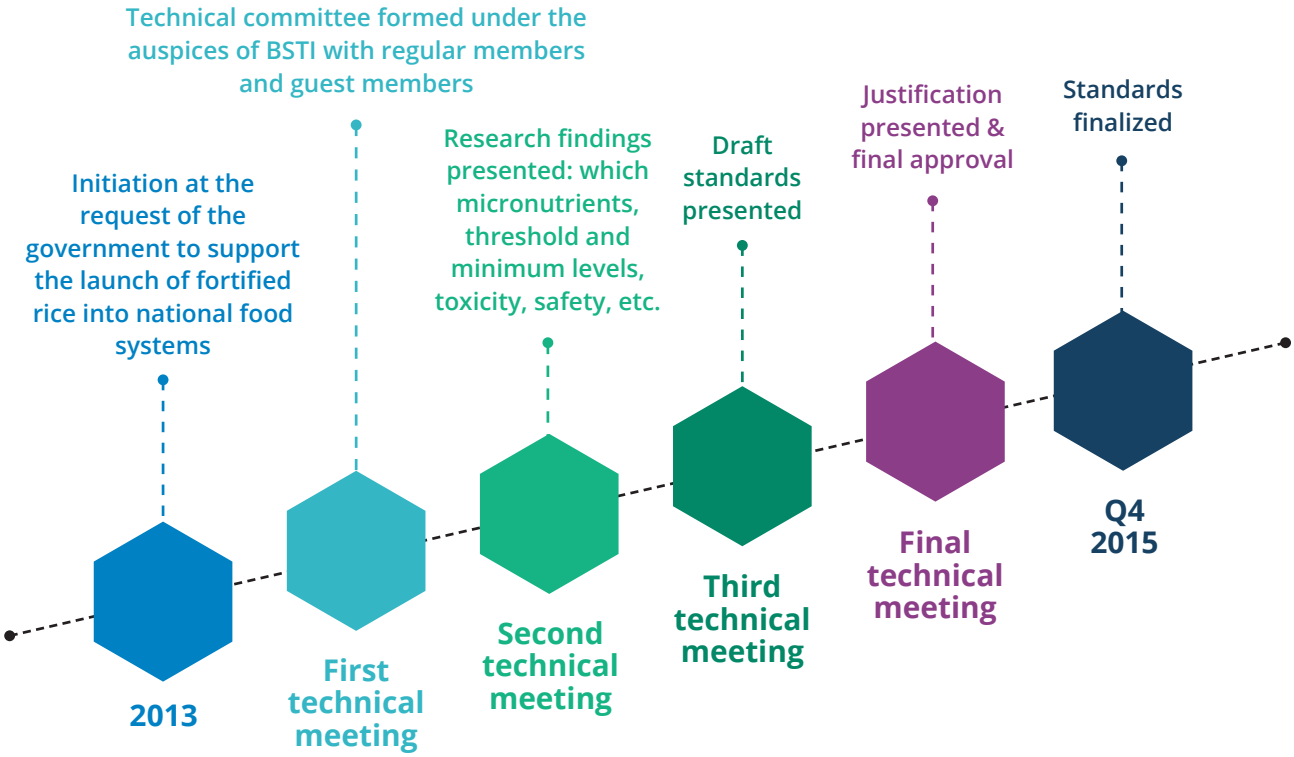
Updating the standard

Over the years, practical experience revealed a number of weaknesses in the standard that was initially developed; this led to upgrading the standard in 2022, following the same process already described. The update focused on two main points: 1) the addition of test methods to the standard, and 2) the addition of 30 percent overage for three of the micronutrients in the standard. The decision to add 30 percent to strengthen the existing standard arose after a retrospective study of traditional rice cooking methods in Bangladesh showed that rice is cooked in excess water which is discarded once cooking is complete, risking significant degradation/loss for three of the micronutrients.

Political game changer

One of the effects of the introduction of the fortified rice standard was that it replaced the compulsory wheat flour fortification programme. The development of the new fortification standard revealed that rice was better adapted to local consumption habits and was therefore more likely to deliver convincing results in the fight against micronutrient deficiencies.

Figure 2: Bangladesh journey



India (2016–2018)

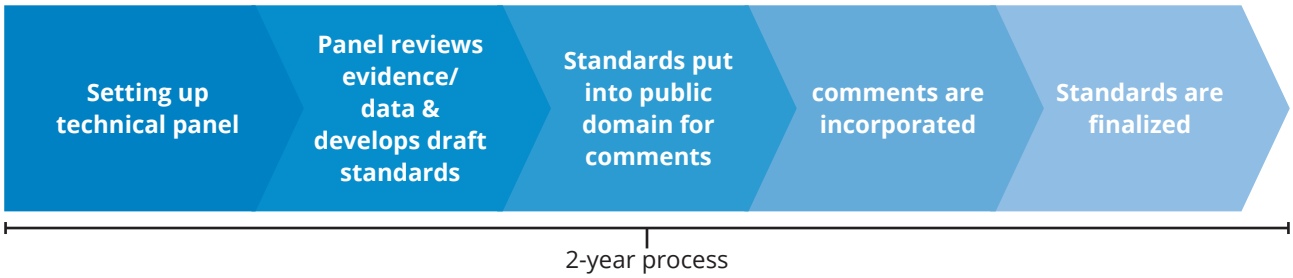
Creating a rigorous overarching process

The Government of India wanted to reduce levels of anaemia in the country, hence its rice fortification initiative. It was led by the Food Safety Standard Authority (FSSAI) – hosted under the auspices of the Ministry of Health – and its scientific panel, which works on setting and updating food fortification standards. The scientific panel was tasked with developing the draft standards using recommended dietary allowances and available micronutrient deficiency data. The aim was to collect as much input as possible from external subject experts to ensure that standards were technically sound and in line with international guidelines. Comments were taken to the scientific panel and incorporated following technical discussions within the panel. The process lasted two years from development of draft standards and their operationalization in 2016 to their publication (gazetting) in 2018.

Experience has shown that it is important to ensure that members of such technical committees are not only subject experts but that they are also motivated and informed of the benefits of developing such standards. This enables them to become

strong advocates of the law once it is gazetted and implemented. A detailed description of the India rice fortification scale-up journey can be found in two documents (a) Journey of scaling up rice fortification Asia: Connecting food systems with social protection to enhance diets of those who need it most (8). (b) The proof is in the pilot: 9 Insights from India's rice fortification pilot to scale approach (9).

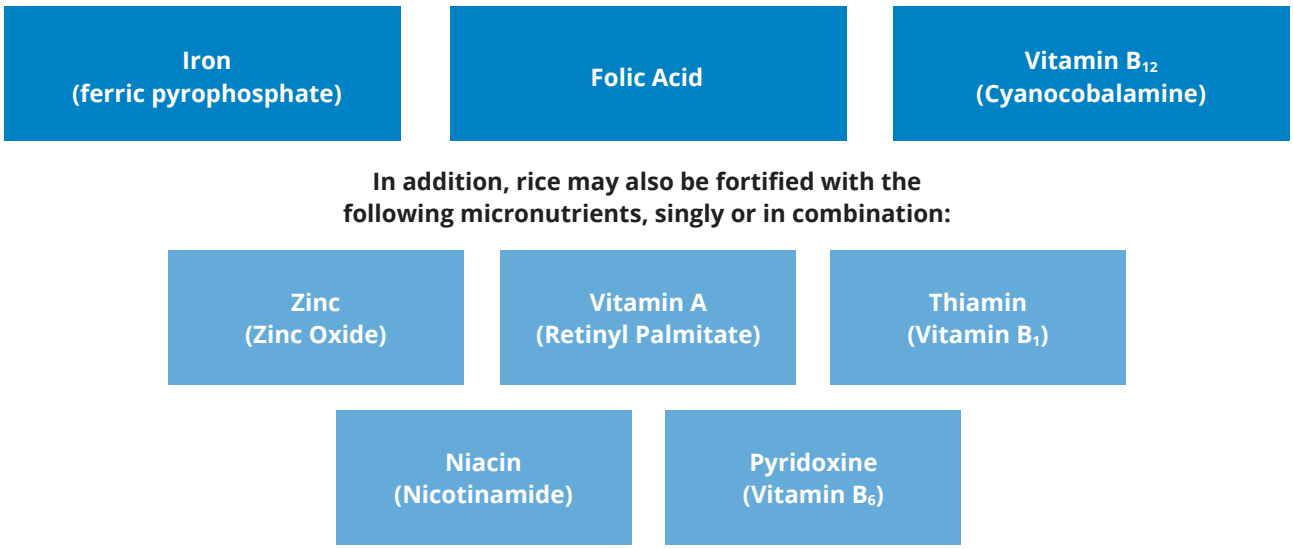
Figure 3: India 2-year journey to rice fortification standard gazetting



Offering flexibility for expanded standards

One of the original features of the Indian standard is that it proposed two lists of micronutrients: a blend that met minimum micronutrient criteria and another that included additional micronutrients, which would be voluntary. This flexibility was introduced so as not to overwhelm rice millers with a potentially expensive blend of micronutrients while ensuring that a minimum set of micronutrients were present in the rice (especially those targeted at addressing anaemia). When distributing fortified rice, the state and the private sector decide whether to use a formulation adding three mandatory micronutrients (iron, folic acid and vitamin B_{12}) or a more comprehensive formula containing one or a combination of the following micronutrients: zinc, vitamin A, vitamin B_1, vitamin B_3 and/or vitamin B_6.

Figure 4: Mandatory & voluntary micronutrients for rice in India



Timor-Leste (2021–present)

In Timor-Leste, where 70 percent of the food is imported, there was no regulatory framework until the country embarked on its journey to develop multiple standards simultaneously. Because their process started in 2021, Timor-Leste was able to leverage WFP's expertise and experience gained in accompanying other countries in the region, resulting in the fast-tracking of the fortification standards adoption process. The process was extremely inclusive with external partners playing an important technical role, in particular the private sector which provided expertise and insights into the discussions and guaranteed the operational viability of the standards.

Developing a regulatory framework from scratch

Unlike Bangladesh and India which had long-standing experiences of setting fortification standards, Timor-Leste was unique in that none of the country's staple foods were fortified and they had never been through the fortification process. This created additional complexities, not least the need to justify such an intervention. WFP, with other partners, conducted a Fill the Nutrient Gap (FNG) analysis which recommended, among other things, the introduction of fortified rice as an essential intervention for the country. In parallel, a rice landscape analysis and an acceptability trial were conducted. They provided evidence for the technical and logistical feasibility of fortifying rice.

The accumulation of this evidence led the Ministry of Tourism, Commerce, and Industry of the Government of Timor-Leste to ask WFP to support a food fortification programme in the country and to institute a legal and regulatory framework around the fortification of three staple foods: wheat flour, rice and edible oil.

A multisectoral approach

Developing food fortification standards is often led by Ministry of Health who reviews and revises the levels of fortification as per the micronutrient needs of the population and endorses the national food fortification law technically. While this approach has obvious advantages and rationale, a more holistic approach has been considered in Timor Leste with active leadership of additional stakeholders, in particular Ministries of Industry, Tourism and Commerce.

Specific roles were assigned to different ministries which contributed to building accountability across the board. The specific roles and responsibilities of key ministries are detailed in Figure 5.

Figure 5: Roles of relevant stakeholders

Ministry of Health	• Endorse the national food fortification law technically. • Insitute a national level reference laboratory for testing of fortified food products in the country. • Issue license and regulate the private sector laboratories for testing of fortified rice kernels. • Review and revise the levels of fortification as per the micronutrient needs of the population. • Monitor the quality of fortified food items as mentioned in the fortification law.
Multi-stakeholder coordination platform	• Facilitate the legislation of fortification decree law. • Lead the development of roadmap to roll out the decree law on food fortification in Timor-Leste. • Oversee and provide technical inputs in various food fortification initiatives of the government. • Advocate with relevant stakeholders to introduce and allocate adequate resources to scale up fortified foods through safety nets and open market. • Facilitate inter-ministerial and inter-departmental coordination to scale up food fortification in Timor-Leste.
Ministries of Tourism, Commerce & Industry	• Issue licenses to food business operators and premix manufaturers/importers. • Lead food fortification law process along with the Ministry of Health to legislate the law. • Allocate resources for food fortification. • Work to produce and distribute fortified foods across all social saftey net programs. • Collaborate with national health lab to ensure quality assurance. • Support in demand generation and creating awareness amongst public on importance of consuming fortified foods.
Education, Youth and Sport and Social Solidarity & Indusion	• Introduce fortified food items through their programmes. • Build capacity of relevant officials at national level on technical and program aspects of food fortification. • Include messages on benefits of consuming fortified food items in existing communication channels and generate awareness amongst beneficaries.
Finance	• Allocate adequate budget for food fortification programs. • Include fortified foods in the existing customs processes and procedures. • Register and monitor the food business operators and premix manufacturers.

This holistic approach ensured that fortification standards were not only health-focused but also considered the broader food value chain and economic implications, resulting in a more comprehensive and effective fortification strategy. Involving multiple ministries fostered cross-sectoral coordination and alignment of objectives. Ministries often have their unique priorities and goals. By engaging several ministries in the development of the standards, it became easier to align these priorities.

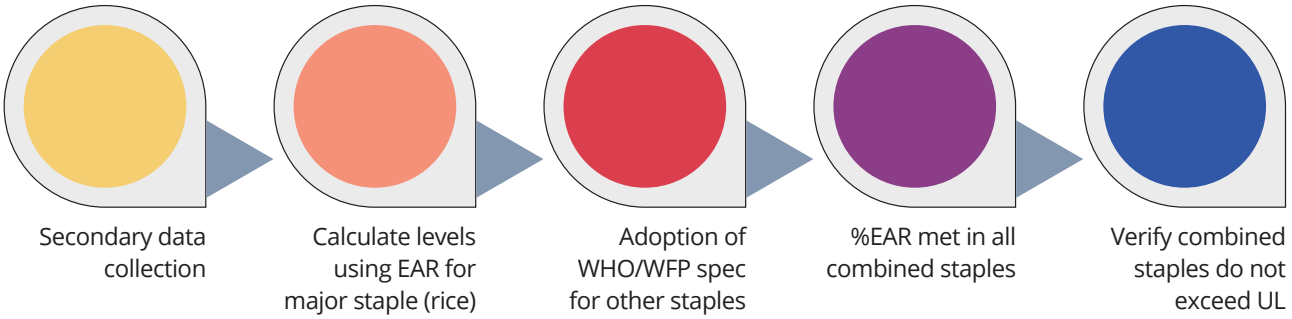
Relying on international methodologies

As Timor-Leste was new to the fortification of staple foods, the role of WFP and all the main technical stakeholders was important. WFP helped to put in place a consultative framework that enabled a technical consensus on the standards developed. Given the lack of experience nationally, the country used available evidence, data and internationally recognized methods, such as WHO/FAO guidelines on fortifying food with micronutrients. The estimated average requirement (EAR), recommended nutrient intake (RNI) and upper limit (UL) values from the guidelines were used to set levels for each of the selected micronutrients. Harmonization with regional and global standards and specifications was pursued through technical consultations with internal and external subject experts.

Defining a road map to implement the law

Timor-Leste is in the process of finalizing and issuing the law and operationalization is yet to be realized. At the request of the government, WFP developed a road map to operationalize the law. It envisions a gradual adoption of the new standard to increase the percentage of rice to be fortified progressively over three years: from 25 percent in year one to a targeted 90 percent in year three for local rice, and from 50 percent in year one to 100 percent in year three for imported rice. This strategy enables industry to plan and adapt manufacturing processes and defray investment costs over a longer period.

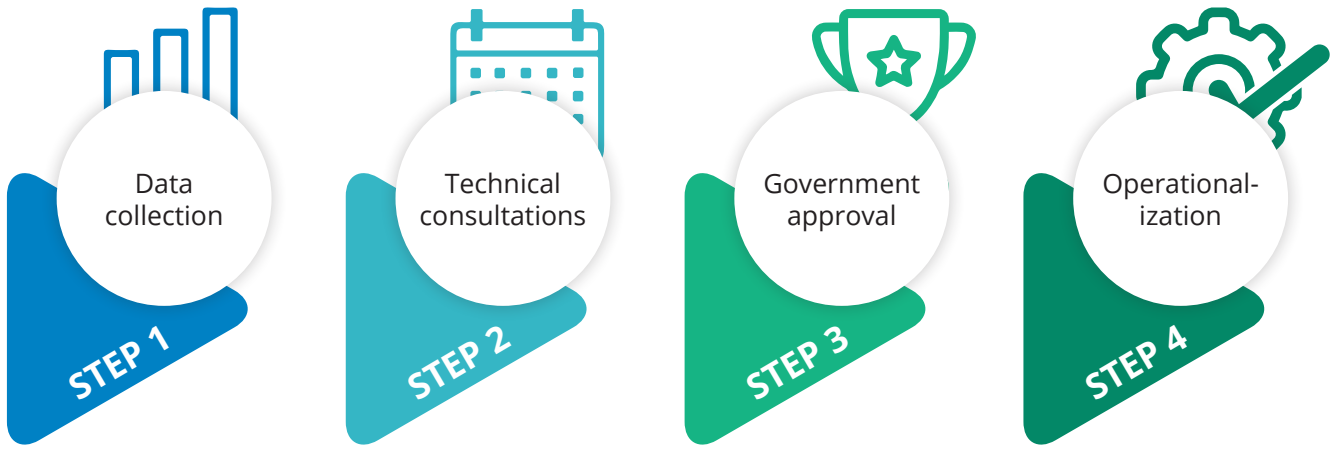
Figure 6: Timor-Leste standard development methodology



4. Guide to standard development: four-step framework

The lessons learned from Bangladesh, India and Timor-Leste can be summarized as the four-step framework described in Figure 7. The process should be iterative, starting with a data collection phase that aims to define the nutritional goals of the fortification programme and identify the key micronutrients to be used and at what levels. It should be led by a national technical committee with a view to develop the draft standards through continuous consultation with relevant ministries and subject experts. The endorsement and subsequent gazetting of the standard should be accompanied by an operationalization plan to ensure that relevant stakeholders have the capacity to enforce and monitor that fortified foods meet the standard at all times.

Figure 7: Four-step framework for the fortification standard development process



- Biochemical data.
- Dietary patterns.
- Dietary intakes.

- Drafting the standard using international guidelines.
- Iterative process led through technical committee(s).

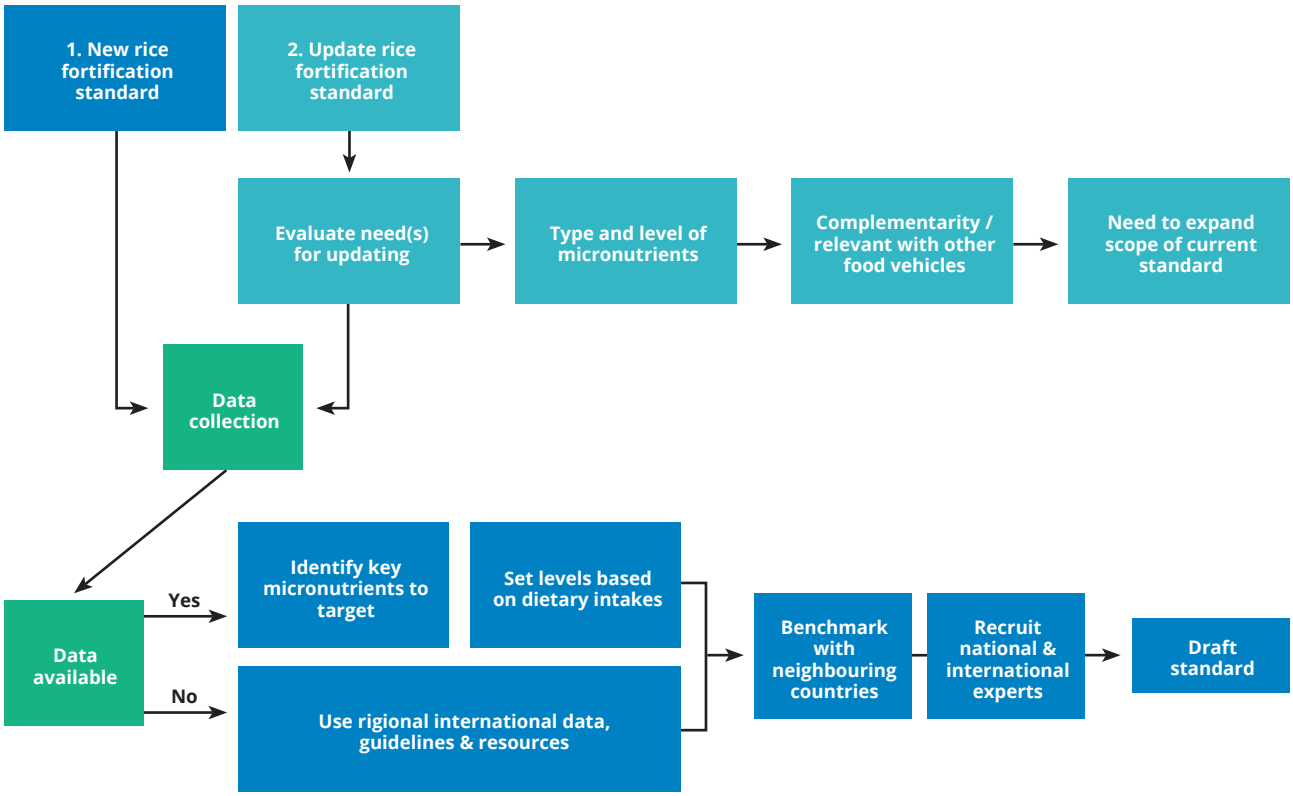
- Standard is gazetted.
- Relevant ministries/ councils endorse the law.

- Roadmap to operationalize the law.
- Build capacity of stakeholders through technical assitance to ensure effective implementaion.

Before a rice standard is developed, the staple needs to be identified as a vehicle to support and complement ongoing strategies to address micronutrient deficiencies in the population. A rice fortification standard is developed in one of two scenarios: either because one doesn't already exist, or because an existing standard needs to be updated to meet national, regional and international guidelines and recommendations. Updating an existing fortified rice standard should consider the need for updating the set of micronutrients and/or their levels , the relevance of the standard in terms of fortification of other staple foods, and the potential need to expand the scope of the standard (e.g., to include labelling, testing requirement, etc.).

As illustrated in Figure 8, regardless of whether the standard is being developed anew or being updated, it should be driven by available national data or use supporting evidence from available national, regional and international data, resources and guidelines.

Figure 8: Drafting decision tree



Collecting data to define nutritional gaps and goals

The decision to implement a rice fortification programme requires documented evidence that the micronutrient content of the diet is insufficient, that micronutrient deficiencies are widespread and/or that fortification will result in a health benefit. This will confirm the need and provide the rationale for a fortification programme.

The first step in the process consists of collecting food intake data, supported by ancillary information such as biochemical data on nutritional status of the population. This information is necessary to justify the programme, to make an informed judgement about the types and amounts of specific nutrients to include, and to understand which foods would make suitable vehicles for fortification. Given the long-term effort and investment required to implement and sustain appropriate fortification programmes, this initial investment in the collection of adequate food intake data should include:

- Biochemical/chemical data on nutritional status (e.g., the scale and severity of specific nutrient deficiencies in different population groups);
- Data on dietary patterns (e.g., the composition of the usual diet); and
- Detailed information on dietary intakes of micronutrients of interest (e.g., the distribution of usual intakes of specific micronutrients in a population).

Data sources should include micronutrient surveys, health and nutrition surveys (undertaken every four years in some countries), household consumption and expenditure surveys, etc.

Availability of recent accurate data may be a bottleneck at this early and important step. As shown in Figure 7, in the absence of quality data, several strategies can enable the collection and triangulation of as much data as possible.

In addition to data collection, it is important at this initial stage to collect existing global and regional evidence on the impact, effectiveness and safety of the food selected for fortification to reassure those who may initially be sceptical of the proposed intervention.

Drafting the standards through a consultative and iterative approach

When the data collection phase is complete, a consultative process needs to be set up under the auspices of a national technical committee to start drafting the rice fortification standard. At this stage it is important to leverage existing expertise of national and international food safety authorities, bureaux of standards, scientific panels and technical committees. This will ensure that the standards built are technically sound.

The selection of micronutrients to be included into the formulation should consider their stability in rice, potential organoleptic impacts of a given micronutrient (e.g., impact on taste or smell), price, and the extent to which the micronutrient is already being used in other fortification and/or supplementation interventions in the country.

This process should be iterative with recurring technical consultations to build consensus and ensure that the draft standard is technically and operationally sound. The successful experiences of setting rice fortification standards in Asia show how crucial this approach has been to achieving technical consensus among a wide variety and diversity of stakeholders involved in the decision making process.

From an operational standpoint, it is important to adopt a cross-sectoral consultation approach by bringing in the practical expertise of additional partners beyond the scientific community. External partners, and in particular the private sector, should be invited to take part in the process to provide expertise and insights into the discussions and encourage the operational viability of the standards developed. These should include premix manufactures, fortified rice kernel producers, equipment manufacturers, rice millers, etc.

Adoption and publication of the standard

In the case of Bangladesh and Timor-Leste, the process of developing new standards from scratch took between 12 and 18 months. In India, the draft standards were published in the public domain for a specified duration and all comments were then reviewed by the national scientific panel and modifications were made as necessary. Publishing the standard in the national registry is the last step in the process; it provides the necessary regulatory framework for the standards to be adopted and operationalized and enables implementation and monitoring.

Operationalizing the standard

Implementation of the new or updated standard will require some time to allow for preparation by all parties in the value chain. These are many and varied, including food manufacturers, suppliers of fortificants, quality control and testing laboratories, and distributors and retailers. Preparations include production and procurement of inputs (fortificants/premix), industrial trials, staff training, and capacity building to enable monitoring and tracking of implementation.

In Timor-Leste, a road map to implementation of the rice fortification standard was developed in three stages over three years. It was designed to facilitate the gradual adoption of the new standard, increasing the percentage of rice to be fortified progressively, from 25 percent in year one to a targeted 90 percent in year three for local rice, and from 50 percent in year one to 100 percent in year three for imported rice. This enables businesses to plan and adapt their processes and defray investment costs over a longer period.

A phased approach to the implementation of standards offers the opportunity to gradually train and build capacity of monitoring officers and laboratory technicians throughout the country to test and verify the quality and quantity of nutrients and ensure they meet the regulatory standards.

Developing a rice fortification standard should not be seen as a one-off project but rather as an ongoing activity that requires consistent monitoring and adapting to shifting trends, new scientific evidence and ever-changing economic and consumption patterns. In Bangladesh, the rice fortification standard was revised in 2022, seven years after it was initially published, to adopt new methods of testing.

5. Lessons learned

The journeys of Bangladesh, India and Timor-Leste in developing new rice fortification standards has identified strategic lessons learned, specifically around the positioning of such projects with local authorities and stakeholders to raise their profile and leverage adequate support throughout the process.

Adequately positioning the project

When a government prioritizes improving the food value chain, this can be leveraged to build the accountability of relevant ministries, especially those that have a stake in developing food value chains and helping private companies, for example the Ministry of Industry.

Leading standard development processes as a public health initiative only can ignore the opportunity to make the right connections and get the necessary buy-in of private sector partners, who play a central role

in implementing fortification legislation further down the line. Identifying which ministries in each country context have a stake in strengthening the national rice value chain will broaden support.

When different ministries work together, they can create a framework where fortified foods benefit both public health and the economy. This alignment ensures that fortification initiatives are sustainable and not isolated efforts.

Building review mechanisms into the legislation

Integrating and planning for the ongoing revision of standards in light of new data and shifting consumption patterns is necessary.

Updating standards on an ongoing basis offers an opportunity for policy review and ensures that fortification legislations are current with the needs of the population. A clear illustration of the opportunity offered by such reviews was witnessed in Bangladesh, where mandatory fortification of wheat flour was dropped on the adoption of the rice fortification mandate.

For countries embarking on standard development processes from scratch, it is important to ensure that periodic and systematic reviews of the standards are built into the law to reflect dietary needs/shifts and updated scientific evidence and developments.

Appendix 1

Technical guide: Developing fortified rice standards

The goal of fortification is to increase the regular nutrient intake of a target population, but not so much that high consumption levels will put them at risk of excessive intake. Although this guide focuses on methodologies recommended to develop standards for fortified rice specifically, fortification of any staple food shouldn't be seen in isolation but rather in coordination and harmonization with fortification of other staples, current and future. It will be important to identify the proportion of staple food consumption and micronutrient deficiencies of highest public health concern to determine the micronutrients to be added to rice, their quantities, and the suitability of rice as a vehicle for that specific micronutrient.

Fortified rice standards globally

Countries that have already embarked on the journey to develop rice fortification standards provide guidance and benchmarks on the set of micronutrients used and the target levels to be added (Table 1).

Table 1: Examples of national fortified rice standards

Fortification Levels (mg/kg)											
	Vitamins							Minerals			
	Thiamin (B_1)	Riboflavin (B_2)	Niacin (B_3)	Pyridoxine (B_6)	Folic Acid (B_9)	Cyanocobalamine (B_{12})	Vitamin A (RE)	Iron	Type of Iron	Selenium	Zinc
Bangladesh	4.00		-	-	1.30	0.01	1.50	60.00	Ferric FePP	-	40.00
Costa Rica	5.30		35.00	-	1.80	0.01	-	-	-	0.105	7.50
India	*	*	*	*	0.075-0.125	0.00075-0.00125	*	28-42.5	FePP		*
Nicaragua	5.00		40.00	4.00	1.00	0.01	-	24.00	FepPP	-	25.00
Panama	5.00		40.00	4.00	1.00	0.01	-	24.00	FePP	-	25.00
Papua New Guine	5.00		60.00		-	-	-	30.00	Not Specified	-	-
Philippines	-		-		-	-	-	60-90		-	-
The Gamia	TBC		TBC	TBC	TBC	TBC	TBC	TBC	TBC	TBC	TBC
USA	4.4-8.8		35.2-70.4	-	1.54-3.08	-	-	28.6-57.2	Not Specified	-	-

* Optional
Source: Adapted from: Rice Fortification: Evidence, Status, and Lesson's Learned in Grain Fortification, Tsang B.L, Pachan H, Sight & Life supplement - Rice Fortification in Latin America

Based on WHO recommendations for wheat and maize flour fortification, various levels of micronutrients have been recommended according to per capita rice consumption (10) (Table 2). WFP has developed the standards it uses when procuring fortified rice distributed in food assistance programmes, offering a good benchmark for nutrient selection and proposed levels of fortification.

Table 2: WFP standards for nutrient levels proposed for fortified rice at moment of consumption

Nutrient levels proposed for fortified rice at moment of consumption (mg/kg)						
Micronutrient	Chemical form	<75 g/d	75-149 g/d	150-300 g/d	>300 g/d	World Food Programme
Iron	Micronized ferric pyrophosphate	120.00	120.00	70.00	70.00	40.00
Folic Acid (B_9)	Folic Acid	5.00	2.60	1.30	1.00	1.69
Cobalamin (B_{12})	Cyanocobalamine	0.04	0.02	0.01	0.01	0.01
Vitamin A (RE)	Vitamin A palmitate	5.90	3.00	1.50	1.00	1.95
Zinc	Zinc oxide	95.00	80.00	60.00	50.00	60.00
Thiamin (B_1)	Thiamin mononitrate	20.00	10.00	5.00	3.50	6.50
Niacin (B_3)	Niacinamide	260.00	130.00	70.00	40.00	91.00
Pyridoxine (B_6)	Pyridoxine Hydrochloride	24.00	12.00	6.00	4.00	7.80

Source: Adapted from: De Pee, Annals of New York Academy of Sciences, 2014

Methodology

For the majority of micronutrients, the highest recommended intakes are for adult males, with the notable exception being iron for women of reproductive age. The adult male subgroup usually has the lowest risk of micronutrient deficiencies due to higher food intake and lower micronutrient requirements per unit of body weight. Individuals most at risk of not meeting their RNI are infants, young children, and women of reproductive age, especially pregnant and breastfeeding women. Some of these groups (e.g., pregnant and breastfeeding women) have higher requirements for specific nutrients than do adult men.

Various national and international bodies, including FAO and WHO, have specified dietary requirements for specific micronutrients aimed at minimizing the risk of nutrient deficit or excess. Two sets of dietary reference values are traditionally used to develop fortification standards:

- The recommended nutrient intake (RNI), which is defined by FAO/WHO as the daily dietary intake level that is sufficient to meet the nutrient requirement of almost all (i.e., 97–98 percent) healthy individuals in a particular age, gender and physiological status group; and
- The estimated average requirement (EAR).

The EAR cut-point (i.e., cut-off point, the limit at which something is no longer applicable) approach is different from the past practice of using the RNI of a nutrient as the desirable or 'target' intake. As suggested in the WHO/FAO 2006 Guidelines on Food Fortification with Micronutrients (11), the RNI approach is valid for deriving the desired nutrient intake of an individual, but not that of a population. This is why the approach recommended in the WHO/FAO guidelines for setting fortificant levels in foods is the EAR cut-point method.

The most appropriate reference value for determining safe levels of micronutrient intakes of population subgroups (i.e., the levels at which there is no risk of excessive intake), is the tolerable upper intake level (UL). This is the highest average intake that will not pose a risk of adverse health effects to most of the population. The risk of adverse effects increases at intakes above the UL.

The methodology suggested to develop and set fortification levels is based on the approach recommended in the WHO/FAO guidelines mentioned above. In particular, the recommended intakes for each of the micronutrients studied are based on the EAR, except for iron, for which the RNI is recommended as reference. The recommended levels of EAR and RNI and the ULs can be found in detail in the "Food fortification: An effective and safe way to fight micronutrient malnutrition and its consequences" document (12). It is important to note that the intake estimates and the calculated ULs do not consider the distribution of micronutrient intake from other sources such as the diet or supplementation programmes.

Defining nutritional targets

The suggested values (percent of EAR) presented in Table 3 can be used as guidance to define the nutritional targets for each selected micronutrient. Based on these suggested levels, various alternative formulae can be designed and assessed in terms of their calculated impact on a particular segment of the population and their cost. The percentage of EAR for females aged 15–50 years, who have high micronutrient needs, constitutes a good benchmark.

Table 3: Suggested nutritional objectives for increasing micronutrient intakes

Suggested nutritional objectives for increasing micronutrient intakes on low-middle income countries			
100% EAR	80% EAR	60 EAR	40% EAR
Iodine	Vitamin A	Vitamin B_2	Vitamin B_1
-	Folate	Calcium	Niacin
-	Vitamin B_{12}	(Vitamin D)*	Vitamin B_6
-	Iron	-	Vitamin C
-	Zinc	-	-

* In locations where skin exposure to sunlight is low.
Source: The Food Fortification Formulator: Technical Detemination of Fortification Levels and Standards for Mass Fortification Omar Dary and Michael Hainsworth

Suggested formulation scenario for fortified rice

The micronutrients used to fortify rice include minerals such as iron and zinc and vitamins such as A and the B vitamins (B_1, B_2, B_3, B_6, folic acid, B_{12}). However, two vitamins need to be carefully considered before finalizing the formulation for rice, particularly given the sensitivities and importance of this staple in the diet of Asian populations.

From an organoleptic perspective, it has been documented that vitamin B_2 (riboflavin) colours fortified kernels, which can prove unacceptable to consumers, and vitamin A, which is costly and highly sensitive to heat and oxidation, is already recommended in many countries for addition to vegetable oils. It is advisable to put forward formulations that include the following micronutrients:

- Vitamin B_1 as thiamine mononitrate
- Vitamin B_3 as niacinamide
- Vitamin B_6 as pyridoxine hydrochloride
- Folic acid
- Vitamin B_{12} as cyanocobalamin
- Iron as micronized ferric pyrophosphate
- Zinc as zinc oxide.

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Abbreviations

BSTI	Bangladesh Standards and Testing Institution
EAR	Estimated average requirement
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FNG	Fill the Nutrient Gap
FSSAI	Food Safety and Standards Authority of India
RBB	Regional Bureau Bangkok
RNI	Recommended nutrient intake
UL	Upper limit
WFP	World Food Programme
WHO	World Health Organization

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