Standards and Specifications for Fortified Rice

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Key Messages

- Standards and specifications for fortified rice should specify quality in terms of safety, acceptability (organoleptic and optical) and nutrient content for the benefit of consumers and manufacturers.
- Drafting standards and specifications should be a consultative process.
- Codex Alimentarius provides global standards for rice and for food fortification.
- The recently published WHO guideline *Fortification of Rice with Vitamins and Minerals as a Public Health Strategy* supports rice fortification and recommends that decisions on which micronutrients to add and in what amount be, among other things, based on nutritional needs and gaps in dietary intake of the target population.[1]
- Micronutrient levels should be set such that the intake of the micronutrient in the general population, from all sources, is above the estimated average requirement (EAR) and below the tolerable upper limit (UL) for almost everyone.
- Where intake is not well known and dietary deficiencies are likely, it is a good approach to set the micronutrient level of fortified rice such that, at prevailing consumption levels, it provides the EAR for adults.[2,3]

Introduction

When a country chooses to fortify rice to increase micronutrient intake across the population, standards that specify the required quality, the visual and organoleptic characteristics and the nutrient content provide clarity and protection for both manufacturers and consumers. They also ensure acceptability. Standards are more general than specifications or Commodity Requirement Documents (CRD). For example, fortified rice standards might cover a range in terms of the types of rice, nutrient content and quality specifications. Specifications for rice for a contract – such as a government contract for distribution under a social safety net scheme – are more specific, including, for example, the type of rice, the quality in terms of percentage of broken kernels that can be included, the required chemical form and composition of the micronutrients, the technology or technologies used to produce fortified kernels, the visual characteristics of the fortified kernels, the blending ratio of fortified kernels to rice grains, the required packaging, the limits for foreign matter and heavy metals, and the shelf life.

> "Standards that specify the required quality and nutrient content for fortified rice provide clarity and protection for both manufacturers and consumers"

This paper discusses standards and specifications that exist or are being developed for fortified rice, and how to set the desired micronutrient content of fortified rice.

Codex Alimentarius standards

The global source for food standards is the Codex Alimentarius Commission (www.codexalimentarius.org), established by the Food and Agriculture Organization of the United Nations and the World Health Organization (WHO) in 1963. This Com-

FIGURE 1: Normal distribution of nutrient needs, where 50% of the population meets their requirements at the level of the estimated average requirement (EAR) and 97.5% meets requirements at the level of the recommended nutrient intake (RNI)

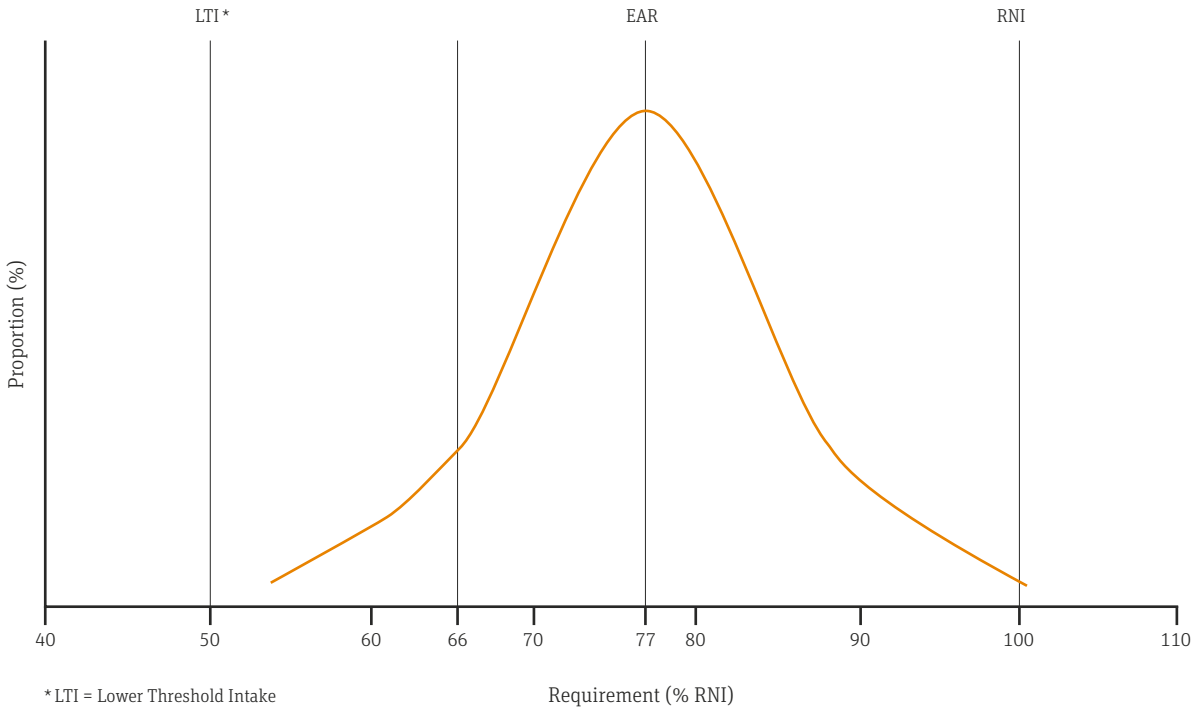
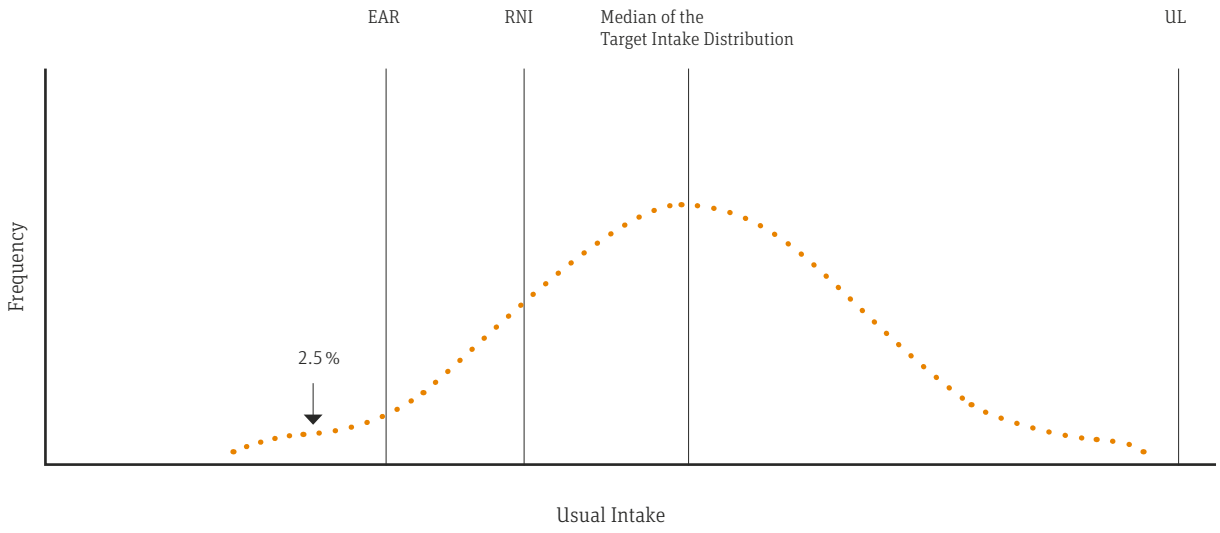


FIGURE 2: The target for micronutrient intake distribution, where 2.5% or less is below the EAR and the majority is above the RNI but below the tolerable upper limit (UL)



mission develops harmonized international food standards, guidelines and codes of practice to protect the health of consumers and ensure fair trade practices. The Commission also promotes coordination of all food standards work undertaken by international governmental and nongovernmental organizations. While the adoption of Codex recommendations is voluntary for countries, Codex standards are often the basis for national legislation.

For fortified rice, two Codex documents can be referenced: the Codex standard for rice (CODEX STAN 198-1995)[4] and the guideline for the addition of essential nutrients to foods (CAC/GL 09-1987, amended in 1989 and 1991)[5], which governs for-

tification of foods in general. There is no Codex standard or guideline specifically for fortified rice, nor is there a guideline specifically for other fortified staple foods. Countries should decide whether to have the same structure, i.e., a standard for rice and a standard for food fortification, and should then develop specifications for individual fortified foods, such as fortified rice, that are for a particular use, such as school feeding, or for particular contracts. These specifications can include more details (e.g., micronutrient content, packaging specifications, etc.) and can be modified more easily when required. Standards and specifications should be developed through a consultative process that includes public- and private-sector partners, academia and consumer representatives (e.g., civil society organizations). Countries that have developed a standard for fortified rice include Costa Rica, the Philippines, and the USA.

Setting the micronutrient content

The level of micronutrients for fortified rice should be determined after consideration of four country-specific conditions.[6]

- **First:** The consumption levels of the food in the target population: if average consumption is high, as in most rice-consuming countries, lower amounts of micronutrients are needed per kilogram of rice to achieve a target level of micronutrient intake.

- **Second:** Whether other foods are fortified and with which nutrients: for example, if vegetable oil or sugar are adequately fortified with vitamin A and these foods are consumed by more or less the same group of the population that will consume the fortified rice, vitamin A may be included at a lower level in the fortified rice, or not at all. Also, when more than one staple food is fortified, e.g., wheat flour and rice, the fortification level of each should be based on their combined intake so that micronutrient intake will be the same whether 300 g of one of the staples or 150 g of each is consumed per day.

- **Third:** Whether the food, and the diet in general, contains compounds that may affect stability or absorption of minerals or vitamins that are added, such as the phytate in grains that inhibits mineral absorption (e.g., iron and zinc); this information affects the form and level of the nutrient to be added for fortification (e.g., sodium iron EDTA is the only recommended form of iron for fortification of high extraction flour).[7]

- **Fourth:** Consumer acceptability: the micronutrient fortification levels and technology used to produce the fortified kernels should be such that the rice is acceptable to the consumer in terms of visual appearance (color and shape), smell, and taste, both before and after preparation.

If rice will be the only food fortified with the specific micronutrient(s), the level of the micronutrient should be set to provide approximately the estimated average requirement (EAR) of the micronutrient(s) for healthy adults. The EAR is the average (median) daily nutrient intake level estimated to meet the needs of half the healthy individuals in a particular age and gender group. The EAR is used to derive the recommended nutrient intake (RNI). The RNI, established by FAO/ WHO, is set at the EAR plus two standard deviations, which means that it would meet the needs of 97.5% of all normal, healthy individuals in an age- and sex-specific population group (see **Figure 1**).

Most people already consume some amount of the specific micronutrients. Therefore, setting the micronutrient contribution from the fortified food at the EAR level shifts the average micronutrient intake to a level above the EAR and likely just above the RNI (see **Figure 2**). The proportion of people below the EAR should be less than 2.5% of the population, to minimize the proportion of people that do not consume adequate amounts of the micronutrient to meet their needs.

The fortified rice should make a good contribution to intake for most consumers and at the same time be safe for those who have the highest rice intake. To assess the risk of too high an intake, one has to refer to the tolerable upper limit (UL). The UL is defined as the daily nutrient intake level that is considered to pose no risk of adverse health effects to almost all (97.5%) healthy individuals in an age- and sex-specific population group. The UL applies to daily intake over a prolonged period of time and to healthy individuals with no micronutrient deficits to be corrected. The UL typically includes a large safety margin as it is set at a much lower level than the lowest level at which an adverse effect of a chronically high intake has been observed.

It is important to note that the level at which acute toxicity may occur is well above the UL level. Furthermore, as the UL is well above the RNI, and rice will be fortified at a level so that the amount of rice that is typically consumed per capita per day provides the EAR, which is approximately 70% of the RNI, one would have to consume several times the expected daily amount of fortified rice in order to reach the UL. Thus, if 300 g of uncooked rice provides the EAR, only daily consumption of 1–10 kg (depending on the micronutrient) of uncooked rice over a prolonged period of time could potentially put the consumer at risk of too high an intake from consuming fortified rice (consistently going over the UL). This scenario is unrealistic.

Determining the micronutrient level per 100 g of fortified rice that is required for the total fortified rice intake to provide the EAR requires an estimate of the per capita rice consumption. For example, the EAR for vitamin B_1 (thiamine) is 0.9 mg

TABLE 1: Nutrient levels proposed for fortified rice at moment of consumption (mg/100 g[2])

Nutrient	Compound	<75 g/d	75–149 g/d	150–300 g/d	>300 g/d	EAR
Iron	Micronized ferric pyrophosphate	12	12	7	7	
	Ferric pyrophosphate with citrate and trisodium citrate, possibly other solubilising agents [a,b]	7	7	4	4	
Folic acid (B_9)	Folic acid	0.50	0.26	0.13	0.10	0.192
Cobalamin (B_{12})	Cyanocobalamin	0.004	0.002	0.001	0.0008	0.002
Vitamin A	Vitamin A palmitate	0.59	0.3	0.15	0.1	0.357 (f)
						0.429 (m)
Zinc	Zinc oxide	9.5	8	6	5	8.2 (f)
						11.7 (m)
Thiamine (B_1)	Thiamine mononitrate	2.0	1.0	0.5	0.35	0.9 (f)
						1.0 (m)
Niacin (B_3)	Niacin amide	26	13	7	4	11 (f)
						12 (m)
Pyridoxine (B_6)	Pyrodoxine hydrochloride	2.4	1.2	0.6	0.4	1.1

[a] Reported effective molar ratio Fe/citrate/trisodium citrate: 1/0.1/2.1.
[b] See article by Saskia de Pee, Diego Moretti, Cecilia Fabrizio and Jennifer Rosenzweig on p. 55 of this supplement for evidence.

for adult women and 1.0 mg for adult men. This means that the amount of fortified rice consumed in a day should provide approximately 0.9–1.0 mg of thiamine. The interim consensus statement on flour fortification proposed the following categories for flour consumption: <75 g/d, 75–149 g/d, 150–300 g/d, and >300 g/d.[7] The same categories were adopted for rice consumption. In countries where rice is the main staple food, average per capita rice consumption typically falls into the higher categories. In the case of thiamine, a level of 0.5 mg/100 g is proposed for the category of 150–300 g/d and 0.35 mg/100 g for >300 g/d, as these would provide approximately 1.0 mg of thiamine per day at a consumption of 200 g (200 x 0.5/100 g) or 300 g (300 x 0.35/100 g), respectively.

Nutrients and nutrient levels for rice fortification have been recommended based upon this consideration of the EAR and average per capita rice consumption (**Table 1**). For more information on the rationale for choosing the eight recommended micronutrients for fortification of rice, see Rice fortification by de Pee et al, p. 55.[3] This recommendation by de Pee is also in line with the very recently published WHO guideline on rice fortification, which recommends that micronutrients for fortification of rice be selected based on nutritional needs and gaps in dietary intake, that reconstitution of intrinsic levels of thiamine, niacin, vitamin B_6 and riboflavin that have been lost due to milling should remain a regular practice in fortification, that iron status can benefit from fortification with iron and vitamin A and folate nutritional status from fortification with folic acid, and that vitamin B_{12} should also be added when folic acid is added.[1] It is important to note though that addition of riboflavin would color the fortified kernel yellow, making the fortified kernels easy to pick out, and intrinsic levels of riboflavin are already low, so that its addition is not recommended.

As mentioned above, when there are already other good sources of specific micronutrients consumed by a population, such as vitamin A–fortified vegetable oil, or parboiled rice that has higher levels of thiamine, niacin, and vitamin B_6 than polished rice, the levels proposed in Table 1 should be adjusted to meet that population's specific needs. In the case of fortified vegetable oil, the average intake level of vitamin A can be calculated from the per capita consumption of vegetable oil and its fortification level. For example, if the vegetable oil provides 50% of the target EAR, the remaining 50% could be added to rice. Similar considerations can be applied when other staple foods, such as wheat flour or maize flour, are fortified – in which case, fortification level should be set based on the per capita daily intake of the different staples together.

Table 1 and the above explanation have specified levels of micronutrients at the moment of consumption. However, as losses may occur over time, i.e., during storage, and during processing and preparation, an overage may be added at the moment of production, especially for vitamins that are heat-sensitive. Vitamin A is the most heat-sensitive of the vitamins and will require the highest overage. In addition, since there will be variation around the amount of micronutrients that are in the premix and in the fortified kernels, the blending ratio, and the

laboratory measurements, specifications for fortified rice also need to specify a minimum–maximum range at the moment of production. Finally, specifications should also specify the allowed minimum content by the best-before date (i.e., the end of the fortified rice's shelf life).

> "Rice fortification should be part of an integrated strategy for improving micronutrient intake and status of a population"

Introducing fortified rice among other fortified foods

Rice fortification should be part of an integrated strategy for improving micronutrient intake and status of a population. Therefore, as mentioned above, when there are other fortified foods, the fortification and consumption levels of those and of other main sources of the specific micronutrients need to be taken into consideration when setting the micronutrient fortification levels for rice. A program such as the Intake Monitoring, Assessment and Planning Program (IMAPP)[8] can assist in calculating safe intake levels of the proposed micronutrients. The program integrates data on the intake of specific foods and additional supplementation among specific target groups, using data that need to be collected by both a food frequency and a 24-hour recall method.

Conclusion

Standards for a specific category of foods (e.g., rice or food fortification in general) and specifications for a specific food (e.g., fortified rice that the government buys for the social safety net program) aim to protect the health of consumers, guarantee high quality of fortification practices and products and provide for fair trade practices for those in the rice supply chain. These standards and specifications define quality, in terms of what is safe (e.g., foreign matter), acceptable (e.g., maximum proportion of broken kernels, organoleptic and visual characteristics) and nutritious (nutrient content). Standards and specifications should be clear without the need for further interpretation and should also be feasible to achieve, monitor and enforce. Experience demonstrates that standards and specifications are best developed through a consultative process, led by a government's food regulatory authority, informed by Codex Alimentarius and data, and supported by expert and consumer groups. This article has reviewed the rationale for the proposed nutrient levels for fortified rice, which can be used as is, or else adapted to a specific country context, taking existing food fortification and micronutrient intake levels into account.

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