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 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.
- 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, setting the micronutrient level of fortified rice such that, at prevailing consumption levels, it provides the EAR for adults is a good approach.[1,2]

Introduction

When a country chooses to fortify rice to increase micronutrient intake across the population, standards that specify the required quality and nutrient content provide clarity and protection for both manufacturers and consumers. These standards help ensure the nutritional quality of the rice and that the rice is safe and acceptable for consumption. 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 from a government 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 micronutrient content to be met, the technology/ies used to produce 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 Commission develops harmonized international food standards, guidelines, and codes of practice to protect the health of the consumers and ensure fair trade practices. The Commission also promotes coordination of all food standards work undertaken by international governmental and non-governmental 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[3]) and the guideline for the addition of essential nutrients to foods (CAC/GL 09-1987, amended in 1989 and 1991[4]), which governs fortification 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 then develop specifications for individual fortified foods, such as fortified rice, that are for a particular use or for particular contracts. These specifications can include more details (e.g., micronutrient content for specific target groups, 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 civil society. Countries that have developed a standard for fortified rice include Costa Rica, the Philippines and the USA.

> "Standards and specifications should be developed through a consultative process"

Setting the micronutrient content

The level of micronutrients for fortified rice should be determined after consideration of four country-specific conditions.[5]

- **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 the same people who will consume fortified rice, vitamin A may be included at a lower level in the fortified rice, or not at all.
- **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).[6]
- **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 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 receive 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 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.

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 to provide 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 consumption of approximately 1–10 kg (depending on the micronutrient) of uncooked rice daily 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

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)

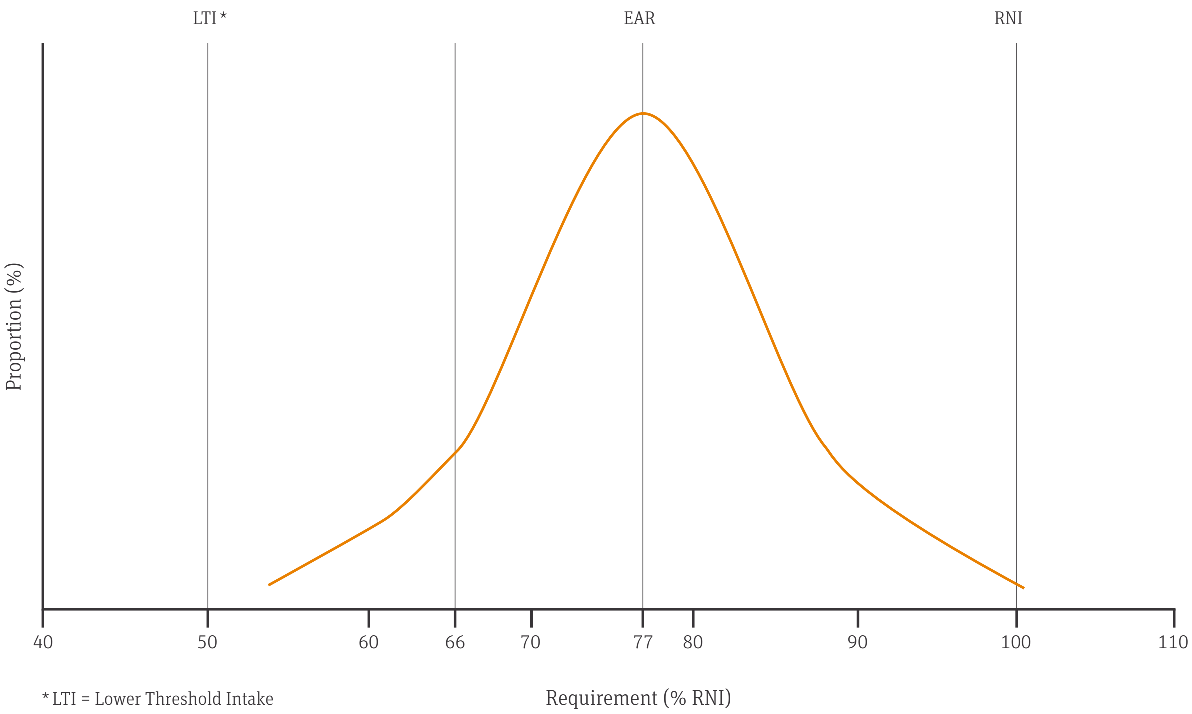
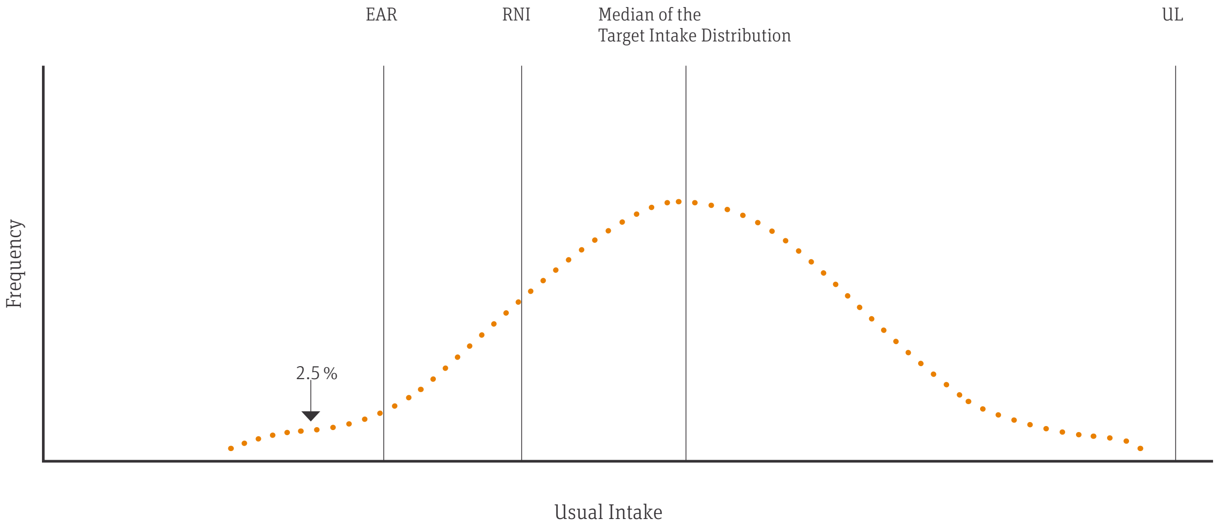


FIGURE 2: The target for micronutrient intake distribution, where 2.5% or less is below the EAR and the majority is above the RNI but below the tolerable upper limit (UL)



the EAR requires an estimate of the per capita rice consumption. For example, the EAR for vitamin B_1 (thiamin) is 0.9 mg 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 thiamin. 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.[6] The same categories have been 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 thiamin, a level of 0.5 mg/100 g is proposed for the category of 150 – 300 g/d

TABLE 1: Nutrient levels proposed for fortified rice at moment of consumption[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	
Folic acid	Folic acid	0.50	0.26	0.13	0.10	0.192
Vitamin 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)
Thiamin	Thiamin mononitrate	2.0	1.0	0.5	0.35	0.9 (f) 1.0 (m)
Niacin	Niacin amide	26	13	7	4	11 (f) 12 (m)
Vitamin B_6	Pyrodoxine hydrochloride	2.4	1.2	0.6	0.4	1.1

and 0.35 for > 300 g/d, as these would provide approximately 1.0 mg of thiamin 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 choice of the eight recommended micronutrients for fortification of rice, please refer to the contribution by de Pee et al (p. 143) and de Pee[2] (note that research conducted after the paper by de Pee was published has found a possible way of increasing iron bioavailability in rice so that lower levels may be included of approx. 4 mg/100 g instead of 7 mg/100 g in the 150–300 and > 300 g/d categories).[7]

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 which has higher levels of thiamin, 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.

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 and will require more overage, while other nutrients are more stable. 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 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 a food frequency method 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 will buy for the social safety net program) aim to protect the health of consumers and to 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), 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 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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