

# Overview of Evidence and Recommendations for Effective Large-scale Rice Fortification

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### Key Messages

- Multiple efficacy and effectiveness studies have established the impact of fortified rice on micronutrient status.
- To prepare for the introduction of fortified rice, countries should conduct a landscape analysis to assess feasibility. Given the existing evidence base, it is not necessary to conduct additional efficacy trials prior to the introduction of rice fortification.
- Based on available evidence of efficacy, stability and micronutrient needs, the following micronutrients are recommended for rice fortification: iron, zinc, and vitamins A, B<sub>1</sub> (thiamine), B<sub>3</sub> (niacin), B<sub>6</sub> (pyridoxine), B<sub>9</sub> (folic acid), and B<sub>12</sub> (cobalamin), which is also in line with the very recently published WHO guideline on the fortification of rice with vitamins and minerals as a public health strategy.<sup>1,2</sup>
- Based on results of very recent studies, novel formula-

tions for optimized bioavailability of iron and zinc can further optimize nutrient delivery.

- Rice fortification programs should use technology and micronutrient fortificant forms that produce fortified rice that is acceptable to consumers, retains micronutrients during storage and preparation, and releases them for absorption by the body.
- When introducing fortified rice, countries should monitor implementation. This includes appropriate fortification (i.e., of fortified kernels and their blending), storage and distribution, and monitoring of acceptance and consumption.

### Introduction

In populations where rice is a major staple food, fortification of rice with micronutrients has the potential to increase micronutrient intake. Decades-long experience with the fortification of other staple foods and condiments has proven that large-scale fortification is efficacious. This article discusses country-level considerations for rice fortification and reviews the global evidence base for the efficacy and effectiveness of rice fortification.

### Country-level considerations for food fortification Identifying suitable micronutrients for fortification

An analysis of which micronutrient deficiencies are likely to exist and are of public health significance will help determine which micronutrients should be used to fortify rice and in what form. The comprehensive publication by the World Health Organization (WHO) and the Food and Agricultural Organization of the United Nations (FAO), *Guidelines on Food Fortification with Micronutrients*, assists countries in the design



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Schoolchildren participating in a school feeding trial in northern Ghana (Tamale)

and implementation of appropriate food fortification programs and is particularly helpful for low- and middle-income countries.<sup>3</sup> The WHO/FAO publication provides guidance on the selection of food vehicles and which micronutrients to add, in what chemical form, and in what quantities. In addition, WHO recently published the guideline *Fortification of Rice with Vitamins and Minerals as a Public Health Strategy*, which supports rice fortification and recommends that decisions on which micronutrients to add and in what amount are, among other things, based on nutritional needs and gaps in dietary intake of the target population.<sup>1</sup>

“An analysis of which micronutrient deficiencies are likely to exist will help determine which micronutrients should be used to fortify rice”

#### Requirements for rice fortification to be effective

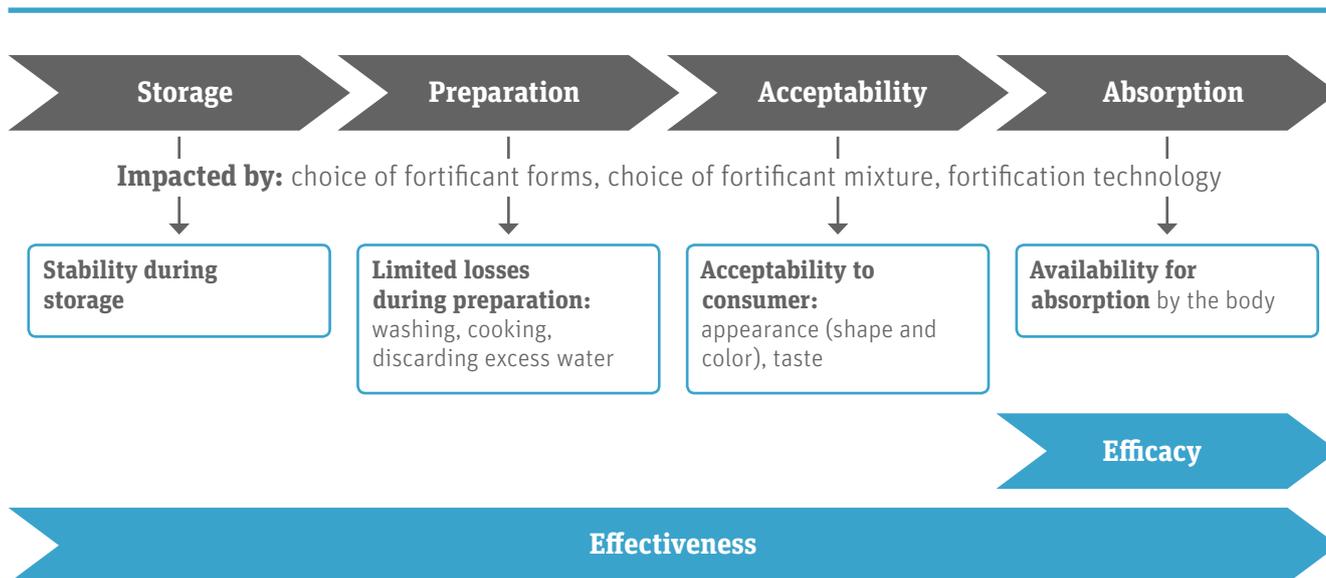
For a rice fortification program to be effective, the following conditions need to be met (see **Figure 1**):

- a) The micronutrients used to fortify the rice should remain stable during storage, i.e., losses over time should be limited.
- b) The micronutrients should be retained after preparation (washing, cooking and discarding excess water).
- c) The fortified rice should be acceptable to the consumer in appearance (shape and color), taste and smell.
- d) The micronutrients remaining post-cooking should be available for absorption by the body.

These requirements are affected by the fortificants’ chemical forms and formulation, the fortification technology and any possible interaction between micronutrients, or the rice matrix. Finally, the fortified rice needs to be consumed regularly and in the expected quantities by the desired population groups in order to make a good contribution to micronutrient intake.

#### Global evidence for rice fortification

The following is a review of two types of studies conducted on micronutrient fortification of rice that address the conditions illustrated in **Figure 1**. One type of study examines the efficacy of key micronutrients used in rice fortification. These carefully controlled studies assessed whether consumption of a

**FIGURE 1:** Factors that determine the efficacy and effectiveness of rice fortification

given amount of rice, fortified with micronutrients in a specific concentration, using specific fortificant forms and fortification technology, resulted in the micronutrients being absorbed and utilized by the body. In effectiveness studies, people in specific population groups were provided with fortified rice under less controlled circumstances. The studies assessed whether these groups – who prepared and consumed the fortified rice in their homes – showed a reduction in the signs of micronutrient deficiencies or changes in micronutrient status. Under these studies, the impact on the micronutrient status of participants was also dependent on storage, preparation, acceptance and unsupervised consumption of the fortified rice.

### Efficacy studies of fortified rice

Since early 2000, 16 efficacy studies have been published that assessed the impact of fortified rice on micronutrient status or absorption.<sup>4–20</sup> All studies except one used fortified kernels that were produced using extrusion technology. One pilot study was conducted with coated rice fortified with ferrous sulfate ( $\text{FeSO}_4$ ).<sup>17</sup> Each study was conducted in a controlled setting and aimed to compare impact on micronutrient status among individuals who received fortified rice versus individuals who received non-fortified rice, rice with micronutrients added after cooking, and/or micronutrients provided in supplement form. In 10 of the studies the rice was fortified only with iron, in one study only with vitamin A,<sup>20</sup> and in five studies a combination of micronutrients was used, i.e., iron, zinc, and vitamin A in the studies by Pinkaew et al;<sup>13,14</sup> iron, zinc, vitamins A, B<sub>1</sub>, B<sub>6</sub>, and B<sub>12</sub> and folic acid in the study by Thankachan et al;<sup>15</sup> iron, zinc, vitamins B<sub>1</sub>, and folic acid and in part vitamins B<sub>3</sub>, B<sub>12</sub>, B<sub>6</sub>, and A by Perignon et al;<sup>19</sup> and iron, zinc, folic acid, and vitamin B<sub>1</sub> by Della Lucia et al.<sup>18</sup> The studies were conducted

in low- and middle-income countries including the Philippines, India, Nepal, Thailand, Mexico, Brazil and Cambodia, while the study with coated rice was conducted in iron-deficient anemic subjects in the USA. Study populations included children aged 6–23 months, preschool and school-age children, women of reproductive age, and anemic individuals.

### Iron results

Fourteen of the 15 efficacy studies on iron-fortified rice used ferric pyrophosphate ( $\text{FePP}$ ) as the iron form. One of them also included a group that received ferrous sulfate<sup>4</sup> and a pilot study used ferrous sulfate ( $\text{FeSO}_4$ ) to fortify rice using coating technology.<sup>17</sup> Although  $\text{FePP}$  is not the most bioavailable iron fortificant, it has so far been the only type of iron identified that does not affect the color and taste of rice. Research has very recently been conducted that successfully increased the bioavailability of this type of iron (see below).<sup>16</sup> The amount of fortified rice that was provided in the different studies ranged from 50 g/week to 140 g/day and was often provided as one meal per day. The blending ratios of the fortified rice ranged from 0.5% to 2.5%, and the iron content of the fortified rice meal ranged from 6 to 56 mg. The studies did not report on the color of the fortified kernels or the acceptability of the fortified rice but, as feeding took place under controlled conditions, all participants were apparently willing to consume the rice. Fourteen of the 15 studies with rice fortified with iron assessed impact on hemoglobin concentration or anemia. None of the studies found a negative impact, while six found an increase in status. Nine of the 11 studies that assessed iron status found an increase. In total, 13 of the 14 studies found a positive impact on either hemoglobin concentration or iron status, or on both. The authors of the one study that found no impact on hemoglobin concen-

tration or iron status reported that they discovered post-study that the participants had received iron supplements until a few months before the study started.<sup>15</sup>

These results provide strong evidence that the fortification with iron was effective. The fact that a greater proportion of studies found an impact on iron status as compared to the proportion that found an impact on hemoglobin concentration may be due to homeostatic control (i.e., there is limited room for improvement of hemoglobin concentration among non-anemic individuals) and due to the multifactorial causes of anemia. As other nutritional and non-nutritional causes also affect anemia, there are limits to the impact of iron on hemoglobin concentration.

### Recent findings for further improving iron bioavailability

Recent studies have shown the possibility to further enhance the bioavailability of iron in both extruded and coated rice by using a mixture of citrate and trisodiumcitrate as solubilizing agents. During rice cooking, this moiety solubilizes ferric pyrophosphate within the grain and renders it more soluble *in vitro* and more bioavailable in human subjects.<sup>16</sup> These findings have been confirmed in a second trial in which it was also applied to coated rice, in which bioavailability was found to be almost as good as in hot extruded rice. In view of these results, the possibility arises to use lower iron fortification levels for rice when containing the solubilizing agent citrate/trisodiumcitrate compared with formulations containing micronized ferric pyrophosphate (see **Table 1** in the article in this magazine on specifications and standards, p. 66) and to also apply it to coating technology.

Another relevant finding with regard to iron bioavailability from fortified rice is that zinc oxide (ZnO) tends to lower it, which is not seen when using zinc sulfate (ZnSO<sub>4</sub>) as a zinc fortification compound.<sup>22,23</sup> It should be noted though that it has been reported that zinc sulfate decreases the stability of vitamin A in rice slightly faster than zinc oxide,<sup>24</sup> which would be important to consider when rice is also fortified with vitamin A. The study on the impact of zinc compounds also found that iron bioavailability when EDTA was added in combination with zinc oxide was comparable to the combination of citrate/trisodiumcitrate and zinc sulfate as well as to when ferrous sulfate was added to the rice meal (gold standard for assessing iron bioavailability). The sensory attributes were also comparable. While those findings on zinc compounds and EDTA likely offer further possibilities for optimizing iron bioavailability from rice at lower levels, they have as yet been reported by one multiple meal stable iron isotope absorption study<sup>23</sup> and we await further studies to confirm the findings.

When considering fortification of rice with iron at scale, cost and consumer acceptability are key. Blending ratio as well as

level and choice of iron fortificant impacts cost. Color and taste, which depend on choice and level of iron fortificant, can affect consumer acceptance. These aspects were less important in the efficacy studies. When using micronized ferric pyrophosphate, the concentration of iron cannot exceed 7 g/kg without imparting color. When fortified kernels are blended with normal rice at 1%, which is a commonly used ratio, the iron content of the fortified rice will be 7 mg/100 g. However, the novel formulations described above offer the possibility for lower iron fortification levels, further reducing the risk of changing color and ensuring acceptability while maintaining high bioavailability.

### Vitamin A results

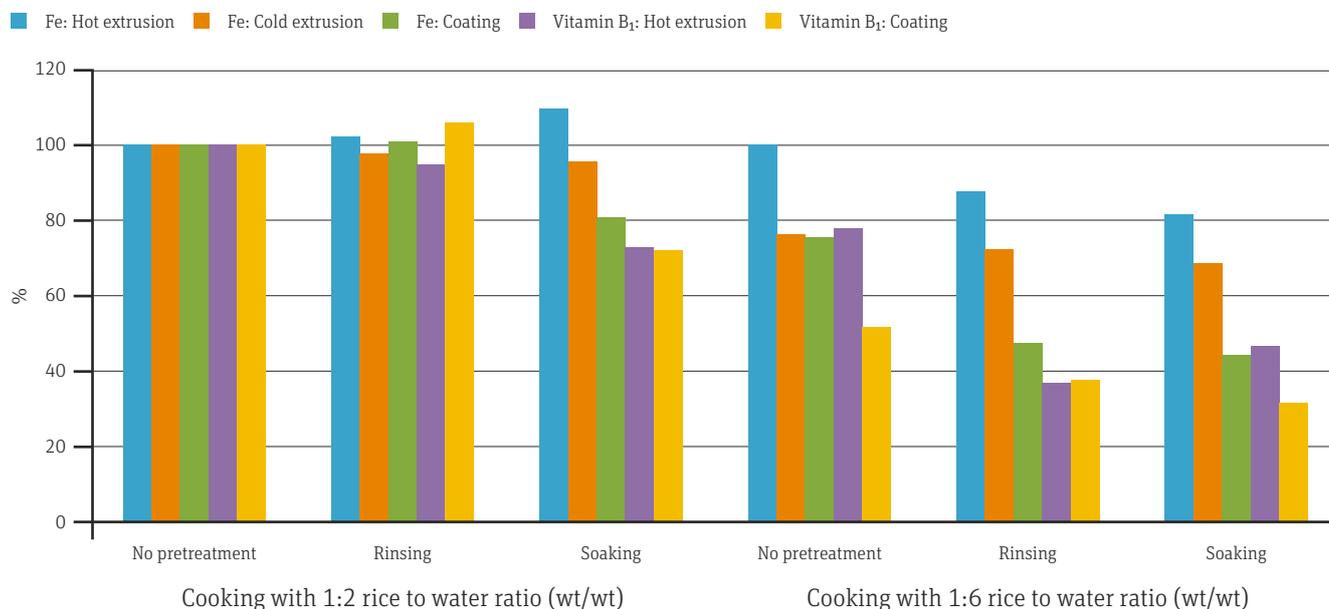
Five studies included rice fortified with vitamin A, four of which were also fortified with other micronutrients. The one study that fortified rice only with vitamin A was conducted among night-blind pregnant women in Nepal and provided study groups with different sources and levels of vitamin A.<sup>20</sup> This study reported an improvement of vitamin A status in all groups, with the greatest improvement in the two groups that received vitamin A from either a high-dose capsule or liver. The other four studies were conducted among schoolchildren. In three of the studies the children had an average baseline serum retinol concentration considered indicative of adequate, or close to adequate, vitamin A status.<sup>13,14,15</sup> In those studies, the serum retinol concentration did not increase further due to homeostatic regulation. However, the one study that also measured total body retinol reported an improvement.<sup>14</sup> A large efficacy study in Cambodia including 2,440 schoolchildren (FORSICA trial) was effective in improving vitamin A status and in decreasing vitamin A deficiency compared to the control group.<sup>19</sup>

This evidence shows that vitamin A can effectively be added to rice. However, it is important to consider whether rice is the most appropriate vehicle. For example, where cooking oil is already adequately fortified with vitamin A and consumed in sufficient quantities, it may not be necessary to also fortify rice with vitamin A, and its stability is also likely lower in rice compared to cooking oil.<sup>25</sup>

### Results with other micronutrients

The impact of fortification of rice with zinc, folic acid, vitamins B<sub>1</sub> (thiamine) and B<sub>12</sub> on micronutrient status has also been assessed. Thankachan et al<sup>15</sup> studied rice fortified with iron, zinc, vitamins A, B<sub>1</sub>, B<sub>6</sub>, and B<sub>12</sub> and folic acid. In a study by Pinkaew et al,<sup>13</sup> impact on zinc status by rice fortified with iron, vitamin A and zinc was assessed. Thankachan et al found an improvement of vitamin B<sub>12</sub> status and a decrease of homocysteine levels.<sup>15</sup> This indicated that both vitamin B<sub>12</sub> and folic acid were well absorbed and utilized. They found no change of indicators of thiamine or zinc status. Thiamine status was already sufficient.

**FIGURE 2:** Retention (%) of iron and vitamin B<sub>1</sub> by cooking procedure (in 1:2 rice to water ratio, absorption method, and with 1:6 rice to water ratio, excess water with different pretreatments). The retention with no pretreatment with the absorption method is by definition 100%<sup>20</sup>



A recent study investigated the bioavailability of folic acid from pectin-coated rice. Folic acid absorption was slightly lower than that of the reference given in aqueous solution, but these results also support the view that folic acid can be readily absorbed from fortified rice, which was coated rice in this case. The absence of impact of zinc fortification on serum zinc concentration, which has also been reported by other studies, may be due to the fact that only a small fraction of the body's zinc pool appears in serum. This makes it insensitive to modest changes of status. The study by Pinkaew et al<sup>13</sup> reported a decline of zinc deficiency in both the intervention and the control groups. The decline of serum zinc concentration was smaller in the fortified rice group compared with the unfortified rice group.<sup>13</sup> In addition, a recent study from a school feeding program in Brazil showed improvements in serum zinc and serum folate as well as for erythrocyte thiamine compared to the control group receiving unfortified rice.<sup>18</sup>

### Stability and retention of micronutrients in fortified rice during cooking

#### Minerals

As shown in **Figure 2**, the losses of minerals during preparation, i.e., pretreatment (rinsing or soaking) and cooking, range from being negligible with no pretreatment and using the absorption method (1:2 rice to water ratio wt/wt) to more important losses (up to 55%) when cooking in excess water and soaking

the rice prior to cooking. Generally, irrespective of rice fortification technology (hot or cold extrusion, coating) and the pretreatment step (rinsing, soaking, no pretreatment), when rice was prepared with the absorption method, retention exceeded 80%. When rice was prepared by discarding excess cooking water, losses were greater (up to 55%), with higher retention found for hot extrusion followed by cold extrusion and coating, in this order. In these circumstances, the pretreatment contributed to the lower retention.<sup>21</sup>

#### Water-soluble vitamins

As a proxy of water-soluble vitamins, vitamin B<sub>1</sub> was used in a recent study commissioned by WFP/USDA. The retention followed a similar pattern to the one for minerals, but tended to be lower with excess water (lowest retention 31% when cooking in excess water and soaking the rice prior to cooking). Rinsing *per se* did not affect the retention in hot or coated rice, whereas soaking reduced retention by 30%, also when cooking with the absorption method (see **Figure 2**).

#### Acceptability studies with fortified rice

Several acceptability studies have been conducted over the years investigating acceptability and ability of consumers to distinguish fortified from unfortified rice. In general, as only a very small proportion of the kernels in fortified rice are fortified (0.5%–2%) and the color change by ferric pyrophosphate

is minimal, no differences in rice appearance between fortified and unfortified rice have been reported.<sup>28,10,5</sup> In a larger acceptability study in Vietnam and Cambodia, fortified rice could correctly be identified by participants, but was found to be highly, and sometimes even more, acceptable.<sup>29</sup>

Recently, extruded and coated rice formulations including the novel solubilizing agent citrate/trisodium citrate have been tested for their acceptability in Cambodia. The results show a high degree of acceptability of the rice among women and school children, as measured by the degree to which they finished the rice meal and the total intake of rice over a week. Consumers liked the rice and identified small differences in the appearance of different fortified rice products produced by different manufacturers.<sup>30</sup>

These results indicate that fortified rice, when produced according to specifications and guidelines (see **Table 1** in the article in this magazine on specifications and standards, p. 66), can be well accepted across a range of settings and products. Nonetheless, it is always good practice to assess retention under the locally prevailing preparation methods and consumer acceptability of the actual fortified rice product that will be introduced, as the application of specific production methods can vary substantially among manufacturers. Furthermore, it is important to ensure that the fortified kernels match the shape, appearance and color of the rice to be fortified.

### Effectiveness studies – impact of rice fortification under programmatic circumstances

Four studies analyzed the effectiveness of rice fortification under less controlled, more programmatic, circumstances.<sup>31–34</sup> The first study, conducted in the Philippines in 1947–1949, used coated rice fortified with thiamine, niacin and iron. Results showed a substantial reduction of beriberi, a well-known consequence of thiamine deficiency, as well as a lower incidence of infant deaths in the areas that received fortified rice.<sup>34</sup> No biochemical indicators of micronutrient status were assessed at that time. A second effectiveness study in the Philippines in 2008 provided rice fortified with iron at approximately 3–4 mg/100 g. This study found higher hemoglobin concentrations among children after the program than before and a decline in anemia prevalence. No changes were found among mothers.<sup>32</sup> A study conducted in Thailand between 1971 and 1975 distributed fortified rice among different age groups of children. No significant differences were found in anthropometry, hemoglobin and hematocrit between children of the villages that received the fortified rice and those that received non-fortified rice. According to the authors, caloric insufficiency was widespread and may have affected the results.<sup>33</sup> More recently, after observing declines in neural tube defects (NTD) after the introduction of flour fortification with folic acid, Costa Rica also be-

gan fortifying rice and milk with folic acid. Studies conducted in 2011 demonstrated further NTD declines.<sup>31</sup>

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“The above evidence supports the fortification of rice with iron, vitamin A, folic acid, vitamin B<sub>12</sub> and thiamine, and the addition of zinc, niacin and vitamin B<sub>6</sub> is also recommended”

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### Recommended micronutrients for rice fortification

The above reviewed evidence from efficacy and effectiveness studies supports the fortification of rice with iron, vitamin A, folic acid, vitamin B<sub>12</sub> and thiamine. Zinc is also recommended, although two studies found an impact on zinc status while the other one did not. These mixed findings are consistent with findings from studies on zinc fortification of other foods and may partly be due to the fact that zinc status is difficult to assess accurately.<sup>27</sup> For niacin and vitamin B<sub>6</sub>, data of impact on micronutrient status have not yet been collected, but adding these is recommended as well; because polished rice is a poor source of these essential micronutrients,<sup>35</sup> restoring nutrient levels lost during milling is good practice.<sup>1</sup> Bioavailable forms of these nutrients exist and adding them to rice together with the other micronutrients does not markedly increase the cost of fortified rice.

### Research and development

Further research to further optimize the mineral absorption from rice is currently ongoing. Recent results have shown ways to increase iron bioavailability (see iron section above) which is important for safeguarding the impact on iron while maintaining good consumer acceptability.

### What to assess when introducing rice fortification at scale

**Figure 1** shows essential components for effective rice fortification. First is the choice of the appropriate fortification technology and identification of required micronutrients. The selected fortificants must be in efficacious forms and required amounts, and stable. Required evidence and information for this step is presented in this article, in the article on technology by Montgomery et al (see p. 48), and in the paper on standards by de Pee, Moretti and Fabrizio (see p. 63). After technology and types of levels of fortificants have been chosen, it is very important to assess production feasibility (initially, just for blending, later also fortified kernel production) and consumer acceptability. Then the following should be put in place:

#### • **Quality assurance, quality control and monitoring**

Manufacturers should conduct their own quality assurance and quality control. Separately, independent monitoring should determine whether the rice is fortified as expected, i.e., the fortified kernels have the required composition with micronutrient content within the permitted range of variation, and they are blended at the required ratio. In addition, stability testing needs to be conducted under prevailing storage, preparation and cooking conditions to assure content remains adequate.

#### • **Monitoring of coverage and consumption levels**

These aspects need to be monitored and adjusted where necessary. The contribution of fortified rice to micronutrient intake depends on whether consumers obtain, accept and consume it in required quantities. When this is ascertained, changes of micronutrient status are likely.

#### • **Monitoring of micronutrient intake, morbidity and micronutrient status**

Since rice fortification is one component of a broader strategy to address micronutrient deficiencies, monitoring should assess whether the combination of strategies is improving the health and nutritional status of different target groups in the population over time and/or whether additional measures may be required.

## “Countries considering rice fortification do not need to conduct additional efficacy studies”

### Conclusion

Multiple studies have established that with the appropriate levels of micronutrients and fortificant forms, and with effective technology, fortified rice is an effective intervention to improve micronutrient status. Countries considering rice fortification as an intervention to address micronutrient deficiencies do not need to conduct additional efficacy studies. Rather, countries should apply their resources to assess their own public health needs for micronutrient fortification and ensure close monitoring of implementation. The recommended micronutrients for rice fortification are iron, zinc, folic acid, niacin and vitamins A, B<sub>1</sub> (thiamine), B<sub>6</sub> and B<sub>12</sub>, although if vitamin A is added to vegetable oil, it may not need to be added to rice. These recommendations are based on efficacy data and on the public health significance of the deficiencies of these micronutrients. In addition, consideration can be given to the feasibility of adding specific fortificants while maintaining consumer acceptability

and stability during storage. Countries should therefore focus on ensuring appropriate fortification (i.e., suitable fortified kernels that blend in well with unfortified rice, implementing blending at desired ratio), storage and distribution, and monitoring acceptance and consumption (adequate quantities and by different subgroups).

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