NUTRITION

Food fortification:

An effective and safe way to fight micronutrient malnutrition and its consequences

February 2022

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Introduction

Food fortification is one of the most accepted, scientifically proven and cost-effective ways to tackle micronutrient deficiencies on a large scale. Despite the available evidence on food fortification, there remain questions, concerns and misunderstandings around its efficacy and associated risks.

This brochure seeks to provide guidance and answers by drawing on the latest evidence to explain why this form of nutritional intervention is generally safe and effective in improving micronutrient status across target populations.

Why fortify staple foods?

Vitamin and mineral deficiencies affect around 2 billion people worldwide and have been identified as a global health issue in many low- and middle-income countries. Micronutrients (often referred to as vitamins and minerals) are essential for the body to function. Deficiency of micronutrients can be linked to anemia, adverse birth outcomes, night blindness, increased risk of mortality in children and pregnant women, increased risk of osteoporosis in adults and rickets in children, reduced resistance to infectious diseases, fatigue, and impaired cognitive function [1].

These outcomes have far-reaching social and economic consequences, not only placing a massive burden on individuals and families, but also increasing pressure on core public services such as health, social care and education. Studies show that micronutrient deficiencies can contribute to a loss of up to 5% Gross Domestic Product (GDP) [2]. For example, iron deficiency can contribute to a loss of up to 2% GDP in the worst affected countries [3]. Therefore, addressing micronutrient deficiencies on a large scale represents a proven opportunity to build healthy societies and sustainably boost local economies.

The ideal solution to addressing micronutrient gaps is improving diets through dietary diversification. Yet, the high level of resources, the availability and the accessibility required to ensure diets are varied enough to meet the micronutrient needs, often prevent reaching this goal through this approach alone. In this situation, food fortification, micronutrient supplements and biofortification are widely recognized as highly effective and affordable complementary strategies [4]. Well-implemented food fortification programmes significantly impact the health and productivity of target groups for a comparatively low cost. Food fortification with micronutrients has been ranked among the top three strategies in terms of economic return on investment due to its high cost-benefit ratio, according to analysis carried out by a panel of global economic experts for the Copenhagen Consensus Center [5]. The well-respected think tank noted its "tremendously high benefits compared to costs."

By successfully addressing micronutrient deficiencies on a large scale with relatively limited budget, food fortification can help countries reach their nutrition goals, improve the nutritional and health status of populations, enable them to achieve their potential and support economic prosperity on a national level. In addition, fortified foods can support households in meeting nutrition needs by improving affordability of a nutritious diet [6].

What is staple food fortification and how does it work?

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 [7].**

In terms of staple foods, fortification can occur either before harvesting, in a process known as biofortification, or after harvesting, otherwise known as post-harvest or staple food fortification. Both routes offer benefits and can complement each other. This brochure focuses on post-harvest fortification. Biofortification uses technology to breed staple crops with enriched levels of micronutrients and is mainly focused on zinc, iron and provitamin A carotenoids. Whereas post-harvest fortification is the process of adding micronutrients to a commonly consumed food through one or more of the following approaches [1]:

- **Large-scale fortification:** 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 [1]. For example, rice, wheat and maize flour, vegetable oils, salt or condiments, and milk. Very often mandated and regulated by law.
- **Small-scale fortification:** a large proportion of consumers depend on small-scale milling for staple cereals. These consumers can be reached by fortifying for instance, wheat, maize, cassava, sorghum, and millet at small-scale millers.
- **Targeted fortification:** Aimed at specific sub-groups rather than the population as a whole. Examples of this approach include 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.
- **Market-driven and purpose-led fortification:** Voluntary action taken by manufacturers to add one or more micronutrients to foods to improve public health, at affordable costs.

Support for Large Scale Food Fortification

Large-scale food fortification has been proven to be a highly successful nutritional intervention strategy as evidenced by a substantial body of research. For example, a recent systematic review and meta-analysis found that iron-fortified foods can reduce the likelihood of developing anaemia by 34%, iodine-fortified salt can reduce the risks of goitre by 74%, and folic acid-fortified flour can reduce the risk for neural tube defects by 41% [8]. It is also estimated that large-scale food fortification with vitamin A could protect nearly 3 million children per year from deficiency [8].

As a result, this form of public health intervention has gained the support of numerous global organizations. The WHO, for example, sets out clear recommendations for the fortification of staple foods appropriate to the target population, such as rice, oil, salt, maize flour and corn meal, and wheat flour [9]. The WHO, the United Nations Children's Fund (UNICEF), the World Food Programme (WFP), the US Centers for Disease Control and Prevention (CDC), the Global Alliance for Improved Nutrition (GAIN), Nutrition International (NI), Food Fortification Initiative (FFI), Bill & Melinda Gates Foundation (BMGF), PATH (Program for Appropriate Technology in Health), Helen Keller International (HKI), United States Agency for International Development (USAID), and others are also endorsing fortification initiatives as a means to fight malnutrition, especially where a nutritious diet including a diversity of fresh foods is inaccessible for a large proportion of the population. In Africa, 26 countries have mandates to fortify wheat flour, in Latin America 35 countries have mandatory wheat or maize flour fortification and nine countries in Asia have either mandatory or voluntary fortification of rice or wheat flour in place.

The role of micronutrients in health

Micronutrients are essential to healthy development, disease prevention, and wellbeing. Micronutrients must be obtained from the food as they cannot be produced in the body. The exception is vitamin D that the human body produces naturally when the skin is exposed to sunlight. Though only small amounts of micronutrients are needed, consuming the recommended amount can be challenging. Micronutrient deficiencies can have devastating consequences. Globally, at least 1 in 2 children under 5 suffer from hidden hunger due to deficiencies in micronutrients. The role of a selection of essential micronutrients is outlined in Table 1.

Table 1: Selection of micronutrients and their benefits*

Iron	Iron is critical for motor and cognitive development. Children and pregnant women are especially vulnerable to the consequences of iron deficiency. Iron deficiency is a leading cause of anemia which is defined as low haemoglobin concentration. Anemia affects 43% of children younger than 5 years of age and 38% of pregnant women globally. Anemia during pregnancy increases the risk of death for the mother and low birth weight for the infant. Fortifying flour with multiple micronutrients including iron is globally recognized as an effective, cost-effective intervention and was shown to reduce the risk for anemia by 32% [10].
Vitamin A	Vitamin A supports healthy eyesight and immune system functions. Children with vitamin A deficiency face an increased risk of blindness and death from infections such as measles and diarrhea. Globally, vitamin A deficiency affects an estimated 190 million preschool-age children. Vitamin A deficiency increases the risk for night blindness and infectious diseases and severity of respiratory infections. Fortification with multiple micronutrients including vitamin A has been shown to reduce the risk for vitamin A deficiency by 58% [10].
Vitamin D	Vitamin D builds strong bones by helping the body absorb calcium. This helps protect older adults from osteoporosis. Vitamin D deficiency causes bone diseases, including rickets in children and osteomalacia in adults. Vitamin D helps the immune system resist infections from bacteria and viruses. Vitamin D deficiency is associated with increased risk and greater severity of infection, particularly of the respiratory tract. Vitamin D is required for muscle and nerve functions. Available data suggest that vitamin D deficiency may be widespread globally. The human body naturally produces vitamin D when exposed to sunlight, but this varies based on geography, skin color, air pollution, and other factors. Also, sunlight exposure needs to be limited to avoid risk of skin cancer.
Iodine	Iodine is required during pregnancy and infancy for the infant's healthy growth and cognitive development. Globally, an estimated nearly 2 billion people have insufficient iodine intake [11]. Iodine content in most foods and beverages is low. Fortifying salt with iodine is a successful intervention – about 86% of households worldwide consume iodized salt. The amount of iodine added to salt can be adjusted so that people maintain adequate iodine intake even if they consume less salt.
Folate (vitamin B9)	Folate (vitamin B9) is essential in the earliest days of fetal growth for healthy development of the brain and spine. Ensuring sufficient levels of folate in women prior to conception can reduce neural tube defects (such as spina bifida and anencephaly). Folic acid is another form of vitamin B9. Providing folic acid supplements to women 15-49 years and fortifying foods such as wheat flour with folic acid reduces the incidence of neural tube defects and neonatal deaths.

Zinc

Zinc promotes immune functions and helps people resist infectious diseases including diarrhea, pneumonia and malaria. Zinc is also needed for healthy pregnancies. Globally, 17.3% of the population is at risk for zinc deficiency due to dietary inadequacy; up to 30% of people are at risk in some regions of the world. Zinc contributes to normal cognitive function. Fortification with multiple micronutrients including zinc has been shown to reduce the risk for zinc deficiency by 16% [10].

The B-vitamins

The B-vitamins are critical for supporting red blood cells and thereby, transporting oxygen throughout the body. While iron deficiency is regarded as the major cause of nutritional anaemia, vitamins B12, folic acid and riboflavin (vitamin B2), together with vitamin A, C and E have also been linked to anemia development and control [12]. B-vitamins play also a role in extracting energy from food and presenting it in a physiologically usable form. Through these functions, B-vitamins helps to reduce fatigue or low energy linked to inadequate status of B-vitamins. Thiamine (vitamin B1) deficiency causes beri-beri.

*Based on Micronutrient Facts website [13]

How to implement an effective and safe staple food fortification program

Food fortification programs should follow clearly defined steps in order to improve micronutrient status and achieve optimum health outcomes.

1. Select appropriate nutrients for fortification

While different vitamins and minerals are used to fortify staple foods, it is essential that each program is tailored for the target population; both in terms of fit with the dietary habits and addressing the co-occurring micronutrient deficiencies. Micronutrient deficiencies can be estimated 1) from consumption data providing an estimate of micronutrient availability or 2) from actual biological biomarkers for micronutrient status. Both approaches provide valuable data to define the most problematic micronutrients in population groups, though the latter approach is usually more expensive and more invasive than the former.

Household consumption and expenditure surveys

Household consumption and expenditure surveys are relatively inexpensive and give an indication of micronutrient intake shortfalls. Dietary questionnaires or food records provide more precise information but can be more resource intensive. Moreover, household surveys aid in choosing which foods to fortify and in determining how much of a micronutrient to add to that food. Country food balance sheets using FAO data, only give a proxy of food consumption in the absence of intake data, and are only available at national level.

Biological markers

Biological markers (e.g., blood-borne; plasma, serum, blood cells, or urine) of micronutrient status provide information on actual prevalence of deficiencies, which result from inadequate intakes and/or increased needs due to e.g. high losses (infection, menstruation etc), and on how prevalence evolves as different strategies are being implemented. However, measuring has also limitations such as costs, invasiveness, and lack of biomarkers for some of the micronutrients [14], which limits public health interventions. Anemia is an indicator of general poor nutrition. However, anemia may be due to iron or other micronutrient deficiencies or may point to acute or chronic infections. Owing to their widespread occurrence, serum retinol and ferritin and urinary iodine are most frequently measured as indicators of vitamin A, iron, and iodine deficiencies, respectively. Less frequently measured are folate, zinc, vitamins B2 and B12, niacin, vitamin D and calcium. High rate of neural tube defects may indicate low folic acid intake by women of reproductive age.

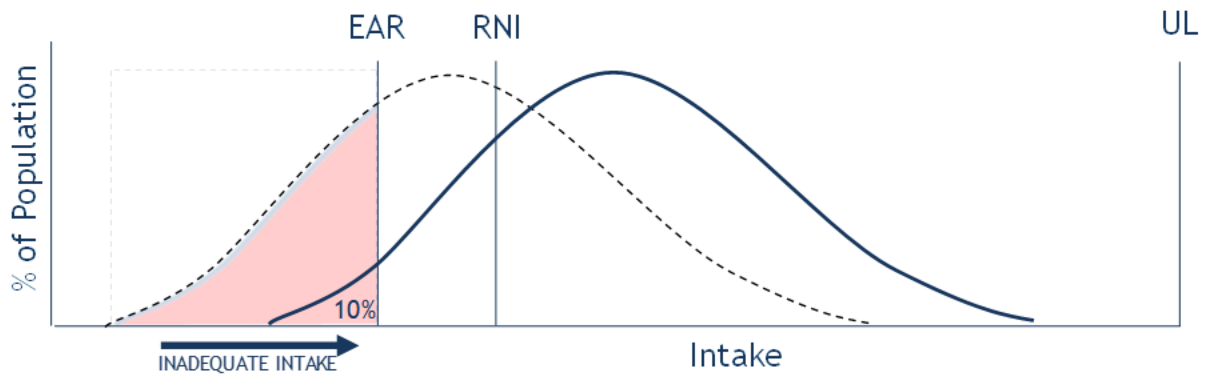
2. Identify suitable food vehicle(s) to fortify

The chosen food to be fortified must be highly accessible for most of the target population [15], which means it needs to be affordable and available. It also needs to be eaten regularly in relatively constant amounts to achieve a meaningful impact. To that end, it is crucial to establish a realistic view of how much of the chosen staple food is consumed per day based on quantitative food consumption data. If this is not possible, the most suitable alternative method is to estimate the daily food vehicle consumption from the FAO's food balance sheets [16]. In order to reach different segments of the population who may have different dietary habits, selecting more than one food vehicle may be necessary. Furthermore, it is important to identify what portion of the vehicle is fortifiable (i.e. processed by millers who would likely be able to fortify) and whom that reaches, and through which channels (supermarkets, wholesale markets, social assistance packages etc).

3. Determine the target micronutrient intake distribution

Current micronutrient intake distributions of the population (obtained by survey) are used to plan for fortification. The aim of fortification is to shift a population's intake distribution upwards such that no more than 10% has intakes below the average requirements (EAR)[1] for that micronutrient. Meanwhile, no more than 2.5% of the population should exceed the maximum safe upper level (UL) (See Figure 1). In practice, this means that the target median intake in the population should be approximately 1.3-fold greater than the RNI.

Figure 1: Shifting micronutrient intakes such that no more than 10% of people have inadequate intakes



The increase in micronutrient intake needed to realize this target micronutrient intake distribution (i.e. <10% below the EAR or 90% meeting the EAR), is to be added to the selected food(s). Table 2 gives an example of how a food can be fortified with folic acid and vitamin A.

1 Average requirement (EAR) refers to the level that would be sufficient for 50% and inadequate for the other 50% of a population (see Box 1). As needs of individuals are unknown, and having an insufficient intake has many health consequences, the goal is that no more than 10% of a population have an intake below the EAR, to ensure that most people will meet their (unknown) individual needs. For the same reason, the proportion of the population that has an insufficient intake is defined at the pro portion with an intake below the EAR.

Table 2: Increasing micronutrient intakes such that 90% meet their EAR

	Current intake met by 90% of people	EAR = Target intake to be met by 90% of people	Micronutrient intake to increase by	Current median intake	Target median intake
	mg/d	mg/d	mg/d	mg/d	mg/d
Folate	0.2	0.32	0.12	0.40	0.52
Vitamin A	0.15	0.56	0.41	0.60	1.01

4. Select the preferred, effective, and safe fortification level

The micronutrient level to be added to the selected food vehicle(s) needs to be based on the 1) the desired increase of micronutrient intake and 2) amount of the food consumed in the population. A software program called IMAPP (Intake Monitoring and Planning Program) has been developed to identify the level of micronutrient to be added to food to reach the target distribution in a population (i.e. predict what is required for a fortification intervention to be effective) using dietary intake data [17]. IMAPP models the proportion with inadequate micronutrient intakes before and after adding micronutrients to the food. As such, the user can model the effect of various micronutrient levels in the foods of choice on the proportion of micronutrient inadequacy and overconsumption. If no intake distribution data are available, micronutrient fortification levels have been proposed for, for instance, fortified rice based on the mean estimated rice consumption amounts in the population and having that provide the EAR so that the population's intake distribution will be to the right of the EAR for most people in the population [18].

If multiple food vehicles are fortified with the same micronutrient(s), their levels added to each food will need to be adjusted downwards, such that the total quantity of the micronutrient "to increase" is contributed by the combined intake of the foods that it has been added to.

When setting safe and effective fortification levels, there are also technical aspects of fortification to consider: stability during storage, losses during preparation, how fortification may affect appearance and sensory properties of the food, which is also matrix dependent, and thereby acceptability by the consumer, and the availability of micronutrients for absorption by the body.

5. Information analysis tool

WFP's Fill the Nutrient Gap tool [19] supports analysing the country's nutrition situation and identifies the barriers most vulnerable families face in accessing healthy, nutritious foods to meet their nutrient intake requirements. Stakeholders in nutrition often lack the information needed to determine appropriate forms of fortification and may lack sufficient evidence to justify investment in fortification. The Fill the Nutrient Gap analysis helps navigate these questions and supports stakeholders in identifying opportunities, understanding benefits, and planning fortification. The analyses can also inform concrete programming, the design of food assistance packages, and food selection for school meals. Information in this analysis helps to identify which fortified product(s) would be most appropriate for a given setting, which products should target which population groups, which micronutrients to add and at what level, and how the costs and benefits of fortification compare with other options. The Cost of the Diet tool, which is also used for Fill the Nutrient Gap analyses, can calculate how fortified foods can increase affordability of nutritious diets for specific countries or regions, considering the distinct needs of individual household members.

6. Assessment of programmatic feasibility

This document aims to provide guidance on safe and effective food fortification. In addition, it is important to consider that large-scale rice fortification is most successful when driven by a multisectoral coalition, which includes national government, the private sector, non-governmental and civil society organizations.

Conducting a fortification landscape analysis is strongly recommended to determine factors that will influence the potential impact. The following aspects must be taken into account:

- The bottlenecks and complexity of the existing supply chains of fortifiable food(s)
- Existing distribution channels - when the milling landscape is fragmented and mandatory fortification is not feasible, distribution through social safety nets is an alternative to achieve public health impact in targeted populations that are most nutritionally vulnerable
- Cost analysis, consumer consumption and purchasing preferences
- Policy and regulatory environment.

Wider sources of information should also be consulted to support the decision-making process. A comprehensive range of guidelines, technical notes and Excel tools are available from the WHO, WFP and A2Z USAID (see Appendix).

7. Additional actions

Consideration may also be given to further measures designed to ensure the positive impact and safety of the fortification program. Such actions, once legal framework is in place, may include [20]:

- Setting standards, such as technical specifications, that specify the micronutrients required, their form and bioavailability and minimum and maximum level.
- Monitoring documents that help industry and government to track and ensure the quality of and presence of micronutrients in the fortified foods
- Monitoring the impact of fortification over time, e.g., by dietary surveys in the population to estimate sustained relevant coverage (i.e. reach amongst those who are most in need of the fortified commodities to reach adequate micronutrient intake) and assessing micronutrient markers in blood to verify whether combination of strategies is effective enough.
- Social Behaviour Change Communication is important to educate both professionals in the health sector and consumers about the benefits of fortified foods to ensure their adequate preparation and consumption.
- Each stage of the program needs to be regularly evaluated, from set up through to implementation, so that potential issues can be highlighted and corrected without causing any major disruption, while providing valuable learnings for future program activity. In addition, it is equally important to understand the extent to which a project achieves its expected impact on participants, so benchmarking and analysis against health objectives should be regularly carried out.

Background: use of dietary reference values for micronutrients

1 How to use dietary reference values to prevent risks of inadequate and excess intake?

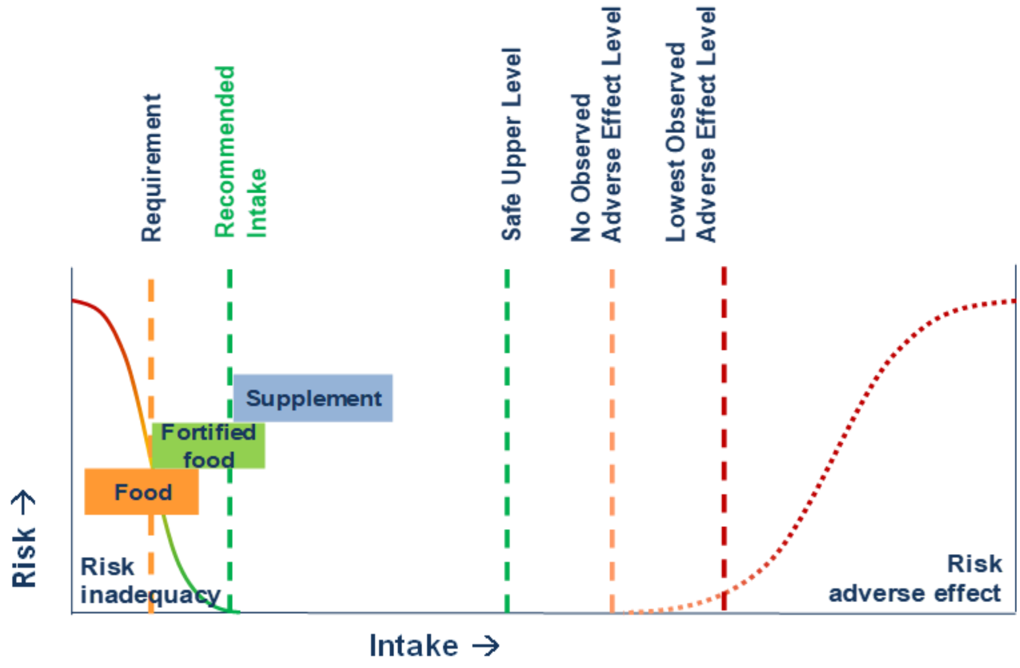
When knowing the micronutrient intake distribution in a population, dietary reference values for micronutrients can build a picture of the proportion in a population group having adequate and safe intakes for that micronutrient. Analysis may show, for example, that the majority of people have inadequate micronutrient intakes, i.e. below the **Estimated Average Requirement** (EAR). In rare cases, a small percentage may exceed the tolerable **Upper Level** of intake (UL). Reference values have been developed by various national and international bodies, including the European Food Standards Authority (EFSA), Codex Alimentarius, and the National Academy of Medicine (NAM, formerly Institute of Medicine, IOM). Moreover, harmonized intake reference values have been developed [21]. The main reference values applied by the major authoritative organizations are explained in **Box 1**.

BOX 1: Main dietary reference values explained [21]

- The **Recommended Nutrient Intake** (RNI), the **Population Reference Intake** (PRV) or the Recommended Daily Intake (RDI) is the daily intake level of a nutrient considered to be sufficient to meet the requirements of 97–98% of the population in a given age and gender group.
- The **Estimated Average Requirement** (EAR): The EAR meets the needs of 50% of the population in a given age and gender group but does not meet the needs of the other 50%. When mean intakes are at the EAR, 50% is at risk of inadequacy. The proportion of the population below the EAR is defined as having an inadequate intake. The EAR is a reference intake and not a target intake.
- The **Lowest Observed Adverse Effect Level** (LOAEL) is the lowest of all observed and reported intake levels that may cause adverse effects.
- The tolerable **Upper Level** of intake (UL): The highest safe level of daily nutrient intake that is likely to pose no risk of adverse effects to almost all individuals in a population. The UL is not a limit for toxicity, but a level of security, as it has a built-in safety margin, the so-called Uncertainty Factor (UF).
- The UL is set an **Uncertainty Factor** (margin) of at least 1.5 times lower (different factor for different micronutrients, depending on the certainty of the evidence) than the **Lowest Observed Adverse Effect Level** (LOAEL);. When relatively high uncertainty exists around the lowest level at which adverse effect may occur, the safety margin between this lowest level and the UL is large (factor 5) to protect the most vulnerable population subgroups.

Figure 2 illustrates how risks for adverse health effects increase in relation to the reference values. The figure shows that the intakes below the EAR and above the UL do not represent the same risk in terms of magnitude. That is because intakes below the EAR reflect a risk of inadequacy, whereas the UL is unlikely to pose a risk as it has a built-in safety margin.

Figure 2: Risks for adverse health effects relative to reference intakes



2 Micronutrients with a risk of exceeding the maximum safe upper intake level

For some micronutrients, there is no evidence of any risk of a high intake [22], while for others, a maximum safe intake level (UL) has been established. For consumer safety, the UL still includes a margin of safety below the daily chronic intake that carries risk of adverse effects.

Likelihood of exceeding the UL are higher for some micronutrients than for others. Vitamin A, iron, zinc, calcium, copper and iodine are among the micronutrients for which high-end intake levels can be close to the UL for some population subgroups [22].

Intakes of micronutrients well below the EAR have been reported globally, especially for low-and middle-income countries. Health risks related to the proportion of the population with micronutrient intakes below the EAR are of much larger concern than intakes close to the UL, which represents a high probable safe intake [23]. The reported biomarkers or clinical adverse effects of intakes below the EAR and above the LOAEL are shown in Table 3.

Table 3: Reference values and adverse health effects

	Institute	Underconsumption	EAR	EAR	RNI	RNI	UL	UL	Uncer-tainty Factor	LOAEL	Lowest (or No) observed adverse effect observed
			≥18 y	1-3 y	≥18 y	1-3 y	≥18 y	1-3 y	≥18 y	≥18 y	
Iron	IoM	Iron deficiency anemia, fatigue, lower work capacity, depressed cognitive function	6/8.1 mg/d	3 mg/d	8/18 mg/d	7 mg/d	45 mg/d	40 mg/d	1.5x	70 mg/d	60 mg/d From supplements plus 10 mg of dietary iron showed mostly mild adverse gastrointestinal effects in healthy men, 30 mg/d from supplements showed no adverse gastrointestinal effects in toddlers
	EFSA	See above	6/6-7 mg/d	5 mg/d	11 /11-16 mg/d	7 mg/d	not set	not set	not set	not set	not set
Vitamin A	IoM	Xerophthalmia which may progress into blindness; increased risk and severity of infections; measles, diarrhea, increased mortality.	625/500 µg/d	210 µg/d	900/700 µg/d	300 µg/d	3000 µg/d	600 µg/d	5x	14 mg/d	Hepatotoxicity was reported at vitamin A supplement doses of 14,000 µg/d
	EFSA	See above	570/490 µg/d	205 µg/d	750/650 µg/d	250 µg/d	3000 µg/d	800 µg/d	2.5x	7.5 mg/d	7.5 mg/d For several years may be the upper threshold of the storage capabilities of the liver
	IoM	See above	550/900 µg/d PLW		770/1300 µg/d PLW		3000 µg/d PLW		1.5x	>4500 mg/d PLW	4,500 µg/d Represents a conservative value for a NOAEL in light of the evidence of no adverse effects at or below that level
	EFSA	See above	540/1020 µg/d PLW		700/1300 µg/d PLW		3000 µg/d PLW		not set	>3000 mg/d PLW	3,000 µg/d Represents a very conservative value for a LOAEL in light of the evidence of no adverse effects below that level
Folic Acid	IoM	In pregnant women increased risk for neural tube defects of the child. Fatigue. Megaloblastic anaemia.	320/320 µg/d	120 µg/d	400/400 µg/d	150 µg/d	1000 µg/d	300 µg/d	5x	>5000 µg/d	>5000 µg/d Folic acid from supplements without supplemental vitamin B12 may mask the diagnosis of vitamin B12 deficiency. Severe B12 deficiency may increase the risk of neurological manifestations
	EFSA	See above	250/250 µg/d	90 µg/d	330/330 µg/d	120 µg/d	1000 µg/d	200 µg/d	5x	>5000 µg/d	>5000 µg/d Folic acid from supplements without supplemental vitamin B12 may mask the diagnosis of vitamin B12 deficiency. Severe B12 deficiency may increase the risk of neurological manifestations
Zinc	IoM	Growth retardation, loss of appetite, and impaired immune function. Hair loss, diarrhea, and eye and skin lesions	8.5/7.7 mg/d	2.5 mg/d	11/8 mg/d	3 mg/d	40 mg/d	7 mg/d	1.5x	60 mg/d	50 mg/d From supplement plus 10 mg of dietary zinc for 10 wk was based on depressed erythrocyte superoxide dismutase activity although clinical significance is unknown
	EFSA	See above	7.5-12.7/6.2-10.2 mg/d	3.6 mg/d	9.4-16.3/7.5-12.7 mg/d	4.3 mg/d	25 mg/d	7 mg/d	2x	50 mg/d	A NOAEL <50 mg/d was based on absence of adverse effect on a wide range of indicators of copper status

EAR: Estimated Average Requirement, RNI: Reference Nutrient Intake, IoM: Institute of Medicine/National Academy of Medicine [24, 25], EFSA: European Food Safety Authority [26].

National dietary surveys show the contribution of fortified foods to micronutrient overconsumption is relatively small - even in high-income countries [27]. A recent study modelling potential of micronutrient contribution of fortified maize flour, oil, rice, salt, and wheat flour in 153 countries suggests there is minimal risk to countries of exceeding Tolerable Upper Intake Levels and causing harm to populations due to excess nutrient intakes from staple food fortification [28]. In fact, the main way in which people can exceed the UL is by taking micronutrient supplements at a higher-than-recommended dosage on a daily, long-term basis [29]. This is unlikely through consumption of fortified staple foods alone, as micronutrient fortification levels are set according to guidelines or regulations specific to the context, and due to the extremely large portion of these staples that would need to be consumed in order to exceed safe levels.

Figures 4A, B, C and D show an example of wheat flour fortified according to the WHO guidelines at 200 g/d per capita consumption, and the amount of wheat flour that would need to be consumed on a long-term, daily basis to reach the lowest observed adverse effect levels for vitamin A, iron, zinc and folic acid. The possible adverse effects are based on lowest observed adverse effect levels (Table 3) for pregnant women and adults (vitamin A), elderly patients with pernicious anemia (folic acid), adults (iron and zinc).

Figure 3A: Example of vitamin A fortification of wheat according to WHO guidelines – the regular daily amount represents 200 g flour (approximately 750 kcal).

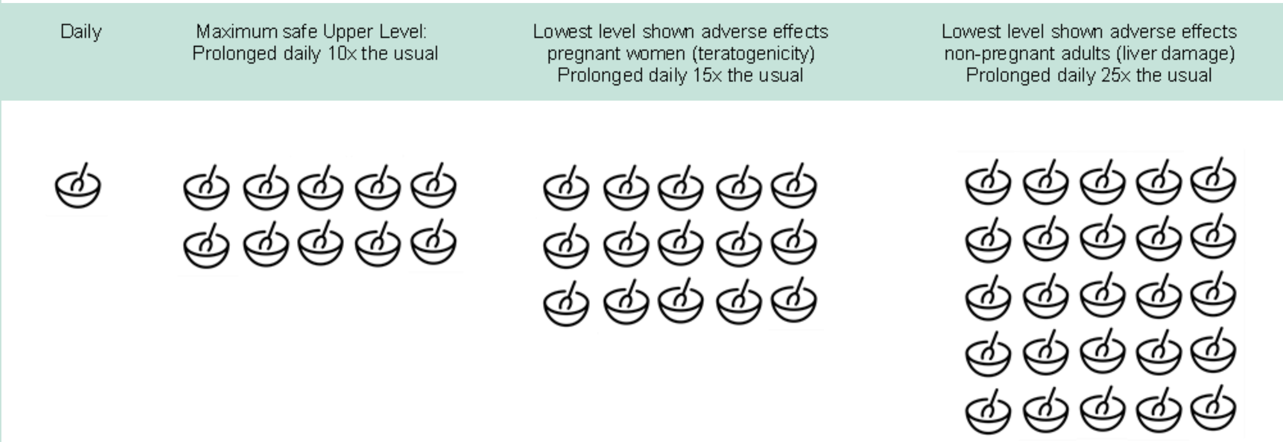


Figure 3B: Example of folic acid fortification of wheat according to WHO guidelines

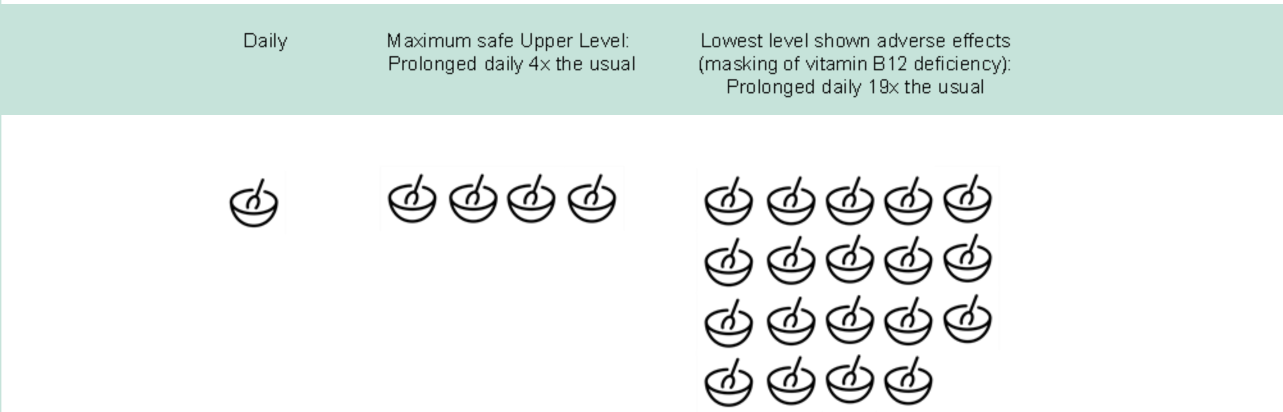


Figure 3C: Example of iron fortification of wheat according to WHO guidelines

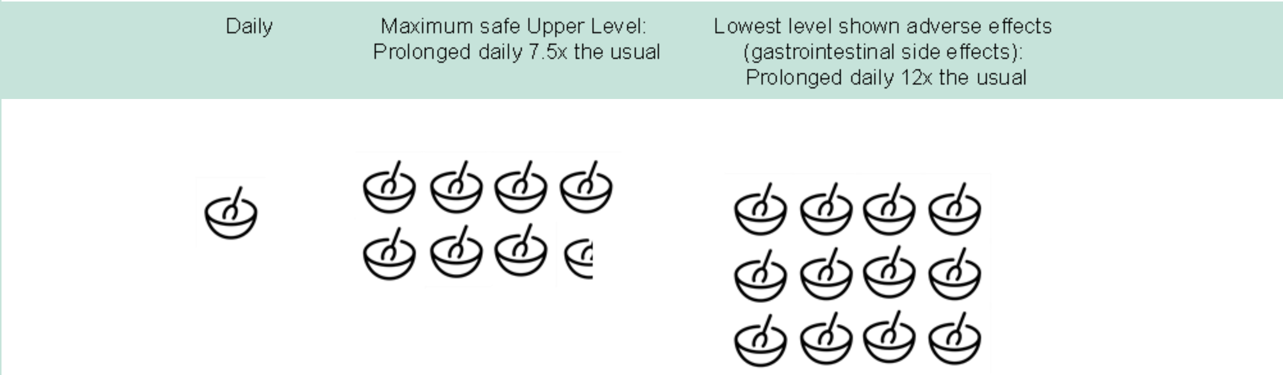
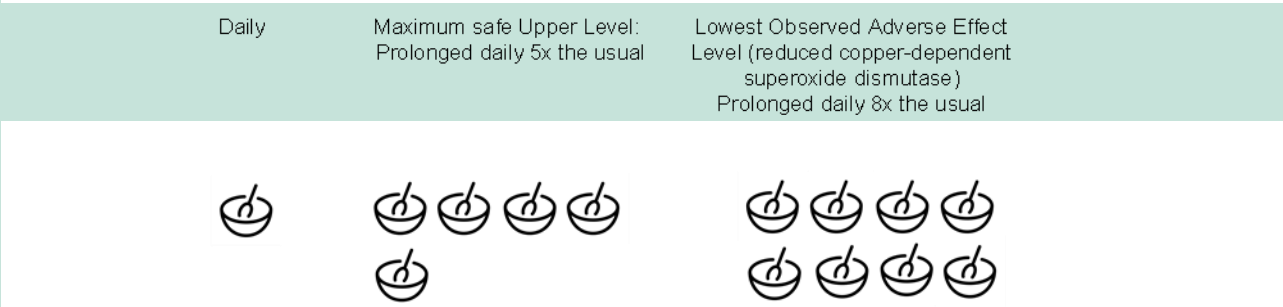


Figure 3D: Example of zinc fortification of wheat according to WHO guidelines



Common misconceptions

Separating fact from fiction is critical when it comes to food fortification, which is why it's important to provide evidence and fact-based answers. The **Frequently asked questions** document addresses some of the most common concerns, misconceptions, and myths.

Conclusion

Fortification of commonly consumed foods is a cost-effective and safe approach to improve micronutrient intakes and provides tremendous public health benefits. If fortification programs are planned, using established fortification guidelines or standards and are well-implemented, the quantity of micronutrients added to staple foods during fortification is highly unlikely to be unsafe. Overall, the health consequences of inadequate micronutrient intakes are of much greater concern than health risks of overconsumption.

The way forward

THE WAY FORWARD to have a significant impact on micronutrient deficiencies, fortification must involve a number of actors and partners, from governments to nongovernmental organizations, advocacy groups and the private sector. WFP will continue to work with all of these groups in a joint effort to improve nutrition. Fortification contributes to a healthy, nutritious diet by adding much needed micronutrients to diets that do not provide enough for example because of too low diversity due to economic, market-access, seasonality and other reasons. As such, fortification is an effective tool that is required to fight micronutrient deficiencies and can play a valuable role on the path to zero hunger.

Appendix

Guidelines and tools for setting effective and safe food fortification levels

- **WHO-FAO fortification guidelines** exist to set micronutrient levels in food that can be used if population-based data are available for food consumption and micronutrient intakes that assist in setting micronutrient levels in the food to fortify [15].
- **WHO guidelines** are available for fortification of wheat [30], maize flour and corn meal [31], rice [32], and salt [33]. WHO nutrition recommendations can be found in the library of Evidence for Nutrition Actions [9].
- **WHO and WFP Technical notes** are available for setting the preferred level of micronutrients in the fortifiable food based on estimated per capita staple consumption; per capita staple consumption data are available from FAO for most consumed staples in a country. These technical notes provide levels of nutrients to consider based on flour extraction, micronutrient form (absorption), and estimated per capita availability
  - WHO technical notes are available for setting micronutrient levels in wheat and maize fortification per capita consumption [31].
  - WFP Fortified rice specifications are available for recommended micronutrient levels in rice per capita consumption [18].
- An **Excel tool** developed by the A2Z USAID project exist that helps to set micronutrient levels in food [34].
  - Excel tools exist for sugar, rice, wheat, maize, oil, salt/condiments
  - Requires input on estimated per capita intake of the food to fortify
  - If available, input on mean nutrient intakes from various sources (food, supplements)
  - Excel tool takes into consideration: costs, bioavailability etc
  - Different nutrient levels in the food can be simulated
- A **Software tool IMAPP** helps to set micronutrient levels in food [17].
  - Estimation of usual nutrient intake distributions
  - Estimation of prevalence of inadequate intakes and intake above the UL

Guidelines and tools for implementation

- Rice fortification: Supply chain and technical feasibility [35] balanced and effective food fortification strategy for countries [36]
- Handbook for the Production of Extruded Fortified Rice Kernels [37]

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