

## GUIDELINES ON DESIGN AND PROCUREMENT OF PREMIXES FOR THE FORTIFICATION OF MILLED CEREALS (from MI's Fortification Manual)

This section provides practical advice on the type and source of fortification premix to add to milled cereal staples (primarily wheat flour and maize meal) in different countries or regions. It is arranged in a series of steps that depend on a country's food laws and regulations. Additional information on this topic is provided here.

There are three situations discussed:

1. Meeting a country's existing cereal fortification standards.
2. Voluntary flour and maize fortification.
3. Working to establish cereal fortification standards.

### In Countries with Existing Fortification Standards

Currently, nearly 50 countries have cereal fortification standards or customary fortification practices (see Figure 1 below and Tables 5.2A for wheat flour and 5.2B for maize meal in Section 5 of the Fortification Manual for actual fortification standards in different countries.)

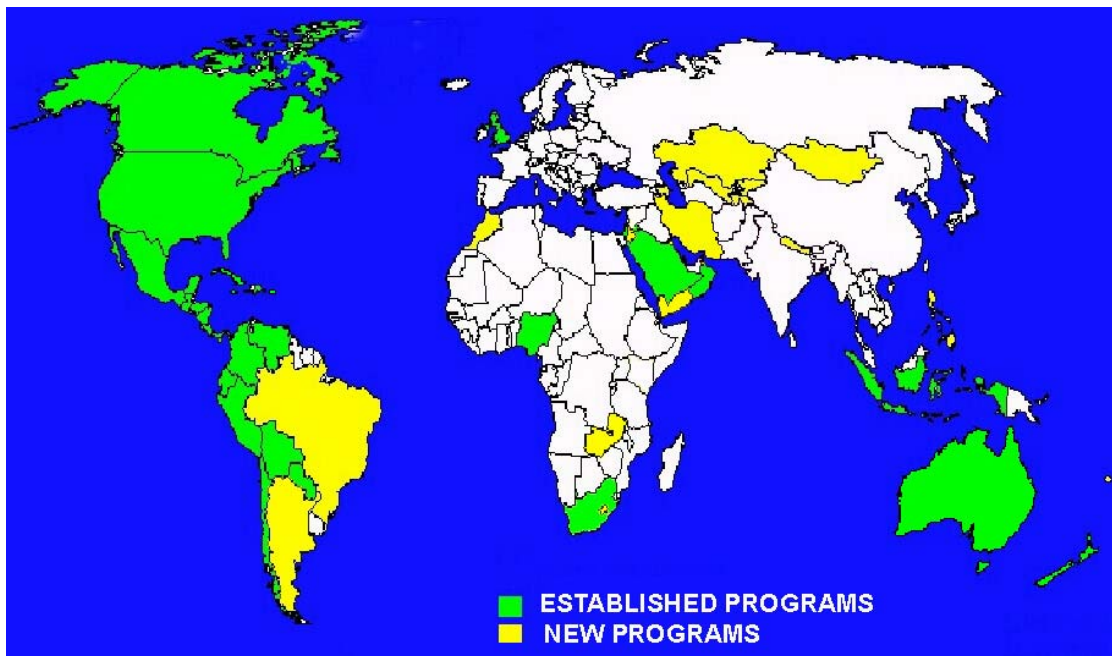


Figure 1. Countries with Fortification Programs

If a country does have fortification standards there are likely to be appropriate fortification premixes available from one of the many premix suppliers. While any of these premixes could be used, they may differ in the following aspects.

1. *The source of the micronutrients used.* For example, one supplier may use niacinamine as the source of niacin (vitamin B<sub>3</sub>) while another may use nicotinic acid. Some countries specify the type of micronutrients that can be added so one should check to make sure the premix is in compliance with those regulations.
2. *The levels of micronutrients added.* There is some leeway in the levels of micronutrients that can be added to meet a particular fortification standard. The premix supplier should provide evidence that they are adding sufficient but not excessive amounts of micronutrients to insure compliance with the appropriate standard. A few countries, such as South Africa, specify the amounts of micronutrients to add, but this is not the usual practice.
3. *The type of flour or meal the premix is designed to fortify.* Premixes can differ in the type and levels of micronutrients added based on the type of flour or meal it is designed to fortify. For example, lower levels of micronutrients may be needed for high ash, high extraction flour than for white refined flours. Also, the type of iron used on different types of flours can differ.
4. *The addition rate or premix dilution.* Premixes can be very concentrated to save on shipping and storage requirements, or dilute to better allow control of addition at the mill, particularly small mills. Higher addition rates require more dilution with an appropriate carrier such as starch or calcium salts. Mills should determine what addition rate they need and use a premix that meets that requirement. Alternatively, they can buy a concentrated premix and dilute it at the mill, usually with flour, to make its addition more manageable.
5. *Local availability.* Mills may prefer to procure premix from a local supplier. Most countries will not have premix manufacturing operations, so they will have to import it from a country that does. Shipping can add to the cost of the premix. Hopefully, the country will have minimal duties on imported premix. Some suppliers may maintain stocks of premix in country making it easier for mills to obtain it.
6. *Packaging.* Premix suppliers differ in how they package the premix. Containers can vary in size from 100 kg to 10 kg or less. The container itself can vary, from fiber or plastic drums to cardboard boxes or bags. The inner liners used may differ in their composition and how they are sealed.
7. *Quality, reliability and service.* While all premix suppliers promise these, differences may show up in actual practice. The supplier should provide Certificates of Analysis (COAs) for all the micronutrients present in each lot of premix. A good premix supplier should be able to advise the mill on what premix to use along with recommendations on how best to add it in the mill.

8. Cost. If everything else is equal, which is usually not the case, mills will want to buy from the supplier with the lowest cost. Costs can vary greatly for a variety of reasons, so mills should look around before purchasing.

There may be situations where a mill wants to add micronutrients that are not specified in the current standards. An example would be adding folic acid. Short of changing the standards, this could be possible depending on the regulation. For example, a country may require or specify fortification with certain micronutrients but allow fortification with others. Mills should consult with the government authorities prior to doing this.

### **In Countries without Fortification Standards**

If a mill desires to fortify flour or meal in a country that does not currently have cereal fortification standards or regulations, the first step is to determine whether flour fortification is even allowed. A few countries have regulations that specifically prohibit adding most anything to flour. In that case the law must be changed or a special permit obtained before fortification can be practiced.

The next step is to find out if there are any regulations on the types and levels of vitamins and minerals that can be added to foods in general. Some countries have general regulations on food fortification that should be observed.

Assuming that the first two steps are completed and that fortification is possible, there are a couple of different approaches that can be taken in determining what type of fortification to use.

#### Comply to Regional Practices or Standards

For mills in countries that are located near countries with active cereal fortification programs and established standards, it may be sensible to fortify flour or meal in the same manner. This makes a lot of sense if the populations of the two countries are similar and there is active trade of cereal products between them. One big advantage in doing this is that the same premix can be used, which greatly improves its ability to be procured and helps lower the cost.

Examples of this situation include countries in Southern Africa using premixes designed to meet South African standards and countries in the South Pacific using the Indonesia premix. Countries may also wish to adopt regional standards, such as those in Central Asia, Central America and the Middle East, as shown in Table 1.

**Table 1 Actual or Proposed Regional Flour Fortification Standards**

*(levels added)*

	<i>WHO/EMRO Middle East</i>	<i>ADB/KAN Central Asia</i>	<i>ADB Proposed Southeast Asia</i>	<i>Southern Africa</i>
Iron (ppm)	30/60*	50**	30/60*	35**
Zinc (ppm)		22	30	15
Folic acid (ppm)	1.5	1.5	2	2
Thiamin (ppm)		2	2.5	1.94

Riboflavin (ppm)	3	4	1.78	
Niacin (ppm)	10		23.68	
Vitamin B <sub>6</sub> (ppm)			2.63	
Vitamin A (IU/kg)			5951	
Cost (\$/MT) <sup>1</sup>	\$0.32	\$0.69	\$0.74	\$1.99

\*30 ppm iron if ferrous sulfate, 60 ppm if elemental iron powder.

\*\*As electrolytic reduced iron

### Comply to Food Aid Standards

A number of developing countries get large amounts of fortified wheat flour or maize meal in the form of food aid, usually from the United States under their *Food for Peace* (PL-480) program. This is fortified with iron, calcium, vitamin A and four B vitamins.

**Table 2 PL-480 Food Aid Fortification Standards**  
(final level)

	<i>Wheat</i>	<i>Maize</i>
Iron (ppm)	44	28.7
Folic acid (ppm)	1.54	1.54
Thiamin (ppm)	6.4	4.4
Riboflavin (ppm)	4.0	2.65
Niacin (ppm)	52.9	35
Calcium (ppm)	1100	1100
Vitamin A (IU/kg)	22,050	22,050
Cost (\$/MT) <sup>1,2</sup>	\$4.30	\$4.10

. Sometimes the World Food Program (WFP) and other donors obtain flour or meal locally. This could be fortified to PL-480 standards or other standards set by the WFP (as is the case for flour milled in Pakistan destined for Afghanistan). The PL-480 premixes are readily available but costly since they add a high level of vitamin A. WFP has yet to adopt a clear policy on what type of fortification they require for different regions.

### Comply to a Milling Company Standard

Some international milling companies have routinely fortified flour to certain standards, often those used in the country in which the company is based. Examples of this are U.S. and Canadian milling companies fortifying to U.S./Canadian standards (now the same but once somewhat different in levels) and South African milling companies fortifying to RSA standards. An example of this is the long term, voluntary fortification of wheat flour in Haiti to U.S. standards, which does not have any requirement that the flour be fortified.

### Use a Flour Enrichment Scheme

*Enrichment* is a type of fortification involving the replacement of micronutrients lost in the milling process. The lower the extraction, the lower the ash and the less

<sup>1</sup> The *Costs* shown are estimated, undelivered (FOB) costs of the premix at a major U.S. port given in the cost in U.S. \$ needed to fortify one metric ton of flour. These costs are subject to change and are provided here only for comparison purposes. They are for the premix only and do not include equipment, quality control or other associated costs of fortification.

<sup>2</sup> This cost is for the premix that does not include calcium. The cost of calcium fortification is discussed in section 6 of the Fortification Manual (Minerals).

micronutrients that are present in the final flour versus what was present in the original grain. A mill may choose to simply restore lost nutrients using a premix designed for that purpose. This approach has some major complications and limitations.

One first has to determine which of the possible ten micronutrients that are lost in milling are to be restored<sup>3</sup>. This approach precludes adding vitamin A, vitamin D, vitamin B<sub>12</sub> (which are not naturally present in grains) or the high levels of folic acid that have been widely recommended and used. Another complication is the wide variation in natural levels of some micronutrients in whole grains, particularly iron, making it difficult to establish what the restoration level should be.

Despite these problems, it is possible to go with a simple enrichment scheme and obtain a premix that will accomplish that purpose, an example of which is shown in Table 3, the estimated cost of which is \$0.80 per metric ton of fortified flour. The advantage of this approach is that it deflects criticism in countries not accustomed to flour fortification since you are simply adding back nutrients that were removed. One major disadvantage is that it may not meet the nutritional needs of the population that will consume the flour. Note that the percentage of the dietary requirements provided are comparatively low for riboflavin and folic acid.

**Table 3 Possible Flour Enrichment to Whole Wheat Levels**

<i>Micronutrient</i>	<i>Level added (ppm)</i>	<i>Final minimum level (ppm)</i>	<i>% RDA per 100g</i>
Thiamin	3.5	4.1	34
Riboflavin	1.1	1.1	8
Niacin	48	48	30
Folic Acid	0.23	0.4	10
Pyridoxine	3.2	3.4	26
Iron	47	54	30
Zinc	31	35	35

#### Meet Customer Specifications

There can be cases where a major flour user, such as a national bakery or food aid donor, requests that flour be fortified to certain specifications that they provide. Such flour may be used locally or exported. Fortification premix companies can provide the appropriate premix. In rare cases the flour purchaser provides the premix.

#### Devise Customized Fortification

In lieu of any of the above situations, mills in countries without fortification standards may wish to develop their own fortification scheme and applicable premix that meets their particular nutritional, economic and technical requirements. Ideally a mill or

<sup>3</sup> There are other nutrients lost in the milling process but only ten have nutritional significance as discussed in Section 1.

milling industry should do this in collaboration with local health and government authorities, but there may be situations where that is not practical or would result in an extended delay in implementation. In that case the milling company may want to call on experts, such as are available through the Micronutrient Initiative or WHO, to devise a suitable premix.

### **Types of Fortification**

An important distinction should be made on whether the planned fortification of flour falls under the category of *open market, mass or targeted* fortification, in the parlance of the WHO guidelines. If the former, the mill's primary objective is to increase sales and market share of a couple of their flour products, typically their premium, higher priced white flour. This may be accompanied by special labeling and promotion. Open market fortification is likely to be discontinued if the hoped for sales do not materialize.

Mass fortification, on the other hand, is generally applied to more flour products and its long term continuation is not dependent on sales. A milling company, or even the whole milling industry within a country, may decide on their own that fortification is a good thing and should be practiced as a general rule, even if there are no requirements to do so. This is not a common occurrence; nearly all mass programs result from government action.

Targeted fortification occurs when a major mill customer or potential customer, such as a food aid agency like CARE or WFP, requests a special, fortified flour for distribution in their food aid programs.

This distinction in the type of program impacts the nature and possible source of the fortification premix to use. An open market program would lean towards those micronutrients that have the greatest recognition and appeal to the intended market, usually the higher socioeconomic group that would purchase the premium products. Folic acid and calcium are current examples of such micronutrients. Premix cost is generally not an issue in this situation. Established fortification premix companies would be a good resource to use in devising premixes for this purpose.

Mass and targeted fortification programs would want to focus on those micronutrients that are in the greatest need by the general population, with iron and folic acid being good examples. Cost becomes an important factor in mass programs since milling companies are not as able to regain the cost of fortification in the case of low priced products as they can from the higher priced, premium ones. Premixes for use in mass programs should involve the collaboration of different stakeholders, particularly those in government and the milling industries. Premix or micronutrient manufacturers, while a useful source of information, should not be directly involved in deciding the types and levels of micronutrients to add in a mass program.

### **Fortification for Different Types of Flours**

Mills produce different types of wheat and maize products, as discussed in Section 4 of the Fortification Manual. These products can differ greatly in their micronutrient content,

which is dependent on the extraction rate and the degree of refinement. A good measure of this is the flour *ash* content – the greater the ash level, the higher the micronutrient content. Whole-wheat flours contain all of the original micronutrient content in the wheat kernel, while micronutrients are concentrated in some mill products (eg. *second clears, red dogs*) causing them to have actual higher levels of some micronutrients than those present in the whole wheat.

Historically, only the refined, white flours with ash contents below 0.7% have been fortified since they contain the lowest level of micronutrients and are the primary mill products that go to direct human consumption. There are many countries, however, where a high extraction, high ash flour, such as *atta* flour, is common if not prevalent. Should such flours be considered for fortification, and if so, with what? This is one of the more difficult questions to answer.

These high ash, high extraction flours could act as a convenient carrier for certain deficit micronutrients, such as folic acid and vitamin A, which are not naturally present in wheat. They would be less than ideal for iron and zinc because of a high level of phytic acid they contain, which would decrease the absorption of these minerals, unless special forms such as iron-EDTA were used. Also, these types of flours are often made in smaller mills making fortification more difficult but not impossible.

### **Guidelines on Devising Mass Cereal Fortification Standards**

Each country or region should establish their cereal fortification program based on the situation in their region taking into account the different considerations in this manual. The process of establishing standards and associated regulations is difficult and involved. It should always involve representatives from the medical community, the milling and baking industry, and the government, usually through the Ministry of Health. Consumer groups, educational/research institutions and interested NGOs may also be involved. This alliance must assess what is needed and what is feasible. All major stakeholders must “buy in” to the final regulations if acceptance and compliance are to be achieved. While the cost of the fortification may not appear to be a major constraint at the beginning, experience shows us that it always will be one at the end. As a general rule of thumb, fortification programs for cereal staples that have an ingredient or premix cost in excess of \$1.00 per metric ton of flour are difficult for the milling industry to accept. This restricts the types and levels of micronutrients to include, and makes it very difficult to require vitamin A and calcium. On the other hand, it makes little practical sense to go through all the trouble of adding just one or two micronutrients, when additional ones could be included for very little additional cost, providing the general population needs them.

Consideration of what vitamins and minerals to include in a mass fortification program can be broken down into the following hierarchy depending on the recognized level of deficiency and cost:

1. Extensive deficiency problems - Should be included in all fortification programs: Iron and folic acid.
2. Common deficiency problems, reasonable cost and well suited to flour fortification – should be considered for most fortification programs where their

specific deficiency can be shown: Zinc, thiamin, riboflavin, niacin (in maize), pyridoxine

3. Common deficiencies but cost restraints – Consider inclusion if added cost is acceptable: vitamin A, niacin (in flour), calcium
4. Deficiencies less common but known to occur – Consider for inclusion only if a deficiency problem can be proven and there is no other reasonable intervention: selenium, vitamin B12, vitamin D

Following are some specific guidelines on cereal fortification on different types of flours.

**White refined wheat flour (with an ash content below 0.80%) and refined, degermed maize meal**

1. Most refined flours **should be enriched** with those micronutrients that are naturally present in the whole-grain and highly reduced in the milling process and that are known to be deficit in the general population consuming these products.
2. The level of micronutrients to add to refined flours and meals should be at least sufficient to achieve the natural levels in the whole grains (i.e. enrichment or replacement levels, see Tables 3.7 and 3.8.)
3. Appropriate adjustments should be made on the basis of bioavailability of the iron source used in the amount added. Current guidelines on iron fortification from SUSTAIN, PAHO and WHO should be considered.
4. Folic acid should be added to this type of flour at higher than replacement levels (e.g. 1.5 to 2.4 ppm) because of the now recognized need and benefits for this vitamin.
5. Higher than replacement levels for riboflavin (2 to 4 ppm) for this type of flour should be considered if the need exists.
6. Some non-staple refined flours, such as cake flour, may be exempted from enrichment in order to allow consumers to have a choice of an unfortified product.
7. All developing countries should, at a minimum, fortify this type of flour with iron and folic acid, and strongly consider including zinc and riboflavin.
8. If niacin and vitamin A are added, their levels should be kept low enough so that the cost of the full fortification is reasonable and acceptable. Vitamin A addition greater than 10,000 IU per kg is not recommended because of the high cost.

**Medium extraction flours (ash content 0.8% to 1.0%) and maize meals**

1. This type of flour should only be fortified if fortification of refined flours will not achieve the desired nutrition objectives or coverage of the target population.
2. Elemental reduced iron is acceptable but not ideal. Ferrous sulfate is not recommended but ferrous fumarate is possible. Iron-EDTA should be considered. Otherwise, the same types and levels of the other micronutrient used in refined flour can be applied. Vitamin A can be added if desired.
3. The level of added nutrients naturally present in cereals may be reduced due to the higher natural content in order to achieve the same final levels or standards.

**High extraction flour (ash content >1.0%) and maize meal**

1. Fortify this type of flour only if absolutely necessary to reach a target population.
2. If iron needs to be included, use iron-EDTA but at low levels (~15 ppm Fe).
3. The levels of vitamins added and the fortification standards for this type of flour should be based on meeting nutritional intake objectives and not on levels in whole grain.