SMALL SCALE MILL FORTIFICATION MANUAL

January 2005

The Micronutrient Initiative
Ottawa, Canada

L'Initiative pour les micronutriments

The Micronutrient Initiative

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Acknowledgments

The authors would like to thank all those whose contributions have made the preparation of this manual possible. These contributions have been made during visits to several countries where Small Scale Fortification is being pioneered.

In particular the contributions by personnel from the following organizations must be gratefully recognized:

CIDA, UNICEF, WHO
Micronutrient Initiative - Ottawa, Asia and Africa Offices
World Food Programme in Rome, Kenya, Uganda and Zambia
CARE Canada, CARE Zimbabwe
World Vision MICAH teams in Canada, Malawi, and Tanzania
Helen Keller International in Burkina Faso, Cote d'Ivoire, Mali, Niger
NISIR and NFNC Zambia
Ministries of Health in Malawi, Tanzania, Zambia and Zimbabwe

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FOREWORD

Evidence from large-scale centralized fortification programs in developed countries has shown staple cereal fortification to be among the most cost effective and sustainable strategies for alleviating micronutrient deficiencies. This success was largely possible because cereals in developed countries are centrally processed, therefore making fortification operationally convenient and cost effective.

In most African countries, staple cereals are not centrally processed. A large percentage of consumers (surpassing 50% and up to 90% in some countries) depend on small-scale milling for processing staple cereals including wheat, maize, sorghum and millets. These consumers cannot be reached using the large-scale, centralized fortification model. Ironically, these consumers are also the poorest of the poor; the very ones who are most in danger of micronutrient malnutrition.

The MI recognizes the crucial importance and the difficulty of going the extra mile to reach the poorest of the poor. During discussions with partners in sub-Saharan Africa and South Asia the enormous importance attached to small-scale fortification (SSF) by governments and nutritionists was evident. It is also seen as a political as well as a development issue. For this reason, since 1999 we have been involved in projects to understand the technical and operational feasibility of SSF so that it could be part of a combination of interventions to combat the micronutrient malnutrition in the developing countries.

With support from CIDA and in collaboration with partners like UNICEF, CARE, World Vision and national governments we have attempted to understand the technology, challenges and possibilities surrounding small-scale fortification. During workshops and field visits, the need for a technical manual on small-scale fortification has been made clear. Therefore we have commissioned this manual to serve as a tool through which the existing technical knowledge on SSF could be disseminated. Though most of the examples and practices described in this manual come from maize milling in Africa, where small scale processing is very common, some of the recommended procedures given in this manual are as well applicable to small scale processing of other cereals in different parts of the world.

We hope that the manual will be useful to organizations and governments exploring the feasibility of small-scale fortification and/or trying to initiate and implement SSF as an intervention to improve the nutritional status of the vulnerable populations.

M.G. Venkatesh Mannar
President
Micronutrient Initiative

Section 1
INTRODUCTION

The poorest segments of many populations suffer from micronutrient malnutrition and associated disorders because they are not able to grow, purchase or consume adequate quantities or a variety of foods. Fresh meat, vegetables and fruits are not often available in sufficient quantities or at affordable prices.

Living mostly in rural and periurban areas, these people harvest grains like maize, wheat, rice, sorghum and millet, or starchy roots like cassava that are grown on small plots of land. These foods are then dried in the sun, before being ground to flour (also called "meal") in a small, local mill. Some can afford only to hand pound the grain to a coarse meal. Milling on this small scale is usually done in 3 to 20 kg batches of grain, or an amount a household requires for 1 to 14 days. In periurban or suburban areas, people often buy grain at the market and grind it to a meal at a local mill. The meal may be cooked to a porridge or dough like consistency, and more often than not it is eaten without fresh meat or vegetables.

Fortification has proven to be an effective strategy for combating micronutrient malnutrition around the world, but it is most often applied to processed foods made at industrial scale plants. In poorly developed countries in Africa, Asia, South America and Eastern Europe, less than half of the population consumes pre-processed, packaged foods. As a result a large portion of the population in many countries do not benefit from fortification.


Pounding maize in Zambia

The women and children in these situations are nearly always anemic, due mainly to iron deficiency, along with being prone to a host of other micronutrient deficiency problems. The amount of absorbable iron in their diet is low and the diet itself inhibits iron absorption because of high levels of phytic acid in whole grain cereals and polyphenols in tea and coffee, which inhibit absorption, and low intakes of meat and citrus fruits, which enhance absorption.

Scope of Manual

This manual shows how fortification can be effectively extended to small scale milling operations, particularly those found in Africa, so as to benefit the poor and needy segments of the population.

The purpose of this manual is to inform NGOs, international agencies and government authorities how Small Scale Fortification (SSF) can be established and used to combat micronutrient deficiencies in less developed countries. Small scale milling is defined here as mills with a daily capacity of less than 5 metric tones of grain per day, but they are typically less than 1 ton/day. Most of the examples and practices described in this manual come from maize milling in Africa, where small scale milling is very common. Some of the SSF recommended procedures given in this manual will be applicable in other situations, such as rice milling and wheat milling of *atta* in India, but there will be many situations where local practices and needs necessitate modified or quite different methods.

Stone grinding of maize by Hopi Indian in 1900

The manual will:

- Outline the essential conditions for considering SSF,
- Describe the methods of assessing the feasibility and potential of introducing SSF,
- Identify appropriate fortification technologies and methods of selecting them,
- Describe how to conduct localized field trials to demonstrate SSF and test its acceptance,
- Describe how to scale-up the practice to a district or national level.

While small-scale mill owners may wish to take the initiative to implement SSF to gain a marketing edge, they should preferably participate in trials or programs run by NGOs or government authorities.

Example of a Small Scale Milling Scenario in Africa

In a typical rural setting the customer is either a woman or a child. The grain is brought in a sack, the amount depending on what can be carried, how much the mill can handle or the amount necessary for one's family for 1 to 14 days. Grain is volumetrically measured out using a "tin". This can be a metal container typically holding about 17 kg of maize grain as in Zambia. In some areas, a smaller scoop or vessel is used to measure the amount of grain to be milled.

The miller, almost always a male, discharges the contents of each tin into the mill's hopper tray, where he screens for pebbles (that could damage the mill) with his fingers, while the mill is operating. Meanwhile the customer ties her sack to the end of the discharge pipe to collect the meal. If the customer has brought more than one tin of grain, the miller fills the hopper as needed. The mill is run continuously as much as possible. The customer collects the sack of meal, pays the miller what he demands, the fee per tin generally being displayed on a chart on the wall. The customer generally never queries the miller about the milling fee he charges or the amount of meal that has been returned. There is no measurement of the amount of meal collected in the sack. Neither the customer nor miller verifies if one tin of grain yields the requisite amount of meal; thus losses via the cyclone separator or other parts of the mill are not monitored.

If the customer wants a very white maize meal, free of bran, the grain is doused with water to wet the surface and fed to a dehuller, which has a typical extraction rate of about 60-65%. In some areas, the grain may be soaked for a few hours or even a day. The residue, about 35-40% of the weight of feed grain, is often left on the mill floor, to be collected later by the miller and sold as chicken or animal feed. The miller does not share the resulting revenue with the customer. The dehulled product is often sifted on-site by the customer, and then dried in the sun at home for a few hours, before milling to a flour or meal, which may need to be further sun-dried if it is damp.

In essence, the customer is very compliant, very trusting of the miller who is fully occupied with running the mill, feeding the grain, and collecting and recording the revenue. There is often a queue and customers can wait up to a couple of hours or longer. Conditions in the mill can be quite dusty, cluttered and bustling, with varying degrees of cleanliness. Record keeping varies from mill to mill, depending on the owner's diligence. It is under these conditions that introduction of any SSF technologies for adding premix to the meal needs to be considered, on technical, economic and sociological grounds.

Section 2
MICRONUTRIENT INTERVENTIONS

It can generally be assumed that micronutrient deficiencies will exist in all developing countries where small-scale milling is common. Nutritional and food consumption surveys of the local population can be used to determine the extent and specific nature of the micronutrient deficiencies in order to better assess appropriate intervention strategies. It is generally the responsibility of a country's ministry of health (MOH) to determine and establish appropriate strategies for overcoming these disorders. Events such as droughts, floods, pest infestation of crops, economic downturns, etc. can worsen the problem increasing the need for action.

Strategies for Micronutrient Intervention

International agencies (UNICEF, WHO etc.) and NGOs (the Micronutrient Initiative, CARE, World Vision, HKI, Oxfam etc.) work in collaboration with national governments to combat micronutrient malnutrition. One of the strategies to reach *target* population is through distribution of micronutrient *supplements*, such as vitamin A capsules and iron/folate tablets. While supplement programs are generally effective they are considered to be difficult to sustain. Fortification of staple foods offers a less expensive and easier to maintain program; but it should not be thought of as a replacement to supplements, rather a complement to such programs.

Home fortification using Sprinkles™ or crushable tablets is a fairly new concept that is gaining acceptance. It requires the person preparing meals to add the fortificants to the meal as it is being prepared or served. In the case of maize meal this normally means mixing the fortificants into a porridge or gruel. This might be considered to be an intermediate method having aspects of both small-scale fortification and supplementation.

In most developed countries, fortification of staples such as cereals (milled or processed), salt, and processed foods (milk, bread etc.) has been legislated and practiced for over 60 years. In developed countries almost the entire nutrient intake is based on people consuming processed, packaged foods (pasta, milk, flour, breakfast cereals, beverages, snacks etc.) supplemented with an abundant supply of fresh meat, fruits and vegetables. Packaged foods are produced on a large scale, so they can be fortified with micronutrients at negligible cost. Similarly, in cities in most less developed countries, one can get a comparable array of package foods fortified at minimal cost in large mills (both locally produced and imported), as well as products such as common salt which are iodized in small to medium scale plants.

Food fortification should always be an integral part of a comprehensive strategy of micronutrient deficiency prevention and control that includes supplementation, dietary diversification, breast feeding promotion, improved complementary feeding and other public health measures implemented throughout the life cycle.

The Micronutrient Initiative (MI) has been developing and promoting technologies for fortification of salt with iodine as well as iron and vitamin A. Double or multiple fortification of salt as well as fortification of condiments like sugar, soy sauce and fish sauce are also promising with the development of new technology and novel iron sources.

Strategies such as distribution of supplements or import of fortified food aid commodities would be short to medium term in scope and effect. Fortification of staple foods at the local mill, increasing supplies of such foods, growing vegetable gardens and diet modification would be medium to long term strategies. It is not unusual to implement short term strategies even as longer term options such as SSF are being assessed and introduced.

Reaching the neediest population with fortified staple foods - such as wheat or maize flour, salt, sugar, cooking oil and beverages - continues to be difficult because these people can rarely afford processed foods, and the necessary distribution channels may not exist. Given their meager financial and food resources, this target population may be reached only through free supplementation or by implementing SSF at small local mills.

The challenge of SSF is to do it in a manner that it is safe, timely and acceptable to the target population, at a cost marginally above that of milling. Moreover, the target population needs to demonstrate that they have the technical, human, logistical and economic resources to sustain SSF over the long term, independent of foreign donors or government subsidies. Local governments have the added responsibility of passing laws permitting food fortification and enforcing them through reliable monitoring and testing.

Fortification Office for small-scale fortification project in Kabadula, Malawi

Section 3
PLANNING SMALL SCALE FORTIFICATION (SSF)

The design of a food fortification program is governed by a number of factors, including:

- The extent and nature of the micronutrient deficiencies within the target population,
- The laws and regulations governing fortification in a given country,
- The types of food staples suitable for fortification (typically cereal flour, salt, sugar, cooking oil, condiments, soups etc.) that are consumed by the target population,
- The quantities and frequency by which the target population consumes these foods,
- How the target population acquires these foods (selected on the basis of frequency and quantity of consumption),
- The methods of food processing,
- How the foods are transported, stored and prepared,
- How and where the selected foods could be fortified (e.g, at a local hammer mill).

Conditions for SSF

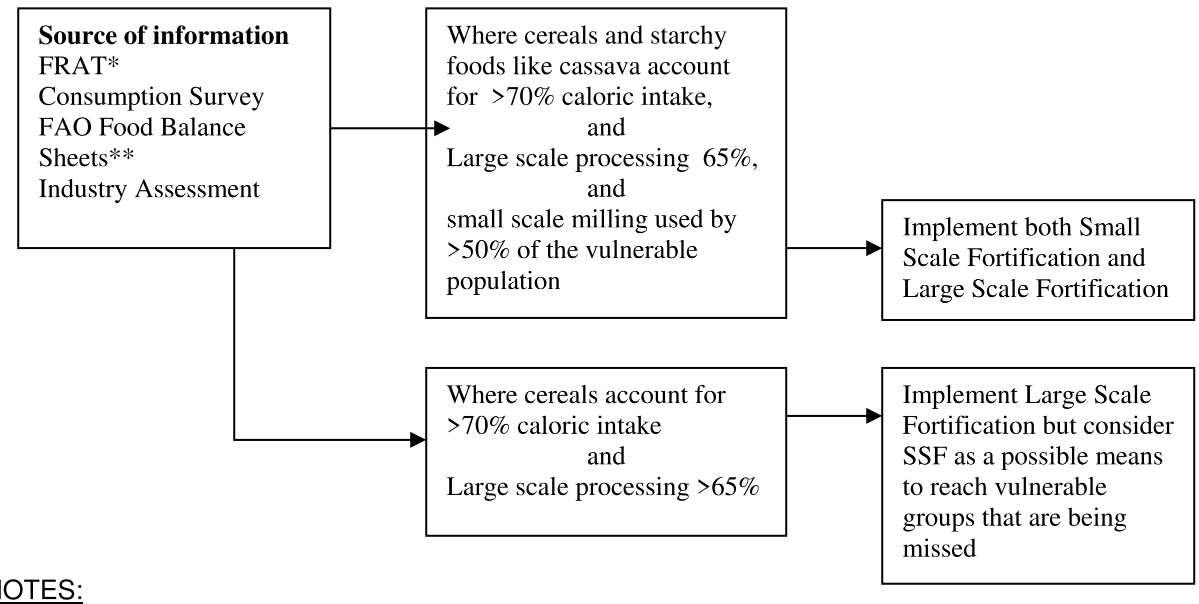
Conditions that warrant consideration of small-scale fortification are when the affected or target population:

- Consumes little or no processed and packaged foods.
- Eats primarily what they grow themselves.
- Processes the foods they harvest at the local mill.
- Processes a small amount of food, usually 3 - 20 kg of grain, at any one time.
- Relies on food processed in a manner specific to the local area that is not conducive to replication in a large mill or plant. (local processing can involve a variety of pre-milling or post-milling practices such as fermentation of grain, dehulling, solar drying, milling followed by sieving and drying, or converting the meal into a dough that is submerged in water and used as needed.)
- Consumes food that can be fortified with minimum added technology using a premix that blends easily with minimal organoleptic effect.
- Consumes food, such as cereal grains, that is processed in a local mill where SSF can be introduced, where they can be trained on handling premix, and where the customers' practices can be monitored by health authorities.

- Reside in remote locations that are not easily accessible to regular distribution channels for large-scale producers.

Figure 1 shows the conditions under which Small Scale Fortification (SSF) would be warranted.

Figure 1. FORTIFICATION DECISION TREE



NOTES:

*FRAT or Fortification Rapid Assessment Technique: (http://www.pathcanada.org/english/fratt.cfm)

** FAO Food Balance Data: http://faostat.fao.org/faostat/collections?subset=nutrition

In some countries dried cassava is milled at the small village and periurban based mills. The consumption data for cassava should be included in the cereals intake data.

In countries where supplementation programs are in effect for vulnerable groups and SSF is being considered the added micronutrient levels in SSF need to take into account the supplementation levels provided. For example, if the target population is receiving sugar fortified with vitamin A, the level of that vitamin, if used in SSF, should be reduced accordingly.

Recommended Procedures Leading up to SSF Implementation

1. Conduct a *situation analysis* to study local diet and select which staple foods (typically, cereal grains) are candidates for SSF.

2. Determine how, where, and by whom the foods are processed, from the cereal grain to the product that is consumed.

3. Document every step in the *food preparation process* including:

    - Pre-milling procedures, such as cleaning, dehulling, fermenting, etc.,

    - Milling methods, such as hand pounding or mechanical (document the type of mill used: e.g. stone, disc, pin mill, hammer mill, etc.). Include duration of milling and type of equipment used for each stage of transformation,

    - Post-milling procedures (sieving, drying etc.),

    - Note quantities, frequencies and persons doing specific tasks,

    - Charges levied (based on volume or weight) and how they are paid (in-kind or cash),

    - Note details of the mill operating system including power source, drive mechanism, use of cyclone separators, direct feed-discharge or other mechanisms,

    - Note operator's activities during entire process.

4. Determine the *extraction rate* or *flour yield* of the milling process. For whole grain products this will range from 95% to 100%. *Ash content* is a good indicator of extraction rate.

5. Note the *storage* (duration, conditions) of raw materials and processed grain.

6. Study how the food is cooked and handled up until it is ready for consumption. Note quantities cooked and consumed per meal per person, the form in which the food is consumed and whether it served with specific condiments, such as soups, gravy, meat or vegetable dishes.

The above information will help in determining the properties, composition and dosage rate (amount to be added per unit weight of flour/meal) of the fortification *premix*, and at what stage in the process the premix should be added. It will also help in determining the best method for adding the premix and ensuring it is adequately blended into the flour.

The results and conclusions from this stage should help determine whether SSF has potential and is technically feasible. If so, consider running field trials at between 5 and 10 mills over 3 - 6 months guided by the above results. This activity is dealt with in detail in Chapter 7.

Program Objectives

The typical objectives of an SSF program are to:

- Fortify staple foods at the point where the target population produces them. That involves adding a micronutrient premix to maize meal or wheat flour at small local mills, in order to provide micronutrients to those who typically don't purchase and consume staple foods that are processed and fortified in large mills.

- Devise and test appropriate technology for micronutrient dosing involving addition and blending of fortificants into the meal produced in local hammer/disc mills.

- Assess feasibility of using specific premixes, dosing technology, quality assurance, monitoring, etc.

- Assess and advocate local acceptance of a SSF program.

- Determine long-term sustainability, including full recovery of the fortification cost, and indigenous production of preblend (diluted premix), dosing equipment and analytical lab facilities.

- Ensure that the national government recognizes the value of food fortification, and develops laws permitting fortification, as well as standards and regulations for enforcing these laws.

- Develop in-country capacity through training of monitoring/enforcement practices, and setting up laboratories to provide reliable analytical support.

- Provide incentives to local businesses to develop indigenous supplies of fortification preblends by permitting importation of ingredients and equipment, creating a demand for fortificants by making fortification mandatory, and ensuring that local production meets international standards such HACCP, GMPs, etc.

Section 4
FOODS AND MILLING PROCESSES IN SSF

Selection of a Staple Food for Fortification

In many cases the foods processed at small scale operations can be used as vehicles for fortification in the same way as centrally or large scale processed foods but certain criteria need to be met before small scale processed food is considered as a vehicle. These criteria include:

- The selected food is consumed by high proportion of at-risk population
- Regular consumption with known lower and upper intake levels
- Minimal variation in individual consumption patterns
- Minimal variation in regional consumption patterns
- Adequate serving size of staple food to allow for sufficient intake of added micronutrients
- Minimal potential for over consumption of staple foods
- No change in consumer acceptability of fortified food

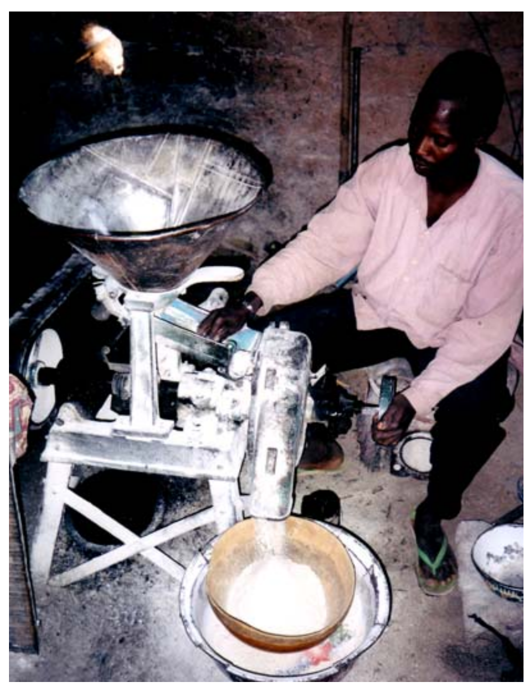
The processing and storage criteria are that there be:

- Simple, inexpensive technology for addition of micronutrients i.e. pre or post milling blending.
- Adequate stability and bioavailability of added micronutrients
- No interaction of micronutrients with the staple food
- Adequate storage conditions and stability of micronutrients during storage

Small Scale Milling

Table 1 Grains and staple foods

Raw Material	*Type*	*Staple Food*
Maize	Cereal	Porridge Bread
Wheat	Cereal	Bread
Millet	Cereal	Porridge
Sorghum	Cereal	Porridge
Rice	Cereal	Whole grain
Beans	Legume	Porridge, stew Porridge blend
Soy Bean	Legume	Oil/Paste Paste
Groundnuts	Nuts	Paste
Cassava	Root/Tuber	Paste
Manioc	Root/Tuber	
Yams	Root/Tuber	



Very small village maize mill in Niger

Table 1 identifies the typical raw material used to make staple foods that may be considered as vehicles for fortification. These are processed at the village level in small-scale mills and other processes. Not all of the raw materials may be suitable for use as vehicles for fortification at the small-scale level. This is due to the method of preparation and intermediate steps before the final food is consumed. For example, the preparation of the root tubers usually requires some form of wet processing such as soaking and wet grinding followed by drying and then cooking into a paste.

In general, grains and legumes that can be ground into flour before cooking lend themselves readily as vehicles for fortification. Table 2 illustrates the different types of grains and legumes that are processed into flours and meals, the preparation steps, the process and flour extraction, any post milling process and the typical quantity of grain that is brought into the mill for conversion into flour or meal, all steps that should be considered before selecting a staple food as a vehicle for small-scale fortification.

Table 2 Grains and processing steps

Staple Raw Material	*Preparation*	*Process/Extraction*	*Post milling Processing*	*Typical Quantity*
Maize	Dry clean	Hammer Mill 85% - 100% Stone Mill 100% Plate Mill 100%	Converted into porridge	2.5 – 20 kg
	De-germ, wet De-hull by hand pounding	Hammer Mill 100% Stone Mill 100% Plate Mill 100%	Dried in sun before cooking	2.5 – 5 kg
Wheat	Dry Clean	Hammer Mill 100% Stone Mill 100% Plate Mill 100% Roller Mill 85-100%	Converted into bread, chapattis	2.5 – 20 kg
Millet	Decortication Wet	Hammer Mill 100% Stone Mill 100% Plate Mill 100%	Sun Dried occasionally Converted into Porridge	2.5 –10 kg
Sorghum	Decortication Wet	Hammer Mill 100% Stone Mill 100% Plate Mill 100%	Sun Dried occasionally Converted into porridge	2.5 – 10 kg
Beans	Dry Clean	Hammer Mill 100% Stone Mill 100% Plate Mill 100%	Blended with other staples and cooked	2.5 – 5kg
Nuts	Dry clean	Plate mill 100%	Separated into paste and oil	4 - 8 kg

Notes:
Raw Materials: In some countries the raw materials may be blends of grains and legumes.

Preparation: As all the materials are raw agricultural commodities they are usually cleaned by hand to remove foreign material. In the case of maize, millet and sorghum a wet decortication process may be carried out prior to milling.

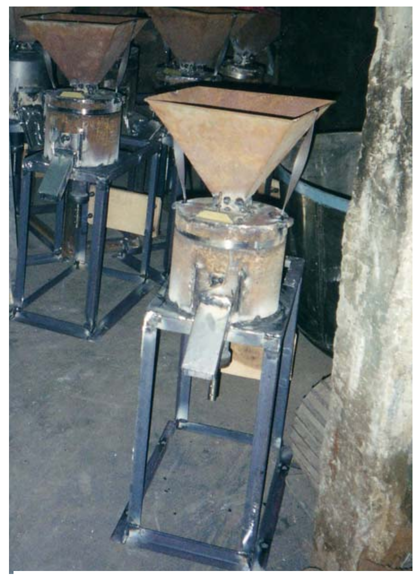
Process/Extraction: The process describes the type of mill used. Extraction is the amount of the grain that is collected as the flour or fine meal after milling.

Post Milling Processing: In some cases the milled grains may be damp and will be stored before processing into the final food. In this case the flour is dried in the sun.

Quantity: This is the typical range of the weight of grain brought to the village mill for processing. This amount may represent the food for several meals or for the meal the day of milling.

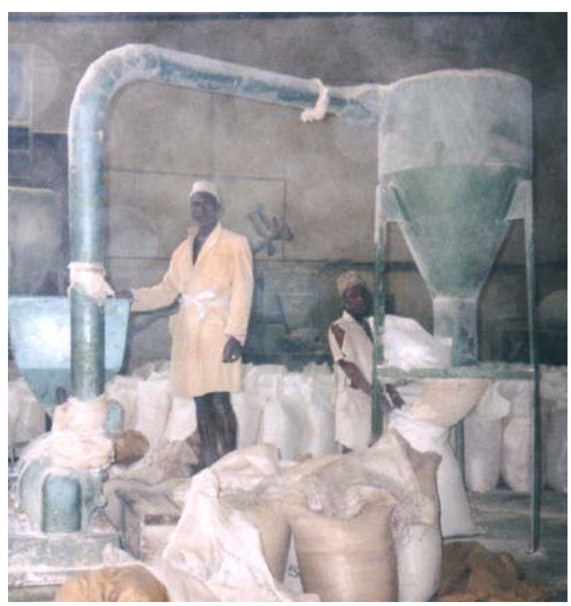
The information in this manual is limited to fortification of cereal staples that are processed into flour or meal at small-scale mills. Many of the processes and examples are from experiences with maize milling, though the information could be adopted for other cereals like wheat, sorghum and millets as the case may be.

Diesel driven stone mill for wheat in Tajikistan



Stone mills in Pakistan

Pin type “chakki” mill in Faisabad, Afghanistan



Malawi hammer mill

Section 4
SMALL SCALE FORTIFICATION TECHNOLOGIES

Technologically, SSF is neither sophisticated nor does it require large investment in equipment to dispense and blend in the premix. Fortification technology primarily concerns blending fortification premix or a diluted premix (called a *preblend* in this manual) into the flour. This can be achieved by any of the following methods:

- Simply mixing in a container with fingers or by hand shaking (practical for flour batches less than 5-6 kg),
- Continuous addition of premix with the grain (whole or dehulled) in the mill feed hopper, either by hand sprinkling or with a small mechanical feeder. This works best with whole grain or very high extraction flour, so that the premix is not removed with the bran.
- Continuous addition of premix to the flour during sifting.
- Batch mixing the premix and flour using a hand cranked or motorized blender.

Fortification Procedures in Small Mills

The stages of SSF (not including the grain preparation or flour/meal processing steps, which can vary from region to region, or from family to family) involve:

1. Obtaining a diluted premix (preblend) packaged in bulk or pre-weighed sachets.
2. Adding the appropriate amount of preblend to the grain while it is being milled, or

   Adding the preblend to the product meal in a blender, after the grain is milled.

Cereal flours can be fortified on a small scale by adding a diluted micronutrient preblend to the grain during milling or to the flour/meal after milling, using:

(a) A calibrated *scoop/spoon* to measure an amount proportional to the weight of grain, or

(b) A *sachet*, containing an amount appropriate for a pre-set weight of grain, or

(c) A *dosifier* that dispenses an amount proportional to the weight of grain. The dosifier may be attached to the mill and powered by the mill drive.

Fortification Premixes and Preblends
Vitamin/mineral mixtures used to fortify foods are made by large premix manufacturers that have the capability to secure the proper ingredients, mix them into a homogenous product in the correct proportions and to test for all the micronutrients in each batch of product. The premix is generally quite concentrated to increase shelf life and to save on shipping cost. Its normal addition rate is 100 to 400 grams per metric ton of product (equivalent to 0.1 to 0.4 g per kg).
Dilution of premix to a preblend is essential because the quantity of concentrated premix (1.5 to 6 grams) required to fortify a typical 15 kg batch of maize meal is too minute to measure out and achieve good distribution in SSF situations.
As an example, the dilution might involve adding one part concentrated premix to 19 parts maize meal or some other suitable diluent, and blending the mixture to ensure uniform distribution of preblend. This gives a preblend that would be added at 20 times the rate required for the premix. The resulting product now has the bulk that is necessary for ensuring good distribution of fortificants in the food. This dilution can be done by the mill or at a centralized location serving a number of mills. More information on fortification premixes is provided in Section 5 of this manual.

During milling, the scoop and sachet measuring methods could be used whether the grain is milled by hand- pounding or milled mechanically, whereas a mechanical dosifier could only be used in a mechanical milling process. The milling action can adequately blend the premix and the cereal flour/meal, but this should be tested out to make sure.

Dosifier feeding premix into bran separator of small wheat roller mill in Tajikistan

If a preblend is to be mixed into the meal after milling, it can be done using any one of:

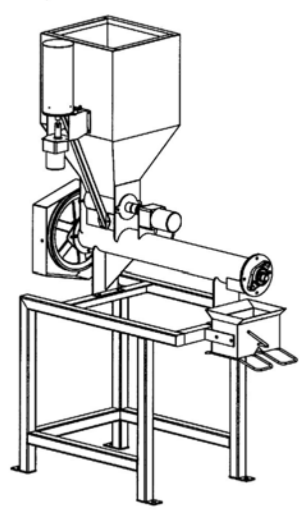
- A large spoon/paddle,
- A mechanical blender attached to the mill drive,
- A stand-alone mechanical blender operated by hand,
- A mixing pail.

Small, hand operated blender for fortifying maize meal in Tanzania

Where the milling operation permits, continuous ***direct addition*** of the premix during milling can be an option using one of the small dosifiers (feeders) available for this purpose. A combination dosifier and mixer, such as the *Snell vitamin doser* shown below, is another option.

But when it is necessary to blend the premix with the maize meal after the milling process is complete, batch type of blending may be necessary. The following two types of blenders were used in Zambia and Zimbabwe:

1) A hand operated blender (HOB) which has a helical ribbon on a shaft that is rotated with a handle for mixing, with an outlet to discharge product. A stainless steel HOB originally designed in India for salt iodization programs was used for SSF of maize meal in Zambia. A less expensive cast iron model of the HOB was designed in Zimbabwe.



Snell Africa 3 in 1 Vitamin Doser provides preblend metering, mixing and bagging in one device.

2) The second option is a rotating barrel with inside mixing flutes. The barrel could be rotated mechanically or by hand, rolling across the floor, to mix in the fortification premix. While this method seems rudimentary, it is effective for

small batches and has low labour costs. A 25 litre plastic pail called ODJOB, containing an integral baffle was identified to meet this purpose. The ODJOB is commonly used in North American homes for cement mixing by rolling the pail on the ground. For improving efficiency and human workload, the ODJOB can be mounted on a stand if desired.

Figure 2 diagrams the various points that the fortification preblend can be introduced into the milling process.

Oddjob mixer used to fortify maize meal in Zambia.

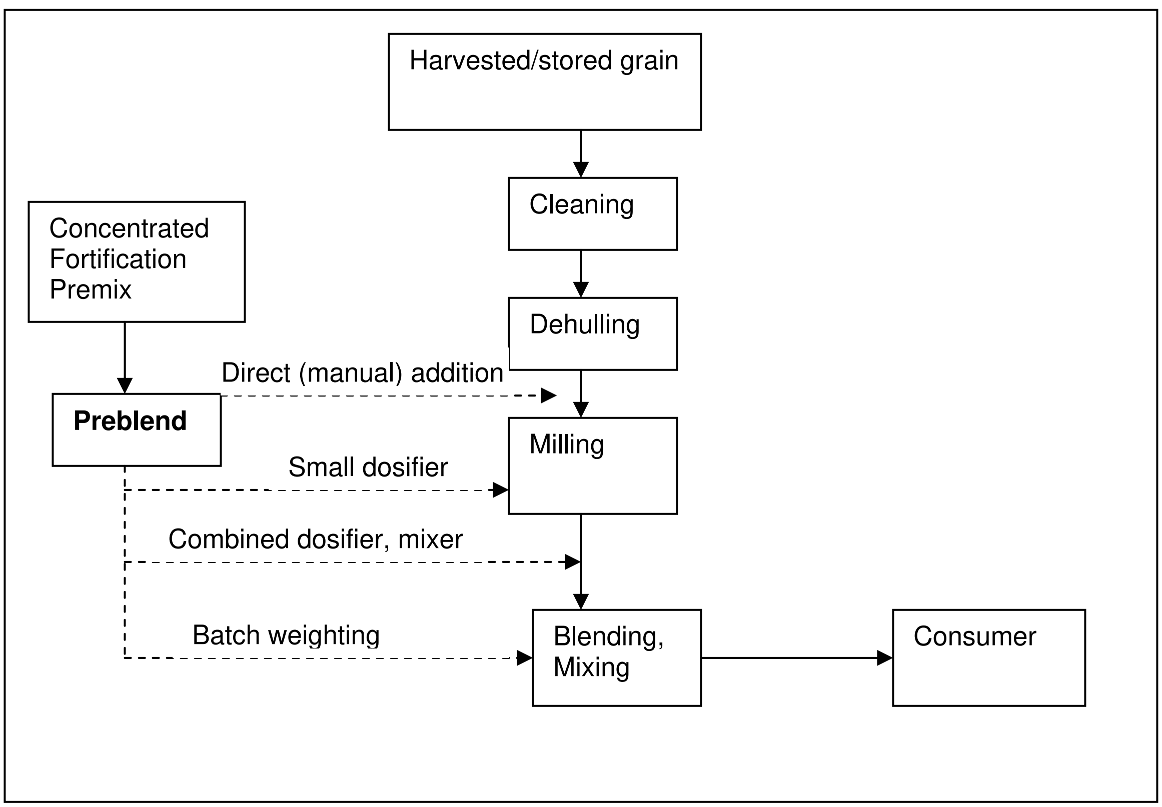


Figure 2. Small Scale Fortification Process Diagram

Large vs. Small Scale Fortification

To better understand SSF, it is useful to note the key differences and similarities of small versus large-scale milling and fortification, as shown in the following table. In addition to the two scales of milling shown here, there is an intermediate or medium scale of 5 to 50 tons per day capacity whose characteristics and fortification is similar to large-scale milling.

Table 3 Comparison of large vs. small scale fortification

Parameter	***Large scale***	***Small Scale***
1. Quantity (wheat or maize)	> 50 tons per day	< 5 tons per day
2. Process	Usually continuous	Batch
3. Investment in equipment	Can be high	Low or none
4. Process control	Yes; industrial level	None or minimal; artisan or cottage industry level
5. Cost per unit of fortified product	Minimal, built into price of flour	Can be significant percentage of milling cost; recovery by toll
6. Quality assurance	Consistent, established and manageable practices	Inconsistent, not well established; requires constant attention
7. Human resources	Minimal but skilled	Moderate but largely unskilled
8. Consumer acceptance	High, because it is invisible	Uncertain because of high visibility and repeated consumer buying decision
9. Premix supply, packaging	Not of concern	Of concern: distribution and availability can be uncertain
10. Sustainability	High probability	Uncertain, depends on too many factors
11. Premix cost, shelf life	Not significant	Can be significant issues
12. Regulatory compliance	Easier to enforce	Difficult to enforce
13. Risk of contamination	Can be low	Can be high
14. Training	Minimal	Can be high
15. Promotion, IEC resources	Minimal	Usually significant
16. Grain	Purchased by miller	Purchased or brought by customer
17. Product	May be segregated into fractions	May be sifted at mill or home; may be sun-dried afterwards

The following Table 4 shows the how fortification can be accomplished with the different types of milling equipment and designs currently in use.

Table 4 Different types of small-scale mills and SSF methods

Mill Type	***Power Source***	***Mill Equipment Configuration***	***Process type***	***Capacity***	***Fortification method Direct pre-mill***	***Fortification method Post-mill blender***
Rollermill Single/double pass	Electrical	Roller mills Sifters	Single or double pass, sifting	120-1,000kg Per hour	Not recommended due to sifting of by-products	Recommended
Hammermill-cyclone	Electrical Diesel	Metal hammers Screen Cyclone separator	Single pass with high air volumes	Up to 120 kg per hour	Recommended	Optional
Hammermill – no cyclone	Electrical Diesel	Metal hammers Screen	Single pass	Up to 120 kg per hour	Combined grain premix dosifier recommended	Recommended
Pin mill with cloth collection	Electrical Diesel	Metal pins Screen Cloth collection bag	Single pass with high air volumes	Up to 120 kg per hour	Recommended	Optional
Plate mill	Electrical Diesel	Metal plates in vertical configuration	Single pass	Up to 90 kg per hour	Combined grain premix dosifier recommended	Recommended
Stone Mill	Electrical Diesel	Stones in vertical configuration	Single pass	Up to 90 kg per hour	Combined grain premix dosifier recommended	Recommended
Stone Mill	Electrical Diesel Water	Stones in horizontal configuration	Single pass	Up to 90 kg per hour	Combined grain premix dosifier recommended	Recommended

<u>Definitions of terms used in Table 4</u>
Direct Addition: The premix is added either by weight or volumetric measure (cup) to a known volume or weight of grain before milling. Applicable to *cylone* type *hammermills* only.

Combined grain/premix dosifier: The premix and the grain is metered out simultaneously in a ratio that allows for uniform distribution of premix in the grain prior to milling. Applicable to all types of small scale mills.

Post Milling Blender: The premix is added by weight or volumetric measure to a known volume or weight of <u>milled grain</u> in a batch blender.

Effect of post milling drying

In some cases grains may need to be dried after milling if they are to be stored for any length of time. Moist maize meal is sometimes spread out on mats to dry in the sun. This will effectively destroy any added vitamin A, riboflavin (vitamin B2), folic acid and damage NaFeEDTA. Since these are critical nutrients, fortification prior to sun drying is not recommended.

Section 5
PREMIXES AND PREBLENDS

This chapter introduces the subject of micronutrient premixes and preblends for use in SSF of cereals and staple foods. This chapter will help implementers make informed decisions about the selection and use of micronutrient premixes in successful SSF programs. The following topics are covered:

- Types, composition and properties of premixes,
- How to determine premix composition,
- Premix use, packaging, dilution and dosages,
- Safety and handling issues,
- Procurement and sources,
- Costs.

Premix Types, Composition and Properties

A **fortification premix** is a mixture of micronutrients (vitamins and minerals) and an inert carrier, usually starch, maltodextrin or a mineral such as calcium carbonate or calcium sulphate. It may also contain a free-flow agent, such as silica or tricalcium phosphate, to prevent caking. Premixes are made by commercial companies, each batch of which has a certified analysis of micronutrient content. Fortification premixes are typically made concentrated to reduce shipping charges, but some diluted products are available. Concentrated premixes are not well suited for use in SSF.

The physical properties and consistency of the premix used should mirror that of the flour/meal to be fortified. Both must be powders of similar particle size distribution and colour in order to achieve effective distribution of the premix in the flour by blending.

A fortification premix:
- Allows for multiple micronutrient fortification of a staple food with both minerals and vitamins,
- Allows for accurate addition by using dilution of potent ingredients,
- Generally must be further diluted for smaller mills in SSF or for mills with low flour production rates,
- Has been used for wheat and maize flour fortification in large mills for over 50 years.

Most vitamin/mineral concentrates or fortification premixes have been designed for use in large scale milling with production rates over one metric tonne per hour. The typical addition rate, depending upon the number and type of vitamins and minerals contained, ranges from 100 grams to 300 grams per metric tonne of cereal flour. These vitamin mineral concentrates cannot be used for SSF, since the addition rate that would be needed for small quantities of grain or flour is too small to be accurately measured and homogeneously blended.

A **fortification preblend** is made by diluting a commercial premix with a suitable diluent, usually the cereal flour or meal being produced by the mill, but calcium sulfate or carbonate is also possible. This makes it more suitable for small-scale fortification. Preblends are typically produced nearby where they will be used so shipping is not a major consideration. They are also not tested for all the individual micronutrients, as are premixes.

Selection of Micronutrients

Following are the general criteria for the selection of micronutrients applicable for both large and small-scale fortification programs.

1. Prevalence and identification of micronutrient deficiency or deficiencies
2. Consumption patterns of target food or foods
3. Good bioavailability during normal shelf life of fortified food
4. No interaction with flavour or colour of finished food
5. Affordable cost to ensure long term sustainability
6. Acceptable colour, solubility and particle size
7. Commercial availability of food grade materials
8. No detrimental interaction of multiple micronutrients in premixes

Potential micronutrients for flours

The following micronutrients can be added to cereal flours in fortification projects:
Vitamins:

- Vitamin B_1 (Riboflavin)
- Vitamin B_2 (Thiamin)
- Vitamin B_3 (Niacin or Nicotinic Acid)
- Vitamin B_6 (Pyridoxine)
- Vitamin B_{12}
- Folic Acid
- Vitamin A
- Vitamin D

Minerals:

- Iron
- Calcium
- Magnesium
- Phosphorus
- Selenium
- Zinc
- Iodine

Most of the micronutrients in the list above are found naturally in cereal flours; the exceptions are vitamins A and D and vitamin B_{12}. While the extent of each deficiency is the main criteria in selection of which micronutrients to add, limiting factors are cost, the ability of the target population to pay for the added cost and the stability of the micronutrient in the premix and food.

Vitamin C

Vitamin C is difficult to use in general cereal flour fortification because it is expensive and is lost during cooking. There is a good advantage in having vitamin C present since it greatly enhances the absorption of iron. Vitamin C is being added to maize meal, such as corn soy blend (CSB) where the cooking losses are high but acceptable. The loss of vitamin C in bread baking, however, is nearly total. Coating forms of vitamin C are available that increase its stability during cooking.

Selection of iron form

The selection of the iron compound is important since it will have a direct bearing on the stability of the premix and potential interactions with other micronutrients in the premix, the stability of the fortified flour - particularly in tropical climates - and the bioavailability of the iron.

As shown in Table 2, most of the flour or meal produced in small-scale mills is of high extraction, meaning that it has high levels of phytic acid, which inhibits iron absorption. Because of this, the current recommendation is to add iron in the form of NaFeEDTA to such flours, since its absorption is not inhibited by phytic acid.

The use of fine particle size ferrous fumarate or dried ferrous sulfate could be considered for lower extraction flours providing they cause no problems with reduced shelf life, color, flavor or lowered consumer acceptance problems in the fortified product. If there are such problems the use of coated forms of these two iron salts should be investigated. This may be necessary since the high extraction flours produced in small scale milling will have high fat content which can undergo oxidative rancidity that ferrous sulfate can accelerate. Elemental iron powders do not cause this problem but are not recommended due to their low bioavailability, unless combined with one of the more bioavailable iron sources. In that case electrolytic iron is the recommended form of elemental iron powder. The granulation profile of the iron salts should be similar to that of milled cereal flour so that separation will not occur.

Table 5 Properties of iron sources

Iron Source	*Conc. (% Fe)*	*Cost ($/kg)*	*Cost ($/kg Fe)*	*Color*	*Magnetic*
Ferrous Sulfate	32	1.30	4.06	Tan	No
Coated Ferrous Sulfate	~16	3.00	18.75	Tan	No
Ferrous Fumarate	32	2.85	8.91	Red	No
Iron, Hydrogen Reduced	97	1.75	1.80	Black	Yes
Iron, Electrolytically Reduced	98	4.00	4.10	Black	Yes
Iron EDTA	13.5	6.30	46.67	Tan	No

Table 6 Micronutrient fortification levels and costs

Nutrient	*Chemical Compound*	*Levels Added*			*Cost***
		As nutrient ppm	*As compound gram/MT*	*As % of RDA per 100g*	*US$ per MT of fortified flour*
Iron*	Electrolytic Reduced Iron	50	51		0.16 –0.36
	Ferrous Sulfate	25	78		0.14
	Ferrous Fumarate	25	78		0.31
	Sodium Iron EDTA	15	111		0.96
Zinc	Zinc Oxide	15 – 25	19 - 31	15% - 25%	0.04 – 0.07
Calcium	Calcium Sulfate	1 – 2 g/kg	4400 – 8700	10% - 20%	0.57 – 1.14
	Calcium Carbonate		2500 – 5000		0.55 – 1.10
Selenium	Sodium Selenate	0.1 – 0.2	0.2 – 0.5	18% - 36%	0.01
Iodine	Calcium Iodate	0.2 – 0.4	0.3 – 0.7	13% - 27%	0.01
Folate	Folic acid	1.5 – 2.2	1.7 – 2.5	38% - 55%	0.06 – 0.08
Vitamin B1	Thiamin Mononitrate	2 – 5	2 – 5	17% - 42%	0.04 – 0.10
Vitamin B2	Riboflavin	2 – 4	2 – 4	15% - 31%	0.07 – 0.14
Niacin	Niacin (Nicotinic Acid)	20 – 50	20 – 50	13% - 33%	0.15 – 0.37
	Niacinamide				0.16 – 0.39
Vitamin B6	Pyridoxine Hydrochloride	3.2	3.8	25%	0.16
Vitamin B12	Cyanocobalamine, 1%	0.01	1.0	42%	0.17
Vitamin A	250SD Palmitate	5 – 10 IU/g		17% - 33%	0.78 – 1.54
Vitamin D	Vitamin D3, 100 SD	0.4 IU/g		20%	0.08

* Iron levels added adjusted for bioavailability.
** Cost estimate does not include shipping or duties. These costs are as of 2004 and can vary greatly with time.

Types and levels of micronutrients added in small-scale fortification

Table 6 lists the different types and sources of micronutrients that could be added to flour or maize meal in SSF. The addition levels shown are those in actual use with low extraction (white) flour around the world. Table 6 also gives a cost estimate for adding each of the micronutrients. This cost does not include the added cost of having to dilute the premix into a preblend or any costs associated with the testing, transport and handling of a preblend.

Micronutrient interactions

Some micronutrients may adversely react with each other in multiple fortificant premixes and in the fortified food. For example, ferrous sulfate can interact with vitamin A reducing its potency. Using coated forms of the problem micronutrient can reduce such interactions.

Examples of Fortification Premixes

There are many different premixes used to fortify wheat flour and maize meal around the world[1]. Following are some that may have application with SSF because of where they are used and that they are readily available. Note that the premix composition is different from the fortification standards for some of the micronutrients because of the contribution from the natural content of the flour or maize meal.

[1] See the Micronutrient Initiative Fortification Handbook for a complete listing.

Table 7 South African fortification standards and premix composition

7A. Fortified food vehicle standards for RSA

Fortificant	Unit	Wheat foodstuffs	Maize foodstuffs	Unsifted maize meal
Vitamin A	IU/kg	5400.00	6400.00	6400.00
Thiamin	Mg/kg	3.60	3.85	3.85
Riboflavin	Mg/kg	2.00	1.85	1.85
Niacin	Mg/kg	31.00	28.50	28.50
Folic acid	Mg/kg	1.50	1.50	1.50
Pyridoxine	Mg/kg	3.20	3.20	3.20
Iron	Mg/kg	43.00	37.00	14.00
Zinc	Mg/kg	20.00	18.50	18.50

(b)The following micronutrient mix composition shall be used:

7B. Fortification micronutrient mix specification for RSA

Fortificants	Wheaten flour (g/kg)	Maize meal (g/kg)	Unsifted Maize meal (g/kg)
Vitamin A Palmitate, 250 000 IU/g	119.04 g	138.88 g	138.88 g
Thiamin Mononitrate	12.34 g	13.93 g	13.93 g
Riboflavin	8.90 g	8.50 g	8.50 g
Nicotinamide	118.40 g	125.00 g	125.00 g
Folic acid	7.15 g	7.15 g	7.15 g
Pyridoxine HCL	16.24 g	19.32 g	19.32 g
Electrolytic iron	178.57 g	178.57 g	89.28 g
Zinc oxide (min. 80% activity)	93.40 g	93.40 g	93.40 g
Calcium carbonate (min. 40% activity), As carrier	To complete 1000 g	To complete 1000 g	To complete 1000 g

The dosage of 200g of micronutrient mix per ton of wheat or maize foodstuffs is necessary to cover the minimum fortification levels.

(c)The quality standard for fortificants, independently or mixed with a diluent shall be the Food Grade Standard in accordance with the standards as determined in the latest edition of Food Chemicals Codex (FCC).

(d)The fortification standards referred to in paragraph (c) shall be the minimum levels in the dry wheat flour, dry maize meal when analyzed at the point of manufacturing or importation and include the micronutrient levels naturally present.

The above are actual South African regulations[2] for wheat flour and maize meal fortification. These premixes are now readily available throughout Southern African. They are currently intended to be used in both large and small-scale mills.

Table 8 Zimbabwe maize meal premix

Micronutrient	***Level Added*** *mg per 100 g maize meal*	***Dosage*** *per 200gm of dry product*
Vitamin A	123 RE	246 RE
Vitamin B1	0.39mg	0.78mg
Vitamin B2	0.26mg	0.52mg
Vitamin B6	0.39mg	0.77mg
Vitamin B12	0.22µg	0.44µg
Nicotinamide	2.93mg	5.85mg
Folic Acid	0.055mg	0.11mg
Iron (Fe)	4.3mg	8.5mg
Zinc (Zn)	6.62mg	13.246mg

Table 9 Zambia maize fortification

Fortificant	***Level of addition per kilogram maize meal including overage***	***Level per 250 grams maize meal***	***% overage* (Approx)***
Vitamin A	1680 IU	420 IU	40
Vitamin B1	2.4mg	0.6mg	40
Vitamin B2	2.0mg	0.5mg	20
Vitamin B6	2.4mg	0.6mg	20
Nicotinamide	22.4mg	5.6mg	20
Folic Acid	0.4mg	0.1mg	50
Iron (Fe)	12.0mg	3.0mg	10
Zinc (Zn)	12.0mg	3.0mg	10

*Overage for vitamins to compensate for processing and cooking losses.

[2] http://www.doh.gov.za/docs/regulations/foodstuff/fortification.html

Determining Premix Composition

Determining level of micronutrient deficiency

The main determining factor for the development of a premix will be the level of any micronutrient deficiency found in the national or regional population. The following tools can be used to determine the level of micronutrient deficiency and therefore the composition of premixes for use in fortification:

- National Nutrition Surveys carried out by the Ministry of Health
- National Health Surveys carried out by Ministry of Health
- Target population surveys carried out by international agencies such as UNICEF, World Health Organization, World Food Program
- Surveys conducted by International and National Non-government Organizations (NGOs or PVOs)
- Surveys sponsored by bilateral aid agencies such as CIDA, USAID, DIFD, KIT, GMZ, etc.

These surveys can also be used as baseline surveys before any fortification program is implemented.

In the absence of any national survey it may be necessary to carry out a baseline survey. A "*cluster" survey* is a cost-effective technique that will provide sufficient information to establish both the level of deficiency and subsequently the composition of a premix.

Surveys should provide the following information in order to determine premix composition.

1. Staple food types
2. Frequency of consumption
3. Consumption quantity per day
4. Adult consumption patterns
5. Children consumption patterns
6. Other foods consumed
7. Foods considered as micronutrient inhibitors
8. Clinical data on nutritional health
9. Prevalence of diseases due to micronutrient malnutrition

Determining level of fortification

There is no universal specification for the level of fortification of the chosen staple food vehicle. Numerous factors influence the recommended fortification level. The practical amounts used will depend upon the following three factors:

1. The recommendations by appropriate health and nutrition expert organizations based on sound nutrition surveys,

2. Organoleptic effects that may adversely affect consumer acceptance, and;

3. The ability of the consumer and the nation to pay for the added cost of the fortification process.

The main factors used to determine the fortification levels are:

- Recommended Daily Intake (RDI)
- Estimated Average Requirement EAR (based on RDI)
- Prevalence of the micronutrient deficiency
- Per capita consumption of the food vehicle
- Extent of processing, transit, storage, and food preparation losses
- Current dietary habits of the population with regard to food selection and preparation, and
- Other dietary foods affecting absorption and bioavailability of the added micronutrients.

Vitamin A

The following tables can be used in the determination of Vitamin A levels to be added to the staple food for the target population. Table 11 shows the serum retinol deficiencies in various African countries compared to the WHO cut off level of 20% - the level above which the WHO deems a nation or region to be suffering from Vitamin A deficiency.

Table 10 Vitamin A requirements

	Vitamin A requirements	
	µg retinol/day	*IU/day*
Infants	350	1155
Children 1 to 6 years	400	1320
Adults (US RDA)	1000	3333
Adults (WHO safe level)	600	2000

Table 11 Incidence of vitamin A deficiency in African countries

Using WHO Population Cut-Off % < 20 µg/dL retinol

Nation	***% Population <20 µg/dL retinol***
Botswana	33
Madagascar	73
Namibia	20
South Africa	30
Tanzania	49
Zambia	66
Zimbabwe	35
WHO Cut-Off	20

Iron requirements

The RDI of iron varies by age and physiological group and will depend on the iron bioavailability in the diet. Women of childbearing age and teenage girls require a higher iron intake of 40-48 mg per day for low (5%) bioavailable diets. Young children, aged 1-6 years old, require the lowest 12-14 mg per day. Pregnant and lactating women have much higher iron requirement, which cannot be met through fortification of the staple food. In this case the use of supplements will be required.

In countries where SSF is being considered the diet tends to be one that is plant based and therefore the iron availability will be low 5%.

Table 12 Recommended Daily Intake (RDI) for iron

Iron Availability in diet:	***RDI - mg Fe/day***	
	Low 5%	***Medium 10%***
Adults		
Men >16 years	23	11
Women childbearing age	48	24
Children		
1-6 years	12-14	6-7
6-12 years	23	12
Girls 12-16	40	20
Boys 12-16	36	18

Adapted from FAO/WHO. *Vitamin and mineral requirements in human nutrition*. (in press) Geneva, World Health Organization, 2004.

Specifying premixes and premix ingredients

Premix ingredients and premixes should meet the following criteria:

- All components must be food grade materials fit for human consumption. This is usually indicated by meeting the specifications of the Food Chemicals Codex (FCC).[3] *Vitamins and minerals marketed for animal consumption in feedstuffs must not be used for human consumption.*

- In the case of minerals, especially iron, the fine particle size is a critical specification to ensure that adequate bioavailability is achieved. In addition heavy metal (contaminants) specifications are important to be adhered to. Elemental reduced iron powders should be no larger than 325 mesh (44 microns).

- Premix ingredients must also meet any national standards that are published by national governments where staple food fortification is proposed.

Food Consumption Data

The levels of micronutrients to add to a particular food staple are highly dependent on how much of that food is consumed by the target populations. Good consumption data is necessary not only to make sure that the fortification is effective in getting adequate amounts of deficit vitamins and minerals to the people who need them, but also to make sure that people will not be consuming

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[3] FCC is published under Codex Alimentarius. If no FCC standards exist for a particular componet, the United States Pharmacopeia (USP) published by the US Food and Drug Adminstration, or British Pharmacopeia (BP) published by the British Government can be used. These international standards will provide specifications for chemical, microbiological and physical purity, particle size and potency.

excessive or potentially dangerous amounts. Getting meaningful consumption data is one of the more difficult tasks in designing a safe and effective fortification program.

The FAOSTAT Nutrition Data[4] provides estimates on national consumption levels of different basic foods by country. Country milling associations, ministries of supply and some commercial companies may have more specific data on the different types of wheat flour or maize meal. While this or similar data is helpful it must be used with caution. It does not normally differentiate on the age, sex or geographic location of the consumer. Also, with SSF only a portion of the flour can be realistically fortified.

Food conversion factors

When determining additional levels for micronutrients it may be necessary to take into consideration the conversion of the staple food into the final food form. The following lists the different types of foods and some conversion rates.

Wheat

Convert wheat in metric tonnes by *extraction rate* from wheat to flour. In the case of SSF the conversion from wheat to flour is 95-100% unless the consumer sifts the flour at home before it is used. This is common practice in India and Pakistan

Bread
- Flat bread: contains 80% flour
- White bread: contains 64% flour
- Brown bread: contains 68% flour

Maize porridge (pap, mealy-meal, ugali)
- Maize porridge: contains 33%-50% maize meal

Cooking and food preparation losses

In addition to taking into account the conversion rate of food into the final form it is important to recognize that cooking methods will have an influence on the levels of added micronutrients. Normally there will be cooking losses of micronutrients particularly the added vitamins. Cooking losses can range from 10-25% or the original amount added to the staple flour.

Regional Premixes and Shared Fortification Standards

In some parts of the world the problem of micronutrient malnutrition is common to various nations within a region. For example, in Sub-Saharan Africa many nations have well documented instances of vitamin A and iron deficiency in all segments of the population and the consumption of maize is widespread. Under such circumstance the development and use of a regional premix is considered to be beneficial because it will address the problem on a regional level. As an example, six countries in Central Asia have the same wheat flour fortification standards and use the same premix, called KAP Komplex #1.

[4] http://faostat.fao.org/faostat/collections?subset=nutrition

<u>Advantages of a regional premix:</u>

- Economies of scale for purchasing premix concentrate or ingredients from suppliers thus reducing costs
- Ability to trade premix between countries.
- Common QA and QC procedures can be adopted.
- Common regulations and standards within the region.
- Can be established within existing political/economic organizations, i.e. SARC and SADRC in Africa.

<u>Disadvantages of a regional premix:</u>

- Not all countries have the same deficiency levels, which may lead to either over fortification or under fortification.
- Not all countries may have the same consumption patterns of the staple food.
- Other foods may be consumed.
- Post milling and fortification processing may be used which reduces the bioavailability of the added micronutrients.

Fortification Premixes and Preblends

Fortification premixes and preblends are designed to be used at mills. They are generally not designed to be used at the household level. Premixes are supplied in concentrate form to a central or regional location and then diluted to a preblend as needed.

Premix concentrate packaging

The following conditions are required for the packaging and handling of premix concentrates:

1. Packaged in sealed polyethylene bags in corrugated cardboard, fiber cartons or metal containers.
2. Properly labeled with name of premix, product code, ingredient statement, production lot number, country of origin, date of manufacture or expiration date, and manufacturer's contact information. It is recommended that the label be in both English and the primary language used by the customer.
3. Usage instructions including recommended addition rate with a warning statement that contents must be added to food at the indicated rate before consumption.
4. Storage and handling instructions.

Premix dilution and preblend dosing levels

Premix supplied in concentrate form needs to be diluted before use at the community mill level. The final dilution level should be determined based on the types of mills and proposed fortification methods to be used, i.e. manual direct addition, combined grain/premix dosifier, or post-milling blending system.

The preblend dosing level depends on the following factors:

1. Proposed method of addition to the staple food
2. Proposed number and quantity of vitamins and minerals to be added

3. Range of weight of staple food brought to the mill for processing

The following table shows how premixes can be diluted to preblends for different methods of small-scale fortification.

Table 13a Recommended preblend preparation for different fortification methods

Fortification Method:	*Manual Direct Addition*	*Combined grain/premix dosifier*	*Post mill blending*
Weight of carrier (wheat or maize flour)	18.0 kg	19.5 kg	19.0 kg
Weight of premix concentrate	2.0 kg	0.5 kg	1.0 kg
Factor to multiply premix add rate to get preblend add rate	10	50	20
Typical grain lot size range	5 – 20 kg	5 – 10 kg	15 – 20 kg
Preblend addition range per grain lot size for 200 g/ton premix dilution	50–200 grams	10–20 grams	60 – 80 grams

The following table illustrates the steps in the preparation of 20 kg batch of preblend from a micronutrient concentrate (dosage 200 grams per MT) for the different dilutions shown in the table above.

Table 13b Examples of preblend preparation[5]

Step	***Activity***	***Example***
1	Determine concentrate addition rate	200 grams added to 1 Metric Ton or 0.20 grams per kg
2	Determine fortification method i.e Manual Direct Addition Combined grain/premix dosifier Post mill blending	Recommended dilution of concentrate i.e. 1 part concentrate to xx parts carrier 1:50 1:10 1:20
3	Manual Direct Addition	0.2 grams concentrate multiplied by Dilution factor (1:50) i.e. 10 grams to be added to each 1 kg of cereal grain
4	Combined grain/premix dosifier	0.2 grams concentrate multiplied by Dilution factor (1:10) i.e. 2 grams to be added to each 1 kg of cereal grain
5	Post mill blending	0.2 grams concentrate multiplied by Dilution factor (1:20) i.e. 4 grams to be added to each 1 kg of cereal grain

[5] The recommended dilution rates used as examples have been based on the following SSF project trials: Manual Direct Addition: Blending trials, MICAH, World Vision Canada, Malawi, January 2004, Combined grain/premix dosifier: Nepal combined dosifier, MI Nepal, March 2004 Post mill blending: Care and Oxfam, Zimbabwe 1999-2002.

The following table gives some of the preblend dosing levels used in various SSF projects underway in Africa:

Table 14 Examples of preblend addition rates used in different countries

Country	***Preblend Weight grams***	***Food Weight kg***	***Dilution Rate (from concentrate***
Malawi	150	5 kg	1:200
Tanzania	10	1 kg	1:66.7
Zimbabwe	50	17 kg tin	1:16.7

Sources: World Vision, Care, Oxfam, Care

Preblend manufacturing requirements

Following are the requirements in the preparation of fortification preblends:

(a) Buildings
The building used must be well maintained and clean and suitable for food handling. Roof, floors, walls, doors and windows must be in good working order and in good repair. Washrooms and change rooms for staff are required. A pest control programme should be in place.

(b) Equipment
The equipment must be in good condition, preferably made from steel or plastic of rugged construction that will meet food plant standards. Equipment required for preparing preblend includes:.

- Blender/mixer
- Large weigh scale to measure carrier ingredient such as maize meal
- Small accurate weigh scale to measure micronutrient ingredients
- Packaging equipment for small packages if sachet system is to be used
- Packaging weigh scale
- Box sealers
- Labelers, if no labels are supplied

(c) Supplies needed

- Carrier or diluents such as maize meal, maize flour or starch
- Premix concentrate
- Packaging bags and boxes
- Labels
- Date stamp for production date
- Pallets to keep all ingredients and finished products off the floor
- Timer or clock to record blending times
- Scoops
- Production record book
- Laboratory coats or protective coats
- Disposable gloves and dust masks

Preblend packaging

Proper packaging of premixes, preblends and fortified foods is essential to minimize losses of added micronutrient potency and to prevent spoilage.
Suitable packages for premixes are:

- Multiwall paper bags for any sizes from 1kg to 40kg
- Woven polypropylene bags for any sizes from 20kg to 50 kg
- Small Polyethylene bags for premix sachets
- Corrugated cardboard boxes for sachets and 1 kg paper bags

Preblend labeling

The diluted premix or preblend should be labeled with:

- Name of product,
- Purpose of product,
- Addition rate,
- Date made or expiration date
- Warning statement that product is not to be consumed directly as food.

This should be in the primary language of the people using the product. Warning statements advertising that the premix must not be consumed without adding it to the flour maize meal are essential.

Distribution

Fortification premixes and preblend and fortified foods should be distributed in the same way as any perishable foodstuff with particular attention to:

- Stock rotation by first in first out (FIFO) system
- Protection from direct exposure to moisture, heat and sunlight. Note that vitamin A, iron-EDTA, folic acid and riboflavin are particularly sensitive to light and their potency will deteriorate very rapidly if the premix is stored in sunlight
- Proper stock control recording inventory in record books that can be audited
- Protection from pest damage by proper storage conditions

At the community mill the premix or preblend must be held under lock and key in a suitable location such as a cupboard or separate room. Access must be limited to the miller and any monitor assigned to that mill.

Dosing methods

The preblend may be added to the milled flours and meals in the following ways:

- By weighing the premix amount for a specific weight of grain
- Using a sachet containing a preweighed amount of premix
- Using a volumetric measure such as a measuring cup or measuring spoon.

See Section 4 for more information on this topic.

Shelf life

Like any food, premixes in concentrated or diluted form have a limited shelf life. The shelf life of a premix is predicated upon the storage conditions. Minerals are quite stable, but vitamins, which are biochemical products, have limited shelf life. Vitamin A and vitamin C are far less stable than niacin and the B vitamins. *A preblend (a dilution of a premix with maize meal or wheat flour) has a much shorter shelf life than the starting premix.* Assuming that the storage conditions listed above in the section on distribution have been maintained then the following table lists the expected shelf life.

Table 15 Expected shelf life of fortification premixes and preblends

Premix form	***Expected maximum shelf life***
Premix concentrate without vitamin A	36 months*
Premix concentrate with vitamin A	12 months*
Dilute premix (preblend) without vitamin A or ferrous sulfate	3 months
Dilute premix (preblend) with vitamin A or ferrous sulfate	1 month

*The premix or micronutrient supplier should be contacted to confirm the shelf life of their products.

Note: These are guidelines only and actual conditions of temperature, light and humidity must be taken into consideration as well.

The usual problem of shelf life for vitamins is that they lose their potency. If a concentrate or vitamin is close to its "use by date" the supplier should be contacted. The supplier can test a sample of the premix to see if it still meets specifications. Increasing the addition rate of expired premixes is not a recommended action.

Changes in formulation or premix usage rates can only be made following consultation with the supplier. Production records should note when the change was made AND the original formulation must be adopted to the application once a new supply has been received.

Sources of fortification premixes

The following is a list of premix suppliers and micronutrient suppliers[6] that are known to supply various countries and international organizations with premixes and ingredients for existing fortification programmes around the world.

1. ADM Arkady, 100 Paniplus Roadway, OLATHE. KS 66061 USA
TEL +1 913 782-8800 FAX +1 913 782-1598
2. American Ingredients Company, 3947 Broadway, KANSAS CITY MO. 64111 USA
TEL +1 816 561-9050 FAX +1 816 561-0422
3. BASF, 3000 Continental Drive North, MOUNT OLIVE, NJ 07828-1234 USA

[6] This is not a complete list. The authors do not endorse any supplier over another.

TEL +1 973 426-5316 FAX +1 973 426-5399
4. Daminco Inc. 2770 Portland Drive, OAKVILLE ONTARIO L6H 6R4 CANADA
TEL +1 905 829-2414 FAX +1 905 829-8097
5. Fortitech Inc., Riverside Technology Park, 2105 Technology Drive, SCHENECTADY, NY 12308 USA TEL +1 518 372-5155 FAX +1 518 372-5599
6. Hexagon Chemoils Pvt. Ltd., 229 Oshiwara Indl. Centre, Opp.. Bus Depot, Link Rd., Goregaon (W), MUMBAI – 400 104 INDIA TEL +91 22 877 8529 FAX +91 22 873 9404
7. IHFA Ltd, Tanzania Project, PO Box 11740 ARUSHA TANZANIA
TEL +255 27 250 9649 FAX +255 27 250 9648
8. Makonde Industries Pvt. Ltd., Martin Dr./Citroen Rd., Msasa, P.O.Box 1229, HARARE, ZIMBABWE TEL +263 4 487 285 FAX +263 4 487 371
9. Research Flour Service Products Company, P.O. Box 1460, SALINA KS 67402-1460 USA
TEL +1 913 825-2181 FAX +1 913 825-8908
10. DSM Nutritionals Inc., 45 Eisenhower Drive, PARAMUS, NJ 07652 USA
TEL +1 201 909-5578 FAX +1 201 909-8414
11. Watson Foods Company Inc. 301 Heffernan Drive, WEST HAVEN CT 06516 USA
TEL +1 203 932-3000 FAX +1 203 932-8266

Examples of costs of premix concentrates

The following table lists the typical cost of premix concentrates and the micronutrients included in the premixes. These concentrates are designed for use in large-scale mills and the addition rates shown are designed for that use only. *In small scale fortification these premix concentrates must be diluted prior to use, which will significantly add to the cost.*

Table 16 Examples of cost of concentrated fortification premixes

Premix	***Components***	***Cost per kg $***	***Addition rate Grams per MT***	***Cost in $ per MT of fortified food***
Iron	Iron, carrier	$1.00	100	0.10
Iron, Folic Acid (WHO-EMRO)	Iron, Folic Acid, carrier	$2.25	200	0.45
Vitamin B1, B2, B3 Folic Acid Iron (N.America premix)	Vitamin B1, B2, B3 Folic Acid Iron, carrier	$9.38	160	1.50
Vitamin A, B1, B2, B3, B6, Iron Zinc (IS254 for Malawi)	Vitamin A, B1, B2, B3, B6, Iron, Zinc	$17.50	150	2.63

Note: The number of micronutrients in the premix, and the concentration of the micronutrients will predicate the FOB cost of the concentrate. These costs are guidelines only and based on FOB production plant. *For any proposed fortification programme current costs must be obtained from the supplier. Quotations should be obtained from at least 2 different suppliers.*

Dilution and distribution costs

In any small scale fortification programme the vitamin mineral concentrate must be diluted so that the micronutrients can be added in a consistent and safe manner. In order to establish a final cost of the diluted premix the cost of all the components used in the dilution process must be taken into consideration. See Table 6 for cost estimates of individual micronutrients.

The following components need to be considered

1. Fortification premix concentrate cost
2. Carrier cost
3. Packaging material cost
4. Label costs
5. Labour costs to blend and package dilute premix
6. Analytical testing costs
7. Overhead costs including allocation of plant and equipment costs, management costs and QA/QC costs
8. Profit margins
9. Distribution costs

Distribution costs

In many regions of the world the cost of distribution of any product or foodstuff can be very significant and can even be greater than the cost of the preblend. Under such circumstances it may be more economical to have regional centres for the preparation and distribution of dilute preblend..

Safety Considerations

As long as a food fortification programme is properly designed and implemented and the levels of micronutrients to be added are carefully evaluated and controlled there will be no reason to be concerned about possible toxic effects of the vitamins and minerals. Research and long experience has shown that the benefits of fortification far outweigh any potential toxicity problems.

The following factors should be considered when determining whether fortified foods are safe to use for a particular person:

- The number of doses and the time interval between them
- The health status of the person, i.e. age, pregnancy, and vitamin and mineral status
- Interference by food or food components and drugs
- The mode of administration

Table 17 Safety Index of micronutrients

Micronutrient	***RDI***	***Minimum Toxic Dose (MTD)***	***Safety Index MTD/RDI***
Iodine	0.15	2 mg	13
Iron	18 mg	100 mg	5.5
Vitamin A	5,000 IU	10,000-12,000 IU	2-2.4

Sources: Bailey, Clydesdale, Hathcock, NAS

All micronutrients are considered to be safe provided the RDI is not exceeded. The above table illustrates the safety indices for vitamin A, iodine and iron, the only micronutrients for which there may be any safety concern.

The main safety concerns with fortification premixes and preblends are that they not be consumed directly and that they not be added at excessive rates. These can be prevented with proper training, quality control and labeling. *Training will play a key role in the proper handling of premixes and their preparation.* If riboflavin (vitamin B2) is included, as it usually is, food that has been accidentally overfortified to possibly cause harm if used on a continuous basis, will be noticeably yellow in color. This warns the consumer that something is wrong and that the food should probably not be eaten.

Volumetric measurement of a preblend being added to maize meal in an oddjob blender in Zambia

Section 6
COMPLEMENTARY FOOD FORTIFICATION

In many countries of Sub-Saharan Africa and South and South-East Asia infant foods (known as complementary or weaning foods) have been traditionally prepared on a village based or small-scale level. These foods can be made from locally grown or indigenous crops and often include legumes or pulses to provide protein. The food is made into a flour or meal that is then cooked with boiling water to make a porridge or paste. The manufacturing process of these foods readily lends itself to including added micronutrients to make a fortified infant food. Examples of such foods are *Indiamix* and *Likuni Phala.*

Fortified complementary foods, sometimes referred to as *blended foods*, are also provided as food aid to many countries. This includes products such as Corn Soy Blend (CSB) and Wheat Soy Blend (WSB) distributed under the U.S. Food for Peace Program. The target groups for complementary foods are infants, young children, pregnant and lactating women, and HIV/AIDS patients. These foods should never be used to replace breast feeding. They are often designed to be slightly granular after cooking so they cannot be fed as a liquid through a rubber nipple on a baby bottle.

As a result of development assistance from various international aid agencies such as Royal Tropical Institute, Netherlands (KIT) in the 1990s, several countries received assistance to construct small-scale labour intensive production units to manufacture fortified complementary foods. Examples of these include Likuni Phala units in Malawi, MISOLA units in Mali, Senegal and Burkina Faso, and complementary food production units in Nepal and Bangladesh.

Composition

The following table shows the typical ingredients that can be used in the production of complementary foods.

Table 18 Ingredients used in complementary foods

Staple	Percentage
Cereals - Maize, Millet, Rice, Sorghum	70-80%
Pulses - Chickpea, Cowbean, Lentils, Mungbean	10-15%
Oilseeds - Groundnut, Soya bean, Sesame seed	10-15%
Sugar	0 - 5%
Salt	0.5 – 1%
Vitamins and Minerals	0.5 – 1%

One attraction of this type of food is that it can be locally produced from natively grown ingredients. It can use local labour providing employment in the rural and peri-urban areas. The resultant complementary food is an improved nutritional formula compared to any of the single ingredients.

Fortification

The total level of vitamins and minerals that can be added will be based on the nutritional requirements of the target group. Fortification of complementary foods is generally more extensive than fortified cereal staples, as shown by the following products, since it often has to supply all or most of the nutrients required in the diet. Premixes to meet these fortification levels are readily available. Ferrous fumarate is the standard iron source used in complementary foods.

Table 19 Examples of fortification of complementary foods

Micronutrient	*units*	*USAID CSB/WSB*	*WFP CSB & Likuni Phala*	*Indianmix*
Calcium	ppm	7750	1000	1908
Calcium d Pantothenate	ppm	26.6	--	--
Folic acid	ppm	2.0	0.6	1.025
Iodine	ppm	0.57	--	--
Iron	ppm	147	80	146
Magnesium	ppm	825	--	--
Niacin	ppm	49.6	48	100
Pyridoxine (vitamin B6)	ppm	1.7	--	--
Riboflavin (vitamin B2)	ppm	3.9	4.5	6.0
Thiamin (vitamin B1)	ppm	2.8	1.3	6.0
Vitamin A	IU/kg	23,150	16,640	14,540 mg*
Vitamin B12	ppB	13	12	10
Vitamin C	ppm	401	480	300
Vitamin D	IU/kg	1980	1000 I	--
Zinc	ppm	39.8	50	112

* from beta-carotene

Small-Scale Processing

Cleaning

Cereals and pulses are cleaned using a mechanical winnower/separator and/or by hand. In some cases the cereals and pulses may need to be cleaned by washing and drying. Groundnuts are cleaned and selected manually and may need to be dipped in boiling salted water to remove mould infested groundnuts which are discoloured by this type of treatment.

Roasting

The prepared staples are then roasted in a scorcher, electric oven or a rotating drum above a heat source. The foods are then cooled. Pulses, such as soybean, need to be soaked and steamed using a special process to inactivate trypsine inhibitors.

Blending

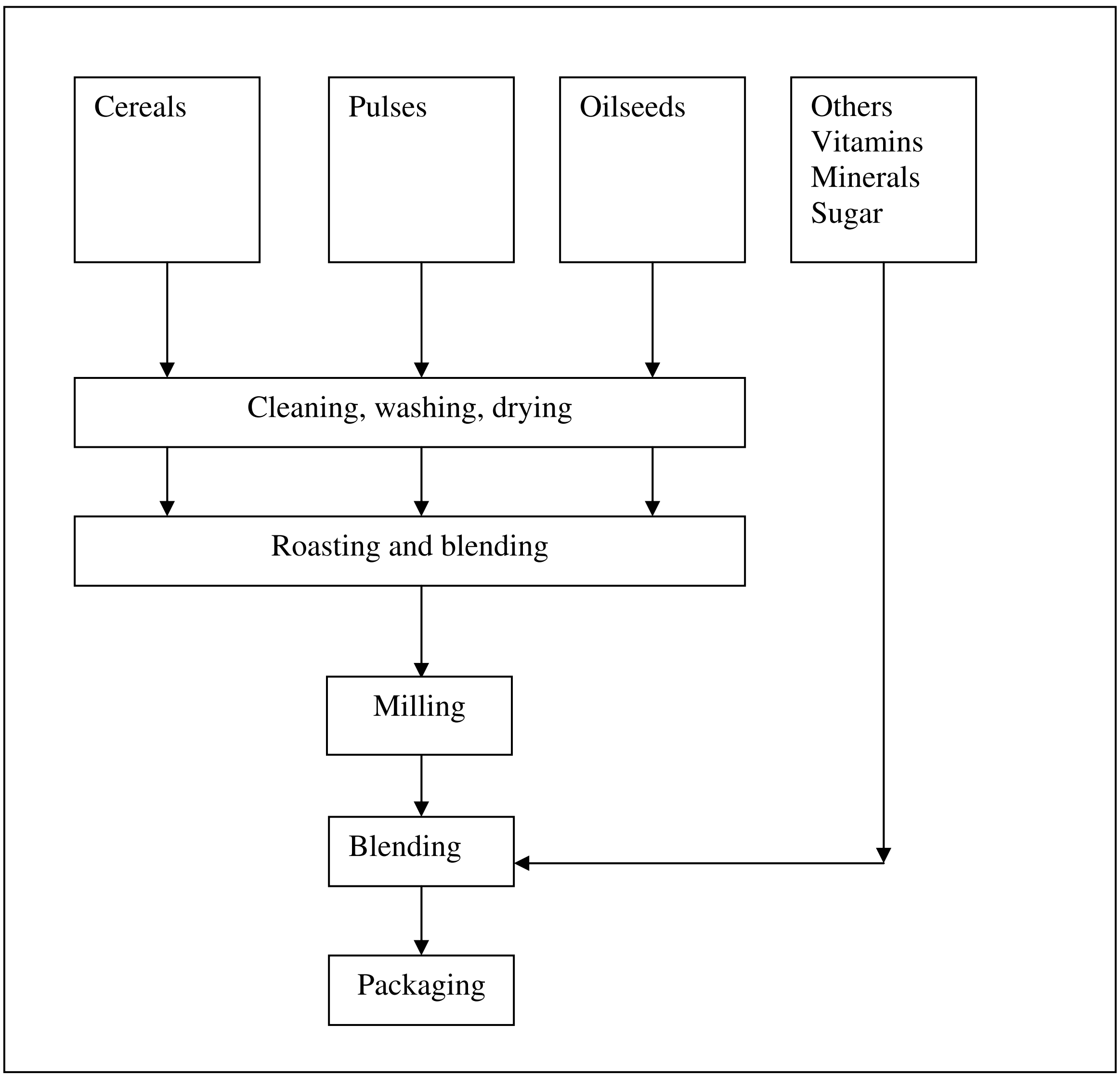
The staples are blended together using an electric or hand operated drum mixer,

Milling
The blended food is then milled using either a hammermill or plate mill into a fine meal or flour.

Fortification
The milled meal or flour is batch blended with a micronutrient premix containing vitamins and minerals.

Packaging
The final product is then packaged in polythene bags of different sizes depending upon the customer requirements and the market conditions. Typical bags sizes range from 500 grams, 1 kilo, 5 kilo and 20 kilo bags.

Figure 4 Processing Flow Chart for Complementary Food Production



Processing Equipment

- Cleaning: Winnower/mechanical separator, Hand sifter, Washing buckets
- Roasting: Electric oven, Wood fired drum roaster, Scorcher
- Blending: Drum blender, Weigh Scale or Spring Scale, Scoops
- Milling: Hammermill or plate mill, electric or diesel driven
- Flour Blending: Drum blender, scoops, small scale or measuring cups
- Packaging: Plastic bags, Heat sealer, bag stitcher, Scoops

Section 7
QUALITY CONTROL & QUALITY ASSURANCE

Since Small- Scale Fortification (SSF) is a food manufacturing process it is essential that there be some form of Quality Control and Quality Assurance (QC/QA) system in place. A QC/QA system is required to ensure that the process is in control and that the delivery of micronutrients to the consumer is consistent.

In the case of SSF, the conditions in the rural areas are not ideal and the mill locations are remote making normal QC/QA practices difficult to achieve. It is still recommended that a QC/QA system that is practical and measurable be followed.

Quality Assurance

The *Objective* of Quality Assurance is to ensure that products meet quality standards for their intended use at the consumer level.

Quality assurance includes the following:

- All matters and activities that individually and severely influence the quality of a product.
- All equipment, product design, processing, supplies, logistics, management and human resources used in the manufacture of the food.
- For SSF: feeders/blenders, premix, packaging, labeling, sampling plans, etc.

Sources of data and activities used in fortification QA

Fortified Food Standards
These are normally established by regulations in each country but may be provided by NGOs or UN groups, such as UNICEF and the World Food Program (WFP).

Premix specifications
These are normally premix supplier specification but can be specified by food producers or premix purchasers and suppliers, including flour milling companies, the Micronutrient Initiative, WFP, USAID/USDA and UNICEF.. In rare situations they can be specified by government regulations.

Safety Assessment of Vitamins/Minerals (Toxicity)
These are based on National Academy of Science/Food Nutrition Board, Food Chemicals Codex, WHO guidelines and Codex Alimentarius standards.

Shelf life of Premix and Fortified Food
The shelf-life for premix is up to 3 years. Maximum premix storage periods, as shown in Table 15, are normally determined by the premix manufacturer. The shelf-life of the fortified flour is 1 to 12 months depending on extraction rate or fat content of the flour, the types and levels of nutrients added and the conditions under which the flour is packaged and stored. The usual problem with shelf life of premix and preblends is reduced biological activity of the vitamins. With fortified flour vitamin activity and off-flavors due to oxidative rancidity are both limiting factors.

Critical Control Points (HACCP)
This should be applied to the inventory control of the premix or preblend, the operation of the blender/feeder, and the check weighing system.

Recall System
A documented procedure for identifying and recalling faulty or suspect product is recommended.

Audit and Corrective Action Plan
An audit plan with corrective action procedures is recommended for all food fortification programs.

QA System Documentation
The QA system must include documentation procedures so that it can be used for training and auditing purposes. An ISO 9000 system can be employed for this purpose but it is not a requirement in SSF.

Analytical Laboratory Facilities and Methods
These can be either a national or a regional facility, either commercial or government run. In many cases these facilities will be available.

Legal Provisions
Ideally the national government should have adequate laws or regulations, a monitoring system and standards of enforcement to insure compliance or prevent fraud, such as labeling an unfortified product as being fortified.

Equipment and premix supplies
The milling industry or the project manager needs to be responsible for the purchase of blending equipment, weigh scales and premix supplies. A good distribution system is needed to be able to distribute premix during the year to remote locations.

Inspections
A third party inspection system or the project management should routinely inspect processing equipment to ensure that the blending method and system used is capable of producing a consistently homogeneous fortified product.

Validation protocol for SSF

This Validation Protocol for SSF has been developed to assist programme managers to determine the effectiveness and consistency of the various fortification methods used.

Objectives of the validation process

The objectives of the validation process are:

- ✓ To evaluate the various fortification methods for consistency of addition of preblends using a range of premix dilutions.
- ✓ To determine the optimum dilution rate for a specific small-scale fortification method.
- ✓ To provide acceptance criteria for a suitable fortification method.

Process validation of blending method

As part of the initiation of the SSF project, the blending equipment and method used for fortification should be validated for consistency and ease of use. This would include a series of test runs (10 runs with 3 samples from each run of milled flour is recommended) using the same types of equipment and fortification methods that will be used in the country. Samples of unfortified food, fortified food and premix need to be collected and analyzed quantitatively for the premix indicator, which is usually iron but can be any of the added micronutrients.

Preparation of dilute premix (preblends)

Once the fortification scheme and method of fortification has been determined and a suitable premix obtained to accomplish that, three different dilutions of the premix can be prepared for testing purposes (see Section 5 for this procedure). The preblends should include the best guess of the required dilution, with another preblend at one half that concentration and another twice the concentration (e.g. dilution factors of 10, 20 and 40 if 20 was the best guess). The preblends should be prepared in the order of their concentration, from highest to lowest, to reduce the chance of the more concentrated preblends contaminating the more dilute ones. The weighing equipment to be used can be scales for cereal flour and a digital scale for vitamin mineral concentrate.

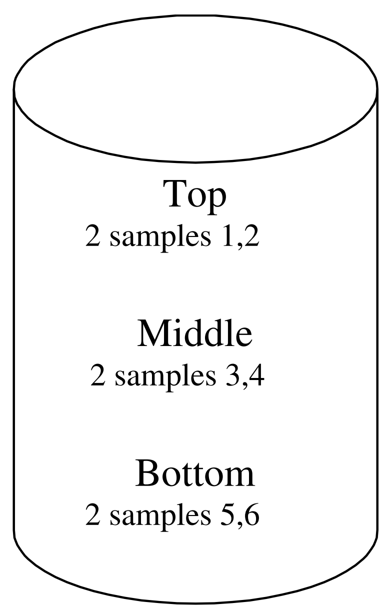
Sampling plans

A minimum of 3 runs is required to ensure that enough samples can be taken to cover any variation in the total process. The following sampling plan is recommended using 6 samples per test run, so as to provide statically significant results.

Table 20 Sampling plans

Activity	Runs	Samples*
Unfortified maize flour	3	6
Whole Maize grain	3	6
Dilute Premix Preparation		
Vitamin-mineral concentrate	1	1
Dilute premix	1	6
Fortification Method i.e. Direct Addition		
Using 1:50 premix	3	6
Random duplicate	3	1

*Sample weight 150 grams
1 random duplicate sample will be taken, for each run of a fortification trial run.



Sampling location map

The following sampling plan location will be used to take the 6 samples from the containers to ensure that the samples are representative of the whole container. At each level (top, middle and bottom), the 2 samples will be taken from opposite sides. At each level (top, middle and bottom) the samples will be taken so that they are not directly above or below each other.

Sample splitting and labeling

Once the samples have been taken they will be split into two or three and labeled with the following information:

- Fortified maize/premix used:
- Date:
- Run:
- Sample #:

Each set of samples will be sent to a certified laboratory for analysis. Analytical laboratories should be instructed to retain unused samples until the results have been reviewed by the programme manager. Repeat analysis should be carried out if any result is 3 times above or below the expected analysis.

Statistical analysis

The following statistical calculations will be carried out on each run for each dilution:

- Average
- Standard Deviation (SD)
- Coefficient of Variation (SD as a percentage of the average)

In addition, all the results from the three runs of each dilution trial can be statistically analyzed as above. This should be carried out if more than one dilution is being evaluated or more than one fortification method is being used.

Acceptance criteria

The CV of the blending method should ideally be from 8 to 20% when the "within lab" analytical error is below 5%. If the analytical error is high (e.g. over 20%), there is no point in collecting these samples and running these tests. Within lab analytical error can be determined by running multiple tests (at least 7) on the same sample or on a certified fortified standard, such as provided by the AACC or NIOSH.

The accuracy of "between lab" iron analysis of foods can be as large as ± 25% of the found iron content for large scale fortification programmes and for other processed foods. In the case of small scale fortification where the precision of the process is less than that found in large scale fortification and where the added amount of iron is 60 ppm or less (depending upon the form of iron fortificant used), a range of ± 40% variation of the calculated average iron content of the analyses is considered to be satisfactory.

Quality Control at the Community Mill Level

Feeder/dosifier calibration

In some countries such as CIS states, Moldova, Pakistan, and South Africa, community mills may be large enough to use a feeder. In these cases it is appropriate to calibrate the feeder to the flour production rate. The premix should be diluted to a suitable preblend when the mill capacity is below 1 tonne/day. The feeder or dosifier is normally equipped with a variable speed drive which allows for different discharge rates. The feeder should be calibrated with the preblend to be used so that the delivery rate, in grams/min, is known at each feeder setting.

Preblend addition rates

The amount of preblend that can be added to the cereal flour in current SSF projects ranges from 10 to 30 grams per kilogram of cereal flour. Actual quantities of premix added in these projects ranges from 10 grams to 200 grams depending upon the amount of cereal brought to the mill for fortification and the amount and number of micronutrients added to the flour. Current research has shown that premix added at the above rates does get uniformly dispersed into the cereal flour in community mills at the village level.

Process controls

The following process controls are recommended for use at the community mill level:

Check Weighing

At the community mill the use of scales and volumetric measures for cereals and premix is required to assure that the right amount of premix or preblend is added to the cereal flour. In some cases the preblend is pre-weighed and packaged in sachets so that one sachet is added to a unit of cereal.

The preblend can be either weighed using simple spring scales or measured volumetrically using a standard tin of known volume. When volumetric methods are followed it is recommended that the weight of grain in a known volume is measured and recorded. When mixed grains and legumes are brought for milling, the use of a volumetric measure is NOT recommended as each component has a different bulk density and the proportion of cereals and legumes is not always the same.

Iron Spot Test

Fortified flour ready for distribution is normally monitored through the use of an *Iron Spot Test*. This method will detect the presence of *added* iron to cereal flours and can give an indication of the kind of iron used. This test is best run by comparing the unknown sample with a standard flour samples with known levels of added iron. The procedure for the *Iron Spot Test* is included in this manual. As in any testing program, it is essential that adequate records of the sampling and test results be retained. This allows for monitoring of the program and to facilitate auditing.

The Iron Spot Test is an essential tool to confirm that flour has been properly fortified. When used with known standards it will give an indication if the level of fortification is excessively high or low. The test can be used by millers, project team members and government inspectors as part of the quality control and quality assurance program.

Sampling Schedule

A sampling and inspection schedule needs to be in place to assure that fortification is being carried out consistently. The *iron spot test* can be performed daily and inspections by project teams can be set up according to existing supervisor duties.

Quantitative Testing

It is recommended that samples be taken from the field and mill sites on a periodic basis for quantitative analysis. Sampling frequency at the start of a project will be higher than after the project has been running for several months. Initially samples should be taken monthly but after 6 months the frequency can be reduced to once every 3 months.

In some countries government laboratories may already be equipped to measure minerals such as iron and some vitamins. Generally vitamin analysis is more expensive and harder to determine than minerals. Iron is always going to be in a premix together with vitamins. It is easier to measure iron, so it is recommended that iron be used as the indicator for the addition of premix into cereal flours at the community level.

Practical Options for SSF Programs

Small Scale Fortification is designed to assist those who live in the rural and peri-urban areas of developing countries. Circumstances, conditions and standards will not be the same as for organized food industry sectors in developing and developed countries. Consequently it is not practical to impose a highly rigorous quality assurance and quality control system on a food processing system that may not be ideal. On this basis it is recommended that the following quality control and quality assurance points be adopted for SSF projects:

Table 21 Process controls in SSF

SSF Process/ Component	***QC/QA Point***	***Frequency***
Premix Manufacture	Certificate of Analysis Quantitative Testing	Each Production lot
Preblend Production (Premix Dilution)	Production records Certificate of Analysis Quantitative Testing	Each production lot Each production lot Each production lot
Milling/blending	Milling Records Iron Spot Test Premix stock records Quantitative Analysis Equipment/Facility Inspection	Each customer Daily Weekly Monthly Monthly
At the Household	Iron Spot Test Quantitative Analysis	3 months Start, End of project and every 6 months during

Premix Control Records and *Milling Records*, preferably in Electronic format, can be used as Quality Assurance and Quality Control tools to monitor the programme:

APPENDIX

Semi-Quantitative Spot Test for Iron

Adaptation of the AACC 40-40 qualitative method for iron

I. Reagents
Hydrochloric acid, HCl, 37% Merck 317
Hydrogen peroxide, H_2O_2, 30%, Merck 7209 (it is possible to replace this reagent with commercial oxygenated water)
Potassium thiocyanate, KSCN, Merck 5124 or 5125

II. Solutions
KSCN - 10%: Dissolve 10 g of KSCN in 100 ml distilled water.
HCl - 2M: To a 500 ml beaker, add 100 ml distilled water, then 17 ml concentrated HCl and, finally 83 ml distilled water.
H_2O_2 - 3%: Add 9 ml concentrated H_2O_2 (30%) to 81 ml distilled water.

Reagent 1
Immediately before using, mix equal amounts of 10% KSCN and 2M HCl. Mark the levels of 20 and 40 ml on a flask, using a pipette. Add 2M HCl up to the 1st mark and then add 10% KSCN up to the 2nd mark. This is reagent 1. Use within 1 day. Discard the remaining.

Reagent 2
3% H_2O_2. Discard remaining solution at the end of the day.

III. Materials
Watch glass
Droppers

IV. Procedure
1. Take a sample of 100 g of flour and place it on the watch glass. With the lower part of another watch glass, press on the flour sample so that it forms a flat surface.

2. Add 5 drops of reagent 1 with the dropper so that it covers an area of 4x4 cm (1.5x1.5 inches). Let stand for 15-30 seconds.

3. Add 5 drops of reagent 2 on the surface covered by reagent 1. Let stand for 1-2 minutes.

V. Interpretation
The appearance of red colored spots indicates the presence of iron. The number of spots is a broad estimation of the amount and homogeneity of iron in the sample. If a more accurate estimation is required, testing with known concentrations of iron (30, 60, and 90 ppm) is recommended in order to compare results of these samples with those of the flour being tested.

Example of Assessing Technical Feasibility Of SSF

Based on pilot studies in Zambia, Zimababwe and Mozambique, the following steps could be taken to conduct such an assessment.

Assessment Objectives

The main objective of this assessment, to be conducted for example by a local NGO or government organization, is to determine *Technical Feasibility*, i.e., whether fortification is technically feasible at local hammer/disc mills where grains are ground to a meal. As a result of this assessment, one could proceed with a longer *Field Trial*.

It is important that the organization first determines if it has the ability and resources to conduct such an assessment. Retaining a consultant with experience in conducting such assessments, especially from foreign countries, is not essential, but it may be a route to take if the NGO wishes to complete the task rapidly. The consultant could concurrently train staff on various elements of SSF. The information in this manual can enable local groups to do such assessments themselves.

Assessment Methodology

Gathering detailed information about the food cultivation, procurement, processing and consumption practices in a target area forms the basis of an assessment. The mill owners' interest in food fortification needs to be ascertained and his participation in the assessment encouraged. The local political authorities need to be consulted to make them aware of the (NGO's) intent and to generate public support. The observations and tests should be oriented towards assessing technical feasibility, but also to determine economic sustainability (e.g., the long-term ability of the community to generate revenue to buy premix).

Task A-1 (Documentation)

A key element of this assessment is observing and documenting millers' and customers' practices at each mill to gather information about:

a) Milling practices and cost of milling rates, including recent rate increases and customers' reactions to such increases, as well as potential increases due to SSF,
b) mill equipment design, operation and condition; mill manufacturer should be contacted if possible,
c) customers' practices, (e.g., types of cereals milled, dehulling methods, quantity of grain milled grain milled per customer visit to mill, frequency of visits, distance from home to mill),
d) processing of grain before milling and of the meal after milling (e.g., soaking of grain, dehulling, sieving and solar drying of meal), and details on fermentation of grain and meal, if performed,
e) customers' diets and food consumption patterns (e.g., meal cooking methods),
f) family size and demographics, and access to potable water, fuel, vegetables, meat etc.,
g) distribution of mills in the area, their accessibility and typical traffic.

An excerpt from an assessment conducted for HKI in Mozambique is suggestive of the types of observations recorded while doing an assessment:

> *"The mills visited in Manica district were of good design and generally in good operating condition. All of the mills inspected employed the conventional hammer mill design with a cyclone separator, and losses from the separator were negligible. The meal produced in these mills had dry, flour-like consistency and displayed adequate flow properties. It therefore seems technically feasible to fortify that meal by adding diluted premix directly but gradually to the grain mixture as it is being fed from the hopper to the mill, in order to achieve an acceptable degree of distribution of premix in the meal. Since both the meal and premix contain iron, samples of the unfortified meal, dilute premix and fortified meal can be taken and analyzed for iron content in order to determine the degree of distribution of premix in the fortified meal."*

Task A-2 (Acceptability)

It is also important to contact the head of the local small millers association, if one exits, and work through their group to obtain the cooperation of millers in doing the assessment. The groups targeted for promoting the SSF concept include the millers and the community served by each mill. At each mill visited, the concept of fortification should be introduced by giving the miller and customers a synopsis of projects underway in other countries or regions, e.g., Zambia and Zimbabwe, showing them sachets of the diluted premix used in Zimbabwe, the Odjob mixing pail used in Zambia to achieve fortification, and mentioning the benefits of the micronutrients in the premix. Avoid raising expectations with assurances or commitments about fortifying customers' food in the future. If possible, observations should be recorded on film, video cassette or digital camera.

Task A-3 (Technical Feasibility)
Having gathered the background information and after ensuring that the residents in the chosen area are receptive (through IEC and community sensitization activities) to having some preliminary tests conducted at their mills, one may proceed with a technical feasibility assessment. The number of mills selected for this assessment and the amounts of grain required for the following tasks will have to be adapted to the needs of the local situation. Typically, the tasks for conducting a technical feasibility are:

Task TF-1 (Mill Selection): The *Extraction Rate* is used as a key indicator in mill selection. Select two mills, one that looks clean and the other dusty, i.e., a sign that its cyclone separator is not as efficient.

1) Purchase 40 kg of grain. Take along weigh scales, empty sack and calculator.
2) Obtain the weight (WT kg) of an empty tin, which is the volumetric unit of measurement used by the miller to levy milling costs.
3) Fill it to the brim with grain (maize or a mixture of maize and other grains) and weigh it to determine the net weight of grain in a tin (WG kg).
4) Have that maize dehulled in the dehuller. Note the time taken to do so and weigh the dehulled grain, (WDG kg).
5) If it is traditional practice to dry the dehulled grain and then to sieve it, do so.
6) Weigh the end product (WDSG kg) just before it is milled.
7) Empty the tin containing dehulled maize into the mill hopper and start the mill. Using a stopwatch, note the time taken to grind one tin of grain to a meal, which is collected in a sack.
8) Empty the sack into the tin and weigh the tin to calculate the weight of just the meal (WM kg).

$$\text{Extraction Rate for the hammer mill} = \frac{(WM)}{(WDSG)}\ \%$$

This rate is a good indicator of the mill's operating condition. An extraction rate of at least 95% suggests that losses of meal and premix, especially via the cyclone's top vent, are acceptable. Also of interest is the extraction rate for the dehulling stage, calculated as follows:

$$\text{Extraction Rate for dehulling} = \frac{(WDSG)}{(WG)}\ \%$$

This rate indicates the loss of bran and other nutrient containing components of whole grain.

Checklist of weight data collection:

1) WT, 1 empty tin
2) WG, 1 tin, filled with whole grain
3) WDG, ~1 tin, dehulled grain
4) WDSG, ~1 tin, dehulled, sieved grain
5) WM, meal from 1 tin of grain

Also note the general condition of the mill and the building housing the mill. These observations should be repeated at about 10 mills, from which one may select 6 mills for the longer term SSF Field Trial.

Resources:

Time: ~30 minutes per mill
Personnel: – 2 people including driver
Materials: – approx. 20 kg grain (hulled or dehulled) per mill
- clean empty sack, weigh scales, calculator, notebook, stopwatch or appropriate watch,
- two or three compartment meal sampler made from aluminum by DTA for the MI

Transportation- to the mills.

Task TF-2 (Dosing Feasibility): Select any 6 mills in the area using extraction rate as a guide, but also consider criteria such as traffic, proximity to roads, demographics etc.

Initiate community sensitization activities to generate enthusiasm and support for the conduct of these tasks, which could disrupt regular operations at the mills.

First, measure out two tins of maize and determine the net weight of grain. Mill one tin of grain and take samples at two or three different depths from the tin of maize meal. Send samples away for lab assay of iron content (gm Fe per kg of meal).

Using sachets of the fortification preblend obtained, fortify the other tin of maize. Add preblend from one sachet gradually to the maize as it is being fed to the mill. Take samples at two or three different depths in the ground meal and again assay for iron. If the preblend gets well distributed in the meal, then the iron content in the different samples of fortified meal should be similar. An acceptable variation in iron content is ± 40% as explained in section 5.

Since the iron spot test can easily distinguish ± 40%, it may be easier and a lot faster to use it for this purpose rather than quantitative iron assays, which take time and are subject to considerable analytical error.

The method of dosing micronutrients would be acceptable if the samples of fortified meal assay an iron content that is no larger than ± 40%. While this may seem to be a large variation, it should be recognized that additional blending will occur during subsequent sifting, spreading of meal for drying, collecting of meal after drying, and cooking. This procedure should be performed at all 6 mills, especially those where the feedstock varies to include other cereals, tapioca or sweet potatoes with maize.

Resources:

Time: ~1 hr. per mill
Personnel: – 2 people including driver
Materials: – approx. 40 kg grain (hulled or dehulled) per mill
- 1 dilute premix sachet per mill
- clean empty sack, weigh scales, calculator, notebook, stopwatch or appropriate watch

Lab assays: - 6 to 9 samples for iron content per mill
Transportation - to the mills.

Task A-4 (Customer Acceptance):

While doing an assessment, it is important to record observations about customer acceptance of SSF, not just to gauge the receptivity for SSF, but also to help design the subsequent Field Trial if the assessment is positive.

There are three categories of “customers” for SSF,

- the person who brings the grain to the mill, i.e., the customer
- the mill owner
- the health department in the local government

The Customer – The customer at almost every mill is either a woman or a child, who brings grain in a sack, the amount depending on what one can carry, afford to mill, or is necessary for one's family for 1 to 14 days. If SSF is to become sustainable, yet remain voluntary, the customer must be convinced through education and by keeping costs low, to be prepared to pay for fortification on each visit to the mill. Also, if the premix has to be added separately by the customer using blending equipment, it requires the customer to drastically modify her behaviour at the mill. Finally, the customer must confirm acceptance of the premix, with an understanding that fortified meal is beneficial to her and her family.

Mill Owner - One cannot succeed without the mill owner's (and by inference his employee, the miller's) full cooperation, because introducing SSF will require him to modify his practices, and possibly his equipment. If additional dosing or blending equipment is required, the mill owner will incur investment costs that will affect milling rates, and possibly entail physical changes to the facilities.

Health Department – Food fortification is not universally accepted or practiced in developing countries. If food fortification is permitted by law, and made mandatory, the job of monitoring and enforcing SSF is made easier. If not, considerable resources may be required to ensure that the public's acceptance of SSF is maintained. Whether voluntary or mandatory, additional resources are required to periodically visit mills to observe SSF practices, take samples and analyze them to determine if fortification using quality premix is actually being practiced. Similar inspections of premix manufacturers are also required to maintain a reliable supply of premix that meets international standards. Without the commitment of the health department to execute these tasks, SSF may be difficult to sustain.

Field Trial Evaluation

If the above assessment suggests that SSF shows promise from a technical perspective and customer acceptability, a field trial is a likely next step.

Dosing methods

If the assay results from the SSF test done at each of 6 mills show that the premix added to the grain itself yields an acceptable distribution in the meal (per the iron assay), then the technical feasibility of this dosing method will have been proven. Consequently, a decision to proceed with a 3 to 6 months SSF Field Trial is justified strictly on technical grounds.

However, if the assay results show distribution of premix in the meal to be less than adequate when it is added directly with the grain, a hand driven blender should be considered. The 2004 price of that blender is around USD $400, FOB Harare. Improvements to blender design are ongoing at the Harare manufacturer. Additionally, the NGO should determine the feasibility of manufacturing the blender and producing preblend locally. This could save money, generate employment and maximize indigenous content, but must be accomplished without sacrificing quality or the ingredient and manufacturing standards previously discussed. Before making the decision to proceed, all relevant and current information on the blending equipment (price, footprint, operating parameters, maintenance, etc.) should be obtained from a knowledgeable organization, such as CARE Zimbabwe.

An alternative to the steel blender is the Odjob mixing pail (or Odjob blender) now being tested in Zambia. The Odjob's drawback is that its current design has a capacity of 13.5 kg, which can be less than what most, if not all, customers bring for milling in some countries. Its low cost of USD $15, its ease of operation, and its use as a sanitary, sealed container for maize meal partly make up for its lower capacity. In Zambia, the Odjob blender had been mounted on a stand, which makes it less strenuous and more convenient to operate.

Situations where SSF may not be feasible

One must consider the conditions and results of the Technical Feasibility study that would lead to the conclusion that SSF is not appropriate in certain circumstances. Based on the authors' experiences in 15 countries, SSF may not be technically feasible when:

1. There is considerable duration and a large number of steps involved in processing the cereal product to be fortified. In Ghana, for example, maize grain is first fermented, then dehulled, milled to a flour, steamed, set aside and then consumed as a fermented dough called *Kenkey*. The process takes up to 6 days, during which the materials are exposed to the elements under unsanitary conditions. The best time to blend premix and maize meal is when it is milled to a flour on day 3, yet the subsequent combination of moisture, heat and light over another 3 days would be expected to significantly degrade some of the more expensive ingredients such vitamin A. Consequently, it would not be technically feasible to fortify traditional, moist Kenkey dough. The only alternative is to dehydrate the Kenkey dough to a dry powder, and only then fortify with a premix.

2. The reaction between micronutrients in the premix and the recipient flour/meal may produce either a discolouration, bad odour, bad taste or textural change such as clumping or curdling. Iron salts, such as ferrous sulphate, can discolour some cereal foods. Consequently, other source of iron must be tested to see which, if any, will produce an acceptable product.

3. The reaction between micronutrients and ingredients in the recipient food could result in the former getting chemically bound up by the latter ingredients, causing the bioavailability of the added micronutrients to be significantly minimized.

4. The target population may not be able to obtain adequate food supplies, say during prolongued drought or floods or insect infestation or war. In such cases, it may be totally uneconomical to procure and distribute premix on a sustained basis.

These are just some examples of situations where technical feasibility of SSF is neither assured nor easy to achieve.

EXAMPLES OF PLANNING & IMPLEMENTATION OF SSF

FIELD TRIALS

If technical feasibility shows promise the next step is to design and run a field trial, say at 6 to 8 mills over at least 6 months, to establish feasibility. Describe the project's scope, key tasks, estimate duration, human and financial resources, schedule and milestones along with an estimated budget and suggested infrastructure requirements (transportation, laboratory testing, premix handling etc.). Identify any concerns about the role of NGOs, government, potential partners, etc. Describe economic feasibility and social marketing required to achieve community acceptance. Identify factors that affect logistics, cost and dependability of delivering premix year-round to all mills.

The following is a typical description of how to do a field trial:

Example of Field Trial Project

The following project design is based on the experiences in Zambia and Zimbabwe. It assumes that diluted premix (preblend) can be added directly to the maize grain being fed to the mill. The overall objective of this hypothetical project is for an NGO to demonstrate and practice small scale fortification in 6 selected hammer mills for at least 6 months with the full cooperation and participation of about 20 volunteer families from the communities served by each mill.

This demonstration will be expected to establish proper procedures for:

1. The safe preparation of the fortification preblend from the supplied premix,
2. delivering preblend to each mill,
3. dosing of the preblend into the volunteer families' meal,
4. promoting fortification and enhancing its understanding and acceptance in the community served, by each mill, so as to create a significant demand for fortification on a sustainable basis;
5. monitoring fortification, quality assurance practices (including lab testing of samples periodically) to be followed by local government testing,
6. providing the justification for a GO / NO GO decision on scaling up this method of fortification to more mills or even to a district wide level.

The challenge for the NGO is to establish proper procedures and practices, from introducing SSF to a community up to ongoing monitoring, and ensuring proper practices are adhered to by mill customers, millers and by NGO staff guiding and monitoring the project.

Project components in target region

Using nutrition intake data from a baseline survey and health centres' records of micronutrient deficiencies , develop specifications and compositions for the premix and preblend. This is best done with direct assistance from the Ministry of Health and other health or nutrition professionals.

One rule of common guideline is that the upper limit of micronutrients in the fortified food should not exceed 33% of RDA under average intake, and should not exceed 100% of the RDA for the highest possible consumption level. Other guidelines on the premix formulation are available from WHO, PAHO and the Micronutrient Initiative.

The fortification preblend composition and addition rate will help calculate the micronutrient loading per kilo of meal, and consequently the quantity of preblend required for a 6 month trial.

Estimate or set a limit on the number of persons or families who will participate in this project. It is beneficial to request the miller to keep a daily log of the number of customers, and the number of tins each customer brings to the mill over a month period. This data will further help select the 6 mills, and help estimate the quantity of premix and preblend required for the entire project.

While it would be ideal to request at least three manufacturers to provide quotations on supplying premix, this may not be possible for the initial pilot project. Addresses of several premix manufacturers are listed in Section 5, and a more comprehensive list is available at the MI website: www.micronutrient.org/resources/publications/pubs.htm.

It is important to specify packaging, labeling and colour, as well as any fillers one may or may not want added. Based on the premix composition and quantity ordered, estimate the quantity and cost of maize meal to be purchased for diluting the premix. The cheapest route to adding the diluted premix to the mill is to pack the dilute premix (preblend) in bulk, plastic lined, air-tight sacks, then dispense it at the mill with a scoop calibrated for one tin of maize meal. Estimate the cost of dilution and packaging, as well as that of delivering the sacks on a monthly or fortnightly basis to the selected mills. It is preferable to actually make one batch of dilute premix to better estimate production time and costs. A dual cone or a tumbling blender such as the ones used in Zambia would suffice for achieving dilution. Prepacking weighted amounts of diluted premix can also be considered as done in Zambia and Zimbabwe.

Logistically, preblend could be distributed by the seed companies or through diesel supply depots, or through supply depots in local towns. This should be investigated.

Approach the community in partnership with the appropriate health service workers, politicians and others in authority to introduce the project and its objectives to them. This reinforces the contacts and information sessions established earlier, during the Technical Feasibility. Select the 20 volunteer families at each mill, using criteria developed in Zambia and Zimbabwe (refer to country specific reports, accessible from the MI). Identify their concerns, if any.

Identify laboratories and their ability to meet the project's assay requirements, i.e., assay for iron in meal, before and after it is fortified, as well as the meal used as diluent. Determine their costs, lead time, duration of assays and sample size requirements.

Develop an education campaign for introducing SSF to the volunteer families, millers and other interested parties in the community. Prepare a script for the SSF introduction session at each mill and assign roles. Address up front any concerns expressed earlier by the community, such as the rumored medicinal or sterilizing effects of the premix.

Stage a "show and tell" session at each mill, involving the entire community, and initiate their education about nutrition, deficiencies, disorders, SSF, and their roles and responsibilities. Train each family to measure and add premix. The NGO could opt to either donate the preblend or begin the 6 month trial by donating premix, then gradually charging them for it, perhaps achieving a target price that is 50-75% or even 100% of the true, delivered cost of preblend. Avail of the services of a local entertainment troupe to animate the education campaign.

Initiate the SSF trials at each mill and follow the sampling protocol established, i.e., sample the meal of up to three customers before and after it is fortified, to determine iron content and assess degree of premix distribution in the meal.

Schedule visits to each mill by a team of two NGO staff initially on a fortnightly basis, coinciding where possible with the visits to the mill by the volunteer families. The staff should conduct organoleptic tests and survey all families to assess customer satisfaction. As before, use protocols already tested and proven in Zambia and Zimbabwe. Verify how the meal is processed (sieved, dried, cooked etc.) after it leaves the mill. During mill visits, communicate with millers and mill owners, as well as other families who may be interested in having their meal fortified. If the latter's interest is significant, consider increasing the population whose meal is fortified at each mill and accelerating the cost recovery process. Communicate to the community the results from the lab, to either reinforce or re-educate the recipients regarding fortification procedures.

Take spot samples monthly of fortified meal from product remaining with three families, just before they return to the mill. Assay samples to determine premix settling and residual potency of vitamin A.

<u>Resources:</u>

Time - 2 hrs. per mill visited once every two weeks
Personnel – 3 people including driver, but two per team
- IEC troupe, to visit each mill once at the start

Materiel – Premix in bulk, and lined bags for diluted premix (preblend)
- Maize meal sufficient for dilution, or 19 times premix weight (degree of dilution depends on cost of filler and transportation of diluted premix to target regions, among others)
- 1 package of dilute premix per mill sufficient for one visit every two weeks by the 20 families
- clean empty sack, weigh scales, calculator, notebook, stopwatch or appropriate watch
- posters for each mill outlining procedures

Lab assays - 6 to 9 samples for iron content per mill
- 3 samples/month/per mill to assay vitamin A

Transportation - to the mills.

Budget & schedule

<u>Budget:</u> A rough estimate is about USD150,000, divided approximately, in percentages,

Local staff salaries - 35%
Social marketing - 10%
Training by consultant - 10%
Local transportation - 25%
Premix, incl. dilution - 10%
Lab tests, evaluation - 5%
Contingencies - 5%

These percentages can vary significantly from one country to another and possibly due to the food being fortified.

<u>Schedule:</u> It is estimated that the Technical Feasibility can be planned and completed within 2 months, after which a more realistic estimate of the schedule for Field Trials could be prepared.. At present, the Field Trials could take at least 10 months to plan, organize, implement and evaluate.

MONITORING & EVALUATION OF FIELD TRIAL

There are many indicators that are appropriate for monitoring and evaluating the field trial, so that the NGO, which is the implementing organization, can make GO / NO GO decisions at key milestones on scaling up this method of fortification to a district-wide level, and possibly a national level. An example of a method used in Zimbabwe for monitoring and evaluation during a field trial is:

Potential indicators checklist (for program monitoring)

The following checklist/questionnaire is to be completed by field officers during routine visits to mills to monitor the field trial. Remember to take along a weigh scale, sampling cup and enough sample bags which should be labeled (see below for label content) before visiting the mills.

This form is an example that was used successfully by CARE in Zimbabwe. It can no doubt be tailored to meet local needs

MONITORING QUESTIONNAIRE/CHECKLIST

Date:_________________Officer: _______________Mill location: __________________

Observe mill customers and operator. Approach a mill customer who is dosing maize meal and make the following enquiries. Do not distract or disturb the customer who is doing the dosing.

Adult: Gender: __M__F; Age____; Occupation:______________; Education:____Grade

Child/Youth:Gender___M___F; Age_____; School Grade_____

Now, it is important to weigh, with the customer's permission, a tin/bucket of maize (empty and full). Also weigh the sack brought by the customer, both empty and with maize meal.

No. of tins of maize milled today:_____;

Weight of tin (use weigh scale)______kg; Weight of tin filled with maize______kg;

Weight of empty sack______kg; Weight of sack with maize meal_______kg

How many in the family?_____Adults____Children

For how many days is this quantity of maize meal sufficient?________

Did you fortify?______Yes _____No; Why________________________________

Last visit to mill: Date_____; No. of tins of maize____; Did you fortify? ___Yes____No

If No, give reason:____

Effect of dosing on Nshima (Maize Meal Porridge)

Taste: _____No difference; ____sweeter; _____more bitter; _____more salty

Colour: _____No difference; ____darker; _____lighter; looks like_____ salty

Smell: _____No difference; ____Smells different; Smells like____________________

Who in your family doesn't like it:_________; Reason:_________________________

Knowledge and Acceptance of Fortification

What do you understand about fortification?____improves health; ____adds nutrients

____not beneficial; ____afraid/suspicious of it; ___don't understand it

Need more info. on fortification? ___Yes __No; If Yes, what______________________

Community Opinion: _Favourable; __Not Favourable; _Don't Know; __Need More Info.

Monitoring Questionnaire/Checklist continued

Fortification Process

___disruptive; ___not disruptive; ___too long; ___not long; ___like it;

___needs improvement; suggestions____

Premix packaging: Acceptable? ___Yes___No; If No, reason_______________________

Who does dosing in your family:____adult;____gender; ____age; ___usually___occasionally

____child/youth; ____gender; ____age; ___usually___occasionally

Mixer: ___easy to use; ___not easy; why?____

Mixes well? ___Yes___No;_____no opinion or don't know;

If No, Why? ____too heavy; ___too stiff; ___tough to turn; ___tough to load/unload

Any other changes?____

Questions to Mill Owner/Operator: __accept dosing;__not disruptive; __disruptive? If so,

Why____

Concerns:____

____

One cup Samples taken: _____maize meal; ____fortified meal; _____diluted premix;

Sample label content: date/mill #/MM (maize meal); date/mill#/FM (fortified meal); date/mill#/DP (diluted premix);

Samples sent to: office_______(date); lab________(date); by whom_____________________

Request lab to test for moisture and iron in all samples; test for vitamin A (in fortified meal and premix only) if concerned about potency losses during storage

Field Officer's overall impression about fortification program:____

____

____

Suggestions, concerns and comments (from mill owner, operator or mill customers) to be passed on to Program coordinator concerning any aspect of mill level fortification:

____

____

Criteria for Scale-up

The key criteria for consideration on the issue of scaling up SSF from a field trial involving just 6 mills to a district/province/nation wide program are:

- Customer satisfaction (organoleptic etc.) and perceived demand for fortification, including willingness to pay for SSF; ideally the local community served by each mill will be able to share in mill-based revenues, e.g., from the sale of dehulling residue as animal feed, in order to collectively pay for all or some portion of the premix,
- Stability and cost of diluted premix, as well ability to procure a reliable supply of diluted premix at a reasonable price,
- Degree of adherence to procedures and practices at each mill, i.e., willingness of customers to take on and execute responsibility for fortification of their own meal in the manner prescribed,
- Degree of interest from families not enrolled in the trial, and their willingness to pay for premix,
- Scope and cost of premix dilution, packaging, distribution, as well as education campaign for entire province,
- Cost of quality assurance and ongoing monitoring,
- Availability of trained staff or its partners to run the program,
- Government approval and willingness to introduce legislation permitting, if not mandating, fortification. If mandated, then it essentially eliminates the onerous need to reinforce the “premix buying” decision every time the customer comes to the mill.

Samples of Premix Specification Sheets

WHO/MI Middle East - Elemental Iron/Folic Acid Premix

PRODUCT

Elemental Iron and Folic Acid Premix

DESCRIPTION:
Elemental Iron/Folic Acid Premix is a mixture of food grade elemental iron, Folic Acid and an inert carrier for the fortification of wheat flour or maize meal. The source of iron is reduced (elemental) iron having a very fine particle size (99% less than 200 micron particle size). The bioavailability of this form of iron is moderate but it has excellent stability in flour.

COMPOSITION:

ELEMENTAL IRON, FCC	60.00%
FOLIC ACID	1.50%
INERT CARRIER	28.50%

All components of the premix should meet USP, BP or FCC standards.

INGREDIENT DECLARATION: Elemental Iron, Folic Acid, Inert carrier

INGREDIENT SPECIFICATIONS:
ELEMENTAL IRON: See attached sheet
FOLIC ACID: Meets USP, BP, FCC standards
INERT CARRIER: Food grade wheat or corn starch, calcium sulphate

APPLICATION:
The premix is a free flowing powder that can be easily added to flour using standard ingredient feeders. If a lower addition rate is required then the premix can be diluted with wheat flour or starch.

ADDITION RATE:
At 100 grams per metric tonne (1000 kg) of wheat flour the premix will contribute:
60 ppm Iron (6.0 mg per 100 g)
1.5 ppm Folic Acid (0.15 mg per 100 g)

PACKAGING:
The premix is packaged in 25 kg net weight polyethylene lined heavy duty corrugated cardboard boxes.

WHO/MI Middle East Premix - Ferrous Sulphate (Iron)/Folic Acid

PRODUCT
Ferrous Sulphate (Iron)/Folic Acid Flour Fortification Premix

DESCRIPTION:
Ferrous Sulphate (Iron)/Folic Acid Premix is a mixture of food grade iron in Ferrous Sulphate, Anhydrous form, Folic Acid and an inert carrier for the fortification of wheat flour or maize meal. The source of iron is Ferrous Sulphate, dried having a fine particle size (90% less than 200 micron particle size). The bio-availability of this form of iron is excellent but it has moderate stability in flour.
The colour of the premix must be a light tan colour. Green is unacceptable.

COMPOSITION:

FERROUS SULPHATE, DRIED, FCC	84.0%
FOLIC ACID, USP, BP, FCC	1.5%
INERT CARRIER	14.5%

All components of the premix should meet USP, BP or FCC standards.

INGREDIENT DECLARATION: Ferrous Sulphate Dried, Folic Acid, Inert carrier

INGREDIENT SPECIFICATIONS:
FERROUS SULPHATE, DRIED: See attached sheet
FOLIC ACID: Meets USP, BP, FCC standards
INERT CARRIER: Food grade Wheat or Corn Starch, Calcium Sulphate

APPLICATION:
The premix is a free flowing powder which can be easily added to flour using standard ingredient feeders. If a lower addition rate is required then the premix can be diluted with wheat flour or starch.

ADDITION RATE:
At 100 grams per metric tonne (1000 kg) of wheat flour the premix will contribute:

30 ppm Iron (3.0 mg per 100 g)
1.5 ppm Folic Acid (0.15 mg per 100 g)

PACKAGING:
The premix is packaged in 25 kg net weight polyethylene lined heavy duty corrugated cardboard boxes.

Iron and Iron Compound Specifications

Iron, Reduced

DESCRIPTION

Reduced iron for use in the enrichment or fortification of wheat or corn flour should be a USP/FCC grade, very fine particle size, elemental iron produced by a hydrogen reduction or electrolytic process. It is black in color, magnetic and dissolves in dilute mineral acids.

Assay	96.0% Fe Min.
Hydrogen loss	1.75 % Max.
Acid-insoluble substances	1.0 % Max.
Arsenic (as As)	8 ppm Max.
Lead (as Pb)	25 ppm Max.
Mercury (as Hg)	5 ppm Max.
Particle Size (Fisher subsieve analyzer or equivalent)	
Through 200 mesh	99 % Min.
Through 325 mesh	95 % Min.
Iron solubility (optional)	>95% in 0.1% (w/w) slurry in 1 M HCl at 37° C after 1 hr.

Ferrous Sulfate

Ferrous sulfate used in the enrichment or fortification of flour and semolina should be a USP/FCC grade, light tan, dried (desiccated) form with a fine particle size.

Assay	
As $FeSO_4$	86.0 % - 89.0 %
As Iron (Fe)	31.6 % - 32.6 %
Insoluble substances	0.05% Max.
Arsenic (as As)	3 ppm Max.
Lead (as Pb)	10 ppm Max.
Mercury (as Hg)	3 ppm Max.
Particle size	
Through 100 mesh (U.S.)	99.5 % Min.
Through 200 mesh (U.S.)	90 % Min.
Bulk density	
Loose	30 lbs/cu.ft. typical
Packed	45 lbs/cu.ft. typical