# RECOMMENDED PRACTICES FOR THE PRODUCTION AND PROCUREMENT OF PREMIX USED IN CEREAL FORTIFICATION PROGRAMS

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#### **1. Introduction**

- 1.1. This document provides recommended or best practices to use in the production, distribution and procurement of flour fortification premixes.
- 1.2. It is limited to premixes and preblends (diluted premixes) used in the fortification (or enrichment) of wheat flour and maize meal at the mill. While many of the same recommended practices apply to premixes used in other types of food fortification (such as the voluntary fortification of wheat and maize based cereal based food products like bread, snacks and breakfast cereals), These recommendations are not intended for that application, even though the same premix manufacturer may participate in both types of markets.
- 1.3. This document is not intended to replace the "Code of Practice for Food Premix Operations" developed by PAHO, which is broader in scope and incorporates general principles of quality management, ISO 9000, food safety and HACCP programs not included here. All of those quality programs along with JEFCA standards are highly recommended and desired by milling customer for their premix producer to follow, but they are not required in so far as this document is concerned.
- 1.4. A *Premix Committee* has been formed under the Flour Fortification Initiative (FFI) that is open to all producers of fortification premixes. There will be additional non-voting members from NGOs and UN agencies involved in the distribution of premixes and manufactures of food grade vitamins and minerals. The committee is to be chaired by a person not directly connected with the business of micronutrients.
- 1.5. Premix manufacturers who are members of the *FFI Premix Committee* will be asked to review and agree to follow the recommended practices in the final approved document. The committee will regularly review and possibly revise the recommended practices as needed. Membership on this committee can be communicated to mills and premix distributors as a means of verifying that these recommended practices would be followed.

#### 2. Rationale for Recommended Best Practices.

- 2.1. Finding and ordering the "correct" fortification premix at a competitive price can be a new and difficult experience for many mills, particularly those in developing countries where flour fortification (FF) has not been a common practice. Consequently there will be thousands of mills that will need to start ordering premix and fortifying flour. This will greatly expand the need for premix and require establishing good communications and practices between the milling and premix industries.
- 2.2. Experience has shown that one of the major constraints and reasons for delay in implementing and sustaining FF programs in developing countries has been difficulties in securing premix.
- 2.3. Effective premix procurement involves responsibilities, actions and procedures in the entire supply chain, from the premix producer down through to the mill that uses the premix. This document presents best practices in that entire

chain, but concentrates on those of the premix producer. It is recognized, however, that the premix producer is limited in what they can do, and that proper actions by other parties (local suppliers, milling associations/co-ops, mills, government regulatory agencies) are necessary in order for FF to be an effective public health program.

- 2.4. When a country establishes a FF program there is often a desire to produce and procure premix locally. Local production is to be encouraged providing it meets the standards and quality necessary to make the program effective and safe. These "best practices" can assist those companies involved with or intending to start local production.
- 2.5. There have been situations where premixes of clearly inferior quality or incorrect formulation have been offered for sale at attractively low prices. Use of such premixes can greatly damage a FF program, both in the eyes of the milling industry and the public. Bad publicity on quality, safety, compliance and effectiveness needs to be avoided. Utilization of these best practices by all organizations in the premix supply chain will greatly help prevent that from occurring.
- 2.6. Fortification premixes are unique in the following ways, which require their production and procurement to be treated differently from other health products.
  - 2.6.1. They are industrial, food ingredients used in the further processing of food products. They are not pharmaceuticals and are not to be purchased or used by individual consumers.
  - 2.6.2. They are not standardized products and have to be custom made to satisfy each country or mill's situation and requirements.
  - 2.6.3. They have a limited shelf life that varies with the composition. The expiry clock is ticking the day they are made by the primary manufacturer.
  - 2.6.4. They have special storage and security requirements.
  - 2.6.5. The use and procurement of premix is expected to be continuous and sustainable.

#### 3. Definitions and Abbreviations

- 3.1. A "premix" is defined as any blend of micronutrients (vitamins and minerals) used to fortify or enrich foods at the production plant, in this case a wheat flour or maize meal mill.
- 3.2. A "premix manufacturer" is a commercial company that blends individual micronutrients to make a premix.
- 3.3. A "premix distributor" is any operation that warehouses and distributes premix made by a premix manufacturer.
- 3.4. The "formulation overage" is the additional amount of a micronutrient added by a premix to insure that a minimum fortification standard is achieved. (e.g. 1100 IU/kg of vitamin A may be specified to be added in order to achieve a minimum standard of 1000 IU/kg.)

- 3.5. The "manufacturing overage" is the additional level of a micronutrient included in the premix to make sure it assays out above the minimum content requirement. A manufacturing overage should not be used to compensate for vitamin forms which may have poor stability. This overage is at the discretion of the premix manufacturer and need not be made known outside the company.
- 3.6. FF (flour fortification) is used here to denote the fortification of any milled cereal staple from wheat or maize, whether accomplished at the mill or in a separate blending facility.
- 3.7. A premix "lot" is product that has been mixed together either during the original blending of the ingredients or afterwards by mixing together different batches and to which has been assigned a separate code number.
- 3.8. CoA is the Certificate of Analysis, which gives the analytical test results for the micronutrient content in a batch/lot of premix.
- 3.9. CoA by Audit is where the manufacturer does not actually analyze a micronutrient in a batch/lot of premix but guarantees it has been added at the specified amount. Such guarantees must be supported by third party quality audits. Such audits should be carried out on a regular basis as agreed between the supplier and customer such as annual audit.
- 3.10. FFI is the *Flour Fortification Initiative* a global consortium of organizations involved with the promotion and implementation of flour fortification.

# 4. Cereal Fortification

- 4.1. Micronutrient fortification of milled cereal staples is recognized as an effective, safe, inexpensive and sustainable way to increase consumption of deficit vitamins and minerals and improve the nutritional health of the general population.
- 4.2. In virtually every situation, multiple micronutrients will be added.<sup>1</sup>
- 4.3. Cereal fortification is most easily, controllably and economically accomplished at the mill using a single premix of the micronutrients to be added rather than attempting to add them individually. The one exception to this is calcium, which because of the high bulk required is best added separately.
- 4.4. In order for mill fortification to be successful it requires:
  - 4.4.1. A property produced, packaged and labeled fortification premix that is homogeneous, free-flowing, sanitary and containing the correct levels and types of micronutrients as specified by the government and/or purchaser.
  - 4.4.2. Quality premixes available to all mill locations at a competitive price.
  - 4.4.3. Timely delivery of the premix to the mill.

<sup>&</sup>lt;sup>1</sup> The FFI will be involved with other organizations in making expanded recommendations on the types and levels of micronutrients to add to different types of wheat flour and maize meal.

- 4.4.4. Proper storage and handling of the premix in the mill.
- 4.4.5. Suitable premix feeding equipment properly installed, calibrated and maintained to uniformly and accurately add the correct amount of premix.
- 4.4.6. Good quality assurance and quality control programs within the mill on fortification with regular training of mill personnel on proper fortification procedures.
- 4.4.7. Regular communications between the mill with the fortification equipment and premix suppliers.
- 4.4.8. Access to technical support regarding the different stages of the fortification process.

#### 5. Premix Formulation and Ingredients

- 5.1. Premix producers and suppliers should be familiar with the national laws and regulations related to FF in the countries they are operating and refuse to sell a premix product that violate those laws or regulations, even if asked to by a potential customer.
- 5.2. All the ingredients used in a premix should be food grade, preferably meeting the purity requirements of the Food Chemicals Codex (FCC), vol. 4 or higher. If there is no FCC status for a particular ingredient, other standards, such as B.P., EU.P., or U.S.P. can be followed. In no event are animal feed grade ingredients to be used.
- 5.3. Suppliers and lot numbers of each ingredient used in each lot of premix should be recorded and available for at least 3 years after production.
- 5.4. A premix formulation is established by agreement between the premix manufacturer and customer (which can be a milling company, central purchasing group or premix distributor). It can be based on one of the following criteria:
  - 5.4.1. A premix formulation set by government standards (as in South Africa).
  - 5.4.2. Specified levels of micronutrients required to be added. (as with the KAP Complex premix used in Central Asian Countries).
  - 5.4.3. A formulation suitable to meet a country's fortification standards that takes into account the natural micronutrient content and possible processing losses during milling. (as in the United States and Canada)
    - 5.4.3.1. Premix manufacturers should consider flour fortification standards as minimum and not targets, unless they are specifically stated as being target values. In some cases the flour standards will be set as a target ± X percentage or X amount. In that case the standard minus X should be considered as the minimum.
    - 5.4.3.2. The natural content of the micronutrients to be added (both the average and variation) of the flour to be fortified should be known in order to best devise a premix formulation in this situation. This can be

established on the basis of testing or literature values for flours or meals with similar extraction rates and ash values. These values should be kept on file and available to outside inspection if asked. There is no natural content of vitamin A and vitamin  $B_{12}$  in cereals flours so they must be taken at zero. In the case of Folic Acid the natural folate level in flour is very low compared to normal fortification levels so it is normally taken at zero.

- 5.4.3.3. Vitamin A addition levels should not be adjusted based on natural beta –carotene levels, nor should niacin addition levels be adjusted according to tryptophan content.
- 5.4.3.4. To meet the fortification standards, the levels to add in this situation may be established by mutual agreement of the premix and milling companies or milling association. This agreement should be made known along with the supporting data. If there is such an agreement, all premix manufacturers and suppliers should provide only premix in conformance with that agreement. It is strongly encouraged, but not required, that agreement be made on the levels to add where possible. There are situations and flour products that will need specially formulated premixes.
- 5.4.3.5. The *formulation overage* for the levels added for each micronutrient included in the premix in this type of formulation will vary depending on processing conditions in the mill, the stability of the micronutrient and the end use of the flour.
- 5.4.3.6. If quantitative testing on the fortified flour regularly shows high or low values for all or most of the micronutrients, the mill is advised to adjust the premix addition rate accordingly. If testing shows high or low values for only one or two of the micronutrients, the levels added and premix formulation can be adjusted accordingly.
- 5.4.4. Where no country flour fortification standards exist, a formulation agreed upon between the mill and premix producer that is in accordance with all other pertinent laws and regulations.
- 5.4.5. For exported flour, the premix used should match the requirements of the importing country.
- 5.5. Along with the levels of micronutrients to be added, premixes may differ in their addition rate or concentration. Smaller mills may require more dilute premixes with higher addition rates. The addition rate is also dependent on the concentration of some of the ingredients, particularly iron. In order to simplify comparison of premixes and their mill application, it is recommended that premix addition rates be stated in grams of premix per metric ton (g/MT) of flour, and that this be limited to differences of 50 g/MT units. Exceptions to this would be where other units (e.g. g/cwt, oz/cwt) have historically been used.
- 5.6. <u>Iron</u>

- 5.6.1. Because of the high nutritional importance of iron in FF along with large differences in its bioavailability, cost and stability the types, sources and levels of iron in premixes need special consideration and control.
- 5.6.2. Some countries specify the type of iron to be added while others do not. When not specified the choice of iron is by agreement between the premix manufacturer or supplier and the mill. Since many international mills will not know much about iron fortification they may rely on the premix manufacturer to advise them on the best source to use. Premix manufacturers and suppliers should be aware of the relative advantages and disadvantages of the different iron sources but they are under no obligation to recommend a certain type unless required by law.
- 5.6.3. When "electrolytic iron" is specified the premix manufacturer is obligated to use that source of iron and be able to verify it.
- 5.6.4. When country regulations do not specify the source or properties of iron to be used, premix manufacturers are recommended to use ferrous sulphate, ferrous fumarate or Sodium Iron EDTA. Elemental iron powder should only be used when sensory or shelf-life problems prevent their use. Electrolytic iron is the first choice. Any elemental iron powder used must be a product 95% of which is finer than 45 microns in particle size and must be shown to have demonstrated biological effectiveness. They further agree to inform the customer on the manufacturing process of elemental iron (e.g. hydrogen reduced, atomized, electrolytic, carbonyl).
- 5.6.5. When ferrous sulfate is used the premix manufacturer <u>must</u> use dried ferrous sulfate of a very fine particle size. In no event should they use the fully hydrated form of ferrous sulfate.
- 5.6.6. The *FFI Premix Committee* will kept abreast of scientific developments regarding iron nutrition and consider recommendations on types of iron to use in particular situations. This could include adopting standards other than particle size, such as acid solubility, for acceptable elemental iron powders to use in flour fortification.
- 5.7. Vitamin A
  - 5.7.1. Vitamin A preparations are particularly susceptible to loss of activity if not properly made<sup>2</sup>. The premix manufacturer has the responsibility of making sure the vitamin A preparation used has suitable stability for use in Flour Fortification. The optimum method for ensuring adequate stability of vitamin A in powder form is considered to be encapsulation.

<sup>&</sup>lt;sup>2</sup> Both ester types, namely palmitate or acetate, which are both approved in FCC, USP and Ph Eur, can provide proper stability. The use of palmitate, even though historically widely in use, is no indicator for evidence of stability of a vitamin A preparation

- 5.7.2. To accomplish this it is recommended that each lot of vitamin A be subjected to a standardized accelerated stability test<sup>3</sup> with results available to the purchaser on request. The supplier of vitamin A should be subject to a prequalification test for vitamin A stability and a periodic audit as part of the Premix Manufacturers Quality System.
- 5.7.3. The premix manufacturer should also include a suitable *manufacturing overage* to insure the level of vitamin A in the premix meets the specified minimum level at the time it is used in the mill. This should extend through the allowable storage period of the premix (e.g. 6 months after manufacture).
- 5.7.4. It is recommended that the form of vitamin A used be defined as precisely as possible without specifying actual brand names.<sup>4</sup>
- 5.8. Excipients: Fillers and Free-flow agents
  - 5.8.1. Excipients are used to adjust the dilution of the premix to achieve a certain addition rate, to keep it free-flowing and non-clumping, and to lower its bulk density. The types of excipients used should be made known or labeled, but not the levels used since they are variable.
  - 5.8.2. Free flowing agents should be included in all premixes where they are considered to be required to ensure uniform flow properties
  - 5.8.3. It is recommended that if starch is used as filler, wheat starch be used for wheat flour fortification and corn starch for maize meal fortification to prevent any concerns on allergies. Excipients like maltodextrin and mineral salts are non-allergenic.
  - 5.8.4. Any changes to excipient types which may have significantly different Specific Gravity must be informed by the supplier to the milling industry advised so that feeders can be recalibrated.
  - 5.8.5. Unless required by government regulations excipients need not be labeled on fortified food products.

#### 6. Premix Ordering and Tenders

- 6.1. Purchasers of premixes (be they distributors, flour mills, milling associations, government agencies or NGOs) should attempt to be very clear on what they want to order. It is recognized that this will not always be possible due to a lack of information or experience by the purchaser, in which case it is the duty of the premix producer to clarify the order making sure it makes common sense and conforms to national regulations.
- 6.2. Premix orders and tenders should include the following:

<sup>3</sup> A moist flour test has been proposed by the Working Group on Vitamin A, Atlanta April 2008. The testing procedure is to be established by the AACC International Vitamin Assay Committee, which is represented on the FFI Premix Committee. The acceptable stability level using that procedure will then be established by consensus of the FFI Premix Committee.

<sup>4</sup> It is understood that Vitamin A product names such as 250 SD and 250 CWS can be generic.

- 6.2.1. The country in which the premix will be used.
- 6.2.2. The food product that will be fortified.
- 6.2.3. The quantity of premix to be ordered.
- 6.2.4. Where the premix is to be delivered.
- 6.2.5. When the premix is to be received or shipped.
- 6.2.6. The addition rate of the premix, stated in grams of premix per metric ton of flour along with whatever units are used.
- 6.2.7. The type of iron to be used.
- 6.2.8. If known, the fortification standards that the premix must achieve or the types and levels of micronutrients to be added at a specified addition rate, but not both.
- 6.3. Where FF has become a standard practice for which specific premixes have been designed (e.g. KAP #1 in Central Asian countries), ordering that premix by name or code number can be sufficient to specify composition.
- 6.4. It is recommended that the purchaser specify the exact composition of the premix (i.e. the percentage of each ingredient in the premix) unless specified by country regulations
- 6.5. Purchasers should always try to order premix in a timely fashion to avoid *hurried orders* that require special production and delivery. They should also avoid ordering excessive amounts that will result in the product exceeding its expiration period.
- 6.6. Tenders <u>may</u> specify package type, container net weight and religious dietary status.
- 6.7. If samples are requested, the manufacturer should provide production samples of the same premix if they have made it in the past. If they have not previously made this particular premix or have no samples of it, manufacturers are required to provide a sample using all the same ingredients that they would use under actual production.
- 6.8. If the purchaser requires some form of pre-shipment inspection, it is the responsibility of the purchaser to make arrangements for doing that.<sup>5</sup>

#### 7. Premix Manufacturing

- 7.1. Premix manufacturing consists of the following facilities:
  - 7.1.1. Receiving and warehousing of raw materials
  - 7.1.2. Weighing devices for ingredients and finished product
  - 7.1.3. Mixing equipment
  - 7.1.4. Packaging

<sup>&</sup>lt;sup>5</sup> The FFI Premix Committee can assemble a list of organizations that can provide pre-shipment inspections and reputable laboratories in different parts of the world able to provide third party analyses if requested.

- 7.1.5. Laboratory for analytical testing of ingredients and finished product
- 7.1.6. Shipping and storage.
- 7.2. Premix manufacturing should be conducted by an organization and facility independent and separate from the premix user or flour milling company. It is acceptable for mills to dilute premixes to make fortification preblends if required.
- 7.3. All of these facilities should be kept in a reasonable state of sanitation and security that include:
  - 7.3.1. Separation from outside space so that animals, insects, pests or nonemployees cannot enter processing area.
  - 7.3.2. Periodic integrated pest management and sanitation inspections using documented procedures.
- 7.4. The production and warehouse facilities must be a separate area dedicated to human food products. The same space and equipment must not be used for making pharmaceuticals, animal feed products or chemicals. If such products are made in the same building the warehouse and production must be separated by a wall with access between the two areas through offices only.
- 7.5. Mixers and packaging equipment with which the final product comes into contact must be cleaned out between batches of products containing different ingredients. (As an example, the equipment must be cleaned between a batch of premix containing ferrous sulfate and one containing elemental iron powder.) The cleanout method must be checked for adequacy and documented.
- 7.6. The mixing process and equipment used must have been validated to ensure that the premix is mixed uniformly and consistently. The mixing process should be validated on a periodic basis as part of the Good Manufacturing Procedures.

#### 8. Quality Control

- 8.1. Premix manufacturers are required to include the following in their regular quality assurance and quality control procedures.
  - 8.1.1. At the start of production of a new premix formula the supplier shall demonstrate that the CV of the micronutrients is less than 10% based on a minimum of 3 samples per batch. Samples from the first 3 lots shall be checked for the declared shelf life and that samples shall be retained as per 8.1.3
  - 8.1.2. Maintaining records for at least 3 years of ingredients and manufacturing formulation used for each lot of premix produced.
  - 8.1.3. Retaining samples of each lot of premix produced for at least 3 years.
  - 8.1.4. Analytical testing of all micronutrients (see exception) in each lot of premix and reporting results in a Certificate of Analysis (CoA).
    - 8.1.4.1. Vitamin  $B_{12}$  is the one vitamin exempted from this requirement due to the difficulty and error in its testing. Its inclusion and level may

be "verified by audit". The procedure used for doing this must be documented and made available to the customer.<sup>6</sup>

- 8.1.4.2. The analytical testing can be on a separate site from the manufacturing and can be done by an outside or independent laboratory.
- 8.1.5. The analytical methods used to test for levels of micronutrients in a premix are at the discretion of the premix company. They need not be "approved" procedures unless required to be so by regulation in a country. However, the following information should be available on the procedures used when asked:
  - 8.1.5.1. A complete description of the method, reagents and equipment used.
  - 8.1.5.2. The within house error or repeatability of the method, preferably expressed as the % coefficient of variation or CV (the standard deviation as a percentage of the mean). This is to be determined by testing the same sample of premix at least 7 times on different days, preferably determined once each year.

#### 9. Technical Information and Labeling

- 9.1. **A product information or fact sheet** should be prepared on each premix. This sheet should contain the following information. The premix supplier should check to make sure the mill has this document and that it is made available to all operating plant employees.
  - 9.1.1. The name, address and contact information of the premix company.
  - 9.1.2. Location where the premix is manufactured if different from the above.
  - 9.1.3. The name or code number of the premix.
  - 9.1.4. The intended use of the premix.
  - 9.1.5. The ingredient composition of the premix usually in descending order. This is to be shown as the chemical name: e.g. *ferrous sulfate* and not iron.
  - 9.1.6. The recommended addition rate of the premix to flour, which should always be stated in grams of premix per metric ton of flour along with whatever other units are used.
  - 9.1.7. The levels of micronutrients added at the recommended addition rate. This is to be shown as the nutrient name: e.g. *iron* and not dried ferrous sulfate.
  - 9.1.8. The assay standards for the premix against which the CoAs can be compared. This should be in the same units as used in the CoA.
  - 9.1.9. Safe handling instructions and other safety precautions.

<sup>&</sup>lt;sup>6</sup> The committee needs to agree on the procedure for "verification by audit, the conditions under which it can be used, and how it should be reported.

- 9.1.10. Recommended storage with allowable storage periods or shelf life of premix.
- 9.2. A **product handling sheet** in the local language. In situations where the plant employees can not read the above product information sheet, a separate, abbreviated sheet should be prepared in their language. This should include the product name with information on its addition rate, storage and handling.

#### 9.3. Certificate of Analysis (CoA)

- 9.3.1. The CoA should show the lot number of each lot along with its analysis.
- 9.3.2. It should be dated and include contact information on the person to contact in case of questions.
- 9.3.3. CoAs can be included with a shipment, or sent ahead of time by fax or email or both. Mills will be instructed not to use product lots for which there is no CoA available.
- 9.3.4. In may indicate the date of manufacture or expiration date or "use by" date if not imbedded in the lot number.

#### 9.4. Labels

- 9.4.1. A label should be firmly affixed to every box of premix. The label should show:
  - 9.4.1.1. The manufacturer name with contact information
  - 9.4.1.2. The name or code number of the product
  - 9.4.1.3. The intended use of the product
  - 9.4.1.4. Handling precautions if any (in the local language and English)
  - 9.4.1.5. The lot number
  - 9.4.1.6. The date of manufacturer or "use by" date. (This is sometimes imbedded in the lot number, in which case it should be explained on the product information sheet on how to extract the date)
  - 9.4.1.7. The recommended application rate
  - 9.4.1.8. The net weight
  - 9.4.1.9. A list of ingredients is optional depending on the requirements in the country.
- 9.4.2. When supplying multiple premixes to the same plant it is advisable that their labels have different colors so that plant personnel can easily determine which one to use.

#### 10. Mill Responsibilities and Relationship with Premix Supplier

10.1. The Mill Purchasing Department should maintain and update the following information about the supplier on file:

- 10.1.1. The name and address of the supplier's company or organization.
- 10.1.2. The name and phone number of the principal contact to which the order should be directed.
- 10.1.3. The name or type of the premix to order
- 10.1.4. The standard amount of the premix that is ordered and order placement frequency
- 10.1.5. The price history of the premix
- 10.1.6. The method and time of delivery
- 10.2. Mills are responsible for ordering premix in time so as not to run out. Premix suppliers can assist by keeping tabs on their usage and notifying them when it might be time to order.
- 10.3. On receiving a premix shipment the mill should check that it complies with the order in type and quantity, that it has a CoA with each lot and that none of the boxes are damaged. If there is damage that the mill assesses to have harmed the integrity of the premix, they can return the damaged boxes to the supplier for credit or replacement.
- 10.4. On opening a box of premix the miller should run a gloved hand through the premix to check for lumps, noticeable granulation, contamination or a color different from what they are used to. If a problem is found they should immediately contact the supplier and arrive at some mutually agreeable solution for dealing with it. The supplier or premix manufacturer if contacted must be willing to assist the mill in situations like this since it indicates a quality problem that needs to be solved. A reluctance or avoidance in doing would be an unacceptable practice.
- 10.5. Mills are responsible for premix on their premises that has exceeded its expiration date. If the premix manufacturer is willing, a sample of the premix can be sent to them for analysis. If it assays within acceptable specifications it can be used for an additional period given by the manufacturer. If not, the mill is responsible for its disposal following local requirements. Mills should not expect producers or distributors to accept return of expired or unused premix.
- 10.6. It is recommended that mill staff meet with the premix supplier or agent at least once per year to review premix performance with respect to usage, timeliness of delivery, quality, and price. The supplier is expected to be available in person at the mill or at some location agreeable to the mill for this purpose.
- 10.7. It is desirable to have the premix manufacturer visited and inspected by the purchasing agent and/or its representative, but this is not always possible. A third party inspection and/or certification may be considered as fulfilling this requirement.

#### **11. Pricing and Quotations**

- 11.1. The most effective method to reduce premix cost is to have a healthy competition between different premix manufacturers. This requires straightforward comparison of costs.
- 11.2. One of the objectives of these recommended practices is to standardize the way premixes are priced so that purchasers can better compare costs and avoid confusion. All premix prices and quotations should include the "cost/insurance freight or CIF" cost of the delivered product in U.S. \$ per metric ton of fortified flour or meal at the intended premix addition rate.
  - 11.2.1. This price need not include local duties or taxes. If it does include them it should be so noted.
  - 11.2.2. Additional forms of price quotations can be included, such as the cost per unit premix weight or box of the premix in other currencies and the FOB (undelivered) price, but these forms are supplemental and not to replace the aforementioned method.
- 11.3. In some cases premix manufacturers may provide quotations and prices using a combination of premix, equipment such as feeders and technical assistance such as analytical capacity, quality control and or training of key personnel at start up phase of flour fortification. This can occur in cases where long-term supply agreements may be considered. If such arrangements are being proposed the sales agreements and contracts must specify that additional support is being included. Millers are encouraged to determine what the actual cost of the premix will be in such arrangements. It is recommended to always consider, if separate procurement of equipment, technical service and premix is a more favorable option.
- 11.4. It is understood that premix producers and suppliers are free to price their product at whatever value they wish to with no interference or price controls by government.
- 11.5. Countries are strongly urged to eliminate tariffs and import duties on premixes, as that would constitute a tax on a public health program.

#### References

Guidelines for the Fortification of Foods with Micronutrients, FAO/WHO 2007

Vitamin and Mineral Fortification of Wheat Flour and Maize Meal, The Micronutrient Initiative, 2005