

THE MICRONUTRIENT INITIATIVE MICRONUTRIENT PREMIX STANDARD

1. PURPOSE:

This document is designed to provide guidelines for international organizations, government agencies, non government organizations, and others who are involved in the procurement of micronutrient premixes and or staple foods fortified with micronutrients. These premixes and fortified foods are used in refugee and vulnerable group feeding programmes.

2. SCOPE:

This document describes the standards to be applied to the ingredients, processing, quality assurance, packaging and distribution requirements for the manufacture of micronutrient premixes.

3. APPLICABILITY:

The standards and requirements in this document are specific to the manufacture of micronutrient premixes to be used for fortifying staple foods for populations suffering from micronutrient malnutrition caused by low caloric intake and or low micronutrient content and foods used in emergency rations distributed to human populations affected by famine, natural disasters and war.

These premixes can be used in the processing of the following types of foods:

- 3.1 Staple foods such as flours and meals processed from wheat, maize, barley, sorghum, millet, other cereals and legumes such as beans, lentils, peas and other pulses.
- 3.2 Blended foods such as wheat/soy and maize/soy blends, cereal/pulse/oil blends, other precooked foods and fortified drink rations.
- 3.3 Processed foods such as emergency ration biscuits, nutrition biscuits, etc.

4. DESCRIPTION:

Micronutrient premixes are blends of vitamins and minerals which when added to staple foods will improve the micronutrient profile of the staple food as consumed by the recipient. Premixes may contain multiple vitamins and minerals at levels to be determined by qualified nutritionists to assure that the recipients receive sufficient percentage of Recommended Daily Allowance, (RDA)

5. COMPOSITION:

Micronutrient premixes shall consist of vitamins, minerals and a carrier. The granulation profile of all the ingredients including the carrier shall be similar so that they can be uniformly dispersed during blending and that the dispersion remains uniform during distribution and storage. It is recommended that the carrier used be a flour or fine meal of a staple food familiar and acceptable to the recipient.

The table below lists vitamins, minerals and carriers which can be used in such premixes:

Table S.1 List of Vitamins, Minerals, and Carriers

Vitamin	Mineral	Carrier
Vitamin A Vitamin B1 Vitamin B2 Vitamin B3 Vitamin B6 Vitamin B12 Folic Acid	Iron, reduced Calcium Carbonate Zinc Sulphate	Wheat flour Corn (maize) flour Wheat starch Corn starch Rice flour

The quantity of vitamins and minerals shall be determined from:

- 5.1 The assessment of the micronutrient need of the recipients by qualified nutritionists or current available data of existing premixes.
- 5.2 The percentage Recommended Daily Allowance
- 5.3 The dosage rate of the premix at the point of blending with the staple food
- 5.4 The degree of bio-availability of each.

Vitamin C

Vitamin C is not recommended for micronutrient premixes which will be used to fortify staple cereal based meals and flours. These staple foods are usually cooked with water. During this process any vitamin C in the staple food will react with the protein and starch and will dissipate. Secondly, Vitamin C can interact with the Vitamin A upon storage. It is recommended that alternative methods of introducing Vitamin C into the diet be used.

6. INGREDIENTS SPECIFICATIONS:

The following specifications should be applied to each of the ingredients

6.1 Vitamins:

- 6.1.1 All vitamins shall meet either Food Chemical Codex standards or national pharmacopeia standards (i.e. U.S.P., BP or equivalent etc.).
- 6.1.2 All vitamins shall be readily bio-available.
- 6.1.3 All Vitamins are considered to be highly reactive (to light, moisture and other vitamins) such as Vitamin A. All shall be stabilized or encapsulated.
- 6.1.4 The granulation profile shall be appropriate for the carrier used.

6.2 Minerals:

- 6.2.1 All minerals shall meet either Food Chemical Codex standards or national pharmacopeia standards (i.e. U.S.P., BP or equivalent etc.).
- 6.2.2 All minerals shall have some degree of bio-availability
- 6.2.3 The granulation profile shall be appropriate for the carrier used.

- 6.3 **Carrier:**
- 6.3.1 All carriers shall meet Food Chemical Codex standards or national standards of identity (i.e. applicable food and drug regulations)
- 6.3.2 The moisture content of the carrier should not exceed 13.5%
- 6.3.3 The granulation profile should be compatible with the granulation of the vitamins and minerals and the staple food which will be fortified with the premix.
- 6.3.4 The carrier shall be acceptable as a food to the recipient of the fortified staple.

7. MANUFACTURING:

The manufacturer of the premix shall:

- 7.1 Comply with the applicable Food and Drug Legislation and Regulations.
- 7.2 Have the production capacity to produce the quantity of premix required in a timely manner
- 7.3 Have established and documented good manufacturing procedures (GMPs)
- 7.4 Equipment suitable for the manufacture of micronutrient premixes such as scales, sifters, blenders and packaging equipment. Stainless steel equipment is recommended.
- 7.5 Maintain adequate written records of production
- 7.6 Be registered or licensed (as applicable) as a food manufacturer or pharmaceutical company.

8. QUALITY ASSURANCE:

Preference should be given to those companies which have a formal Quality Assurance System such as ISO 9001 or 9002, HACCP or formal GMP programme.

The manufacturer shall:

- 8.1 Have a properly trained person who is responsible for the management of the quality assurance programme.
- 8.2 Ingredients will be used on a first-in, first-out basis
- 8.3 Ingredients will have a documented certificates of analysis
- 8.4 Operating personnel will have been trained in Good Manufacturing Practices and Workplace Hazardous Material Information System
- 8.5 Have Critical Control Points identified.
- 8.6 Have a system to monitor Critical Control Points and to take corrective action when appropriate.
- 8.7 Have a Finished Product Testing programme in place. Outside testing laboratories may be used to analyze finished products.
- 8.8 Provide a certificate of analysis for each lot of premix produced to include lot number or date of manufacture, vitamin and mineral content and expiry date. Methods for testing should be official methods (i.e. AOAC, AACC or national standard reference methods)

It is recommended that each manufacturer be subject to a pre-qualification audit prior to acceptance of any tenders.

**THE MICRONUTRIENT INITIATIVE
MICRONUTRIENT PREMIX
SAMPLE TENDER FORM**

1. **PRODUCT:** PREMIX <name>
2. **DESCRIPTION:** Premix <name> is a special premix for the fortification of <type> cereal flour or <name> blend in <name of country> or <name of agency>. The product must be manufactured under applicable Food and Drug legislation and regulations following Good Manufacturing Practices.

The addition of <grams> of premix per 100 kg will add the following nutrients:

Nutrient	Standard in mg per kg
Vitamin 1 Vitamin 2 Vitamin 3 etc	
Mineral 1 Mineral 2 etc	
Carrier	Wheat and or maize flour or starch

Vitamins used in this premix must be stabilized or encapsulated. All ingredients should meet applicable Food Chemicals Codex and National Pharmacopeia standards.

3. **APPEARANCE:** <name of colour>, free flowing powder
4. **APPLICATION RATE:** <grams> per 100 kg of flour or meal
5. **PRODUCT SPECIFICATIONS:**

Assay	Specification % minimum
Vitamin 1	< >
Vitamin 2 etc	< >
Mineral 1	< >
Mineral 2	< >

Microbiological Specifications (per gram)

Total plate count	300 max
Yeast & Mold	150 max

Certificates of analysis shall be furnished for each lot.

6. **PACKAGING:** Premix should be packed in 25 kg quantities in multi-wall polythene lined bags or polythene bag lined corrugate boxes.
7. **STORAGE:** The premix must be kept covered and tightly sealed when not in use. The shelf life shall be not less than six months.
8. **FOOD SAFETY:** Applicable Material Safety Data sheets must be provided.

EFFECTIVE DATE:

REVISION LEVEL:

PREPARED BY:

APPROVED: