

**GUIDELINES on the REGISTRATION of PREMIXES FOR
FOOD FORTIFICATION in UGANDA
(3rd DRAFT, July 2007)**

1.0 GENERAL

These guidelines apply to regulation of fortificants used to enrich commonly eaten food stuffs e.g. salt, wheat flour, maize flour, rice, milk or sugar with essential micronutrients to prevent and eliminate nutritional deficiencies and other related health problems.

Under these guidelines, the focus of NDA will be on how fortificant premixes are manufactured and handled before they are added into the food vehicles.

Note: The responsibility of controlling and regulating food products that have been fortified shall be the responsibility of UNBS.

Definitions:

Diluent:

Means a suitable, inert, food-grade carrier for micronutrients.

Enrichment:

Refer to adding nutritional value to a food stuff by fortifying it with one or more nutrients.

Food vehicle:

Means foodstuff that is selected to carry selected micronutrients.

Fortificant:

Means the prescribed compound which provides the specified micronutrient e.g Nicotinamide, Pyridoxine Hydrochloride, Thiamine mononitrate or Retinol palmitate.

Fortification mix:

Means a premixed blend of fortificants and diluents formulated to provide specified and determinable amounts of micronutrients.

Fortification:

Means the addition of one or more micronutrients by means of a fortificant or fortification mix to a foodstuff, whether or not it is normally contained in a food stuff, for the purpose of preventing or correcting a demonstrated deficiency in one or more micronutrients in the general population or a specific population group of Uganda.

Micronutrient:

Means a natural or synthesized vitamin, mineral or trace element that is essential for normal growth, development and maintenance of life and of which deficit will cause characteristic biochemical or physiological changes.

2.0 REGULATION OF FORTIFICANT/PREMIXES

2.1 National Drug Authority (NDA) shall regulate premixes based on standards for food fortification established by Uganda National Bureau of Standards (UNBS). UNBS shall be responsible for the control and regulation of foodstuffs that have been fortified.

2.2 NDA shall maintain a database of authorized suppliers/manufacturers of premixes. Only approved manufacturers shall be allowed to supply premixes in Uganda.

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- 2.3 For a manufacturer to be approved, the manufacturer shall have to be inspected by NDA for compliance to the required cGMP standards. Each approved manufacturing site shall be re-inspected every after 3 years.
- 2.4 After the initial inspection, subsequent inspection shall be waved off for manufacturers in countries with strong regulatory agencies. Guidelines for approval of sites from strong regulatory agencies shall be followed.
- 2.5 The registration shall be on basis of the supplier/manufacturer. Database of registered firms that can supply premixes shall be maintained giving details of Name and full address of the manufacturer, registration number, date of inspection, cGMP status of the manufacturer, type of premix supplied i.e. solid powder form or liquid form, Targeted food vehicles for the supplied premixes, date of next inspection.
- 2.6 Applicant intending to export into Uganda premixes, will have to fill a form that gives particulars of the applicant and the types of fortificant products intended to be introduced on the Ugandan Market.
- 2.7 Each applicant shall pay an inspection fee for each manufacturing facility as per structure below:

Location of manufacturing site	Inspection fees (US dollars)
Within East Africa	\$2,000.00
Within Africa	\$3,000.00
Outside Africa	\$4,000.00

- 2.8 No manufacturer of fortified foodstuffs shall be allowed to import into Uganda and use fortification premixes from suppliers/manufacturers that have not been approved and registered by NDA.

3.0 MONITORING AND CONTROL OF FORTIFICANT/PREMIKES

- 3.1 Each consignment of fortification premix that is imported into Uganda shall receive a verification certificate before importation.
- 3.2 An importer shall apply for the verification stating name of fortification premix, generic names of ingredients in the premix, quantities of each ingredient per unit pack, pack size, total quantity to be imported and name of manufacturer. The application shall be accompanied by a fee for verification of imports and two copies of the proforma invoices.
- 3.3 Each consignment of fortification premix that is imported into Uganda shall be inspected at the port of entry for assurance of quality, integrity of packaging, appropriateness of labelling and to ensure supplies are from approved sources and premix standards established by Uganda National Bureau of Standards (UNBS).
- 3.4 Where there is reason to suspect that quality of fortificants is questionable, such consignments shall be sampled for testing at National Drug Quality Control Laboratory. The cost of analysis shall be covered by the importer.
- 3.5 Premix batches that fail tests for analysis shall be rejected.
- 3.6 Each batch of every consignment shall be accompanied by an authenticated certificate of analysis that states;
 - i). Name of the premix

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- ii). Batch Number
 - iii). Manufacturing date
 - iv). Packaging Date if different from Manufacturing date
 - v). Expiry date
 - vi). Identification for each micronutrient
 - vii). Assay for each micronutrient
 - viii). Impurity tests
 - ix). Tests for microbial limits
 - x). Certification that premix is food grade
- 3.7 The inspector at the port of entry shall ensure that premixes are properly labelled. Labels should contain the following minimum information:
- i) Name of the premix
 - ii) quantity per pack.
 - iii) date of manufacture
 - iv) date of expiry
 - v) batch number
 - vi) storage conditions
 - vii) name and address of manufacturer
 - viii) Direction for usage/Mixing directions
- 3.8 **Manufacturer's of Fortificants/fortification Premixes:**
- i) All manufacturers of premixes shall keep monthly records of premixes sold to wheat, Maize meal, oil or salt manufacturers (the purchasers). The premix Manufacturer shall include names and addresses of the purchasers in the record.
 - ii) The premix manufacturer shall ensure that the quality standards for diluents and fortificants before and after mixing are in accordance with established official reference specification e.g. USP or Food Chemicals Codex (FCC).
 - iii) The manufacturer shall also ensure that each batch of a fortification mix for the various vehicles complies with fortification standards issued by UNBS.
- 3.9 **Importer's of Premixes:**
- i) Importers of fortification premixes shall be Food processing industries involved in fortification of their food products.
 - ii) Stores used by food processing industries for fortification premixes are to be inspected by NDA for suitability of premises. The facilities are to apply for a certificate of suitability of premises for the premix stores annually.
 - iii) Food fortifying facilities with approved suitability of premises for premix stores would be allowed to import, handle and store the premixes.
- 3.10 **Monitoring and surveillance:**
- Monitoring and surveillance for the storage, handling and use of fortification premixes by the fortifying industries shall be carried out periodically.
- i) Fortifying industries are to ensure that monthly records of the amount of premixes used every month are kept. These records are to correspond with the monthly production records.
 - ii) Premixes are to be kept within the storage conditions laid down by the manufacturer.

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- iii) All critical stages of that involve handling and use of premixes are to be carried out in accordance to cGMP requirements to ensure quality, safety and effectiveness of premixes is guaranteed.