# GOVERNMENT NOTICES
# GOEWERMENTSKENNISGEWINGS

## DEPARTMENT OF HEALTH
## DEPARTEMENT VAN GESONDHEID

**No. R. 900** **16 September *2005***

FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, **1972**
(ACT NO. **54 OF 1972)**

REGULATIONS RELATING TO THE FORTIFICATION OF CERTAIN FOODSTUFFS: AMENDMENT

The Minister for Health intends, in terms of Section 15 (1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. **54** of 1972), to make the regulations in the Schedule.

interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for attention of the Director: Nutrition), within one month of the date of publication of this notice.

SCHEDULE

DEFINITIONS

1. In these regulations any word or expression defined in the Act and not defined herein bears the same meaning as in the Act and unless the context otherwise indicates-

"Department" means the national Department of Health;

"**diluent**" means a suitable, inert, food-grade carrier for the micronutrients;

"**electrolytic** iron" means elemental iron as per specification in the latest edition of Food Chemical Codex:

"enrichment" means the addition of one or more nutrients to a foodstuff whether or not it **is** normally contained in a foodstuff with the sole purpose of adding nutritional value to the food;

"**food** vehicle" means dry and uncooked wheat flour, dry and uncooked maize meal and bread prepared with and containing at least 90% fortified wheat flour, excluding water;

"**fortificant**" means the prescribed compound which provides the specified micronutrient;

"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 fortification mix to a foodstuff whether or not it is normally contained in a foodstuff for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the general population or specific population group of South Africa as determined by the Department;

"**maize** meal" means all milled, uncooked maize products and includes super, special, sifted and un-sifted maize meal, but excludes samp, grits, maize rice; and maize flour;

**'*micronutrient"** means a natural or synthesised vitamin, mineral, or trace element that is essential for normal growth, development and maintenance of life and of which a deficit will cause characteristic biochemical or physiological changes;
**"quality control"** means the measures applied and the steps taken by a manufacturer of wheat and maize meal foodstuffs to ensure that the correct procedures are being followed and the set criteria are being met in administering fortificants to food vehicles;
**"SABS"** means the South African Bureau of Standards, a statutory organization established in terms of the Standards Act, 1993 (Act 29 of 1993);

**"the Act"** means the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972);

**"Vitamin A"** means protected, stabilized Vitamin A/retinyl palmitate containing 75 000 mcg Retinol equivalents (RE) activity per gram and specifying on the label of its container, the transport and storage conditions and date up to which the product will comply with the requirements stipulated in Tables 1, 2a, 2b, 3 and 4 of these regulations;

**"wheat bread"** means all baked bread prepared with and containing at least 90% fortified wheat flour excluding water;

**"wheat flour"** means all milled, dry and uncooked wheat products with an ash content of more than 0.60% on a moisture-free basis but excludes crushed wheat, pearled wheat, semolina, wheat flour with an ash content of less than 0.60% on a moisture-free basis and self-raising flour.

**GENERAL PROVISIONS**

2 Any person who manufactures, imports, or sells foodstuffs identified as food vehicles, which have not been fortified in accordance with these regulations, including the requirements specified in Annexure I, is be guilty of an offence.

**3.** Any person who manufactures, imports or supplies a fortification mix for the purpose of these regulations, without being registered with the Department, including the requirements specified in Annexure II, is guilty of an offence.

**4** A person desiring to manufacture, import or supply a fortification mix must apply to the Director-General for registration by submitting the information specified in Annexure III.

5. The registration referred to in regulation **4** is valid for a period of one year.

6. Registered manufacturers, importers or suppliers of fortification mixes must issue a certificate of compliance as indicated in Annexure IV.

*7.* Registered manufacturers, importers or suppliers of fortification mixes must comply with the principles set out in Annexure II.

***8*** Manufacturers and importers of food vehicles-

(a) may only obtain the fortification mix from companies that have registered with the Department; and

(b) must keep on record a certificate of compliance for every batch of fortification mix in the format specified in Annexure IV.

SPECIAL PROVISIONS

9. (a) The formulation of the fortification mix for wheat flour based on the micronutrient requirements specified in Annexure V, Table 4a must comply to the minimum levels as follows:

TABLE ▮ :FORTIFICATION **MIX** FOR WHEAT FLOUR

| Fortificants and diluent | **Micronutrient requirements** (per **1 kg** flour) | **Fortificant requirements** (per **1 kg** flour) | **Fortification mix (g/kg)** |
|---|---|---|---|
| Vitamin A palmitatel (Activity: 75 000 mcgRE2/g) | 1786 mcgRE | 23.8095 mg | 119.0475 **g** |
| Thiamin mononitrate (Activity: 78% min.) | 1.9444 mg | 2.4929 mg | 12.4644 **g** |
| Riboflavin | 1.7778 mg | 1.7778 mg | 8.8809 g |
| Nicotinamide/niacinamide | 23.6842 mg | 23.6842 mg | 118.4210 **g** |
| Pyridoxine HCl (Activity: 81% min.) | 2.6316 mg | 3.2489 mg | 16.2443 **g** |
| Folic acid (Activity: 90.5% min.) | 1.4286 mg | 1.5786 mg | 7.8927 **g** |
| Electrolytic iron3 (Activity: 98% min.) | 35.00 mg | 35.7143 mg | 178.5714 g |
| Zinc oxide (Activity: 80% min.) | 15.00 mg | 18.7500 mg | 93.7500 g |
| Diluent | - | **To** complete ,200 mg | To complete 1000 g |

1. Protected, stabilized Vitamin A palmitate containing 75 000 mcg RE activity per gram.
2. Retinol equivalents (RE) = 1 mcg retinol = 3.33 IU (International units) vitamin **A**
3. Elemental iron powder where more than 95% passes through a 325 mesh (45 microns particle size) made by an electrolytic process.

**(b)** The formulation of the fortification mix for maize meal based *on* the micronutrient requirements specified in Annexure V, Table 4b must comply with the minimum levels as follows:

TABLE **2a:** FORTIFICATION **MIX** FOR **MAIZE MEAL**

**(Super, special, sifted, unsifted)**

| **Fortificants and diluent** | **Micronutrient requirements (Per 1 kg meal)** | **Fortificant requirements (Per 1 kg meal)** | **Fortification mix (g/kg)** |
|---|---|---|---|
| Vitamin A palmitate1 (Activity: 75 000 mcgRE2/g) | 2085 mcgRE | 27.8000 mg | 139.0000 g |
| Thiamine mononitrate (Activity: 78% min.) | 2.1875 mg | 2.8045 mg | 14.0224 g |
| Riboflavin | 1.6875 mg | 1.6875 mg | 8.4375 g |
| Nicotinamide/niacinamide | 25.000 mg | 25.0000 mg | 125.0000 g |
| Pyridoxine HCl (Activity: 81% min.) | 3.1250 mg | 3.8580 mg | 19.2901 g |

| | | | |
|---|---|---|---|
| Folic acid (Activity: 90.5% min.) | 2.0000 mg | 2.2099 mg | 11.0497 g |
| Electrolytic iron3 (Activity: 98% min.) | 35.0000 mg | 35.7143 mg | 178.6714 g |
| Zinc oxide (Activity: 80% min.) | 15.00 mg | 18.7500 mg | 93.7500 g |
| Diluent | - | To complete 200 | To complete 1000 |

1. Protected, stabilized Vitamin A palmitate containing 75 000 mcg RE activity per gram
2. Retinol equivalents (RE) = 1 mcg retinol = 3.33 IU (International units) vitamin A
3. Elemental iron powder where more than 95% passes through a 325 mesh (45microns particle size) made by an electrolytic process.

10. (a) Manufacturers, importers and suppliers of un-sifted maize meal may apply to the Director-General for special permission to use a fortification mix with a reduced level of electrolytic iron.

**(b)** Where special permission was granted in terms of paragraph (a), the formulation of the fortification mix for un-sifted maize meal based on the micronutrient requirements specified in Annexure V, Table 4c must comply with the minimum levels as follows:

**TABLE 2b: FORTIFICATION MIX FOR UNSIFTED MAIZE MEAL**

**(Special permission)**

| Fortificants and diluent | Micronutrient requirements (per 1 kg meal) | Fortificant requirements (per 1 kg meal) | Fortification mix (g/kg) |
|---|---|---|---|
| Vitamin A palmitate1 (Activity: 75 000 mcgRE2/g) | 2085 mcgRE | 27.8000 mg | 139.0000 g |
| Thiamine mononitrate (Activity: 78% min.) | 2.1875 mg | 2.8045 mg | 14.0224 g |
| Riboflavin | 1.6875 mg | 1.6875 mg | 8.4375 g |
| Nicotinamide/niacinamide | 25.000 mg | 25.0000 mg | 125.0000 g |
| Pyridoxine HCl (Activity: 81% min.) | 3.1250 mg | 3.8580 mg | 19.2901 g |
| Folic acid (Activity: 90.5% min.) | 2.0000 mg | 2.2099 mg | 11.0497 g |
| Electrolytic iron3 (Activity: 98% min.) | 17.5000 mg | 17.857 mg | 89.2857 g |
| Zinc oxide (Activity: 80% min.) | 15.00 mg | 18.7500 mg | 93.7500 g |
| Diluent | - | To complete 200 mg | To complete 1000 g |

1. Protected, stabilized Vitamin A palmitate containing 75 000 mcg RE activity per gram.
2. Retinol equivalents (RE) = 1 mcg retinol = 3.33 IU (International units) vitamin A
3. Elemental iron powder where more than 95% passes through a 325 mesh (45 microns particle size) made by an electrolytic process.

(c) The fortification mix must be used at an addition rate of 200 g per ton of food vehicle indicated in Annexure VII, provided the final minimum levels in the food vehicles comply with the requirements stipulated in Tables 3 and **4.**

**(d)** The fortification of wheat flour containing wheat bran must allow for the addition of **the** fortification mix to the base flour (white bread flour) only.

11. (a) The final, minimum levels of micronutrients (fortification standards) in the fortified wheat flour at 14% moisture–basis and wheat bread at 39% moisture basis must be not less than the levels shown in Table 3 below and must be in accordance with Annexure VI, Tables 5a, 5b, 5c and 5d:

**TABLE 3: FORTIFICATION STANDARDS - WHEAT FLOUR AND BREAD**

| Micronutrient | Unit | WHEAT FLOUR | | WHEAT BREAD | |
|---|---|---|---|---|---|
| | | White | Brown | White | Brown |
| Vitamin A1 | mcgRE/kg | 1610 | 1415 | 800 | 700 |
| Thiamine | mg/kg | 3.91 | 3.79 | 2.49 | 2.54 |
| Riboflavin | mg/kg | 2.05 | 1.95 | 1.41 | 1.39 |
| Niacin | mg/kg | 38.42 | 54.76 | 27.91 | 41.59 |
| Pyridoxine | mg/kg | 2.82 | 3.07 | 2.13 | 2.67 |
| Folic acid | mg/kg | 1.36 | 1.24 | 0.74 | 0.74 |
| Iron | mg/kg | 43.65 | 47.97 | 32.26 | 34.69 |
| Zinc | mg/kg | 20.70 | 26.73 | 15.30 | 20.07 |

1. Retinol equivalents (RE) = 1 mcg retinol = 3.33 IU (International units) vitamin **A**

(b) The final, minimum levels of micronutrients (fortification standards) in fortified maize meal at 12.5% moisture basis must be not less than the levels shown in Table 4 below and must be in accordance with Annexure VI, Tables 6a, 6b, 6c and 6d:

**TABLE 4: FORTIFICATION STANDARDS - MAIZE MEAL**

| Micronutrient | Unit | MAIZE MEAL | | | |
|---|---|---|---|---|---|
| | | Super | Special | Sifted | Un-sifted |
| Vitamin A1 | mcgRE/kg | 1877 | 1877 | 1877 | 1877 |
| Thiamine | mg/kg | 3.09 | 3.86 | 4.76 | 5.57 |
| Riboflavin | mg/kg | 1.79 | 1.88 | 1.97 | 2.06 |
| Niacin | mg/kg | 29.70 | 31.86 | 34.65 | 38.25 |
| Pyridoxine | mg/kg | 3.89 | 4.25 | 4.79 | 5.42 |
| Folic acid | mg/kg | 1.89 | 1.90 | 1.92 | 1.94 |
| Iron | mg/kg | 37.35 | 40.14 | 44.28 | 50.402 |
| Zinc | mg/kg | 18.90 | 22.55 | 26.60 | 30.20 |

1. Retinol equivalents (RE) = 1 mcg retinol = 3.33 IU (International units) vitamin A.
2. Where special permission was granted in terms of regulation 10, a lower iron content of 34.65 mg/kg is allowed.

(c) The fortification standards referred to in Table 3 and Table **4** of these Regulations must be the minimum micronutrient levels in uncooked wheat flour and uncooked maize meal when sampled at the point of manufacturing, importation or sale.

(d) A sample of a fortified food vehicle, taken by an inspector in terms of the Act, must be analysed for the amounts of nicotinamide / niacinamide, or riboflavin and retinol / vitamin A palmitate, and the results of such a sample must be considered as representative of the standards prescribed by these Regulations in Table 3 and Table 4.

**Labelling of fortified foodstuffs**

12. In addition to the Regulations Governing the Advertising and Labelling of Foodstuffs made under the Act, all food vehicles must be labelled as follows:

(a) the nutrient content claims may only be used in addition to the word "fortified" on one label in cases where a micronutrient other than the specified fortificants is added to a food vehicle: provided that the claim complies with the conditions of the specific nutrient content claim.

(b) the claim "Fortified for better health" and the official fortification logo to that effect as indicated in Annexure VII are reserved only for food vehicles, that have been identified in these regulations and may be displayed on the label or in an advertising material;

(c) any person who uses the official logo referred to in Annexure VII on labels or n advertising material for foodstuffs other than in accordance with these regulations or any other regulations made in terms of the Act, is guilty of an offence;

(d) (i) the claim "Manufactured with fortified maize meal for better health" or "Manufactured with fortified wheat flour for better health", whatever the case may be, may be used for foodstuffs, other than food vehicles, prepared with and containing at least 90% of one or more of the identified food vehicles as ingredient, excluding water;

(ii) a logo as indicated in Annexure VIII, may be displayed on the label or at the point of sale on a notice displayed in the direct vicinity of where the foodstuff referred to in subparagraph (i) is displayed on the shelf and within clear sight of the consumer;

(e) minerals of the fortification mix must-

(i) in the list of ingredients, be identified individually by the compound names (electrolytic iron, zinc oxide), and

(ii) indicate the elemental mineral in the table with nutritional information;

(f) the fortification addition rate must be clearly indicated on the label of fortification mixes;

(g) The label or container of a fortification mix sold as such must indicate the date up to which the product will comply with the requirements stipulated in Tables 1, 2a and 2b of these regulations;

(h) The nutritional information declaration as described in Annexure 2 of the Regulations Relating to the Labeling and Advertising of Foodstuffs must be printed by the manufacturer on the back or side panel of food vehicles and those foodstuffs manufactured with fortified wheat flour or

fortified maize meal in letters at least 1 mm in height for lower case letters, or a bigger letter size in the case of woven polypropylene packaging material, provided the information is easily legible;

(i) The nutritional information declaration referred to in paragraph (9 as well as nutritional information relevant to the fortification specifications must be declared per daily serving and per 100 g, provided that in the case of dry, uncooked wheat flour and dry, uncooked maize meal as purchased, the daily serving may be regarded as 100g;

(j) Wherever the official logo is used, it must be utilized in the format of either Annexure VIII or Annexure IX and must be printed in a prominent position on the main panel in bold print against a contrasting or clear background on all types of packaging material. The logo must be clearly visible, legible and indelible;

(k) The official logo must be a minimum size of 25 mm for paper and plastic packaging and a minimum size of 100 mm for woven polypropylene packaging;

(l) The design of the logo must be constructed as indicated in facsimile ▮ in Annexure VIII or Annexure IX;

(m) The logo may be printed in monochrome as per facsimile 1 in Annexure VIII or Annexure IX, or in any of the selected main colours of the packaging; and

(n) Where the full colour version of the logo is used, the following colours must be used in accordance with facsimile 2 in Annexure VIII or Annexure IX:

**Grass:**
Green 1 Pantone 390 (45c 100y)

**Male's shorts:**
Green 2 Pantone 349 (100c 100y 54k)

**Sun:**
Orange 1 Pantone 123 (28m 100y)

**Back female's arms x 2, legs x 2, head:**
Orange 2 Pantone 138 (53m 100y 8k)

**Back female's skirt, front female's eyes x 2:**
Blue 1 Pantone 3015 (100c 40k)

**Front female's T-shirt:**
Blue 2 Pantone 274 (100c 100m 30k)

**Sky :**
Blue 3 Pantone 290 (10c)

**Front female's arms x 2, legs x 2, head :**
Flesh Pantone 719 (15m 18y)

**Male's T-shirt:**
Yellow Process yellow (100y)

**Male's arms x 2, legs x 2, head:**
Brown Pantone 470 (56m 78y 40k)

**Back female's T-shirt, mouth, front female's skirt and mouth:**
Red Pantone 485 (100m 100y)
**Male's hair, eyes x 2, mouth, back female's hair, eyes x 2, front female' s hair, outer circular border, all payoff lines:**
Black Process black

**Exemption**

13. Any manufacturer or importer of food vehicles who wish to be exempted from the provisions stipulated under regulation 2 should apply in writing, giving full reasons for such a request to the Director-General of the Department of Health.

**Repeal**

14. The Regulations on the Enrichment of Maize Meal, promulgated under Government notice No. R 504 of 7 April 2003 is hereby amended.

**Commencement**

15. These regulations comes into operation on the date of final publication.

**ME TSHABALALA-MSIMANG**
**MINISTER OF HEALTH**

## ANNEXURE I

## QUALITY CONTROL PRINCIPLES

## MANUFACTURERS OF FORTIFIED WHEAT FLOURS AND MAIZE MEALS

Manufacturers of wheat flours and maize meals must:

1. keep monthly records of the amount of fortification mixes used every month. These records must correspond with the monthly production records;

2. ensure that fortification mixes are stored under the conditions laid down by the manufacturer;

3 ensure that strict stock rotation procedures are adhered to in order to prevent old stock losing potency and to comply with the shelf life expiry date;

4. ensure that all critical stages of the manufacturing process are monitored to ensure that the correct dosage levels are maintained through the following measures:

   (a) checking of fortification mix feeders at least once a day to ensure that they are delivering the correct dosage levels;

   (b) performing visual checks at least twice per shift to ensure that fortification mixes are being used and that no blockages have occurred and keeping record of this;

   (c) performing two-hourly spot checks to ensure that the product has been dosed correctly by determining one of the components of a fortification mix according to the appropriate analytical method.

## ANNEXURE II

## QUALITY CONTROL PRINCIPLES

## MANUFACTURERS OR SUPPLIERS OF FORTIFICATION MIXES

Manufacturers, importers or suppliers of fortification mixes must:

1. keep monthly records of the quantities of fortification mixes sold to wheat flour and maize meal manufacturers as well as a list of the names and addresses of the aforesaid purchasers;

2. ensure that the quality standard for diluents and fortificants, independently or mixed with a diluent must be in accordance with the standards as determined in the latest edition of Food Chemicals Codex (FCC).

3. ensure that each batch of a fortification mix for the various vehicles complies with the fortification standards described in Tables 1, 2(a) and 2(b) of regulations 9 and 10 respectively;

4. keep at least one labelled retention sample per batch for the expected shell life period.

5. bear the costs of the audits and analyses mentioned in Annexure IIA.

## ANNEXURE IIA

## THE SOUTH AFRICAN BUREAU OF STANDARDS

1. The **SABS** must conduct at least two inspection audits and take two fortification mix samples per food vehicle for laboratory analysis per year in respect of all registered manufacturers/suppliers/importers, to monitor adherence to compliance with the regulations relating to the fortification of certain foodstuffs.

2. The **SABS** may if a registered manufacturer/supplier/importer no longer complies with the requirements as prescribed, suspend for such period as it may deem fit, or cancel the registration of such manufacturer/supplier/importer. Once registration is cancelled the manufacturer/supplier/importer must reapply for registration in the prescribed manner.

3. If the **SABS** suspends or cancels the registration of a manufacturer/supplier/importers, the **SABS** must notify such manufacturer/supplier/importer of such suspension or cancellation and the reason thereof, and must notify the DG of DOH for any action deemed necessary.

**4.** The SABS could institute legal actions against manufacturers/suppliers/importers in the event of transgressions of the regulations relating to fortification of certain foodstuffs.

## ANNEXURE III

**APPLICATION FORM FOR REGISTRATION OF FORTIFICATION MIXES: MANUFACTURERS, IMPORTERS & SUPPLIERS**

**1. Company Name:**
**2. Company address (Postal):**
**3. Company street address:**
**4. Company Tel. No.**
**5. Company Fax No.**
**6. E-mail address:**
**7.**

| | |
|---|---|
| **Managing Director** | |
| **Quality Assurance Manager** | |
| **Production Manager** | |

**8. Activities/facilities:**

| **Are you:** | **Yes** | **No** |
|---|---|---|
| **A packer?** | | |
| **A co-packer?** | | |
| **A manufacturer?** | | |
| **A distributor?** | | |
| **an importer?** | | |

9. Are you a Medicines Control Council (MCC) registered facility?
10. Has the company been inspected by the Inspectors (appointed in terms of section 26 of the Medicines and Related Substances Act, 1965 (Act No 101 of 1965) Yes/No
11. If yes, mention the date of the last inspection:
12. Does your company have ISO certification? Yeslno
13. Does your company have HACCP accreditation? Yes/No
14. Do you have a Quality Control Laboratory? Yes/No
15. Of those ingredients used in the manufacturing of fortification mixes, indicate which ingredients are:
Self manufactured by your company in South Africa:

Imported from the mother company elsewhere in the world:

Acquired from outside the borders of South Africa:

Acquired in South Africa:

How long has the company been in the business of manufacturing or selling fortification mixes?

| Micronutrient | Laboratory | Analytical method |
|---|---|---|
| Vitamin A | | |
| Thiamine (Vit B1) | | |
| Riboflavin (Vit 62) | | |
| Niacin (Vit B3) | | |
| Pyridoxine (Vit B6) | | |
| Folic acid | | |
| Iron | | |
| Zinc | | |

* Only accredited analytical methods for which an original certificate or certified copy from SANAS or another internationally accreditation body has been obtained and which are attached to the application (Annexure 111) will be accepted.

18. Are the original or a certified copy of accreditation for each of the above-mentioned micronutrients as per specified laboratory attached to this application form? Yes/No

ANNEXURE IV

CERTIFICATE OF FORTIFICATION MIX COMPLIANCE

(This certificate is not transferable from one batch to another)

1. Company Name:

2. Company address (Postal):

3. Company street address:

4. **Company Tel. No.**
5. **Company Fax No.**

6. **E-mail address:**

7. **DECLARATION:**
**It is hereby certified that (batch) _____ fortification mix, complies qualitatively and quantitatively with the following specification:**

**FORTIFICATION MIX SPECIFICATION**

| **Fortificants** | **Wheat flour (g/kg)** | **Maize meal (g/kg)** |
|---|---|---|
| Vitamin A palmitatel, (Activity: 75 000 mcgRE/g) | 119.0475 g | 139.0000 g |
| Thiamine mononitrate (Activity: 78% min.) | 12.4644 g | 14.0224 g |
| Riboflavin | 3.6889 g | 8.4375 g |
| Nicotinamide/Niacinamide | 118.4210 g | 125.0000 g |
| (Activity: 81% rnin.) | | 19.2901 g |
| Folic acid (Activity: 90.5% rnin.) | 7.8927 g | 11.0497 g |
| Electrolytic iron (Activity: 98% min.) | 178.5714 g | 178.5714 g2 |
| Zinc oxide (Activity: 80% min.) | 93.7500 g | 93.7500 g |
| **Diluent(s) (specify): .....** | **To complete 1000 g** | **To complete 1000 g** |

1. Retinol equivalents (RE) = 1 mcg retinol = 3.33 IU (International units) vitamin A
2. Where special permission was granted for un-sifted maize meal, a lower electrolytic iron level of 89.2857 g/kg must be used.

8. Fortification mix addition rate: _____ g/kg

**Signed by:**
**Authorised signatory** **Printed name**
**Date:**
**Seal**

ANNEXURE V

MICRONUTRIENT REQUIREMENTS FOR FORTIFICATION OF FOOD VEHICLES

**TABLE 4(a): WHEAT FLOUR**

| | | MICRONUTRIENT REQUIREMENTS | | | | |
|---|---|---|---|---|---|---|
| | | Per 200 g white bread flour | | | | Per 1 kg flour |
| | | Nutritional Goal | | | Required | Required |
| Micronutrients | RDA | %RDA | Amount | Retention | Addition | Addition |
| Vitamin A (mcg RE) | **800** | 31% | 250 | 70% | 357 | 1786 |
| Thiamine (mg) | **1.40** | 25% | 0.3500 | 90% | 0.3889 | 1.9444 |
| Riboflavin (mg) | **1.60** | 20% | 0.3200 | 90% | 0.3556 | 1.7778 |
| Niacin (mg) | **18** | 25% | 4.5000 | 95% | 4.7368 | 23.6842 |
| Pyridoxine (mg) | **2.00** | 25% | 0.5000 | 95% | 0.5263 | 2.6316 |
| Folic acid (mg) | **0.40** | 50% | 0.2000 | 70% | 0.2857 | 1.4286 |
| Iron (mg) | **14** | 50% | 7.0000 | 100% | 7.0000 | 35.0000 |
| Zinc (mg) | **15** | 20% | 3.0000 | 100% | 3.0000 | 15.0000 |

| | | MICRONUTRIENT REQUIREMENTS | | | | |
|---|---|---|---|---|---|---|
| | | Per 200 g maize meal | | | | Per **1 kg** meal |
| | | Nutritional Goal | | | Required | Required |
| Micronutrients | RDA | %RDA | Amount | Retention | Addition | Addition |
| Vitamin A (mcg RE) | **800** | 31% | 250 | **60%** | 417 | 2085 |
| Thiamine (mg) | **1.40** | 25% | 0.3500 | **80%** | 0.4375 | 2.1875 |
| Riboflavin (mg) | **1.60** | 17% | 0.2700 | **80%** | 0.3375 | 1.6875 |
| Niacin (mg) | **18** | 25% | 4.5000 | **90%** | 5.0000 | 25.0000 |
| Pyridoxine (mg) | **2.00** | 25% | 0.5000 | 80% | 0.6250 | 3.1250 |
| Folic acid (mg) | **0.40** | 50% | 0.2000 | 50% | 0.4000 | 2.0000 |
| Iron (mg) | **14** | 50% | 7.0000 | 100% | 7.0000 | 35.0000 |
| Zinc (mg) | **15** | 20% | 3.0000 | 100% | 3.0000 | 15.0000 |

| | | MICRONUTRIENT REQUIREMENTS | | | | |
|---|---|---|---|---|---|---|
| | | Per 200 g maize meal | | | | Per **1 kg** meal |
| | | Nutritional Goal | | | Required | Required |
| Micronutrients | RDA | %RDA | Amount | Retention | Addition | Addition |
| Vitamin A (mcg RE) | **800** | 31% | 250 | 60% | 417 | 2085 |
| Thiamine (mg) | **1.40** | **25%** | 0.3500 | **80%** | 0.4375 | 2.1875 |
| Riboflavin (mg) | **1.60** | 17% | 0.2700 | 80% | 0.3375 | 1.6875 |
| Niacin (mg) | **18** | 25% | 4.5000 | **90%** | 5.0000 | 25.0000 |
| Pyridoxine (mg) | **2.00** | 25% | 0.5000 | 80% | 0.6250 | 3.1250 |
| Folic acid (mg) | **0.40** | **50%** | 0.2000 | 50% | 0.4000 | 2.0000 |
| iron (mg) | **14** | 25% | 3.5000 | 100% | 3.5000 | 17.5000 |
| Zinc (mg) | **15** | 20% | 3.0000 | 100% | 3.0000 | 15.0000 |

## ANNEXURE VI

## MICRONUTRIENT COMPOSITION OF FORTIFIED FOODSTUFFS

| | COMPOSITION PER 1kg FLOUR | | | | |
|---|---|---|---|---|---|
| Micronutrients | Fortification | Natural | Total | Tolerance | Netto |
| Vitamin A (mcg RE) | 1786 | 0 | 1786 | ±10% | 1610 |
| Thiamine (mg) | 1.9444 | 2.4000 | 4.3444 | ±10% | 3.9100 |
| Riboflavin (mg) | 1.7778 | 0.5000 | 2.2778 | ±10% | 2.0500 |
| Niacin (mg) | 23.6842 | 19.0000 | 42.6842 | ±10% | 38.4158 |
| Pyridoxine (mg) | 2.6316 | 0.5000 | 3.1316 | ±10% | 2.8184 |
| Folic acid (mg) | 1.4286 | 0.0800 | 1.5086 | ± 10% | 1.3577 |
| Iron (mg) | 35.0000 | 13.5000 | 48.5000 | ± 10% | 43.6500 |
| Zinc (mg) | 15.0000 | 8.0000 | 23.0000 | ±10% | 20.7000 |

| | COMPOSITION PER 1 kg FLOUR | | | | |
|---|---|---|---|---|---|
| Micronutrients | Fortification | Natural | Total | Tolerance | Netto |
| Vitamin A (mcg RE) | 1572 | 0 | 1572 | ±10% | 11415 |
| Thiamine (mg) | 1.7111 | 2.5000 | 4.2111 | ±10% | 3.7900 |
| Riboflavin (mg) | 1.5645 | 0.6000 | 2.1645 | ±10% | 1.9481 |
| Niacin (mg) | 20.8421 | 40.0000 | 60.8421 | ±10% | 54.7579 |
| Pyridoxine (mg) | 2.3155 | 1.1000 | 3.4155 | ±10% | 3.0740 |
| Folic acid (mg) | 1.2572 | 0.1200 | 1.3772 | ±10% | 1.2395 |
| Iron (mg) | 30.8000 | 22.5000 | 53.3000 | ±10% | 47.9700 |
| Zinc (mg) | 13.2000 | 16.5000 | 29.700 | ±10% | 26.7300 |

**TABLE 5(c): WHITE BREAD**

| | COMPOSITION PER 1 kg BREAD (± 667 g flour) | | | | |
|---|---|---|---|---|---|
| Micronutrients | Fortification | Natural | Total | Tolerance | Netto |
| Vitamin A (mcg RE) | 834 | 0 | 834 | ± 5% | 800 |
| Thiamine (mg) | 1.1673 | 1.6000 | 2.7673 | ± 10% | 2.4901 |
| Riboflavin (mg) | 1.0672 | 0.5000 | 1.5672 | ± 10% | 1.4105 |
| Niacin (mg) | 15.0075 | 16.0000 | 31.0075 | ± 10% | 27.9068 |
| Pyridoxine (mg) | 1.6675 | 0.7000 | 2.3675 | ± 10% | 2.1308 |
| Folic acid (mg) | 0.6670 | 0.1500 | 0.8170 | ± 10% | 0.7353 |
| Iron (mg) | 23.3450 | 12.5000 | 35.8450 | ± 10% | 32.2605 |
| Zinc (mg) | 10.0050 | 7.0000 | 17.0050 | ± 10% | 15.3045 |

| Micronutrients | COMPOSITION PER 1 kg BREAD (± 667 g flour) | | | | |
|---|---|---|---|---|---|
| | Fortification | Natural | Total | Tolerance | Netto |
| Vitamin A (mcg RE) | 734 | 0 | 1734 | ± 5% | 700 |
| Thiamine (mg) | 1.0272 | 1.8000 | 2.8272 | ± 10% | 2.5445 |
| Riboflavin (mg) | 0.9391 | 0.6000 | 1.5391 | ± 10% | 1.3852 |
| Niacin (mg) | 13.2066 | 33.0000 | 46.2066 | ± 10% | 41.5859 |
| Pyridoxine (mg) | 1.4674 | 1.5000 | 2.9674 | ± 10% | 2.6707 |
| Folic acid (mg) | 0.5870 | 0.2300 | 0.8196 | ± 10% | 0.7353 |
| Iron (mg) | 20.5436 | 18.0000 | 38.5436 | ± 10% | 34.6892 |
| Zinc (mg) | 8.8044 | 13.5000 | 22.3044 | ± 10% | 20.0740 |

| Micronutrients | COMPOSITION PER 1 kg FLOUR | | | | |
|---|---|---|---|---|---|
| | Fortification | Natural | Total | Tolerance | Netto |
| Vitamin A (mcg RE) | 2085 | 0 | 2085 | ±10% | 1877 |
| Thiamine (mg) | 2.1875 | 1.2500 | 3.4375 | ±10% | 3.0938 |
| Riboflavin (mg) | 1.6875 | 0.3000 | 1.9875 | ±10% | 1.7888 |
| Niacin (mg) | 25.000 | 8.0000 | 33.0000 | ±10% | 29.7000 |
| Pyridoxine (mg) | 3.1250 | 1.2000 | 4.3250 | ±10% | 3.8925 |
| Folic acid (mg) | 2.0000 | 0.1000 | 2.1000 | ±10% | 1.8900 |
| Iron (mg) | 35.000 | 6.5000 | 41.5000 | ±10% | 37.3500 |
| Zinc (mg) | 15.0000 | 6.0000 | 21.0000 | ±10% | 18.9000 |

| Micronutrients | COMPOSITION PER 1 kg FLOUR | | | | |
|---|---|---|---|---|---|
| | Fortification | Natural | Total | Tolerance | Netto |
| Vitamin A (mcg RE) | 2085 | 0 | 2085 | ±10% | 1877 |
| Thiamine (mg) | 2.1875 | 2.1000 | 4.2875 | ±10% | 3.8588 |
| Riboflavin (mg) | 1.6875 | 0.4000 | 2.0875 | ±10% | 1.8788 |
| Niacin (mg) | 25.000 | 10.4000 | 35.4000 | ±10% | 31.8600 |
| Pyridoxine (mg) | 3.1250 | 1.6000 | 4.7250 | ±10% | 4.2525 |
| Folic acid (mg) | 2.0000 | 0.1200 | 2.1200 | ±10% | 1.9080 |
| Iron (mg) | 35.000 | 9.6000 | 44.6000 | ±10% | 40.1400 |
| Zinc (mg) | 15.0000 | 10.0500 | 25.0500 | ±10% | 22.5450 |

| Micronutrients | COMP OSITION PER 1 kg FLOUR | | | | |
|---|---|---|---|---|---|
| | Fortification | Natural | total | Tolerance | Netto |
| Vitamin A (mcg RE) | 2085 | 0 | 2085 | ±10% | 1877 |
| Thiamine (rng) | 2.1875 | 3.1000 | 5.2875 | ±10% | 4.7588 |
| Riboflavin (mg) | 1.6875 | 0.5000 | 2.1875 | ±10% | 1.9688 |
| Niacin (mg) | 25.000 | 13.5000 | 38.5000 | ±10% | 34.6500 |
| Pyridoxine (rng) | 3.1250 | 2.2000 | 5.3250 | ±10% | 4.7925 |
| Folic acid (mg) | 2.0000 | 0.1400 | 2.1400 | ±10% | 1.9260 |
| Iron (mg) | 35.000 | 14.2000 | 49.2000 | ±10% | 44.2800 |
| Zinc (mg) | 15.0000 | 14.5500 | 29.5500 | ±10% | 26.5950 |

| Micronutrients | COMPOSITION PER 1 kg FLOUR | | | | |
|---|---|---|---|---|---|
| | Fortification | Natural | Total | tolerance | Netto |
| Vitamin A (mcg RE) | 2085 | 0 | 2085 | ±10% | 1877 |
| Thiamine (mg) | 2.1875 | 4.0000 | 6.1875 | ±10% | 5.5688 |
| Riboflavin (mg) | 1.6875 | 0.6000 | 2.2875 | ± 10% | 2.0588 |
| Niacin (mg) | 25.000 | 17.5000 | 42.5000 | ±10% | 38.2500 |
| Pyridoxine (mg) | 3.1250 | 2.9000 | 6.0250 | ±10% | 5.4225 |
| Folic acid (mg) | 2.0000 | 0.1600 | 2.1600 | ±10% | 1.9440 |
| Iron (mg) | 35.000 | 21.0000 | 56.000 | ±10% | 50.4000* |
| Zinc (mg) | 15.0000 | 18.5500 | 33.5500 | ±10% | 30.1950 |

* **Where special permission was granted for un-sifted maize meal , a lower netto iron content of 34.65 mg/kg must be applicable**

## ANNEXURE VII

## ADDITION RATE OF FORTIFICATION MIXES

| Addition Rate per ton Maize Meal | 200g | 300 g | 400 g | 500 g |
|---|---|---|---|---|
| Ingredient | G / kg | g / kg | g / kg | g / kg |
| Vitamin A Palmitate 250 000 IU / g | 139.0000 | 192.6667 | (46.3333 | 118.5333 |
| Thiamine Mononitrate (Activity 78% minimum) | 14.0224 | 9.3483 | 4.6741 | 1.8697 |
| Riboflavin | 8.4375 | 5.6250 | 2.8125 | 1.1250 |
| Niacinamide | 125.0000 | 83.3333 | 41.6667 | 16.6667 |
| Pyridoxine HCI (Activity 81% minimum) | 19.2901 | 12.8601 | 6.4300 | 2.5720 |
| Folic Acid (Activity 98% minimum) | 11.0497 | 7.3665 | 3.6832 | 1.4733 |
| Electrolytic Iron (Activity 98% minimum) | 178.6714 | 119.1143 | 59.5571 | 23.8229 |
| Zinc Oxide (Activity 80% minimum) | 93.7500 | 62.5000 | 31.2500 | 12.5000 |
| Diluent | To complete 1ooog | To complete 1ooog | To complete 1ooog | To complete 1ooog |

| Addition Rate per ton unsifted Maize Meal (special permission) | 200g | 300 g | 400 g | 500 g |
|---|---|---|---|---|
| Ingredient | G / kg | g / kg | g / kg | g / kg |
| Vitamin A Palmitate 250 000 IU / g | 139.0000 | 92.6667 | 46.3333 | 18.5333 |
| Thiamine Mononitrate (Activity 78% minimum) | 14.0224 | 9.3483 | 4.6741 | 11.8697 |
| Riboflavin | 8.4375 | 5.6250 | 2.8125 | 1.1250 |
| Niacinamide | 125.0000 | 83.3333 | 41.6667 | 16.6667 |
| Pyridoxine HCl (Activity 81% minimum | 19.2901 | 12.8601 | (6.4300 | 2.5720 |
| Folic Acid (hctivity 98% minimum) | 11.0497 | 7.3665 | 3.6832 | 1.4733 |
| Electrolytic Iron (Activity 98% minimum) | 89.2857 | 59.5238 | 29.7619 | 11.9048 |
| Zinc Oxide (Activity 80Y | 093.7500 | 62.5000 | 31.2500 | 12.5000 |
| Diluent | To complete 1ooog | To complete 1ooog | To complete 1ooog | To complete 1ooog |

**TABLE 7 (c): WHEAT FLOUR**

| Addition Rate per ton Wheat Flour | 200g | 300 g | 400 g | 500 g |
|---|---|---|---|---|
| Ingredient | G / kg | g / kg | g / kg | g / kg |
| Vitamin A Palmitate 250 000 IU / g | 119.0475 | 79.3650 | 39.6825 | 15.8730 |
| Thiamine Mononitrate (Activity 78% minimum) | 12.4644 | 8.3096 | 4.1548 | 1.6619 |
| Riboflavin | 8.8889 | 5.9259 | 2.9630 | 1.1852 |
| Niacinamide | 118.4210 | 78.9473 | 39.4737 | 15.7895 |
| Pyridoxine HCl (Activity 81% minimum) | 16.2443 | 10.8295 | 5.4148 | 2.1659 |
| Folic Acid (Activity 98% minimum) | 7.8927 | 5.2618 | 2.6309 | 1.0524 |
| Electrolytic Iron (Activity 98% minimum) | 178.5714 | 119.0476 | 59.5238 | 23.8095 |
| Zinc Oxide (Activity 80% minimum) | 93.7500 | 62.5000 | 31.2500 | 12.5000 |
| Diluent | To complete 1ooog | To complete 1ooog | To complete 1ooog | To complete boog |

## ANNEXURE VIII

**Facsimile 1 (Monochrome copy)**

**Facsimile 2 (Full colour copy)**

## ANNEXURE IX

**Facsimile 1 (Monochrome copies)**

**Facsimile 2 (Full colour copies)**