**DEPARTMENT OF HEALTH**

**NO. 217** **03 MARCH 2016**

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

## REGULATIONS RELATING TO THE FORTIFICATION OF CERTAIN FOODSTUFFS

The Minister of Health has, under Section 15(1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), made the regulations in the Schedule.

Interested persons are hereby invited to submit written comments on the proposed amendments to the Director-General: Health, Private Bag X828,Pretoria, 0001 (for the attention of the Director: Nutrition), within three months from the date of publication of this Notice.

### SCHEDULE

**Definitions**

1. In these Regulations any word or expression defined in the Act 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;

"**food vehicle**" means dry and uncooked wheat flour, dry and uncooked maize meal, precooked maize meal and, bread prepared with and containing at least 90% fortified wheat flour (including brown bread 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;

**"highly fortified maize meal or maize flour"** means maize meal or maize flour that have been fortified at levels of at least 30% of the Nutrient Reference Values of individuals older than 36 months of age, as required for nutrient content claims in the Regulations relating to the Labelling and Advertising of Foodstuffs.;

**"maize meal"** means all milled, uncooked maize products and includes super, special, sifted and unsifted maize meal and precooked maize meal, but excludes samp, grits, maize rice and maize flour and maize meal certified organic according to the latest Codex Alimentarius standards and packed in quantities not larger than 1kg;

**"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;

**"precooked"** means maize meal which has undergone further processing following the main milling process in such a manner as to enable it to be prepared for consumption using limited or no additional cooking;

**"quality control"** means the measures applied and the steps taken by a manufacturer of wheat flour, maize meal, maize flour or fortification mixes to ensure that the correct procedures are being followed and the set criteria are being met in the manufacturing and distribution of fortification mixes or the administering of fortificants to wheat flour, maize meal or maize flour;

**"SANAS"** means the South African National Accreditation Services as defined in the Regulations relating to the Labelling and Advertising of Foodstuffs;

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

**"the Regulations relating to the Labelling and Advertising of Foodstuffs"** means the Regulations relating to the Labelling and Advertising of Foodstuffs (Government Notice No. R.146 of 1 March 2010),made under section 15 of the Act;

**"Vitamin A"** means protected, stabilized vitamin A/retinylpalmitate containing 75 000 mcg 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, 2, 3, 4,5, of the Regulations;

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

**"wheat flour"** means the following milled, dry and uncooked wheat products as defined in the Regulations relating to the grading, packing and marking of wheat products intended for sale in the Republic of South Africa, 2008 (Government Notice No. R.186 of 22 February 2008) made under section 15 of the Agricultural Products Standards Act,1990 (Act No. 119 of 1990), but excludes crushed wheat, pearled wheat, semolina, stabilised wheat products and wheat flour certified organic according to the latest Codex Alimentarius standards and packed in quantities not larger than 1 kg :

(a) Brown bread wheat flour;
(b) cake wheat flour;
(c) high bran wheat flour;
(d) industrial wheat flour;
(e) self-raising wheat flour;
(f) soft wheat flour;
(g) whole wheat brown flour; and
(h) whole wheat flour.

**General provisions**

**2.**(1) 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 B, shall be guilty of an offence.

(2) Any person who manufactures, imports or sells maize meal or maize flour, may manufacture, import or sell highly fortified maize meal or maize flour provided it meets the minimum levels specified by the requirements of these regulations for such a foodstuff.

(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 C, shall be guilty of an offence.

(4) A person desiring to manufacture, import or supply a fortification mix shall apply to the

Director-General for registration by submitting the information specified in Annexure D.

(5) The registration referred to in subregulation (4) is valid for a period of one year.

(6) Registered manufacturers, importers or suppliers of fortification mixes shall—

(a) comply with the principles set out in Annexure C; and

(b) issue a certificate of compliance as indicated in Annexure E.

(7) Manufacturers and importers of food vehicles or highly fortifiedmaize meal or maize flour—

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

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

**Special provisions**

**3.**(1) (a) The formulation of the fortification mix for wheat flour shall comply with the minimum levels indicated in Annexure A, Table 1.

(b) The formulation of the fortification mix for maize meal shall comply with the minimum levels indicated in Annexure A, Table 2.

(c) The formulation of the fortification mix for maize meal or maize flour that is highly fortified shall comply with the minimum levels indicated in Annexure A, Table 3.

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

(e) The fortification mix shall be used at an addition rate per ton of food vehicle indicated in Annexure F.

(2) (a) Additives and flavourants used in the manufacturing of highly fortified maize meal or maize flour shall be in accordance with additives and flavourants permitted in the Act.

(b) Manufacturers of fortified food vehicles or highly fortified maize meal or maize flour, will be audited by an inspector for compliance with the requirements of these regulations as indicated in Annexure B.

**Labelling of fortified foodstuffs**

**4.** In addition to the Regulations relating to the Labelling and Advertising of Foodstuffs all food vehicles shall be labelled as follows:

(a) The nutrient content claims may be used in addition to the word 'fortified' on a label only 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 criteria based on SANAS accredited laboratory analyses.

(b) The claim 'Fortified for better health' and the fortification logo to that effect as indicated in Annexure G are reserved only for food vehicles that have been identified and mandatory fortified in accordance with the Regulations and may be displayed on the label or in advertising material.

(c) Any person who uses the official logo referred to in Annexure H on labels or in advertising material for foodstuffs other than in accordance with these Regulations or any other regulations made in terms of the Act, shall be 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 H 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 shall—

(i) in the list of ingredients be identified individually by the compound names (for example NaFeEDTA, ferrous fumarate, zinc oxide); and

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

(f) The design of the logo accompanying the claim 'fortified for better health' or the claim 'manufactured with fortified wheat flour for better health' or 'manufactured with fortified maize meal for better health' shall be constructed as indicated in facsimile 1 in Annexure G or Annexure H.

(g) Where the full colour version of the logo accompanying the claims 'fortified for better health', 'manufactured with fortified wheat flour for better health' or 'manufactured with fortified maize meal for better health' is used, the following colours shall be used in accordance with facsimile 2 in Annexure F or Annexure H:

**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

(h) The claim "Highly fortified" and accompanying logo may only be used for food vehicles complying with the requirements of Table 6 of these Regulations and shall be constructed as indicated in Annexure I.

(i) The fortification logos shall 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 logos shall be clearly visible, easily legible and indelible.

(j) The fortification logos may be printed in monochrome as per facsimile 1 in Annexure G or Annexure Hor Annexure I or in any of the selected main colours of the packaging.

(k) The official logo shall be a minimum size of 35 mm for bread. The size of the fortification logos for maize meal, wheat flour, highly fortified maize meal or maize flour shall be as follows:

| Weight (kg) | Size of fortification logos |
|---|---|
| ≤ 1 kg | 25 mm |
| 2 – 5 kg | 35 mm |
| 6 – 24 kg | 50 mm |
| ≥ 25 kg | 100 mm |

(l) In addition to the requirements of these Regulations and the Regulations relating to the Labelling and Advertising of Foodstuffs made under the Act, the label of highly fortified maize meal or maize flour should comply with the labelling requirements of the Regulations relating to Foodstuffs for Infants and Young Children made under the Act.

**Labelling of fortification mixes**

**5.**(1) In addition to the requirements of the Regulations relating to the Labelling and Advertising of Foodstuffs made under the Act, the label or container of the fortification mix sold as such must indicate the date up to which the product will comply with the requirements stipulated in Table 1, Table 2 and Table 3 of Annexure A of the regulations when stored under the fortification mix manufacturers, suppliers or importers recommended conditions.

(2) The fortification addition rate must be clearly indicated on the label of the fortification mixes referred to in Table 1, Table 2 and Table 3 of Annexure A of these Regulations.

**Delegations**

**6.**(1) The Director-General may, subject to such conditions as she or he may determine, in writing, in general, in a particular case or in cases of a particular nature delegate, to any officer in the Department any power conferred upon her or him by or under these Regulations.

(2) The Director-General shall not be divested of a power delegated by her or him under subregulation (1), and may alter or set aside any decision by an officer taken in the exercise of a power so delegated.

**Repeal**

**7.** The Regulations published under Government Notice No. R. 504 of 7 April of 2003 as amended by Government Notice No. R. 1206 of 14 November of 2008, are hereby repealed.

**DR A MOTSOALEDI, MP**
**MINISTER OF HEALTH**
**DATE:** 8/9/2015

## ANNEXURE A

## FORTIFICATION MIX

### TABLE 1

### FORTIFICATION MIX[1] FOR WHEAT FLOUR

| Fortificants and diluent[2] | Minimum micronutrient requirements (per 1 kg flour) | Minimum micronutrient requirement (per 1 kg fortification mix) | Minimum fortificant requirement(g/ kg fortification mix) |
|---|---|---|---|
| Vitamin A palmitate (Activity: 75 000 mcg RE[3]/g) | 1786 mcg | 5953 mg | 79.38 g |
| Thiaminmononitrate (Activity: 81% minimum) | 1.94 mg | 6.47 g | 7.98 g |
| Riboflavin (Activity: 100% minimum) | 1.77 mg | 5.9 g | 5.90 g |
| Nicotinamide/niacinamide (Activity: 99% minimum) | 23.7 mg | 79.0 g | 79.80 g |
| Pyridoxine HCl (Activity: 82% minimum) | 2.63 mg | 8.77 g | 10.69 g |
| Folicacid (Activity: 90.5% minimum) | 1.43 mg | 4.77 g | 5.27 g |
| Cyanocobalamin (water soluble) (Activity: 0.1% minimum)[4] | 0.005 mg | 0.017 g | 16.67 g |
| NaFeEDTA (Activity: 13% minimum)[5] | 15.0 mg | 50.0 g | 384.62 g |
| Zinc oxide (Activity: 80% minimum) | 30.0 mg | 100.0 g | 125.0 g |
| Diluent | | | To complete 1000 g |

**Notes**

1. Based on a dosage rate of 300 g per metric tonne (300 g/MT) dosage. Adjustment of the dosage rate should comply with the relevant minimum requirements indicated in Table 4, Annexure V.
2. Fortificants and diluents should pass through a 212 um sieve.

3. Retinol equivalents (RE) = 1 mcg retinol = 3.33 IU (International units) vitamin A.
4. Use of 1% cyanocobalamin is permitted with suitable adjustment of the fortification mix formulation.
5. NaFeEDTA shall comply with the requirements given in the latest edition of the Food Chemicals Codex.

## TABLE 2

## FORTIFICATION MIX[1] FOR MAIZE MEAL

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

| Fortificants and diluent[2] | Minimum micronutrient requirements (per 1 kg maize meal) | Minimum micronutrient requirement (per 1 kg fortification mix) | Minimum fortificant requirement (g/kg fortification mix) |
|---|---|---|---|
| Vitamin A palmitate[3] (Activity: 75 000 mcgRE/g) | 2090mcg | 6950 mg | 92.67 g |
| Thiaminmononitrate (Activity: 81% minimum) | 2.19 mg | 7.30 g | 9.01 g |
| Riboflavin (Activity: 100%minimum) | 1.69 mg | 5.63 g | 5.63 g |
| Nicotinamide/niacinamide (Activity: 99% minimum) | 25.0 mg | 83.33 g | 84.18 g |
| Pyridoxine HCl (Activity: 82% minimum) | 3.13 mg | 10.43 g | 12.72 g |
| Folicacid (Activity: 90.5% minimum) | 2.0 mg | 6.67 g | 7.37 g |
| Cyanocobalamin (water soluble) (Activity: 0.1% minimum)[4] | 0.005 mg | 0.017 g | 16.67 g |
| NaFeEDTA (Activity: 13% minimum)[5] | 15.0 mg | 50.0 g | 384.62 g |
| Zinc oxide (Activity: 80% minimum) | 30.0 mg | 100.0 g | 125 g |
| Diluent | | | To complete 1000 g |

**Notes**

1. Based on a dosage rate of 300 g per metric tonne (300 g/MT) dosage. Adjustment of the dosage rate should comply with the relevant minimum requirements indicated in Table 5, Annexure V.
2. Fortificants and diluents should pass through a 250µm sieve.
3. Retinol equivalents (RE) = 1 mcg retinol = 3.33 IU (International units) vitamin A.

4. Use of 1% cyanocobalamin is permitted with suitable adjustment of the fortification mix formulation.
5. NaFeEDTA shall comply with the requirements stipulated in the latest edition of the Food Chemicals Codex.

## TABLE 3

## FORTIFICATION MIX[1] FOR HIGHLY FORTIFIED MAIZE MEAL OR MAIZE FLOUR

| Fortificants and diluents | Minimum micronutrient requirements (per 1 kg maize meal/flour) | Minimum micronutrient requirement (per 1 kg fortification mix) | Minimum fortificant requirement(g/kg fortification mix) |
|---|---|---|---|
| Vitamin A palmitate[2] (Activity: 75 000 mcg RE | 5600 mcg | 1244.45 mg | 16.59 g |
| Thiaminmononitrate (Activity: 81% minimum) | 7.0mg | 1.56 g | 1.92 g |
| Riboflavin (Activity: assumed 100%) | 4.0mg | 0.89 g | 0.89g |
| Nicotinamide/niacinamide (Activity: 99% minimum) | 72.0mg | 16.00 g | 16.16 g |
| Pyridoxine HCl (Activity: 82 % minimum) | 6.0mg | 1.33 g | 1.63 g |
| Folicacid (Activity:90.5% minimum)[3] | 1.2mg | 0.27 g | 0.29g |
| Cyanocobalamin (water soluble) (Activity: 0.1% minimum)[4] | 10.8mcg | 2.4 mg | 2.4 g |
| D-Biotin (Activity: 100% minimum) | 0.2mg | 0.04 g | 0.04 g |
| Calcium D panthothenate (Activity:89.3% minimum) | 24.0mg | 5.33 g | 5.98 g |
| NaFeEDTA (Activity: 13% minimum)[5] | 52.5mg | 11.67 g | 89.74 g |
| Ferrous Fumarate (Activity: 31.5% minimum)[6] | 52.5mg | 11.67 g | 37.01 g |
| Zinc gluconate (Activity: 12.5% minimum) | 33mg | 7.33 g | 58.86 g |
| Potassium iodide[7] (Activity: 74.3% | 0.95mg | 0.21 g | 0.28 g |

| | | | |
|---|---|---|---|
| minimum) | | | |
| Sodium selenite (Activity: 45.6% minimum) | 0.18mg | 0.04 g | 0.09 g |
| L-LysineHCl (Activity: 80% minimum) | 2000.0mg | 444.44 g | 555.56 g |
| Diluent | | | To complete 1 000 g |

**Notes**

1. Based on a dosage rate of 4 500 g per metric tonne (4 500 g/MT) dosage. Adjustment of the dosage rate should comply with the relevant minimum requirements indicated in Table 6, Annexure V.
2. Retinol equivalents (RE) = 1 mcg retinol = 3.33 IU. (International units) vitamin A.
3. Use of 10% dilution or adequate dilution with pro rata adjustment of the fortification formulation.
4. Use of 1% cyanocobalamin is permitted with pro rata adjustment of the minimum requirements indicate in Table 3.
5. NaFeEDTA shall comply with the requirements stipulated in the latest edition of the Food Chemicals Codex.
6. Ferrous fumarate shall comply with the requirements stipulated in the latest version of the Food Chemicals Codex.
7. Use of 10% dilution or adequate dilution with pro rata adjustment of the minimum requirements indicated in Table 3.

## ANNEXURE B

## QUALITY CONTROL PRINCIPLES

### MANUFACTURERS OF FORTIFIED WHEAT FLOUR, MAIZE MEAL AND HIGHLY FORTIFIED MAIZE MEALOR MAIZE FLOUR

Manufacturers of wheat flour and maize meal shall according to the requirements stipulated in the Code of Practice—

(a) keep and submit monthly records of the amount of fortification mixes used every month and the total production of food vehicles required to be fortified per month, as indicated by the Department;

(b) ensure that fortification mixes are stored under the conditions laid down by the manufacturer;

(c) ensure that strict stock rotation procedures are adhered to in order to prevent old stock losing potency and to comply with requirements of regulation 5(1);

(d) ensure that all critical stages of the manufacturing process are monitored to ensure that the correct dosage levels are maintained by—

(i) process control for premix addition;

(ii) finished product inspection; and

(iii) inspection and internal audit

(e). submit any report on fortification quality control as required by the Department.

## ANNEXURE C

## QUALITY CONTROL PRINCIPLES

## REGISTERED MANUFACTURERS OR SUPPLIERS OF FORTIFICATION MIXES

Registered manufacturers, importers or suppliers of fortification mixes shall—

(a) 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;

(b) submit to the Department of Health the total fortification mixes for fortifiable maize meal, wheat flour and highly fortified maize meal or maize flour sold to millers per province;

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

(d) ensure that each batch of a fortification mix for the various vehicles complies with the fortification standards described in Tables 1, Table 2 and Table 3;

(e) have one inspection audit per year at their premises, as well as the taking of samples for laboratory analysis by means of methods that are SANAS accredited and for vitamin A stability;

(f) have samples taken for laboratory analysis, by means of methods that are SANAS accredited from their warehouses and from the premises of manufacturers of food vehicles

(g) bear the costs of the audit and analysis mentioned in paragraphs(e)and (f).

## ANNEXURE D

## 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. Names of: (Print please)

| | |
|---|---|
| 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. Is the company registered for Good Manufacturing Practices in terms of the Medicines and Related Substances Act, 1965 (Act No 101 of 1965)?
10. Has the company been inspected by the Inspectors (appointed in terms 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? Yes/no
    (If yes, attach a copy of applicable certification)
13. Does your company have HACCP accreditation? Yes/No
    (If yes, attach a copy of applicable certification)
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:

_____

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

_____(number) years

17. Source of vitamin A compound (specify the manufacturers in the case of multiple sources and attach a certificate for each manufacturer):

17.1 Spray-dried vitamin A powder _____,

17.2 Oil-based vitamin A _____, and

17.3 Spray-dried _____

18. Sources of NaFeEDTA and where applicable, ferrous fumarate (specify manufacturer and attach certificate/s)

_____;

19. Is vitamin A compound stable as per specification*? (Attach findings of internal vitamin A stability trials for each source as indicated in question 17)

Vitamin A stability specification:

The stability of the vitamin A compound should comply with the DOH specification, i.e a loss of not more than 15% at 40 °C and 75 RH after 15 days

## ANNEXURE E

## 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:

**TABLE 1**

**TEST FORMAT FOR FORTIFICATION MIX SPECIFICATION FOR WHEAT FLOUR**

| Fortificants | Minimum micronutrient requirement added per 1 kg fortification mix | Result |
|---|---|---|
| Vitamin A | | |
| Thiamin | | |
| Riboflavin | | |
| Niacinamide | | |
| Pyridoxine | | |
| Folicacid | | |
| Cyanocobalamin | | |
| Iron | | |
| Zinc | | |
| Fortification mix dosage rate | | |
| Fortification mix particle size | | |
| Iron EDTA | Respective batch certificate from manufacturer attached | |

**Signed by:**

**Authorised signatory** **Printed name**

**Date:**

**Seal**

**TABLE 2**

**TEST FORMAT FOR FORTIFICATION MIX SPECIFICATION FOR MAIZE MEAL**

| **Fortificants** | **Minimum micronutrient requirement added per 1 kg fortification mix** | **Result** |
|---|---|---|
| Vitamin A | | |
| Thiamin | | |
| Riboflavin | | |
| Niacinamide | | |
| Pyridoxine | | |
| Folicacid | | |
| Cyanocobalamin | | |
| Iron | | |
| Zinc | | |
| Fortification mix dosage rate | | |
| Iron EDTA | Respective batch certificate from manufacturer attached | |

**Signed by:**

**Authorised signatory** **Printed name**

**Date:**

**Seal**

**TABLE 3**

**TEST FORMAT FOR FORTIFICATION MIX SPECIFICATION FOR HIGHLY FORTIFIED MAIZE MEAL OR MAIZE FLOUR**

| Fortificants and diluent | Minimum micronutrient requirement added per 1 kg fortification mix | Result |
|---|---|---|
| Vitamin A | | |
| Thiamin | | |
| Riboflavin | | |
| Niacinamide | | |
| Pyridoxine | | |
| Folicacid | | |
| Cyanocobalamin | | |
| Biotin | | |
| Panthothenic acid | | |
| Iron | | |
| Zinc | | |
| Iodine | | |
| Selenium | | |
| L-Lysine | | |
| Fortification mix dosage rate | | |
| Iron EDTA | Respective batch certificate from manufacturer attached | |

**Signed by:**

**Authorised signatory** **Printed name**

**Date:**

**Seal**

## ANNEXURE F

## ADDITION RATE OF FORTIFICATION MIXES

### TABLE 1:

**Minimum fortificant requirement (g/kg fortification mix): wheat flour**

| **Addition rate per ton wheat flour** | **300 g** | **350 g** | **400 g** | **500 g** |
|---|---|---|---|---|
| **Ingredient** | **g/kg** | **g/kg** | **g/kg** | **g/kg** |
| Vitamin A palmitate (Activity: 75 000 mcg RE[3]/g) | 79.38 | 68.04 | 59.53 | 47.63 |
| Thiaminmononitrate (Activity: 81% minimum) | 7.98 | 6.84 | 5.99 | 4.79 |
| Riboflavin (Activity: 100% minimum) | 5.90 | 5.06 | 4.43 | 3.54 |
| Nicotinamide/niacinamide (Activity: 99% minimum) | 79.80 | 68.40 | 59.85 | 47.88 |
| Pyridoxine HCl (Activity: 82% minimum) | 10.69 | 9.16 | 8.02 | 6.41 |
| Folicacid (Activity: 90.5% minimum) | 5.27 | 4.51 | 3.95 | 3.16 |
| Cyanocobalamin (water soluble) (Activity: 0.1% minimum)[4] | 16.67 | 14.29 | 12.5 | 10.0 |
| NaFeEDTA (Activity: 13% minimum)[5] | 384.62 | 329.67 | 288.46 | 230.77 |
| Zinc oxide (Activity: 80% minimum) | 125.0 | 107.14 | 93.75 | 75.0 |
| Diluent | To complete 1000 g | To complete 1000 g | To complete 1000 g | To complete 1000 g |

**TABLE 2**

**Minimum fortificant requirement (g/kg fortification mix): Maize meal(super, special, sifted, unsifted, precooked)**

| **Addition rate per ton maize meal** | **300 g** | **350 g** | **400 g** | **500 g** |
|---|---|---|---|---|
| **Ingredient** | **g/kg** | **g/kg** | **g/kg** | **g/kg** |
| Vitamin A palmitate (Activity: 75 000 mcg RE[3]/g) | 92.67 | 79.43 | 69.50 | 55.60 |
| Thiaminmononitrate (Activity: 81% minimum) | 9.01 | 7.72 | 6.76 | 5.41 |
| Riboflavin (Activity: 100% minimum) | 5.63 | 4.83 | 4.23 | 3.38 |
| Nicotinamide/niacinamide (Activity: 99% minimum) | 84.18 | 72.15 | 63.13 | 50.51 |
| Folicacid (Activity: 90.5% minimum) | 7.37 | 6.31 | 5.52 | 4.42 |
| Cyanocobalamin (water soluble) (Activity: 0.1% minimum)[4] | 16.67 | 14.29 | 12.50 | 10.0 |
| NaFeEDTA (Activity: 13% minimum)[5] | 384.62 | 329.67 | 288.46 | 230.77 |
| Zinc oxide (Activity: 80% minimum) | 125 | 107.14 | 93.75 | 75.0 |
| Diluent | To complete 1000 g | To complete 1000 g | To complete 1000 g | To complete 1000 g |

**TABLE 3**

**Minimum fortificant requirement (g/kg fortification mix): Highly fortified maize meal or maize flour**

| **Addition rate per ton maize meal or maize flour** | **4 500 g** | **5 000 g** |
|---|---|---|
| **Ingredient** | **g/kg** | **g/kg** |
| Vitamin A palmitate[2] (Activity: 75 000 mcg RE | 16.59 | 14.93 |
| Thiaminmononitrate (Activity: 81% minimum) | 1.92 | 1.73 |
| Riboflavin (Activity: assumed 100%) | 0.89 | 0.8 |
| Nicotinamide/niacinamide (Activity: 99% minimum) | 16.16 | 14.55 |
| Pyridoxine HCl (Activity: 82 % minimum) | 1.63 | 1.46 |
| Folicacid (Activity:90.5% minimum)[3] | 0.29 | 0.27 |
| Cyanocobalamin (water soluble) (Activity: 0.1% minimum)[4] | 2.4 | 2.16 |
| D-Biotin (Activity: 100% minimum) | 0.04 | 0.04 |
| Calcium D panthothenate (Activity:89.3% minimum) | 5.98 | 5.38 |
| NaFeEDTA (Activity: 13% minimum)[5] | 89.74 | 80.77 |
| Ferrous Fumarate (Activity: 31.5% minimum)[6] | 37.01 | 33.31 |
| Zinc gluconate (Activity: 12.5% minimum) | 58.79 | 52.97 |
| Potassium iodide[7] (Activity: 74.3% minimum) | 0.28 | 0.25 |

| | | |
|---|---|---|
| Sodium selenite (Activity: 45.6% minimum) | 0.09 | 0.08 |
| L-LysineHCl (Activity: 80% minimum) | 555.56 | 500 |
| Diluent | To complete 1 000 g | To complete 1 000 g |

**ANNEXURE G**

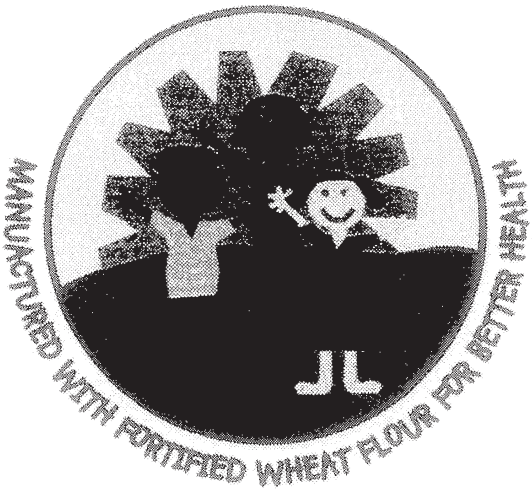
**Facsimile 1 (Monochrome copy)**


**Facsimile 2 (Full colour copy)**

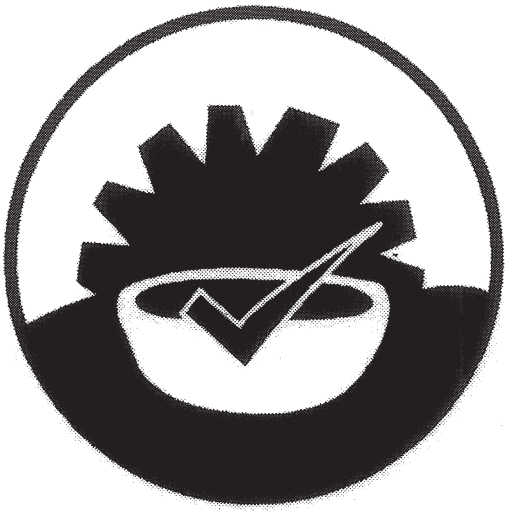
## ANNEXURE H

**Facsimile 1 (Monochrome copies)**


**Facsimile 2 (Full colour copies)**

**ANNEXURE I**



HIGHLY FORTIFIED