

(14 November 2008 – to date)

FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT 54 OF 1972

Government Notice 923 in Government Gazette 3530 dated 2 June 1972. Commencement date: 1 January 1973 [Proc. No. 247 in Gazette No. 3669 dated 6 October 1972]

REGULATIONS RELATING TO THE FORTIFICATION OF CERTAIN FOODSTUFFS

Government Notice R504 in Government Gazette 24715 dated 7 April 2003. Commencement date: 7 October 2003

As amended by:

Government Notice R1206 in Government Gazette 31584 dated 14 November 2008. Commencement date: 14 November 2008

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

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 powder 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 unsifted 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;

"SANAS" means the South African National Accreditation Services, a non-profit organisation registered in terms of section 21 of the Companies Act, 1973 (Act No. 61 of 1973) registration number No. 199600354/08;

"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 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 the Regulations.

(Definition of "Vitamin A" inserted by GNR 1206 of 2008)

"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, shall 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, 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 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 shall issue a certificate of compliance as indicated in Annexure IV.
7. Registered manufacturers, importers or suppliers of fortification mixes shall 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) shall keep on record a certificate of compliance for every batch of fortification mix in the format specified in Annexure IV.
9. **SPECIAL PROVISIONS**
 - (a) The formulation of the fortification mix for wheat flour, based on the micronutrient requirements specified in Annexure V, Table 4a, shall comply with the minimum levels as follows:

TABLE 1: 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 palmitate ¹ (Activity: 75 000 mcg RE ² /g)	1 786 mcg RE	23,8095 mg	119,0475 g
Thiamine mononitrate (Activity: 78% min.)	1,9444 mg	2,4929 mg	12,4644 g

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Riboflavin	1,7778 mg	1,7778 mg	8,8889 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 iron ³ (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 shall 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 palmitate ¹ (Activity: 75 000 mcg RE ² /g)	2 085 mcg RE	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	2,099 mg	11,0497 g
Electrolytic iron ³ (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 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.

(Regulation 9 substituted by GNR 1206 of 2008)

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 unsifted maize meal based on the micronutrient requirements specified in Annexure V, Table 4c, shall 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 palmitate ¹ (Activity: 75 000 mcg RE ² /g)	2 085 mcg RE	27,8000 mg	139,0000 g
Thiamine mononitrate (Activity: 78% min.)	2.1875 mg	2,8045 m g	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 iron ³ (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	To complete

Prepared by:

		200 mg	1000 g
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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.

(Regulation 10(b) substituted by GNR 1206 of 2008)

- (c) The fortification mix shall be used at an addition rate per ton of food vehicle indicated in Annexure VIA: Provided that the final minimum levels in the food vehicle comply with the requirements stipulated in Table 3 and Table 4.

(Regulation 10(c) substituted by GNR 1206 of 2008)

- (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 shall 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 A ¹	mcg RE/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 shall be not less than the levels shown in Table 4 below and shall 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 A ¹	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	50.40 ²
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 shall be the minimum micronutrient levels in uncooked wheat flour and uncooked maize meal when sampled at the point of manufacturing or importation.

(Regulation 11(c) substituted by GNR 1206 of 2008)

- (d) A sample of a fortified food vehicle, taken by an inspector in terms of the Act, shall be analysed for the amounts of nicotinamide / niacinamide, or riboflavin and retinol / vitamin A palmitate, and the results of such a sample shall 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 shall be labelled as follows:

- (a) the nutrient content claims may be used in addition to the word 'fortified' on one 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;

(Regulation 12(a) substituted by GNR 1206 of 2008)

- (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 and fortified in accordance with the Regulations and may be displayed on the label or in advertising material;

(Regulation 12(b) substituted by GNR 1206 of 2008)

- (c) any person who uses the official logo referred to in Annexure VII 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 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 shall –
 - (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 the fortification mixes;
(Regulation 12(f) substituted by GNR 1206 of 2008)
- (g) 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 2a and Table 2b of the Regulations.
(Regulation 12(g) substituted by GNR 1206 of 2008)
- (h) Wherever the official logo is used, it shall be used in the format of either Annexure VII or Annexure VIII and 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 logo shall be clearly visible, easily legible and indelible;
- (i) The official logo shall be a minimum size of 25 mm for paper and plastic packaging and a minimum size of 100 mm for woven polypropylene packaging;
- (j) The design of the logo shall be constructed as indicated in facsimile 1 in Annexure VII or Annexure VIII;

- (k) The logo may be printed in monochrome as per facsimile 1 in Annexure VII or Annexure VIII, or in any of the selected main colours of the packaging.
- (l) Where the full colour version of the logo is used, the following colours shall be used in accordance with facsimile 2 in Annexure VII or Annexure VIII:

Grass:

Green 1	Pantone 390	(45c 100y)
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Male's shorts:

Green 2	Pantone 349	(100c 100y 54k)
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Sun:

Orange 1	Pantone 123	(28m 100y)
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Back female's arms x 2, legs x 2, head:

Orange 2	Pantone 138	(53m 100y 8k)
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Back female's skirt, front female's eyes x 2:

Blue 1	Pantone 3015	(100c 40k)
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Front female's T-shirt:

Blue 2	Pantone 274	(100c 100m 30k)
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Sky:

Blue 3	Pantone 290	(10c)
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Front female's arms x 2, legs x 2, head:

Flesh	Pantone 719	(15m 18y)
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Male's T-shirt:

Yellow	Process yellow	(100y)
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Male's arms x 2, legs x 2, head:

Brown	Pantone 470	(56m 78y 40k)
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Back female's T-shirt, mouth, front female's skirt and mouth:

Red	Pantone 485	(100m 100y)
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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	
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- (m) Any manufacturer or importer of food vehicles who wishes to be exempted from the provisions of regulations *[sic]* 12 must apply in writing, giving full reasons for the request, to the Director-General for the attention of the Directorate: Nutrition.

(Regulation 12(m) inserted by GNR 1206 of 2008)

Repeal

13. The Regulations on the Enrichment of Maize Meal, promulgated under Government notice No. R 2839 of 21 December 1979 are hereby repealed.

Publisher's Note:

Prepared by:

The amendment of regulation 13 by regulation 7 of GNR 1206 of 2008 by the insertion of a subregulation (6) is clearly an error, as there are no subregulations under regulation 13 and the wording to be inserted is exactly the same as the wording inserted as subregulation (m) of regulation 12.

Commencement

14. These regulations shall come into operation 6 months after the date of final publication.

(Signed)

ME TSHABALALA-MSIMANG

MINISTER OF HEALTH

3-4-2003

ANNEXURE I

QUALITY CONTROL PRINCIPLES

MANUFACTURERS OF FORTIFIED WHEAT FLOURS AND MAIZE MEALS

Manufacturers of wheat flours and maize meals shall:

1. keep monthly records of the amount of fortification mixes used every month. These records shall 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 shall:

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 shall 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. submit one 500 g sample of a fortification mix every six months for each food vehicle to a laboratory that has accreditation for the methods of analysis as indicated by the fortification mix manufacturer, importer or supplier from SANAS or another international accreditation body; keep the analysis report on record and submit a copy of the report to the Director-General; and

Publisher's Note:

The wording of Item 4 of Annexure II has been retained as the said Item 4 has been substituted twice by regulation 8 of GNR 1206 of 2008 as follows:

"8. Annexure II of the Regulations is hereby amended by the substitution for –

(a) item 4 of the following item:

At least two inspection audits per year, including the taking of samples for laboratory analysis, in respect of all registered fortification mix manufacturers, suppliers and importers. to monitor compliance with the Regulations relating to the Fortification of Certain Foodstuffs shall be conducted at their premises and the manufacturers, suppliers or importers themselves shall bear the costs of such audits and analysis.

(b) item 4 of the following item:

"4. keep at least one labelled retention sample per batch for the expected shelf-life period"; and"

5. bear the costs of the analysis mentioned in paragraph 4.

ANNEXURE III

APPLICATION FORM FOR REGISTRATION OF FORTIFICATION MIXES:

MANUFACTURERS, IMPORTERS & SUPPLIERS

1. Company Name:
2. Company address (Postal):

Prepared by:

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. 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? Yes/no
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:

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

(Question 17 of Annexure III substituted by regulation 9(a) of GNR 1206 of 2008)

18. Source of iron compound (specify manufacturer and attach certificate)

(Question 18 of Annexure III substituted by regulation 9(a) of GNR 1206 of 2008)

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)*

* For more information on the vitamin A stability specification, contact the Directorate: Nutrition, Department of Health.

(Question 19 of Annexure III inserted by regulation 9(b) of GNR 1206 of 2008)

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 palmitate ¹ , (Activity: 75 000 mcgRE/g)	119.0475 g	139.0000 g
Thiamine mononitrate (Activity: 78% min.)	12.4644 g	14.0224 g
Riboflavin	8.8889 g	8.4375 g
Nicotinamide/Niacinamide	118.4210 g	125.0000 g
Pyridoxine HCl (Activity: 81 % min.)	16.2443 g	19.2901 g
Folic acid (Activity: 90.5% min.)	7.8927 g	11.0497 g
Electrolytic iron (Activity: 98% min.)	178.5714 g	178.5714 g ²
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 shall be used.

Signed by:

Authorised signatory

Printed name

Date:

Seal

8. Fortification mix addition rate: _____. g/kg.

(Item 8 of Annexure IV inserted by regulation 10 of GNR 1206 of 2008)

ANNEXURE V

MICRONUTRIENT REQUIREMENTS FOR FORTIFICATION OF FOOD VEHICLES

TABLE 4(a): WHEAT FLOUR

Prepared by:

Micronutrients	RDA	MICRONUTRIENT REQUIREMENTS					
		Per 200 g white bread flour					Per 1 kg flour
		Nutritional Goal		Retention	Required Addition	Required Addition	
		%RDA	Amount				
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

TABLE 4(b): MAIZE MEAL (Super, special, sifted, unsifted)

Micronutrients	RDA	MICRONUTRIENT REQUIREMENTS					
		Per 200 g maize meal					Per 1 kg meal
		Nutritional Goal		Retention	Required Addition	Required Addition	
		%RDA	Amount				
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

TABLE 4(c): UNSIFTED MAIZE MEAL (Special permission)

Micronutrients	RDA	MICRONUTRIENT REQUIREMENTS					
		Per 200 g maize meal					Per 1 kg meal
		Nutritional Goal		Retention	Required Addition	Required Addition	
		%RDA	Amount				
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

Prepared by:

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

TABLE 5(a): WHITE BREAD FLOUR

Micronutrients	COMPOSITION PER 1 kg FLOUR				
	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

TABLE 5(b): BROWN BREAD FLOUR (88% White bread flour + 12% Bran)

Micronutrients	COMPOSITION PER 1 kg FLOUR				
	Fortification	Natural	Total	Tolerance	Netto
Vitamin A (mcg RE)	1572	0	1572	±10%	1415
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	26.5000	29.700	±10%	26.7300

TABLE 5(c): WHITE BREAD

Micronutrients	COMPOSITION PER 1 kg BREAD (± 667 g flour)				
	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

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Zinc	(mg)	10.0050	7.0000	17.0050	±10%	15.3045
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TABLE 5(d): "BROWN BREAD

Micronutrients	COMPOSITION PER 1 kg BREAD (± 667 g flour)				
	Fortification	Natural	Total	Tolerance	Netto
Vitamin A (mcg RE)	734	0	734	±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

TABLE 6(a): SUPER MAIZE MEAL

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

TABLE 6(b): SPECIAL MAIZE MEAL

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

TABLE 6(c): SIFTED MAIZE MEAL

Micronutrients	COMPOSITION PER 1 k FLOUR				
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		Fortification	Natural	Total	Tolerance	Netto
Vitamin A	(mcg RE)	2085	0	2085	±10%	1877
Thiamine	(mg)	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	(mg)	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

TABLE 6(d): UNSIFTED MAIZE MEAL

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	56.00	±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 shall be applicable

ANNEXURE VIA ADDITION RATE OF FORTIFICATION MIXES

TABLE 6(e): MAIZE MEAL (super, special, sifted)

Addition rate per ton maize meal	200 g	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	1,8697
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 (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 1000 g	To complete 1000 g	To complete 1000 g	To complete 1000 g

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TABLE 6(f): UNSIFTED MAIZE MEAL (special permission)

Addition rate per ton unsifted maize meal (special permission)	200 g	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	1,8697
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 (Activity 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 80% minimum)	93,7500	62,5000	31,2500	12,5000
Diluent	To complete 1000 g	To complete 1000 g	To complete 1000 g	To complete 1000 g

TABLE 6(g): WHEAT FLOUR

Addition rate per ton Wheat Flour	200 g	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 1000 g	To complete 1000 g	To complete 1000 g	To complete 1000 g

(Annexure VIA inserted by regulation 11 of GNR 1206 of 2008)

ANNEXURE VII

Facsimile 1 (Monochrome copy)



Facsimile 2 (Full colour copy)



ANNEXURE VIII

Facsimile 1 (Monochrome copies)



Facsimile 2 (Full colour copies)



