



Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Regulation Gazette

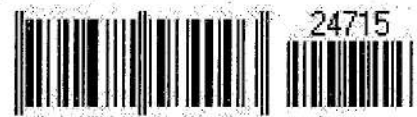
No. 7634

Regulasiekoerant

Vol. 454

Pretoria, 7 April 2003

No. 24715



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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 504

7 April 2003

**FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, 1972
(ACT NO. 54 OF 1972)****REGULATIONS RELATING TO THE FORTIFICATION OF CERTAIN
FOODSTUFFS**

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 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;

"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);

"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.

SPECIAL PROVISIONS

9. (a) The formulation of the fortification mix for wheat flour based on the micronutrient requirements specified in Annexure V, Table 4a shall be 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 mcgRE ² /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	8.8889 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 be 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 mcgRE ² /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 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.
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 shall be 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 mcgRE ² /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 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 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 shall be used at an addition rate of 200 g per ton of food vehicle.

(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	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 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, importation or sale.

(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 claim "enriched with" or "enriched" 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 or in cases where at least 15% more than the prescribed amounts of fortificants are added to a food vehicle;

(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 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 nutritional information declaration as described in Annexure 2 of the Regulations Relating to the Labeling and Advertising of Foodstuffs shall 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;
- (g) The nutritional information declaration referred to in paragraph (f) as well as nutritional information relevant to the fortification specifications shall 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;
- (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)

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

Repeal

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

Commencement

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

M Tshabalala

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
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):**
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. Specify the laboratory and methods* that will be used for the analyses of each of the micronutrients in the fortification mix:

Micronutrient	Laboratory	Analytical method
Vitamin A		
Thiamine (Vit B ₁)		
Riboflavin (Vit B ₂)		
Niacin (Vit B ₃)		
Pyridoxine (Vit B ₆)		
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 III) 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 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****Date:****Seal****Printed name**

ANNEXURE V

MICRONUTRIENT REQUIREMENTS FOR FORTIFICATION OF FOOD VEHICLES

TABLE 4(a): WHEAT FLOUR

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
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	16.5000	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
Zinc (mg)	10.0050	7.0000	17.0050	± 10%	15.3045

TABLE 5(d): "BROWN BREAD"

Micronutrients	COMPOSITION PER 1 kg BREAD (\pm 667 g flour)				
	Fortification	Natural	Total	Tolerance	Netto
Vitamin A (mcg RE)	734	0	734	\pm 5%	700
Thiamine (mg)	1.0272	1.8000	2.8272	\pm 10%	2.5445
Riboflavin (mg)	0.9391	0.6000	1.5391	\pm 10%	1.3852
Niacin (mg)	13.2066	33.0000	46.2066	\pm 10%	41.5859
Pyridoxine (mg)	1.4674	1.5000	2.9674	\pm 10%	2.6707
Folic acid (mg)	0.5870	0.2300	0.8196	\pm 10%	0.7353
Iron (mg)	20.5436	18.0000	38.5436	\pm 10%	34.6892
Zinc (mg)	8.8044	13.5000	22.3044	\pm 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	\pm 10%	1877
Thiamine (mg)	2.1875	1.2500	3.4375	\pm 10%	3.0938
Riboflavin (mg)	1.6875	0.3000	1.9875	\pm 10%	1.7888
Niacin (mg)	25.000	8.0000	33.0000	\pm 10%	29.7000
Pyridoxine (mg)	3.1250	1.2000	4.3250	\pm 10%	3.8925
Folic acid (mg)	2.0000	0.1000	2.1000	\pm 10%	1.8900
Iron (mg)	35.000	6.5000	41.5000	\pm 10%	37.3500
Zinc (mg)	15.0000	6.0000	21.0000	\pm 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	\pm 10%	1877
Thiamine (mg)	2.1875	2.1000	4.2875	\pm 10%	3.8588
Riboflavin (mg)	1.6875	0.4000	2.0875	\pm 10%	1.8788
Niacin (mg)	25.000	10.4000	35.4000	\pm 10%	31.8600
Pyridoxine (mg)	3.1250	1.6000	4.7250	\pm 10%	4.2525
Folic acid (mg)	2.0000	0.1200	2.1200	\pm 10%	1.9080
Iron (mg)	35.000	9.6000	44.6000	\pm 10%	40.1400
Zinc (mg)	15.0000	10.0500	25.0500	\pm 10%	22.5450

TABLE 6(c): SIFTED MAIZE MEAL

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

TABLE 6(d): UN-SIFTED 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	56.000	±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 shall be applicable

ANNEXURE VII

Facsimile 1 (Monochrome copy)



Facsimile 2 (Full colour copy)



ANNEXURE VIII

Facsimile 1 (Monochrome copies)



Facsimile 2 (Full colour copies)



**WET OP VOEDINGSMIDDELS, SKOONHEIDSMIDDELS EN
ONTSMETTINGSMIDDELS (WET NO. 54 VAN 1972)****REGULASIES BETREFFENDE DIE FORTIFISERING VAN SEKERE
VOEDINGSMIDDELS**

Die Minister van Gesondheid het kragtens Artikel 15 (1) van die Wet op Voedingsmiddels, Skoonheidsmiddels en Ontsmettingsmiddels, 1972 (Wet No. 54 van 1972), die regulasies in die Bylae opgestel.

BYLAE**WOORDOMSKRYWING**

1. In hierdie regulasies het enige woord of uitdrukking waaraan 'n betekenis in die Wet toegeken is, daardie betekenis en, tensy uit die samehang anders blyk, beteken-

“Departement” beteken die nasionale Departement van Gesondheid;

“die wet” beteken die Wet op Voedingsmiddels, Skoonheidsmiddels en Ontsmettingsmiddels, 1972 (Wet No. 54 van 1972);

“elektrolietyster” beteken elementele ysterpoeier soos gespesifiseer in die nuutste uitgawe van die “Food Chemical Codex”;

“fortifikant” beteken die voorgeskrewe verbinding wat die gespesifiseerde mikronutriënt voorsien;

“fortifisering” beteken die byvoeging van een of meer mikronutriënte by 'n voedselsoort deur middel van 'n fortifiseringsmengsel, ongeag of dit normaalweg in die voedselsoort voorkom of nie, met die doel om 'n bewese gebrek in die algemene bevolking of by 'n spesifieke bevolkingsgroep in Suid-Afrika soos deur die Departement bepaal, te voorkom of reg te stel;

“fortifiseringsmengsel” beteken 'n voorafvermengde mengsel van fortifikante en verdunners wat geformuleer is om gespesifiseerde en bepaalbare hoeveelhede mikronutriënte te voorsien;

“koringbrood” beteken alle gebakte brood berei met en bevattende minstens 90 % gefortifiseerde koringmeel, met die uitsondering van water;

“koringmeel” beteken alle gemaalde, droë en rou koringprodukte met 'n asinhoud van meer as 0.60 % op 'n vogvrye basis, uitgesluit gerolde koring, stampkoring, semolina, koringmeel met 'n asinhoud van minder as 0.60 % op 'n vogvrye basis, asook bruismeel;

“kwaliteitskontrole” beteken die maatreëls wat getref en die stappe wat geneem moet word deur die vervaardigers van koring- en mieliemeelvoedingsmiddels om te verseker dat die korrekte prosedures gevolg word en dat daar aan die kriteria vir die toediening van fortifikante aan voedseldraers voldoen word;

“mieliemeel” beteken alle gemaalde, rou mieliemeelprodukte met inbegrip van super, spesiale, gesifte en ongesifte mieliemeel, maar nie stampmielies, gruis, mielierys en mielielblom nie;

“mikronutriënt” beteken 'n natuurlike of sintetiese vitamien, mineraal of spoorelement wat noodsaaklik is vir normale groei, ontwikkeling en instandhouding van lewe en waarvan 'n gebrek tot kenmerkende biochemiese en fisiologiese veranderinge aanleiding sal gee;

“SANAS” beteken die Suid-Afrikaanse Nasionale Akkrediteringsstelsel, 'n nuwingsgewende organisasie wat geregistreer is kragtens artikel 21 van die Maatskappywet, 1973 (Wet No. 61 van 1973) registrasienommer No. 199600354/08;

“verdunner” beteken 'n geskikte, onreaktiewe voedselgraaddraer vir die mikronutriënte;

“verryking” beteken die byvoeging van een of meer nutriënte by 'n voedingsmiddel, ongeag of dit normaalweg daarin voorkom of nie, met die uitsluitlike doel om die voedingswaarde van die voedingsmiddel te verhoog;

“voedseldraer” beteken droë rou koringmeel, droë rou mieliemeel en brood, berei met en bevattende minstens 90 % gefortifiseerde koringmeel, met die uitsondering van water.

ALGEMENE BEPALINGS

2. 'n Persoon wat voedingsmiddels vervaardig, invoer of verkoop, sal aan 'n misdryf skuldig wees indien sodanige voedingsmiddels as voedseldraers aangewys is, maar nie kragtens hierdie regulasies gefortifiseer is nie, met inbegrip van die vereistes gespesifiseer in Aanhangsel I.
3. 'n Persoon wat 'n fortifiseringsmengsel vervaardig, invoer of voorsien wat nie by die Departement geregistreer is nie, met inbegrip van die vereistes gespesifiseer in Aanhangsel II, sal by die toepassing van hierdie regulasies, aan 'n misdryf skuldig wees.
4. 'n Persoon wat verlang om 'n fortifiseringsmiddel te vervaardig, in te voer of te voorsien, moet by die Direkteur-Generaal aansoek om registrasie doen deur voorlegging van die inligting gespesifiseer in Aanhangsel III.
5. Die registrasie waarna in regulasie 4 verwys is, is vir een jaar lank geldig.

6. Geregistreeerde vervaardigers, invoerders of leweransiers van fortifiseringsmengsels moet 'n sertifikaat ten opsigte van navolging uitreik, soos aangedui in Aanhangsel IV.
7. Geregistreeerde vervaardigers, invoerders of leweransiers van fortifiseringsmengsels moet voldoen aan die vereistes gespesifiseer in Aanhangsel II.
8. Vervaardigers en invoerders van voedseldraers-
- (a) kan die fortifiseringsmengsel slegs verkry van maatskappye wat by die Departement geregistreer is; en
- (b) moet 'n sertifikaat van navolging hou ten opsigte van elke lot fortifiseringsmiddel, in die formaat gespesifiseer in Aanhangsel IV.

SPESIALE BEPALINGS

9. (a) Die formulering van die fortifiseringsmengsel vir koringmeel, gebaseer op die mikronutriëntvereistes soos gespesifiseer in Aanhangsel V, Tabel 4a, moet soos volg wees:

TABEL 1: FORTIFISERINGSMENGSEL VIR KORINGMEEL

Fortifikante en verdunner	Mikronutriënt= vereistes (per l kg meel)	Fortifikant= vereistes (per l kg meel)	Fortifiserings= mengsel (g/kg)
Vitamiën A-palmitaat ¹ (Aktiwiteit: 75 000 mkg RE ² /g)	1 786 mkg RE	23.8095 mg	119.0475 g
Tiamienmononittraat (Aktiwiteit: 78% min.)	1.9444 mg	2.4929 mg	12.4644 g
Riboflaviën	1.7778 mg	1.7778 mg	8.8889 g
Nikotienamied/ Niasienamied	23.6842 mg	23.6842 mg	118.4210 g
Piridoksien-HCl (Aktiwiteit: 81 % min.)	2.6316 mg	3.2489 mg	16.2443 g
Foliensuur (Aktiwiteit: 90.5 % min.)	1.4286 mg	1.5786 mg	7.8927 g
Elektrolietyster ³ (Aktiwiteit: 98 % min.)	35.0000 mg	35.7143 mg	178.5714 g
Sinkoksied (Aktiwiteit: 80 % min.)	15.0000 mg	18.7500 mg	93.7500 g
Verdunner	-	Ter aanvulling tot 200 mg	Ter aanvulling tot 1 000 g

- Beskermd, gestabiliseerde vitamien A-palmitaat bevattende 75 000 mkg RE-aktiwiteit per gram.
- Retinol-ekwivalente (RE) = 1 mkg retinol = 3.33IE (Internasionale eenhede) vitamien A.
- Elementele ysterpoeier waar meer as 95% deur 'n 325-maas kan gaan (<45-mikron-partikelgrootte), soos deur 'n elektrolitiese proses geskep.

(b) Die formulering van die fortifiseringsmengsel vir meliemeel, gebaseer op die mikronutriëntvereistes soos gespesifiseer in Aanhangsel V, Tabel 4b, moet soos volg wees:

**TABEL 2a: FORTIFISERINGSMENGSEL VIR MELIEMEEL
(Super, spesiale, gesifte en ongesifte)**

Fortifikante en verdunner	Mikronutriënt= vereistes (per 1 kg meel)	Fortifikant= vereistes (per 1 kg meel)	Fortifiserings= mengsel (g/kg)
Vitamiën A-palmitaat ¹ (Aktiwiteit: 75 000 mkg RE ² /g)	2 085 mkg RE	27.8000 mg	139.000 g
Tiamienmononitraat (Aktiwiteit: 78% min.)	2.1875 mg	2.8045 mg	14.0224 g
Riboflaviën	1.6875 mg	1.6875 mg	8.4375 g
Nikotienamied/ Niasienamied	25.0000 mg	25.0000 mg	125.0000 g
Piridoksien-HCl (Aktiwiteit: 81 % min.)	3.1250 mg	3.8580 mg	19.2901 g
Foliensuur (Aktiwiteit: 90,5 % min.)	2.0000 mg	2.2099 mg	11.0497 g
Elektrolietyster ³ (Aktiwiteit: 98 % min.)	35.0000 mg	35.7143 mg	178.6714 g
Sinkoksied (Aktiwiteit: 80 % min.)	15.0000 mg	18.7500 mg	93.7500 g
Verdunner	-	Ter aanvulling tot 200 mg	Ter aanvulling tot 1 000 g

1. Beskernde, gestabiliseerde vitamien A-palmitaat bevattende 75 000 mkg RE-aktiwiteit per gram.
 2. Retinol-ekwivalente (RE) = 1 mkg retinol = 3.33 IE (Internasionale eenhede) vitamien A.
 3. Elementele ysterpoeier waar meer as 95 % deur 'n 325-maas kan gaan (<45-mikron-partikelgrootte), soos deur 'n elektrolietiese proses geskep.
10. (a) Vervaardigers, invoerders en leweransiers van ongesifte meliemeel kan die Direkteur-Generaal om spesiale toestemming nader vir die gebruik van 'n fortifiseringsmengsel met 'n verminderde elektrolietystervlak;
- (b) waar spesiale toestemming in terme van paragraaf (a) verleen is, moet die formulering van die fortifiseringsmengsel vir ongesifte meliemeel, gebaseer op die mikronutriëntvereistes soos gespesifiseer in Aanhangsel V, Tabel 4c, soos volg wees:

**TABEL 2b: FORTIFISERINGSMENGSEL VIR ONGESIFTE MIELIEMEEL
(Spesiale toestemming)**

Fortifikante en verdunner	Mikronutriënt= vereistes (per l kg meel)	Fortifikant= vereistes (per 1 kg meel)	Fortifiserings= mengsel (g/kg)
Vitamiën A-palmitaat ¹ (Aktiwiteit: 75 000 mkg RE ² /g)	2 085 mkgRE	27.8000 mg	139.0000 g
Tiamienmononittraat (Aktiwiteit: 78% min.)	2.1875 mg	2.8045 mg	14.0224 g
Riboflaviën	1.6875 mg	1.6875 mg	8.4375 g
Nikotienamied/ Niasienamied	25.0000 mg	25.0000 mg	125.0000 g
Piridoksien-HCl (Aktiwiteit: 81 % min.)	3.1250 mg	3.8580 mg	19.2901 g
Foliensuur (Aktiwiteit: 90,5 % min.)	2.0000 mg	2.2099 mg	11.0497 g
Elektrolietyster ³ (Aktiwiteit: 98 % min.)	17.5000 mg	17.8570 mg	89.2857 g
Sinkoksied (Aktiwiteit: 80 % min.)	15.0000 mg	18.7500 mg	93.7500 g
Verdunner	-	Ter aanvulling tot 200 mg	Ter aanvulling tot 1 000 g

1. Beskermdde, gestabiliseerde vitamien A-palmitaat bevattende 75 000 mkg RE-aktiwiteit per gram.
2. Retinol-ekwivalente (RE) = 1 mkg retinol = 3.33 IE (Internasionale eenhede) vitamien A.
3. Elementele ysterpoeier waar meer as 95 % deur 'n 325-maas kan gaan (<45-mikron-partikelgrootte), soos deur 'n elektrolitiese proses geskep.

(c) die fortifiseringsmengsel moet teen 'n byvoegingskoers van 200 g per ton voedseldraer gebruik word;

(d) daar moet met die fortifisering van koringmeel wat koringsemels bevat, toelating gemaak word vir die byvoeging van die fortifiseringsmengsel by die basismeel (witbroodmeel) alleenlik.

11. (a) Die finale minimum vlakke van die mikronutriënte (fortifiseringstandaarde) vir gefortifiseerde koringmeel op 'n 14 %-vogbasis en vir koringbrood op 'n 39 %-vogbasis, moet nie minder wees as die vlakke aangetoon in Tabel 3 nie en moet ooreenkomstig Tabelle 5a, 5b, 5c en 5d wees;

TABEL 3: FORTIFISERINGSTANDAARDE - KORINGMEEL EN KORINGBROOD

Mikronutriënte	Eenheid	KORINGMEEL		KORINGBROOD	
		Wit	Bruin	Wit	Bruin
Vitamiën A ¹	mkg RE/kg	1 610	1 415	800	700
Tiamien	mg/kg	3.91	3.79	2.49	2.54
Ribofavien	mg/kg	2.05	1.95	1.41	1.39
Niasien	mg/kg	38.42	54.76	27.91	41.59
Piridoksien	mg/kg	2.82	3.07	2.13	2.67
Foliensuur	mg/kg	1.36	1.24	0.74	0.74
Yster	mg/kg	43.65	47.97	32.26	34.69
Sink	mg/kg	20.70	26.73	15.30	20.07

1. Retinolekwivalente (RE) = 1 mkg retinol = 3.33 IE Internasionale eenhede) vitamien A.
- (b) die finale minimum vlakke van mikronutriënte (fortifiseringstandaarde) vir gefortifiseerde meliemeel op 'n 12.5 %-vogbasis, moet nie minder wees nie as die vlakke aangegee in Tabel 4 en moet in ooreenstemming wees met Aansluiting VI, Tabelle 6a, 6b, 6c en 6d;

TABEL 4: FORTIFISERINGSTANDAARDE – MELIEMEEL

Mikronutriënte	Eenheid	MELIEMEEL			
		Super	Spesiale	Gesifte	Ongesifte
Vitamiën A ¹	mkg RE/kg	1 877	1 877	1 877	1 877
Tiamien	mg/kg	3.09	3.86	4.76	5.57
Ribofavien	mg/kg	1.79	1.88	1.97	2.06
Niasien	mg/kg	29.70	31.86	34.65	38.25
Piridoksien	mg/kg	3.89	4.25	4.79	5.42
Foliensuur	mg/kg	1.89	1.90	1.92	1.94
Yster	mg/kg	37.35	40.14	44.28	50.40 ²
Sink	mg/kg	18.90	22.55	26.60	30.20

1. Retinolekwivalente (RE) = 1 mkg retinol = 3.33 IE (Internasionale eenhede) vitamien A.
2. Waar spesiale toestemming kragtens regulasie 10 verleen is, is 'n laer ysterinhoud van 34.65 mg/kg toelaatbaar.

(c) die fortifiseringstandaarde waarna verwys is in Tabel 3 en Tabel 4 van hierdie Regulasies, moet die minimum mikronutriëntvlakke vir rou koringmeel en rou meliemeel wees wanneer monsters op die vlak van vervaardiging, invoer of verkoop geneem word;

(d) 'n monster van 'n gefortifiseerde voedseldraer wat deur 'n inspekteur kragtens die Wet geneem word, moet vir die hoeveelheid nikotienamied/niasienamied of riboflaviën en retinol/vitamiën A-palmitaat ontleed word en die resultate van sodanige monster moet as verteenwoordigend beskou word van die standaard wat deur hierdie Regulasies in Tabel 3 en Tabel 4 voorgeskryf word.

Etikettering van gefortifiseerde voedingsmiddels

12. Benewens die Regulasies Betreffende die Advertering en Etikettering van Voedingsmiddels, kragtens die Wet uitgevaardig, moet alle voedseldraers soos volg geëtiketteer wees:
- (a) die aanspraak "verryk met" of "verryk" mag slegs benewens die woord "gefortifiseer" op 'n enkele etiket gebruik word in gevalle waar 'n nutriënt, met uitsondering van die gespesifiseerde fortifikante, by 'n voedseldraer gevoeg word, of in gevalle waar minstens 15 % meer as die voorgeskrewe hoeveelheid fortifikante tot 'n voedseldraer toegevoeg is;
 - (b) die aanspraak "Gefortifiseer vir beter gesondheid" en die amptelike fortifiseringslogo te dien effekte soos in Aanhangsel VII aangedui, word slegs vir voedseldraers wat in hierdie regulasies aangewys is, voorbehou en dit mag op die etiket of in die adverteringsmateriaal aangedui word;
 - (c) 'n persoon wat die amptelike logo waarna verwys is in Aanhangsel VII, gebruik op etikette of in adverteringsmateriaal uitgesonderd dié ooreenkomstig hierdie regulasies of enige ander regulasies kragtens die Wet uitgevaardig, sal aan 'n misdryf skuldig wees;
 - (d)
 - (i) die aanspraak "Gemaak van gefortifiseerde meliëmel vir beter gesondheid" of "Gemaak van gefortifiseerde koringmel vir beter gesondheid", wat ook al die geval mag wees, mag gebruik word vir voedingsmiddels, uitgesonderd voedseldraers, berei van en bevattende minstens 90 % van een of meer aangewese voedseldraers as bestanddeel, met die uitsondering van water;
 - (ii) 'n logo soos aangedui in Aanhangsel VIII kan op die etiket vertoon word of dit kan by die verkooppunt as 'n kennisgewing vertoon word in die direkte omgewing waar die voedingsmiddel waarna in subparagraaf (i) verwys is, op die rak uitgestal word, binne duidelike sig van die verbruiker;
 - (e) minerale vir die fortifiseringsmengsel moet-
 - (i) individueel volgens die verbindingsname (elektrolietyster, sinkoksied) in die lys van bestanddele aangewys wees; en
 - (ii) die elementele mineraal in die tabel met voedingsinligting aangee;
 - (f) Die voedingsinligtingsverklaring soos beskryf in Aanhangsel 2 van die Regulasies Betreffende die Etikettering en Advertering van Voedingsmiddels moet vir voedseldraers en voedingsmiddels wat van gefortifiseerde meliëmel

Voorste vrouefiguur se arms x 2, bene x 2, kop:

Vleeskleur Pantone 719 (15m 18y)

Mansfiguur se T-hemp

Geel Process yellow (100y)

Mansfiguur se arms x 2, bene x 2, kop:

Bruin Pantone 470 (56m 78y 40k)

Agterste vrouefiguur se T-hemp, mond, voorste vrouefiguur se halfrok en mond:

Rooi Pantone 485 (100m 100y)

Mansfiguur se hare, oë x 2, mond, agterste vrouefiguur se hare, oë x 2, voorste vrouefiguur se hare, buitenste sirkelvormige rand, alle teksstrepe:

Swart Process black

Herroep

13. Die Regulasies oor die Verryking van Mieliemeel, afgekondig onder Goewermentskennisgewing No. R 2839 van 21 Desember 1979, word hiermee herroep.

Inwerkingtreding

14. Hierdie regulasies sal 6 maande na die finale publikasiedatum in werking tree.



ME TSHABALALA-MSIMANG

MINISTER VAN GESONDHEID

3-4-2003

AANHANGSEL I**BEGINSELS VAN KWALITEITSBEHEER****VERVAARDIGERS VAN GEFORTIFISEERDE KORINGMEEL EN MIELIEMEEL**

Vervaardigers van koringmeel en mieliemeel moet:

1. maandelikse rekords hou van die hoeveelheid fortifiseringsmengsels wat elke maand gebruik word. Hierdie rekords moet met die maandelikse produksierekords ooreenstem;
2. verseker dat die fortifiseringsmengsels geberg word onder die toestande neergelê deur die vervaardiger;
3. verseker dat daar met streng rotasieprosedures volgehou word om te voorkom dat ou voorraad in sterkte afneem en om die rakleeftydsvervaldatum te handhaaf
4. verseker dat alle kritieke stadia van die vervaardigingsproses gemonitor word om te verseker dat die korrekte doseringsvlakke gehandhaaf word deur middel van die volgende maatreëls:
 - (a) kontrolering van die toevoeryn vir die fortifiseringsmiddel minstens een keer per dag om te verseker dat die korrekte doseringsvlak gelewer word;
 - (b) uitvoering van uitwendige inspeksie minstens 2 keer per skof om te verseker dat fortifiseringsmiddels gebruik word en dat geen blokkering voorgekom het nie, asook rekordhouding hiervan;
 - (c) neem van twee-uurlikse steekproewe om te verseker dat die produk korrekte dosering ondergaan het deur die bepaling van een van die komponente van die fortifiseringsmengsel ooreenkomstig die toepaslike ontledingsmetode.

AANHANGSEL II**BEGINSELS VAN KWALITEITSBEHEER****VERVAARDIGERS OF LEWERANSIERS VAN FORTIFISERINGS- MENGSELS**

Vervaardigers, invoerders of leweransiers van fortifiseringsmengsels moet:

1. maandelikse rekords hou van die hoeveelhede fortifiseringsmengsels wat verkoop word aan vervaardigers van koringmeel en mieliemeel, sowel as 'n lys van name en adresse van die vermelde kopers;
2. verseker dat die kwaliteitstandaarde vir verdunners en fortifikante, as sodanig of met 'n verdunner gemeng, in ooreenstemming sal wees met die standaard soos bepaal in die nuutste uitgawe van die "Food Chemicals Codex (FCC);
3. verseker dat elke lot van die fortifiseringsmengsel vir die verskillende draers sal voldoen aan die fortifiseringstandaarde soos beskryf in Tabela 1, 2(a) en 2(b) van regulasies 9 en 10 onderskeidelik;
4. een 500-g-monster van 'n fortifiseringsmengsel vir elke voedseldraer sesmaandeliks voorlê aan 'n laboratorium wat geakkrediteer is vir die metode van analise soos aangedui deur die vervaardiger van die fortifiseringsmengsel, invoerder of leweransier van SANAS of enige ander internasionaal geakkrediteerde liggaam; die analiseverslag op rekord hou en 'n afskrif daarvan aan die Direkteur-Generaal voorlê; en
5. die koste dra van die analise gemeld in paragraaf 4.

AANHANGSEL III

AANSOEKVORM VIR REGISTRASIE VAN FORTIFISERINGSMENGSELS:
VERVAARDIGERS, INVOERDERS EN LEWERANSIERS

1. Naam van maatskappy:
2. Adres van maatskappy (Pos-):
3. Straatadres van maatskappy:
4. Telefoonnommer van maatskappy:
5. Faksnommer van maatskappy:
6. E-posnommer van maatskappy:
7. Name van: (Drukskrif asseblief)

Besturende Direkteur	
Kwaliteitsversekeringsbestuurder	
Produksiebestuurder	

8. Aktiwiteite/fasiliteite:

Is u?	Ja	Nee
'n pakker?		
'n medepakker?		
'n vervaardiger?		
'n verspreider?		
'n invoerder?		

9. Is u fasiliteit by die Medisynebeheerraad (MCC) geregistreer?
10. Is die maatskappy deur Inspekteurs wat aangestel is in terme van Artikel 26 van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965)? Ja/Nee
11. Indien ja, meld die datum van die laaste inspeksie?
12. Besik u maatskappy oor ISO-sertifisering? Ja/Nee
13. Besik u maatskappy oor HACCP-akkreditering? Ja/Nee
14. Besik u oor 'n kwaliteitsbeheerlaboratorium? Ja/Nee
15. Dui aan watter van die bestanddele wat vir die vervaardiging van die fortifiseringsmengsel gebruik word, is:
Selfvervaardig deur u maatskappy in Suid-Afrika:

Deur die moedermaatskappy elders ter wêreld vervaardig:

In Suid-Afrika verkry:

16. Hoe lank is die maatskappy by die vervaardiging van fortifiseringsmiddels betrokke?

_____ aantal jaar

17. Spesifiseer die laboratorium en metodes* wat vir die analise van elk van die mikronutriënte in die fortifiseringsmengsel gebruik sal word:

Mikronutriënt	Laboratorium	Analismetode
Vitamien A		
Tiamien (Vit. B ₁)		
Riboflaviën (Vit. B ₂)		
Niasien (Vit. B ₃)		
Piridoksien (Vit B ₆)		
Foliensuur		
Yster		
Sink		

* Slegs geakkrediteerde analitiese metodes waarvoor 'n oorspronklike sertifikaat of 'n gesertifiseerde kopie van SANAS of 'n ander geakkrediteerde, internasionale liggaam verkry is en wat aan die aansoekvorm (Aanhangsel III) geheg is, sal aanvaar word.

18. Is die oorspronklike of 'n gesertifiseerde kopie van die akkreditering vir elk van die bogenoemde mikronutriënte van 'n gespesifiseerde laboratorium by hierdie aansoek aangeheg? Ja/Nee

AANHANGSEL IV**SERTIFIKAAT VIR NAVOLGING VAN FORTIFISERINGSMENGSEL****(Hierdie sertifikaat is nie oordraagbaar van een lot na 'n ander nie)**

1. Naam van maatskappy:
2. Adres van maatskappy (Pos-):
3. Straatadres van maatskappy:
4. Telefoonnommer van maatskappy:
5. Faksnommer van maatskappy:
6. E-posadres:
7. VERKLARING:

Hiermee word verklaar dat (lot) _____ fortifiseringsmengsel kwalitatief en kwantitatief aan die volgende spesifikasie voldoen:

SPESIFIKASIE VIR FORTIFISERINGSMENGSEL

Fortifikante	Koringmeel (g/kg)	Mieliemeel (g/kg)
Vitamiën A-palmitaat ¹ (Aktiwiteit: 75 mkg RE/g)	119.0475 g	139.0000 g
Tiamienmonnitraat (Aktiwiteit: 78 % min.)	12.4644 g	14.0224 g
Riboflaviën	8.8889 g	8.4375 g
Nikotienamied/Niasienamied	118.4210 g	125.0000 g
Piridoksien-HCl (Aktiwiteit: 81% min.)	16.2443 g	19.2901 g
Foliensuur (Aktiwiteit: 90.5 % min.)	7.8927 g	11.0497 g
Elektrolietyster (Aktiwiteit: 98 % min.)	178.5714 g	178.5714 g ²
Sinkoksied (Aktiwiteit: 80 % min.)	93.7500 g	93.7500 g
Verdunner(s) (spesifiseer)	Ter aanvulling tot 1 000 g	Ter aanvulling tot 1 000 g

1. Retinolekwivalente (RE) = 1 mkg retinol = 3.33 IE (Internasionale eenhede) vitamien A.
2. Waar spesiale toestemming vir ongesifte meliemeel verleen is, moet 'n laer elektrolietystervlak van 89.2857 g/kg gebruik word.

Geteken deur:

Gemagtige handtekening

Naam in drukskrif

Datum:

Seël

AANHANGSEL V

MIKRONUTRIËNTVEREISTES VIR DIE FORTIFISERING VAN
VOEDSELDRAGERS

TABEL 4(a): KORINGMEEL

Mikronutriënte	RDA	MIKRONUTRIËNTVEREISTES				
		Per 200 g meliemeel				Per 1 kg meel
		Voedingsdoelwit		Retensie	Vereiste Byvoeging	Vereiste Byvoeging
		% RDA	Hoef.			
Vitamiën A (mkg RE)	800	31 %	250	70 %	357	1 786
Tiamien (mg)	1.40	25 %	0.3500	90 %	0.3889	1.9444
Riboflaviën (mg)	1.60	20 %	0.3200	90 %	0.3556	1.7778
Niasien (mg)	18	25 %	4.5000	95 %	4.7368	23.6842
Piridoksien (mg)	2.00	25 %	0.5000	95 %	0.5263	2.6316
Foliensuur (mg)	0.40	50 %	0.2000	70 %	0.2857	1.4286
Yster (mg)	14	50 %	7.0000	100 %	7.0000	35.0000
Sink (mg)	15	20 %	3.0000	100 %	3.0000	15.0000

TABEL 4(b): MELIEMEEL (Super, spesiale, gesifte en ongesifte)

Mikronutriënte	RDA	MIKRONUTRIËNTVEREISTES				
		Per 200 g meliemeel				Per 1 kg meel
		Voedingsdoelwit		Retensie	Vereiste Byvoeging	Vereiste Byvoeging
		% RDA	Hoef.			
Vitamiën A (mkg RE)	800	31 %	250	60 %	417	2 085
Tiamien (mg)	1.40	25 %	0.3500	80 %	0.4375	2.1875
Riboflaviën (mg)	1.60	17 %	0.2700	80 %	0.3375	1.6875
Niasien (mg)	18	25 %	4.5000	90 %	5.0000	25.0000
Piridoksien (mg)	2.00	25 %	0.5000	80 %	0.6250	3.1250
Foliensuur (mg)	0.40	50 %	0.2000	50 %	0.4000	2.0000
Yster (mg)	14	50 %	7.0000	100 %	7.0000	35.0000
Sink (mg)	15	20 %	3.0000	100 %	3.0000	15.0000

TABEL 4(c): ONGESIFTE MIELIEMEEL (Spesiale toestemming)

Mikronutriënte	RDA	MIKRONUTRIËNTVEREISTES				
		Per 200 g meliemeel				Per 1 kg meel
		Voedingsdoelwit		Retensie	Vereiste Byvoeging	Vereiste Byvoeging
		% RDA	Hoëv.			
Vitamiën A (mkg RE)	800	31 %	250	60 %	417	2 085
Tiamien (mg)	1.40	25 %	0.3500	80 %	0.4375	2.1875
Riboflaviën (mg)	1.60	17 %	0.2700	80 %	0.3375	1.6875
Niasien (mg)	18	25 %	4.5000	90 %	5.0000	25.0000
Piridoksien (mg)	2.00	25 %	0.5000	80 %	0.6250	3.1250
Foliensuur (mg)	0.40	50 %	0.2000	50 %	0.4000	2.0000
Yster (mg)	14	25 %	3.5000	100 %	3.5000	17.5000
Sink (mg)	15	25 %	3.0000	100 %	3.0000	15.0000

AANHANGSEL VI

MIKRONUTRIËNTSAMESTELLING VAN GEFORTIFISEERDE VOEDINGSMIDDELS

TABEL 5(a): WIT BROODMEEL

Mikronutriënte	SAMESTELLING PER 1 kg MEEL				
	Fortifisering	Natuurlik	Totaal	Toleransie	Netto
Vitamiën A (mkg RE)	1 788	0	1 786	±10 %	1 610
Tiamien (mg)	1.9444	2.4000	4.3444	±10 %	3.9100
Riboflaviën (mg)	1.7778	0.5000	2.2778	±10 %	2.0500
Niasien (mg)	23.6842	19.0000	42.6842	±10 %	38.4158
Piridoksien (mg)	2.6316	0.5000	3.1316	±10 %	2.8184
Foliensuur (mg)	1.4286	0.0800	1.5086	±10 %	1.3577
Yster(mg)	35.0000	13.5000	48.5000	±10 %	43.6500
Sink (mg)	15.0000	8.0000	23.0000	±10 %	20.7000

TABEL 5(b): BRUIN BROODMEEL (88 % wit broodmeel + 12 % semels)

Mikronutriënte	SAMESTELLING PER 1 kg MEEL				
	Fortifisering	Natuurlik	Totaal	Toleransie	Netto
Vitamiën A (mkg RE)	1 572	0	1 572	±10 %	1 415
Tiamien (mg)	1.7111	2.5000	4.2111	±10 %	3.7900
Riboflaviën (mg)	1.5645	0.6000	2.1645	±10 %	1.9481
Niasien (mg)	20.8421	40.0000	60.8421	±10 %	54.7579
Piridoksien (mg)	2.3155	1.1000	3.4155	±10 %	3.0740
Foliensuur (mg)	1.2572	0.1200	1.3772	±10 %	1.2395
Yster(mg)	30.8000	22.5000	53.3000	±10 %	47.9700
Sink (mg)	13.2000	16.5000	29.7000	±10 %	26.7300

TABEL 5 (c): WITBROOD

Mikronutriënte	SAMESTELLING PER 1 kg MEEL				
	Fortifisering	Natuurlik	Totaal	Toleransie	Netto
Vitamiën A (mkg RE)	834	0	834	±5 %	800
Tiamien (mg)	1.1673	1.6000	2.7673	±10 %	2.4901
Riboflaviën (mg)	1.0672	0.5000	1.5672	±10 %	1.4105
Niasien (mg)	15.0075	16.0000	31.0075	±10 %	27.9068
Piridoksien (mg)	1.6675	0.7000	2.3675	±10 %	2.1308
Foliensuur (mg)	0.6670	0.1500	0.8170	±10 %	0.7353
Yster(mg)	23.3450	12.5000	35.8450	±10 %	32.2605
Sink (mg)	10.0050	7.0000	17.0050	±10 %	15.3045

TABEL 5 (d): BRUINBROOD

Mikronutriënte	SAMESTELLING PER 1 kg MEEL				
	Fortifisering	Natuurlik	Totaal	Toleransie	Netto
Vitamiën A (mkg RE)	734	0	734	±5 %	700
Tiamien (mg)	1.0272	1.8000	2.8272	±10 %	2.5445
Riboflaviën (mg)	0.9391	0.6000	1.5391	±10 %	1.3852
Niasien (mg)	13.2066	33.0000	46.2066	±10 %	41.5859
Piridoksien (mg)	1.4674	1.5000	2.9674	±10 %	2.6707
Foliensuur (mg)	0.5870	0.2300	0.8196	±10 %	0.7353
Yster(mg)	20.5436	18.0000	38.5436	±10 %	34.6892
Sink (mg)	8.8044	13.5000	22.3044	±10 %	20.0740

TABEL 6(a): SUPER MIELIEMEEL

Mikronutriënte	SAMESTELLING PER 1 kg MEEL				
	Fortifisering	Natuurlik	Totaal	Toleransie	Netto
Vitamien A (mkg RE)	2 085	0	2 085	±10 %	1 877
Tiamien (mg)	2.1875	1.2500	3.4375	±10 %	3.0938
Riboflaviën (mg)	1.6875	0.3000	1.9875	±10 %	1,7888
Niasien (mg)	25.0000	8.0000	33.0000	±10 %	29.7000
Piridoksien (mg)	3.1250	1.2000	4.3250	±10 %	3.8925
Foliensuur (mg)	2.0000	0.1000	2.1000	±10 %	1.8900
Yster(mg)	35.0000	6.5000	41.5000	±10 %	37.3500
Sink (mg)	15.0000	6.0000	21.0000	±10 %	18.9000

TABEL 6(b): SPESIALE MIELIEMEEL

Mikronutriënte	SAMESTELLING PER 1 kg MEEL				
	Fortifisering	Natuurlik	Totaal	Toleransie	Netto
Vitamien A (mkg RE)	2 085	0	2 085	±10 %	1 877
Tiamien (mg)	2.1875	2.1000	4.2875	±10 %	3.8588
Riboflaviën (mg)	1.6875	0.4000	2.0875	±10 %	1.8788
Niasien (mg)	25.0000	10.4000	35.4000	±10 %	31.8600
Piridoksien (mg)	3.1250	1.6000	4.7250	±10 %	4.2525
Foliensuur (mg)	2.0000	0.1200	2.1200	±10 %	1.9080
Yster(mg)	35.0000	9.6000	44.6000	±10 %	40.1400
Sink (mg)	15.0000	10.0500	25.0500	±10 %	22.5450

TABEL 6 (c): GESIFTE MIELIEMEEL

Mikronutriënte	SAMESTELLING PER 1 kg MEEL				
	Fortifisering	Natuurlik	Totaal	Toleransie	Netto
Vitamiën A (mkg RE)	2 085	0	2 085	±10 %	1 877
Tiamien (mg)	2.1875	3.1000	5.2875	±10 %	4.7588
Riboflaviën (mg)	1.6875	0.5000	2.1875	±10 %	1.9688
Niasien (mg)	25.0000	13.5000	38.5000	±10 %	34.6500
Piridoksien (mg)	3.1250	2.2000	5.3250	±10 %	4.7925
Foliensuur (mg)	2.0000	0.1400	2.1400	±10 %	1.9260
Yster(mg)	35.0000	14.2000	49.2000	±10 %	44.2800
Sink (mg)	15.0000	14.5500	29.5500	±10 %	26.5950

TABEL 6(d): ONGESIFTE MIELIEMEEL

Mikronutriënte	SAMESTELLING PER 1 kg MEEL				
	Fortifisering	Natuurlik	Totaal	Toleransie	Netto
Vitamiën A (mkg RE)	2 085	0	2 085	±10 %	1 877
Tiamien (mg)	2.1875	4.0000	6.1875	±10 %	5.5688
Riboflaviën (mg)	1.6875	0.6000	2.2875	±10 %	2.0588
Niasien (mg)	25.0000	17.5000	42.5000	±10 %	38.2500
Piridoksien (mg)	3.1250	2.9000	6.0250	±10 %	5.4225
Foliensuur (mg)	2.0000	0.1600	2.1600	±10 %	1.9440
Yster(mg)	35.0000	21.0000	56.0000	±10 %	50.4000*
Sink (mg)	15.0000	18.5500	33.5500	±10 %	30.1950

* Waar spesiale toestemming vir ongesifte meliëmeel verleen is, sal 'n laer netto ysterinhoud van 34.65 mg/kg van toepassing wees.

AANHANGSEL VII

Faksimilee 1 (Monochroom kopie)



Faksimilee 2 (Volkleur kopie)



AANHANGSEL VIII

Faksimilee 1 (Monochroom kopie)



Faksimile 2 (Volkleur kopie)



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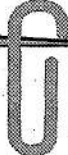
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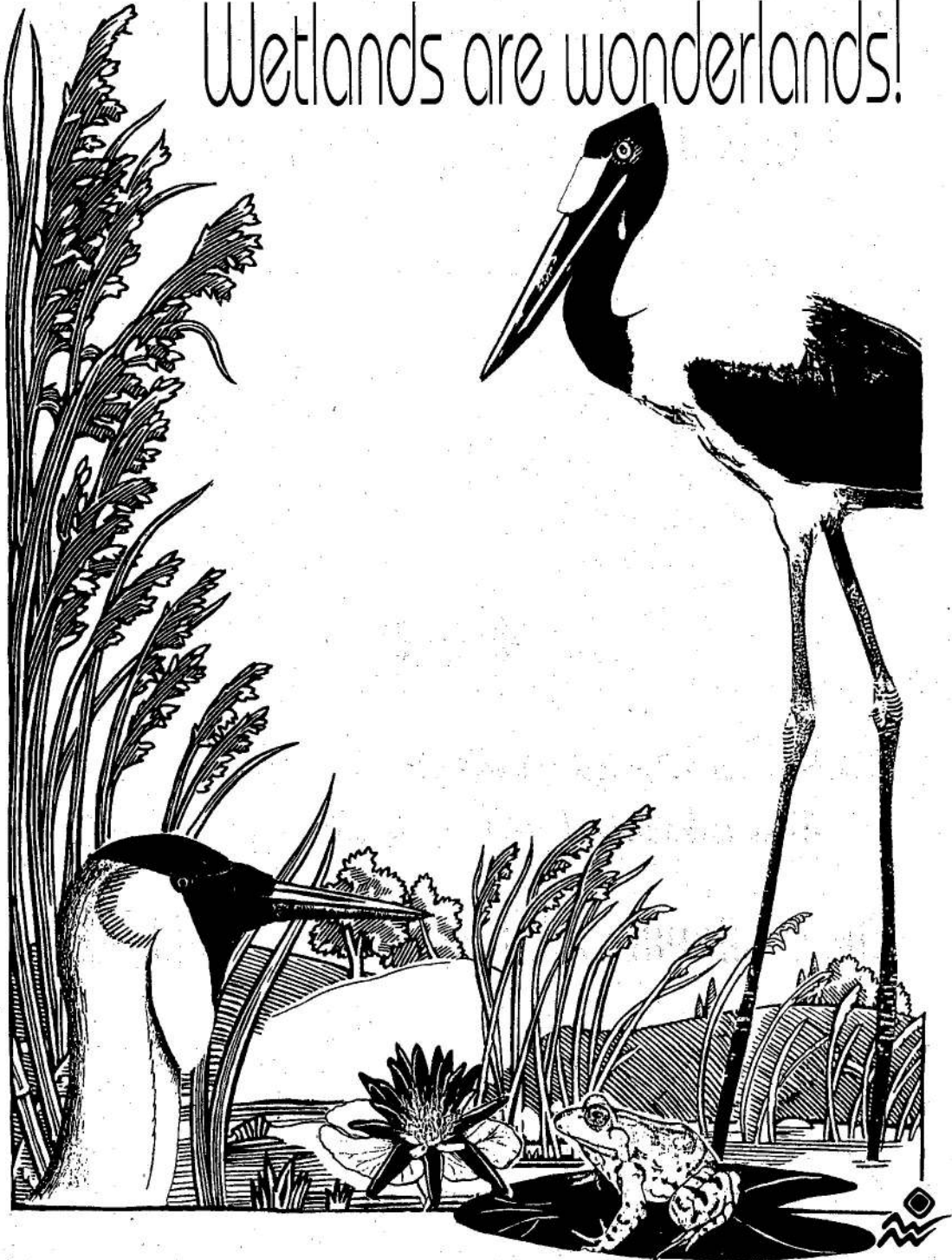
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Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 334-4508, 334-4509, 334-4510
Advertisements: Tel: (012) 334-4673, 334-4674, 334-4504
Subscriptions: Tel: (012) 334-4735, 334-4736, 334-4737
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Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001
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