

GOVERNMENT NOTICES GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH DEPARTEMENT VAN GESONDHEID

No. R. 1206

14 November 2008

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

AMENDMENT OF 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.

SCHEDULE

1. Definitions

In this Schedule, "the Regulations" means the Regulations relating to the Fortification of Certain Foodstuffs, as published in Government Notice No. R. 504 of 7 April 2003.

Amendment of regulation 1 of the Regulations

2. Regulation 1 of the Regulations is hereby amended by –

(a) the insertion after the definition of "the Act" of the following definition:

"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."

Amendment of regulation 9 of the Regulations

3. Regulation 9 of the Regulations is hereby amended by the substitution for regulation 9 of the following regulation:

"9(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
Thiamine mononitrate (Activity: 78% min.)	1,9444 mg	2,4929 mg	12,4644

Riboflavin	1,7778 mg	1,7778 mg	8,8889
Nicotinamide/ niacinamide	23,6842 mg	23,6842 mg	118,4210
Pyridoxine HCl (Activity: 81% min.)	2,6316 mg	3,2489 mg	16,2443
Folic acid (Activity: 90,5% min.)	1,4286 mg	1,5786 mg	7,8927
Electrolytic iron ³ (Activity: 98% min.)	35,00 mg	35,7143 mg	178,5714
Zinc oxide (Activity: 80% min.)	15,00 mg	18,7500 mg	93,7500
Diluent	-	To complete 200 mg	To complete 1 000 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."

Amendment of regulation 10 of the Regulations

4. Regulation 10 of the Regulations is hereby amended by –
 - (a) the substitution for paragraph (b) of the following paragraph:
 - "(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
Thiamine mononitrate (Activity: 78% min.)	2.1875 mg	2,8045 mg	14,0224
Riboflavin	1.6875 mg	1,6875 mg	8,4375
Nicotinamide/niacinamide	25.000 mg	25,0000 mg	125,0000
Pyridoxine HCl (Activity: 81% min.)	3.1250 mg	3,8580 mg	19,2901
Folic acid (Activity: 90,5% min.)	2.0000 mg	2,2099 mg	11,0497
Electrolytic iron ³ (Activity: 98% min.)	17.5000 mg	17,857 mg	89,2857
Zinc oxide (Activity: 80% min.)	15.00 mg	18,7500 mg	93,7500
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) by the substitution for paragraph (c) of the following paragraph:

- “(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.”

Amendment of regulation 11 of the Regulations

5. Regulation 11 of the Regulations is hereby amended-
- (1) by the substitution for-
- (a) paragraph (c) of the following paragraph
- “(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.

Amendment of regulation 12 of the Regulations

6. Regulation 12 of the Regulations is hereby amended-
- (1) by the substitution for-
- (a) paragraph (a) of the following paragraph:
- “(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;”
- (b) paragraph (b) of the following paragraph:
- “(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;”
- (c) paragraph (f) of the following paragraph:
- “(f) the fortification addition rate must be clearly indicated on the label of the fortification mixes;”; and
- (d) paragraph (g) of the following paragraph:
- “(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.”
- (2) by the insertion after subregulation (l) of the following new subregulation:

“(m) Any manufacturer or importer of food vehicles who wishes to be exempted from the provisions of regulations 12 must apply in writing, giving full reasons for the request, to the Director-General for the attention of the Directorate: Nutrition.”

Amendment of regulation 13 of the Regulations

7. Regulation of the regulations is hereby amended by the insertion after subregulation (5) of the following subregulation:

“(6) Any manufacturer or importer of food vehicles who wishes to be exempted from the provisions of regulation 12 must apply in writing, giving full reasons for the request, to the Director-General for the attention of the Directorate: Nutrition.”

Amendment of Annexure II of the Regulations

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

Amendment of Annexure III of the Regulations

9. Annexure III of the Regulations are hereby amended by -

(a) the substitution for questions 17 and 18 of Annexure III of the Regulations of the following questions:

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

(b) the insertion after question 18 of the following question:

- "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."

Amendment of Annexure IV of the Regulations

10. Annexure IV of the Regulations is hereby amended by the insertion after item 7 of the following item:

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

Insertion of Annexure VIA in the Regulations

11. The following Annexure is hereby inserted after Annexure VI of the Regulations:

"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

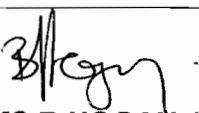
TABLE 6(f): UNSIFTED MAIZE MEAL (special permission)

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


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MINISTER OF HEALTH