# Government Gazette
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REPUBLIEK VAN SUID-AFRIKA

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

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# GOVERNMENT NOTICE

## DEPARTMENT OF HEALTH

**No. R. 591** **7 July 2015**

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

### REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN: AMENDMENT

The Minister of Health intends, under section 15 (1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No.54 of 1972), to make the Regulations set out in the Schedule hereto.

Interested persons are invited to submit any substantiated comments in writing on the proposed amendments to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for attention of the Cluster Manager: Health Promotion and Nutrition), within three months from the date of publication of this notice.

### SCHEDULE

**Amendment of Regulation 1 of the Regulations**

1. Regulation 1 of the Regulations Relating to Foodstuffs for Infants and Young Children (hereinafter referred to as "the Regulations"), is hereby amended by:

(a) the substitution for the definition "complementary food" of the following definition:

**"complementary food"** means any foodstuff, whether in liquid, solid or semi-solid form, given to an infant and young child from the age of six months as part of the transitional process during which an infant learns to eat food appropriate for his or her developmental stage while continuing to breastfeed or be fed with an appropriate formula;", and

(b) The substitution for the definition "infant" of the following definition:

**"infant"** means a child not more than 12 months of age;".

**Amendment of Regulation 3 of the Regulations**

2. Regulation 3 of the Regulations is hereby amended by:

(a) the substitution for paragraph (a) of Sub-regulation 1 of the following paragraph:

"(a) The front panel shall contain the following:

(i) the age range of the infants or young children for which such product is suitable, under the name or description of the product in letters that are not less than 3mm in height for the smallest letters for a 400g tin and shall increase proportionally with the size of the tin;

(ii) these clear, conspicuous and easily readable messages in bold letters at least 3mm in height, which shall be at the top of the front main panel of the label:

(aa) "does not contain breast milk" and

(bb) "breast milk is the best food for babies";

(iii) these clear, conspicuous and easily readable messages in bold letters at least 2mm in height, which shall be at the bottom of the front main panel of the label –

(aa) "this product shall only be used on the advice of a health professional"; and

(bb) this product is not always sterile. It must be prepared and used appropriately.".

(b) the substitution for paragraph (a) of Sub-regulation 2 of the following paragraph:

"(a) The front panel shall contain the following:

(i) the indication for use, which shall be specified in letters not less than 2mm as follows: "For the dietary management of ..." with the blank filled in with the specific disease(s), disorder(s), or medical condition(s) for which the product is intended, and for which it has been shown to be effective;

(ii) the statement "Breast milk is the best food for babies" in bold letters at least 3mm in height, which shall be at the top of the front main panel of the label, provided that in the case of infant and follow-up formula for special dietary management for infants with specific medical conditions, for which breast milk is contraindicated based on medical grounds, the aforementioned message need not appear on the label;

(iii) the age range of the infants for which such product is suitable, under the name or description of the product in letters that are not less than 3mm in height for the smallest letters for a 400g tin and shall increase proportionally with the size of the tin;

(iv) a clear, conspicuous and easily readable message in bold letters at least 2mm in height: "This product is not always sterile. It must be prepared and used appropriately;

(v) A prominent statement that says "USE UNDER MEDICAL SUPERVISION", which shall appear in bold letters at least 3mm in height.".

(c) the substitution for Sub-regulation 5 of the following Sub-regulation:

"(5) (a) The label of liquid ready to use formula is exempted from the requirements in Regulation 3(3)(b), (c) and (e) and the messages in Regulation 3(1)(a)(iii)(bb) and 3(2)(a)(iv).

(b) The information required to appear on the label of a single serving liquid ready to use formula, shall be in English and where possible, at least one other official language of the Republic of South Africa.

(c) A single serving liquid ready to use formula is exempted from the requirement in Regulation 3(6).".

(d) the insertion of the following Sub-regulations:

"(12) Infant formula, follow-up formula and infant and follow-up formula for special dietary or medical purposes shall indicate on the label or container a date marking which guarantees the product's safety, nutritional potency and nutritional properties.

(13) No person shall:

(a) sell an infant formula, follow-up formula and infant and follow-up formula for special dietary or medical purposes after the date marking mentioned in 3(12) has expired; and

(b) change the date marking on the infant formula, follow-up formula and infant and follow-up formula for special dietary or medical purposes.".

**Amendment of Regulation 6 of the Regulations**

3. Regulation 6 of the Regulations is hereby amended by:-

(a) the substitution for Sub-regulation 3 of the following Sub-regulation:

"(3) A feeding bottle, teat or feeding cup or the label, package or container thereof shall not show any graphic representation other than:

(a) for illustrating cleaning and sterilisation; and

(b) the logo of the manufacturer or distributor.".

(b) the substitution for Sub-regulation 5 of the following Sub-regulation:

"(5) A feeding bottle, teat or feeding cup or the label, package or container of a feeding bottle, teat or feeding cup shall not contain any words or images that create the impression that such feeding bottle and teat are manufactured in accordance with the recommendation of a medical or dental practitioner, or another person registered

under the Health Professions Act, 1974 (Act No. 56 of 1974), or the Allied Health Professions Act, 1982 (Act No. 63 of 1982) or any other health profession legislation.".

**Amendment of Regulation 9 of the Regulations**

4. Regulation 9 of the Regulations is hereby amended by the substitution for Regulation 9 of the following Regulation-

"9 (1) No manufacturer, distributor, retailer, importer or person shall subject to Sub-regulation 9 (2), (3) and (4), distribute free, or at low cost, supplies or samples of designated products to health care personnel or any other person, or to a health establishment.

(2) Notwithstanding the provisions of Sub-regulation 9 (1), a person, manufacturer or distributor may distribute free, or at low cost sales of designated products referred to in Sub-regulation 7 (1) to hospices, orphanages or places of safety, provided that such:

(a) designated products shall comply with all of the relevant provisions in Codex Standards and in these regulations;
(b) the supply of the products shall be guaranteed for as long as the infants concerned need them; and
(c) designated products may not be resold.

(3) Notwithstanding the provisions of Sub-regulation 9(1), a person, manufacturer or distributor may distribute for free or at low cost, complementary foods to hospices, orphanages, places of safety, other social welfare institutions and emergency relief operations provided that such complementary foods shall:

(a) comply with all of the relevant provisions in Codex Standards and in these Regulations; and
(b) may not be resold.

(4) No person in a health establishment shall accept or give to any other person for free or at low cost supplies or samples of a designated product.".

**Amendment of Regulation 12 of the Regulations**

5. Regulation 12 of the Regulations is hereby deleted.

**Amendment of Regulation 13 of the Regulations**

6. Regulation 13 of the Regulations is hereby deleted.

**Amendment of Regulation 16 of the Regulations**

7. Regulation 16 of the Regulations is hereby amended by the substitution for Regulation 16 of the following Regulation:

"16 (1) Regulations 2, 3, 4, 5, and 6 shall enter into force **24 months** from date of the publication of these regulations;

(2) Regulations 7, 8 and 11 shall enter into force **12 months** from date of the publication of these regulations;

(3) Regulations 9 and 10 shall enter into force **6 months** from date of the publication of these regulations.".

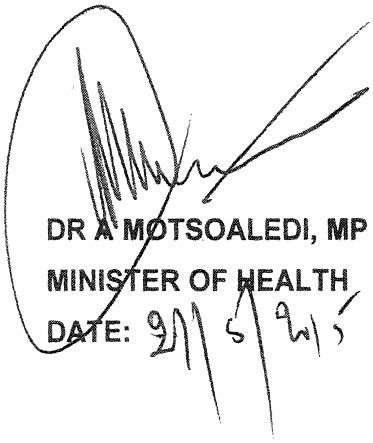
**Amendment of Regulation 17 of the Regulations**

8. Regulation 17 of the Regulations is hereby amended by the substitution for Regulation 17 of the following Regulation:

"17 (1) Subject to the provisions of Sub-regulation 14(1) the date of manufacture of designated products will be considered the date from which full compliance are applicable; and

(2) Manufacturers, distributors and retailers must, **within 48 months** of the date of

publication of these Regulations, remove all non-compliant products from the market.".



DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 9/5/2015

**Amendment of Annexure A of the Regulations**

9. Annexure A of the Regulations is hereby amended by the substitution for Annexure A of the following Annexure:

**"ANNEXURE A**

**Minimum Mandatory Nutritional Information for infant formula, follow-up formula, or infant formula or follow-up formula for special dietary management for infants with specific medical conditions.**

Typical nutritional information:

| | Per 100g powder as sold | Per 100 ml reconstituted ready to use | Per 100 kJ ready to use |
|---|---|---|---|
| Energy (kJ) | | | |
| Protein (g) | | | |
| Added individual amino* acids (mg) | | | |
| Total Carbohydrate (g) | | | |
| of which lactose (g) and/or glucose (g) | | | |
| Total fat (g) | | | |
| Linoleic acid (mg) | | | |
| Linolenic acid (mg) | | | |
| Docosahexaenoic acid* | | | |
| Eicosapentanoic acid* | | | |
| Arachidonic acid* | | | |
| Dietary fibre (g) | | | |
| Total Sodium (mg) | | | |
| Vitamins in alphabetic order (in appropriate unit of measurement) | | | |
| Minerals and trace elements in alphabetic order (in appropriate unit of measurement) | | | |
| Nucleotides* | | | |
| L(+) lactic acid producing bacteria* | | | |

* When applicable"

**Amendment of Annexure B of the Regulations**

10. Annexure B of the Regulations is hereby amended by the substitution for Annexure B of the following Annexure:

**"ANNEXURE B**

**Required Nutritional Information for complementary foods and liquid milks, powdered milks, modified powdered milks, and powdered drinks should be indicated in the format as prescribed by the latest Regulations Relating to the Labelling and Advertising of Foodstuffs published in terms of the Act, including all amendments. In addition to include a column indicating the % NRV per serving.**

**All nutritional information shall be given in respect of the foodstuff actually in the package or container.".**

**Amendment of Annexure C of the Regulations**

11. Annexure C of the Regulations is hereby amended by the substitution for Annexure C of the following Annexure:

**"ANNEXURE C**

**Nutrient Reference Values for Infants and Young Children**

| | | **Infants** | **Young children** |
|---|---|---|---|
| | | **6months – 12 months** | Individuals 13 months to 36 months" |
| Energy | kJ | 440/kg body mass | 5 600 |
| Protein | G | 1,5/kg body mass | 13 |
| Vitamin A activity | | | |
| (1) Vitamin A | IU | **1665** | 1000 |
| (2) Retinol equivalent | µg $RE^2$ | 500 | 300 |
| Vitamin D | IU | 200 | 200 |
| | µg | 5 | 5 |
| Vitamin E activity | IU | 7,5 | 8,9 |
| | mg $\alpha$ $TE^4$ | 5 | 6 |
| Ascorbic acid | mg | 50 | 50 |
| Biotin | µg | 50 | 65 |
| Folic acid | µg | 80 | 150 |
| Pantothenic acid | mg | 1,8 | 2,0 |
| Nicotinic acid | mg | 4,0 | 6,0 |
| Riboflavin(Vitamin B2) | mg | 0,4 | 0,5 |
| Thiamin (Vitamin B1) | mg | 0,3 | 0,5 |
| Pyridoxine (Vitamin B6) | mg | 0,3 | 0,5 |
| Cyanocobalamin (Vitamin B12) | µg | 0,5 | 0,9 |
| Vitamin K | µg | 2,5 | 30 |
| Calcium | mg | 270 | 500 |
| Phosphorus | mg | 275 | 460 |
| Iodine | µg | 130 | 90 |

| | | | |
|---|---|---|---|
| Iron | mg | 11 | 7,0 |
| Magnesium | mg | 75 | 80 |
| Copper | mg | 1,0 | 1,2 |
| Zinc | mg | 3,0 | 3,0 |
| Potassium | mg | 1 275 | 1 650 |
| Sodium | mg | 750 | 975 |
| Chloride | mg | 1 200 | 1 500 |
| Manganese | mg | 1,0 | 1,5 |
| Fluoride | mg | 0,5 | 0,7 |
| Chromium | mg | 5,5 | 5,5 |
| Selenium | µg | 20 | 20 |
| Molybdenum | mg | 0,08 | 0,1 |
| Choline | mg | 150 | 200 |

"

**Amendment of Annexure D of the Regulations**

12. Annexure D of the Regulations is hereby amended by the substitution for Annexure D of the following Annexure:

**"ANNEXURE D**

**HEALTH MESSAGES**

1. Infant formula increases an infant's risk of allergy.
2. Infant formula increases an infant's risk of ear infections.
3. Infant formula increases an infant's risk of acute respiratory disease.
4. Infant formula increases an infant's risk of gastrointestinal infections.".

# IMPORTANT

## *Information*

## from Government Printing Works

Dear Valued Customers,

Government Printing Works has implemented rules for completing and submitting the electronic Adobe Forms when you, the customer, submits your notice request.

Please take note of these guidelines when completing your form.


**GPW Business Rules**

1. No hand written notices will be accepted for processing, this includes Adobe forms which have been completed by hand.
2. Notices can only be submitted in Adobe electronic form format to the email submission address submit.egazette@gpw.gov.za. This means that any notice submissions not on an Adobe electronic form that are submitted to this mailbox will be **rejected**. National or Provincial gazette notices, where the Z95 or Z95Prov must be an Adobe form but the notice content (body) will be an attachment.
3. Notices brought into GPW by "walk-in" customers on electronic media can only be submitted in Adobe electronic form format. This means that any notice submissions not on an Adobe electronic form that are submitted by the customer on electronic media will be **rejected**. National or Provincial gazette notices, where the Z95 or Z95Prov must be an Adobe form but the notice content (body) will be an attachment.
4. All customers who walk in to GPW that wish to submit a notice that is not on an electronic Adobe form will be routed to the Contact Centre where the customer will be taken through the completion of the form by a GPW representative. Where a customer walks into GPW with a stack of hard copy notices delivered by a messenger on behalf of a newspaper the messenger must be referred back to the sender as the submission does not adhere to the submission rules.
5. All notice submissions that do not comply with point 2 will be charged full price for the notice submission.
6. The current cut-off of all Gazette's remains unchanged for all channels. (Refer to the GPW website for submission deadlines – www.gpwonline.co.za)
7. Incorrectly completed forms and notices submitted in the wrong format will be rejected to the customer to be corrected and resubmitted. Assistance will be available through the Contact Centre should help be required when completing the forms. (012-748 6200 or email info.egazette@gpw.gov.za)
8. All re-submissions by customers will be subject to the above cut-off times.
9. All submissions and re-submissions that miss the cut-off will be rejected to the customer to be submitted with a new publication date.
10. Information on forms will be taken as the primary source of the notice to be published. Any instructions that are on the email body or covering letter that contradicts the notice form content will be ignored.

You are therefore advised that effective from **Monday, 18 May 2015** should you not comply with our new rules of engagement, all notice requests will be rejected by our new system.

Furthermore, the fax number **012- 748 6030** will also be **discontinued** from this date and customers will only be able to submit notice requests through the email address submit.egazette@gpw.gov.za.

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