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# GOVERNMENT NOTICE GOEWERMENTSKENNISGEWING

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## DEPARTMENT OF HEALTH DEPARTEMENT VAN GESONDHEID

No. R. 991

6 December 2012

FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, 1972 (ACT 54 OF 1972)

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

The Minister of Health has, under section 15 (1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), made the regulations set out in the Schedule hereto.

#### SCHEDULE

##### 1 DEFINITIONS

In these regulations, any expression to which a meaning has been assigned in the Act shall bear such meaning, and unless the context otherwise indicates-

“**blends**” means a blend or mixture of cow’s milk, components of cow’s milk, vegetable fats and/or glucose;

“**brand name**” means the trademark or name given by a manufacturer or distributor to a designated product or range of designated products and includes brand logos;

“**breastfeeding**” means the suckling of the infant or young child on the mother’s breast;

“**breast milk**” means human milk, and can be obtained by means of the infant or young child suckling on the mother’s breast or by the expression of milk from the breast;

“**Codex Standards**” means the latest adopted version of the relevant Codex Standards as issued by the Codex Alimentarius Commission of the Joint FAO/WHO Food Standards Programme;

“**community pharmacy**” means a pharmacy wherein or from which some or all of the services as prescribed in regulation 18 of the Regulations Relating to the Practice of Pharmacy , published in terms of Pharmacy Act, 1974 (Act No. 53 of 1974) under Government Notice No. R. 1158, are provided to persons requiring pharmaceutical services, but excludes an institutional pharmacy;

“**comparative claim**” is a claim that compares the nutrient levels and/or energy value of two or more similar foodstuffs;

“**complementary food**” means any foodstuff, whether in liquid, solid or semi-solid form, given to an infant 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;

“**container**” includes anything in which or with which food is served, stored, displayed, packed, wrapped, kept or transported and with which food is in direct contact;

“**designated product**” means—

- (a) infant formula;
- (b) follow-up formula;
- (c) infant or follow-up formula for special dietary management for infants with specific medical conditions;
- (d) complementary foods;
- (e) liquid milks, powdered milks, modified powdered milks, or powdered drinks marketed or otherwise represented as suitable for infants or young children;
- (f) feeding bottles, teats and feeding cups with spouts, straws or teats; and
- (g) any other products marketed or represented as suitable for feeding infants and young children that the Minister may so designate by notice published in the Gazette.

“**Directorate**” means the Directorate responsible for nutrition in the National Department of Health;

“**Director-General**” means the Director-General: Department of Health;

“**distributor**” means a person, corporation or other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing and or distributing any designated product; at a wholesale or retail level;

**“educational information”** means any written or audio-visual material or information disseminated by an individual that seeks to impart knowledge, such as presentations, brochures or articles;

**“educational material”** means any written or audio-visual material intended for the general public, such as flyers, brochures, books, newspaper articles, video tapes, information from the Internet or other forms, that purports to give guidance on the appropriate use of products for infants and young children;

**“feeding cup”** means a cup with an artificial teat, spout or straws which is used to feed infants or young children;

**“feeding bottle”** means a device with an artificial teat, which is used to feed infants or young children;

**“follow-up formula”** means a product formulated industrially according to the composition of which is based on the applicable Codex standard and marketed or otherwise represented as suitable for an infant from six months on or a young child;

**“gift”** means something given free of charge, and in this context, includes, but is not limited to, free samples of designated products, meals and refreshments, diaries, stationery, calendars, cot tags, stickers, growth charts, prescription pads, tongue depressors or any item of whatever value by manufacturers, distributors, retailers and their representatives, of the designated products;

**“graphic representation”** means illustrations, photographs, drawings or pictures of infants, young children, child characters, cartoons or any other forms that resemble them, human or not, such as humanized fruits, vegetables, animals and/or flowers, among others;

**“health claim”** means any representation that states, suggests or implies that a relationship exists between a food or a constituent of a food and health, and includes, but is not limited to nutrient function claims, enhanced function claims, reduction of disease risk claims, pre-biotic claims and pro-biotic claims;

**“health establishment”** means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient

treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services;

**“health care personnel”** means health care providers and health workers;

**“health care provider”** means any person providing health services and/or social services in terms of any law, including in terms of the Allied Health Professions Act, 1982 (Act No.63 of 1982), Health Professions Act, 1974 (Act No. 56 of 1974), Nursing Act, 1978 (Act No. 53 of 1974), Pharmacy Act, 1974 (Act No. 53 of 1974) and Dental Technicians Act, 1978 (Act No. 19 of 1979);

**“health worker”** means any person who is directly or indirectly involved in the provision of health services to a user or in training to provide health care services, but does not include a health care provider. This includes social workers, lay counsellors, trainers or voluntary unpaid workers;

**“hermetically sealed container”** means an unopened container which cannot be opened without breaking or damaging such container or a seal, adhesive label or other part of or attachment to such container and which is intended to safeguard the hygienic and other qualities of the products and to protect its contents against the entry of micro-organisms;

**“imitation dairy product”** means any product other than a dairy product, that is of animal or plant origin and in general appearance, presentation and intended use corresponds to a dairy product;

**“industrially produced trans-fatty acids”** means all the geometrical isomers of monounsaturated fatty acids with one trans double bond, i.e. C14:1, C16:1, C18:1, C20:1, C22:1, and polyunsaturated fatty acids with one or more trans double bonds, i.e. C18:2, C18:3, C20:2, C22:2 having non-conjugated, interrupted by at least one methylene group, carbon-carbon double bonds in the trans configuration and excludes natural trans-fatty acids;

**“infant”** means a person not more than 12 months of age;

**“infant formula”** means a formulated product specially manufactured in accordance with the applicable Codex standard to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding;

**“infant or follow-up formula for special dietary management for infants with specific medical conditions”** means a formulated product that complies with the latest adopted version of the Codex Standard 72-1981 titled “Standard for infant formula and formulas for special medical purposes intended for infants”.

**“institutional pharmacy”** as defined in the Regulations Relating to the Practice of Pharmacy, published in terms of Pharmacy Act, 1974 (Act No. 53 of 1974) under Government Notice No. R. 1158 means a pharmacy situated in—

- (a) a public health facility, wherein or from which some or all of the services as prescribed in regulation 18 of these regulations are provided to persons requiring pharmaceutical services from or at that public health facility; or
- (b) a private health facility, wherein or from which some or all of the services as prescribed in regulation 18 of these regulations are provided to persons requiring pharmaceutical services from or at that private health facility,

**“label”** means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of any designated product within the scope of these regulations;

**“low cost”** means a price lower than the whole-sale price or in absence of such a price, lower than 80% of the retail price;

**“manufacturer”** means a person, corporation or other entity engaged in the business of manufacturing, such as production, preparation, processing, preservation or any other manufacturing process of a designated product, whether directly, through an agent, or through a person controlled by or under an agreement with such a person, corporation or other entity;

**“marketing”** means promoting, distributing, selling, or advertising a designated product, and includes product public relations and information services, including the use of professional service representatives, or any person acting on behalf of a manufacturer or distributor;

**“marketing personnel”** means any person who is involved in the marketing of a designated product;

**“medicinal claim”** means a claim which states or implies that a product has the property of treating, preventing or curing human disease, in order to be permitted to make a medicinal claim, a product must be classed as a medicine in accordance with the definition in section 1 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965);

**“modified powdered milk”** means a product made of natural milk or of whole, skimmed or partially skimmed powdered milk, or of a combination of these;

**“non-exclusive breastfeeding”** means feeding breast milk as well as other milks (including commercial formula or home-prepared milk), foods or liquids;

**“non-nutritive sweetener”** means a sweetener or a mixture of non-nutritive sweeteners, of which the level of sweetening equals 5g of sucrose and does not have an energy value of more than 8kJ;

**“nutrient content claim”** means a claim that describes the level of a nutrient or energy contained in a foodstuff;

**“nutrition claim”** means any representation that refers to a specific nutrient or food constituent content of a particular foodstuff such as but not limited to nutrient content or comparative claim.

The following do not constitute nutrition claims:

- (a) the mention of substances in the list of ingredients;
- (b) the mention of nutrients as a mandatory part of nutrition labelling;
- (c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation;

**“official language”** means any one of the 11 official South African languages: Afrikaans, English, Ndebele, Pedi, Sotho, Swazi, Tsonga, Tswana, Venda, Xhosa, Zulu;

**“pack-shot”** means any representation of a designated product, including photographs, pictures, graphics or line drawings;

**“pharmacy”** means community pharmacy and institutional pharmacy;

**“powdered drink”** means a substance intended to be added to liquid milk, powdered milk, modified powdered milk, water, or other beverages;

**“processed cereal-based foodstuff for infants or young children”** has the meaning as described in the latest adopted version of the Codex Standard 74-1981 titled “Codex Standard for processed cereal-based foods for infants and young children”.

**“promote”** means to employ any method scheme or design, of encouraging or enticing a person or group of persons, in whatever form, to purchase or use a designated product, and includes but is not limited to, advertising, point-of-sale advertising, the giving of samples, special sales, free supplies, donations, sponsorships, gifts, whether related or unrelated to purchases of designated products, free utensils or other articles, prizes, carrier bags with pack-shots or product logos, prizes or special displays at retail outlets, discount coupons, premiums, loss-leaders, tie-in sales, rebates and other give-aways;

**“proprietary product”** means a designated product which is explicitly associated with a particular manufacturer, distributor or retailer;

**“reputable laboratory”** means a laboratory that is accredited according to the International Laboratory Accreditation Cooperation (ILAC) or South African National Accreditation System (SANAS);

**“resealable container”** means containers, including packaging materials, made only of substances which are safe, suitable for their intended uses, safeguard the hygienic and other qualities of the foodstuff, that will ensure that the product cannot be opened without breaking or damaging such package and after opening, can be closed again in such a way as to prevent spoilage and contamination;

**“retail outlet”** means a pharmacy, shop, supermarket or any other premises or outlet such as direct mail, indirect marketing and sales or other virtual premises used by a manufacturer, distributor, agent or importer or any other person, to sell any designated product;

**“sample”** means any quantity of a designated product provided at no cost;

**“serving”** in relation to a foodstuff, means an appropriate serving size suitable for consumption as a single meal by infants or young children;

“**sponsorship**” means any financial or in-kind assistance to a person, group or activity, alone or with others, and “sponsor” has a corresponding meaning;

“**substance**” means a collective term for any chemical, microbiological or physical component present in or added to a foodstuff;

“**sweeteners**” means any substance listed as a sweetener in the General Standard for Food Additives (GSFA) of the Codex Alimentarius Commission, or a mixture of two or more thereof;

“**teat**” means a device for an infant or young child to suck on and which is used to feed food from a bottle, feeding cup or other feeding device;

“**technical scientific material**” means any material containing proven technical and/or scientific data about designated products or related to knowledge of nutrition, intended for health care personnel;

“**tie-in sales**” means the sale of any designated product that is linked to the purchase of any other product including any designated product;

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

“**young child**” in this context, means a child older than 12 months but younger than the age of 36 months (three years).



**LABELLING, COMPOSITION, PACKAGING AND MANUFACTURING MATTERS****GENERAL LABELLING, COMPOSITION, PACKAGING AND OTHER MANUFACTURING MATTERS OF DESIGNATED PRODUCTS**

2 (1) No person shall import, offer for sale or sell any—

- (a) foodstuff other than infant formula or infant formula for special dietary management for specific medical conditions which are represented as suitable for infants younger than 6 months of age;
- (b) infant formula, follow-up formula, infant or follow-up formula for special dietary management for specific medical conditions, complementary food, or liquid milk, powdered milk, modified powdered milk, or powdered drinks marketed or otherwise represented as suitable for infants or young children that are not manufactured, labelled and packed appropriately according to the stipulations of these regulations, other applicable regulations published under the Act and relevant Codex Standards, provided that where a conflict exists between Codex Standards and these regulations, these regulations take precedence;
- (c) infant formula, follow-up formula, or infant or follow-up formula for special dietary management for specific medical conditions, complementary food, or liquid milk, powdered milk, modified powdered milk, or powdered drinks marketed or otherwise represented as suitable for infants or young children which are not packed in a hermetically sealed container and which cannot be resealed or closed tightly during usage and subsequent appropriate storage.

(2) The container and/or label of a product referred to in sub-regulation (1) shall—

- (a) not show graphic representation, apart from those necessary to show the correct method of preparing and using the product such as the—

- (i) illustration of the method for safe preparation of an infant formula, a follow-up formula, or an infant formula or follow-up formula for special dietary management for specific medical conditions, or a powdered milk, modified powdered milk, or powdered drink marketed or otherwise represented as suitable for infants or young children, or a complementary food;
  - (ii) illustration of the sterilisation of equipment and utensils in the case of an infant formula, follow-up formula and infant formula or follow-up formula for special dietary management for specific medical conditions;
  - (iii) ingredients, composition or prepared product of a complementary food for infants or young children.
- (b) not contain any information or make any negative claim relating to the nutritional content or other properties of human milk;
  - (c) not contain words that may, directly or indirectly, indicate that such a product is suitable for all infants;
  - (d) contain the nutritional information on the label according to the requirements of these regulations and other applicable regulations under the Act.
- (3) The company logo, brand name, and logos indicating endorsement by specific religious certifying organisations shall be permitted, provided they do not contain a picture of an infant, young child or other humanized figure.
- (4) (a) Notwithstanding the provisions of the Regulations Relating to the Labelling and Advertising of Foodstuffs—
- (i) no health, medicinal or nutrition claims shall be permitted in any manner for any designated product;
  - (ii) should a medicinal claim be made on a designated product, or claim that a substance controlled in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) is an ingredient of such a designated product, such a product

should be submitted to the Medicine Control Council for registration in terms of section 13 of the Medicines Act.

- (b) The minimum nutritional information as per Annexure B shall appear on the label of complementary food and liquid milks, powdered milks, modified powdered milks, and powdered drinks marketed or otherwise represented as suitable for feeding infants older than 6 months or young children.
  - (c) A claim with regard to fortification, including the use of the fortification logo may be used if it is in compliance with the provision of the Regulations relating to the Fortification of Certain Foodstuffs.
- (5) No food intended for infants and young children shall use any industrially produced trans-fatty acids.
  - (6) The nutritional information as required by these regulations shall be real, typical values as determined by a reputable laboratory through chemical or microbiological analysis and sampling in accordance with Codex Standards and other relevant regulations and guidelines under the Act.
  - (7) The addition of optional ingredients and permitted additives as specified in Codex Standards shall be reflected in the list of ingredients as required by the labelling regulations under the Act.
  - (8) No person shall import, offer for sale or sell designated products that do not comply with the hygiene requirements as stipulated in applicable regulations published under the Act and the latest adopted version of the Codex Standard 66-2008 titled "Code of hygienic practice for powdered formulae for infants and young children".
  - (9) No hormone residues, antibiotics, pathogenic micro-organisms, toxins or other contaminants shall be present in foodstuff for infants or young children, unless the levels thereof are in compliance with the relevant regulations under the Act and applicable Codex Standards.
  - (10) Any foodstuff for infants or young children shall be prepared under good manufacturing and good hygiene practices as stipulated by Codex Standards and other relevant regulations under the Act so that—

- (a) residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain in the foodstuff, or
  - (b) if unavoidable, contaminants are reduced to the concentration below that established as maximum standard for that contaminant.
- (11) The label of a designated product shall contain the name, address and customer care telephone number of the manufacturer, importer or seller.
- (12) The label of a designated product shall not refer to, promote or advertise any other designated product.
- (13) No toys or any other form of gifts or tokens may be referred to, inserted or sold with the designated products referred to in sub-regulation 2 (1), excluding measuring spoons and scoops.
- (14) No incentives, enticements or invitations of any nature, which might encourage consumers to make contact with the manufacturer or distributor of a designated product which might result in the sale or the promotion of a designated product for infants or young children, shall be used on the label or in the marketing of a designated products for infants or young children.
- (15) The addition of honey or maple syrup as a component in a foodstuff for infants older than 6 months or young children will be permitted: Provided that -
- (a) such honey or maple syrup complies with applicable regulations published under the Act; and
  - (b) there is recorded proof that such honey or maple syrup is free from Botulism toxins.
- (16) The addition of herbs and spices as a component in a foodstuff for infants or young children is permitted, provided that such herbs and spices comply with the Regulations Governing Microbiological Standards for Foodstuffs and Related Matters.
- (17) No foodstuff intended for infants and young children may contain any sweeteners as listed in the General Standard for Food Additives (GSFA) of the Codex Alimentarius Commission, or a mixture of two or more thereof.

- (18) No statement or claim shall be made on the label or in any other manner, which conveys a message that a specific company name or logo or brand name represents itself as the experts with regard to infant and young child feeding or nutrition.
- (19) Subject to the provisions of these regulations, the labelling of foodstuffs for infants and young children must also comply with the provisions of the Regulations Relating to the Labelling and Advertising of Foodstuffs published in terms of the Act, including all amendments.

**SPECIFIC LABELLING AND OTHER REQUIREMENTS FOR INFANT FORMULA, FOLLOW-UP FORMULA, OR INFANT OR FOLLOW-UP FORMULA FOR SPECIAL DIETARY MANAGEMENT FOR INFANTS WITH SPECIFIC MEDICAL CONDITIONS,**

3 (1) The container or label of any infant or follow-up formula shall contain the following information:

(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:
- (a) "Does not contain breast milk" and
- (b) "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 –
- (a) "This product shall only be used on the advice of a health professional"; and
- (b) **"This product is not always sterile and may contain harmful microorganisms. It must be prepared and used appropriately"**.

- (b) The above messages specified in 3 (1) (a) including the requirements for specific letter sizes, must be repeated on the self adhesive label or package insert in at least five other official languages as specified in sub-regulation 3 (6) (a).
- (2) The container or label of infant or follow-up formula for special dietary management for infants with specific medical conditions shall contain the following information:
- (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 and may contain harmful microorganisms. 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;
- (b) all infant formula for special dietary management for infants with specific medical conditions shall in addition to the requirements of paragraph (2)(a) above, comply with

the latest adopted version of the Codex Standard 72 -1981, Section B, titled "Formula for Special Medical Purposes Intended for Infants";

- (c) the nutritional modifications, if any, which shall be indicated in the nutritional information table.
- (3) The container or label of any infant and follow-up formula or infant and follow-up formula for special dietary management for infants shall provide instructions for the proper sterilisation of equipment and utensils and instructions for appropriate preparation and use according to the latest FAO/WHO guidelines, Safe Preparation, Storage and Handling of Powdered Infant Formula Guidelines and which shall –
- (a) be in easily understandable words and in graphics, depicting only the use of feeding bottles with teats and ordinary cups;
  - (b) indicate that safe drinkable, previously boiled water should be used;
  - (c) indicate that only the enclosed scoop should be used;
  - (d) indicate the feeding chart and direction for use and instruction for discarding left over feed;
  - (e) indicate that only one feed should be prepared at a time;
  - (f) indicate proper storage and keeping before and after container has been opened;
  - (g) indicate that the infant must be held upright while feeding;
  - (h) indicate that the package insert provides instructions for the proper preparation and use in other languages;
  - (i) be in the English language; provided that the requirements of paragraph (a) to (h) shall be repeated in at least five other official languages as specified in sub-regulation 3 (6) (a) on the self adhesive label or package insert.

- (4) The container or label of any infant and follow-up formula or infant and follow-up formula for special dietary management for infants shall not include, in the brand name or any other phrases the terms “maternalised”, “humanized” or any derivative form of these terms, or any similar expression that may suggest a strong similarity between the product and breast milk.
- (5) The label of liquid ready to use formula is exempted from the requirements in regulation 3(3)(b)(c)(e) and the messages in regulation 3(1)(a)(iii)(b) & 3(2)(a)(iv).
- (6) A manufacturer or distributor shall not import, offer for sale or sell infant and follow-up formula or infant and follow-up formula for special dietary management for infants with specific medical conditions if—
  - (a) it does not include a self adhesive label or information leaflet inserted between the label or container or the resealable container that includes the information referred to in regulation 3(1)(a), 3(2)(a) and 3(3) in five other official languages one in the Nguni group, one in the Sotho group, Afrikaans, Xitsonga and Tshivenda. The language groups are the Nguni group (isiZulu, isiXhosa, isiNdebele, siSwati), the Sotho Groups (Sesotho, Setswana, Sepedi), Afrikaans, Xitsonga and Tshivenda.
- (7) Containers and/or labels of infant formula and infant formula for special dietary management of infants with specific medical conditions must contain at least one of the health messages set out in annexure D to these regulations. The message must be visible, legible, clear, and conspicuous.
- (8) All labels of infant formula, follow-up formula and infant and follow-up formula for special dietary management for infants with specific medical conditions shall contain the nutritional information of all the nutrients and substances which form part of the essential composition of the product according to Codex Standards in the prescribed format provided in Annexure A.
- (9) If soy protein is the only source of protein, the product shall be labelled “Soy protein based infant or follow-up formula”.
- (10) Only protein isolates from soya shall be used in the cases where infant formula or follow-up formula use soya as a source of protein alone or in a mixture of soya and cow’s milk proteins.



- (11) All ingredients and additives used in infant formula, follow-up formula, or infant or follow-up formula for special dietary management for infants with specific medical conditions, shall be gluten free and no claim to this effect shall be made on the label or in any other manner.

**SPECIFIC LABELLING AND OTHER REQUIREMENTS FOR COMPLEMENTARY FOODS AND LIQUID MILKS, POWDERED MILKS, MODIFIED POWDERED MILKS, AND POWDERED DRINKS MARKETED OR OTHERWISE REPRESENTED AS SUITABLE FOR INFANTS OR YOUNG CHILDREN**

- 4 (1) A manufacturer or distributor shall not import, offer for sale or sell complementary food(s) or liquid milks, powdered milks, modified powdered milks, or powdered drinks marketed or otherwise represented as suitable for infants or young children if the container or label affixed to such product does not, in bold letters and in clear, conspicuous and easily readable language -
- (a) indicate the age range of infants 6 months and older or young children for which such product is suitable, under the name or description of the product on the front main panel of the label in letters that are not less than 2mm in height for the smallest letters;
  - (b) provide instructions for safe and appropriate preparation where applicable, as well as the use and appropriate serving sizes for different ages;
  - (c) provide instructions for safe storage before and after the container has been opened;
  - (d) include a warning preceded by the expression "Important notice" against the health hazards of unsafe and inappropriate preparation, use and storage where appropriate;
  - (e) include the following statement: "This food is not intended for infants under 6 months of age and early introduction is not recommended";
  - (f) specify where label space permits, the following message: "From 6 months of age, together with breast milk, infants should be fed a variety of foods ". Ask a health worker or health professional for advice";

- (g) include the expression "Do not add salt and/or sugar" in close proximity to the preparation instructions in capital letters at least 2 mm in height.
- (2) Notwithstanding the provisions of regulation 4(1), the label or container of processed cereal based foodstuffs for infants and young children shall –
- (a) in the case of a cereal with a protein content of 15% or more of the NRV for the particular age group per serving and where the total protein quality of which the analysed amino acids of the foodstuff shall contain at least 80% of each of the amino acids as per the reference amino acid pattern listed in Annexure 5 of the Regulations Relating to the Labelling and Advertising of Foodstuffs, bear a statement to the effect that the cereal has to be prepared with previously boiled, cooled water;
- (b) in the case of a cereal with a protein content less than 15% of the NRV for the particular age group per serving, the label must bear a statement to the effect that the cereal has to be prepared with breast milk or formula if fed to an infant between 6 months and 12 months, in bold capital letters at least 3 mm in height.
- (c) Subject to sub-regulation (2) (a) bear a statement that where no further cooking is required the cereal shall be prepared with boiled cooled water.
- (3) Complementary foods and liquid milks, powdered milks, modified powdered milks, or powdered drinks marketed or otherwise represented as suitable for infants or young children shall not:
- (a) use names, phrases or expressions such as "maternalised", "humanized", "breast milk substitute" or any derivative form of these terms, or any similar expression that may suggest a strong similarity between the product and breast milk;
- (b) use expressions or names that may be understood to identify the product as suitable to feed infants, such as the expression "first growth", "first food", "from the start", "best start in life" or similar terms or expressions.

## **SPECIFIC LABELLING AND OTHER REQUIREMENTS OF SWEETENED CONDENSED MILK, IMITATION DAIRY AND GOAT'S MILK PRODUCTS**

- 5 (1) Containers of imitation dairy products, sweetened condensed milk, and goat's milk shall be clearly marked with the following words "**Not for infant feeding**", which shall be:
- (a) on the front label or main panel;
  - (b) in the English language; and
  - (c) in capital letters at least 3 mm in height.

## **SPECIFIC LABELLING AND OTHER REQUIREMENTS OF FEEDING BOTTLES, FEEDING CUPS AND TEATS**

- 6 (1) A manufacturer or distributor shall not offer for sale or sell any feeding bottle or teat and feeding cup if it does not have a label, package or container affixed to such product.
- (2) The label, package or container of a feeding bottle, teat or feeding cup specified in sub-regulation 6 (1) shall include -
- (a) a statement on the superiority of breast milk for feeding infants which shall be -
    - (i) on the label;
    - (ii) in capital letters at least 3 mm in height a label of which the main panel is equal or bigger than 12 000mm<sup>2</sup>; provided where the main panel is less than 12 000mm<sup>2</sup> the letter size may decrease proportionately.
  - (b) instructions for proper cleaning and sterilisation of feeding bottles, teats and feeding cups shall be in the English language; provided that the information shall be repeated in at least five other official languages on a self adhesive label or package insert.
  - (c) a warning on the potential health hazards of using a feeding cup, feeding bottle, if bottle, cup and teat are not properly sterilised, in two official languages of which English is one.

- (d) the warning "If you are breastfeeding your baby, using a feeding bottle and teat may interfere with the baby's natural way of suckling your breast"; and
  - (e) the name and address of the manufacturer and distributor of the product or the local agent.
- (3) A label, package or container of a feeding bottle, teat or feeding cup shall not show any graphic representation other than:
- (a) for illustrating cleaning and sterilisation; and
  - (b) the logo of the manufacturer or distributor.
- (4) In the case of an imported feeding bottle and or teat, the labelling requirements referred to in regulation 6 could be added on an adhesive sticker on the back of the package or a wrap-around label or packaging material.
- (5) 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.
- (6) Any action, motion or benefits with regard to the feeding or sucking on a feeding bottle, and teat or the physical properties of such feeding bottle and teat shall not in any form or manner be compared to the action, motion or benefits of suckling on a human breast or the physical properties of such human breast.
- (7) A manufacturer or distributor shall not import, offer for sale or sell any feeding bottle if it does not comply with the Regulations Relating to the Prohibition of the Manufacturing, importation, Exportation and Sale of Polycarbonate Infant Feeding Bottles Containing Bisphenol A, R878 of 2011.

## PROMOTION-RELATED MATTERS

### SALE AND PROMOTION

- 7 (1) No person shall undertake or participate in any promotional practice or device advertising in respect of—
- (a) infant formula;
  - (b) follow-up formula;
  - (c) infant or follow-up formula for special dietary or medical purposes;
  - (d) liquid milks, powdered milks, modified powdered milks, or powdered drinks marketed or otherwise represented as suitable for infants or young children;
  - (e) feeding bottles, teats and feeding cups with spouts, straws or teats;
  - (f) any other products that the Minister may publish by notice in the Gazette.
- (2) Promotional practices or devices in respect of the products listed in sub-regulation 7 (1) include, but are not limited to —
- (a) sale devices such as rebates, benefits in kind, kickbacks or any other pecuniary advantages, special displays to promote sales, advertisements about the availability of the product at a specific retail outlet and the price of the product, tie-in sales, discounts in any form, competitions with prizes, or any other incentives and gifts;
  - (b) direct or indirect contact between company personnel and members of the public in furtherance of or for the purpose of promoting the business of the company with regard to the products referred to in sub-regulation 7 (1) and for purposes of these regulations "indirect contact" specifically includes internet sites hosted on behalf of a South African entity or an entity that does business in South Africa, television and radio, telephone or internet help lines and mother and baby clubs but excludes contact in regards to product quality complaints and adverse events;
  - (c) the distribution of any information or educational material on the nutrition or feeding of infants and young children, except in accordance with sub-regulation 7 (4);

- (d) promotional items such as stationery, T-shirts or other items of clothing, headgear, household utensils, and household linens that refer to products contained in sub-regulation 7 (1) of these regulations;
  - (e) the brand name of a product referred to in sub-regulation 7 (1) when used at any event for the general public;
  - (f) advertisements in written publications, television, radio, film, electronic media, email, video, telephone displays, exhibitions and outdoor advertisements such as billboards, posters, signs and electronic signs;
  - (g) donation to or distribution of any equipment including the building, renovation or maintenance of a health establishment bearing the company name or logo, which is specifically intended for providing care to infants, young children, pregnant women or mothers of infants and young children without the prior approval of the Director General or person designated on his or her behalf;
  - (h) research grants or any other financial assistance relating to infant or young child nutrition provided to health care personnel working in a health establishment or health care personnel linked to a health establishment, unless prior approval has been obtained by the Director-General or a person designated on his or her behalf;
  - (i) financial contributions or sponsorship to health care personnel working in infant and young child nutrition;
  - (j) sponsorship of meetings targeting health care personnel where infant and young child nutrition is the sole or partial topic of discussion, unless contribution or sponsorship is made into a pool of funds for congress organisers with the proviso that a fair and transparent process be followed in the election and sponsoring of delegates to attend such events. Sponsored delegates should have no obligations to the company involved.
- (3) No person shall sell, promote, or advertise any designated product, including complementary foods, through health care personnel or health establishments. Prohibited promotional practices include, but are not limited to:

- (a) provision or offer, direct or indirect, of any gift in cash or in kind, contribution, or benefit to health care personnel whether intended for such worker's personal use or not; and
  - (b) Notwithstanding the provisions of sub-regulation 7 (3), an institutional pharmacy in a private health establishment may sell a designated product but shall not advertise or engage in the promotion of any designated product.
- (4) No manufacturer, distributor, retailer, importer or person on behalf of the aforementioned shall produce or distribute any educational material on infant and young child feeding that promotes any products referred to in sub-regulation 7 (1).
- (5) No manufacturer, distributor, retailer, importer or person on behalf of the aforementioned shall produced, distribute and present educational information relating to infant and young child nutrition.

#### **PROHIBITION OF THE PROMOTION AND/OR DISTRIBUTION OF GIFT PACKS**

- 8 No health establishment shall promote and/or distribute gift packs that contain or refer to any designated products, individually or in combination with other goods.

#### **PROHIBITION OF THE DISTRIBUTION OF FREE OR LOW-COST DESIGNATED PRODUCTS OR SAMPLES**

- 9 (1) No manufacturer or distributor shall 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 subject to sub-regulation 9 (2) and (3).
- (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 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; and
  - (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.

**PROHIBITION OF THE DISPLAY OF A DESIGNATED PRODUCT OR EDUCATIONAL MATERIAL**

- 10** No person within any health establishment shall display or cause or permit to be displayed in a unit taking care of infants or young children, pregnant mothers or mothers of infants and young children—
- (a) designated products;
  - (b) any educational material which bears the brand name, or any description of a designated product; or
  - (c) the name and or logo or both of the manufacturing or distributing company of designated products, when the material includes any message about infant and young child nutrition or feeding practices.

**MATERIAL DIRECTED AT HEALTH CARE PROVIDERS**

- 11** A person, manufacturer or distributor may provide technical scientific material to a health care provider, provided that—
- (1) such information or material is restricted to current scientific and factual matters, and is in accordance with the relevant regulations under the Act;
  - (2) the material bears no health, medicinal or nutrition claims, whether in text or picture format;
  - (3) it relates only to the technical aspects and methods for use of the designated product; and
  - (4) it excludes any promotion of the designated product in any manner.

**LODGING OF COMPLAINTS**

- 12** Any person, group, body or institution may submit a written complaint supported by adequate evidence to the Director-General.



**INSPECTION**

- 13 Inspectors appointed by the Director-General in terms of Section 10 of the Act are responsible for the enforcement of these regulations.

**OFFENCES**

- 14 Any person who contravenes these regulations is guilty of an offence and is liable to penalties as prescribed by the Act.

**REPEAL**

- 15 Government Notice No. R. 1130 of 8 June 1984, as amended by Government Notices R. 2542 of 15 November 1985, R. 1256 of 15 July 1994 and R. 1210 of 17 December 2010, is hereby repealed.

**COMMENCEMENT**

- 16 (1) Regulations 2, 3, 4, 5, and 6 shall enter into force **12 months** from date of publication of these regulations;
- (2) Regulations 7, 8 and 11 shall enter into force **6 months** from date of publication of these regulations;
- (3) Regulations 9 and 10 shall enter into force **immediately** from date of publication of these regulations.

**TRANSITIONAL MEASURES**

- 17 Manufacturers, distributors and retailers must, **within 18 months** of the date of publication of these regulations, remove all non-compliant products from the market.



MINISTER OF HEALTH

DATE: 8/12/2012

**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:

Quantified single serving size expressed in grams or millilitres, whatever is appropriate

	Per 100g powder as sold	Per 100 ml reconstituted ready to use	Per 100 kJ ready to use
Energy (kJ)			
Total 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*			
Total dietary fibre (g)			
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

**ANNEXURE B****Required Nutritional Information****Format for minimum mandatory nutritional information for complementary foods and liquid milks, powdered milks, modified powdered milks, and powdered drinks**

Typical nutritional information:

Quantified single serving size expressed in grams or millilitres, whatever is appropriate

	Per 100g/ml	Per single serving	Per % NRV serving
Energy (kJ)			
Protein (g)			
Glycaemic Carbohydrate (g) or carbohydrate of which total sugar (g)			
Total fat (g)			
of which Saturated fat (g)			
**			
**			
**			
***			
Total dietary fibre <sup>#</sup> (g)			
Sodium (mg)			
Vitamins in alphabetic order (in appropriate unit of measurement)			
Minerals and trace elements in alphabetic order (in appropriate unit of measurement)			
<ul style="list-style-type: none"> <li>▪ Any other nutrient or food component to be declared in accordance with these Regulations.</li> <li>▪</li> </ul>	Indicate in grams (g), milligrams (mg), micrograms (mcg/µg), or appropriate unit of measurement	Indicate in grams (g), milligrams (mg), micrograms (mcg/µg), or appropriate unit of measurement	

\* NRV: Nutrient Reference Values for individuals from 6 months to 36 months (see Annexure C) expressed per single serving. (whatever is appropriate)

\*\* place for a sub-group nutrient, such as mono-unsaturated fat, polyunsaturated fat, omega-3 fatty acids etc.

\*\*\* place to insert cholesterol where cholesterol information is provided.

# indicate method of analysis used to determine dietary fibre.

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

## 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	2,0/kg body mass	23
Vitamin A activity			
(1) Vitamin A	IU	1 330	1330
(2) Retinol equivalent	$\mu\text{g RE}^2$	500	300
Vitamin D	IU	400	400
	$\mu\text{g}$	5	5
Vitamin E activity	IU	6	7,5
	$\text{mg } \alpha \text{ TE}^4$	5	6
Ascorbic acid	mg	50	50
Biotin	$\mu\text{g}$	50	65
Folic acid	$\mu\text{g}$	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)	$\mu\text{g}$	0,5	0,9
Vitamin K	$\mu\text{g}$	2,5	30
Calcium	mg	270	500
Phosphorus	mg	275	460
Iodine	$\mu\text{g}$	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	$\mu\text{g}$	20	20
Molybdenum	mg	0,08	0,1
Choline		150	200

**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