GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 1013 **26 October 2007**

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

REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS, YOUNG CHILDREN AND CHILDREN

The Minister of Health intends, in terms of section 15 of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for the attention of the Director: Nutrition), within three months of the date of publication of this notice.

DR M E TSHABALALA-MSIMANG, MP
MINISTER OF HEALTH
Date: 4-10-2007

SCHEDULE

INDEX

Generic Label	E
Guidelines involving the research on the use of Designated Products	F

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 of cow's milk, components of cow's milk, vegetable fats and/or glucose;

"brand name of a designated product" means the name given or trademarked 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 or the wet nurse's breast;

"breast milk" means human milk obtained by means of the infant or young child suckling on the mother's breast or by the expression of milk from the breast;

"child-care institutions" means the whole or part of a public or private institution, facility, agency, building or place caring for babies and young children required to be registered with the Child Care act, 1983 (Act 74 of 1983), whether part-time or full-time, whether organised for profit or not;

"children" mean persons from the age of 3 years through to the age of 10 years.

"Codex" means the latest 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 the regulations relating to the practice of pharmacy are provided to persons requiring pharmaceutical services, but excludes an institutional pharmacy;

"complementary food" means any foodstuff, whether in solid or semi-solid form, given to an infant after 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 infant formula, follow-up formula, or infant or follow-up formula for special dietary or medical purposes and includes, but is not limited to, bottled or canned foodstuffs for infants and young children and processed cereal-based foodstuffs for infants or young children;

"container" means any form of packaging of foodstuffs for sale as a retail unit, including wrappers;

"designated product" means -

(a) infant formula,
(b) follow-up formula,
(c) infant or follow-up formula for special dietary or medical purposes;
(d) complementary foods;
(e) products or devices that may interfere with breastfeeding, including but not limited to feeding bottles, teats and feeding cups with spouts, straws or teats; and
(f) any other products that the Minister may so designate by notice published in the Gazette.

"Directorate" means the Directorate: Nutrition in the national Department of Health;

"Director-General" means the head of the national Department of Health;

"distributor" means a person, corporation or other entity engaged in the business, whether wholesale or retail, of marketing any designated product;

"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 includes, but is not limited to, free sample of a designated product, meals and refreshments, diaries, stationery, calendars, cot tags, stickers, growth charts, prescription pads, tongue depressors or any item of whatever value;

"**health claim**" means any representation that states, suggests or implies that a relationship exists between a food or a constituent of such food and health, namely nutrient function claims, enhanced function claims, reduction of disease risk claims, pre-biotic claims and pro-biotic claims;

"health establishment" means the whole or any part of a public or private institution including child-care institutions, facility, agency, building or place, excluding a retail outlet, whether organised for profit or not, and which is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing or rehabilitative, palliative, preventative, regulatory or other health services;

"**health care personnel**" means health care providers and health workers.

"health care provider" means any person providing health 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 lay counsellors, a trainer or a voluntary unpaid worker;

"hermetically sealed package" means an unopened container which forms an airtight closure, is impervious to liquid and which cannot be opened without breaking or damaging such package or the seal, adhesive label or any other part thereof or attachment thereto and which, after opening, can be closed again in an airtight manner;

"**imitation dairy product"** means a foodstuff containing vegetable oils and includes, but is not limited to, tea or coffee creamer or dairy or milk blend powder;

"infant" means a person from birth to the age of 12 months;

"infant formula" means an industrial formulated product manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary foods according to the composition of which is based on the applicable Codex standard;

"infant or follow-up formula for special dietary or medical purposes" means an industrial formulate product that complies with the relevant Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes and is specifically manufactured to satisfy, the special nutritional requirements of infants with specific disorders, diseases or medical conditions, where these are medically indicated.

"**institutional pharmacy**" means a pharmacy situated in –

(a) a public health facility, wherein or from which some or all of the services as prescribed in the regulations relating to the practice of pharmacy 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 the regulations relating to the practice of pharmacy are provided to persons requiring pharmaceutical services from or at that private health facility, but excludes a community pharmacy;

"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, 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 any promotion, distribution, sale, or advertisement technique which is intended to promote the sale or encourage the use of a designated product and which is brought to the notice of the public in any manner;

"marketing personnel" means any person who is involved in the marketing of a designated product with the intention of promoting the sale of a designated product or encouraging its use;

"maternal nutritional supplement" means a substance, whether in capsule, tablet, soft gel, liquid or powder form, which is marketed or otherwise represented as being beneficial if taken by pregnant and lactating mothers, in addition to or as part of their normal diet;

"negative claim" means a declaration or implication made on a label, in an advertisement or in any other manner, that a particular foodstuff possesses specific characteristics or properties when in fact, similar foodstuffs possess the same characteristics or properties;

"**nutrition claim**" means any representation that refers to a specific nutrient content of a particular foodstuff such as but not limited to nutrient content or comparative claim;

"packaged foodstuff for infants or young children" means a foodstuff, whether in a ready-to-eat form or in a dry form requiring reconstitution with breast milk, infant formula, follow-up formula,

or infant or follow-up formula for special dietary or medical purposes the composition of which is based on the applicable Codex standard, or water, which is packed in a hermetically sealed package and is intended primarily for use after the age of six months and/or for the progressive adaptation of infants and young children to ordinary foodstuffs;

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

"pharmacy" means community pharmacy and institutional pharmacy;

"processed cereal-based foodstuff for infants or young children" has the meaning as described in the relevant Codex Standard;

"promote" means to employ a method of directly or indirectly encouraging a person 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, 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 or distributor;

"retail outlet" means a pharmacy, shop, supermarket, medical hall or any other premises used by a manufacturer, distributor, agent or importer or any other person, to sell any designated product;

"sample" means a single or small quantity of a designated product provided at no cost;

"scientific research material" means health-related research material published in peer-reviewed reputable public health, health-related or scientific journals;

"serving", in relation to a foodstuff, means a reasonable quantity of food suitable for consumption as a single meal by infants, young children or 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;

"sugar" means the sugars listed in Annexure A under the heading "Sugars";

"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;

"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" means a person older than 12 months and up to the age of 36 months (three years).

CHAPTER 1: LABELLING, COMPOSITION, PACKAGING AND MANUFACTURING MATTERS

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

(1) The requirements specified in regulations 2, 3, 4, 5, 6 and 7 of these regulations are supplementary to the other labelling and advertising requirements laid down by the Act.

(2) No person shall offer for sale or sell any foodstuff or beverage other than infant formula or infant formula for special dietary or medical purposes which are represented as suitable for infants younger than 6 months;

(3) No person shall offer for sale or sell any –

(a) infant formula;

(b) follow-up formula;

(c) infant or follow-up formula for special dietary or medical purposes;

(d) complementary food;

that is not packed in a hermetically sealed package.

(4) No person shall offer for sale or sell any infant formula, follow-up formula, or infant or follow-up formula for special dietary or medical purposes, or complementary food for infants or young children that does not comply with the relevant Codex standards in all respects.

(5) The label of a product referred to in subregulation (3) shall -

(a) not show any photograph, drawing or graphic representation including in logos and brand names other than –

(i) for illustrating the method for preparation of an infant formula, a follow-up formula, or an infant or follow-up formula for special dietary or medical purposes, as indicated in regulation 3(1)(e), or for complementary food for infants or young children;

(ii) for illustrating the sterilisation of equipment and utensils in the case of an infant formula, follow-up formula and infant or follow-up formula for special dietary or medical purposes as indicated in regulation 3(1)(c);

(iii) the ingredients or composition of a complementary food for infants or young children;

(b) not contain any information relating to the nutritional content or other properties of human milk or make any negative claim;

(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.

(6) (a) No health or nutrition claims shall be permitted with regards to any nutrient or substance that:

(i) is required as part of the essential composition of an infant formula, follow-up formula or infant or follow-up formula for special medical purposes, or cereal-based complementary food for infants and young children as determined by Codex., and

(ii) that is naturally, present or added to any of these products.

(b) No health claim shall be permitted in any manner for any designated product.

(c) No nutrient claim shall be permitted for any complementary food and any beverage, liquid or other product which is marketed or otherwise represented as suitable for feeding infants older that 6 months or young children.

(d) The minimum nutritional information as per Annexure A shall appear on the label of any product referred to in sub-regulation (6) (c) above.

(e) Where a product, referred to in sub-regulation (6) (c) above is naturally "high in" or "a source of" a particular nutrient, without the addition thereof, the relevant information may be added to the minimum nutritional information table as per Annexure C; Provided the information regarding the nutrient content shall not be mentioned anywhere else on the label except in the nutritional information table, as stipulated.

(f) 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.

(7) Subject to sub-regulation (6) any claim or information on the label of any beverage or complementary food, which indicates that the product has been specifically developed or has been uniquely formulated for infants older than 6 months, young children and children shall be substantiated in writing, for the written approval of the Director-General prior to any market appearance.

(8) No food intended for infants and young children shall use any fully hydrogenated or partially hydrogenated fat as an ingredient or any compound ingredient that contains fully hydrogenated or partially hydrogenated fat.

(9) The nutritional value of a foodstuff for the purpose of nutrition information on a label shall be done according to the methods of analysis and sampling as stipulated in Codex and other relevant regulations under the Act.

(10) The addition of optional ingredients and permitted additives as specified in Codex shall be reflected in the list of ingredients as required by the labelling regulations under the Act.

(11) The presence of hormone residues, antibiotics, pathogenic micro-organisms, toxins or other contaminants any foodstuff for infants or young children shall comply with the relevant Codex standard.

(12) Any foodstuff for infants or young children shall be prepared under good manufacturing practices so that 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, if technically unavoidable, are reduced to the maximum extent possible in the end product.

(13) Any foodstuff for infants or young children shall -

(a) be prepared and handled in accordance with the hygienic requirements of Codex; and

(b) comply with any microbiological criteria determined in Codex.

(14) The name and address of the manufacturer shall appear on the label of a designated product in accordance with other labelling requirements laid down by the Act, and, in the case of an imported designated product, such label shall contain the contact details of the South African distributor or importer as well.

(15) The label of a designated product shall not refer to, promote or advertise any other designated product.

(16) No toys or any other form of gifts or tokens may be inserted or sold with the designated products referred to in sub-regulation (3).

(17) No incentives, enticements or invitations of any nature, including pictures of telephones, help lines or customer care lines, which might encourage consumers to make contact with the manufacturer or distributor of a designated product and/or 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.

(18) 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 has been irradiated according to existing legislation;

(b) such honey or maple syrup complies with Codex microbiological standards; and

(c) there is recorded proof that such honey or maple syrup is free from Botulism toxins.

(19) The addition of herbs and spices as permitted under other regulations under the Act, as a component in a foodstuff for infants or young children is permitted, provided that such herbs and spices will have been irradiated according to existing legislation.

(20) Subject to subregulations (18) and (19), the products referred to in subregulation (3) and the components of such products shall not be treated by ionizing radiation;

(21) No foodstuff intended for infants, young children or children may contain any non-nutritive sweeteners.

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

(23) No statement of 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:

(a) represents itself as the experts with regard to infant and young child feeding or nutrition; or

(b) inspires mothers to trust or rely on or have confidence in the products manufacture red by the manufacturer.

3. SPECIFIC LABELLING AND OTHER REQUIREMENTS FOR INFANT FORMULA, FOLLOW-UP FORMULA, OR INFANT OR FOLLOW-UP FORMULA FOR SPECIAL DIETARY OR MEDICAL PURPOSES, ACCORDING TO THE GENERIC EXAMPLE IN ANNEXURE E.

(1) A manufacturer or distributor shall not offer for sale or sell any infant formula, follow-up formula or infant or follow-up formula for special dietary or medical purposes if the container or label affixed to such products –

(a) does not indicate the age and age range of the infants 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 3mm in height for the smallest letters for a 400 g tins and shall increase proportionally with the size of the tin.

(b) does not have, in English and in bold letters at least 3mm high the following clear, conspicuous and easily readable messages:

(i) "Breast milk is the best food for babies" except on labels of infant or follow-up formula for special dietary or medical purposes. "This product does not contain breast milk", and which shall be at the top of the front main panel of the label.

(ii) "Before you decide to use this product, get advice from your health professional", "This product is not sterile. It may contain harmful organisms, which may grow once it is prepared with water. You must always strictly follow the instructions on the label " and which shall be at the bottom of the front main panel of the label in bold letters at least 3mm high;

(iii) The above messages specified in (i) and (ii) including the requirements for specific letter sizes, must be repeated on the fix-o-form or package insert in at least five other official languages as specified in subregulation (3).

(c) does not provide instructions for the proper sterilisation of equipment and utensils and the proper preparation and use which shall -

(i) be in easily understandable words and in graphic representations, excluding pictures of infants, that depict only the use of feeding bottles with teats and ordinary cups;

(ii) which shall be in English; Provided that the requirements of paragraph (i) shall be repeated in at least five other official languages of as specified in subregulation (3) on the fix-o-form or package insert.

(iii) indicate that potable, previously boiled water should be used.

(d) does not include a heading "How to Prepare the Feed for Bottles and Cups" in bold letters and directly underneath the words "Always wash your hands with soap and water before preparing the feed".

(e) does not also include all the following preparation and feeding instructions in English

(i) Boil the water and do NOT let it cool for more than ten minutes before adding the powder.
(ii) Prepare only one bottle or cup at a time.
(iii) Cool the feed in cold water as quickly as possible, covering the teat.
(iv) Make sure that the feed is cool enough before you give it to the baby.
(v) Feed the baby immediately.
(vi) Do NOT keep leftover feed or use it later.
(vii) Use only the enclosed scoop.
(viii) Feeding table according to the following example:

Age of infant	Weight of infant	Quantity per feed		Number of feeds per day recommended	Number of tins needed each month
		Boiled cooled water in ml	Number of measuring scoops		

(ix) Close the tin tightly after each use and store in a cool dry place.

(x) Always hold the baby while feeding. The baby may choke if you leave the baby alone.

(xi) After six months, give the baby other foods like cereal, vegetables and fruit in addition to the infant formula or follow-up formula.

(xii) Visit the clinic regularly, to make sure that the baby is growing well.

(xiii) See the fix-o-form or package insert for instructions for the proper preparation and use in other languages.

(f) Includes, in the brand name or any other phrases the terms "maternalised", "humanized" or any derivative form of these terms, or any similar expression.

(g) Shall not reduce the label size in any way of the generic label as indicated in Annexure E.

(2) A manufacturer or distributor shall not offer for sale or sell follow-up formula or follow- up formula for special dietary and medical purposes if the container or label affixed to it does not include a warning that the foodstuff is not intended for infants under six months of age and that introduction of the foodstuff before 6 months may have adverse health consequences for infants younger than 6 months.

(3) A manufacturer or distributor shall not offer for sale or sell infant formula, follow-up formula, or infant or follow-up formula for special dietary or medical purposes if it does not include an fix-o-form or information leaflet inserted between the label or container or the hermetically sealed package that includes the information referred to in regulation 3(1)(b)(I and ii); 3(1)(c)(i); 3(1)(d and e), 3(2) 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, isiZulu, isiXhosa, isiNdebele, siSwati), the Sotho Groups (Sesotho, Setswana, Sepedi), Afrikaans, Xitsonga and Tshivenda.

(4) All the labels of infant formula and follow-up formula should be according to the generic example as indicated in Annexure E. The information as indicated in regulation 3(1)(e)(viii) need to be amended accordingly.

(5) All labels of infant formula, follow-up formula and infant and follow-up formula for special medical purposes shall contain the nutritional information of all the nutrients and substances which form part of the essential composition of the product according to Codex in the format provided in Annexure B.

(6) A manufacturer or distributor shall not offer for sale or sell any powdered infant formula, powdered follow-up formula or powdered infant or -follow-up formula for special dietary or medical purposes if the product is not reconstituted in the ration of 1 scoop of powder to 25 ml of water.

4. GENERAL LABELLING AND OTHER REQUIREMENTS FOR COMPLEMENTARY FOOD FOR INFANTS AND YOUNG CHILDREN

(1) A manufacturer or distributor shall not offer for sale or sell complementary food 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) provide instructions for proper preparation where applicable, as well as the use and appropriate serving sizes for different ages in English and at least 1 (one) other official language.

(b) provide instructions for proper storage before and after the package has been opened;

(c) include a warning preceded by the expression "Important notice" against the health hazards of improper preparation and use;

(d) include a warning that such foodstuff is not intended for infants under 6 months of age and that early introduction of such foodstuff may have health hazards for infants;

(e) include the message: "From 6 months onwards, together with breast milk you should also give the baby other foods like mashed fruit and vegetables, minced meat, soft porridge and cereals. Ask a health worker or health professional for advice".

(f) indicate the age range of the infants older than 6 months or young children for which the 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

(g) include the expression "Warning: Do not add salt and/or sugar" on the main panel in capital letters at least 2 mm height; and

(h) contain the words "Home prepared foods are also suitable for infants older than six months" on the main panel in capital letters at least 2 mm height.

(2) Notwithstanding the provisions of regulation 4(1), the label or container of a processed cereal based foodstuffs for infants or young children shall –

(a) in the case of a cereal with a protein content of 15% or more of the RDA for the particular age group and where the total protein has a PDCAAS value or 90 or more, 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 RDA for the particular age group and where the protein has a PDCAAS of less than 90, bear a statement to the effect that the cereal has to be prepared with breast milk or formula, only in bold capital letters at least 3 mm in height.

(c) Subject to subregulation (2)(a) bear a statement that where no further cooking is required the cereal shall be prepared with boiled and cooled water.

5. REGULATIONS RELATING TO FOODSTUFFS FOR CHILDREN

(1) No person shall sell foodstuff for children from the age of 3 to 10 years-

(a) in the processing of which water which contains more than 10mg/Pofnitrate as N (equivalent to 45mg/P No_3) is used;

(b) Which contain pathogenic micro-organisms and/or toxins thereof, hormones, antibiotics or other antimicrobial substances or any ingredient that contain hormones, antibiotics or other antimicrobial substances, in amounts more that what is stipulated under other applicable regulations under the Act.

6. SPECIFIC LABELLING AND OTHER REQUIREMENTS OF SWEETENED CONDENSED MILK AND IMITATION DAIRY PRODUCTS

The labels of sweetened condensed milk and imitation dairy products shall be clearly marked with the following words "Not for infant feeding", or similar wording as requested by provisions of the Agricultural Product Standards def, 1990 (October 119 of 1990) which shall be -

(a) on the front label or main panel;
(b) in three official languages of which English is one;
(c) in capital letters at least 3 mm high; and
(d) framed with a solid black line at least 1 mm thick.

7. SPECIFIC LABELLING AND OTHER REQUIREMENTS OF FEEDING BOTTLES, AND TEATS

(1) A manufacturer or distributor shall not offer for sale or sell any feeding bottle or teat if it does not have a label, package or container affixed to such product.

(2) The label, package or container of a feeding bottle or teat specified in subregulation (1) shall include -

(a) a statement on the superiority of breast milk for feeding infants which shall be -

(i) on the front label or main panel;

(ii) in capital letters at least 3 mm high for a label of which the main panel is equal or bigger than 12 000mm^2; provided where the main panel is less than 12 000mm^2 the letter size may decrease proportionately according to other labelling regulations under the Act.

(b) instructions for proper cleaning and sterilisation of feeding bottles and teats which shall be in two official languages of which English shall be one;

(c) a warning on the potential health hazards of using a feeding bottle and teat if it is 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 or teat shall not show any photograph, drawing or graphic representation of an infant or young child, or any photograph, drawing or 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 7 could be added on an adhesive sticker on the back of the package.

(5) The label, package or container of a feeding bottle and teat 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).

(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 offer for sale or sell any feeding bottle if the grading is not only marked in 25 ml increments.

(8) Not withstanding subregulation (7) a manufacturer or distributor shall not offer for sale or sell any feeding bottle if the grading is not moulded into the bottle.

CHAPTER 2: PROMOTION-RELATED MATTERS

8. SALE AND PROMOTION

(1) No person shall undertake or participate in any promotional practice or device in respect of -

(a) infant formula;

(b) follow-up formula;

(c) infant or follow-up formula for special dietary or medical purposes;

(d) products or devices that may interfere with breastfeeding, including but not limited to feeding bottles, teats and feeding cups with spouts, straws or teats;

(e) any other products that the Minister may, by notice, publish in the Gazette.

(2) No person shall sell, promote, advertise or assist in the sale, promotion or advertisement of any designated products including complementary foods via health care personnel, or in any health establishment.

(3) Notwithstanding the provisions of subregulation (2), an institutional pharmacy in a private health facility may sell a designated product but shall not advertise or engage in the promotion of any designated product.

(4) Promotional practices or devices in respect of the products listed in subregulation (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, 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 subregulation (1) and for purposes of these regulations "indirect contact" specifically includes the internet, television and radio, telephone or internet help lines and mother and baby clubs;

(c) the distribution of any information, educational material or other material on the feeding of infants and young children, except in accordance with regulation 14;

(d) electronic communications including internet websites and email except in accordance with regulation 14;

(e) promotional items including but not limited to T-shirts or other items of clothing, headgear, household utensils, and household linens that refer to products contained in regulation 8(1) of these regulations;

(f) the brand name of a product referred to in subregulation (1) when used at any event for the general public ;

(g) advertisements in written publications, television, radio, film, electronic transmission, video, telephone displays, exhibitions and outdoor advertisements such as billboards, posters, signs and electronic signs; and

(h) practices or communications in any form whatsoever which create, or may create, any association, to any degree whatsoever, with breastfeeding.

(5) A promotional practice or device in respect of a complementary food shall -

(a) not contain, compare, include, refer to or provide any information related to the nutritional content or other properties of human milk;

(b) contain the following statement:: "The World Health Organisation recommends continued breastfeeding for up to two years of age or beyond."

(c) not contain, include, refer to or provide toys or any other gifts or tokens or any other incentives; and

(d) not create any association with any products specified in subregulation (1);

(6) The name or label of a maternal nutritional supplement shall not be used to promote or create an association with a designated product or imply or create the impression that breast milk in itself may be inadequate without a particular supplement.

9. PROHIBITION OF THE DISTRIBUTION OF GIFT PACKS

No hospital or health establishment shall distribute gift packs that contain or refer to any designated products, individually or in combination with other goods.

10. PROHIBITION OF THE DISTRIBUTION OF FREE OR LOW-COST DESIGNATED PRODUCTS OR SAMPLES

(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.

(2) Notwithstanding the provisions of subregulation (1), a person, manufacturer or distributor may distribute free, or at low cost, supplies or samples of designated products to hospices, orphanages or places of safety, provided that such designated products or samples shall comply with all of the relevant provisions in Codex and in these regulations.

(3) No person in a health establishment shall accept or give to any other person free or at low cost supplies or samples of designated products referred to in subregulation (1).

(4) A health establishment referred to in subregulation (1) shall procure all designated products it requires through the normal procurement channels.

11. PROHIBITION OF THE DISPLAY OF A DESIGNATED PRODUCT OR MATERIAL

No person within any health establishment shall display or cause or permit to be displayed in a unit taking care of infants and young children, pregnant mothers or mothers of infants and young children –

(1) designated products; or
(2) any material which bears the brand name or any description of a designated product;
(3) manufacturing company name and or logo or both where applicable.

12. PROHIBITION OF DONATION OR DISTRIBUTION OF EQUIPMENT

No manufacturer or distributor of designated products shall directly or indirectly fund the construction of a health establishment or any facility in a health establishment, or shall donate, pay

for, distribute or endorse any equipment, which is specifically intended for providing care to infants, young children, pregnant women or mothers of infants and young children.

13. PROVISION OF SPONSORSHIPS PROHIBITED

(1) No manufacturer or distributor of designated products shall directly or indirectly -

(a) provide research grants or any other financial assistance relating to infant or young child health or nutrition to health care personnel or a health establishment; or

(b) sponsor any cost of the attendance of health care personnel working in the field of infant or young child health or nutrition at a conference, seminar or any health related professional meeting where to infant or young child health or nutrition is the sole or partial topic of discussion .

(2) No manufacturer of designated products shall directly or indirectly offer a gift in cash or in kind, whether intended for her or his personal use or not, to a worker of a health establishment.

(3) No worker of a health establishment shall accept a gift in cash or in kind, whether intended for her or his personal use or not, from a manufacturer or distributor of designated products.

14. EDUCATIONAL AND INFORMATIONAL MATERIAL IN ALL TYPES OF MEDIA INTENDED TO REACH THE PUBLIC

(1) General

(a) No material referred to in regulation 14 shall be used to promote, or be written in such a way as to promote, the use or sale of designated products.

(b) No manufacturer or distributor of a designated product shall publish or cause or permit to be published any informational or educational material on infant and young child nutrition unless the Director: Nutrition has approved the material and its use, prior to its use.

(c) All informational or educational material on infant and young child nutrition that has been approved by the Directorate shall be used in the exact form in which it was approved, and no material may be changed or omitted.

(d) Within ninety days after receiving an application in terms of this subregulation, the Directorate shall examine the material concerned and may-

(i) approve it, either absolutely or subject to conditions; or

(ii) refuse to approve it; and

(iii) shall notify the applicant in writing of its decision and, where it has refused to approve the material, of its reasons.

(e) Where the Directorate has refused to approve any informational and educational material in terms of subregulation (1), the applicant may at any time resubmit the material to the Directorate, having made such alterations to the materials as considered necessary to secure the Directorate's approval.

(2) Material on infant and young child nutrition and feeding intended to reach the public

(a) Notwithstanding subregulation (1) any information, educational material or other material, excluding scientific research material on infant and young children nutrition and feeding, whether in written or audio-visual format, which is made available by any person, shall clearly state the following:

(i) the superiority of exclusive breastfeeding for six months followed by sustained breastfeeding for two years and beyond;

(ii) at least three (3) health risks of mixed feeding;

(iii) how to ensure an adequate milk supply by feeding on demand; and

(iv) that working mothers can breastfeed successfully.

(b) Notwithstanding the provisions of subregulation 2 (a) any information, educational material or other material about the use of any infant formula, follow-up formula or infant or follow-up formula for special dietary or medical purposes whether written, audio or visual made available by any person shall clearly and unambiguously explain the following:

(i) the proper preparation and use of any infant formula, follow-up formula, or infant or follow-up formula for special dietary or medical purposes, including the cleaning and sterilisation of feeding utensils;

(ii) the social and financial implications of its use including –

a. how many containers infant formula will be needed per month for the first year of life;

b. the need for a good supply of safe clean water;

c. the equipment needed to sterilise the feeding utensils;

d. the need for an adequate supply of fuel for sterilisation and preparation of feeds or other sterilisation solutions; and

e. the method and process of formula-mixing;

(iii) the health hazards of any infant formula, follow-up formula or infant and follow-up formula for special dietary or medical purposes and the health hazards of improper preparation and use;

(iv) cup feeding is preferred rather than bottle feeding;

(v) that imitation dairy products and sweetened condensed milk are not suitable for infant feeding.

(c) Any information, educational material or other material about the use of complementary food whether written, audio or visual made available by any person shall include the following:

(i) clear instructions for the proper preparation and use of the product including the cleaning of feeding utensils;

(ii) a warning that such complementary food is not intended for an infant under 6 months of age and that the introduction of such complementary before the infant is 6 months old may have health risks;

(iii) the superiority of exclusive breastfeeding for 6 months followed by sustained breastfeeding with the introduction of appropriate complementary foods for at least two years and beyond; and

(iv) a clear and unambiguous statement that home prepared complementary foods are suitable for infants older than 6 months and young children.

(d) Information, educational materials or other materials referred to in subregulations (2)(a, b and c) shall:

(i) not use any text or images, including but not limited to images of animals, story-book characters, cartoon characters, or any other images of, or associated with, infants and young children, that encourage the use of any formula or that discourage breastfeeding;

(ii) contain only correct and current information;

(iii) not give the impression or create the belief that a designated product is equivalent to, comparable with, or superior to breast milk or to breastfeeding;

(iv) bear the name of the publisher, the date of publication and printing; and

(v) not make any reference to any proprietary product or contain the name or logo of any manufacturer or distributor of a designated product except by way of indicating that the educational or informational material is developed and /or printed and/or sponsored by a specific company.

(e) The statements and explanations in the information, educational material or other material referred to in subregulations (2) (a, b and c) that are written, shall be:

(i) in the same font type and letter size as the rest of the material; and

(ii) clear and conspicuous.

(3) Material directed at health care providers

A person, manufacturer or distributor may provide informational or educational material or any other material about a designated product to a health care provider, provided that such information or material is restricted to current scientific and factual matters reflected in total, and not to any selected parts that can be used in a misleading way, that it relates only to the technical aspects and methods for use of the designated product along with the information specified in subregulation (2) as appropriate, and that excludes promotion of the designated product in any manner.

(4) Research article

Research articles are exempted from the requirements of subregulation (1) (b) and (2) (b, c, and d) provided that the funder of the research is mentioned in the article and it excludes promotion of any designated product in any manner.

15. HEALTH CARE PERSONNEL

(1) Heads of health establishments and national, provincial and local health authorities shall take measures to promote, support and protect breastfeeding, and shall give information and

advice to health care personnel regarding their responsibilities, in particular ensuring that they are familiar with all of the information specified in these regulations.

(2) Health care personnel shall work to eliminate practices such as prelacteal feeds that directly or indirectly retard the initiation and continuation of exclusive breastfeeding for six months and sustained breastfeeding for at least two years.

(3) Health care personnel shall report in writing to the head of his or her workplace, regarding any offers he or she receives for samples, gifts, sponsorships or any other benefits from a manufacturer or distributor of designated products or any other contravention of the provisions of the regulations.

(4) Health care personnel, provided that they are not be employed or paid for (partly or fully) by a manufacturer or distributor, shall subject to the requirements determined in subregulations (1), (2) and (3) and when necessary for the purpose of giving nutrition support or feeding advice to individual mothers or members of their families or care givers of an infant or young child that needs to be fed with a designated product, be permitted to: -

(a) demonstrate the correct usage of a designated product; or

(b) explain the hazards on the dangers of improper use of designated products,

16. RESEARCH INVOLVING THE USE OF DESIGNATED PRODUCTS

(1) Research involving the use of designated products in human subjects shall be subject to the written approval of a properly constituted committee for research on human subjects. The Guidelines on research should be followed as specified in Annexure E.

(2) Any public presentation and /or publication resulting from research shall include a verbal declaration and in print upon publication a statement disclosing the source funding.

17. LODGING OF COMPLAINTS

Any person, group, body or institution may submit a written complaint to the local authority concerned or to the Directorate.

18. PENALTIES

19. REPEAL

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

20. COMMENCEMENT

(1) The provision of Chapter 1 of these regulations shall come into operation 12 months after the promulgation of these regulations; and

(2) The provisions of Chapter 2 of these regulations shall come into operation 3 months after the promulgation of these regulations.

ANNEXURE A

Minimum Mandatory Nutritional Information

Typical nutritional information:

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

	Per 100g/ml	Per % RDA serving
Energy (kJ)		
Protein (g)		
Carbohydrate (g)		
**		
Total fat (g)		
**		
**		
** etc		
***		
Total dietary fibre (g)		
Sodium (mg)		

• RDA: Recommended Dietary Allowance for infants or young children (see Annexure D) (whatever is appropriate)

** place for a sub-group nutrient

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

ANNEXURE B

Required Nutritional Information

Format for mandatory nutritional information

Typical nutritional information:

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

	Per 100g/ml	Per % RDA serving
Energy (kJ)		
Protein (g)		
Carbohydrate (g)		
**		
Total fat (g)		
**		
**		
** etc		
***		
Total dietary fibre (g)		
Sodium (mg)		
Inset the essential micronutrient as specified in the applicable Codex standard in the order: Vitamins in alphabetic order and then mineral in alphabetic order (in g, mg, mcg or other unit as appropriate)		

* RDA: Recommended Dietary Allowance for infants or young children (see Annexure D) (whatever is appropriate)

** place for a sub-group nutrient

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

ANNEXURE C

Required Nutritional Information

Format for mandatory nutritional information

Typical nutritional information:

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

	Per 100g/ml	Per % RDA serving
Energy (kJ)		
Protein (g)		
Carbohydrate (g)		
**		
Total fat (g)		
**		
**		
** etc		
***		
Total dietary fibre (g)		
Sodium (mg)		
Source of / High in (name of nutrient) (in g, mg, mcg, or other units as appropriate)		

* RDA = Recommended Dietary Allowance for infants or young children (see Annexure D) (whatever is appropriate)

** place for a sub-group nutrient

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

ANNEXURE D

Recommended Dietary Allowance for Infants and Young Children

	UNIT	Infants		Young children
		Birth – 6 months	7months – 1,0 yr	1 through 3 yr
Energy	kJ	480/kg body mass	440/kg body mass	5 600
Protein	G	2,2/kg body mass	2,0/kg body mass	23
Vitamin A activity				
(1) Vitamin A	IU	1 400	1 330	1330
(2) Retinol equivalent	µg RE^2	420	400	500
Vitamin D	IU	400	400	400
	µg	10	10	10
Vitamin E activity	IU	4.5	6	7,5
	mg α TE^4	3	4	5
Ascorbic acid	mg	35	35	35
Biotin	µg	35	50	65
Folic acid	µg	30	45	100
Pantothenic acid	mg	2	3	3
Nicotinic acid	mg	6	8	9
Riboflavin (Vitamin B2)	mg	0,4	0,6	0,8
Thiamin (Vitamin B1)	mg	0,3	0,5	0,7
Pyridoxine (Vitamin B6)	mg	0,3	0,6	0,9
Cyanocobalamin (Vitamin B12)	µg	0,5	1,5	2,0
Vitamin K	µg	12	15	25
Calcium	mg	360	540	800
Phosphorus	mg	240	360	800
Iodine	µg	40	50	70
Iron	mg	10	15	15
Magnesium	mg	50	70	150
Copper	mg	0,7	1,0	1,2
Zinc	mg	3	5	10
Potassium	mg	925	1 275	1 650
Sodium	mg	350	750	975
Chloride	mg	700	1 200	1 500
Manganese	mg	0,7	1,0	1,5
Fluoride	mg	0,5	1,0	1,5
Chromium	mg	0,04	0,06	0,08
Selenium	mg	0,04	0,06	0,08
Molybdenum	mg	0,06	0,08	0,1

GENERIC EXAMPLE

Annexure E

FAILURE TO FOLLOW INSTRUCTIONS MAY MAKE YOUR BABY ILL

- Use only cooled, boiled water.
- Prepare only one bottle or cup at a time.
- Feed immediately.
- Do not keep leftover feed for later use.
- Use only the enclosed scoop.

FEEDING TABLE

Age of infant	Weight of infant	Quantity per feed		Number of feeds per day recommended	Number of tins needed each month
		Boiled cooled water in ml	Number of measuring scoops		
1st and 2nd weeks					
3rd and 4th weeks					
2nd month					
3rd and 4th months					
5th and 6th months					
from 7th month onwards					

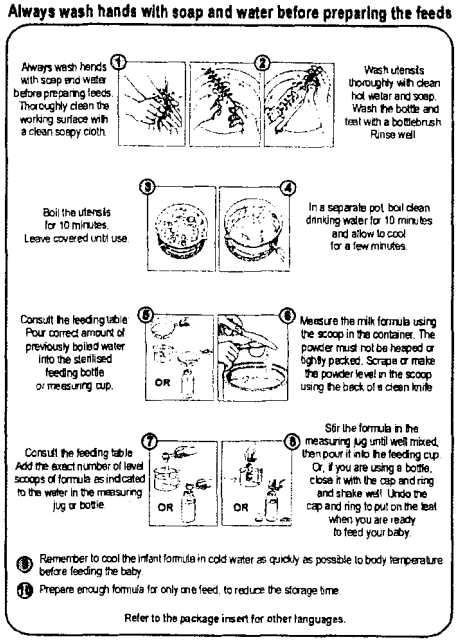
- Close the container tightly after each use and store in a cool dry place.
- Always hold baby while feeding. Leaving baby unattended may cause choking.
- After six months introduce complementary foods in addition to the formula.
- Visit a health facility (clinic) regularly to ensure that your baby is growing well.

Produced in South Africa
Use by expiry date indicated on base of container

Manufactured by
Brand (South Africa) Pty Ltd
46664 Nelson Mandela Drive,
Vosburg 9214,
South Africa

PREPARATION OF FEEDS FOR CUPS AND BOTTLES

Always wash hands with soap and water before preparing the feeds



9 Remember to cool the infant formula in cold water as quickly as possible to body temperature before feeding the baby.

10 Prepare enough formula for only one feed, to reduce the storage time.

Refer to the package insert for other languages.

Breast milk is the best food for babies. This product does not contain breast milk.

Brand

NAME

Infant formula
From Birth to 6 months

This product is not sterile. It may contain harmful organisms which may grow once it is prepared with water.
You must always strictly follow the instructions on the tin.

Before you decide to use this product, get advice from your health professional.

450 g

NUTRITIONAL INFORMATION

Ingredients:

Average Composition	Unit	Per 100 g powder	Per 100 ml formula	* % RDA per 100 ml
Fat	g			
Linoleate	g			
Alpha Linolenic Acid	mg			
Protein	g			
Carbohydrate	g			
Soya Lecithin	g			
Ash	g			
Moisture	g			
Energy	kcal			
	kJ			
Vitamin A	IU			
	mcg RE			
Vitamin D	IU			
	mcg			
Vitamin E	IU			
Vitamin K	mcg			
Vitamin C	mg			
Thiamine (B1)	mg			
Thiamine (B2)	mg			
Niacin (PP)	mg			
Biotin	mcg			
Folic Acid	mcg			
Pantothenic Acid	mg			
Vitamin (B6)	mg			
Vitamin (B12)	mcg			
Choline	mg			
Inositol	mg			
Calcium	mg			
Phosphorus	mg			
Magnesium	mg			
Potassium	mg			
Sodium	mg			
Chloride	mg			
Iron	mg			
Copper	mg			
Iodine	mcg			
Manganese	mcg			

Scoop mass = 3,7 g. 1 litre = 132 g powder + 900 ml water.
* % RDA for infants 0 - 5 years.

Size: Approximately 11,7cm x 30,7cm (may be larger, but not smaller)
*Length of Generic label example (30,7cm) does **NOT** include overlap for pasting*
*Generic example **NOT** to scale*

ANNEXURE F

Guidelines on Infant and Young Child Feeding Research

1. Distinction shall be made between research on infants and young children and research on adults. Infants and young children are a vulnerable group and cannot consent on their own behalf. Therefore they require special protection. Research on infants and young children should only be done if it cannot be done on an adult population and only when all the necessary animal studies have been completed.
2. There shall be no coercion to get infants and young children to participate in any research. The need to boost the numbers of artificially fed infants to achieve statistical significance should not result in aggressive recruitment. The presence of a commercial component increases the risk for coercion. Safe guards against coercion should be build into the study design and spelled out in the research protocol.
3. An independent person should request participation in the research.
4. The availability of free products is an inducement for parents to enrol their infants in research, especially for poor parents. Research should therefore not be done to create a market for a product.
5. Research involving the use of designated products in human subjects shall be subject to the written approval of a properly constituted committee for research on human subjects.
6. The Ethics Review Committee needs full information on the implications of the research and the protocol should be passed by the full committee.
7. The control for any research on infant and young child feeding should always be the best standard of practice.
8. When the randomised control method is used it should be justified and parents should understand the methodology fully.
9. Information to parents to enable them to make an informed consent should include the short- and long term risks of the new formula.
10. Recipients of research awards should not allow themselves, their organisations or their subjects, to be used directly or indirectly for any promotional activity related to any of the designated products.