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GOVERNMENT NOTICE
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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 **a**pplicable Codex standard and marketed or otherwise represented as suit**a**ble 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 organisatións 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 millk, 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^2; provided where the main panel is less than 12 000mm^2 the letter size may decrease proportionately.

(b) instructions for proper cleaning and sterilisation of feeding bottles, teats and feeding cups shall be 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: 3/12/2012

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# (g)			
Sodium (mg)			
Vitamins in alphabetic order (in appropriate unit of measurement)			
Minerals and trace elements in alphabetic order (in appropriate unit of measurement)			
▪ Any other nutrient or food component to be declared in accordance with these Regulations. ▪	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	µg RE^2	500	300
Vitamin D	IU	400	400
	µg	5	5
Vitamin E activity	IU	6	7,5
	mg α TE^4	5	6
Ascorbic acid	mg	50	50
Biotin	µg	50	65
Folic acid	µg	80	150
Pantothenic acid	mg	1,8	2,0
Nicotinic acid	mg	4,0	6,0
Riboflavin(Vitamin B2)	mg	0,4	0,5
Thiamin (Vitamin B1)	mg	0,3	0,5
Pyridoxine (Vitamin B6)	mg	0,3	0,5
Cyanocobalamin (Vitamin B12)	µg	0,5	0,9
Vitamin K	µg	2,5	30
Calcium	mg	270	500
Phosphorus	mg	275	460
Iodine	µg	130	90
Iron	mg	11	7,0
Magnesium	mg	75	80
Copper	mg	1,0	1,2
Zinc	mg	3,0	3,0
Potassium	mg	1 275	1 650
Sodium	mg	750	975
Chloride	mg	1 200	1 500
Manganese	mg	1,0	1,5
Fluoride	mg	0,5	0,7
Chromium	mg	5,5	5,5
Selenium	µg	20	20
Molybdenum	mg	0,08	0,1
Choline		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

No. R. 991 **6 Desember 2012**

WET OP VOEDINGSMIDDELS, SKOONHEIDSMIDDELS EN ONTSMETTINGSMIDDELS, 1972 (WET NO. 54 VAN 1972)

REGULASIES BETREFFENDE VOEDINGSMIDDELS VIR BABAS EN JONG KINDERS

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

BYLAE

Woordomskrywing

1 In hierdie regulasies het 'n uitdrukking waaraan daar in die Wet 'n betekenis geheg is, daardie betekenis en, tensy uit die samehang anders blyk, beteken-

"aangewese produk"—
(a) formule vir babas;
(b) opvolgformule;
(c) formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande;
(d) aanvullende voedsel;
(e) vloeibare melk, poeiermelk, gemodifiseerde poeiermelk of poeierdrankies bemark of op 'n ander manier voorgestel as geskik vir babas of jong kinders;
(f) voedingsbottels, kunsspene en voedingskoppies met tuite, strooitjies of kunsspene; en
(g) enige ander produkte bemark of voorgestel as geskik vir die voeding van babas en jong kinders, wat die Minister as sodanig kan aanwys by kennisgewing in die *Staatskoerant* gepubliseer;

"aanvullende voedsel" enige voedingsmiddel, hetsy in vloeistof-, vaste of semi-vaste vorm, wat vir 'n baba gegee word vanaf die ouderdom van ses maande as deel van die oorgangsproses waartydens 'n baba leer om voedsel te eet wat geskik is vir sy of haar ontwikkelingstadium, terwyl borsvoeding aanhou of hy of sy met 'n geskikte formule gevoed word;

"amptelike taal" enige een van die 11 amptelike Suid-Afrikaanse tale: Afrikaans, Engels, isiNdebele, isiXhosa, isiZulu, Sepedi, Sesotho, Setswana, Siswati, Tshivenda en Xitsonga;

"apteek" 'n gemeenskapsapteek of 'n institusionele apteek;

"baba" 'n persoon nie ouer as 12 maande nie;

"bababottel" 'n artikel met 'n kunsspeen wat gebruik word om babas en jong kinders te voed;

"bemarking" die bevordering, verspreiding, verkoop of advertering van 'n aangewese produk, en ook produkreklame- en produkinligtingsdienste, met inbegrip van die gebruik van beroepsdiensverteenwoordigers of enige persoon wat namens 'n vervaardiger of verspreider optree;

"bemarkingspersoneel" enigiemand wat betrokke is by die bemarking van 'n aangewese produk;

"betroubare laboratorium" 'n laboratorium wat geakkrediteer is ooreenkomstig die International Laboratory Accreditation Cooperation (ILAC) of Suid-Afrikaanse Nasionale Akkreditasiestelsel (SANAS);

"bevorder" om enige metode, skema of ontwerp te gebruik om 'n persoon of groep persone aan te moedig of oor te haal, in watter vorm ook al, om 'n aangewese produk te koop of te gebruik, en sluit in, maar is nie beperk nie tot, advertering, verkooppuntadvertering, die gee van monsters, spesiale verkope, gratis voorraad, donasies, borgskappe, geskenke, hetsy dit verband hou met die aankope van aangewese produkte al dan nie, gratis gebruiksvoorwerpe of ander artikels, pryse, drasakke met verpakkingsfoto's of produklogo's, pryse of spesiale uitstallings by kleinhandelafsetpunte, afslagkoepons, premies, lokartikels, koppelverkope, kortings en ander winskopies;

"borgskap" enige bystand, hetsy finansieel of in goedere, aan 'n persoon, groep of aktiwiteit, alleen of saam met ander, en het "borg" 'n ooreenstemmende betekenis;

"borsmelk" menslike melk, wat verkry word deur middel van die baba of jong kind wat soog aan die moeder se bors of deur melk uit die bors te druk;

"borsvoeding" die soog van die baba of jong kind aan die moeder se bors;

"Codex-standaard" die jongste goedgekeurde weergawe van die betrokke Codex-standaard soos uitgereik deur die Codex Alimentarius Kommissie van die Gesamentlike VLO/WGO-voedselstandaardeprogram;

"die Wet" die Wet op Voedingsmiddels, Skoonheidsmiddels en Ontsmettingsmiddels, 1972 (Wet No. 54 van 1972);

"Direkteur-generaal" die Direkteur-generaal: Departement van Gesondheid;

"Direktoraat" die direktoraat verantwoordelik vir Voeding in die Departement van Gesondheid;

"eie produk" 'n aangewese produk wat uitdruklik in verband gebring word met 'n spesifieke vervaardiger, verspreider of kleinhandelaar;

"etiket", binne die bestek van hierdie regulasies, 'n kaartjie, handelsmerk, merk, geïllustreerde of ander beskrywende inhoud, wat op die houer van 'n aangewese produk geskryf, gedruk, gestensil, geteken, gebosseleer of afgedruk is, of daaraan geheg is;

"formule vir babas" 'n formuleproduk spesiaal vervaardig ooreenkomstig die toepaslike Codex-standaard om alleen te voldoen aan die voedingsvereistes van babas tydens die eerste maande van lewe tot die bekendstelling van geskikte aanvullende voedsel;

"formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande" 'n formuleproduk wat voldoen aan die jongste goedgekeurde weergawe van Codex-standaard 72-1981 getiteld "*Standard for infant formula and formulas for special medical purposes intended for infants*";

"gemeenskapsapteek" 'n apteek waarin of waaruit sommige van of al die dienste soos voorgeskryf in regulasie 18 van die *Regulasies betreffende die praktyk van aptekerswese* wat ingevolge die Wet op Aptekers, 1974 (Wet No 53 van 1974), as Goewermentskennisgewing No. R. 1158 gepubliseer is,

verskaf word aan persone wat farmaseutiese dienste nodig het, maar uitgesonderd 'n institusionele apteek;

"gemodifiseerde poeiermelk" 'n produk vervaardig uit natuurlike melk of van volmelkpoeier, afgeroomde melkpoeier of gedeeltelik afgeroomde melkpoeier of 'n kombinasie daarvan;

"geprosesseerde voedingsmiddel met 'n graanbasis vir babas en jong kinders" het die betekenis soos beskryf in die jongste goedgekeurde weergawe van Codex-standaard 74-1981 getiteld "*Codex Standard for processed cereal-based foods for infants and young children*";

"geskenk" iets wat gratis gegee word, en, in hierdie konteks, sluit in, maar is nie beperk nie tot, gratis monsters van aangewese produkte, maaltye en verversings, dagboeke, skryfbehoeftes, kalenders, bababed-identifikasieplaatjies, plakkers, groeikaarte, voorskrifskryfblokke, tongspatels of enige item van watter waarde ook al, deur die vervaardigers, verspreiders, kleinhandelaars, en hul verteenwoordigers, van die aangewese produkte;

"gesondheidsaanspraak" enige voorstelling wat verklaar, suggereer of impliseer dat 'n verwantskap bestaan tussen 'n voedsel of 'n voedselbestanddeel en gesondheid, en sluit in, maar is nie beperk nie tot, voedingstoffunksieaansprake, aansprake op verhoogde funksie, aansprake op vermindering van die gevaar van siekte, asook prebiotiese en probiotiese aansprake;

"gesondheidsinstelling" die geheel of 'n gedeelte van 'n openbare of private instelling, fasiliteit, gebou of plek wat, hetsy vir wins of nie, bedryf word of ontwerp is om binnepasiënt- of buitepasiëntbehandeling, diagnostiese of terapeutiese ingrypings, verpleging en rehabilitatiewe, palliatiewe, herstellende, voorkomende of ander gesondheidsdienste te verskaf;

"gesondheidsorgpersoneel" gesondheidsorgverskaffers en gesondheidswerkers;

"gesondheidsorgverskaffer" enigiemand wat gesondheidsdienste en/of maatskaplike dienste verskaf ingevolge enige wet, met inbegrip van die Wet op Verwante Gesondheidsberoepe, 1982 (Wet No. 63 van 1982), Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), "Nursing Act, 2005" (Wet No. 33 van 2005), Wet op Aptekers, 1974 (Wet No. 53 van 1974), en die Wet op Tandtegnici, 1978 (Wet No. 19 van 1979);

"gesondheidswerker" enigiemand wat regstreeks of onregstreeks betrokke is by die verskaffing van gesondheidsdienste aan 'n gebruiker of wat opleiding ontvang om gesondheidsdienste te voorsien, maar uitgesonderd 'n gesondheidsorgverskaffer. Dit sluit in maatskaplike werkers, lekeberaders, opleiers of onbetaalde vrywillige werkers;

"grafiese voorstelling" illustrasies, foto's, tekeninge of prente van babas, jong kinders of kinderkarakters, spotprente of enige ander vorme wat na hulle lyk, menslik al dan nie, soos onder meer vermenslikte vrugte, groente, diere en/of blomme;

"handelsnaam" die handelsmerk of naam wat 'n vervaardiger of verspreider aan 'n aangewese produk of 'n reeks aangewese produkte gee, en sluit handelslogogramme in;

"hermeties verseëlde houer" 'n onoopgemaakte houer wat nie oopgemaak kan word sonder dat sodanige houer of 'n seël, aangeplakte etiket of 'n ander deel van of hegsel aan so 'n houer gebreek of beskadig word nie, en wat daarop bereken is om die higiëniese en ander eienskappe van die produkte te beskerm en die inhoud daarvan teen die ingang van mikroörganismes te beskerm;

"herseëlbare houer" houers, ook verpakkingsmateriale, wat slegs uit stowwe vervaardig word wat veilig en geskik is vir die bedoelde gebruike daarvan en die higiëniese en ander eienskappe van die voedingsmiddel beskerm, wat verseker dat die produk nie oopgemaak kan word sonder dat die pakket gebreek of beskadig word nie en, nadat dit oopgemaak is, weer op so 'n wyse toegemaak kan word dat bederf en kontaminasie voorkom word;

"houer" enigiets waarin of waarmee voedsel bedien, gestoor, vertoon, verpak, toegedraai, gehou of vervoer word en waarmee voedsel in regstreekse kontak is;

"industrieel vervaardigde transvetsure" al die geometriese isomere van monoönversadigde vetsure met een transdubbelbinding, te wete C14:1, C16:1, C18:1, C20:1 en C22:1, en poli-onversadigde vetsure met een of meer transdubbelbindinge, te wete C18:2, C18:3, C20:2 en C22:2, wat niegekonjugeerde koolstof-koolstofdubbelbindinge, onderbreek deur minstens een metileengroep, in die transkonfigurasie het, en sluit natuurlike transvetsure uit;

"institusionele apteek", soos omskryf in die *Regulasies betreffende die praktyk van aptekerswese* wat ingevolge die Wet op Aptekers, 1974 (Wet No 53 van 1974), as Goewermentskennisgewing No. R. 1158 gepubliseer is, 'n apteek geleë in–

(a) 'n openbare gesondheidsfasiliteit, waarin of waaruit sommige van of al die dienste soos voorgeskryf in regulasie 18 van hierdie regulasies verskaf word aan persone wat die farmaseutiese dienste van of by daardie openbare gesondheidsfasiliteit nodig het; of
(b) 'n private gesondheidsfasiliteit, waarin of waaruit sommige van of al die dienste soos voorgeskryf in regulasie 18 van hierdie regulasies verskaf word aan persone wat die farmaseutiese dienste van of by daardie private gesondheidsfasiliteit nodig het,

"jong kind", in hierdie konteks, 'n kind ouer as 12 maande maar jonger as 36 maande (3 jaar);

"kleinhandelafsetpunt" 'n apteek, winkel, supermark of enige ander perseel of afsetpunt soos direkte pos, indirekte bemarking en verkope of ander virtuele persele wat deur 'n vervaadiger, verspreider, agent of invoerder of enige ander persoon gebruik word om 'n aangewese produk te verkoop;

"koppelverkoop" die verkoop van 'n aangewese produk wat gekoppel word aan die aankoop van 'n ander produk, insluitende 'n aangewese produk;

"kunsspeen" 'n artikel waaraan 'n baba of jong kind suig en wat gebruik word om voedsel uit 'n bottel, voedingskoppie of 'n ander voedingsartikel te gee;

"lae koste" 'n prys laer as die groothandelprys of, in die afwesigheid van so 'n prys, laer as 80% van die kleinhandelprys;

"medisinale aanspraak" 'n aanspraak wat verklaar of impliseer dat 'n produk die eienskap het van behandeling, voorkoming of genesing van menslike siekte, en, ten einde toegelaat te word om 'n medisinale aanspraak te maak, moet 'n produk geklassifiseer word as 'n medisyne ooreenkomstig die woordomskrywing in artikel 1 van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965);

"mengsel" 'n mengsel van koeimelk, komponente van koeimelk, plantaardige vette en/of glukose;

"monster" enige hoeveelheid van 'n aangewese produk wat kosteloos verskaf word;

"nagemaakte suiwelproduk" 'n ander produk as 'n suiwelproduk, wat van dierlike of plantaardige oorsprong is en in algemene voorkoms, voorstelling en die bedoelde gebruik met 'n suiwelproduk ooreenkom;

"nie-eksklusiewe borsvoeding" voeding met borsmelk asook ander melk (ook kommersiële formules of tuisbereide melk), voedsel of vloeistowwe;

"nievoedende versoeter" 'n versoeter of 'n mengsel van nievoedende versoeters, waarvan die vlak van versoeting gelyk is aan 5 g sukrose en wat nie 'n energiewaarde van meer as 8 kJ het nie;

"opvoedkundige inligting" enige skriftelike of oudiovisuele materiaal of inligting soos aanbiedings, brosjures of artikels wat deur 'n individu versprei word om kennis oor te dra;

"opvoedkundige materiaal" enige skriftelike of oudiovisuele materiaal bedoel vir die algemene publiek, soos strooibiljette, brosjures, boeke, nuusbladartikels, videobande, internetinligting of ander vorme, wat die gee van voorligting oor die gepaste gebruik van produkte vir babas en jong kinders behels;

"opvolgformule" 'n produk wat industrieel geformuleer is ooreenkomstig 'n samestelling wat gebaseer word op die toepaslike Codex-standaard en wat bemark of op 'n ander manier voorgestel word as geskik vir 'n baba vanaf ses maande of 'n jong kind;

"poeierdrankie" 'n substansie wat bedoel is om by vloeibare melk, poeiermelk, gemodifiseerde poeiermelk, water of ander dranke gevoeg te word;

"porsie", met betrekking tot 'n voedingsmiddel, 'n toepaslike porsiegrootte wat geskik is vir verbruik as 'n enkele maaltyd deur babas of jong kinders;

"substansie" 'n versamelwoord vir enige chemiese, mikrobiologiese of fisiese komponent aanwesig in of gevoeg by 'n voedingsmiddel;

"tegnies wetenskaplike materiaal" enige materiaal wat bewese tegniese en/of wetenskaplike data oor aangewese produkte bevat of rakende kennis van voeding , wat bestem is vir gesondheidsorgpersoneel;

"vergelykende aanspraak" 'n aanspraak wat die voedingstofvlakke en/of die energiewaarde van twee of meer soortgelyke voedingsmiddels vergelyk;

"verpakkingsfoto" enige voorstelling van 'n aangewese produk, ook foto's, grafika of lyntekeninge;

"versoeter" enige substansie gelys as 'n versoeter in die *"General Standard for Food Additives (GSFA)"* van die Codex Alimentarius Kommissie of 'n mengsel van twee of meer daarvan;

"verspreider" 'n persoon, korporasie of ander entiteit in die openbare of private sektor wat betrokke is by die saak (hetsy regstreeks of onregstreeks) van bemarking en/of verspreiding van 'n aangewese produk op groot- of kleinhandelvlak;

"vervaardiger" 'n persoon, korporasie of ander entiteit wat betrokke is by die saak van vervaardiging, soos die produksie, voorbereiding, verwerking, preservering of enige ander vervaardigingsproses, van 'n aangewese produk, hetsy regstreeks deur 'n agent of deur 'n persoon wat beheer word deur, of kragtens 'n ooreenkoms met, sodanige persoon, korporasie of ander entiteit;

"voedingsaanspraak" 'n voorstelling wat 'n spesifieke voedingstof- of voedselbestanddeelinhoud van 'n bepaalde voedingsmiddel noem, soos maar nie beperk nie tot 'n voedingstofinhoud of 'n vergelykende aanspraak;

Die volgende maak nie voedingsaansprake uit nie:
(a) die noem van die substansies in die lys van bestanddele;
(b) die noem van voedingstowwe as 'n verpligte deel van die voedingsetikettering;
(c) kwantitatiewe of kwalitatiewe verklaring van sekere voedingstowwe of bestanddele op die etiket, indien by nasionale wetgewing vereis;

"voedingskoppie" 'n koppie met 'n kunsspeen, tuit of strooitjie wat gebruik word om babas of jong kinders te voed;

"voedingstofinhoudaanspraak" 'n aanspraak wat die vlak van 'n voedingstof of die energie vervat in 'n voedingsmiddel beskryf.

ETIKETTERING, SAMESTELLING, VERPAKKING EN VERVAARDIGINGSAANGELEENTHEDE

ALGEMENE ETIKETTERING, SAMESTELLING, VERPAKKING EN ANDER VERVAARDIGINGSAANGELEENTHEDE VAN AANGEWESE PRODUKTE

2(1) Geen persoon mag enige van die volgende invoer, te koop aanbied of verkoop nie:-

(a) 'n ander voedingsmiddel as 'n formule vir babas of 'n formule vir babas vir die besondere voedinghantering van spesifieke mediese toestande, wat voorgestel word as geskik vir babas jonger as ses maande;

(b) 'n formule vir babas, 'n opvolgformule, 'n formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande, aanvullende voedsel of vloeibare melk, poeiermelk, gemodifiseerde poeiermelk of poeierdrankies, wat bemark of op 'n ander manier voorgestel word as geskik vir babas of jong kinders, wat nie na behore ooreenkomstig die bepalings van hierdie regulasies, ander toepaslike regulasies gepubliseer kragtens die Wet en toepaslike Codex-standaarde vervaardig, geëtiketteer en verpak is nie, met dien verstande dat waar 'n konflik bestaan tussen die Codex-standaarde en hierdie regulasies, hierdie regulasies voorrang geniet;

(c) 'n formule vir babas, 'n opvolgformule, 'n formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande, aanvullende voedsel of vloeibare melk, poeiermelk, gemodifiseerde poeiermelk of poeierdrankies wat bemark of op 'n ander manier voorgestel word as geskik vir babas of jong kinders, wat nie in 'n hermeties verseëlde houer verpak is nie en wat nie tydens gebruik en die daaropvolgende toepaslike berging weer geseël of dig gesluit kan word nie.

(2) Die houer en/of etiket van 'n produk in subregulasie (1) genoem, mag-

(a) nie grafiese voorstelling toon nie, afgesien van daardie wat nodig is om die korrekte metode van bereiding en die gebruik van die produk te toon, soos die-

(i) illustrasie van die metode vir die veilige bereiding van 'n formule vir babas, 'n opvolgformule, 'n formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande, of van poeiermelk,

gemodifiseerde poeiermelk of poeierdrankies, wat bemark of op 'n ander manier voorgestel word as geskik vir babas of jong kinders, of 'n aanvullende voedsel;

(ii) illustrasie van die sterilisering van toerusting en gebruiksvoorwerpe in die geval van 'n formule vir babas, 'n opvolgformule en 'n formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande;

(iii) bestanddele, samestelling of die bereide produk van 'n aanvullende voedsel vir babas of jong kinders;

(b) nie enige inligting bevat of enige negatiewe aanspraak maak betreffende die voedingsinhoud of ander eienskappe van menslike melk nie;

(c) nie woorde bevat wat regstreeks of onregstreeks daarop dui dat so 'n produk vir alle babas geskik is nie;

(d) die voedingsinligting op die etiket bevat ooreenkomstig die vereistes van hierdie regulasies of ander toepaslike regulasies kragtens die Wet.

(3) Die maatskappylogo, die handelsnaam en logo's wat onderskrywing deur spesifieke godsdienstige sertifiserende organisasies aandui, word toegelaat, met dien verstande dat hulle nie 'n prent van 'n baba, jong kind of ander vermenslikte figuur bevat nie.

(4) (a) Ondanks die bepalings van die *Regulasies betreffende die etikettering en advertering van voedingsmiddels-*

(i) word geen gesondheids-, medisinale of voedingsaansprake op enige wyse vir enige aangewese produk toegelaat word;

(ii) sou 'n medisinale aanspraak gemaak word op 'n aangewese produk of 'n aanspraak dat 'n substansie wat ingevolge die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965), beheer word 'n bestanddeel van so 'n aangewese produk is, moet sodanige produk by die Medisynebeheerraad voorgelê word vir registrasie ingevolge artikel 13 van die voornoemde Wet.

(b) Die minimum vereiste voedingsinligting soos per Aanhangsel B moet op die etiket verskyn van aanvullende voedsel en vloeibare melk, poeiermelk, gemodifiseerde poeiermelk en poeierdrankies wat bemark of op 'n ander manier voorgestel word as geskik vir die voeding van babas ouer as ses maande of jong kinders.

(c) 'n Aanspraak met betrekking tot fortifisering, ook die gebruik van die fortifiseringslogo, kan gemaak word indien dit met die bepalings van die *Regulasies betreffende die fortifisering van sekere voedingsmiddels* ooreenstem.

(5) Geen voedsel bestem vir babas en jong kinders mag enige industrieel vervaardigde transvetsure gebruik nie.

(6) Die voedingsinligting wat by hierdie regulasies vereis word, moet die werklike, tipiese waardes wees wat deur 'n betroubare laboratorium vasgestel is deur chemiese of mikrobiologiese ontleding en steekproeftrekking ooreenkomstig die Codex-standaarde en ander toepaslike regulasies en riglyne kragtens die Wet.

(7) Die byvoeging van opsionele bestanddele en toelaatbare additiewe, wat in Codex-standaarde uiteengesit word, moet in die lys van bestanddele weergegee word soos vereis deur die etiketteringsregulasies kragtens die Wet.

(8) Geen persoon mag aangewese produkte invoer, te koop aanbied of verkoop wat nie aan die higiënevereistes voldoen wat in die toepaslike regulasies kragtens die Wet gepubliseer en die jongste goedgekeurde weergawe van Codex-standaard 66-2008 getiteld "*Code of hygienic practice for powdered formulae for infants and young children*" uiteengesit is nie.

(9) Geen hormoonresidue, antibiotika, patogene mikroörganismes, toksiese stowwe of ander kontaminante mag in voedingsmiddels vir babas of jong kinders aanwesig wees nie, tensy die vlakke daarvan in ooreenstemming is met die toepaslike regulasies kragtens die Wet en die toepaslike Codex-standaarde.

(10) Enige voedingsmiddel vir babas of jong kinders moet berei word volgens goeie vervaardigings- en goeie higiënepraktyke wat deur Codex-standaarde en ander toepaslike regulasies kragtens die Wet bepaal word, sodat —

(a) residue van plaagdoders wat vir die produksie, berging of prosessering van die rou materiaal of die bewerkte voedselbestanddeel nodig is, nie in die voedingsmiddel agterbly nie; of

(b) indien onvermydelik, kontaminante verminder word tot 'n konsentrasie laer as daardie wat as die maksimum standaard vir die kontaminant vasgestel is.

(11) Die etiket van 'n aangewese produk moet die naam, adres en kliëntediensnommer van die vervaardiger, invoerder of verkoper bevat.

(12) Die etiket van 'n aangewese produk mag nie enige ander aangewese produk meld, bevorder of adverteer nie.

(13) Geen speelgoed of enige ander vorm van geskenk of aandenking mag saam met die aangewese produkte genoem in subregulasie 2(1), gemeld, ingevoeg of verkoop word nie, met die uitsondering van maatlepels en skeplepels.

(14) Geen aansporings, lokmiddels of uitnodigings van enige aard wat verbruikers kan aanmoedig om met die vervaardiger of verspreider van 'n aangewese produk kontak te maak en wat tot die verkoop of die bevordering van 'n aangewese produk vir babas of jong kinders kan lei, mag op die etiket of in die bemarking van 'n aangewese produk vir babas of jong kinders gebruik word nie.

(15) Die byvoeging van heuning of esdoringstroop as 'n komponent in 'n voedingsmiddel vir babas ouer as ses maande of jong kinders word toegelaat, met dien verstande dat -

(a) sodanige heuning of esdoringstroop voldoen aan die toepaslike regulasies gepubliseer kragtens die Wet; en

(b) daar aangetekende bewyse is dat sodanige heuning of esdoringstroop vry van botulinustoksine is.

(16) Die byvoeging van kruie en speserye as 'n komponent in 'n voedingsmiddel vir babas of jong kinders word toegelaat, met dien verstande dat sodanige kruie en speserye voldoen aan die *Regulasies betreffende mikrobiologiese standaarde vir voedingsmiddels en verwante aangeleenthede*.

(17) Geen voedingsmiddel bedoel vir babas of jong kinders mag enige versoeters gelys in die *"Codex general standard for food additives (GSFA)"* van die Codex Alimentarius Kommissie, of 'n mengsel van twee of meer daarvan, bevat nie.

(18) Geen verklaring of aanspraak wat 'n boodskap oordra wat 'n spesifieke maatskappynaam of logo of handelsnaam voorstel as die kundiges met betrekking tot die voed of voeding van babas en jong kinders mag op die etiket of op enige ander wyse gemaak word nie.

(19) Behoudens die bepalings van hierdie regulasies moet die etikettering van voedingstowwe vir babas en jong kinders ook voldoen aan die bepalings van die *Regulasies betreffende die etikettering en advertering van voedingsmiddels* gepubliseer ingevolge die Wet, met inbegrip van alle wysigings.

SPESIFIEKE ETIKETTERINGS- EN ANDER VEREISTES VIR FORMULE VIR BABAS, OPVOLGFORMULE, OF FORMULE VIR BABAS OF OPVOLGFORMULE VIR DIE BESONDERE VOEDINGHANTERING VAN SPESIFIEKE MEDIESE TOESTANDE

3(1) Die houer of etiket van 'n formule vir babas of 'n opvolgformule moet die volgende inligting bevat:

(a) Die hoofpaneel moet die volgende bevat:

(i) die ouderdomsperke van die babas en jong kinders vir wie sodanige produk geskik is, onder die naam of beskrywing van die produk, in letters wat minstens 3 mm hoog is vir die kleinste letters vir 'n houer van 400 g, wat proporsioneel tot die grootte van die houer moet vergroot;

(ii) die volgende duidelike, opvallende en maklik leesbare boodskappe in vetdruk in letters wat minstens 3 mm hoog is, wat aan die bokant van die hoofpaneel van die etiket moet wees:

(a) "Bevat nie borsmelk nie"; en

(b) "Borsmelk is die beste voedsel vir babas";

(iii) die volgende duidelike, opvallende en maklik leesbare boodskappe in vetdruk in letters wat minstens 2 mm hoog is, wat aan die onderkant van die hoofpaneel van die etiket moet wees:

(a) "Hierdie produk moet slegs gebruik word soos deur 'n beroepsgesondheidspraktisyn aanbeveel.";

(b) "Hierdie produk is nie altyd steriel nie en kan skadelike mikroörganismes bevat. Dit moet korrek berei en gebruik word."

(b) Die boodskappe uiteengesit in 3(1)(a) hierbo, ook die vereistes vir die spesifieke lettergroottes, moet op die multibladsykleefetiket of voubiljet in minstens vyf ander amptelike tale herhaal word, soos in subregulasie 3(6)(a) gemeld.

(2) Die houer of etiket van 'n formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande moet die volgende inligting bevat:

(a) Die hoofpaneel moet die volgende bevat:

(i) die aanduiding vir gebruik, wat aangebring moet word in letters wat minstens 2 mm hoog is, soos volg: "Vir die voedinghantering van..." met die spesifieke siekte/s, siektetoestand/e of mediese toestand/e waarvoor die produk bedoel en doeltreffend bewys is in die oop spasie aangebring;

(ii) die stelling "Borsmelk is die beste voedsel vir babas" in vetdruk in letters wat minstens 3 mm hoog is, wat aan die bokant van die hoofpaneel van die etiket moet wees, met dien verstande dat in die geval van 'n formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande waarvoor borsmelk op mediese gronde teenaangedui word, die voornoemde boodskap nie op die etiket hoef te verskyn nie;

(iii) die ouderdomsperke van die babas vir wie sodanige produkte geskik is, onder die naam of beskrywing van die produk, in letters wat minstens 3 mm hoog is vir die kleinste letters vir 'n houer van 400 g, wat proporsioneel tot die grootte van die houer moet vergroot;

(iv) die volgende duidelike, opvallende en maklik leesbare boodskap in vetdruk in letters wat minstens 2 mm hoog is: "Hierdie produk is nie altyd steriel nie en kan skadelike mikroörganismes bevat. Dit moet korrek berei en gebruik word."

(v) 'n prominente verklaring wat sê "GEBRUIK ONDER MEDIESE TOESIG", wat in vetdruk in letters wat minstens 3 mm hoog is moet verskyn;

(b) alle formule vir babas vir die besondere voedinghantering van spesifieke mediese toestande moet, bykomend tot die vereistes in paragraaf (2)(a) hierbo, voldoen aan die jongste goedgekeurde weergawe van Codex-standaard 72-1981, Afdeling B, met die opskrif *"Formula for special medical purposes intended for infants"*;

(c) die voedingsmodifikasies, indien enige, wat in die voedingsinligtingtabel aangedui moet word.

(3) Die houer of etiket van 'n formule vir babas, of 'n opvolgformule, of 'n formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande moet instruksies verskaf vir die behoorlike sterilisering van toerusting en gebruiksartikels, en instruksies vir die korrekte bereiding en gebruik ooreenkomstig die jongste VLO/WGO-riglyne getiteld *"Safe preparation, storage and handling of powdered infant formula guidelines",* wat-

(a) in maklik verstaanbare woorde en grafika moet wees wat slegs die gebruik van voedingsbottels met kunsspene en gewone koppies uitbeeld;

(b) aandui dat veilige, voorafgekookte water gebruik moet word;

(c) aandui dat slegs die ingeslote skeplepel gebruik moet word;

(d) die voedingskaart en gebruiksaanwysing en instruksies vir die wegdoening van oorskietvoeding aandui;

(e) aandui dat slegs een voeding op 'n slag berei moet word;

(f) die behoorlike berging en bewaring voor en nadat die houer oopgemaak is, aandui;

(g) aandui dat die baba tydens voeding regop gehou moet word;

(h) aandui dat die voubiljet in ander tale instruksies gee vir die korrekte bereiding en gebruik;

(i) in die Engelse taal is, met dien verstande dat die vereistes in paragraaf (a) tot (h) in minstens vyf ander amptelike tale, soos in subregulasie 3(6)(a) voorgeskryf, op die multibladsykleefetiket of voubiljet herhaal word.

(4) Die houer of etiket van 'n formule vir babas, of 'n opvolgformule, of 'n formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande mag nie, in die handelsnaam of in enige ander frases, die uitdrukkings "moederlik", "menslik" of enige afgeleide vorm van hierdie uitdrukkings, of 'n soortgelyke uitdrukking wat 'n sterk ooreenkoms tussen die produk en borsmelk suggereer, insluit nie.

(5) Die etiket van vloeibare formule wat gereed is vir gebruik word vrygestel van die vereistes in regulasie 3(3)(b), (c) en (e) en die boodskappe in regulasie 3(1)(a)(iii)(b) en 3(2)(a)(iv).

(6) 'n Vervaardiger of verspreider mag nie 'n formule vir babas, of 'n opvolgformule, of 'n formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande invoer, te koop aanbied of verkoop indien-

(a) dit nie 'n multibladsykleefetiket of 'n inligtingsblaadjie insluit nie wat tussen die etiket en houer of herseëlbare houer ingevoeg is wat die inligting genoem in regulasie 3(1)(a), 3(2)(a) en 3(3) in vyf ander amptelike tale bevat wat soos volg bepaal word: een in die Nguni-groep, een in die Sotho-groep, Afrikaans, Xitsonga en Tshivenda. Die taalgroepe is die Nguni-groep (isiZulu, isiXhosa, isiNdebele, Siswati), die Sotho-groep (Sesotho, Setswana, Sepedi), Afrikaans, Xitsonga en Tshivenda.

(7) Houers en/of etikette van 'n formule vir babas of 'n formule vir babas vir die besondere voedinghantering van spesifieke mediese toestande moet minstens een van die gesondheidsboodskappe bevat wat in Aanhangsel D by hierdie regulasies uiteengesit is. Die boodskap moet sigbaar, leesbaar, duidelik en opvallend wees.

(8) Alle etikette van 'n formule vir babas, of 'n opvolgformule, of 'n formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande moet die voedingsinligting bevat van al die voedingstowwe en substansies wat deel vorm van die essensiele samestelling van die produk ooreenkomstig die Codex-standaarde, en in die voorgeskrewe formaat in Aanhangsel A uiteengesit.

(9) Indien sojaproteïen die enigste bron van proteïen is, moet die produk soos volg geëtiketteer word: "Sojaproteïen-gebaseerde formule vir babas of opvolgformule".

(10) Alleenlik proteïenisolate uit soja moet gebruik word in gevalle waar 'n formule vir babas of 'n opvolgformule slegs soja as 'n bron van proteïen gebruik of in 'n mengsel van soja- en koeimelkproteïen.

(11) Al die bestanddele en additiewe wat in 'n formule vir babas, of 'n opvolgformule, of 'n formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande gebruik word, moet glutenvry wees en geen aanspraak te dien effekte mag op die etiket of op enige ander wyse gemaak word nie.

SPESIFIEKE ETIKETTERINGS- EN ANDER VEREISTES VIR AANVULLENDE VOEDSEL EN VLOEIBARE MELK, POEIERMELK, GEMODIFISEERDE POEIERMELK EN POEIERDRANKIES BEMARK OF OP 'N ANDER MANIER VOORGESTEL AS GESKIK VIR BABAS OF JONG KINDERS

4(1) 'n Vervaardiger of verspreider mag nie aanvullende voedsel of vloeibare melk, poeiermelk, gemodifiseerde poeiermelk of poeierdrankies wat bemark of op 'n ander manier voorgestel word as geskik vir babas of jong kinders invoer, te koop aanbied of verkoop nie, tensy die houer of etiket geheg aan sodanige produk, in letters in vetdruk en in 'n duidelike, opvallende en maklik leesbare taal-

(a) die ouderdomsperke aandui van babas van ses maande en ouer of jong kinders vir wie sodanige produk geskik is, onder die naam of beskrywing van die produk op die hoofpaneel van die etiket, en in letters wat minstens 2 mm hoog is vir die kleinste letters;

(b) die instruksies verskaf vir die veilige en korrekte bereiding, waar toepaslik, sowel as die gebruik en geskikte porsiegroottes vir die verskillende ouderdomme;

(c) die instruksies verskaf vir die veilige berging voor en nadat die houer oopgemaak is;

(d) 'n waarskuwing, voorafgegaan deur die uitdrukking "Belangrike kennisgewing", insluit teen die gesondheidsgevare van onveilige en inkorrekte bereiding, gebruik en berging, waar toepaslik;

(e) die volgende stelling insluit: "Hierdie voedsel is nie vir babas jonger as ses maande bedoel nie en vroeë bekendstelling daaraan word nie aanbeveel nie";

(f) waar etiketspasie dit toelaat, die volgende boodskap meld: Babas moet vanaf ses maande, saam met borsmelk, 'n verskeidenheid voedsel gegee word. Vra 'n gesondheidswerker of 'n gesondheidsberoepspraktisyn om raad.";

(g) die uitdrukking "MOENIE SOUT EN/OF SUIKER BYVOEG NIE" insluit in die onmiddellike nabyheid van die bereidingsinstruksies, in hoofletters wat minstens 2 mm hoog is.

(2) Ondanks die bepalings van regulasie 4(1), moet die etiket of houer van geprosesseerde voedingsmiddels met 'n graanbasis vir babas en jong kinders–

(a) in die geval van 'n graan, met 'n proteïeninhoud van 15% of meer van die voedingstofverwysingswaarde (VVW) vir die besondere ouderdomsgroep per porsie, en waar die totale proteïengehalte waarvan die geanaliseerde aminosure van die voedingsmiddel minstens 80% van elk van die aminosure moet bevat soos per die aminosuurverwysingspatroon gelys in Aanhangsel 5 van die *Regulasies betreffende die etikettering en advertering van voedingsmiddels*, 'n verklaring bevat te dien effekte dat die graan met voorafgekookte, afgekoelde water berei moet word;

(b) in die geval van 'n graan met 'n proteïeninhoud van minder as 15% van die VVW vir die besondere ouderdomsgroep per porsie, 'n verklaring bevat te dien effekte dat die graan met borsmelk of 'n formule berei moet word indien dit gegee word aan babas tussen die

ouderdomme van ses en 12 maande, in vetdruk in hoofletters wat minstens 3 mm hoog is;

(c) behoudens subregulasie (2)(a), 'n verklaring bevat dat waar verdere gaarmaak nie vereis word nie, die graan met voorafgekookte, afgekoelde water berei moet word.

(3) Aanvullende voedsel en vloeibare melk, poeiermelk, gemodifiseerde poeiermelk of poeierdrankies wat bemark of op 'n ander manier voorgestel word as geskik vir babas of jong kinders mag nie:-

(a) name, frases of uitdrukkings soos "moederlik", "menslik", "borsmelkvervanging" of enige afgeleide vorm daarvan of enige soortgelyke uitdrukking wat 'n sterk ooreenkoms tussen die produk en borsmelk suggereer, gebruik nie;

(b) uitdrukkings of name, wat vertolk kan word as sou dit die produk identifiseer as geskik vir die voed van babas, gebruik nie, soos die uitdrukkings "eerste groeifase", "eerste voedsel", "van die begin af", "die beste wegspring in die lewe" of soortgelyke terme of uitdrukkings.

SPESIFIEKE ETIKETTERINGS- EN ANDER VEREISTES VIR NAGEMAAKTE SUIWELPRODUKTE, VERSOETE GEKONDENSEERDE MELK EN BOKMELK

5(1) Houers van nagemaakte suiwelprodukte, versoete gekondenseerde melk en bokmelk moet duidelik gemerk word met die woorde **"NIE VIR VOED VAN BABAS NIE"**, welke woorde:-

(a) op die voorste etiket of hoofpaneel;

(b) in die Engelse taal; en

(c) in hoofletters moet wees wat minstens 3 mm hoog is.

SPESIFIEKE ETIKETTERINGS- EN ANDER VEREISTES VIR BABABOTTELS, VOEDINGSKOPPIES EN KUNSSPENE

6(1) 'n Vervaardiger of verspreider mag nie 'n bababottel, voedingskoppie of kunsspeen te koop aanbied of verkoop indien 'n etiket, pakket of houer nie by sodanige produk gevoeg is nie.

(2) Die etiket, pakket of houer van 'n bababottel, voedingskoppie of kunsspeen gemeld in subregulasie 6(1) moet:-

(a) 'n verklaring insluit oor die voortreflikheid van borsmelk vir die voeding van babas-

(i) in hoofletters wat minstens 3 mm hoog is; en

(ii) op die etiket waarvan die hoofpaneel groter of gelyk moet wees aan 12 000 mm^2; met dien verstande dat waar die hoofpaneel kleiner as 12 000 mm^2 is, die lettergrootte proporsioneel verminder kan word;

(b) instruksies insluit vir die behoorlike skoonmaak en sterilisering van bababottels, voedingskoppies en kunsspene in die Engelse taal: met dien verstande dat die inligting in minstens vyf ander amptelike tale op 'n multibladsykleefetiket of voubiljet herhaal word;

(c) 'n waarskuwing insluit oor die potensiële gesondheidsgevare van die gebruik van 'n bababottel of voedingskoppie, indien die bottel, koppie of kunsspeen nie behoorlik gesteriliseer is nie, in Engels en een ander amptelike taal;

(d) dié waarskuwing insluit: "As jy jou baba borsvoed, kan die gebruik van 'n bababottel en kunsspeen inmeng met die baba se natuurlike manier van soog aan die bors"; en

(e) die naam en adres insluit van die vervaardiger en verspreider van die produk of van die plaaslike agént.

(3) Die etiket, pakket of houer van 'n bababottel, voedingskoppie of kunsspeen mag nie enige ander grafiese voorstelling toon nie as:
(a) ter illustrering van wassing en sterilisering;
(b) die logo van die vervaardiger of verspreider.

(4) In die geval van 'n ingevoerde bababottel, voedingskoppie en/of kunsspeen kan die etiketteringsvereistes in regulasie 6 genoem op 'n kleefplakker op die agterkant van die pakket of 'n omloopetiket of die verpakkingsmateriaal gevoeg word.

(5) Die etiket, pakket of houer van 'n bababottel, voedingskoppie of kunsspeen mag nie enige woorde of beelde toon nie wat die indruk wek dat so 'n bababottel, voedingskoppie of

kunsspeen vervaardig is ooreenkomstig die aanbevelings van 'n geneeskundige of tandheelkundige praktisyn of 'n ander persoon wat kragtens die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), of die Wet op Verwante Gesondheidsberoepe, 1982 (Wet No. 63 van 1982), of enige ander gesondheidsberoepswetgewing geregistreer is.

(6) Enige handeling, aksie of voordele met betrekking tot voeding met, of suig aan, 'n bababottel of kunsspeen, of die fisiese eienskappe van sodanige bababottel of kunsspeen, mag nie in enige vorm of op enige wyse met die handeling, aksie of voordele van soog aan 'n menslike bors of die fisiese eienskappe van sodanige menslike bors vergelyk word nie.

(7) 'n Vervaardiger of verspreider mag nie enige bababottel invoer, te koop aanbied of verkoop indien dit nie aan die "*Regulasies wat die vervaardiging, invoer, uitvoer en verkoop van polikarbonaat-bababottels wat bisfenol A bevat, verbied*, R. 879 van 21 Oktober 2011, voldoen nie.

PROMOSIE-VERWANTE AANGELEENTHEDE

VERKOOP EN PROMOSIE

7(1) Geen persoon mag 'n promosiepraktyk of -plan onderneem of daaraan deelneem nie, wat adverteer ten opigte van:-

(a) 'n formule vir babas;

(b) 'n opvolgformule;

(c) 'n formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande;

(d) vloeibare melk, poeiermelk, gemodifiseerde poeiermelk of poeierdrankies wat bemark of op 'n ander manier voorgestel word as geskik vir babas of jong kinders;

(e) bababottels, kunsspene en voedingskoppies met tuite, strooitjies of kunsspene; en

(f) enige ander produkte wat die Minister by kennisgewing in die *Staatskoerant* kan afkondig.

(2) Promosiepraktyke of -planne ten opsigte van die produkte gemeld in subregulasie 7(1) sluit in, maar is nie beperk nie tot-

(a) verkoopsplanne soos kortings, voordele in goedere, terugbetalings of enige ander geldelike voordele, spesiale uitstallings om verkope te bevorder, advertensies oor die beskikbaarheid van die produk by 'n spesifieke kleinhandelafsetpunt en die prys daarvan, koppelverkope, afslag in enige vorm, kompetisies met pryse, of enige ander aansporings en geskenke;

(b) regstreekse of onregstreekse kontak tussen maatskappypersoneel en lede van die publiek ter bevordering van, of vir die doel van die promosie van, die besigheid van die maatskappy met betrekking tot die produkte in subregulasie 7(1) genoem; en vir die doeleindes van hierdie regulasies sluit **"onregstreekse kontak"** met name in internetwebtuistes wat as gashere optree vir 'n Suid-Afrikaanse entiteit of 'n entiteit wat in Suid-Afrika sake doen, televisie en radio, telefoon- of internethulplyne en moeder-en-babaklubs, maar sluit kontak uit met betrekking tot produkgehalteklagte en nadelige gebeure;

(c) die verspreiding van enige inligting of opvoedkundige materiaal oor die voeding of voed van babas en jong kinders, behalwe ooreenkomstig subregulasie 7(4);

(d) promosie-items soos skryfbehoeftes, T-hemde of ander kledingstukke, hoofbedekkings, huishoudelike gebruiksvoorwerpe en huishoudelike linne wat die produkte noem wat in subregulasie 7(1) van hierdie regulasies vervat is;

(e) die handelsnaam van 'n produk genoem in subregulasie 7(1) wanneer sodanige produk by 'n geleenthéid gehou vir die algemene publiek gebruik word;

(f) advertensies in skriftelike publikasies, op televisie, radio of film of in die elektroniese media, e-pos-, video- en telefoonadvertensies, uitstallings en tentoonstellings, asook buite-advertensies soos reklameborde, plakkate, uithangborde en elektroniese uithangborde;

(g) die skenk of verspreiding van enige toerusting, ook die bou, opknapping of instandhouding van 'n gesondheidsinstelling wat die maatskappynaam of -logo dra, wat spesifiek gerig is op die verskaffing van sorg aan babas, jong kinders, swanger vroue of die moeders van babas en jong kinders, sonder die voorafgoedkeuring van die Direkteur-generaal of 'n persoon wat namens hom/haar optree;

(h) navorsingstoelaes of enige ander finansiële bystand met betrekking tot die voeding van babas of jong kinders wat aan gesondheidsorgpersoneel verskaf word wat werksaam is in 'n gesondheidsinstelling of aan gesondheidsorgpersoneel wat aan 'n gesondheidsinstelling gekoppel is, tensy goedkeuring vooraf verkry is by die Direkteur-generaal of 'n persoon wat namens hom/haar optree;

(i) finansiële bydraes of borgskappe aan gesondheidsorgpersoneel wat werksaam is op die terrein van die voeding van babas en jong kinders;

(j) borgskappe van vergaderings toegespits op gesondheidsorgpersoneel, waar die voeding van babas en jong kinders alleenlik of deels die onderwerp van bespreking is, tensy die bydrae of borgskap gemaak is in 'n poel van fondse vir kongresorganiseerders, met dien verstande dat 'n billike en deursigtige proses gevolg word met die verkiesing en borg van die afgevaardigdes wat sodanige geleenthede bywoon. Geborgde afgevaardigdes moet onder geen verpligting staan teenoor die betrokke maatskappy nie.

(3) Geen persoon mag 'n aangewese produk, ook aanvullende voedsel, deur gesondheidsorgpersoneel of gesondheidsinstellings verkoop, bevorder of adverteer nie. Verbode promosiepraktyke sluit in, maar is nie beperk nie tot:-

(a) die gee of aanbied, regstreeks of onregstreeks, van enige geskenk, in kontant of in goedere, bydrae of voordeel aan gesondheidsorgpersoneel, hetsy gerig op sodanige werker se persoonlike gebruik al dan nie; en

(b) ondanks die bepalings van subregulasie 7(3) kan 'n institusionele apteek in 'n private gesondheidsinstelling 'n aangewese produk verkoop, maar mag hy sodanige produk nie adverteer of by die bevordering daarvan betrokke wees nie.

(4) Geen vervaardiger, verspreider, kleinhandelaar, invoerder of persoon wat namens die voornoemdes optree mag enige opvoedkundige materiaal oor die voeding van babas en jong kinders produseer of versprei wat enige produkte in subregulasie 7(1) genoem, bevorder nie.

(5) Geen vervaardiger, verspreider, kleinhandelaar, invoerder of persoon wat namens die voornoemdes optree mag enige opvoedkundige inligting betreffende die voeding van babas en jong kinders produseer,versprei en aanbied nie.

VERBOD OP DIE BEVORDERING EN/OF VERSPREIDING VAN GESKENKPAKKE

8 Geen gesondheidsinstelling mag geskenkpakke bevorder en/of versprei wat enige aangewese produkte, individueel of in kombinasie met ander goedere, bevat of meld nie.

VERBOD OP DIE VERSPREIDING VAN GRATIS OF LAEKOSTE- AANGEWESE PRODUKTE OF MONSTERS

9(1) Geen vervaardiger of verspreider mag voorrade of monsters van aangewese produkte gratis of teen lae koste aan gesondheidsorgpersoneel of 'n ander persoon of aan 'n gesondheidsinstelling, behoudens subregulasie 9(2) en (3), versprei nie.

(2) Ondanks die bepalings van subregulasie 9 (1) kan 'n persoon, vervaardiger of verspreider aangewese produkte gratis of teen 'n lae koste aan hospiese, kinderhuise of plekke van veiligheid versprei, met dien verstande dat-

(a) sodanige aangewese produkte aan al die toepaslike bepalings in die Codex-standaarde en in hierdie regulasies voldoen; en

(b) die voorsiening van die produkte gewaarborg word so lank as wat die betrokke babas dit nodig het; en

(c) die aangewese produkte nie herverkoop word nie.

(3) Geen persoon in 'n gesondheidsinstelling mag voorrade of monsters van aangewese produkte gratis of teen 'n lae koste aanvaar of aan 'n ander persoon gee nie.

VERBOD OP DIE UITSTAL VAN 'N AANGEWESE PRODUK OF OPVOEDKUNDIGE MATERIAAL

10 Geen persoon binne 'n gesondheidsinstelling in 'n eenheid wat babas of jong kinders, swanger moeders of moeders van babas en jong kinders versorg, mag die volgende uitstal of laat uitstal of toelaat dat dit uitgestal word nie:—

(a) aangewese produkte;

(b) enige opvoedkundige materiaal wat die handelsnaam of 'n beskrywing van 'n aangewese produk bevat; of

(c) die naam en/of logo van die vervaardigings- of verspreidingsmaatskappy van aangewese produkte, wanneer die materiaal boodskappe insluit oor voedingspraktyke vir of die voeding van babas en jong kinders.

MATERIAAL GERIG OP GESONDHEIDSORGVERSKAFFERS

11 'n Persoon, vervaardiger of verspreider kan tegnies wetenskaplike materiaal voorsien aan 'n gesondheidsorgverskaffer, met dien verstande dat–

(a) sodanige inligting of materiaal beperk word tot huidige wetenskaplike en feitelike aangeleenthede, en in ooreenstemming is met die toepaslike regulasies kragtens die Wet;

(b) die materiaal geen gesondheids-, medisinale of voedingsaansprake bevat nie, hetsy in teks- of beeldformaat;

(c) dit slegs betrekking het op die tegniese aspekte en metodes vir die gebruik van die aangewese produk; en

(d) dit enige promosie van die aangewese produk op enige wyse uitsluit.

INDIENING VAN KLAGTE

12 Enige persoon, groep, liggaam of instelling kan 'n skriftelike klag gesteun deur voldoende bewyse by die Direkteur-generaal indien.

INSPEKSIE

13 Inspekteurs deur die Direkteur-generaal aangestel ingevolge artikel 10 van die Wet is verantwoordelik vir die toepassing van hierdie regulasies.

MISDRYWE

14 Enige persoon wat hierdie regulasies oortree is skuldig aan 'n misdryf en is by skuldigbevinding strafbaar met die boetes soos voorgeskryf by die Wet.

HERROEPING

15 Goewermentskennisgewing No. R. 1130 van 8 Junie 1984, soos gewysig by Goewermentskennisgewings Nos. R. 2542 van 15 November 1985, R. 1256 van 15 Julie 1994 en R. 1210 van 17 Desember 2010, word hierby herroep.

INWERKINGTREDING

16(1) Regulasies 2, 3, 4, 5 en 6 tree in werking **12 maande** vanaf die datum van publikasie van hierdie regulasies.

(2) Regulasies 7, 8 en 11 tree in werking **ses maande** vanaf die datum van publikasie van hierdie regulasies.

(3) Regulasie 9 en 10 tree in werking **op die datum** van publikasie van hierdie regulasies.

OORGANGSMAATREËLS

17 Vervaardigers, verspreiders en kleinhandelaars moet **binne 18 maande** vanaf die datum van publikasie van hierdie regulasies al die produkte wat nie hieraan voldoen nie van die mark verwyder.

MINISTER VAN GESONDHEID

DATUM: 3/12/2012

AANHANGSEL A

Minimum verpligte voedingsinligting vir formule vir babas, opvolgformule en formule vir babas of opvolgformule vir die besondere voedinghantering van spesifieke mediese toestande

Tipiese voedingsinligting:

Gekwantifiseerde enkelporsiegrootte uitgedruk in gram of milliliter, wat ook al gepas is

	Per 100 g poeier soos verkoop	Per 100 ml Hersaamgestel Gereed vir gebruik	Per 100 kJ Gereed vir gebruik
Energie (kJ)			
Totale proteïen (g)			
Bygevoegde individuele aminosure (mg)			
Totale koolhidrate (g)			
waarvan laktose (g) en/of glukose (g)			
Totale vet (g)			
Linoleïensuur (mg)			
Linoleensuur (mg)			
Dokosaheksaënoësuur*			
Eikosapentanoësuur*			
Aragidoonsuur*			
Totale dieetvesel (g)			
Natrium (mg)			
Vitamiene in alfabetiese orde (aangedui in geskikte meeteenheid)			
Minerale en spoorelemente in alfabetiese orde (aangedui in geskikte meeteenheid)			
Nukleotiede*			
L(+) melksuur-produserende bakterieë*			

* Waar toepaslik

AANHANGSEL B

Vereiste voedingsinligting

Formaat vir minimum verpligte voedingsinligting van aanvullende voedsel en vloeibare melk, poeiermelk, gemodifiseerde poeiermelk en poeierdrankies

Tipiese voedingsinligting

Gekwantifiseerde enkelporsiegrootte uitgedruk in gram of milliliter, wat ook al gepas is

	Per 100 g/ml	Per enkelporsie	Per % VVW-porsie
Energie (kJ)			
Proteïen			
Glisemiese koolhidraat of koolhidraat (g) Waarvan totale suiker (g)			
Totale vet (g)			
Versadigde vet (g)			
**			
**			
**			
***			
Totale dieetvesel# (g)			
Natrium (mg)			
Vitamiene in alfabetiese orde (in geskikte meeteenheid)			
Minerale of spoorelemente in alfabetiese orde (in geskikte meeteenheid)			
▪ Enige ander voedingstof of voedselkomponent wat ooreenkomstig hierdie regulasies verklaar moet word ▪	Aangedui in gram (g), milligram (mg), mikrogram (mkg/µg), of geskikte meeteenheid)	Aangedui in gram (g), milligram (mg) mikrogram (mkg/µg), of geskikte meeteenheid)	

* Voedingstofverwysingswaardes (VVW's) vir individue 6-36 maande (kyk Aanhangsel C) uitgedruk per enkelporsie.

** Plek vir subgroepvoedingstof, soos monoönversadigde vet, poli-onversadigde vet, omega-3-vetsure, ens.

*** Plek om cholesterol in te voeg wanneer cholesterolinligting verstrek word.

Dui ontledingsmetode aan wat gebruik is om dieetvesel te bepaal.

Alle voedingsinligting moet gegee word ten opsigte van die werklike voedingsmiddel in die pakket of houer.

AANHANGSEL C

Voedingstofverwysingswaardes (VVW's) vir babas en jong kinders

		Babas	Jong kinders
		6-12 maande	**Individue 13-36 maande**
Energie	kJ	440/kg liggaamsmassa	5 600
Proteïen	g	2,0/kg liggaamsmassa	23
Vitamien A-aktiwiteit			
(1) Vitamien A	IU	1 330	1330
(2) Retinolekwivalent	µg RE[2]	500	300
Vitamien D	IU	400	400
	µg	5	5
Vitamien E-aktiwiteit	IU	6	7,5
	mg α TE[4]	5	6
Askorbiensuur	mg	50	50
Biotien	µg	50	65
Foliensuur	µg	80	150
Pantoteensuur	mg	1,8	2,0
Nikotiensuur	mg	4,0	6,0
Riboflavien (Vitamien B2)	mg	0,4	0,5
Tiamien (Vitamien B1)	mg	0,3	0,5
Piridoksien (Vitamien B6)	mg	0,3	0,5
Sianokobalamien (Vitamien B12)	µg	0,5	0,9
Vitamien K	µg	2,5	30
Kalsium	mg	270	500
Fosfor	mg	275	460
Jodium	µg	130	90
Yster	mg	11	7,0
Magnesium	mg	75	80
Koper	mg	1,0	1,2
Sink	mg	3,0	3,0
Kalium	mg	1 275	1 650
Natrium	mg	750	975
Chloried	mg	1 200	1 500
Mangaan	mg	1,0	1,5
Fluoried	mg	0,5	0,7
Chroom	mg	5,5	5,5
Seleen	µg	20	20
Molibdeen	mg	0,08	0,1
Cholien		150	200

AANHANGSEL D

GESONDHEIDSBOODSKAPPE

1. Formule vir babas verhoog die risiko van allergieë vir die baba
2. Formule vir babas verhoog die risiko van oorinfeksies vir die baba
3. Formule vir babas verhoog die risiko van akute respiratoriese siekte vir die baba
4. Formule vir babas verhoog die risiko van gastroïntestinale infeksies vir die baba

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