GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 184 **2 March 2012**

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

REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN

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

Interested persons are invited to submit any substantiated comments on the proposed amendment, or any representations they may wish to make in regards thereto, to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for the attention of the Directorate: Nutrition), within two months of the date of publication of this notice.

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 of a designated product" 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;

"child-care institutions" means the whole or part of a public or private establishment, institution, facility, agency, building or place caring for babies and young children registered in terms of the Children's Act, 2005 (Act 38 of 2005), as well as those institutions that although they are required to be registered in terms of the Act are, however, not as yet registered as such. These institutions may be registered either on a part-time or full-time basis, or organised for either profit or non-profit;

"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;

"Advisory Committee" means the National Advisory Committee on Infant Feeding as established by the Minister of Health in terms of the National Health Act, 2004 (Act 61 of 2004);

"community pharmacy" means a pharmacy wherein or from which some or all of the services as prescribed in the Regulations Relating to the Practice of Pharmacy , 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;

"complementary food" means any foodstuff, whether in solid or semi-solid form, given to an infant after the age of six months as part of the transitional process during which an infant learns to eat food appropriate for his or her developmental stage while continuing to breastfeed or be fed with an appropriate formula, but is not limited to, bottled or canned foodstuffs for infants and young children and processed cereal-based foodstuffs for infants and young children;

"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 and young children with specific medical conditions;
(d) complementary foods;
(e) any other liquid or milk-like product marketed or otherwise represented as suitable for feeding an infant or young child;

(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 that the Minister may so designate by notice published in the Gazette.

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

"Director-General" means the 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;

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

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

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

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

"**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 worker, lay counsellors, a trainer or a voluntary unpaid worker;

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

"**infant**" means a person within the age bracket of 0-12 months;

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

"**infant or follow-up formula for special dietary management for infants and young children 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 any promotion, distribution, sale, or advertisement technique which is intended to promote the sale or encourage the use of a designated product and brought to the attention of the public in any manner;

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

"**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);

"mixed breastfeeding or non-exclusive breastfeeding" means feeding breast milk as well as other milks (including commercial formula or home-prepared milk), foods or liquids.

"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 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;

"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 directly or indirectly encouraging or enticing a person or group of persons, in whatever form, whether by chance or skill to purchase or use a designated product, and includes but is not limited to, advertising, point-of-sale advertising, the giving of samples, special sales, free supplies, donations, gifts, whether related or unrelated to purchases of designated products, free utensils or other articles, prizes, carrier bags with pack-shots or product logos, prizes or special displays at retail outlets, discount coupons, premiums, loss-leaders, tie-in sales, rebates and other give-aways;

"proprietary product" means a designated product which is explicitly associated with a particular manufacturer or distributor;

"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 sealed again.

"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;

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

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

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

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

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

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

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

"young child" 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;

(b) infant formula, follow-up formula, infant or follow-up formula for special dietary management for specific medical conditions, complementary food for infants or young children and any other liquid or milk-like product marketed or otherwise represented as suitable for feeding an infant and young child that is not manufactured, labelled and packed, appropriately according to the stipulations of these regulations and the Codex Standard;

(c) infant formula, follow-up formula, or infant or follow-up formula for special dietary management for specific medical conditions, or complementary food for infants or young children which do not comply with these regulations, other applicable regulations published under the Act and relevant Codex standards in all respects.

(d) infant formula, follow-up formula, or infant or follow-up formula for special dietary management for specific medical conditions, complementary food for infants or young children and any other liquid or milk-like product marketed or otherwise represented as suitable for feeding an infant and young child which is not packed in a hermetically sealed container and which cannot be resealed or closed tightly during usage.

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

(a) not show photographs, illustrations, drawings or other 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 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 for complementary food for infants or young children;

(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) the ingredients or composition 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 product brand or logo shall be permitted, provided it does not contain a picture of an infant, young child or other humanized figure. Logos indicating endorsement by specific religious certifying organisations shall be excluded from the prohibition in sub-regulation 2(a).

(4) (a) Notwithstanding the provisions of Regulations Relating to Food Labelling—

(i) no medicinal, health or nutritional claims shall be permitted with regards to any nutrient or substance that is required in terms of these regulations as part of the essential composition of an infant formula, follow-up formula or infant or follow-up formula related to any ingredient, additive or any food or substance, present naturally or added to an infant formula, follow-up formula or infant formula and follow up formula for special dietary management of infants and young children with specific medical conditions shall be permitted.

(ii) no health, medicinal and nutritional claims shall be permitted in any manner for any designated product.

(iii) 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), 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 any beverage, liquid or other product which is marketed or otherwise represented as suitable for feeding infants older than 6 month or young children.

(c) Where a product, referred to in sub-regulation (4) (b) above is naturally "high in" or "a source of" a particular nutrient, without the addition thereof, the relevant information may be added to the minimum nutritional information table as per Annexure B; Provided the information regarding the nutrient content shall not be mentioned anywhere else on the label except in the nutritional information table, as stipulated.

(d) 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 fully hydrogenated or partially hydrogenated fat as an ingredient or any compound ingredient that contains fully hydrogenated or partially hydrogenated fat.

(6) The nutritional value of a foodstuff for the purpose of nutritional information on a label shall be determined according to the methods of analysis and sampling as stipulated in Codex Standards and other relevant regulations 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 does 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 hygiene 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 the Codex Standard.

(10) Any foodstuff for infants or young children shall be prepared under good manufacturing and good hygiene practices 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 and address 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 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, R692 of 1997.

(17) No foodstuff intended for infants and young children may contain any nutritive and non-nutritive sweeteners.

(18) No statement of claim shall be made on the label or in any other manner, which conveys a message that a specific company name or logo or brand name 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 infant 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, under Government Notice No. R.146 on 1 March 2010.

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

3(1) A manufacturer or distributor shall not import, offer for sale or sell any infant, follow-up formula or infant or follow-up formula for special dietary management for infants and young children with specific medical conditions if the container or label affixed to such products –

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

(b) does not have, in the English language and in bold letters at least 3mm in height, the following clear, conspicuous and easily readable messages which shall be at the top of the front main panel of the label a statement that the container does not contain breast milk and a statement of the superiority of breast milk: "Breast milk is the best food for babies" provided that in the case of infant and follow-up formula for special dietary

management for infants and young children with specific medical condition, for which Breast Milk is contraindicated, based on medical grounds, the aforementioned message need not appear on the label.

(c) does not have, in the English language and in bold letters at least 2mm in height, the following clear, conspicuous and easily readable messages which shall be at the bottom of the front main panel of the label that the product shall be used only on the advice of a health professional as to the need for its use and the proper method of use and the health hazards of the unnecessary and improper use including information that powdered infant formula is not a sterile product and may contain pathogenic microorganisms and must be prepared and used appropriately: "This product is not sterile and may contain harmful microorganisms and must be prepared and used appropriately";

(i) The above messages specified in (b) and (c) including the requirements for specific letter sizes, must be repeated on the fix-o-form or package insert in at least five other official languages as specified in sub-regulation 3(2)(a).

(ii) Subject to the provisions of regulation 3(1), a prominent statement for which medical condition and diseases the product is intended for shall appear under the name or description of the product and age range on the front main panel of the label.

(d) does not 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 –

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

(ii) indicate that cup feeding is safer than bottle feeding;

(iii) indicate that safe drinkable, previously boiled water should be used;

(iv) indicate that only the enclosed scoop should be used;

(v) indicate the feeding chart and direction for use and instruction for discarding left over feed;

(vi) indicate that only one feed should be prepared at a time;

(vii) indicate proper storage and keeping before and after container has been opened;

(viii) indicate that the infant must be held while feeding;

(ix) Indicate that the package insert provide instructions for the proper preparation and use in other languages.

(x) which shall be in the English language; Provided that the requirements of paragraph (i) to (viii) shall be repeated in at least five other official languages of as specified in sub-regulation 3(2)(a) on the fix-o-form or package insert.

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

(f) The label of liquid ready to use formula is exempted from the requirements in regulation 3(1)(d)(iii)(iv)(vi) and the message in regulation 3(1)(c): "This product may contain harmful microorganisms and must be prepared and used appropriately".

(2) 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 and young children with specific medical conditions if—

(a) it does not include an fix-o-form or information leaflet inserted between the label or container or the re-sealable container that includes the information referred to in regulation 3(1)(b), 3(1)(c) and 3(1)(d) 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.

(b) All labels of infant formula for special dietary management for infants with specific medical conditions shall in addition to the requirements of paragraph (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".

(3) Infant formula and follow-up formula shall be labelled in such a way that it enables consumers to make a clear distinction between such products so as to avoid any risk of confusion between infant formula and follow-up formula.

(4) Containers 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.

(5) All labels of infant formula, follow-up formula and infant and follow-up formula for special dietary management for infants and young children 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.

(6) If soy protein is the only source of protein, the product shall be labelled "Infant Formula or Follow-up Formula Based on Soy Protein".

(7) 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 cows milk proteins.

(8) All ingredients and additives used in infant formula, follow-up formula, or infant or follow-up formula for special dietary management for infants and young children 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.

GENERAL LABELLING AND OTHER REQUIREMENTS FOR COMPLEMENTARY FOOD AND ANY OTHER LIQUID OR MILK-LIKE PRODUCT MARKETED OR OTHERWISE REPRESENTED AS SUITABLE FOR FEEDING AN INFANT OR YOUNG CHILD

4(1) A manufacturer or distributor shall not import, offer for sale or sell complementary food and any other liquid or milk-like product marketed or otherwise represented as suitable for feeding an infant or young child if the container or label affixed to such product does not, in bold letters and in clear, conspicuous and easily readable language -

(a) provide instructions for proper preparation where applicable, as well as the use and appropriate serving sizes for different ages in the English language and at least 1 (one) other official language;

(b) provide instructions for proper storage before and after the container has been opened where appropriate:

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

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

(e) 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.

(f) Use expressions or names that aim to identify the product as suitable to feed infants, such as the expression "baby", "first growth" or similar ones.

(g) specify where label space permits, the following message, or other words relaying the same message shall be indicated on the label- "From 6 months onwards, together with breast milk complementary food can be prepared at home using local foods. Ask a health worker or health professional for advice".

(h) indicate the age range of the infants older than 6 months or young children for which the product is suitable, under the name or description of the product on the front main panel of the label in letters that are not less than 2mm in height for the smallest letters

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

(2) Notwithstanding the provisions of regulation 4(1), the label or container of a 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 and where the total protein provide protein quality of which the analysed amino acids of the foodstuff shall contain at least 100% of each of the amino acids as per the Reference amino acid pattern listed in Annexure 5 of the Regulations Governed the Advertising and Labelling of Foodstuffs, bear a statement to the effect that the cereal has to be prepared with previously boiled, cooled water.

(d) in the case of a cereal with a protein content less than 15% of the NRV for the particular age group the label 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, only in bold capital letters at least 3 mm in height.

(e) 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.

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

5(1) The labels of imitation dairy products shall be clearly marked with the following words "Not for infant feeding", or similar wording as required by provisions of the Agricultural Product Standards Act, 1990 (Act No. 119 of 1990) and

(2) The labels of sweetened condensed milk and goat's milk products shall be clearly marked with the following words "Not for infant feeding", or similar wording which shall be -

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

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

6(1) A manufacturer or distributor shall not import, 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 or teat and 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 and teats and feeding cups which shall be in 5 official languages, one of which shall be the English language;

(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 or teat and feeding cup shall not show any photograph, drawing or graphic representation of an infant or young child, or any photograph, drawing or graphic representation other than

(a) for illustrating cleaning and sterilisation; and

(b) the logo of the manufacturer or distributor.

(4) In the case of an imported feeding bottle and or teat, the labelling requirements referred to in regulation 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 and teat and 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, including advertisements about the availability of the product at a specific retail outlet and the price of the product in respect of—

(a) infant formula;
(b) follow-up formula;
(c) infant or follow-up formula for special dietary or medical purposes;
(d) feeding bottles, teats and feeding cups with spouts, straws or teats;
(e) any other products that the Minister may publish by notice in the Gazette.

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

(3) Notwithstanding the provisions of sub-regulation 7(2), 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) Promotional practices or devices in respect of the products listed in sub-regulation 7(1) include —

(a) sale devices such as rebates, benefits in kind, kickbacks or any other pecuniary advantages, special displays to promote sales, tie-in sales, discounts in any form, competitions with prizes, or any other incentives and gifts;

(b) direct or indirect contact between company personnel and members of the public in furtherance of or for the purpose of promoting the business of the company with regard to the products referred to in sub-regulation 7(1) and for purposes of these regulations "indirect contact" specifically includes the internet, television and radio, telephone or internet help lines and mother and baby clubs;

(c) the distribution of any information, educational material or other material on the nutrition or feeding of infants and young children, except in accordance with the provisions in regulation 13 and 14;

(d) electronic communications including internet websites and email except in accordance with regulation 13 and 14;

(e) promotional items such as stationery, T-shirts or other items of clothing, headgear, household utensils, and household linens that refer to products contained in regulation 7(1) of these regulations;

(f) the brand name of a product referred to in sub-regulation 7(1) when used at any event for the general public ;

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

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

(5) A promotional practice or material in respect of a complementary food and any other liquid or milk-like product marketed or otherwise represented as suitable for feeding an infant or young child shall -

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

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

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

(d) not create any association with any products specified in sub-regulation 7(1);

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

(7) Personnel employed in marketing designated products shall not, as part of their job description, perform training or any educational functions in relation to pregnant women, mothers of infants and young children, breastfeeding or any other matter relating to nutrition of young children.

PROHIBITION OF THE PROMOTION AND/OR DISTRIBUTION OF GIFT PACKS

8 No hospital or 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 (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.

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

PROHIBITION OF THE DISPLAY OF A DESIGNATED PRODUCT OR MATERIAL

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

(a) designated products; or

(b) any material which bears the brand name or any description of a designated product other than that specified in regulation 13 and 14.

(c) 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.

PROHIBITION OF DONATION OR DISTRIBUTION OF EQUIPMENT

11(1) No manufacturer or distributor of designated products shall directly or indirectly donate, or pay for or distribute or endorse 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 Minister of Health.

PROVISION OF SPONSORSHIPS PROHIBITED

12(1) No manufacturer or distributor excluding retailers of designated products shall –

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

(b) make any financial contribution-

(i) or sponsorship to health care personnel for attending congresses, workshops, seminars; or

(ii) any health related professional meeting where infant or young child nutrition is the sole or partial topic of discussion, unless contribution or sponsorship is made available into a pool of funds for congress organisers with no conditions;

(aa) corporate sponsorships may be acknowledged.

(bb) brand names of designated products are not used; and

(cc) prior to the event, the criteria for sponsorship shall be agreed upon between the organisers, the manufacturer or distributor.

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

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

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

General

13(1) No material referred to in regulation 13 and 14 shall be used to promote, or be written in such a way as to promote, the use or sale of designated products.

(2) No company or distributor or person on behalf of any company or distributor shall publish or cause or permit to be published or distribute any informational or educational material on infant and young child nutrition and feeding, unless the Advisory Committee has recommended approval by the Director-General of the material and its use, prior to publication.

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

(4) (a) At least within ninety days after receiving an application in terms of this sub-regulation, the Director-General shall examine the material concerned and may—

(i) approve it, either absolutely or subject to conditions; or
(ii) refuse to approve it; and
(iii) shall notify the applicant in writing of his or her decision and the reasons for refusing to approve the material,

(b) Where the Director-General has refused to approve any informational and educational material in terms of sub-regulation 13(1), the applicant may at any time resubmit the material to the Director-General, having made such alterations to the materials as considered necessary to secure the Director-General's approval.

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

14(1) Notwithstanding the provisions of regulation 13, any information, educational material or other material, excluding scientific research material on infant and young children nutrition and feeding, whether in written or audio-visual format, which is made available by any person, shall include clear information on all the following points:

(i) the superiority of exclusive breastfeeding for six months followed by sustained breastfeeding for two years and beyond;
(ii) list three (3) health risks associated with mixed feeding; increase risk of diarrhoea, respiratory illnesses and allergies;
(iii) how to ensure an adequate milk supply by feeding on demand; and
(iv) that working mothers can breastfeed successfully.

(2) Notwithstanding the provisions of sub-regulation 13 any information, educational material or other material about the use of any infant formula, follow-up formula or infant formula or follow-up formula for special dietary management for infants and young children with specific medical conditions whether written, audio or visual made available by any person shall clearly and unambiguously explain the following—

(a) the proper preparation and use of any infant formula, follow-up formula, or infant formula or follow-up formula for special dietary management for infants and young children with specific medical conditions, including the cleaning and sterilisation of feeding utensils;

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

(i) how many containers infant formula will be needed per month for the first year of life;

(ii) the need for a good supply of safe clean water;

(iii) the equipment needed to sterilise the feeding utensils;

(iv) the need for an adequate supply of fuel for sterilisation and preparation of feeds or other sterilisation solutions; and

(v) the method and process of formula-mixing;

(aa) the health hazards of any infant formula, follow-up formula or infant formula and follow-up formula for special dietary management for infants and young children with special medical conditions and the health hazards of improper preparation and use;

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

(cc) that powdered infant formula may contain pathogenic microorganisms;

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

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

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

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

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

(d) a clear and unambiguous statement that "from 6 months of age, infants can also be fed with appropriate home prepared foods".

(4) Information, educational materials or other materials referred to in sub-regulations 14(1), (2) and (3) shall—

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

(b) contain only correct and current information;

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

(d) not make any reference to any proprietary product or contain the name or logo of any manufacturer or distributor of a designated product except the company name who developed, printed and/or sponsored the educational or informational material;

(e) indicate the date of publication and printing.

(5) Donations of informational or educational material relating to infant and young child nutrition and feeding in accordance to these regulations should be distributed only in the health establishment and only at the request and with the prior written approval of the head of the provincial department of health concerned.

(6) The statements and explanations in the information, educational material or other material referred to in sub-regulations 14(1), (2) and (3) that are written, shall be—

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

(b) clear and conspicuous.

Material directed at health care providers

15 A person, manufacturer or distributor may provide informational or educational material or any other material about a designated product to a health care provider, provided that—

(1) such information or material is restricted to current scientific and factual matters; and may not selectively use scientific research or facts, that misleads by omission or the emphasis of information;

(2) that material bears no health 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 along with the information specified in regulation 14 as appropriate;

(4) it excludes any promotion of the designated product in any manner.

Research article

16 Research articles are exempted from the requirements of sub-regulation 13(2) and 14(2), (3) and (4) provided that the funder of the research is disclosed in the article and it excludes promotion of any designated product in any manner.

HEALTH CARE PERSONNEL

17(1) Heads of health establishments, national, provincial and local health authorities shall take measures to promote, support and protect breastfeeding, and shall give information and advice to health care personnel regarding their responsibilities, in particular, ensuring that they are familiar with all of the information specified in these regulations.

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

(3) Health care personnel shall report in writing to the head of his or her workplace, regarding any contraventions of the provisions of these regulations.

RESEARCH INVOLVING THE USE OF DESIGNATED PRODUCTS

18(1) Research involving the use of designated products in human subjects shall be subject to written approval of the relevant Provincial and National Research Units.

(2) The research should be in accordance with the relevant Department of Health policies and shall be subject to these and other regulations where applicable.

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

LODGING OF COMPLAINTS

19. Any person, group, body or institution may submit a written complaint supported by adequate evidence to the National Directorate: Nutrition.

INSPECTION

20(1) The Director-General may authorize such persons as s/he sees fit having the prescribed qualifications to be inspectors for purposes of monitoring compliance with the provisions of these regulations within such local limits as s/he may assign to them respectively;

(2) Inspections shall be conducted in accordance with the provisions of the Regulations Relating to the Powers and Duties of Inspectors and Analysts Conducting Inspections and Analyses on Foodstuffs and at Food Premises passed in terms the Foodstuffs, Cosmetics and Disinfectant Act, 1972 under Government Notice No. R. 328 of 2007.

(3) No person who has any direct or indirect financial interest in any designated product shall be appointed as an inspector.

(4) The inspectors may work in close collaboration with Environmental Health Practitioners are authorised to monitor compliance by manufacturers, distributors and retailers with the provisions of these regulations by —

(a) conducting inspections unannounced, but at reasonable times, any premises where any designated product is imported, manufactured, sold, stocked, exhibited for sale, advertised or otherwise promoted; and

(b) conducting at least one inspection audit per cycle, in respect of manufacturers, suppliers, distributors and importers of designated products;

(c) sample, inspect records from the premises of manufacturers, suppliers or importers of designated products and issue an inspector's receipt for the quantity sampled. The audit inspectors may take photographs and document findings, in compliance with the Inspection Regulations, R328 of 2007.

(5) The taking of a sample shall be conducted in the presence;

(a) the person in charge, or

(b) any other adult person who is employed in those premises, as a witness if the person in charge is not present.

(6) An inspector shall, within 14 days after completing an inspection, compile an inspection report for submission to both the owner of the premises and a copy to the Directorate, which shall include any finding of a violation of these regulations and recommendations as to the action to be taken in respect of such contravention.

(7) If an inspector finds a manufacturer, supplier, distributor or importer in violation of the provisions of these regulations, she or he may at her own discretion serve the manufacturer, supplier, distributor or importer concerned with an Improvement Notice regarding the measures to be adopted in order to remedy the situation;

(8) The department may institute legal action against manufacturers, suppliers or importers who repeatedly fail to take remedial actions in the event of violations of any of the provisions of the Regulations Relating to Food for Infants and Young Children.

(9) Inspectors may in the course of the inspection, exercise such other powers so as to ensure compliance with the provisions of these regulations.

(10) Port Health officers will inspect imported products for compliance to these Regulations.

Appeals

7(1) Any one aggrieved or whose rights are adversely affected by the decision of an Inspector may, within a period of 60 days of the decision appealed against having come to the knowledge of that person, company or organisation appeal against such decision to the Minister for the purposes of the appeal concerned.

(2) Such an appeal must clearly state:

(a) against which decision such appeal is lodged; and

(b) the grounds on which such appeal is lodged.

(3) The Minister may consider and make a decision on the appeal or appoint members of an appeal committee that shall consist with no fewer than three persons: Provided that-

(a) the chairperson shall be appointed on account of his or her knowledge of the law;

(b) the skills of the other two members shall be relevant to the case concerned;

(c) no member shall have a direct or indirect interest in the affairs of the appellant or respondent.

(4) The appeal committee must after hearing the appeal, in writing advise the Minister to confirm, set aside or vary the decision of the Inspector.

Transitional measures

Foods for infants and young children placed on the market or labeled prior to the date of publication of these Regulation which do not comply with these regulations may be marketed until their expiry date, but not later than 24 months following the promulgation of these regulations

Products bearing trademarks or brand names in existence before January 2012 which do not comply with these regulations may continue to be marketed until 19 January 2014 after which time the provisions of these regulations shall apply.

Penalties

21(1) Any person convicted of an offence under these regulations shall be punished by penalties provided in the Act-

(a) on a first conviction, to a fine or to imprisonment for a period not exceeding six months or to both a fine and such imprisonment, including the recall of the offending product;

(b) on a second conviction, to a fine or to imprisonment for a period not exceeding twelve months or to both a fine and such imprisonment, including the recall of the offending product;

(a) on a third or subsequent conviction, to a fine or to imprisonment for a period not exceeding twenty-four months or to both a fine and such imprisonment, including the permanent removal or banning of the product from the market.

(d) A magistrate's court shall have jurisdiction to impose any penalty provided for by these regulations.

(2) Manufacturers and distributors of the product covered by these regulations shall be directly liable for any violation of the provisions of these regulations. Should the offense be committed by a juristic person, the Chairperson of the Board of Directors, the President, general manager, or partners and/or persons directly responsible therefore, shall be made accountable.

(3) Agents ore/and representatives of the manufactures or distributors of the designated products, who commit any violation of the provisions of these regulations, shall be jointly and severally liable with the said manufacturers and distributors.

REPEAL

22(1) 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

23(1) The provision of these regulations on labelling, composition, packaging and matters related to manufacturing, shall come into operation 12 months after the promulgation of these regulations; and

(2) The provisions of these regulations relating to matters on the promotion of the designated products, shall come into operation 6 months after the promulgation of these regulations.

MINISTER OF HEALTH

DATE: 9/2/2012

ANNEXURE A

Minimum Mandatory Nutritional Information for infant formula, follow-up formula, or infant formula or follow-up formula for special dietary management for infant and young children 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

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) of which total sugar (g)			
Total fat (g)			
of which Saturated fat (g)			
**			
**			
**			
***			
Total dietary fibre# (g)			
Sodium (mg)			
▪ Any other nutrient or food component to be declared in accordance with these Regulations. ▪ In alphabetical order, in the order: vitamins, minerals, others.	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 7 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 fiber.

ANNEXURE C

Nutrient Reference Values for Infants and Young Children

		Infants	**Young children**
		7months – 1,0 yr	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 risk of allergy
2. Infant formula increases an infant risk of asthma
3. Infant formula increases an infant risk of ear infections
4. Infant formula increases an infant risk to develop diabetes type 2 later in life.
5. Infant formula increases the risk of childhood obesity.
6. Infant formula increases the risk of chronic gastrointestinal diseases.
7. Infant formula increases an infant risk of developing cardiovascular disease
8. Infant formula increases the risk of childhood cancers.
9. Infant formula increases the risk of acute respiratory disease.
10. Infant formula increases the risk of gastrointestinal infections.
11. Infant formula increases an infant risk of hospitalization due to infectious disease
12. Infant formula increases an infant risk of mortality.