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THE FOOD (CONTROL OF QUALITY) (MARKETING OF BREAST-MILK SUBSTITUTES AND DESIGNATED PRODUCTS) REGULATIONS, 1994

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GOVERNMENT NOTICE NO. 256 published on 1/7/94

THE FOOD (CONTROL OF QUALITY) ACT, 1978
(NO. 10 OF 1978)

REGULATIONS

Made under Section 16 and 33

THE FOOD (CONTROL OF QUALITY) (MARKETING OF BREAST-MILK SUBSTITUTES AND DESIGNATED PRODUCTS) REGULATIONS 1994

PART I

PRELIMINARY

Citation and commencement

1. These regulations may be cited as the Food (Control of Quality) (Marketing of Breast-milk Substitutes and Designated Products) Regulations 1994 and shall come into operation on the 1st day of July 1994.

Application

2. These Regulations shall apply to all areas in which the Act applies and shall affect marketing of all Breast-milk Substitutes and Designated Products whether locally made imported and practices related thereto. They shall apply to their quality, availability, and to information concerning their use.

Interpretation

3. In these Regulations, unless the context otherwise requires:—

"Act" means the Food (Control of Quality), Act of 1978;

"Breast-milk substitute" means any food marketed, used or perceived as a partial or total replacement of breast-milk whether or not suitable for that purpose;

"container" means every form of packaging of breastmilk substitute and/or designated products for distribution or sale as a retail unit including wrappers;

The "Commission" means The National Food Control Commission established under the Act.

"Distributor" means a person, a corporation or any other entity in the public or private sector either distributing or engaged in such business, whether wholesale or retail, of marketing any breast-milk substitutes and/or designated products and includes any person engaged in the business of providing information, or public relations services in relation to breast-milk substitutes and/or designated products.

"designated products" means—

(a) infant formula; or
(b) follow up formula; or
(c) any product marketed, or otherwise represented or commonly used for feeding of infants; or

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(d) any product to be fed by use of a feeding bottle; or
(e) beverages, milks and other foods intended for use by infant and young children whether industrially made or occuring naturally; or
(f) feeding bottles, teats and pacifiers; and
(g) such other product as may be specified by the Minister by Notice in the Official *Gazette;*

"exclusive breastfeeding" means giving no food or liquid other than breast-milk not even water until the infant is between 4 and 6 months of age.

"follow up formula" means

(a) food intended for use as a liquid part of the weaning diet for the infant from the sixth month onwards and for young children; it must conform to quality standard scheduled herein;

(b) a food prepared from the milk of dairy animals and/or other constituents of animal and/or plant origin, which have been approved by the Commission to be suitable for infants from the sixth month onwards and for young children;

(c) a food which when in liquid form, is suitable for use either directly or diluted with water before feeding as appropriate; in powdered form it requires water for preparation; the product shall be nitritionally adequate to contribute to normal growth and development when used in accordance with its directions for use;

"health care facility" means governmental, non-governmental or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants, young children and pregnant women, and nurseries or child-care institutions including pharmacies.

"health professional" means any technical personnel involved in matters of human health and/or nutrition and any other person as may be specified by the Minister by notice in the Official *Gazette;*

"health worker" means a person working in a component of such a health care system, whether professional or non professional, including voluntary unpaid workers;

"infant" means a person of not more than twelve months of age;

"infant formula" means a breast-milk substitute formulated to Tanzania Standard 187 "Infant Formula Specification" industrially, in accordance to herein scheduled standard to satisfy the normal nutritional requirements of infants up to between four and six months of age, and adapted to their physiological characteristics, infant formula may also be prepared at home, in which case it is described as home prepared;

"label" means any tag, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, attached or otherwise appearing on a container of breastmilk substitutes and/or designated products;

"manufacturer" means a person or corporation or other entity in the public or private sector engaged in the business of manufacturing of breast-milk substitutes and or designated product whether directly, through an agent, or through a person controlled by or under an agreement;

"marketing" means any method of introducing or selling breast-milk substitutes and or designated product, including promotion, distribution, advertising, display on shelves, production, distribution of samples, product public relations and product informational services;

"Minister" means the Minister for the time being responsible for matters relating to Health.

"prescribed" or "as prescribed" means prescribed or as prescribed by written decision made pursuant to these Regulations;

"promote" includes advertising, giving of samples or gifts of breast-milk substitutes and or designated products or materials or information or decorations related thereto;

"promotion" means any method of introducing, familiarizing or encouraging a person to purchase a breast-milk substitute or designated product;

"Prohibited promotional practice" means and includes;

(a) special displays of or concerning breast-milk substitutes and designated products;

(b) discount coupons;

(c) the selling of breast-milk substitutes and designated products at a reduced price unless such reduction in price is intended to be permanent;

(d) the distribution of gifts or items or little or no cost bearing the name or logo of a manufacturer or distributor;

(e) the use of printed matter including books, pamplets, or posters bearing the name logo, graphic or other representation of a proprietary product or the name or logo of a manufacturer or distributor; or

(f) in any other manner;

"sample" means a single or small quantity of breast-milk substitutes or designated products, provided without cost;

"supplementary food" means any food suitable as an addition to breast-milk and/or breast-milk substitute when either becomes insufficient

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to satisfy the nutritional requirements of an infant. Such foods are also called "complementary" or "eaning foods";

"protected persons" includes infants, young children, pregnant women, guardians, lactating women and/or members of their household family;

"young children" means persons from the age of more than 12 months up to the age of five years;

PART II

EDUCATION AND HEALTH CARE FACILITIES

Informational and Educational Materials on Infant Feeding

4.—(1) The Commission shall have the responsibility for the scrutiny, of the production, provision, planning, design, and dissemination of Informational and Educational Materials on Infant and Young Child feeding for use by families and those involved in the field of Infant and Young Child health and nutrition;

(2) Informational and Educational Materials, Whether written, audio or visual, dealing with the feeding of infants and intended to reach pregnant women, mothers of infants and young children or members of their families shall include clear and appropriate information on all the following points:—

(a) the benefits and superiority of breastfeeding; or

(b) how to prepare for and maintain breastfeeding including maternal nutrition;

(c) the negative effects which the introduction of artificial feeding has on lactation or how too early introduction of supplementary foods interferes with breastfeeding; and

(d) the difficulty of returning to breastfeeding after a period of artificial feeding.

(3) Informational and Educational Materials that include the topic of feeding infants with infant formula, follow up formula or any other food shall explain, in addition to the information specified in these Regulations, the following topics:—

(a) the proper preparation and use of the product;
(b) the approximate financial cost of feeding an infant with the product;
(c) the health hazards of bottle feeding and improper preparation of the product;
(d) how to feed infants with a cup; and
(e) the importance of feeding infants with a cup.

(4) Informational and Educational Materials that include the topic of feeding infants with complementary foods shall explain in addition to the information specified in regulation 4(1) and (2), the following topics:—

(a) the health hazards of feeding with inappropriate food, and feeding at inappropriate age of the child; and

(b) how supplementary foods can easily be prepared at home.

Restrictions regarding informational and educational materials

5.—(1) Informational and Educational Materials shall contain only factual and current information and shall not use any pictures or texts that encourage artificial feeding or use of bottles for feeding or discourage breastfeeding.

(2) Informational and Educational Materials shall be written in Kiswahili and if intended for academic purposes in Kiswahili or English.

(3) Informational and Educational Materials shall not make reference to any brand of breast-milk substitutes or designated product nor contain the name or logo of any manufacturer or distributor of breast-milk substitute or designated product.

(4) Any materials containing information about the use of Infant Formula shall point out the risks entailed for the child's health in the unnecessary and indiscriminate use of such formulas.

(5) Donations of Informational or educational materials or equipment by manufacturers or distributors shall be made through the commission and in accordance with these Regulations.

The Commission to encourage breastfeeding

6.—(1) The Commission shall take appropriate measures to encourage, protect and promote breastfeeding and shall give appropriate feeding practices where infant and young children are concerned.

(2) The Commission shall encourage exclusive breastfeeding and advise health workers in regard to their responsibilities including information specified in these Regulations.

Restrictions regarding health care facility

7.—(1) The facility of health care system shall not be used for the purpose of promoting infant formula or other designated products, or for the display of the products or for placards or posters concerning such products or for the distribution of materials provided by a manufacturer of distributor.

(2) Notwithstanding the provisions of sub-regulation (1) of this regulation, the restrictions prescribed shall not preclude the dissemination of information to health professionals as provided for in these regulations.

(3) Feeding with infant formula or any designated products, whether manuractured or home prepared, shall be demonstrated by health workers, or other community workers if necessary, and only to the mothers or family members who have been prescribed to use it, and the information given shall include a clear explanation of the hazards of improper use.

(4) The head of a health care facility shall:—

(a) present to the Commission, in writing, a full disclosure of any contribution made by a distributor or manufacturers of breastmilk

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substitutes and or designated products to the health care system or health care workers therein; and

(b) prohibit acceptance into the facility gifts of samples of breastmilk substitutes and/or designated product or supplies of the same or gifts of any article or utensil which may idealise or promote the use of breast-milk substitutes or bottle feeding.

Donation to be approved by the Commission

8.—(1) Donation or low price sales or supplies of designated food products to health care facilities or any other institutions whether for use in the facilities or institutions, or for distribution outside the facilities or institutions shall be accepted through and under the written approval of the Commission.

(2) Such supplies or donations made under sub-regulation (1) of this regulation, shall only be used or distributed for infants who have prescription to be fed on breast-milk substitutes or any other designated product.

Distributions outside the health care facility

9.—(1) Where donated supplies of breast-milk substitute or other designated products within the scope of these Regulations are distributed outside the health care facility, the facility shall take such steps as to ensure that supplies can be continued as long as the infants concerned need them;

(2) Subject to sub-regulation (1) of this regulation, health workers shall—

(i) encourage and protect breast-feeding; or
(ii) where necessary, give demonstrations of feeding with infant formula; and
(iii) make a full disclosure to the Commission in writing of any contribution made by a distributor or a manufacturer, on behalf of the health worker, for fellowships, study tours, research grants, attendance to professional conferences, or for other similar purpose.

PART III

HEALTH WORKERS MANUFACTURERS AND DISTRIBUTORS

Prohibitions on the conducts of health workers

10.—(1) Under these regulations, health workers or members of their immediate families shall:—

(a) not be allowed to accept any financial or other benefits from a distributor or a manufacturer to promote any breastmilk substitute and/or designated products or

(b) not give samples of infant formula or other designated product to a protected person, notwithstanding professional evaluation as referred to under regulation 15(2) of these Regulations; and

(c) not demonstrate prelacteal feeding to mothers or family members; whenever necessary it shall be only demonstrated to mothers or family members who are prescribed to use it and the information given at such demonstration shall include a clear explanation of the hazard of improper use.

(2) Pursuant to Regulation 11 every health worker shall—

(a) observe and give effect to appropriate directions; and

(b) have regard to any Informational and Educational Material, and information and advice given or disseminated under these Regulations with respect to that duty and its performance.

Questions regarding the use of products

11.—(1) Health professional with technical questions regarding the use of products within the scope of these Regulations may however, seek information from manufacturers in writing and manufacturers shall respond in writing specifically to such professional enquiries; except that general promotional literature about the product or related products shall not be included unless it answers directly to the questions asked.

(2) Subject to sub-regulation (1) of this regulation all copies of such correspondence between Health professionals, manufacturers and distributors shall be sent to the Commission for perusal.

Prohibition of advertising of breast-milk substitutes and designated products

12.—(1) Under these regulations, advertisements or any other form of promotion to the general public of any breast-milk substitutes and designated products is hereby prohibited.

(2) Any manufacturer, distributor or any other person shall not provide directly or indirectly to pregnant women, mothers or members of their immediate families or health workers samples of products which may promote the use of breast-milk substitutes or bottle feeding.

(3) A manufacturer or distributor or any other person shall not put forth any advertisement that promotes any breast-milk substitute and or designated product; to imply or create the belief that artificial feeding is equivalent to or superior to breast-feeding.

(4) For the purposes of the Regulation. advertisement includes every form of advertising whether—

(a) in a publication, or by television, radio, film, video or telephone; and traditional communication media;

(b) by display or signs, bill boards, notices or goods; or

(c) by exhibition of pictures or models; and

(d) in any other manner.

Manufacturers to disclose their contributions

13.—(1) Manufacturers and distributors of products within the scope of these Regulations shall disclose to the institution to which a recipient health worker is affiliated any contribution made to him/her or on his/her behalf for fellowships, study tours, research grants, attendance at professional conferences, or the like. Similar disclosures shall be made by the recipient.

Prohibitions regarding manufacturers and distributors

14.—(1) A manufacturer or distributor shall not promote breast-milk substitute and or designated products, whether within a health care facility or otherwise.

(2) A manufacturer or distributor shall not apply or distribute one or more samples of breast-milk substitutes and/or designated products to any person except under such conditions as may be prescribed under the approval of the Commission, or under regulation 15 (2) of these regulations.

(3) No distributor or manufacturer shall donate any quantity of breast-milk substitutes and/or designated product to a health care facility or any other institution or organisation unless such facility, institution or organisation requests a donation on a form as may be prescribed by the Commission who shall approve such requests.

(4) No distributor or manufacturer shall donate equipment or a materials to a health care facility or health worker without the approval of the Commission.

(5) No distributor or manufacturer shall offer or make to a health worker or health care facility personnel any gift or other benefit, financial or otherwise, except as provided under sub-regulation (6) of this Regulation.

(6) No manufacturer or distributor shall provide fellowships or research grants for a health worker or shall sponsor a professional meeting or conference or fund the attendance of a health worker at such a professional meeting or conference unless such is requested on a form as may be prescribed and such request is approved by the Commission under the prescribed conditions.

(7) No manufacturer or distributor of products under these Regulations:—

(a) shall use a system of sales incentives for the marketing personnel which includes the volume of sales of any of the products under these Regulations for the purpose of the calculation of bonuses; and

(b) shall set quotas specifically for the sale of any of the product under these regulations.

Persons employed by manufacturers and distributors

15.—(1) Persons employed in marketing products under these Regulations shall not as part of their responsibilities, perform educational functions in relation to pregnant women or mothers of Infants and Young Children.

(2) Without prejudice to the generality of Regulation 14(1) and (2) samples of breast-milk substitutes or other products or Equipment and Utensils for their preparation or use may be provided to health workers when necessary for the purpose of professional evaluation or research at the institutional level such as government food control institutions, laboratories or universities or other recognized research institutions.

PART IV
INFANT FORMULA

Composition of Infant Formula and supplementary foods

16.—(1) The Composition of Infant Formula shall be in accordance with Tanzania Standard 187 "infant formula specification".

(2) Infant formula shall be in powder form prepared by physical means excluding ionization and shall be prepared from dairy animals or other animals or other edible constituents of animal including fish or plants which are suitable for infant feeding and shall contain only oils of plant origin after satisfactory removal of fats of animal origin.

(3) Infant formula shall be free from lumps, coarse particles, dirt, extraneous matter and added colouring substances and shall be free from any material, microorganisms, in amounts which are hazardous to infants as set out in the First Schedule to these Regulations.

(4) Infant formula shall be clean, safe, suitable for ingestion and nutritionally adequate to promote normal growth and developments of infants and shall contain nutrients in quality and composition as set out in the second, third and fourth schedule to these Regulations.

(5) Infant formula shall be packed in air tight and tamper proof containers approved by the Commission and they shall safeguard the hygienic and nutritional qualities of the product.

(6) Subject to sub-regulation (5) of this Regulation, nitrogen or a mixture of carbon-dioxide and nitrogen may be used as packing media in the case of spray dried infant formula.

(7) The Composition of supplementary foods shall be in accordance with Tanzania Standard 180 "processed cereal based weaning food."

(8) Supplementary food shall be clean, safe suitable for ingestion and nutritionally adequate to promote normal growth and development of the young child and shall contain nutrients in quality and composition as set out in Tanzania Standard 180.

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Labels and marks on Infant formula and suppleme ntary foods

17.—(1) Labelling and marking of infant formula and supplementary foods shall be in accordance with Tanzania Standard 187 and Tanzania Standard 180 respectively.

(2) Labels and marks on any infant formula shall include the following information in Kiswahili, English and in any other language where the product is marketed:—

(a) name of the product, that is infant formula, and trade name or brand name;

(b) name and address of the manufacturer and or licenced parker;

(c) batch or code number;

(d) net content by mass/volume;

(e) list of ingredients with the average content of each nutrient indicated in descending order of proportion;

(f) protein source and the proportion of saturated and unsaturated farry acids;

(g) the average content of each nutrient;

(h) directions for storing the unopened container and special directions after the container has been opened;

(i) an indication, with a print letter not less than 5mm. that infant formula is not intended to replace breastfeeding but is a complement where breastfeeding in insufficient;

(j) the words "IMPORTANT NOTICE" or their equivalent, directing on how to prepare and use the formula for consumption and shall include;

(i) a statement of the superiority of breastfeeding;

(ii) a statement that the product should be used only on the advice of a doctor or health worker;

(iii) instruction and a warning against the health hazards of inappropriate preparation;

(iv) a statement that infants should be fed only with cup and or spoon;

(k) advisory not that infacts over 6 months of age should receive supplementary foods in addition to the formula;

(l) date of manufacture and expiry to be printed in tamper proof on the container.

(m) country of origin.

(3) The label shall not show any photographs, drawings or other graphic representations other than for illustrating methods of preparation and in no case, shall depict a feeding bottle.

PART V

LICENCES, IMPORT PERMITS, OFFENCES AND PENALTIES

Licence and import permits

18.—(1) Manufacturers shall obtain a licence for manufacturing breastmilk substitutes and/or any of the designated products from the Commission.

(2) All importers shall obtain import permits of breast mili substitutes and/or designated products from the Commission.

(3) No person shall distribute or sell or display for sale or otherwise any breastmilk substitutes and/or designated product unless he is convinced beyond resonable doubt and can so produce evidence that the designated product in his custody has been manufactured under licence from the Commission, and if imported has been so imported under the permission from the Commission.

Offences and Penalties

19.—(1) Any manufacturer, importer, packer or distributor who contravenes or fails to comply with these Regulations or directly or indirectly aids an individual or any other person in committing an offence under these Regulations shall be guilty of an offence and shall be liable on conviction to a fine not exceeding one million shillings or to imprisonment for a term not exceeding five years or to both such fine and imprisonment.

(2) Any health facility that intentionally contravenes or fails to comply with these Regulations, or directly or indirectly aids any other person in committing an offence under these Regulations shall be guilty of an offence and shall be liable on conviction to a fine not exceeding one million shillings or revocation of its operating licence or to both fine and licence revocation.

(3) Any health worker who intentionally contravenes or fails to comply with these Regulations or directly or indirectly aids another person in committing an offence under these Regulations shall be guilty of an offence and shall be liable on conviction to a fine not exceeding five thousand shillings or to imprisonment for a term not exceeding six months or to both fine and imprisonment.

(4) Any person other than those mentioned under Regulation 19(1), (2) and (3) who intentionally contravenes or fails to comply with these Regulations, or directly or indirectly aids another person in committing an offence under these Regulations shall be guilty of an offence and shall be liable on conviction to a fine not exceeding five thousand shillings or to imprisonment for a term not exceeding six months or to both fine and imprisonment.

Revocation of GN. No. 237 of 1989

20.—(1) The Food (Control of Quality) (Infant Formula and Weaning Food) Regulations 1989 are hereby revoked.

G.N. No. 256 (contd.)

FIRST SCHEDULE

LIMITS OF MICRO-ORGANISMS IN INFANTS AND SUPPLEMENTARY FOOD

Type of Food	*Type of Organisms*	*Maximum number of Organisms allowed*			
Dried biscuits type		n	c	m	M
(1) Plain	Coliform bacteria	5	2	2	20
(2) Coated	Salmonella	10	0	0	—
Dried and Instant products	Mesophollic				
	earobic bacteria	1	2	10	10
	Coliform bacteria	5	1	2	20
	Salmonella	10	0	0	—
Dried products requiring	Mesophollic				
heating before consumption	earobic bacteria	5	3	10	10
	Coliform bacteria	5	2	10	10
	Salmonella	10	0	0	—

n = number of sample units examined.
c = the maximum allowable number of positive unit (defective)
m = represents dividing line between acceptable and defectives
— acceptable when the values aqual to or less than (m)
— defective when values are above (m)
M = Separate marginally acceptable (m) from non-acceptable.

SECOND SCHEDULE

COMPOSITION AND QUALITY FACTORS OF INFANT FORMULA

1. Protein .....Not less than 4.4g and not more than 10g. of protein per MJ or not less than 85% of casein.
2. Fat .....Not less than 0.7gm per MJ of linoleic acid in the form of glycerides. Total fat content shall be not less than 8g and not more than 15g per MJ.
3. Carbohydrates ..Energy content not less than 2,700 KJ per litre of the product ready for consumption with between 35 to 55% of the energy originating from lactose, maltose and dextrins.
4. Moisture .....Not more than 5.0 per cent.
5. Tocopherol .....Not less than 0.7mg per gram linoleic acid but shall not be less than 1.7mg and not more than 5mg per megajoule.
6. Choline .....Not less than 17mg and not more than 70mg per mJ.
7. Vitamins .....As indicated in the following table:—

	Min	*Max*
Retinol (Vitamin A), mcg	120	360
Ascorbic acid (Vitamin C), mg	20	60
Thiamine (Vitamin Bl) mg	0.1	0.3
Riboflavine (Vitamin B2), mg	0.15	0.45
Nicotinamide, mg	0.6	1.8
Pyridoxine (Vitamin B6) mg	0.1	0.3
Pantothemic acid, mg	0.7	2.1
Folic acid mcg	10	30
Cynocobalamin (Vitamin B12) mcg	0.4	1.1
Cholecalcifero (Vitamin D3) mcg	2.5	5.0
Biotin (Vitamin H) mcg	4.0	Not specified
Vitamin K, mcg	10.0	Not specified

8. Minerals .....as indicated in the following table:—

Minerals	*Content per megajoule (mJ)*	
	Min	*Max*
Sodium, mg	50	150
Potassium, mg	200	500
Chloride, mg	140	350
Calcium, mg	120	360
Phosphorous, mg	60	300
Magnesium, mg	114	45
Iron, mg	2.5	5
Zinc, mcg	1.2	Not specified
Iodine, mcg	12	36
Manganese, mcg	12	Not specified
Copper, mcg	140	Not specified

9. Food Additives .as indicated in the following table:—

Food Additive	*Maximum level of use*
Emuslifiers	
Lecithin	0.5/l of the product consumed
mono and diglycerides	0.5/l of the product consumed
Antioxidants	
L-ascorby/palmitate	10mg/l of the product as consumed
Alpha-tocopherol	10mg/l of product as consumed
Citric acid and its sodium salts	3g/l of the product as consumed
pH-Adjusting Agents	
Sodium citrates	
Sodium hydrogen carbonate	
Potassium citrate	

THIRD SCHEDULE

COMPOSITIONS AND QUALITY FACTORS OF SUPPLEMENTARY FOOD

1. Moisture .....not more than 8.0 percent
2. Crude protein .....not more than 14.0 percent
3. Total Fat .....not more than 7.5 percent
4. Total carbohydrates .....not more than 45.0 percent
5. Bacteria count per gram .....not more than 10.000
6. Coliform count per gram .....not more than 10
7. Urease activity test (difference in pH) .....not more than 0.8
8. Total ash .....not more than 5.0 percent
9. Vitamins and minerals ..... as indicated in the following table:—

Characteristics	*Requirements*
Vitamin A, IU/100g	minimum 1,500
Vitamin C, mg/100g	minimum 25
Vitamin D, IU/100g	not less than 300, not more than 800
Thiamine (Bl), hydrochloride mg/100g	minimum 0.5
Riboflavin (B2), mg/100g	minimum 0.6
Nicotinic acid, mg/100g	minimum 5
Calcium, g/100g	minimum 1.0
Iron mg/100g	minimum 10

FOURTH SCHEDULE

3. ESSENTIAL COMPOSITION AND FACTORS OF FOLLOW UP FORMULAS

3.1 *Energy Content*

When prepared in accordance with the instructions for use, 100 ml. of the ready-for-consumption product shall provide not less than 60 kcal (or 355 kJ).

3.2 *Nutrient Content*

"Follow-up Formula" shall contain the following nutrients at minimum and maximum levels indicated below:—

3.2.1 *Protein per 100 Available Calories (or kilojoules)*

3.2.1.1 Not less than 3.0g per 100 available calories (or 0.7g per 100 available kilojoules) of protein of nutritional quality equivalent to that of casein or greater quantity of other protein in inverse proportion to its nutritional quality. The quality of the protein shall not be less than 85% of that of casein. The total quantity of protein shall not be more than 5.5g per 100 available calories (or 1.3 per 100 available kilojoules).

3.2.1.2 Essential amino acids may be added to follow-up formula only to Improve its nutritional value. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L forms of amino acids shall be used.

3.2.2 *Fat per 100 Available Calories (or kilojoules)*

3.2.2.1 Not less than 3g and not more than 6g per 100 calories (0.7 and 1.4g per 100 available kilojoules).

3.2.2.2 The level of linoleic acid (in the form of a glyceride) shall not be less than 300mg per 100 calories (or 71.7mg per 100 available kilojoules).

3.2.3 *Carbohydrates*

The product shall contain nutritionally available carbohydrates suitable for the feeding of the older infant and the young child in such quantities as to adjust the product to the energy density in accordance with the requirements set out in section 3.1.

3.2.4 *Vitamins other than Vitamin E*

	Amounts per 100 available calories		*Amounts per 100 available kilojoules*	
Vitamin A	Minimum 250 I.U. or 75 mcg expressed as retinol	Minimum 750 I.U. or 225 mcg expressed as retinol	Minimum 60 I.U. or 18 mcg expressed as retinol	Minimum 180 I.U. or 54 mcg expressed as retinol

	Amounts per 100 available calories		*Amounts per 100 available kilojoules*	
	Minimum	*Maximum*	*Minimum*	*Maximum*
Vitamin D	40 I.U or 1 mcg	120 I.U or 3 mcg	10 I.U or 0.25 mcg	30 I.U or 0.75 mcg
Ascorbic acid (Vitamin C) Thiamile	8 mg	N.S. 1-/	1.9 mg	N.S. 1-/
Vitamin B Riboflavin	40 mcg	N.S. 1-/	10 mcg	N.S. 1-/
Vitamin B	60 mcg	N.S. 1-/	60 mcg	N.S. 1-/
Nicotinamide	250 mcg	N.S. 1-/	60 mcg	N.S. 1-/
Vitamin B 2-/	25 mcg	N.S. 1-/	11 mcg	N.S. 1-/
Folic acid	4 mcg	N.S. 1-/	1 mcg	N.S. 1-/

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Pantothenic acid	300 mcg	N.S. 1-/	70 mcg	N.S. 2-/
Vitamin B12	0.15 mcg	N.S. 2-/	0.04 mcg	N.S. 2-/
Vitamin K1	4 mcg	N.S. 2-/	1 mcg	N.S. 2-/
Biotin (Vitamin H)	1.5 mcg	N.S. 2-/	0.4 mcg	N.S. 2-/
3.2.5	*Vitamin E*			
	(a-tocopherol compounds	0.7 I.U/g Linoleic acid 3-/ but in no case less than 0.7 LU/100 available calories	N.S. 2-/	N.S. 2-/ Linoleic acid 3-/ but in no case less than 0.15 LU/100 available kilojoules

3.2.6 *Minerals*

	Amounts per 100 available calories		*Amounts per 100 available kilojoules*	
	Minimum	*Maximum*	*Minimum*	*Maximum*
Sodium (Na)	20 mg	85 mg	5 mg	21 mg
Potassium (K)	80 mg	N.S. 2-/	20 mg	N.S. 2-/
Chlorine (C1)	55 mg	N.S. 2-/	14 mg	N.S. 2-/
Calcium (Ca) 1-/	90 mg	N.S. 2-/	22 mg	N.S. 1-/
Phosphorous (P) 1-/	60 mg	N.S. 2-/	14 mg	N.S. 2-/
Magnesium (Mg)	6 mg	N.S. 2-/	1.4 mg	N.S. 2-/
Iron (Fe)	1 mg	2 mg	0.25 mg	0.50 mg
Iodine (I)	5 mcg	N.S. 2-/	1.2 mcg	N.S. 2-/
Zins (Zn)	0.5 mg	N.S. 2-/	0.12 mg	N.S. 2-/

3.3 *Ingredients*

3.3.1 Essential Ingeredients

3.3.1.1. Follow-up formula shall be prepared from the milk of dairy animals and/or other protein products of animal and/or plant origin which have been proved suitable for infants from the 6th month on and for young children and from other suitable ingredients necessary to achieve the essential composition of the product as set out in section 3.1 and 3.2 above.

3.3.1.2. Follow-up Formula based on milk shall be prepared from ingredients as set out in section 3.3.1.1 above except that a minimum of 3 g per 100 available calories (or 0.7. g per 100 kilojoules) of protein shall be derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin of mineral content ot the milk and which presents a minimum of 90% of the total protein.

1-/ N.S. = Not specified.
2-/ Formulae should contain a minimum of 15 mcg vitamin B6 per gram of protein. See section 3.2.1.1.

1-/ The Ca: P ratio shall be not less than 1.0 and not more than 2.0.

2-/ N.S. = Not specified.

3-/ Or per g polyunsaturated fatty acids, expressed as linoleic acid.

3.3.2. Optional Ingredients

3.3.2.1. In addition to the vitamins and minerals listed under 3.2.4 to 3.2.6 other nutrients may be added when required to ensure that the product is suitable to form part of a mixed feeding scheme intended for use from the 6th month on.

3.3.2.2. The unusefulness of these nutrients shall be scientifically shown.

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3.3.2.3. When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children.

3.4. *Purity Requirements*

3.4.1 *General*
All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants from the 6th month on and young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.4.2 *Vitamin compounds and Mineral Salts*

3.4.2.1. Vitamin compounds and mineral salts used in accordance with section 3.3.2 should be selected from the Advisory Lists for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children approved by the Codex Alimentarius Commission.

3.4.2.2. The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in section 3.2.6.

3.5. *Consistency and Particles Size*
When prepared according to the directions for use, the product shall be free of lumps and of large, coarse particles.

3.6. *Specific Prohibition*
The product and its components shall not have been treated by ionizing radiation.

4. FOOD ADDITIVES

		Maximum Level in 100 ml. of Product Ready-for-Consumption
4.1	*Thickening Agents*	
4.1.1	Guar gum	0.1 g
4.1.2	Locust bean gum	
4.1.3	Distarch phosphate	0.5 singly or in combination in
4.1.4	Acetylated distarch phosphate	
4.1.5	Phosphated distarch phospate	
4.1.6	Acetylated distarch adipate	2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based products only
4.1.7	Carrageenan	0.03 g singly or in combination in milk and soy-based products only 0.1 g singly or in combination in hydrolized protein and/or amino acid - based liquid products only.
4.1.8	Pectins	1 g
4.2	*Emulsifiers*	
4.2.1	Lecithin	0.5 g
4.2.2	Mono-and Diglycerides	0.4 g
4.3	*pH-Adjusting Agents*	
4.3.1	Sodium hydrogen carbonate	
4.3.2	Sodium carbonate	
4.3.3	Sodium citrate	
4.3.4	Potassium hydrogen carbonate	
4.3.5	Potassisum carbonate	Limited by Good Manufacturing Practices within the limits for Na in section 3.2.6
4.3.6	Potassium citrate	
4.3.7	Sodium hydroxide	
4.3.8	Potassium hydroxide	
4.3.9	Calcium hydroxide	
4.3.10	L(+) Lactic acid	
4.3.11	L(+) Lactic acid producing cultures	
4.3.12	Citric acid	

4.4	*Antioxidants*	*Maximum Level in 100 ml. of Product Ready-for-Consumption*
4.4.1	Mixed tocopherols concentrate	3 mg singly or in combination
4.4.2	a-Tocopherol	
4.4.3	L-Ascorbyl palmitate	5 mg singly or in combination, expressed as ascorbic acid (See section 3.2.6)
4.4.4	L-Ascorbic acid and its Na. Ca salts	
4.5	*Flavours*	
4.5.1	Natural Fruits Extracts	GMP
4.5.1	Vanilla extract	GMP
4.5.3	Ethyl vanillin	5 mg
4.5.4	Vanillin	5 mg

4.6 *Carry-Over Principles*
Section 3 of the "Principle relating to the Carry-over of Additives into Foods" asset forth in Volume I of the Codex Alimentarius shall apply.

5. *CONTAMINANTS*

5.1 *Pesticide Residues*
The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

5.2 *Other Contaminants*
The product shall be free from residues of hormones and antibiotics, as determined by means of agreed methods of analysis, and practically free from other contaminants, especially pharmocological active substances.

6. *PACKAGING*

6.1 The product shall be packed in containers which will safequard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media.

6.2 The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

7. *FILL OF CONTAINERS*
In the case of products in ready-to-eat form, the fill of container shall be:—

(i) not less than 80% v/v for products weighing less than 150 g (5 1/2 oz.);or

(ii) not less than 85% v/v for products in the weight range 150-250 g (5 1/2-9 oz.); and

(iii) not less than 90% v/v for products weighing more than 250 g (9 oz) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

Dar es Salaam,
15th June, 1994

A. H. MAYAGILA,
Minister for Health