GOVERNMENT NOTICE NO. 60 published on 15/3/2013

THE TANZANIA FOOD, DRUGS AND COSMETICS ACT

———

ARRANGEMENT OF REGULATIONS

———

Regulation *Title*

G.N. 60 (Contd.)

THE TANZANIA FOOD, DRUGS AND COSMETICS ACT
(CAP. 219)

REGULATIONS

(Made under sections 29(1)(2)(b) and 122(1)(c)(e))

THE TANZANIA FOOD, DRUGS AND COSMETICS (MARKETING OF FOODS AND DESIGNATED PRODUCTS FOR INFANTS AND YOUNG CHILDREN) REGULATIONS, 2013

Citation

1. These Regulations may be cited as the Tanzania Food, Drugs and Cosmetics (Marketing of Foods and Designated Products for Infants and Young Children) Regulations, 2013.

Application and scope

2. These Regulations shall apply to all areas in which the Act applies and affect marketing and practices related thereto, safety, quality, availability and information concerning marketing of all foods and designated products for infants and young children whether imported or locally manufactured.

Interpretation

3. In these Regulations, unless the context otherwise requires-

Cap. 219

"Act" means the Tanzania Food, Drugs and Cosmetics Act;

"advertise" means to make any representation by any means whatsoever for the purpose of promoting the sale or use of foods and designated products for infants and young children including but not limited to-

(a) written publication, television, radio, film, electronic transmission including the internet, video or telephone; and traditional communication media;

(b) display or sign, bill boards, notices or goods; or

(c) exhibition of pictures or models;

"Authority" means the Tanzania Food and Drugs Authority or

its acronym "TFDA", established under section 4 of the Act;

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

"Codex" means the Codex Alimentarius Commission responsible for execution of the United Nations Joint Food And Agriculture Organisation or World Health Organisation Food Standards Programme;

"complementary food" means cereal based food or any other food suitable, or represented as suitable, as an addition to breast-milk, or follow-up formula for infants from the age of six completed months or for young children up to the age of five years;

"container" means any form of packaging of a breast milk substitute, complementary food or designated product for distribution or sale as a retail unit and shall include wrappers;

"designated product" means-

(a) feeding bottles, teats and pacifiers, cups with spouts or similar receptacles for feeding infants and young children;

(b) gripe water and other similar products;

(c) any other product marketed, or otherwise represented as suitable for feeding of infants or young children; or

(d) any other product as may be specified by the Minister;

'distributor" means a person, a corporation or any other entity in the public or private sector engaged in the business, whether wholesale or retail, of marketing of a breast-milk substitute, complementary food or designated product and includes any person engaged in the business of providing information, or public relation services in relation to a breast-milk substitute, complementary food or designated

product;

"exclusive breastfeeding" means feeding an infant on breast-milk only without giving any other food, preparations or liquid not even water until the infant is six completed months of age;

"follow -up formula" means a milk or milk like product of animal or vegetable origin formulated industrially in accordance with the national standard or in case there is no national standard, International standard for follow up formula marketed or otherwise represented as suitable substitute for breast-milk for infants and young children older than six months of age;

"food" means any article other than drugs, cosmetics and tobacco used as food or drink for human consumption and includes any substance used in manufacture or treatment of food;

"formula for special medical purposes intended for infants" means formula in liquid or powder form intended for use, as a substitute for breast-milk or infant formula and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical condition during the first six months of life;

"health care facility" means governmental, non- governmental or private institution or organization or private practitioner, directly or indirectly, engaged in provision of health care or health and nutrition education for mothers, infants, young children or pregnant women and shall also include nurseries, child-care institutions and pharmacies;

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

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

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

"infant formula" means breast-milk substitute formulated industrially in accordance with the National standard or in case there is no National standard, International standard for infant formula to satisfy by itself nutritional requirements of infants up to six months of age from birth. Infant formula may also be prepared at home in which case it is described as home prepared;

"international standard" means Codex Standard, East African Standard or any other standard recognized by the Authority;

"label" means any tag, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, attached or otherwise appearing on a container of a breast-milk substitute or designated product;

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

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

"medical indication" means a health or medical condition identified or determined by a health professional as necessitating the need for use of a given product or prescription that is presumed to correct, improve or alleviate the health or medical condition;

"Minister" means the Minister for the time being responsible for Health;

"National standard" means a standard *gazetted* under any written law in force for the time being;

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

"prohibited promotional practice" means and includes-

(a) special displays of or concerning a breast-milk substitute, complementary food or designated product discount coupons;

(b) "tie-in sales";

(c) the selling of a breast-milk substitute, complementary food or designated product at a reduced price unless such reduction in price is intended to be permanent;

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

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

(f) promotional practice in any other manner;

"promote" means any direct or indirect method of encouraging a person to purchase or use a product;

"promotion" means any direct or indirect method of introducing a breast-milk substitute, complementary food or designated product or encouraging the buying or use of a designated product including but not limited to:

(a) sale devices such as rebates, special displays, tie-in sales, loss leaders, rewards, discount coupons, premiums, special sales, prizes, gifts and giving of samples;

(b) direct or indirect contact with protected persons including but not limited to television and radio programmes, electronic communication including websites and electronic mail, telephone or internet help lines, mother or baby clubs and baby competitions;

(c) distribution of promotional items that refer to the

name, logo, trademark of the product; and

(d) any practice that creates an association between a manufacturer or distributor and protected person;

"protected person" means infants, young children, pregnant women, parents, lactating women, care givers, guardians of infants or young children, members of their families or any other persons with Human Immunodeficiency Virus (HIV positive) or who is suffering from Acquired Immunodeficiency Syndrome (AIDS);

"sample" means a single or small quantity of a breast-milk substitute, complementary food or designated product provided without cost;

"supplies" means quantities of breast-milk substitute or complimentary food or designated product provided for use over an extended period free or at low price for promotional purposes including those provided to families in need;

"tie-in sales" means the sale of any breast milk substitute or complementary food or designated product or that is linked to a purchase of any other product;

"young child" means a person from the age of more than 12 months up to the age of five years.

PART II
EDUCATION AND HEALTH CARE FACILITIES

Restrictions regarding informational and educational materials

4.-(1) A manufacturer or distributor shall not distribute or cause to be distributed any informational or educational material related to infant or young child nutrition, except in accordance with these Regulations.

(2) Subject to sub-regulation (1), any informational or educational material related to infant or young child nutrition shall be submitted to the Authority for approval before being distributed for intended use.

(3) The Authority shall, upon consultation with the Government institution responsible for nutrition, have

responsibility for the scrutiny and approval of distribution or dissemination of any informational or educational material related to infant or young child nutrition for use by families or health care facilities.

Conditions for approval of informational and educational materials

5. Before approving distribution or dissemination of an informational and educational material, the Authority shall satisfy itself that the content therein-

(a) is written in Kiswahili but if intended for academic purposes may be written in English;

(b) does not make reference to brand name or *logo* of any breast-milk substitute, complementary food or designated product;

(c) does not include name or logo of any manufacturer or distributor of foods for infants or young children;

(d) includes only factual and current information and is not presented in any picture that encourages bottle feeding or discourages breastfeeding; and

(e) complies with requirements of Regulation 6 of these Regulations.

Content of informational and educational materials

6.–(1) Any informational or educational material related to infant or young child nutrition, whether written, audio or visual, intended to reach protected persons shall include clear and appropriate information on all of the following facts-

(a) the benefits and superiority of breastfeeding;

(b) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years or beyond;

(c) how to prepare for and maintain exclusive breast-feeding including maternal nutrition;

(d) the negative effects which the introduction of artificial feeding has on lactation and how early introduction of complementary foods interferes with breastfeeding; and

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

(2) Any informational or educational material with the subject of feeding infants using breast-milk substitutes or complementary foods or designated products shall include, in addition to the information specified in sub regulation (1), the following topics-

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

(3) Any informational or educational material related to infant or young child feeding with complementary foods shall contain in addition to the information specified in sub-regulation (1) and (2), information on how complementary foods can easily be prepared at home using local ingredients.

Responsibility of the Authority to encourage breast-feeding

7. Upon consultation with the Government institution responsible for nutrition, the Authority shall-

(a) take appropriate measures to encourage, protect and promote breastfeeding; and
(b) encourage exclusive breastfeeding for the first six months of life and advise health workers and health professionals in regard to their responsibilities including restrictions for information dissemination as specified in these Regulations.

Restrictions regarding health care facilities

8.–(1) Any health care facility shall not be used for the purpose of promoting or displaying, including but not limited to display of placards or posters, of any breast-milk substitute, complementary food or designated product or for the distribution of any material provided by a manufacturer, distributor or any other person promoting such a product.

(2) Notwithstanding the provisions of sub-regulation (1) of this regulation, dissemination of information to health care facilities shall be in accordance with regulations (3) and (4) of these regulations.

(3) Pursuant to sub-regulation (1) of this regulation, any head of a health care facility shall prohibit acceptance into the facility of gifts, samples or supplies of breast-milk substitute, complementary food or designated product or any article or utensils which may idealize or promote bottle feeding or the use of breast-milk substitutes, complementary foods or designated products.

(4) Where there is a medical indication for use of infant formula or follow up formula, health workers shall demonstrate only to mothers or family members on how to feed infants with the formula and shall give a clear explanation of the hazards of improper use.

Prohibition regarding donations

9.–(1) A person shall not donate a breast-milk substitute, complementary food, designated product, low price sales, informational and educational materials or equipment to a health care facility or any other institution whether for use in the facility or institution or for distribution outside the facility or institution.

(2) Notwithstanding the prohibition under sub-regulation (1), the Authority may, upon a request from any head of health care facility, approve donation of breast-milk substitutes, complementary foods, or designated products to the health care facility whether for use in the facility or for distribution outside the facility, upon satisfaction that-

(a) in the case of breast milk substitutes, such a donation or supply shall only be used or distributed for infants who have medical indications to be fed on breast-milk substitutes;

(b) there is a state of emergency which may endanger life and health of infant or young children which may include but not limited to mass loss of mothers, floods, drought or

exposure of breast feeding mothers to an agent which may endanger the health of the child;

(3) Where exceptional circumstances provided in sub-regulation (2) of this regulation prevail, the Authority shall take necessary measures to satisfy itself that:

(a) in the case of breast-milk substitutes, mother of the child has passed away or her health status makes it impossible for her to breastfeed;

(b) the father or mother of the child does not have resources to enable him or her procure the breast-milk substitute or complementary food, as the case may be, or the parents are not known or accessible;

(c) the health facility or person taking care of the child does not have sufficient resources to procure the product; and

(d) the donor is committed to sustain the donation for a minimum of first six months of age or as long as the infant or young child concerned needs it.

(4) Without prejudice to the provisions of sub-regulation (2) the Authority may, upon a request from head of any health care facility, approve donation of informational and educational materials or equipment, whether for use in the facility or institution or for distribution outside the facility or institution, upon satisfaction that the restrictions prescribed in Regulation 4 of these Regulations have been complied with.

PART III
HEALTH WORKERS, MANUFACTURERS AND DISTRIBUTORS

Prohibition on the conduct of health workers

10. Under these Regulations, health workers or members of their immediate families shall not-

(a) accept any financial or other benefits from a distributor or manufacturer;

(b) give a sample of breast-milk substitute or designated product to a protected person;

(c) engage in practices such as but not limited to pre-lacteal feeding that directly or indirectly retard the initiation or continuation of breast feeding.

Questions regarding the use of products

11.–(1) Health professionals with technical questions regarding the use of breast-milk substitutes, complimentary foods or designated products within the scope of these Regulations may seek information from manufacturers in writing through the Authority and manufacturers shall respond in writing through the Authority specifically to such professional inquiries.

(2) General promotional literature of a product or related products shall not be supplied to health professional in response to questions raised according to sub-regulation (1), unless the literature contain answers to the questions.

Prohibition of advertising breast-milk substitutes, complementary foods and designated products

12.–(1) A person shall not advertise or perform any form of promotion for any breast-milk substitute, complementary food or designated product.

(2) Pursuant to the provisions of sub-regulation (1) of this regulation, manufacturer or distributor shall not-

(a) use a system of sales incentives for the marketing personnel which includes the volume of sales of a breast-milk substitute, complementary food or designated product for the purpose of the calculation of bonuses;

(b) set quotas specifically for the sale of a breast milk substitute, complementary food or designated product.

Prohibition regarding manufacturers and distributors

13.–(1) A manufacturer or distributor shall not offer or give any sponsorship including but not limited to the funding of seminars, meetings, conferences, educational courses, contests, research or any event or service related to reproductive health, pregnancy, childbirth infant or young child feeding or related topics, or any other benefit, whether pecuniary or in kind to health workers, members of their

family or their associations, except in accordance with these Regulations.

(2) Notwithstanding, the prohibition in sub-regulation (1), a manufacturer or distributor, upon a request from a head of health care facility or any other institution, may offer fellowships, study tours, research grants, attendance to professional conferences to health workers provided that the offer is for learning purpose and does not relate to the marketing of any breast milk substitute, complementary food or designated product.

(3) A head of health care facility which receives any contribution or incentive including but not limited to fellowships, study tours, research grants, attendance to professional conferences, made by a distributor or manufacturer of a breast-milk substitute, complementary food or designated product to the health care facility or to health workers therein shall present to the Authority, in writing, a report with full disclosure of the contribution or incentive.

Responsibilities of manufacturers, distributors and persons employed by manufacturers or distributors

14.–(1) Logo patent owner, manufacturer, or distributor of foods for infants or young children approved for sale in Tanzania shall be responsible for the safety and marketing practices for such products in the country.

(2) Persons employed for marketing of breast-milk substitutes or designated products shall not as part of their responsibilities, perform educational functions in relation to protected person.

PART IV
PRODUCT COMPOSITION, SAFETY, QUALITY AND LABELLING

General product requirements

15. General, safety, quality and essential composition requirements for infant formula, follow up formula, formula for special medical purposes intended for infants and complementary food shall be in accordance with national standard or in case there is no national standard, international standard.

Safety, quality and essential composition

16. Notwithstanding the provisions of Regulation 15 of these Regulations-

(a) infant formula, follow up formula or formula for special medical purposes intended for infants or complementary food shall not be manufactured using genetically modified organisms;

(b) limits of microbial contamination in the formula for special medical purposes intended for infants, Infant formula or follow up formula or complementary food shall be as set out in the First Schedule to these Regulations.

(c) Food additives may be used as set out in the following Schedules-

(i) formula for special medical purposes intended for infants or infant formula in the Second Schedule;

(ii) follow up formula in the Third Schedule; and

(iii) complementary food in the fourth Schedule, to these Regulations.

(d) Notwithstanding the provisions of paragraph (c), essential nutrient composition for Formula for special medical purposes intended for infants shall be modified to meet the special nutritional requirements arising from the disease(s), disorder(s) or medical condition(s) for whose dietary management of the product is specifically formulated, labelled and presented.

Labelling requirements

17.–(1) Labelling and marking of infant formulas, follow-up formulas, formulas for special medical purposes intended for infants or complementary foods shall be in accordance with the national standard for that product or the labelling requirements in force.

(2) Notwithstanding the provision of sub regulation (1), labels and marks on any infant formula, follow-up formula, formula for special medical purposes intended for infants or complementary foods shall include the following

information in Kiswahili and English languages:

(a) trade or brand name;

(b) common name of the product, as infant formula, formula for special medical purposes intended for infants, follow up formula or appropriate name, in the case of complementary foods;

(c) name and address, including country of origin, of the manufacturer or licensed packer;

(d) batch or code number;

(e) net content by mass or volume in International Standard (SI) units;

(f) list of ingredients, including additives declared by their specific names or E numbers, in descending order of proportion;

(g) protein source and the proportion of saturated and unsaturated fatty acids;

(h) the average content of each nutrient;

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

(j) save for complimentary foods, the words "IMPORTANT NOTICE" in capital letters and indicated there-under, the statement "Breast milk is the best food for your baby" with a print letter not less than 5mm;

(k) save for complementary food, directions on how to prepare and use the formula for consumption and shall include:

(i) a statement that the product should be used only on the medical advice;

(ii) warning about the health hazards on inappropriate preparation and feeding and introducing the product prior to recommended age;

(iii) a statement that infants should be fed only with an open cup;

(iv) a statement that reconstituted formula remaining after feeding should be discarded;

(l) advisory note that infants over six months of age should receive complementary foods in addition to the formula;

(m) date of manufacture and expiry in tamper proof print in the container.

(3) Without prejudice to the provision of sub-regulation (2), labels and marks on any Infant formula, follow-up formula, formula for special medical purposes intended for infants or complementary food shall not show any photographs, drawings or pictorial presentations or graphic representations other than for illustrating methods of preparation and in no case, shall it depict a feeding bottle or teat.

PART V
PERMITS AND GENERAL PROVISIONS

Restriction for dealing in unregistered foods

18. Any person shall not manufacture, import, distribute, sell, or expose for sell any breast-milk substitute or complementary food unless the product has been registered with the Authority and the person is in possession of a permit issued by the Authority.

Prohibition of supply

19.-(1) Without prejudice to the generality of these Regulations, a person shall not sell or expose for sell, distribute, offer, donate, import, export, manufacture, promote any dummy or toys or the like products.

(2) Notwithstanding the provisions of sub-regulation (1), a container of breast-milk substitute or complementary food shall not be in a form or shape that depicts any representation or promotion of dummies or toys or the like products.

Offences and Penalties

20.–(1) Any manufacturer, importer, packer or distributor who contravenes or fails to comply with these Regulations or directly or indirectly abates in committing an offence under these Regulations shall be guilty of an offence and upon conviction:

(a) in case of a body corporate shall be liable to the maximum fine prescribed in the Act, and in case

of second offence, to both the maximum fine prescribed in the Act and where applicable revocation of permit;

(b) in case of an individual shall be liable to a fine not exceeding five hundred thousand shillings or to imprisonment for a term not exceeding six months or to both such fine and imprisonment;

(c) for both (a) and (b) shall be liable for destruction of any product that offends these Regulations, upon own cost.

(2) The Authority may suspend, cancel or revoke any permit upon satisfaction that such permit does not comply with the provisions of these Regulations.

Compounding of offences

21.–(1) The Authority may, subject to and in accordance with the provisions of the Act, if circumstances show that a person, corporate or unincorporated body has committed any offence against these Regulations in respect to which he has showed willingness to pay a fine, compound such offence by accepting with the fine or any other thing in respect of which the offence has been committed.

(2) Subject to the provisions of these Regulations authorizing any measures that may be taken pursuant to an order of the court, no further criminal or as the case may be, civil proceedings shall be taken by the Authority against a person in respect of whom a power to compound offence has been exercised.

(3) The Authority, may before accepting any fine prescribed under the Act shall require such a person to fill in a compounding of offence form as provided in the Fifth schedule to these Regulations.

Revocation of G.N. No. 256 0f 1994

22. The Food (Control of Quality) (Marketing of breast milk substitutes and designated products) Regulations, 1994 are hereby revoked.

G.N. 60 (Contd.)

FIRST SCHEDULE

———

[Made under regulation 16(b)]

———

LIMITS OF MICRO-ORGANISMS IN FOODS FOR INFANTS AND YOUNG CHILDREN

Type of food	Type of Organism	Microbiological criteria			
		n	c	m	M
Dried biscuits type (1) Plain (2) Coated	Coliform bacteria	5	2	2/g	20/g
	Salmonella	10	0	0/10g	-
	Enterobacteriaceae	10	0	0/10g	-
Dried and Instant products	Mesophillic Aerobic bacteria	5	2	500/g	5000/g
	Coliform bacteria	5	1	2	20
	Salmonella	60	0	0/25g	-
	Enterobacteriaceae	10	0	0/10g	-
Dried products requiring heating before consumption	Mesophillic Aerobic bacteria	5	3	10^4/g	10^5/g
	Coliform bacteria	5	2	10/g	10^2/g
	Salmonella	5	0	0/25g	-

n = number of sample unit to be examined.

C = the maximum allowable number of positive samples which may contain microorganisms above m

m = Maximum tolerable number of micro organism in c which separate acceptable quality from defective quality in case M is not set or good quality from marginally acceptable quality in case M is set.

M = Maximum allowable number of microorganism in c which separate marginally acceptable quality from defective quality.

SECOND SCHEDULE

[Made under regulation 16(c)(i)]

ESSENTIAL NUTRIENT COMPOSITION AND FOOD ADDITIVES REQUIREMENTS FOR FOODS FOR INFANTS

TABLE 1: NUTRIENT COMPOSITION FOR FOODS FOR INFANTS

1	Energy	Not less than 2,500 KJ and not more than 2950KJ per litre of the product ready for consumption with between 35 to 55% of the energy originating from lactose, maltose and dextrin.
2	Protein	Not less than 4.5g and not more than 7g. of protein per MJ or not less than 85% of casein
3	Fat	Not less than 0.7 g per MJ of linoleic acid in the form of glycerides. Total fat contents shall be not less than 10.5g and not more than 14g per MJ
4	Carbohydrates	Not less than 22g and not more than 33g per MJ
5	Moisture	Not more than 5% for infant formula in powder form
6	Choline	Not less than 17mg and not more than 120mg per MJ
7	Vitamins	As indicated in Table 1
8	Minerals	As indicated in Table 2
9	Food additives	As indicated in Table 3

TABLE 2: LIMITS FOR VITAMINS IN FOODS FOR INFANTS

Name of vitamin, per MJ	*Min*	*Max*
Alpha-tocopherol (Vitamin E)*, µg……	1200	12000
Retinol (Vitamin A), µg ……..……..	140	430
Ascorbic acid (Vitamin C), µg …….	2500	170000
Thiamine (Vitamin B1), µg ……...	140	720
Riboflavine (Vitamin B2), µg ……..	190	1190
Nicotinamide, µg ……...	700	3600
Pyridoxine (Vitamin B6), µg ……..……	100	450
Pantothenic acid, µg ……..	960	4780
Folic acid µg …… ……	25	120
Cynocobalamin (Vitamin B12), µg ……	0.25	3.6
Cholecalciferol (Vitamin D3), µg ……	2.5	6.0
Biotin (Vitamin H), µg …….	4.0	24
Vitamin K, µg ……....……..	10.0	65

G.N. 60 (Contd.)

*, Minimum content of tocopherol per gram of linoleic acid; 0.5mg

TABLE 3: LIMITS FOR MINERALS IN FOODS FOR INFANTS

Minerals, per MJ	*Min*	*Max*
Sodium, mg ……..	50	140
Potassium, mg …….…….	140	430
Chloride, mg ……..	120	380
Calcium, mg ……...……...……..	120	350
Phosphorus, mg …….……..	60	240
Magnesium, mg ……	12	36
Iron, mg ……..……..	1	5
Zinc, mg …….……	1.2	3.6
Iodine, µg ……	25	140
Manganese, µg ……..…	2.5	240
Copper, µg …….…….	85	290
Selenium, µg……	2.4	22

TABLE 4: LIMITS OF FOOD ADDITIVES IN FOODS FOR INFANTS

SN	Additive	Maximum level in one litre of the product ready for consumption
Thickeners		
1	Guar gum	1 g in liquid formulas containing hydrolysed protein
2	Carob bean gum (Locust bean gum)	1 g in all types of infant formula
3	Distarch phosphate	5 g singly or in combination in soy-based infant formula only 25 g singly or in combination in hydrolyzed protein- or amino acid based infant formula only
4	Acetylated distarch phosphate	
5	Phosphated distarch phosphate	
6	Hydroxypropyl starch	
*Emulsifiers**		
7	Lecithins	5 g in all types of infant formula
8	Mono- and diglycerides	4 g in all types of infant formula

SN	Additive	Maximum level in one litre of the product ready for consumption
Acidity Regulators		
9	Sodium hydroxide	2 g singly or in combination and within the limits for sodium, potassium and calcium in Table 3 in all types of infant formula
10		
11	Sodium hydrogen carbonate	
12	Sodium carbonate	
13	Potassium hydroxide	
14	Potassium hydrogen carbonate	
15	Potassium carbonate	
16	Calcium hydroxide	
17	Sodium dihydrogen citrate	Limited by Good Manufacturing Practices
18	Trisodium citrate	
19	Potassium citrate	
20	Citric acid	
21	L (+)-Lactic acid	
Antioxidants		
22	Mixed tocopherol concentrate	10 mg in all types of infant formula singly or in combination
23	Ascorbyl palmitate	

*, If more than one of the emulsifiers are added the maximum level for each of them shall be lowered with the relative part as present of the other

G.N. 60 (Contd.)

THIRD SCHEDULE

[Made under regulation 16(c) (ii)]

ESSENTIAL NUTRIENT COMPOSITION AND FOOD ADDITIVES REQUIREMENTS FOR FOLLOW UP FORMULA

TABLE 1: NUTRIENT COMPOSITION FOR FOLLOW UP FORMULA

1	Energy	Not less than 2,500 KJ and not more than 3550KJ per litre of the product ready for consumption
2	Protein	Not less than 7g and not more than 13g. of total protein per MJ provided that at least 85% of the protein quality is equivalent to that of casein
3	Fat	Total fat contents shall be not less than 7g and not more than 14g per MJ. Not less than 0.717 g per MJ of linoleic acid in the form of glycerides
4	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 item 1 of this table.
5	Moisture	Not more than 5% for follow up formula in powder form
6	Vitamins	As indicated in Table 1
7	Minerals	As indicated in Table 2
8.	Food additives	As indicated in Table 3

TABLE 2: LIMITS FOR VITAMINS IN FOLLOW UP FORMULA

Name of vitamin, per MJ	*Min*	*Max*
Alpha-tocopherol (Vitamin E)*, I.U……	1.5	NS
Retinol (Vitamin A), µg ……..……..	180	540
Ascorbic acid (Vitamin C), µg …….	19000	NS
Thiamine (Vitamin B1), µg ……...	100	NS
Riboflavine (Vitamin B2), µg ……..	140	NS
Nicotinamide, µg ……...	600	NS
Pyridoxine (Vitamin B6), µg ……..…	110**	NS
Pantothenic acid, µg ……..	700	NS
Folic acid µg …… …….	10	NS
Cynocobalamin (Vitamin B12), µg ……	0.4	NS
Cholecalciferol (Vitamin D), µg ……	2.5	7.5
Biotin (Vitamin H), µg …….	4.0	NS
Vitamin K, µg ……....……..	10.0	NS

G.N. 60 (Contd.)

Minimum content of tocopherol per gram of linoleic acid; 71.U**,
Formula should contain a minimum of 15mg of Vitamin B6 per gram of protein,
NS, Not specified

TABLE 3: LIMITS FOR MINERALS IN FOLLOW UP FORMULA

Minerals, per MJ	*Min*	*Max*
Sodium, mg ……..	50	210
Potassium, mg …….…….	200	NS
Chloride, mg ……..	140	NS
Calcium, mg ……...……...……..	220	NS
Phosphorus, mg …….……..	140	NS
Magnesium, mg ……	14	NS
Iron, mg ……..…..……..	2.5	5
Zinc, mg ……..……	1.2	NS
Iodine, µg ……	12	NS

TABLE 4: LIMITS OF FOOD ADDITIVES IN FOLLOW UP FORMULA

SN	Additive	Maximum level in one litre of the product ready for consumption
Thickeners		
1	Guar gum	1 g in liquid formulas containing hydrolysed protein
2	Carob bean gum (Locust bean gum)	1 g in all types of follow up formula
3	Distarch phosphate	5 g singly or in combination in soy-based formula only 25 g singly or in combination in hydrolyzed protein- or amino acid based products only
4	Acetylated distarch phosphate	
5	Phosphated distarch phosphate	
5	Acetylated distarch adipate	
6	Carrageenan	0.3 g in regular milk-and soy-based products only 1 g in hydrolysed protein or amino acid based liquid products only
7	Pectin	10 g in all types of follow up formula
Emulsifiers		
8	Lecithins	5 g in all types of follow up formula
9	Mono- and diglycerides	4 g in all types of follow up formula

G.N. 60 (Contd.)

SN	Additive	Maximum level in one litre of the product ready for consumption
Acidity Regulators		
8	Sodium hydroxide	Limited by Good Manufacturing Practices within the limits for sodium, potassium and calcium in Table 2 in all types of infant formula
9	Sodium hydrogen carbonate	
10	Sodium carbonate	
11	Potassium hydroxide	
12	Potassium hydrogen carbonate	
13	Potassium carbonate	
14	Calcium hydroxide	
15	Sodium citrate	
16	Potassium citrate	
17	Lactic acid	Limited by Good Manufacturing Practices
18	Lactic acid producing cultures	
19	Citric acid	
Antioxidants		
20	Mixed tocopherol concentrate	30 mg in all types of follow up formula singly or in combination
21	Alpha-tocopherol	
22	L-Ascorbyl palmitate	50 mg in all types of follow up formula singly or in combination, expressed as ascorbic acid
23	L-Ascorbic acid and its sodium and Calcium salts	
Flavours		
24	Natural fruit Extracts	Limited by Good Manufacturing Practices
25	Vanilla Extract	
26	Ethyl Vanillin	5mg in all types of follow up formula
27	Vanillin	5mg in all types of follow up formula

G.N. 60 (Contd.)

FOURTH SCHEDULE

[Made under regulation 16 (c) (iii)]

ESSENTIAL NUTRIENT COMPOSITION AND FOOD ADDITIVES REQUIREMENTS FOR COMPLEMENTARY FOODS

TABLE 1: NUTRIENT COMPOSITION FOR COMPLEMENTARY FOODS

SN	Characteristic	Products consisting of cereals which are or have to be prepared for consumption with milk or other appropriate nutritious liquids	Cereals with an added high protein ingredient which are or have to be prepared for consumption with water or other appropriate protein free liquids	Pasta which are to be used after cooking in boiling water or other appropriate liquids	Rusks and biscuits which are to be used ether directly or after pulverization with addition of water, milk or other suitable liquids
1	Energy	Not less than 3,300 KJ per Kilogram of the product ready for consumption	Not less than 3,300 KJ per Kilogram of the product ready for consumption	Not less than 3,300 KJ per Kilogram of the product ready for consumption	Not less than 3,300 KJ per Kilogram of the product ready for consumption
2	Protein	The Chemical Index of the added protein shall be equal to at least 80% of the reference protein casein or the Protein Efficiency Ratio of the protein in the mixture shall be equal to at least 70% of that of the reference protein casein			
			Shall not exceed 13g per MJ. The added protein content shall not be less than 4.8g per MJ		Shall not exceed 13g per MJ. In case of biscuits with added protein ingredient, the added protein shall not be less than 3.6 g per MJ.

G.N. 60 (Contd.)

3	Fat	Total fat content shall not exceed 8 g per MJ	Total fat content shall not exceed 11 g per MJ. If the fat content exceeds 8g per MJ, the linoleic acid content shall not be less than 700 mg per MJ and shall not exceed 2850 mg per MJ	Total fat content shall not exceed 11 g per MJ
4	Carbohydrates	If sucrose, fructose, glucose, glucose syrup or honey are added, the amount of added shall not exceed 18 g per MJ of which fructose shall not exceed 9g.	If sucrose, fructose, glucose, glucose syrup or honey are added, the amount of added shall not exceed 12 g per MJ of which fructose shall not exceed 6g	
5	Vitamin B1	Shall not be less than 125µg per MJ		
6	Vitamin A*, as retinol equivalent		Shall not be less than 140 µg and not more than 430 µg per MJ	
7	Vitamin D*		Shall not be less than 2.5 µg and not more than 7.5 µg per MJ	
8	Sodium	Shall not exceed 240 mg per MJ		Shall not exceed 240 mg per MJ
9	Calcium		Shall not be less than 200 mg per MJ	Shall not be less than 120 mg per MJ, for products manufactured with addition of milk
10	Food additives	As indicated in Table 1		

*, These limits are also applicable to other processed cereal based food when Vitamin A or D is added

Table 2: LIMITS OF FOOD ADDITIVES IN COMPLEMENTARY FOODS

SN	Food Additive	Maximum level in 100g of the product ready for consumption
Emulsifiers		
1	Lecithins	1500 mg
2	Mono- and diglycerides	500 mg singly or in combination
3	Acetic and fatty acid esters of glycerol	
4	Lactic and fatty acid esters of glycerol	
5	Citric and fatty acid esters of glycerol	
Acidity Regulators		
6	Sodium hydrogen carbonate	Limited by Good Manufacturing Practices
7	Potassium hydrogen carbonate	
8	Calcium carbonate	
9	L(+) Lactic acid	
10	Citric acid	
11	Acetic acid	
12	Potassium acetates	
13	Sodium acetate	
14	Calcium acetate	
15	Malic acid (DL) – L(+)-form only	
16	Sodium lactate (solution) – L(+)-form only	
17	Potassium lactate (solution) – L(+)-form only	Limited by Good Manufacturing Practices
18	Calcium lactate – L(+)-form only	
19	Monosodium citrate	
20	Trisodium citrate	
21	Monopotassium citrate	
22	Tripotassium citrate	
23	Calcium citrate	
24	Hydrochloric acid	
25	Sodium hydroxide	
26	Potassium hydroxide	
27	Calcium hydroxide	

SN	Additive	Maximum level in one litre of the product ready for consumption
28	Glucono delta-lactone	500 mg singly or in combination
29	L(+)-Tartaric acid – L(+)form only	
30	Mono sodium tartrate	Tartrates as residue in biscuits and rusks
31	Disodium tartrate	
32	Monopotassium tartrate –L(+)form only	
33	Dipotassium tartrate – L(+)form only	
34	Potassium sodium L(+)tartrate L(+)form only	
35	Orthophosphoric acid	Only for pH adjustment 440 mg Singly or in combination as phosphorus
36	Monosodium orthophosphate	
37	Disodium orthophosphate	
38	Trisodium orthophosphate	
39	Monopotassium orthophosphate	
40	Dipotassium orthophosphate	
41	Tripotassium orthophosphate	
42	Monocalcium orthophosphate	
43	Dicalcium orthophosphate	
44	Tricalcium orthophosphate	
Antioxidants		
45	Mixed tocopherols concentrate	300 mg/kg fat or oil basis, Singly or in combination
46	Alpha-tocopherol	
47	L-Ascorbyl palmitate	200 mg/kg fat
48	L-Ascorbic acid	50 mg expressed as ascorbic acid
49	Sodium ascorbate	
50	Potassium ascorbate	
51	Calcium ascorbate	20 mg expressed as ascorbic acid
Raising Agents		
52	Ammonium carbonate	Limited by Good Manufacturing Practices
53	Ammonium hydrogen carbonate	
54	Sodium carbonate	
55	Sodium hydrogen carbonate	
Thickeners		
56	Carob bean gum	1000 mg singly or in combination
57	Guar gum	
58	Gum Arabic	

SN	Additive	Maximum level in one litre of the product ready for consumption
59	Xanthan gum	2000 mg in gluten-free cereal-based foods
60	Pectins (Amidated and Non Amidated)	
61	Oxidized starch	5000 mg Singly or in combination
62	Monostarch phosphate	
63	Distarch phosphate	
64	Phosphated distarch phosphate	
65	Acetylated distarch phosphate	
66	Acetylated distarch adipate	
67	Starch acetate esterified with acetic anhydride	
68	Starch sodium octenyl succinate	
69	Acetylated oxidized starch	
Anticaking Agents		
70	Silicon dioxide (amorphous)	200 mg for dry cereals only

FIFTH SCHEDULE

[Made under regulation 21(3)]

COMPOUNDING OF OFFENCE FORM

1.Particulars of the offender

Name of the offender:……..……..…..……...
Postal address:……..…..……..
Street/Road: …… Plot/House Number:……
Contact person: ……. E-mail:……..……
Telephone Number: ……. Fax Number: ...…….……..….

2. Type of the offence and the penalty

Offence:…….……...…..….
Penalty: …….…….……
…….……..……..……..…..…..
The following product(s)/equipment used to commit the offence/ were seized:

(i)..…… viii)……..
ii)……..… xi) ……..…….
iii)…… x) ……..
iv)…… xi) ……..
v)…… xii)……...……...
vi)……....…… xiii)……..

3. Declaration by the offender

I/ We……..do hereby admit to have committed the offence specified under the paragraph (2) of this schedule, hence without undue influence, commit myself/ ourselves that I am /we are voluntarily willing and accept to pay fine of TZS…….and that, unless by order of the court, no further criminal or as the case may be, civil proceedings shall be taken against myself /ourselves in respect of this offence to which power to compound offence has been exercised.
Full Name:……
Signature:……..
Dated at :……this…….day of……..201….

4. Payment (For official use only)

Amount of fine to be paid:……..
Name and signature of Authorized officer:……..……...

G.N. 60 (Contd.)

Name and signature of cashier:……..……..….
Receipt number:……
Date and stamp:……
NB: Cashier should attach copy of receipt

Dar es Salaam,
7th February, 2013

HUSSEIN A. MWINYI,
Minister for Health and Social Welfare

SCHEDULE

SCHEDULE

SCHEDULE