

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

REGULATIONS

(Made under sections 95 and 122(1) (r))

THE TANZANIA FOOD, DRUGS AND COSMETICS
(CONTROL OF FOOD PROMOTION) REGULATIONS, 2010
PART I
PRELIMINARY PROVISIONS

- Citation 1. These Regulations may be cited as the Tanzania Food, Drugs and Cosmetics (Control of Food Promotion) Regulations, 2010.
- Interpretation 2. In these Regulations, unless the context otherwise requires:-
- “Act” means the Tanzania Food, Drugs and Cosmetics Act;
- “advertisement” means and includes every form of advertising, whether in a publication, or by the display of any notice or by means of any catalogue, price list, letter, whether circular or addressed to a particular person or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting, or television or any other means of communication;
- “Authority” means the Tanzania Food and Drugs Authority or the acronym “TFDA” established by section 4 of the Act;
- “claim” means any message or representation including pictorial, graphic, or symbolic representation, which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, function, nature, production, processing, composition or any other characteristics;
- “comparative claim” means a claim that compares the nutrient ingredient levels and or energy value of two or more foods.
- “food” means any article including food supplement other than drug, cosmetics and tobacco used as food or drink for human consumption and include any substance used in the manufacture or treatment of food;
- “food promotion” means any method of introducing, familiarizing

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- or encouraging a person to use a particular food product;
- "food supplement", "nutritional supplement", "dietary supplement" or "nutraceutical" means a product other than tobacco intended to supplement the diet, and shall include all of the following characteristics-
- (a) contains one or more of the following: vitamins; minerals; herbs; amino acids; essential oils or any combination of any of the above;
 - (b) is intended to be taken orally in the form of tablet, capsule, powder, softgel, gelcap, granules or liquid;
 - (c) is not represented for use as a conventional food or as a sole item of a meal or the diet;
 - (d) is labelled as food supplement;
- "health claim" means any representation that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health, including nutrient function claims and reduction of disease risk claims;
- "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 food product;
- "Manufacturer" means a person or a firm that is engaged in production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, re-packaging and labelling of food;
- "nutrient" means protein, carbohydrate, fat, fibre, vitamins and minerals and substances, which belong to or are components of one of these categories;
- "nutrient function claim" means a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body which may include; "Calcium aids in the development of strong bones and teeth", "Protein helps build and repair body tissues", "Iron is a factor in red blood cell formation", "Vitamin E protects the fat in body tissue from oxidation", "Folic acid contributes to the normal growth of foetus";
- "nutrition claim" means any claim which states, suggests or implies that a food has particular nutrition properties due to-
- (a) the energy (calorific value) it provides, provides at a reduced or increased rate or does not provide, and or
 - (b) the nutrients or other substances it contains, contains in reduced or increased proportions or does not contain;
- "product" for the purpose of these regulations means food.
- "food promotion" means advertising, giving of samples or gift or materials or information or decorations related to a food, the effect of which being to induce supply, purchase and or use of food product;

“promotional material” means any representation concerning the quality of a product conveyed by any means whatever for the purpose of encouraging the usage of a food product;

“reduction of disease risk claim” means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease;

“Sell” or “Sale” means sell by wholesale or retail and include import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorize, direct to allow a sale or prepare or possess for purposes of sale, and barter or exchange supply or dispose of to any person whether for a consideration or otherwise;

“Used as food” means any substance that people take, eat or drink to maintain life and growth.

PART II PROMOTION

3-111 A person shall not promote any food product in a manner that is false, misleading, or deceptive or is likely to create erroneous impression regarding its character, value, quantity, composition, merit or safety as the case may be.

(2) A person shall not use any promotional material unless its content is accurate, informative, up to date and in good taste.

(3) A person shall not use any promotional material to promote any food product unless he applies and be issued with a written approval from the Authority.

(4) The application for a permit to use a promotional material shall be made to the Authority by submitting a dully filled in Application Form for Approval of Promotional Material as set out in the First Schedule to these Regulations.

(5) Every application for a permit to use promotional material shall be accompanied by fees as prescribed in the Tanzania Food Drugs and Cosmetics (Fees and Charges) Regulations, 2005.

(6) An applicant for food promotion which relate to Trade Fairs shall obtain Permit from the Authority.

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(7) Subject to sub regulation 6, the applicant shall submit a dully filled Application Form set out in the Second Schedule to these Regulations accompanied by fees as prescribed in the Tanzania Food, Drugs and Cosmetics (Fees and Charges) Regulations, 2005.

(8) The Authority shall if satisfied that the proposed promotional material complies with the requirements prescribed in these Regulations, issue a Permit for Advertisement with such conditions as it may consider necessary as set out in the Third Schedule to these Regulations.

Prohibited
claims

4. The following claims whether represented in words, pictorial representations, marks or any descriptions are prohibited:-

- (a) claims which make reference to general, non-specific benefits of the nutrient or food for overall good health or well-being;
- (b) claims which make reference to psychological and behavioural functions;
- (c) claims which make reference to slimming or weight control, or to the rate of amount of weight loss which may result from their use or to a reduction in the sense of hunger or an increase in sense of satiety or to the reduction of the available energy from diet;
- (d) claims which make reference to the advice of doctors or other health professionals, or their professional associations, or charities, or suggest that health could be affected by not *consuming the food*;
- (e) claims which refer to organisations, associations and foundations except if the label of the food bears an indication to the effect that the food is suitable for use or manufactured in accordance with the directions of the organisation, association or foundation;
- (f) claims as to the suitability of a food for use in the diagnosis, prevention, alleviation, mitigation, treatment or cure of a disease, disorder, abnormal physical or mental state or particular physiological condition;
- (g) claims stating that any given food will provide an adequate source of all essential nutrients, except in the case of well-defined products for which the Authority has accepted the products to be an adequate source of all essential nutrients;
- (h) claims implying that a balanced diet of ordinary foods cannot supply adequate amounts of all nutrients;
- (i) claims that cannot be substantiated by generally accepted scientific data;
- (j) claims which could give rise to doubt about the safety of

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similar food or which could bring or is likely to bring or exploit fear or distress to individuals or community.

- (2) Health claims shall only be allowed if:-
- (a) accompanied by the information which is truthful and non-misleading to help consumers choose healthy diets;
 - (b) accompanied by a statement indicating the importance of a balanced diet and a healthy lifestyle;
 - (c) show the quality of the food and pattern of consumption required to obtain the claimed beneficial effect;
 - (d) accompanied by an appropriate statement addressed to persons who should avoid using the food;
 - (e) accompanied by a warning not to exceed quantities of the product that may represent a risk to health.

Restriction on
health claims

5.-(1) A person shall not use the words "health" or "healthy" or other words or symbols implying that the food has health-giving properties, or "wholesome" or "nutritious" as part of the name or description of the food.

- (2) Health claims shall only be allowed if:-
- (a) by the information which is truthful and non misleading consumers on choosing healthy diets;
 - (b) by a statement indicating the importance of a balanced diet and a healthy lifestyle;
 - (c) show the quality of the food and pattern of consumption required to obtain the claimed beneficial effect;
 - (d) appropriate statement addressed to persons who should avoid using the food; and
 - (e) a warning not to exceeds quantities of the product that may represent a risk to health.

(3) Beverages that contains more than 1.2% by volume of alcohol shall not bear health claims, nutritional claims,

Conditions for
using nutrition
claims

6.-(1) Any nutrition claim made shall comply with the levels prescribed in the respective schedules as follows:-

- (a) the claim, 'high' or 'rich' when applied in relation to Proteins, dietary fibres, calcium, Iron, vitamin B₁, vitamin B₂, vitamin B₆, vitamin B₁₂, niacin, Pantothenic acid, biotin, vitamin C, vitamin A, vitamin D, vitamin E and Folic acid, shall comply with levels as provided in the Fourth Schedule to these Regulations;
- (b) the claim, 'source of the nutrient or fortified with' a nutrient when applied in relation to Proteins, Dietary

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fibres, Calcium, Iron, vitamin B₁, Niacin, vitamin B₂, vitamin B₆, vitamin B₁₂, vitamin C, vitamin A, vitamin D, vitamin E and Folic acid, Pantothenic acid, shall comply with levels as provided in the Fifth Schedule to these Regulations;

(c) the claim, 'free, zero, or none' when applied in relation to calorie, fat, saturated fatty acids, cholesterol, simple sugars shall comply with levels as set out in the Sixth Schedule;

(d) the claim 'low, less, reduced, or cut off' when applied in relation to energy, fat, saturated fatty acids, cholesterol, simple sugars or sodium shall comply with levels as set out in the Seventh Schedule to these Regulations;

(2) Claims relating to the function of a nutrient in the body are permitted subject to the following conditions-

(a) only those essential nutrients (proteins, carbohydrates, fat, vitamins and minerals) shall be the subject of a nutrient function claim;

(b) the food for which the claim is made shall be a significant source of the nutrient in the diet.

(c) the nutrient function claim shall only be those approved by the Authority;

(d) the claim shall not imply or include any statement to the effect that the nutrient would afford a cure or treatment for or protection from disease.

(3) Where a nutrition claim is made, and where food is by its nature low in or free of the nutrient that is the subject of the claim, the term describing the level of the nutrient shall not immediately precede the name of the food but shall be in the form of a low (naming the nutrient) food or a (naming the nutrient) free food.

(4) Religious claims such as Halal or ritual preparations of food may be claimed provided that the food conforms to the requirement of the appropriate religion or ritual authorities.

Comparative claims

7.-(1) No claim which compares the nutrient level or energy value of two or more similar food shall be made in an advertisement of a food, unless the following conditions are complied with:-

(a) the food being compared should be different versions of the same category food;

(b) the food being compared shall be clearly identified; a statement of the amount of difference in the energy value or nutrient content, expressed as a percentage, and the

identity of the food to which the food is being compared, shall appear in close proximity to the comparative claim:-

- (i) the comparison shall be based on a relative difference of at least 25% in the energy value or nutrient content of an equivalent mass or volume;
- (ii) the comparison shall be based on a relative difference of at least 25% in the energy value or nutrient content, except for micronutrients where a 10% difference in the Nutrient Reference Value shall be acceptable.

- (a) a nutrition claim which compares the quantity of a nutrient or the energy value of a food with foods of the same category shall only be made if the foods being compared are easily identified by the average consumer or clearly indicated. The difference in the quantity of a nutrient or the energy value shall be stated and the comparison shall relate to the same quantity of food;
- (b) comparative nutrition claims shall compare the composition of the food in question with a range of foods of the same category, which do not have a composition, which allows them to bear a claim, including foods of other brands.

Restrictions on advertising

8.-(1) No person shall conduct an advertisement of food in the form of Breast Milk substitute (BMS) and designated product consumable by infants in any form that shall appear misleading.

(2) Advertisements of food product in the form of Breast Milk substitute (BMS) and designated products shall only be advertised upon obtaining the approval of the Authority.

(3) An advertisement of a food product shall not refer to the Act, or any department or official of the Authority.

PART III OFFENCES AND PENALTY

Offence and Penalty

9. Any person who contravenes any provision of these regulations or requirements as indicated in the schedules to these regulations commits an offence and upon conviction is liable to:-

- (a) if such a person is an individual a fine not less than one hundred thousands shillings or to imprisonment for a term not less than two weeks or to both such fine and imprisonment;

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(b) if such a person is a body corporate or association to a fine of not less than one million shillings.

Compounding of offences

10.-(1) Notwithstanding the provisions of regulation 9 the Director General or the Food Inspector acting on his behalf 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 the fine in respect of the offence is committed.

(2) The Director General or an Inspector authorized to act on his behalf before accepting a fine from the person referred under sub regulation (1) shall require such a person to fill in a Compounding Form as set out in the Ninth Schedule.

(3) Subject to the provisions of these regulations authorizing any measures that may be taken pursuant to an order of the court, no further criminal proceedings shall be taken against a person in respect of whom a power to compound offence has been exercised.

PART IV
GENERAL PROVISION

Material used for more than twelve months

11. Materials used for promotion that exceeds twelve months must be re-certified at intervals of not more than 12 Months to ensure that continuous compliance with these Regulations is maintained.

FIRST SCHEDULE

[Made under regulation 3(4)]

TFDA FORM NO.....

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

Tanzania Food & Drugs Auth., Ltd.

APPLICATION FORM FOR APPROVAL OF PROMOTIONAL MATERIALS

NB: Giving false or misleading information is an offence

(All information supplied in this form must be either typed or written in block capital letters)

1. Applicant particulars

Name of Applicant:
Postal address:
.....
Street/RdPlot/House Number.....
Contact person: E-mail:.....
Telephone Number: Fax Number:

2. Sponsor particulars (if different from above)

Name of Sponsor:
Postal address:
.....
Street/RdPlot/House Number.....
Contact person: E-mail:.....
Telephone Number: Fax Number:

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3. Product Particulars

(a) Product Name/s

(b) Nutritional composition

- 1.
- 2.
- 3.
- 4.
- 5.

c) Product registration status by TFDA (please tick appropriate box)

Registered Not Registered

4. Promotional material (please tick appropriate box)

Poster Leaflet Cinematograph Outdoor/Billboard

In/On public Transport Wall painting Magazines/Newspaper

Literature Radio Television Stickers

Others Please specify.....

This promotional material will be used at (mention place) for a duration and time (where appropriate).....

5. This form shall be accompanied by:

A copy of the proposed advert (script, sketch, audio tape, VCD, CD, Video cassette).

Application fee.

6. Applicant Declaration

I, declare that the information contained within this application is true and correct.

Signed Date

Designation Official stamp

FOR OFFICIAL USE ONLY

Fees Receipt No. of

Permit granted/not granted because.....

Permit No. Approved by of

Date

Director General

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SECOND SCHEDULE

(Made under Regulation 3(7))

TFDA FORM NO.....

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

The Tanzania Food and Drugs Authority

APPLICATION FORM FOR TRADE FAIR PERMIT

NB: Giving false or misleading information is an offence

(All information supplied in this form must be either typed or written in block capital letters)

1. Applicant Particulars

Name of applicant:.....	
Address:	
.....	
Contact person:	E mail:
Telephone Number:	Fax Number:

2. Sponsor Particulars (if different from the applicant)

Name of Sponsor:.....	
Address:	
.....	
Contact person:	E mail:
Telephone Number:	Facsimile Number:

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SECOND SCHEDULE

(Made under Regulation 3(7))

TFDA FORM NO.....

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

APPLICATION FORM FOR TRADE FAIR PERMIT

NB: Giving false or misleading information is an offence

(All information supplied in this form must be either typed or written in block capital letters)

1. Applicant Particulars

Name of applicant:	
Address:	
Contact person:	E mail:
Telephone Number:	Fax Number:

2. Sponsor Particulars (if different from the applicant)

Name of Sponsor:	
Address:	
Contact person:	E mail:
Telephone Number:	Faersimile Number:

THIRD SCHEDULE

(Made under Regulation 3(8))

TFDA FORM NO.....

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

TANZANIA FOOD AND DRUGS AUTHORITY

PERMIT FOR TRADE FAIR ADVERTISEMENT

Permit No.....

Permit is hereby granted to M/S.....for advertisement of through, subject to the maintenance of records such as required by the law and it shall not be transferable.

The validity of this permit expires on:.....

Granted by Tanzania Food and Drugs Authority this.....day of.....20.....

.....
DIRECTOR GENERAL

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FOURTH SCHEDULE

[Made under regulation 6(1)(a)]

TFDA FORM NO.....

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

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CLAIMS USING TERMS, HIGH OR RICH

Nutrient	Minimum level		Energy
	Solid	Liquid	
Protein	12.0 g/100g	6 g/100ml	6 mg/100kcal
Dietary fibres	6.0 g/100g	3 g/100ml	3 mg/100kcal
Calcium	210.0 mg/100g	105 mg/100ml	70 mg/100kcal
Iron	3.6 mg/100g	1.8 mg/100ml	1.2 mg/100kcal
Niacin	4.5 mg/100g	2.3 mg/100ml	1.5 mg/100 kcal
Pantothenic acid	1.5 g/100g	4.5 mg/100ml	0.50 mg/100kcal
Biotin	9.0 mg/100g	4.5 mg/100ml	3.0 mg/100kcal
Folic acid	60.0 mg/100g	30 mg/100ml	20 mg/100kcal
Vitamin B ₁	0.30 mg/100g	0.15 mg/100ml	0.10 mg/100kcal
Vitamin B ₂	0.33 mg/100g	0.23 mg/100ml	0.11 mg/100kcal
Vitamin B ₆	0.45 mg/100g	0.23 mg/100ml	0.15 mg/100kcal
Vitamin B ₁₂	0.72 mg/100g	0.36 mg/100ml	0.2 mg/100kcal
Vitamin C	30 mg/100g	15 mg/100ml	10 mg/100kcal
Vitamin A	162 mg/100g	81 mg/100ml	54 mg/100kcal
Vitamin D	0.75 mg/100g	0.38 mg/100ml	0.25 mg/100kcal
Vitamin E	3.0 mg/100g	1.5 mg/100ml	1.0 mg/100kcal

FIFTH SCHEDULE

[Made under regulation 6(1)(b)]

TFDA FORM NO.....

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

Tanzania Food & Drugs Authority

**CLAIMS USING TERM CONTAINING, SOURCE THE NUTRIENT
OF OR FORTIFIED WITH A NUTRIENT**

Nutrient	Minimum level		
	Solid	Liquid	Energy
Protein	5 mg/100 g	3 mg/100ml	3 mg/100kcal
Dietary fibre	3 mg/100 g	1.5 mg/100ml	1.5 mg/100kcal
Calcium	105 mg/100 g	53 mg/100 ml	35 mg/100 kcal
Iron	1.8 mg/100 g	0.9 mg/100 ml	0.6 mg/100 kcal
Niacin	2.3 mg/100 g	1.1 mg/100 ml	0.8 mg/100 kcal
Pantothenic acid	0.75 mg/100 g	0.38 mg/100 ml	0.25 mg/100 kcal
Biotin	mg/100 g	2.3mg/100 ml	1.5 mg/100 kcal
Folic acid	30 mg/100 g	15 mg/100 ml	10 mg/100 kcal
Vitamin B1	0.15 mg/100 g	0.08 mg/100 ml	0.05 mg/100 kcal
Vitamin B2	0.17 mg/100 g	0.09 mg/100 ml	0.06 mg/100 kcal
Vitamin B6	0.23 mg/100 g	0.11 mg/100 ml	0.08 mg/100 kcal
Vitamin B12	0.36 mg/100 g	0.18 mg/100 ml	0.12 mg/100 kcal
Vitamin C	15 mg/100 g	8 mg/100 ml	5 mg/100 kcal
Vitamin A	81 mg/100g	41 mg/100 ml	27 mg/100 kcal
Vitamin D	0.38 mg/100 g	0.19 mg/100 ml	0.13 mg/100 kcal
Vitamin E	1.5 mg/100 g	0.8 mg/100 ml	0.5 mg/100 kcal

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SIXTH SCHEDULE

[Made under regulation 6(1)(c)]

TFDA FORM NO.....

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

CLAIMS USING TERMS FREE, ZERO OR NONE

Item	Maximum level
Energy	4 kcal/100 ml liquid
Fat	0.5 mg/100 mg
Saturated fatty acid	0.1 mg/100 (solids) or 0.1/100ml (liquids)
Cholesterol	5 mg/100 g (solids) or 5 mg/100 ml (liquids)
	1.5 mg saturated fatty acid/100 mg (solid) 0.75 g saturated fatty acid/100 ml (liquid), and Energy derived from saturated fatty acid: and 10% of saturated fat
Sugars	0.5 mg/100 mg (solids) or 0.5 mg /100 ml (liquids)
Sodium	5 mg/100 mg(solids) or 100 ml
Alcohol	0.5% volume by volume

SEVENTH SCHEDULE

[Made under regulation 6(1)(d)]

TFDA FORM NO.

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

CLAIMS USING TERMS LOW, LESS, REDUCED, OR CUT OFF

Item	Maximum level.
Energy	40 kcal (170kJ)/100 g (solid) 20 kcal (80kJ)/100 ml (Liquid)
Total fat	3 g/100 g (Solid) 1.5 g/100 ml (Liquid)
Saturated fatty acid	1.5 g/100 g (solid) 0.75 g/100 ml (Liquid) and Energy derived from saturated fatty acid and 10% of the total energy
Cholesterol	20mg/100 g (solid) 10mg/100 ml (Liquid) 1.5 g saturated fatty acid/100 g (solid) 0.75 g saturated fatty acid/100 ml (liquid), and Energy derived from saturated fatty acid: 10% of the total energy
Simple sugars	0.5 g/100 g (solid) 0.5g/100 ml (Liquid)
Sodium	120mg/100 g

Note: This requirement does not apply to a food for which the single serving size is 15g or less and in which saturated fatty acid accounts for 15% or less of the total fatty acid.