

**THE TANZANIA FOOD, DRUGS AND COSMETICS
(FOOD FORTIFICATION) REGULATIONS, 2011**

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

REGULATIONS

(Made under section 29 (1) and (2) (a))

THE TANZANIA FOOD, DRUGS AND COSMETICS (FOOD FORTIFICATION)
REGULATION, 2011

ARRANGEMENT OF REGULATIONS

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Tanzania Food, Drugs, and Cosmetics (Food Fortification)

GN No. 205 (contd.)

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

(Made under section 29 (1) and (2) (a))

THE TANZANIA FOOD, DRUGS AND COSMETICS (FOOD FORTIFICATION)
REGULATIONS, 2011

- Citation 1. These regulations may be cited as the Tanzania Food, Drugs and Cosmetics (Food Fortification) Regulations, 2011.
- Application 2. Save for small-scale and micro-scale manufacturers, these Regulations shall apply in areas in which the Act applies including all food imported, domestically manufactured or sold and fortified for human consumption.
- Interpretation
Cap. 219 In these regulations, unless the context otherwise requires:
“Act” means the Tanzania Food, Drugs and Cosmetics Act;
“Authority” means the Tanzania Food and Drugs Authority known in its acronym as “TFDA” established by section 4 of the Act;
“authorised officer” means an officer appointed by the Authority or otherwise authorized to carry out duties under section 105 of the Act;
“Director General” means the Chief Executive Officer of the Tanzania Food and Drugs Authority appointed by section 8(1) of this Act;
“edible oil” means edible vegetable oils, fats or animal fat for sale for human consumption;
“food” means an 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;
“fortificant” means a micronutrient or a micronutrient compound for use in fortification of food;
“food vehicle” means wheat flour, maize flour and edible oils;
“fortification” means the addition of one or more micronutrient(s) to food for the purpose of preventing or correcting a deficiency of one or more micronutrient(s) in the population or in a specific group of the population;
“fortified food” means food into which one or more micronutrient(s) have been added in accordance with these regulations;
“international standards” means any standard developed outside Tanzania

mainland applicable in fortificants or pre mix used in fortification of food under these Regulations;

“Label” means a 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 engaged in production, preparation, processing, fortification, compounding, formulating, filling, refining, transformation, packing, packaging, or re-packaging of food;

“micronutrient” means a natural or synthesized vitamin, mineral, or trace element that is essential for normal growth, development and maintenance of health;

“micronutrient compound” means chemical form of a natural or synthesized vitamin, mineral or trace element that is essential for normal growth, development and maintenance of health;

“minister” means the Minister for the time being responsible for health;

“package” means any box, packet or any other article in which one or more primary containers of products are to be enclosed;

“person” means an individual, company, corporation, firm, partnership, proprietorship, organization, agency, association, facility or any other entity;

“pre mix” means a blend of food fortificants and specific food vehicle for use in fortification of food;

“sale or sell” means sell by wholesale or retail and include import, offer, donate, advertise, keep, expose, display, transmit, consign, convey or deliver for sale, authorize, or direct or 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.

4. No person shall be authorised to manufacture for sale, import or expose for sale any food regulated under these regulations unless that food meets the minimum requirements for fortified food as prescribed in the First Schedule to these regulations or the existing national standard for fortified foods.

Restriction on manufacture, import and sale of unfortified food

5. The Minister may at any time vary, amend or revoke any schedule prescribed in these Regulations.

Amendment of schedules

6. The Authority may, after being satisfied that there is emergency or food shortage, and upon application in the form prescribed in the Second Schedule to these regulations, grant permit for importation, manufacturing or distribution of unfortified food.

Exemption of fortification

7.-(1) In the manufacture of fortified food, manufacturer shall use fortificants or pre mix that complies with the national standard or international standard for such fortificant or pre mix or as may be approved by the Authority from time to time.

Safety and Quality assurance

(2) Manufacturer of a fortified food shall develop, maintain and routinely follow procedures for safety and quality assurance throughout the manufacturing process to ensure that the final product complies with these regulations and any other regulations made under the Act.

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Labelling 8. In addition to the labelling requirements set by the Tanzania Food, Drugs and Cosmetics (Food Labelling) Regulations in force, fortified food shall be conspicuously labelled including the following;

- (a) the word fortified immediately prior to or after the common name of the food.
- (b) specific name and amount of each micronutrient added into the food, in milligram per kilogram in case of solids or milligram per litre in case of liquids;
- (c) the label for fortified food shall bear food fortification logo as prescribed in the third schedule to these regulations.

Use of
food
fortifica-
tion logo

9.-(1) No person shall use the food fortification logo set in the Third Schedule to these regulations for labelling of fortified food unless that food is licensed by the Authority to be fortified.

(2) The Authority may suspend or revoke certificate for food fortification upon satisfaction that the requirements for manufacture of fortified food using applicable checklist in use at that particular time are not complied with.

Offence
and
penalty

10. Any person who contravenes any provision of these Regulations commits an offence under the Act.

Com-
pounding
of
offences

11.-(1) The Director General or any officer authorised by him, may compound any offence committed under these regulations by accepting the fine set in the Act upon admission of the commission of offence and that such person accepts to pay the fine.

(2) The Director General or any officer authorised by him, before accepting any fine prescribed under the Act shall require such a person to fill in a compounding form as provided in the Fourth Schedule to these regulations.

(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 by the Authority against a person in respect of whom a power to compound offence has been exercised.

12. Notwithstanding any provision of these Regulations, any permit, licence, order or any other documents issued by the Authority for registered product or to manufacture, import, distribute, supply and sell of the food vehicles under these regulations shall be deemed revoked, rescinded or suspended after the coming into force of these Regulations. Saving

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FORM NO.....

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE



FIRST SCHEDULE
(Made under section 4)
MINIMUM REQUIREMENT FOR FORTIFIED FOOD

Food vehicle	Nutrient	Fortificant compound	Specifications	
			Minimum	Maximum
Wheat flour		Sodium iron EDTA		
	Iron	Zinc oxide	30 mg/kg	50 mg/kg
	Zinc	Vitamin B12	30 mg/kg	50 mg/kg
	Vitamin B12	Folic acid	0.0005 mg/kg	0.025 mg/kg
	Folate		1 mg/kg	5 mg/kg
Maize flour	Iron	Sodium iron EDTA	5 mg/kg	25 mg/kg
	Zinc	Zinc oxide	20 mg/kg	25 mg/kg
	Vitamin B12	Vitamin B12	0.0002 mg/kg	0.01 mg/kg
	Folate	Folic acid	0.5 mg/kg	2.5 mg/kg
Edible fats and oils	Vitamin A	Retiyl palmitate	6 mg/L	28 mg/L
	Vitamin E	Alpha tocopherol	65 mg/L	190 mg/L

FORM NO.....

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE



SECOND SCHEDULE
(Made under section 6)

APPLICATION FORM MANUFACTURE/ IMPORT OF UNFORTIFIED FOOD
(A separate form should be filled for each product)

1. Application particulars

Name of Application:
Postal address:
.....
Physical address:
.....
Telephone Number: Fax Number
Email:
Website:
Application licence/ registration number

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2. Product Particulars

(a) Product Name:

(b) Manufacturer particulars

Postal address:

Physical address:

.....

Telephone Number: Fax Number

Country of origin:

Manufacture date:

Expiry date:.....:.....

Quantity:kg/metric tonne.....

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

Registered [] Not Registered []

3. Reason for application for exemption of fortification (Tick whatever is applicable)

[] to address an emergency situation in the food supply as approved by the Minister responsible for food security.

[] Deficit in supply of the food fortificants needed for fortification of the food as approved by the public Institution responsible for nutrition.

[] Other (specify):

4. Applicant Declaration

I,
declare that the information contained within this application is true and correct.
Signed: Date:
Designation:
Official stamp:

5. FOR OFFICIAL USE ONLY

Permit granted to import/manufacture unfortified

.....

Reasons:

Permit No: issued on (date):

Approved by (official title):

Name:

Signature:

Official stamp:

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THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE



THIRD SCHEDULE
(Made under Regulation 9)

FOOD FORTIFICATION LOGO



THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE



FOURTH SCHEDULE
(made under Regulation 11(2))

COMPOUNDING 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 products (s)/equipment used to commit the offence/ were seized

(i).....	(viii).....
(ii).....	(ix).....
(iii).....	(x).....
(iv).....	(xi).....
(v).....	(xii).....
(vi).....	(xiii).....
(vii).....	(xiv).....

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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:.....

Name and signature of cashier:.....

Receipt number:.....

Date and stamp:.....

NB: Cashier should attach copy of receipt

Dar es Salaam,
27th June, 2011

HON. HADJI H. MPONDA (MP.),
Minister for Health and Social Welfare