THE TANZANIA FOOD, DRUGS AND COSMETICS ACT

(CAP. 219)

REGULATIONS

(Made under section 28 and 122 (1) (m))

THE TANZANIA FOOD, DRUGS AND COSMETICS (REGISTRATION OF FOODS) REGULATIONS, 2011

PART I
PRELIMINARY PROVISIONS

Citation and commencement

1. These Regulations may be cited as the Tanzania Food, Drugs and Cosmetics (Registration of Food) Regulations, 2011 and shall come into operation on the date of publication.

Application and scope

2. These Regulations shall apply to registration of pre-packaged food and control of non pre-packaged food in Tanzania Mainland.

Interpretation Cap. 219

3. In these Regulations unless the context otherwise requires:–

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

"applicant" means a person or company importing or locally manufacturing food product or their representatives applying for registration or notification of food;

"approve" or "approval" means official consent by the Authority as an acceptance of a food product or practices related to that food to circulate in the Tanzanian market;

"authority" means the Tanzania Food and Drugs Authority or the acronym "TFDA" established by section 4 of the Act;

"brand name" means a trade name for the Food;

"certificate of Good Manufacturing Practices" means a certificate or warranty accompanying an application for registration of food to be imported into Tanzania issued by competent authority;

"Codex" means the Codex Alimentarius issued by the Codex Almentarius Commission responsible for execution of the joint FAO or WHO food standards programme;

"competent Authority" means institution responsible for food safety control recognized by the government of the country of origin;

"common name" means any name by which a food is commonly known;

"composition of food" means names and proportions of ingredients contained in the food;

"container" means a bottle, jar, box, packet, sachet, or other receptacle which contains and has direct contact with food, and where any such receptacle is or is to be contained in another receptacle, includes the former but does not include the latter receptable;

"country of origin" means a country in which the food has been manufactured or produced or dispatched from;

"Director General" means the Chief Executive of the Tanzania Food and Drugs Authority appointed under section 8 (1) of the Act;

"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;

"food additive" means any substance not normally consumed as food by itself and not normally used as a typical ingredient of the food as prescribed in the Food Additives Regulations, in the schedule of permissible food additives prescribed in the national standard TZS 115 or as approved by TFDA. The term does not include substances added to food for maintaining or improving nutritional qualities;

"food donation, food for emergency or food aid" means food grant not meant for commercial purposes;

"food for special occasion" means food occasionally manufactured or imported for special purposes and includes small quantities of food items carried by passengers for personal use;

"food product registration" means official recognition or approval by Authority of food product to be marketed or distributed for human consumption;

"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 concentrated source of one or more of the following: vitamins; minerals; amino acids; assential fatty acids; natural substances of plant or animal origin; enzymes; substances with nutritional or physiological function or contains any combination of any of these;

(b) is intended to be taken orally in the form of tablet, capsule, powder, soft gel, gel cap, granules or liquid;

(c) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(d) is labelled as food supplement.

"Good Manufacturing Practices", or "the acronym GMP", means measures or practices undertaken to ensure that the food product produced, manufactured or processed is of good quality and safe for human consumption;

"Hazards Analysis Critical Control Points", or "the acronym HACCP", means a system, which identifies, evaluates and controls hazards which are significant for food safety along the food chain;

"ingredient" means any substance including a food additive, used in the manufacture or preparation of food excluding processing aid;

"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;

"manufacturer" means all operations involved in the production of food from one or more ingredients and includes, preparation, processing, filling, transforming, packaging, and repackaging and labelling of food;

"manufacturer" means a person that is engaged in the manufacture of food;

"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;

"non-pre-packaged food" means food not pre-packaged;

"occasional foods" means food prepared or imported for special occasions including emergencies;

"perishable food" means pre-packaged or non pre-packaged food in which the shelf life do not exceed thirty days;

"pre-packaged food" means food that is processed to extend its shelf life, packaged, labelled, and complying with specified standards ready for offer to the consumer and includes food supplements;

"product variant" means a similar product manufactured by the same manufacturing plant using the same ingredient(s) at the same levels but different in food additive or type of packaging materials;

"registrant" means a person whose food product is registered;

"registration certificate" means an instrument for official approval of food for circulation in the market;

"registration" means an official approval of the food product to be marketed or distributed in Tanzania;

"Sale or sell" means sell by wholesale or retail and include import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorise, direct or allow a sale or prepare or process for purpose of sale, and barter or exchange supply or dispose of to any person whether for a consideration or otherwise.

PART II
REGISTRATION OF PREPACKAGED FOOD

Restriction for sale of unregistered food products

4. Save for emergency food, food donations and occasional foods, no person shall sell, manufacture, import or export, grant, distribute, provide as gift or offer for sale any pre-packaged food unless it is registered by the Authority.

Application for registration of food products

5.-(1) Every applicant who intends to register for sell of any pre-packaged food in Tanzania shall submit a dully filled application form provided for in the first Schedule to these Regulations.

(2) Applications for registration of prepackaged food may either be made by the local manufacturer, importer or their recognized representatives.

(3) The application for registration of prepackaged food shall be in forms prescribed in the First Schedule to these Regulations depending on the category of the pre-packaged food product.

4. The application made under sub regulation 3 shall be accompanied by:

(a) sample of the food;

(b) certificate of Environmental Impact Assessments (EIA) in case of Genetically Modified Food or product derived thereof;

(c) relevant non-refundable fees as prescribed under the Fees and Charges regulations made under the Act; and

(d) any other relevant information relating to the food.

(5) A sample of the food shall be—

(a) in a size that is enough to enable evaluation and analysis of the product as per tests prescribed in the National Standard or in case there is no National Standard, Codex Standard.

(b) in case of–

(i) products in packaging units of not more than 5kg or litres, five units of sample submitted to the Authority;

(ii) products marketed in packaging unit exceeding 5kg or litres five units each of at least 0.5 Kilograms or litres shall be drawn and submitted to the Authority;

(6) The applicant shall submit a separate application for each product.

(7) The Authority may, from time to time, require the applicant to submit other information in addition to the requirements prescribed under these Regulations.

(8) No information related to the food or any applicant's business submitted to the Authority for registration purposes shall without written consent of the applicant be disclosed to any other person.

Account-ability of the applicant

6. The applicant shall be accountable for the food product and all information supplied in support of his application for registration of the product and alteration thereof.

Category of food products

7.–(1) For purposes of registration of pre-packaged food, there shall be categories of food prescribed by the Authority in the guidelines for registration of food depending on the respective levels of risk on its safety.

(2) The list of foods in each category may vary from time to time depending upon the risk on its safety as determined and prescribed by the Authority.

Conditions for acceptance of applications

8. An application for registration shall not be admitted unless it is accompanied with:

(a) dully filled application form;

(b) respective samples;

(c) verification of payment of prescribed fees;

(d) relevant supportive information as required by the application form in the First Schedule to these Regulations.

Evaluation of food products

9.–(1) The Authority shall, upon being satisfied that the application complies with the requirement under these Regulations, carry out evaluation of the food products for satisfaction of compliance with safety and quality requirements.

(2) The Authority may, during the evaluation of the food product, require the applicant to submit additional samples, documents, information or clarification as the case may be.

(3) Where the Authority requires additional samples, documents, information or clarification pursuant to sub-regulation (2), the Authority shall hold the processing of the application until time when the applicant complies with requirement.

(4) Where the applicant fails to submit or cause to be submitted the additional requirement pursuant to sub regulation (2) within the period of four months without reasonable cause, the application shall be rendered invalid.

(5) The applicant whose application has been invalidated under this regulation may submit another application which shall be considered as a new application.

Conditions for grant of food registration certificate

10. The Authority shall grant food registration certificate as prescribed under the Third Schedule if it is satisfied that–

(a) the food intended to be registered in Tanzania complies with safety and quality requirements;

(b) in case of imported food supplements and infant formulae, follow up formulae and formulae for special medical purposes for infants their repective manufacturing plants shall be inspected prior to grant of registration; or

(c) any registered food product, intended for manufacturing or importation shall be granted permits, subject to fulfilment of specified requirements in relation to manufacturing or importation of such food.

Issuance of registration certificate

11. The Authority may–

(a) after being satisfied that the food product complies with the requirements prescribed in these regulations, grant certificate of registration prescribed under the Third Schedule which shall be valid for a period of five years;

(b) enter the particulars of the food product into a register which shall be kept with the Authority;

(c) in case of application for renewal of certificate of registration under sub regulation; and

(d) the applicant shall apply to the Authority within sixty days before expiry of its validity.

Renewal of certificate

12. Any certificate of registration may be renewed upon submission of application to the Authority as provided for under the First Schedule.

Retention of food in the register

13. Every registration holder shall, in addition to the fee related to registration, pay annual retention fee per product per year for the remaining two years for each product and registration certificate.

PART III
NON PRE-PACKAGED FOOD

Exemption of registration for non pre-packaged foods

14.-(1) Without prejudice to the generality of these regulations non pre-packaged food shall be excluded from being granted registration certificate under these Regulations.

(2) For purposes of these Regulations non pre-packaged foods shall refer to all farm food produce and perishable foods as categorized in the guidelines for registration of food.

(3) Any person dealing with non pre-packaged food shall observe all safety parameters in accordance with the Food Hygiene Regulations that may be in force and are recognized under the Act.

(4) In case of import and export of non pre-packaged food, all permits shall be granted by the Authority.

(5) The permit for importation and manufacturing of non pre-packaged food shall be granted after compliance with the Food Hygiene Regulations that may be in force and are recognized under the Act.

(6) The Authority shall from time to time carry out inspection and monitoring of—

(a) compliance with good hygienic practices;

(b) levels of physical, chemical and microbiological contamints in food and where necessary institute appropriate intervention.

(7) Provision of education and sensitization for compliance and enhancing human health protection.

PART IV
GENERAL PROVISIONS

Exemption from registration of donation, occasional and emergency foods

15.-(1) Without prejudice to the generality of these regulations non pre-packaged food shall be excluded from being granted registration certificate under these Regulations.

(2) The Authority shall grant permit for importation of donation, special occasion or emergency food in accordance with the importation and exportation of food regulations made under the Act.

(3) All persons intending to obtain permit to import food for donation, special occasion food or food for emergency shall provide to the Authority-

(a) food samples for safety evaluation;

(b) proof that the food is for donation, emergency or special occasion; or

(c) proof of safe handling.

(4) The permit for importation of donation, special occasion food or food for emergency shall be granted upon satisfaction that such food is fit for human consumption.

(5) The dealers of these products shall avoid any form of contamination, maintain good hygienic conditions in handling the foods during, distribution, transportation and storage.

Duties of the registrant manufacturer, importer and their representatives

16. It shall be the duty of the registrant, manufacturer, importer or their representative to–

(a) monitor the food product in the market and inform theAuthority immediately after the detection of any problem endangering public health; or

(b) effect the food product recalls whenever necessary or in compliance with any lawful order.

Notification of change

17. If for any reason the certificate holder changes any matter related to a registered food product such as change of composition, packaging, labelling or any other change shall, before marketing the changed product–

(a) submit an application for alteration with reasons for such change and sample of the changed product;

(b) effect payment of alteration fee as provided for under the Fees and Charges Regulations made under the Act; or

(c) obtain approval in writings from the Authority.

Languages

18. All the submitted application information, documents shall be originals or certified copies and communication shall be made in English or Kiswahili or both.

Refusal or revocation of registration

19. The Authority may refuse, suspend, revoke registration of any food or amend conditions subject to which such food was registered whenever it is deemed that such deed shall control the safety of food and protect consumer from any injury, harm, peril or health risk that may likely arise or have been foreseen.

Termination of food products registration

20. Food products registation shall be terminated by--

(a) non-renewal of registration;

(b) non payment of annual retention fees;

(c) notice in writing issued by the registration holder to the Authority on the intention to withdraw from dealing with the product; or

(d) non compliance with the set standards or any lawful order including but not limited to revocation, suspension or cancellation.

Requirements for labelling of foods

21. Every pre-packaged food product shall be labelled in accordance with Food Labelling Regulations in force.

Appeal

22.-(1) Any person aggrieved by any decision of the Authority in relation to registration may, within 60 days appeal to the Minister.

(2) An appeal may be lodged to the Minister in respect of any refusal of the Authority to grant, renew or revoke registration of food provided under this regulation.

(3) The Minister may for any good reason extend time for the lodging of an appeal.

(4) In determining an appeal under this regulation the Minister may-

(a) form an expert committee to advise him on the subject matter of an appeal;

(b) dismiss the appeal;

(c) require the Authority to issue registration or approve notification;

(d) require the Authority to revise its previous decision;

(e) allow the appeal; or

(f) order a person to make a fresh application for registration of food to the Authority.

(5) The Authority shall give effect to any direction given by the Minister.

Administrative review

23. Without prejudice to the appeal remedy the aggrieved person may apply for review of the decision to the Authority prior to the appeal mechanism provided under these Regulations.

Application of other regulations made under the Act

24. These Regulations, including provision for fees of retention of food product shall be read *mutatis mutandis* with other regulations made under the Act.

Fees and Charges

GN No. 431 of 2005

25.-(1) Every application made by the applicant under these regulations shall be accompanied by the payment of fees and charges as prescribed by the Fees and Charges Regulations.

(2) Product variant shall be charged alteration fees as the Regulations for fees and charges in force, may require from time to time.

Penalty

26. Any person who contravenes any provision of these regulations commits an offence and upon convition shall be liable to such fine or imprisonment as provided by the Act.

Compounding of offences

27.-(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.

FIRST SCHEDULES

APPLICATION FORM FOR REGISTRATION OF FOODS

Made under regulation 5(1)

1.0 Particulars of product:

1.1 Brand Name: .....

1.2 Common name: .....

1.3 Brief description of the physical characteristics of the food (form, colour etc):

.....

.....

1.4 Brief description of the use of the food (for direct human consumption/food raw material): .....

1.5 Intended end user (infants, young children, pregnant women, immune compromised, old age, diabetic, general population. State any other conditions or contraindications if any) .....

.....

.....

1.6 Type of materials for the packaging container and liner if any .....

.....

.....

1.7 Type of materials for cap/crown/closure and liner if any .....

.....

.....

1.8 Type of seal (temper proof/non temper proof) .....

1.9 Retail packaging unit in weight or volume: .....

1.10 Shelf life: .....

1.11 Shelf life after opening of container: .....

1.12 Instruction for use: .....

1.13 Recommended storage conditions before and after opening .....

.....

1.14 Attach a scientific description on how the shelf life was established.

2.0 Particulars of applicant

2.1 Name (company/person): .....

name of the country where the company was incorporated ... .

.....

.....

2.2 Physical address (plot/block No./street/village/district/region): .....

.....

.....

2.3 Postal Address: .....

Physical address (country, town/city, street) .....

.....

2.4 Telephone: .....

2.5 Fax: .....

2.6 E-Mail: .....

2.7 Name of local food manufacturer, or importer: .....

3.0 Particulars of manufacturer

3.1 Name (company/person): .....

Name of the country where the company was incorporated .....

.....

3.2 Postal Address: .....

3.3 Physical address (country, town/city, street): .....

.....

3.4 Phone: .....

3.5 Fax: .....

3.6 E-Mail: .....

4.0 In case of imported food provide the following:

4.1 Product health certificate from competent authority; and

4.2 Document from relevant recognized organization indicating that the manufacturing facility complies with GMP, HACCP or other quality assuarance systems.

4.3 Documentary evidence indicating that the product has been approved in the country of origin or country of dispatch.

5.0 Ingredients used

List ingredient in descending order of proportion quantities per unit of measurement of the product and reason of inclusion.

5.1 Main ingredients

S/N	Name	Proportion (e.g. %, ml/L, ml/kg units)

5.2 Food additives

S/N	Name (Specific, common, chemical, technical) or E-number	Levels (e.g. %, ml/L or mg/kg, units	Purpose of Use

6.0 Verification by the applicant

I, ...

The ..... (position in the company) and a dully

authorised representatibve of .....

do hereby certify that all the information filled in this form and all the accompanying

documents are true and correct to the best of my knowledge and confirm that the information referred to in this application is available for proof.

Signature: .....

Date: .....

Official Stamp/Seal: .....

For official use only

Name of receiving officer: .....

Date: .....

SECOND SCHEDULES

CERTIFICATE FOR PRE-PACKAGED FOOD REGISTRATION

(Made under regulation 10)

This is to certify that the food product described below has been registered in Tanzania subject to conditions indicated.

Common name: .....

Brand name: .....

Product Registration Number: .....

Name and address of Registrant: .....

.....

Name and address of manufacturer:

.....

This certificate expires on: .....

Date of registration: .....

Name: .....

Signature and Seal: .....

Designation: Director General

CONDITIONS

1. This certificate shall apply to the product for which it is issued.

2. This certificate shall cease immediately if the registrant contravenes any conditions upon which it was issued.

3. This certificate can be revoked, suspended, cancelled, or cease to operate immediately after the expiry of time.

THIRD SCHEDULES

COMPOUNDING OF OFFENCE FORM

(Made under regulation 27)

1. Particulars of the offender:

Name of the person/Company .....

Postal address: .....

Street/Rd .....Plot/House Number.....

Contact person: ..... E-mail: .....

Telephone Number: ..... Fax Number: .....

2. Type of the offence and the penalty

1. Offence: .....
2. Penalty: .....
.....

3. The following product(s) equipments used to commit the offence/were seized

1. .....
2. .....
3. .....
4. .....
5. .....
6. .....
7. .....
8. .....
9. .....
10. .....
11. .....
12. .....
13. .....
14. .....

GOVERNMENT NOTICE No. 208 published on 22/7/2011

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

ORDER

(Made under Section 77(1))

THE TANZANIA FOOD, DRUGS AND COSMETICS (DECLARATION OF SUBSTANCES TO BE TREATED AS MEDICINES) ORDER, 2011

WHEREAS, the Minister may upon advise of the Director General by order in the *Gazette*, declare a list of substances which shall be treated as medicines for purposes of control of safety and quality; and

WHEREAS, I am satisfied by the advice of the Director General that the substances used in salt iodation and fortification of food be treated as medicine.

NOW THEREFORE, I Hadji H. Mponda the Minister for Health and Social Welfare, under the powers granted to me under section 77(1) of the Tanzania Food, Drugs and Cosmetics, Cap. 219 do hereby declare as follows:

Citation

1. This order shall be cited as The Tanzania Food, Drugs and Cosmetics (Declaration of Substances to be Treated as Medicine) Order, 2011.

Substances specified as treated medicine

2. All substances specified herein the Schedule shall be treated as Medicines for purposes of iodation of salt and food fortification in Tanzania Mainland.

SCHEDULES

FOOD FORTIFICANT COMPOUND

1. Vitamin A (Retinly palmitate)
2. Vitamin B_{12}
3. Folic acid
4. Zinc oxide
5. Sodium iron (EDTA)
6. A tocopherol
7. Potassium iodate

Dar es Salaam,
27th June, 2011

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