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TANZANIA FOOD AND DRUGS AUTHORITY

GUIDELINES FOR APPLICATION FOR REGISTRATION OF PRE-PACKAGED FOOD IN TANZANIA

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ABBREVIATIONS

1.	FAO	-	Food and Agriculture Organization
2.	GMP	-	Good Manufacturing Practices
3.	HACCP	-	Hazard Analysis Critical Control Points
6.	TFDA	-	Tanzania Food and Drugs Authority
7.	TFDCA	-	Tanzania Food, Drugs and Cosmetics Act
8.	WHO	-	World Health Organization

ACKNOWLEDGEMENTS

This is the fourth revision of the Guidelines for Application for Registration of Prepackaged Food in Tanzania. The Tanzania Food and Drugs Authority (TFDA) is highly indebted to the staff who worked tirelessly to formulate the first, second and third revision of the Guidelines which form the basis for this revision. In particular, the Authority is thankful to Ms. Gwantwa Samson, Jasson Kyaruzi, Francis Mapunda, Shanel Kavishe, Mariam Syikilili and Mary Mbwambo for incorporating new ideas in this edition and making it more useful to applicants of food registration. All the other staff, the TFDA management and stakeholders who in one way or another contributed to development of these guidelines, are highly appreciated. I thank them all.

R. N. Wigenge
DIRECTOR FOR FOOD SAFETY

FOREWORD

TFDA is a regulatory body which is mandated among other things to protect consumers against health hazards associated with food.

One of the means for achieving this goal is subjecting pre-packaged food to evaluation to ascertain their compliance with set standards of quality and safety prior to authorizing their sale in Tanzania. Pre-packaged food that passes the pre-market evaluation is registered and registration certificate issued as evidence that it may be allowed for sale in Tanzania.

In 2004, TFDA formulated the first guidelines for application for registration of pre-packaged food in Tanzania. After two years of implementation of the Guidelines, in 2006, the Authority revised the provisions that relate to fees and charges in order to address administrative changes caused by commencement of the Fees and Charges regulations made under the Tanzania Food, Drugs and Cosmetics Act, Cap 219.

Experience gained in the implementing the first (in the year 2006), second (2009) and third revision (in the year 2012) necessitated the development of this fourth revision of the guidelines. The aim being to address the challenges including implementation the TFDA Client Service Charter, addressing various stakeholders' opinions regarding food registration process, and implementation of various regulations made under the Act.

It is our hope that applicants will find the document easier to follow and be encouraged to apply for registration of the their products, so as to comply with provisions of the Tanzania, Food, drugs and Cosmetics Act, Cap. 219 and relevant regulations.

It is expected that evaluation for safety of food products will not only be thorough but also faster so effectively protecting consumers and at the same time promoting business and national economy as a whole.

Hiiti B. Sillo
DIRECTOR GENERAL

CHAPTER I

INTRODUCTION

Section 28 of the Tanzania Food, Drugs and Cosmetics Act, Cap 219, prohibits manufacture, sell, distribution, importation, or exposure for sale of any pre-packaged food unless that food has been registered with TFDA.

The objective of food registration is to safeguard public health by ensuring that all prepackaged foods meet national or international standards before being allowed for sale in Tanzania. These Guidelines have been developed for use by those who may wish to engage in importation or manufacture of pre packaged food for sale in Tanzania.

The guidelines are divided in four chapters. Chapter one contains glossary of terms used in the guidelines whereas chapter two deals with general requirements for preparation and submission of applications for registration of pre-packaged food. It also details requirements for payment of fees, application for alteration of registered food and application for renewal of registration.

Chapter three contains food category-specific requirements for registration of food. In this Chapter foods are categorized into high and low risk categories whereby the former category is further divided into high risk foods for special nutritional purpose and high risk foods for general purpose. Different forms of application for registration of food in each category are prescribed in this chapter and annexed to these guidelines.

Chapter four presents general requirements for labeling of prepackaged food. The objective of including the labeling requirements in the Guidelines is to enhance access by applicants to these requirements. Otherwise, applicants will find these requirements similar to those in the Food Labeling Regulations made under the Act or the National Food Labeling Standards.

In order to ensure safe use of food additives in Tanzania, the Codex General Standard on Food Additives will be used because it is continuously evaluated and updated to take into account new scientific developments on safety of permissible additives.

1.1 DEFINITIONS OF TERMS

For the purposes of these guidelines, the following definitions shall apply:

Act

Means the Tanzania Food, Drugs and Cosmetics Act, CAP 219;

Applicant

Means a person or company who may submit, to the Authority, application for registration of pre-packaged food;

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;

Codex

Means the Codex Alimentarius 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 or country of supplier;

Common name

Means any name by which a food is commonly known in the country of origin or name established in a standard recognised by the Authority;

Country of origin

Means the country in which the pre-packaged food was manufactured or produced or from which the food was re-packaged;

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;

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 a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.

Food product registration

Means official recognition or approval by the Authority of food for sale for human consumption in the country

Food registration certificate

Means a certificate issued by the Authority as evidence that the food has been registered by the Authority.

Food/dietary supplement

Means a product other than tobacco, cosmetics or drugs intended to supplement the diet, and shall include all of the following characteristics:-

a) Contains concentrated source of one or combination of the following:
    i. vitamins;
    ii. minerals;

iii. amino acids,
iv. essential fatty acids;
v. enzymes and other Metabolites
vi. Pre and/or Pro–biotic
vii. natural substances of plant or animal origin with nutritional or physiological function;

b) Intends to be taken orally in the form of tablet, capsule, powder, soft gel, gel cap, pellet, pill, granules or liquid.
c) It is not presented for use as a convectional food or as a substitute of a meal or the diet.
d) Labeled and marketed as food/dietary supplement

e) Does not suggests in any way that the product is meant to diagnose, treat, cure or prevent a disease, disorder, abnormal physical or mental state or a particular physiological function.

Good Manufacturing Practices or the acronym GMP

Means measures or practices undertaken to ensure that the food 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.

Health certificate

Means a certificate or warranty issued by competent authority in the country of origin showing that the food is fit for human consumption and that it meets the standards prescribed for it by the competent authority of that country, stating such standard.

High risk food for general purpose

Means food classified as such by the Authority because of its high possibility of being contaminated or have intrinsic properties which can support growth of pathogenic micro-organisms or contains chemical toxicants.

High risk food for special nutritional purpose

Means high risk food classified as such by the Authority because of its intended use, as food for special nutritional purpose including food supplement or infant formulae, which is for a vulnerable group who due to their physiological conditions are susceptible to adverse health effects when they consume unsafe foods

Ingredient

Means any substance including a food additive and excluding processing aid, used in the manufacture of food;

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;

Low risk food

Means food classified as such by the Authority because of its relatively lower possibility of being contaminated with pathogenic micro-organisms or other chemical toxins compared to the high risk food;

Manufacture

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 or company 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 the Tanzania Standards Act, 2009;

Non -registrable foods

Foods that are exempted from the registration process and this includes but not limited to agricultural/farm food produce such as cereals, pulses, roots and tubers, fruits, vegetables, nuts and oil seeds, spices, raw meat and fish, eggs, raw milk which are used as raw materials or for direct human consumption and all perishable food as prescribed in these Guidelines and The Tanzania Food, Drugs and Cosmetics (Registration of Foods) Regulations, 2011;

Packaging material

Means any material meant for wrapping, enclosing and protecting food substances for sale, distribution, storage or use including caps, corks, leads, crown, food contact surfaces and covering or coating materials which do not

form part of the food and are not intended to be consumed together with such food;

Perishable Food
Means food that have a shelf life not exceeding 30 days when kept at ambient temperatures. Typically such foods require cold chain storage to extend shelf life;

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 supplement;

Qualified Person

Means a person who is a holder of at least diploma in food science, food technology or Nutrition or related sciences from a recognized institution and entrusted with the responsibility of ensuring that each batch/lot of the finished product aspired for registration is manufactured in accordance with Good Manufacturing Practices to meet standards prescribed in respect of that food.

Registrant

A person or company whose food product is registered by the Authority.

CHAPTER 2

GENERAL REQUIREMENTS

According to Section 28 of the Tanzania Food, Drugs and Cosmetics Act, 2003 no person shall be granted with permit to manufacture or import prepackaged food into Tanzania unless the food has been registered with the Authority. Therefore, with the exception of those dealing in non- registrable foods, food dealers must ascertain that the foods they wish to sale in Tanzania have been registered with TFDA.

In general, it is the duty of the manufacturer of food to apply to TFDA for registration of the foods he manufactures. However, importers of food or agents of manufacturers or importers may apply for registration of the food they wish to sale in Tanzania.

All products for which applications for registration are presented to TFDA must conform to safety and quality requirements set under the TFDC Act, 2003 and must have been manufactured in accordance with GMP requirements prescribed under the Act.

In addition, local manufacturer (applicant) should register his food manufacturing premises prior to submission of application for registration of a food product.

2.1 Application for registration

a) Applicant

The applicant shall be responsible for the product and all information submitted to the Authority in support of his application for registration of the product, and alterations thereof. An applicant for registration of a food product can be:-

i. A person (an individual, body corporate, partnerships registered business] responsible for the manufacture of the product and
ii. Any person (an individual, body corporate, partnerships, registered business) who intends to import and sell a food product in Tanzania.

b) Local responsible person

Local responsible person shall be a person or company residing in Tanzania, nominated by the Applicant (in writing) to be his representative in all matters related to product registration. Responsible person shall:

i. Monitor the product in the market and inform the Authority immediately after the detection of any problem such as serious manufacturing defect, accidental contamination of the food or counterfeiting of the food, that relate to the registered product, which may endanger public health;
ii. Facilitate communication between the applicant and the Authority on matters that relate to the product; and
iii. Handle product recalls whenever necessary.

2.2 Application documents

a) The following documents shall be required to make a complete application file:-
    i. Duly filled in application forms annexed to these Guidelines as Annexed I for High Risk Food for Special Nutritional Purpose or Annex II for High Risk Food for General Purpose or Annex IV for Low Risk Foods;
    ii. Any other requirement prescribed for each category of food in Chapter III of the guidelines;
b) Application documents shall be compiled in a well-presented and orderly manner spring file with pages sequentially numbered;
c) Drawings, tables, diagrams, graphs or any authoritative documents etc. where required, shall be well-annotated, numbered and appropriate references or cross-references clearly indicated; and
d) A complete application file shall be required for each food product.

2.2.1 Language of application

Information for registration of food to be submitted shall be in English or Kiswahili. All other communications regarding the application shall be made in any of these two languages.

2.2.2 Paper size and quality of text

a) Paper size for application document shall be of A4 type;
b) Quality (weight) of paper used should be not less than 80g/m^2 such that it allows firm binding and long time storage; and
c) Font size of the text on paper or electronic copy where appropriate shall be legible (preferably size 11 of Bookman Old Style or equivalent font style).

2.2.3 Submission of application

Application for registration of prepackaged food shall be submitted to: The Director General, Tanzania Food and Drugs Authority, EPI Mabibo External, P. O. Box 77150, Dar es Salaam, Tanzania or TFDA Zone offices in Arusha, Mwanza, Mbeya, Tabora, Mtwara and Dodoma. The application shall include the following:-

a) Application documents

One hard copy of complete application document, an electronic copy (if any) and label artwork (in the case labeled sample is not available).

b) Sample

i. Every application file shall be accompanied by a sample of the product, labeled in a way it will be marketed;
ii. Samples to be submitted shall have a shelf life of at least 6 months for products with shelf life of more than 9 months. For products with shelf life of less than 9 months should have 80% of the shelf life remaining;
iii. Samples submitted for registration shall be borne from the same batch;
iv. Number of sample units to be submitted shall depend on the product packaging size as prescribed in the table 1 below;
v. Additional samples may be required depending on the nature of the product, risk category and specific requirements as per National Standard or in case there is no National Standard, Codex Standard.

Table 1: Required Sample Units

SN	PACKAGING SIZE	NUMBER OF SAMPLES	ADDITIONAL REQUIREMENT
1	Less than 20g or 20ml	**3** units of secondary package (eg.box or jar)	NA
2	21g – 100g or 21ml – 100ml	5 units	Empty secondary package (if available)
3	101g – 250g or 101ml – 250ml	4 units	NA
4	251g – 500g or 251ml – 500ml	3 units	Label artwork (if available)
5	551g – 3kg or 551ml – 3L	2 units	Empty labeled packaging container or label artwork
6	More than 3kg or 3L	1 original unit or 3 units of $^1/_2$kg aseptically drawn from the original package of the product.	Empty labeled packaging container or label artwork

c) Payment of fees

i. Application shall be accompanied by relevant non-refundable fees and charges as prescribed under the Fees and Charges Regulations made under the Act;
ii. Payment of fees may be made by bank transfer to: Tanzania Food and Drugs Authority: Account number 2041100069 (NMB Kariakoo branch) or A/c No. 01J1021399100 (CRDB Holland House branch) for local currency;
iii. For foreign currency in USD, payments may be made to A/c No. *02J1021399100* (CRDB Holland House branch) or *Account No. 100380013 (Citibank, Tanzania Ltd. Dar es Salaam, Head office, Dar es Salaam. Swift Code: CITITZTZ*) or by bank draft in favour of Tanzania Food and Drugs Authority; and
iv. All bank charges shall be borne by the applicant.

2.3 Processing of application

a) After receiving a complete application, the Authority shall carry out evaluation of food for registration for satisfaction of compliance with the national or codex standards or any other specifications prescribed by the Authority;
b) Applicant, who may wish to make changes or submit additional information to his or her application, is allowed to do so within 7 working days from the date the Authority officially received the application;
c) The Authority may, during evaluation of food, require the applicant to submit additional information including samples as the case may be;

d) Processing of the application for which additional information or sample has been required by the Authority shall be kept on hold until such time when the additional sample or information is provided by the applicant. In the event that the information is not submitted without reasonable cause within four months from the date when the matter was communicated to the applicant, the application shall be invalid;
e) A person who may wish to continue with registration of a product, for which application has been invalidated, shall be required to submit a fresh application, which shall be considered as a new application; and
f) Applicant who may wish to request for extension of time for submitting additional sample or information to the Authority will be granted a period of not more than two months from the date of request.

2.4 Product registration approval/Refusal

i. In a period not exceeding 45 working days (low risk foods) and 60 days (high risk foods for special nutritional purpose) from the date the complete application was received at TFDA, applicants will be informed the status of his application in writing, where by:-

   a) Certificate of registration will be issued to the applicant whose application for food registration is successful; and
   b) Application which is not successful applicant will be issued with notification letter.

ii. In the case whereby additional information is received, the applicant will be given feedback within 14 working days from the date of receiving the information.

2.5 Validity of registration

The registration of a product shall be valid for five (5) years subject to payment of annual retention fee as prescribed under the Fees and Charges Regulations made under the Act. Validity of registration can be terminated under the following conditions:-

i. Revocation, suspension or cancellation of registration of food or amendment of conditions subject to which the food was registered whenever it is deemed necessary due to new requirements of the law or standard.
ii. Payment of the annual retention fee per product is not made to the Authority as prescribed under the Fees and Charges Regulation made under the Act for the remaining four years; and
iii. The Authority receives a notice in writing issued by the registrant to informing it of his intention to withdraw from dealing with the food.

iv. If new scientific developments reveal that the product or ingredient(s) used are proved to have a significant health effect to the consumer.
v. The applicant provided false information related to the product that has bearing on the safety or quality of the product.

2.6 Notification of change (alteration) of registered product

a) If for any reason a registrant wishes to alter any matter related to a registered food, shall before marketing the changed product, notify the alteration and obtain approval from the Authority:-

i. Application for alteration of any matter of a registered product shall be submitted to TFDA by giving reasons for the alteration, explanation on the extent of alteration and submitting samples of the registered and changed product;
ii. Every application for alteration of a registered food shall be accompanied with alteration fees as prescribed under the Fees and Charges Regulations made under the Act;
iii. Notification of minor changes such as change in name and address of registrant, name and address of manufacturer (except physical address), food packaging unit, shape, size, colour shall not be subject to payment of fees; and
iv. Addition of secondary brand (additional labels) of the registered product, without replacement of the registered product and without changes of ingredients, additives or processing technology shall be subject to payment of fees and charges equivalent to duplicate certificate fee as prescribed under the Fees and Charges Regulations made under the Act;

b) However, the following changes should require new application:-

i. Change of manufacturing site or processing technology; and
ii. Change in type of packaging material, type and proportion of typical ingredients, form of the product, type and concentration of food additives or any other matter that relate to the product safety and quality.

2.7 Renewal of registration

All applications for renewal of registration shall be made as prescribed under section 2.2 to 2.7 of these Guidelines and shall reach the Authority at least 60 days before expiry of the existing registration. During evaluation of application for renewal the Authority may require the applicant to rectify the observed shortcomings as deemed necessary.

2.8 Administrative reviews

a) Any person aggrieved by a decision of the Authority in relation to any application for registration of a food product, may make representations to the Authority, whereby he shall submit information and arguments to convince the Authority to reconsider its decision; and
b) However if after reconsideration of the application, the Authority still rejects the application, the applicant may appeal to the Minister responsible for Health.

CHAPTER 3

SPECIFIC APPLICATION REQUIREMENTS

3.1 Food Product Risk Categories

In these Guidelines, food products have been divided into three groups according to their level of perceived risks. Depending on the contemporary evaluation of the risks, the groups or the respective lists of food in the groups may be changed from time to time as may be perceived by the Authority. Foods have been divided into three groups as follows:-

a. High risk foods for special nutritional purposes
b. High risk foods for general purpose
c. Low risk foods

3.2 High risk foods for special nutritional purposes

Food products under this group shall include food for special nutritional purpose whose intrinsic properties have the potential of being contaminated and support growth of pathogens and or having chemical toxins causing high health risks to vulnerable groups who due to their physiological conditions are targets for these products. Such food products include:-

a) Infant formulae and Follow-up formulae;
b) Complementary foods for infants and young children;
c) Foods intended for special medical purposes (eg. Therapeutic foods);
d) Formula foods for use in weight control diets (eg Meal replacement);
e) Food supplements:-
    i. Vitamins and Minerals;
    ii. Amino acids (eg. Lysine and L-carnitine);
    iii. Essential Fatty acids (eg. Omega 3 Fatty acids, Fish Oil);
    iv. Plant, Plant extracts, and other herbal based supplement (eg. Ginsengs, Ginkgo biloba, Moringa-Mangifera);
    v. Enzymes and other metabolites (eg. Coenzyme Q10);
    vi. Prebiotics (eg.dietary fibres);
    vii. Probiotics (eg. Bifido bacterium);
    viii. Animal products and animal extracts (Colostrum, adrenal extract, egg york and bee products); and
    ix. Protein Concentrates

Applicant who intends to apply for registration of any food product falling under this group shall in addition to fulfilling the general requirements stipulated in chapter 2 (section 2.2 to 2.7) of these Guidelines, do the following:-

a) Effect payment of GMP inspection fees as prescribed under the Fees and Charges Regulations made under the Act;

b) Submit the following documents:-
   i. Brief description of the product (applicable for food supplements and foods intended for special medical purpose);
   ii. Health certificate or certificate of free sale;
   iii. Copy of certificate of GMP or HACCP compliance certificate;
   iv. Certificate of analysis;
   v. Stability study report; and
   vi. Quality and safety data of the product including ingredients used in the manufacture of the product.

3.3 High risk foods for general purpose

Foods in this group are classified as such because of their high possibility of being contaminated or have intrinsic properties which can support growth of pathogenic micro-organisms or chemical toxins. Such food products include:-

a) Milk and milk products:-
   i. Processed liquid milk(UHT/Sterilized milk, pasteurized milk, Butter milk and reconstituted milk) including flavoured;
   ii. Flavored dairy-based drinks(Chocolate milk, cocoa milk, Eggnog, whey based drink and milk shake);
   iii. Fermented and renneted milk products (Drinking yoghurt, yoghurt, sour milk, kefir, kumis);
   iv. Condensed milk and evaporated milk (plain or flavoured, sweetened, non sweetened condensed or evaporated milk, non-dairy creamers);
   v. Cream and cream analogue (cream, whipping cream, whipped cream, clotted cream);
   vi. Milk powder and cream powder (plain, skimmed, full fat, blended and flavoured product);
   vii. Cheese and analogues(Un-ripened or ripened cheese, Rind and rindless, whey cheese, processed cheese and flavoured cheese;
   viii. Dairy-based desserts (e.g., pudding, ice cream, Ice milk);
   ix. Butter (Salted and unsalted); and
   x. Ghee.

b) Meat and meat products, including poultry and game:-
   i. Processed meat, poultry, and game products in whole pieces or cuts;
   ii. Processed comminuted meat, poultry and game products; and
   iii. Edible casings (e.g., sausage casings).

c) Fish and fish products, including molluscs, crustaceans, and echinoderms
   i. Processed fish and fish products, including molluscs, crustaceans, and echinoderms;

ii. Semi-preserved fish and fish products, including molluscs, crustaceans, and echinoderms; and
iii. Fully preserved, including canned or fermented fish and fish products, including molluscs, crustaceans, and echinoderms.

d) Eggs and egg products
i. Egg products (e.g. mayonnaise);
ii. Preserved eggs, including alkaline, salted, and canned eggs; and
iii. Egg-based desserts (e.g., custard).

e) Spices, soups, sauces, salads and protein products
i. Herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles);
ii. Mustards;
iii. Soups and broths;
iv. Sauces and like products (tomato sauce, ketchup, chilli sauce, tomato paste);
v. Salads (e.g., macaroni salad, potato salad) and sandwich spreads;
vi. Yeast and similar products;
vii. Soybean products including soybean based seasonings, condiments and soy milk; and
viii. Other protein products.

f) Processed vegetables and vegetable products (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
i. Dried Vegetables (including in grounded form);
ii. Vegetables in vinegar, oil, brine, or soy sauce;
iii. Fermented vegetable products; and
iv. Cooked, blanched or fried vegetables.

g) Ready-to-eat savories
i. Processed nuts and nuts products, including coated nuts and nut mixtures (eg. Peanut butter, Roasted groundnuts, pistachio, almond and hazelnut); and
ii. Desiccated nuts.

h) Composite foods - foods that could not be categorized in other groups
i) Potable Water (including drinking water); and
j) Herbal tea/ infusions excluding sliming tea (Stinging nettle tea, Fennel tea, Rose-hip tea, Hibiscus blossom tea, Camomile tea, Spearmint tea, Lemon grass, Lime blossom tea, Mate (Paraguay tea), Lemon balm tea, Orange blossom tea, Orange leaf tea, Peppermint tea and Verbena tea.

Applicant who intends to apply for registration of any food product falling under this category shall in addition to fulfilling the general requirements stipulated in chapter 2 (section 2.2 to 2.7) of these Guidelines, submit any of the following documents:-

a) Health certificate or certificate of free sale;
b) Copy of certificate of GMP or HACCP compliance certificate; and
c) Permit from the Vice President's Office-Environment (For Genetically Modified Foods or foods containing Genetically Modified ingredients)

3.4 Low risk foods

This group shall include pre-packaged foods, the risk of which is relatively lower than food products categorized in group one and two above. These foods include:-

a) Fats and oils, and fat emulsions
   i. Vegetable oil and fats eg.(Sunflower, palm, cotton seed, sesame, corn, soybean and olive) oil);
   ii. Fat emulsions containing less than 80% Fat (eg. Mayonnaise, Spreads and other low fat margarine);
   iii. Fat emulsions containing more than 80% Fat (eg. Butter and concentrated butter, Margarine, butter-margarine blends, Shortenings);
   iv. Animal fats (eg. Lard, tallow, fish oil, and other animal fats; and
   v. Fat-based desserts.

b) Edible ices, including sherbet and sorbet;

c) Processed Fruits and Fruits products
   i. Dried fruit;
   ii. Fruit in vinegar, oil, or brine Canned or bottled (pasteurized) fruit;
   iii. Jams, jellies, marmalades, Fruit-based spreads;
   iv. Fruit preparations, including pulp, purees, fruit toppings and coconut milk;
   v. Fruit-based desserts, incl. fruit-flavoured water-based desserts;
   vi. Fermented fruit products (eg. Pickles);
   vii. Cooked or fried fruit eg. Chutney; and
   viii. Fruit juices and nectars and their concentrates.

d) Confectionaries
   i. Hard and soft candy (Candies, Toffees, lollipop, nougat, Candied fruit and candy bar);and
   ii. Chewing gums

e) Coffee, Tea, Cocoa and their products
   i. Coffee (eg. Ground coffee, Instant coffee, Coffee beans);
   ii. Coffee products (Cappuccino, espresso);
   iii. Tea (eg. Black tea/Blended tea, green tea, ice tea, Spiced tea (eg ginger, vanilla etc);

iv. Cocoa (eg, Coco mass, coco cake);and
v. Cocoa products (eg. Coco millo, Coco butter, Chocolates and chocolate products including imitations and chocolate substitutes).

f) Cereals and cereal products, including products derived from cereal grains, from roots and tubers, pulses and legumes
   i. Whole, broken, or flaked grains,(eg. Maize, sorghum, wheat, rice, oats);
   ii. Flours (eg. Maize, sorghum, wheat and rice flours, Batters in powder form);
   iii. Cereal starches (Modified starch, corn starch, Custard Powder and starch sugars (maltodextrin, corn syrup, dextrose);
   iv. Breakfast cereals, including rolled oats (eg. Cornflakes, Rice flakes, rolled oats, muesli, Rice crispies and cereals bars);
   v. Pastas and noodles and like products (e.g. Macaroni, vermicelli, spaghetti, instant noodles);
   vi. Cereal and starch based desserts (e.g., rice pudding, Crisps flakes and tapioca); and
   vii. Pre-cooked or processed rice products.

g) Bakery wares
   i. Breads, cake, biscuits, chapatti, Crackers, cookies; and
   ii. Fine bakery wares (sweet, salty, savoury) and mixes.

h) Sweeteners, including honey
   i. Sugar (Refined and raw sugars, Brown sugar, Sugar solutions and syrups;
   ii. Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings, icing sugar);
   iii. Honey (Including Spiced honey, Table honey, industrial honey, blended honey, Stingless bee honey; and
   iv. Table-top sweeteners, including those containing high-intensity sweeteners

i) Non Alcoholic Beverages, excluding dairy products
   i. Soft drinks (eg. Soda, malt drinks, ready to drink beverages, concentrates, squashes, Flavoured juices drinks, energy drinks, punches and ades beverages;
   ii. Cereal based drinks (eg. Grain beverages, *Togwa, Uji,*and the like*);*
   iii. Ice rollies (eg. Ice bars and ice cubes); and
   iv. Powdered drinks

j) Alcoholic beverages, including alcohol-free and low-alcoholic counterparts
   i. Portable Spirits and Liquors, (eg. Brandy, whisky, vodka, gin, rum, Tequilla, Cachaca and liquors);
   ii. Wines and Rosella alcoholic drink;
   iii. Cider and perry, Mead Alcoholic drinks;
   iv. Cereal based alcoholic beverages (eg. Beers); and
   v. Non cereal based alcoholic beverages (eg. Unfermented fruit flavored alcoholic beverage).

k) Salt and salt substitutes; and
l) Vinegars

Applicant who intends to apply for registration of any food product falling under this category shall fulfil the general requirements stipulated in chapter 2 (section 2.2 to 2.7) of these Guidelines.

3.5 Additional requirements

a) Applicant who intends to apply for registration of Genetically Modified Foods or foods containing Genetically Modified ingredients shall submit a Permit from the Vice President's Office-Environment.

b) Save for small scale and micro scale local food manufacturers, wheat flour, maize flour and edible fats and oils imported or locally manufactured shall be fortified with iron, zinc, folate and vitamin B_{12} (maize and wheat flour) and vitamin A and E (edible fats and oils).

CHAPTER 4

REQUIREMENTS FOR LABELLING OF PREPACKAGED FOODS

4.1 General Requirements

Prepackaged food shall not be described or presented on any label or in any labeling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect. it shall not be described or presented on any label or in any labeling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

4.2 Mandatory requirements

The following information shall appear on the label of prepackaged foods as applicable to the food being labeled, except to the extent otherwise expressly provided in an individual National Standard.

a) Name of the food (Common name and brand name),
b) List of ingredients,
c) Net content,
d) Name and address of the manufacturer
e) Country of origin
f) Batch or Lot number,
g) Date of expiry
h) Date of manufacture, and
i) Recommended storage condition.

4.3 Name of the food

a) The common name shall indicate the true nature of the food and normally be specific and not generic;
b) Where a name or names have been established in a National standard, or in case there is no national standard in Codex standard at least one of these names shall be used;
c) In the absence of any such name, either a common or usual name existing by common usage or an appropriate descriptive term, which is not misleading or confusing to the consumer shall be used;
d) “Brand” name or “trade mark” shall be used to accompany the common name. A brand name that may be associated with the common name of any food or misleads about the true nature of the product is not acceptable;

e) There shall be a close proximity between the brand name, common name and additional words or phrases which prescribe the true nature, physical condition or type of treatment the food has undergone (eg: dried, concentrated, reconstituted, smoked etc.);
f) Label for food containing more than 6% transgenic ingredient(s) shall bear the statement "produced from genetically modified (name of organism); and
g) Manufacture of genetically modified food or foods derived thereof, must take into account the national legislation on environmental assessment.

4.4 List of ingredients

a) Except for single ingredient foods, a list of ingredients shall be declared on the label.

i. The list of ingredients shall be headed or preceded by an appropriate title, which consists of or includes the term 'ingredient'.
ii. All ingredients shall be listed in descending order of ingoing weight (m/m) at time of manufacture of the food.
iii. Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients provided that it is immediately accompanied by a list in brackets of its ingredients in descending order of proportion (m/m). Where a compound ingredient for which a name has been established in a Codex standard or in national legislation constitutes less than 25% of the food, the ingredients other than food additives, which serve a technological function in the finished product, need not be declared.
iv. Added water shall be declared in the list of ingredients except when the water forms part of an ingredient such as brine, syrup or broth used in a compound food and declared as such in the list of ingredients. Water or other volatile ingredients evaporated in the course of manufacture need not be declared.
v. As an alternative to the general provisions of this section, dehydrated or condensed foods which are intended to be reconstituted by the addition of water only, the ingredients may be listed in order of proportion (m/m) in the reconstituted product provided that a statement such as "ingredients of the product when prepared in accordance with the directions on the label" is included.

b) A specific name shall be used for ingredients in the list of ingredients in accordance with the provisions set out in requirement 4.2.2(a) of these requirements except that:-

i. The following class names may be used for the ingredients falling within these classes:

Name of classes	**Class Names**
Refined oils other than olive	'Oil' together with either The term 'vegetable' or 'animal', qualified by the term 'hydrogenated' or 'partially-hydrogenated', as appropriate.
Refined fats	'Fat' together with either, the term 'vegetable' or animal', as appropriate.
Starches, other than chemically modified starches	'Starch'
All species of fish where the fish Constitutes an ingredient of another Food and provided presentation of such food does not refer to a specific species of fish.	'Fish'
All types of poultry meat where such meat constitutes an ingredient of another food and provided that the labeling and presentation of such a food does not refer to a specific type of poultry meat.	'Poultry meat'
All types of cheese where the cheese or mixture of cheese constitutes an ingredient of another food and provided such food does not refer to a specific type of cheese.	'Cheese'.
All spices and spice extracts not exceeding 2% by weight either singly or in combination in the food.	'Spice', 'spices', or 'mixed spices', as appropriate.
All herbs or parts of herbs not exceeding 2% by weight either singly or in combina-	'Herbs' or 'mixed herbs' as appropriate.

tion in the food.

All types of gum preparations used in the manufacture of gum base of chewing gum.	'Gum base'
All types of sugar	'Sugar'
Anhydrous dextrose and monohydrate.	'Dextrose or 'glucose'
All types of caseinates	'Caseinates'.
Press, expeller or refined cocoa butter.	"Cocoa butter'.
All crystallized fruit not exceeding 10% of the weight of the food.	'Crystallized fruit'.

ii. Notwithstanding the provision set out in requirement 4.2.2(b)(i) of these requirements pork fat, lard and beef fat shall always be declared by their specific names.

iii. For food additives falling in the respective classes and appearing in lists of food additives permitted for use in foods generally, the following class titles shall be used together with the specific name or recognized numerical identification as required by these guidelines or relevant National standard.

Acids
Anticaking Agent
Antioxidant
Food Colour
Emulsifier
Emulsifying Salt
Flavour Enhancer
Preservative
Stabilizer
Sweetener
Thickeners/gelling agents
Antiozidaent synergists
Carrier solvents
Enzymes
Flavours
Buffering agents

iv. The expression "flavours" shall be qualified by "natural", "nature identical", "artificial" or a combination of these words as appropriate.

c) Processing Aids and Carry-Over of Food Additives.

i. A food additive carried over into a food in a significant quantity or in an amount sufficient to perform a technological function in that food as a result of the use of raw materials or other ingredients in which the additive was used shall be included in the list of ingredients.

ii. A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients.

d) Transgenic food ingredient

Name of a transgenic ingredient which constitutes more than 6% of the food shall be preceded by the term "transgenic"

4.5 Net Contents and Drained Weight

a) The net contents shall be declared in the metric system ("Systeme International" units) and in the following manner:

i. For liquid foods, by volume;
ii. For solid foods, by weight; and
iii. For semi-solid or viscous foods, either by weight or volume.

b) In additional to the declaration of net contents, a food packed in a liquid medium shall carry a declaration in the metric system of the drained weight of the food. For the purposes of this requirement, liquid medium means water, aqueous solutions of sugar and salt, fruit, and vegetable juices in canned fruits and vegetables only, or vinegar, either singly or in combination.

4.6 Name and Address

Name, postal and physical address (country, town/city, street, plot and block number) of the manufacturer of the food shall be declared.

4.7 Country of Origin

a) In case of food to be imported into Tanzania the country of origin of the food shall be declared.

b) When a food undergoes processing in a second country which changes its nature, the country in which the processing is

performed shall be considered to be the country of origin for the purposes of labeling.

4.8 Batch/Lot Identification

Each container shall be embossed or otherwise permanently marked in code or in clear to identify the producing factory and the batch/lot.

4.9 Date Marking and Storage Instructions

a) If not otherwise determined in the relevant National or Codex standard, the "date of expiry" declared on the label shall consist of at least the day and the month for products with a minimum durability of not more than three months or the month and the year for products with a minimum durability of more than three months.

b) The day, month and year shall be declared in uncoded numerical sequence except that the month may be indicated by letters.

c) Notwithstanding requirement of section 4.9 of these guidelines an indication of the date of expiry shall not be required for:-

i. wines, liqueur wines, sparkling wines, aromatized wines, fruit wines and sparkling fruit wines except for wines having alcohol content of less than 10% by volume
ii. beverages containing 10% or more by volume of alcohol;
iii. vinegar
iv. solid sugars
v. hard boiled sugar candies
vi. chewing gums
vii. Honey

d) In addition to the date of expiry, special conditions for the storage of the food shall be declared on the label if the validity of the date depends thereon.

e) All food products shall be marked with date of manufacture which shall consist at least of;

i. The day and the month for products with a minimum durability of not more than three months.
ii. The month and the year for products with a minimum durability of more than three months.

4.10 Instruction for Use

Instruction for use, including reconstitution, where applicable, shall be included on the label, as necessary, to ensure correct utilization of the food.

4.11 Requirements for irradiated food

a) The label of a food, which has been treated with ionizing radiation, shall carry a written statement indicating that treatment in close proximity to the name of the food. The international food irradiation symbol, as shown below, shall be used, in close proximity to the common name of the food.

b) When an irradiated product is used as an ingredient in another food, this shall be so declared in the list of ingredients.

c) When a single ingredient product is prepared from raw materials, which has been irradiated, the label of the product shall contain a statement indicating the treatment.

4.12 Exemptions from mandatory labeling requirements

With the exception of spice and herbs, small units, where the largest surface area is less than 10cm^2 shall be exempted from the requirements 2.2 and 2.6 to 2.8 of these guidelines.

4.13 Presentation of labeling information

Labels in pre-packaged foods shall be applied in such a manner that they will not become separated from the container.

a) Statement required to appear on the label by virtue of these requirements shall be clear, prominent, indelible and readily legible by the consumer under normal conditions of purchase and use.

b) Where the container is covered by a wrapper, the wrapper shall carry the necessary information or the label on the container shall be readily legible through the outer wrapper or not obscured by it.

c) The common name and net contents of the food shall appear in a prominent position and in the same field of vision.

4.14 Language

Any statement, information or declaration that is required by any requirement under these guidelines to appear on the label of any prepackage food shall be in Kiswahili or English or both Kiswahili and English.

ANNEX I

TFDA
Tanzania Food & Drugs Authority

TFDA/DFS/FR/F/001

APPLICATION FORM FOR REGISTRATION OF HIGH RISK FOOD FOR SPECIAL NUTRITIONAL PURPOSE

New/renewal application:
(Fill in product registration number if renew).....

1.0 Particulars of food

1.1 Brand Name: .....

1.2 Common name.....

1.3 Brief description of the physical characteristics of the food (form (solid, liquid) Colour etc).....

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

1.5 Type of packaging container (eg. bottle, box, sachet etc).....

1.6 Type of materials for the packaging container and liner if any (e.g. Metal, glass, plastic, paper, wood etc.)
.....

1.7 Type of materials for closure and seal
.....
.....

1.8 Retail packaging unit(s) in weight or volume or number
.....

1.9 Shelf life (month).....

1.10 Shelf life after opening of container……..

1.11 Instructions for use ……

1.12 Recommended storage conditions before opening the container ……

1.13 Recommended storage conditions after opening the container ……

2.0 Particulars of applicant

2.1 Name (company/person)……

2.2 Name of the country where the company was incorporated (Provide registration certificate)……

2.3 Physical address (plot/block No./street/Village/district/region……..

……

……

2.4 Postal Address……

……

2.4 Country of origin (food to be imported)……

2.5 Telephone……

2.6 Mobile number……

2.7 E- Mail……

3.0 Particular of a local agent (for imported food products)

3.1 Name (company/person)……

3.2 Physical address (plot/block No./street/Village/district/region……..

……

……

3.3 Postal Address……

……

3.4 Telephone……

3.5 Mobile number……

3.6 E- Mail……

4.0 Particulars of manufacturer

4.1 Name (company/person)……

4.2 Name of the country where the company was incorporated (provide registration certificate) ……

4.3 Postal Address……

4.4 Physical address (country, town/city, street ……

……

4.5 Phone……

4.6 Mobile number ……

4.7 E-Mail……

4.8 Official website ……

5. 0 Ingredients used

List ingredient in descending order of proportion, quantities per unit of measurement of the food and purpose of use

5. 1 Main ingredients

S/N	**Name**	**Proportion (e.g. %, ppm, unit/mass or volume)**	**Purpose of use**

5.2 Food additives

S/N	Name (Specific, common, chemical, technical) or E-number	Level (e.g. %, mg/kg or lt, unit/mass or volume	Purpose of use

6.0 Certification by the applicant

I, ……

The ……(position in the company) and a duly authorised representative 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……

……

ANNEX II

TFDA
Tanzania Food & Drugs Authority

TFDA/DFS/FR/F/002

APPLICATION FORM FOR REGISTRATION OF HIGH RISK FOOD FOR GENERAL PURPOSE

New/renewal application:
(Fill in product registration number if renew).....

1.0 Particulars of food:

1.1 Brand Name: .....

1.2 Common name.....

1.3 Brief description of the physical characteristics of the food (form (e.g. solid, liquid etc., colour etc.).....

1.4 Intended end user .....

1.5 Type of packaging container (eg. bottle, box, sachet etc) .....

1.6 Type of materials for the packaging container and liner if any (e.g. metal, plastic, wood, paper etc.) .....

1.7 Type of materials for closure and seal .....

1.8 Retail packaging unit(s) in weight or volume or number .....

1.9 Shelf life (month).....

1.10 Shelf life after opening of container.....

1.11 Instructions for use .....

1.12 Recommended storage conditions before opening the container .....

1.13 Recommended storage conditions after opening the container .....

2.0 Particulars of applicant

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

2.2 Name of the country where the company was incorporated (Provide registration certificate).....

2.3 Physical address (plot/block No./street/Village/district/region……..
……
……
2.4 Postal Address……
……
2.4 Country of origin (food to be imported)……
2.5 Telephone……
2.6 Mobile number……
2.7 E- Mail……

3.0 Particular of a local agent (for imported food products)

3.1 Name (company/person)……..
3.2 Physical address (plot/block No./street/Village/district/region……..
……
……
3.3 Postal Address……
……
3.4 Telephone……
3.5 Mobile number……
3.6 E- Mail……

3.0 Particulars of manufacturer

3.1 Name (company/person)……..
Name of the country where the company was incorporated …… (Provide registration certificate)
3.2 Postal Address……
3.3 Physical address (country, town/city, street) ……..
……
3.4 Phone……
3.5 Mobile number ……
3.6 E-Mail……

5. 0 Ingredients used

List ingredient in descending order of proportion, quantities per unit of measurement of the food

5. 1 Main ingredients

S/N	Name	Proportion (e.g. %, ppm, unit/mass or volume)	Purpose of use

5.2 Food additives

S/N	Name (Specific, common, chemical, technical) or E-number	Levels (e.g. %, mg/kg or lt, unit/mass or volume	Purpose of use

6.0 Certification by the applicant

I, ……

The ……(position in the company) and a duly authorised representative 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……

ANNEX III

TFDA/DFS/FR/F/003

APPLICATION FORM FOR REGISTRATION OF LOW RISK FOOD

New/ renewal application:
(Fill in product registration number if renew).....

1.0 Particulars of food:

1.1 Brand Name: .....

1.2 Common name.....

1.3 Brief description of the physical characteristics of the food (form (eg. solid, liquid etc. colour etc.).....

1.4 Intended end user .....
.....

1.5 Type of packaging container (eg. bottle, box, sachet etc) .....

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

1.7 Type of materials for closure and seal
.....

1.8 Retail packaging unit(s) in weight or volume or number
.....

1.9 Shelf life (month).....

1.10 Shelf life after opening of container.....

1.11 Instructions for use .....

1.12 Recommended storage conditions before opening the container
.....

1.13 Recommended storage conditions after opening the container
.....

2.0 Particulars of applicant

2.1 Name (company/person)……

2.2 Name of the country where the company was incorporated (Provide registration certificate)……

2.3 Physical address (plot/block No./street/Village/district/region……

……

……

2.4 Postal Address……

……

2.4 Country of origin (food to be imported)……

2.5 Telephone……

2.6 Mobile number……

2.7 E- Mail……

3.0 Particular of a local agent (for imported food products)

3.1 Name (company/person)……

3.2 Physical address (plot/block No./street/Village/district/region……

……

……

3.3 Postal Address……

……

3.4 Telephone……

3.5 Mobile number……

3.6 E- Mail……

4.0 Particulars of manufacturer

4.1 Name (company/person)……

Name of the country where the company was incorporated (provide registration certificate) ……

4.2 Postal Address……

4.3 Physical address (country, town/city, street ……

……

4.4 Phone……

4.5 Mobile number ……

4.6 E-Mail……

5. 0 Ingredients used

List ingredients in descending order of proportion

5. 1 Main ingredients

S/N	Name

5.2 Food additives

S/N	Name (Specific, common, chemical, technical) or E-number

6.0 Certification by the applicant

I, ……

The ……(position in the company) and a duly authorised representative 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……

Revision History

Revision No.	Date	Author	Description of change	Section modified	Approvals
4	10/11/2016	MFR	Email address and TFDA websites	Cover page	DFS /DG
4	10/11/2016	MFR	Definition of food supplement is added	1.1	DFS /DG
4	10/11/2016	MFR	Reference to official standards and/or technical regulations is removed	2.2.1 & 2.2.1	DFS /DG
4	10/11/2016	MFR	Sample size requirements modified	2.2.3(b)	DFS /DG
4	10/11/2016	MFR	"In a period, not shorter than 45 changed to "In a period not exceeding 45"	2.4	DFS /DG
4	10/11/2016	MFR	Subtitle '*termination of product registration*" removed, content are added to subtitle "*validity of registration*"	2.5	DFS /DG
4	10/11/2016	MFR	New clause "Addition of secondary brands/labels" added	2.6 (a)(iv)	DFS /DG
4	10/11/2016	MFR	Sub-categories of food supplements and documentation requirements are added	3.2	DFS /DG
4	10/11/2016	MFR	documentation requirements for high risk foods for general purpose are added	3.3	DFS /DG
4	10/11/2016	MFR	Particulars of local agent added in application forms	Annex 1,2 & 3	DFS /DG